CIMCVGH

INSTITUTIONAL REVIEW BOARD

STANDARD OPERATING PROCEDURES MANUAL

- ***VERSION 3***

THE CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL

INSTITUTIONAL REVIEW BOARD

STANDARD OPERATING PROCEDURES MANUAL

VERSION 3

2023

OVERVIEW

Cebu Institute of Medicine, one of the pioneer medical schools in Cebu, was founded in June 1957 initially in collaboration with the Cebu Institute of Technology. Through the years, it has evolved to become a non-stock, non-profit medical learning institution, and in 1966, it was first named as the Cebu Institute of Medicine. The school ranked as Level IV Category by the Board of Medical Education in 1987 and was awarded as a Center of Excellence for Medicine in 1996 by the CHED. CIM was also made Autonomous by 2001 and has PAASCU level III accreditation and ranked number one among the Top Performing School in the country from 2001 to 2018. Research has been part of the curriculum of CIM for all three-year levels with the finished paper as a requisite for promotion to higher level. This paved the way for the creation of the Clinical Epidemiology Unit that reviewed the technical soundness of the research proposals of the school.

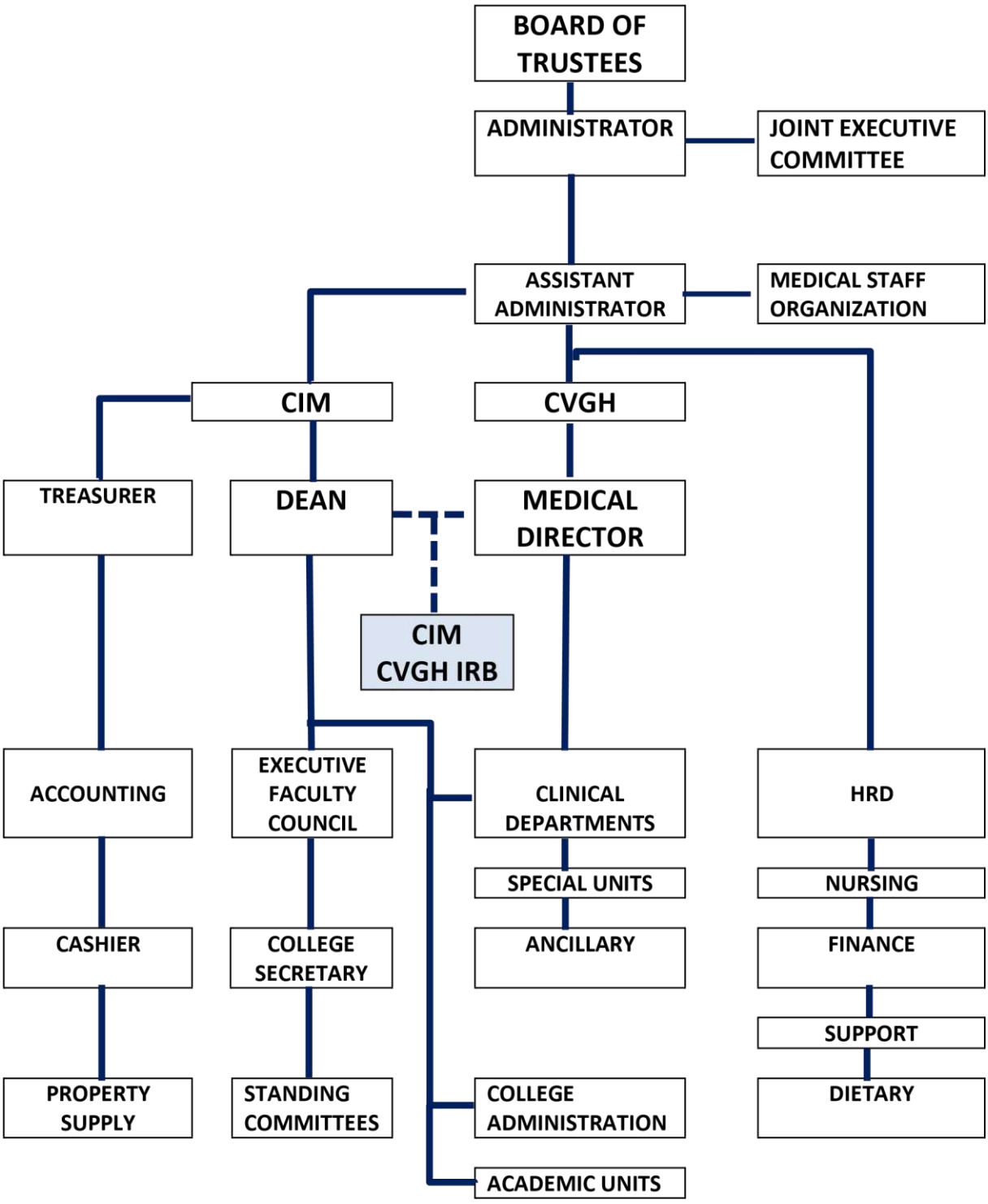
The Cebu Velez General Hospital (CVGH) is the main training hospital of the Cebu Institute of Medicine (CIM). CVGH shares with CIM its clinical and teaching departments which include the departments of Internal Medicine, Surgery, Pediatrics, Family Medicine, OB-GYN and Ophthalmology, and ENT. Similarly, as mandated by the respective accrediting specialty societies, the residents of CVGH have been producing excellent research papers since the start of its training programs. Each department of CVGH has its own technical review committee to attend to the technical soundness of the research proposals of its member resident or consultant staff.

To further assure the ethical soundness of the research proposals for implementation, the two institutions entered into a Joint Memorandum of Agreement (APPENDIX I) to establish the Cebu Institute of Medicine-Cebu Velez General Hospital Institutional Review Board (CIM CVGH IRB). The CIMCVGH IRB had its beginning in 1997 with Dr. Mario Sanchez as Chair. During this time, the IRB reviewed several clinical trials from the residents and consultant staff of CVGH as well as of other institutions. With the untimely demise of Dr. Sanchez, Dr. Melfer Montoya took the helm of the IRB for three years. She was then succeeded by Dr. Ma. Fidelis E. Quiza.

The present IRB was established in 2016 with Dr. Manuel Emerson S. Donaldo as chair. The creation of the present IRB coincided with the Philippine Government's mandate requiring all institutions to create an IRB accredited by the PHREB. Hence, the initial task of setting up an office, selecting and training its members, and the crafting of this SOP fell into the hands of the present IRB.

The relationship of the CIM-CVGH IRB to the other departments is illustrated in the following organizational chart.

INSTITUTIONAL ORGANIZATIONAL CHART



CIM CVGH
IRB
ORGANIZATIONAL CHART

Board of Trustees
Carmen M. Velez, MD
Chairman

CIM
Martiniano C. Zanoria, MD
Dean

Board of Directors
Carmen M. Velez, MD
Chairman

CVGH
Maria Lourdes P. Chan, MD
Medical Director

IRB

Dr. Manuel Emerson Donaldo
Chairman
Medicine Clinical Epidemiology

Dr. Irelan Marie A. Evasco
Obstetrics and Gynecology

Dr. Corazon Tan-Meneses
Vice Chairman
Academe

Ms. Charito Calumpang
Lay Representative

Fr. Rafael John Catane
Religious

Dr. Rudy Amatong
Pediatrics

Atty. Terence Fernandez
Legal

Andrew L. Cuizon, MD
Ophthalmology

Saleshe Anne Fernandez, MD
SURGERY

Dr. Nerissa Sanchez
Pediatrics

Dr. Consolacion Cutillar
Medicine
Member Secretary

Maria Christina Gravador, MD
FAMED

Dr. Leah Wilfreda Pilongo
Social Sciences

Dr. Alvin Christian Borbon
IRB Administrator

Angela Pahayahay
IRB Secretary

Ethical Framework

The CEBU INSTITUTE OF MEDICINE-CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD (CIM-CVGH IRB) is guided in its reflection, advice, and decision by three primary ethical principles as follows:

(a) Respect for Persons – the principle that states that individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection;

(b) Beneficence – the principle that requires investigators to protect participants from harm and secure their well-being; and

(c) Justice – the principle that refers to the sense of "fairness in distribution" and "what is deserved."

Source: Belmont Report, 1979

It is further guided by the ethical principles and procedures as expressed in the following international guidelines:

(a) Declaration of Helsinki (2013 and subsequent revisions);

(b) International Conference on the Harmonization of Good Clinical Practice (ICH-GCP);

(c) CIOMS 2016; and

(d) Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO).

The CIM-CVGH IRB also acts accordance with national laws, regulations, and guidelines, especially the National Ethical Guidelines for Health Research by the Philippine Health Research Ethics Board (PHREB) and the Administrative Orders from DOH, Philippine FDA and other relevant agencies.

In crafting and adopting its SOP, the CIM-CVGH IRB adheres to:

(a) Operational Guidelines for Ethics Committees that Review Biomedical Research (2000) by the World Health Organization (WHO);

(b) DOH-REC SOP Template;

(c) FERCAP SOP Templates; and

(d) PHREB SOP Workbook.

The CIM-CVGH IRB also adheres to national and international ethical standards and recognizes that the protocols it approves may have undergone review and may have been approved by other ethics committees including the Multi-Site Research Ethics Board (MREB) prior to their implementation in specific sites.

In evaluating protocols and ethical issues, the CIM-CVGH IRB is cognizant of the diversity of laws, cultures, and practices governing health research in various local sites/countries around the world. It strives to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines and the requirements and conditions of various localities where proposed research at the Cebu Velez General Hospital is being considered. The CIM-CVGH IRB also takes the initiative to be informed, as appropriate, of the current state-of-the-art research and publications of the impact of the research protocol that it has approved.

The CIM-CVGH IRB accepts the following protocols for review:

- 1) from students of Cebu Institute of Medicine,
- 2) from the residents in training of Cebu Velez General Hospital,
- 3) for all researches to be done in CIM and/or CVGH
- 4) protocols submitted for review from institutions other than CIM/CVGH.

The IRB includes researches on human subjects and reserves the option of exempting researches involving animal subjects and/or do review by expedited process for laboratory experiments among others.

CEBU INSTITUTE OF MEDICINE AND CEBU VELEZ GENERAL HOSPITAL

JOINT MEMORANDUM CIRCULAR NO. 01

Series of 2019

To: (a) Trustees, Deans, Department Heads, Officers, Faculty, Staff, and Students of the Cebu Institute of Medicine; and

(b) Directors, Department Heads, Accredited Physicians, Medical Residents, Officers, and Medical Staff of the Cebu Velez General Hospital

Subject: Guidelines for the Mandatory Submission for Ethics review by the CIM- CVGH Institutional Review Board (IRB) of all researches or studies involving human subjects done in the Premises, under the Authority, or in Compliance with the Requirements of the Cebu Institute of Medicine or the Cebu Velez General Hospital.

I. Prefatory Statement

The faculty and students of the Cebu Institute of Medicine (CIM) and the accredited physicians, medical residents, and staff of the Cebu Velez General Hospital (CVGH) conduct various researches and studies involving different medical subjects, issues, or concerns either in compliance with academic requirements or for professional advancement. CIM and CVGH needs to ensure that the ethical standards and guidelines for the conduct of any research or study involving human subjects will be strictly followed. To ensure faithful compliance with these standards and guidelines, the mandatory submission for ethics review by the CIM-CVGH Institutional Review Board (IRB) for researches and studies involving human subjects is hereby imposed.

II. Purpose

This circular is issued to ensure that the ethical standards and guidelines set by both CIM and CVGH and implemented by the CIM-CVGH IRB for the conduct of any research or study involving human subjects are strictly followed. This circular further recognized the mandate and authority of the CIM-CVGH IRB to conduct an ethics review of all proposed study or research protocols involving human subjects and monitor the ethical conduct of all research protocols it approves.

III. Scope

This circular covers any research or study involving human subjects that will be conducted in the premises, under the authority, or in compliance with the requirements of the CIM or CVGH

IV. General Guidelines

1. Before the conduct of any research or study involving human subjects, the proposed study or research protocol must be first submitted for ethics review by the CIM-CVGH IRB.

2. The proponent of the research or study must comply with the requirements, guidelines, recommendations, and final decision of the CIM-CVGH IRB in the conduct of the ethics review of the proposed study or research protocol.

3. No research or study involving human subjects will be allowed or conducted without the prior ethics and prior written approval of the CIM-CVGH IRB.

4. No director, trustee, officer, faculty, department head, staff, or employee of the CIM or CVGH shall approve, participate in, aid, or assist in any research or study involving human subjects and conducted without the prior ethics review and prior written approval by the CIM-CVGH IRB.

5. In the event that the proponent proceeds with the research or study without the prior ethics review and prior written approval of the CIM-CVGH IRB, CIM and CVGH have the right to disallow the conduct of such research or study within its premises and facilities and prohibit the participation, aid, or assistance of any of its directors, trustees, officers, faculty members, department heads, staff, or employees. CVGH likewise has the right to bar its patients from participating in the research or study.
6. The CIM-CVGH IRB shall monitor the ethical conduct of all approved protocols.

V. Revisions and Amendments

CIM and CVGH expressly reserve the right to revise, modify, or amend this Joint Memorandum Circular at anytime as the need arises.

VI. Effectivity

This Joint Memorandum Circular is issued for the information and guidance of all concerned and shall take immediate effect upon the date of its issuance.

Cebu City, Philippines, Oct. 23,**2019**.

DR. MARTINIANO C. ZANORIA
Dean
Cebu Institute of Medicine

DR. MARIA LOURDES P. CHAN
Medical director
Cebu Velez General hospital

Supersedes:	**Version 2**
Prepared by:	**SOP Team**
Reviewed by:	**Dr Manuel Emerson S. Donaldo** **Chairman** **CIM CVGH IRB**
Review Date	**July 11, 2023**
Approved by	**Dr. Carmen M. Velez** **President CIM** **- CVGH**
Date Approved	**July 20, 2023**
Effectivity Date	**July 21, 2023**

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1. Policy Statement

The selection of CIM-CVGH IRB members shall ensure the representation of different disciplines of medical/scientists and non-medical/non-scientists, gender, and age. At least one non-affiliated member (i.e. a member who is not affiliated with the institution) shall be appointed.

To ensure the proper composition of the CIM-CVGH IRB, the Dean of CIM shall select and appoint the members. The Dean is also vested with the authority to remove any member.

2. Objective

This SOP aims to establish and describe the process of selection and appointment of CIM-CVGH members to ensure that the composition of the CIM-CVGH faithfully complies with the international and national guidelines and considers appropriate individual expertise.

3. Scope:

This SOP begins with the definition of the composition of the IRB and ends with the filing of appointment documents and CVs of IRB members in the membership file.

4. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: *Define the composition of the membership of the IRB*	*Chair, CIM Dean, and CVGH Medical Director*
Step 2: *Call for nominations*	*Chair, CIM Dean and CVGH Medical Director*
Step 3: *Submission of nominations*	*IRB Chair / Members, Hospital Management, Department Chairs, Section Heads*
Step 4: *Shortlisting of nominees*	*Chair and CIM Dean*

Step 5: *Invitation to and confirmation of interest of the nominees*	*Chair*
Step 6: *Appointment of members*	*CIM Dean*
Step 7: *Completion of membership documents and signing of Confidentiality and Conflict of Interest Agreement*	*New IRB Members; Secretariat*
Step 8: *Filing of appointment documents and CVs in the membership file (SOP on Managing Active Files - SOP VII)*	*Member-Secretary*

5. Description of Procedure

5.1. *Define the composition of the membership of the IRB*

5.1.1. The Chair together with the Dean of CIM and the Medical Director of CVGH determines the composition of the membership of the CIM-CVGH IRB subject to the following criteria:

5.1.1.1. The CIM-CVGH IRB shall be composed of at least 9 members.

5.1.1.2. The membership shall be multi-disciplinary. Each IRB member should have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by its own affiliated and non-affiliated researchers.

5.1.1.3. The membership shall comprise of persons whose primary concerns are in medical science and/or public health, one person who is in a non-medical/non-scientific area, and at least one person who is not affiliated with CIM or CVGH.

5.1.1.4. A member must possess good moral character, relevant expertise in his chosen field, knowledge of ethical principles, and willingness to volunteer their time and effort to perform their functions in the IRB.

5.1.1.5. A member's relevant expertise may include medicine and research, social or behavioral sciences, law, philosophy, environmental science, and public health.

5.1.1.6. To the extent feasible and practical, the CIM-CVGH IRB should include as one of its members a person who will represent the interest and concerns of the community.

5.1.1.7. The CIM-CVGH IRB shall aim for adequate representation of men and women members to promote gender sensitivity in its review procedures.

5.1.1.8. The CIM-CVGH IRB shall have representatives from both the older and younger generations.

5.1.1.9. A member shall preferably have prior training in research ethics, research methodology, and Good Clinical Practice and must willing to undergo continuing training for these subjects during their membership. (Refer to SOP 1.4 Training of IRB Members & Staff)

5.2. *Step 2 Call for nominations*

5.2.1. The Chair, the Dean of CIM, and the Medical Director of CVGH shall announce through a written memo the opening of the nomination for members for the CIM-CVGH IRB to the administration, faculty, and personnel of CIM and the hospital management, department chairs, and section heads of CVGH.

5.2.2. The written memo shall indicate the desired qualifications of the nominees, the requirement to submit the Curriculum Vitae (CV) of the nominee and other credentials, and the deadline for the submission of nominations.

5.2.3. The other credentials that need to be submitted together with the CV will depend on the expertise of the member to be appointed.

5.3. ***Step 3*** *Submission of nominations*

5.3.1. Any faculty or employee of CIM and any hospital staff or consultant of CVGH may submit to the Chair within the deadline the names of nominees as members of the CIM-CVGH IRB together with their corresponding CVs and other relevant credentials.

5.4. Step 4 Shortlisting of nominees

5.4.1. For the initial composition of the membership of the CIM-CVGH IRB, the Chair shall submit to the Dean of CIM the list of nominees. The Dean will then deliberate who among the nominees will be invited as members and asked to confirm their interest to join the IRB.

5.4.2. On the other hand, for the selection of an additional or new member of the CIM-CVGH IRB, the Chair shall present to the existing members of the CIM-CVGH IRB the CV and credentials of the nominees. The existing IRB members will then deliberate and decide by consensus on the nominees to be included in the final list to be submitted to the Dean of CIM. Conflict of interest issues of the nominees shall also be discussed.

5.4.3. The Dean will then review the final list of nominees submitted by the IRB and decide on the nominee to be invited as member and asked to confirm his/her interest to join the IRB. The Dean will then convey in writing the decision to the Chair.

5.5. ***Step 5 Invitation to and confirmation of interest of the nominees***

5.5.1. Once the nominee to be invited as a member of the CIM-CVGH IRB has been decided, the Chair will issue an Invitation and Confirmation of Interest Letter (Form 1.1) to the chosen nominee. The purpose of this letter is to ensure the nominee's interest in becoming a member of the IRB.

5.5.2. The Invitation and Confirmation of Interest Letter will include the following details:

5.5.2.1. The duties and responsibilities of each member of the IRB as Primary Reviewers for research protocol documents within their area of expertise and as General Reviewers for all research discussed at convened meetings of the CIM-CVGH IRB;

5.5.2.2. The term of office of three (3) years, renewable for several consecutive terms depending on their performance; and

5.5.2.3. The period for the chosen nominee to accept the nomination, which must not be longer than five (5) working days.

5.5.3. Within the five-working day period, the nominee must confirm interest in becoming a member of the IRB verbally by informing the Chair and formally by signing the Conforme in the Invitation and Confirmation of Interest Letter. The nominee shall then return the letter with the signed Conforme to the Chair.

5.6. Step 6 Appointment of members

5.6.1. Not later than three (3) days after receiving from the nominee the Invitation and Confirmation of Interest Letter with the signed Conforme, the Chair shall inform in writing the Dean of the nominee's interest to become a member of the CIM-CVGH IRB.

5.6.2. The Dean will then appoint the nominee as a member by issuing an Appointment Letter (Form 1.2). The Appointment Letter shall state the following:

5.6.2.1. Term of Office: Members are appointed for a period of three (3) years and renewable for several consecutive terms depending on their performance.

5.6.2.2. Duties: These include —

5.6.2.2.1. Consent to the IRB to make public his/her full name, profession, and affiliation as an IRB member;

5.6.2.2.2. Voluntary disclosure of all financial accountability related to their work in the IRB, which in turn may record and publicly disclose its financial records upon request; and

5.6.2.2.3. Willingness to sign the Confidentiality and Conflict of Interest Agreement (Form 1.4).

5.6.2.2.4. Responsibilities: These include —

5.6.2.2.5. Participating in CIM-CVGH IRB meetings;

5.6.2.2.6. Reviewing, discussing, and considering research proposals submitted for evaluation;

5.6.2.2.7. Reviewing progress reports and monitoring ongoing studies as may be appropriate;

5.6.2.2.8. Evaluating final reports;

5.6.2.2.9. Maintaining confidentiality of the documents and deliberations during IRB meetings;

5.6.2.2.10. Participating in continuing education activities in health research and ethics;

5.6.2.2.11. Declaring any conflict of interest;

5.6.2.2.12. Updating CV and training record every time appointment is renewed;

5.6.2.2.13. Conforming at all times with the legal and ethical principles accepted by the IRB;

5.6.2.2.14. Attending basic and continuing education on Research Ethics at least once a year; and

5.6.2.2.15. Performing other tasks requested or assigned by the IRB Chair.

5.6.2.2.16. For medical Member; Perform ethics review of protocols submitted for review, including reviewing the ICF of the same

5.6.2.2.17. For non-medical Member; Perform ethical review of the ICF of protocols submitted for review

5.6.2.2.18. For members designated to review SAEs/SUSARS; Assessing serious adverse event reports for onsite, performing trending of offsite SAE and SUSARS, and recommending appropriate action if assigned by the Chair;

5.6.2.2.19. For member secretary; To oversee and supervise the staff secretary;

5.7. Step 7 Completion of membership documents and signing of Confidentiality and Conflict of Interest Agreement

5.7.1. Upon appointment, the appointed IRB member must verify that his membership documents submitted to the CIM-CVGH IRB are complete. He must also sign the Confidentiality and Conflict of Interest Agreement.

5.7.2. The Agreement must cover all applications, meeting deliberations, information on research participants, and other matters related to the research proposals/protocols. It must also contain an attachment about the responsibilities of the IRB member and term of office as included in the Appointment Letter.

5.8. Step 8 Filing of appointment documents and CVs in the membership file

5.8.1. The Member-Secretary files the documents and CVs of the members as provided for in SOP 7.4.

6 . Forms

Annex 1:	Form 1.1	Invitation and Confirmation of Interest Letter
Annex 2:	Form 1.2	Appointment Letter
Annex 3:	Form 1.3	Curriculum Vitae
Annex 4:	Form 1.4	Confidentiality and Conflict of Interest Agreement
Annex 5:	Form 1.5.	Training Record of IRB Members

7 . History

Version No.	***Date***	***Authors***	***Main Change***
01	*December 14, 2018*	*SOP team*	*First Draft*
01	*July 2, 2019*	*SOP team*	*Clarified the appointing officer for the Independent Consultant*
02	*June 21, 2021*	*SOP team*	*Revised Detailed Instructions*
03	*July 21, 2023*	*Atty Fernandez*	- *Defined the role of Dean as appointing officer and oversight officer* *Added functions of medical non-medical, member secretary and SAE reviewer*

ANNEX 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

LETTER OF APPOINTMENT IRB MEMBER

FORM 1.1

DATE _____

Dear_____

I have the honor to appoint you as a _____ of the (CIM – CVGH) IRB for a period of _____ years, effective **MM-DD-YYYY** until **MM-DD-YYYY** . As a member, you will have the following duties and responsibilities:

- Duties
- Willingness to make public his/her full name, profession, and affiliation as an IRB member
- Members shall disclose all financial accountability related to their work in the IRB that may record and publicly disclose its financial records upon request
- Members shall sign the Confidentiality and Conflict of Interest Agreements. The agreement should cover all applications, meeting deliberations, information on research participants and related matters.
- Responsibilities:
- Participate in CIM-CVGH IRB meetings
- Review, discuss and consider research proposals submitted for evaluation. • Review progress reports and monitor ongoing studies as appropriate
- Evaluate final reports.
- Maintain confidentiality of the documents and deliberations during IRB meetings • Participate in continuing education activities in health research and ethics
- Declare any conflict of interest.
- Update CV and training record every time appointment is renewed
- Conform at all times with the legal and ethical principles accepted by the IRB • Attend basic and continuing education on Research Ethics at least once a year.
- Perform other tasks requested by the IRB Chair.
- For medical Member; Perform ethical review of protocols submitted for review, including reviewing the ICF of the same
- For non-medical Member; Perform ethical review of ICF submitted for review.
- For members assigned as SAE reviewer; Assess serious adverse event reports for onsite and do trending of offsite SAE and SUSARS and recommend appropriate action if assigned by the Chair.
- For member secretary; To oversee and supervise the staff secretary;

If you agree with the terms of this appointment, please sign on the space provided below, date your signature and return one copy of this letter to the (CIM – CV GH) IRB Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest agreement.
Very truly yours,

_____
Dean

Conforme: Signature over printed name, Date

ANNEX 2

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

CURRICULUM VITAE

FORM 1.2

Personal Information		
	Name:	
	Date of Birth:	

(1 x 1 Picture)	Address:	
	Contact Number:	

Educational Background	
Post Graduate Degree:	
Graduate Degree:	
Bachelor's Degree:	
Other Qualifications and Specializations:	

IRB Membership Record			
Position:		Term of Office:	
Date of Appointment:		End of Term:	

Research Ethics Trainings	
Title of Trainings	***Date***

Work Experiences

Company/Institution	***Position***	***Year***

Name and Signature of Member
< write Full Name herein/Date>

ANNEX 3

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

Confidentiality Agreement

FORM 1.3

CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT

Know all Men by these Presents:

In view of the appointment as a member of the (CIM - CVGH) IRB, and hereinafter referred to as the *Undersigned*, and Whereas: the *Undersigned* has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines; the appointment of the *Undersigned* as a member of the (CIM - CVGH)IRB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; the fundamental duty of an IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and the (CIM - CVGH) IRB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects; The following terms and conditions covering Confidentiality and Conflict of Interest arising in the discharge of said appointed IRB member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the IRB to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the *Undersigned* in conjunction with and/or in the course of the performance of his/her duties as a member/Independent Consultant of the (CIM - CVGH) IRB.

Any written information provided to the *Undersigned* that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.

As such, the *Undersigned* agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"].Moreover, the *Undersigned* agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be dis closed to any third party.

The *Undersigned* further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the *Undersigned* confirms that her performance of this agreement is consistent with (CIM - CVGH)'s policies and any contractual obligations owed to third parties.

performance of this agreement is consistent with (CIM - CVGH)'s policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the IRB to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the IRB that no member/consultant may participate in their view, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IRB.

The *Undersigned* will immediately disclose to the Chair of the (CIM - CVGH) IRB any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the IRB, and to abstain from any participation in discussions or recommendations in respect of such proposals .If an applicant submitting a protocol believes that an IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the IRB member(s) in question. The IRB may elect to investigate the applicant's claim of the potential conflict.

When a member/consultant has a conflict of interest, before any IRB meeting commences, the member should notify the Chairperson and may not participate in the IRB review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

- A member/consultant is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's/consultant's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

(To the *Undersigned*: Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the (CIM - CVGH) IRB. A copy will be given to you for your records.)

In the course of my activities as an INDEPENDENT CONSULTANT of the (CIM - CVGH) IRB, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to

applicable legislation, not to disclose the confidential information to any person; not to use the Confidential Information for any purpose outside the Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an IRB member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____

(CIM - CVGH) IRB Chair Date

Conforme:

_____

Print Name & Sign: Date

ANNEX 4

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

Training Record of an
IRB Member
FORM 1.4

TRAINING RECORD OF AN IRB MEMBER

Last name		First name	

BASIC COURSES	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. GCP Training				
2. Research Ethics				
3.IRBStandard Operating				

CONTINUING ETHICS EDUCATION : Research Ethics Workshops, Conferences, Meetings, Lectures	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. GCP Training				
2.				
3.				
4.				

1. Policy Statement

CIM and CVGH shall jointly ensure a fair designation of competent officers to manage appropriately the CIM-CVGH IRB. To attain this objective, the manner of selection and appointment of its officers is defined under this Section.

2. Objective

This SOP aims to define the process of selection and appointment of the officers of the CIM-CVGH IRB and to ensure that the designation of conforms to institutional practice.

3. Scope

This SOP begins with the call for a meeting and ends with the filing of appointment documents.

General Qualifications of Officers

The officers of the CIM-CVGH IRB must be highly-respected individuals within or outside the institution, fully capable of managing the IRB, and dedicated to ensuring fairness and impartiality in dealing with matters brought to the IRB. They must have the following qualifications:

(a) Good personal characteristics and reputation;
(b) Membership of an Ethics Review Committee for at least 3 years;
(c) Current membership of the CIM-CVGH IRB; and
(d) Willingness to perform the functions as officers of the IRB.

Specific Functions of Officers

A. The Chair

The Chair shall have the following duties and responsibilities:

Ensures that all IRB members receive orientation and undergo basic Research Ethics Training immediately after their appointment and continuing education thereafter;

i. Obtains administrative and logistics support for the sustained operations of the IRB; ii. Approves the agenda and presides over IRB review meetings; however, if the Chair has a Conflict of Interest (COI) over the protocol for deliberation, he or she will abstain from participating in the meeting and will designate either the Vice Chair, the Member

Secretary, or any member of the IRB to preside over the meeting; iii. Selects a suitable (meaning somebody with related expertise) member/independent consultant to be the primary reviewer of a protocol whether by full board or expedited review, and ensures that aforementioned member does not have a COI;

iv. Manages complaints from study participants, authorities, or the general public;
v. Designates a member or group of members to investigate complaints or reports of major non-compliance by the IRB;
vi. Ensures that the IRB is perceived as fair and impartial and complies with institutional, national, and international standards;
vii. Represents the IRB in various local, national, and international meetings and conferences; and
viii. Ensure adherence to quality standards to maintain the accreditation status of the IRB.

B. The Vice Chair

The duties and responsibilities of the Vice Chair are as follows:

i. Performs the duties as may be designated by the Chair;
ii. Presides over the meetings when designated by the Chair in case a COI may arise on the part of the latter over a protocol for deliberation;
iii. Presides over meetings in the absence of the Chair; and
iv. Performs all duties and responsibilities of the Chair in the absence or in the case of the death or incapacity of the latter.

C. The Secretariat

The Secretariat shall be composed of the **Member-Secretary** and the **Administrative Support Staff** who is/are employees of either CIM and CVGH and appointed by the CIM Dean or the CVGH Medical Director as the case may be. The functions of the Secretariat are:

D. Member-Secretary

The Member-Secretary perform the following functions:

(a) In the absence of the Chair, decides which protocols may be expedited or reviewed by full board;
(b) In the absence of the Chair, assigns primary reviewers (as stated in SOP2);
(c) Supervises the Administrative Support Staff as part of good IRB office management;
(d) Prepares and finalizes the meeting agenda of full-board meeting after consultation with the Chair;
(e) Ensures that the members completely fill out necessary forms used for the review of protocol or protocol related submissions;
(f) Supervises the Administrative Support Staff in the preparation of the meeting agenda and minutes;
(g) Ensures good IRB documentation and archiving;

(h) Ensures overall IRB compliance with good clinical practice; and
(i) Ensures good financial management of IRB resources.

ii. Administrative Support Staff

The Administrative Support Staff of the IRB shall have the following functions:

(a) Organize and implement an effective and efficient tracking procedure for each proposal received by the IRB;
(b) Prepare, maintain, and distribute study files;
(c) Organize CIM-CVGH IRB meetings;
(d) Prepare and maintain meeting agenda and minutes;
(e) Establish, implement, and maintain good CIM-CVGH IRB documentation and archiving procedures;
(f) Communicate with the CIM-CVGH IRB members and Investigators;
(g) Arrange the training for personnel and CIM-CVGH IRB members;
(h) Organizing the preparation, review, revision, and distribution of SOPs and guidelines;
(i) Provide the necessary administrative support to the Chair for CIM-CVGH IRB-related activities;
(j) Ensure good CIM-CVGH IRB documentation;
(k) Ensure overall CIM-CVGH IRB compliance with good clinical practice;
(l) Provide CIM-CVGH IRB members updates and literature on relevant and contemporary issues related to ethics in health research;
(m) Create and maintain a library of relevant resource materials and references; and
(n) Provides a copy of the Confidentiality and Conflict of Interest Agreement (Form 1.4) to each member of the CIM-CVGH IRB together with the Appointment Letter (Form 1.2).

4. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: *Call for meeting* (*SOP on Preparing for a Meeting (SOP #5.1)*	*Chair*
Step 2: *Nominations*	*IRB Members*
Step 3: *Election*	*IRB Members*
Step 4: *Appointment of Officers*	*CIM Dean and CVGH Medical Director*
Step 5: *Filing of appointment documents (SOP on Managing Active Files (SOP # 7.2)*	*Secretariat*

5. Description of Procedures

5.1 Step 1: *Call for meeting (Refer to SOP on Preparing for a Meeting SOP #5.1)*

The Chair will call a meeting for the election of the officers of the CIM-CVGH IRB.

5.2 Step 2: *Nominations*

The Chair will open the nominations for officers of the CIM-CVGH IRB other than the Chair, who is appointed jointly by the Dean of CIM. The members shall give their nominees *viva voce*.

Any member of the CIM-CVGH IRB may be nominated as an officer. For the nomination to be valid, there must be at least one nominee for each available or vacant position.

Any conflict-of-interest issues of the nominees shall also be discussed by the members.

5.3 Step 3: *Election*

After the Chair declares the nominations to be closed, all members present will vote by *viva-voce* who among the nominees will be elected as officer. Each member of the CIM-CVGH IRB is entitled to one vote.

The Chair will then declare the results of the election to the members of the IRB present. Within three (3) working days after the election, he will also inform in writing the Dean of CIM and the Medical Director of CVGH of the officers elected by the members.

5.4 Step 4: *Appointment of new officers*

The Dean of CIM and the Medical Director of CVGH shall jointly appoint the Chair. With regard to the Vice Chair and the Secretariat, the Dean and the Medical Director shall jointly appoint those members of the CIM-CVGH IRB who were elected to these positions.

The appointment letter shall contain the position to which the member has been appointed, the term of office, which is three years, and the duties and responsibilities of the position.

5.5 Step 5: *Filing of appointment documents (SOP on Managing Active Files (SOP # 7.2)*

The Secretariat shall file the appointment documents of the as provided for in SOP 7.2

6.Forms

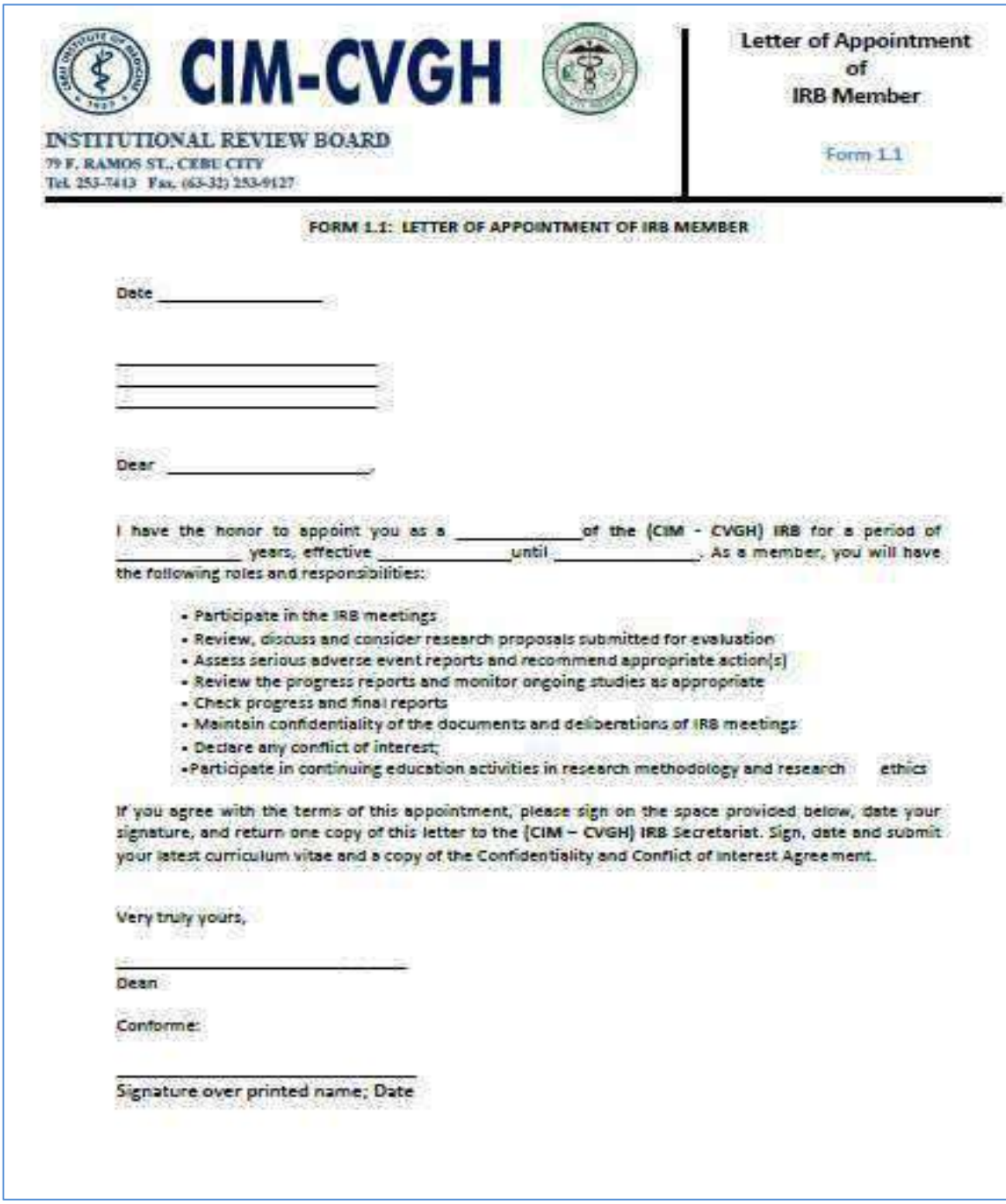
Annex 1: Form 1.1 Appointment Letter
Annex 2: Form 1.2 Curriculum Vitae

Annex 3: Form 1.3 Confidentiality Agreement

7.History

Version No.	***Date***	***Authors***	***Main Change***
01	*July 2019*	*SOP Team*	*First draft--*
02	*July 21, 2021*	*SOP Team*	- *Changed the Policy Statement to include the purpose* - *Included appointment of officers by dean*
03	*July 21, 2023*		- *NONE*

ANNEX 1



CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

Letter of Appointment
of
IRB Member

Form 1.1

FORM 1.1: LETTER OF APPOINTMENT OF IRB MEMBER

Date _____

_____
_____
_____

Dear _____,

I have the honor to appoint you as a _____of the (CIM - CVGH) IRB for a period of _____ years, effective _____until _____. As a member, you will have the following roles and responsibilities:

- Participate in the IRB meetings
- Review, discuss and consider research proposals submitted for evaluation
- Assess serious adverse event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate
- Check progress and final reports
- Maintain confidentiality of the documents and deliberations of IRB meetings
- Declare any conflict of interest;
- Participate in continuing education activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the (CIM – CVGH) IRB Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

_____
Dean

Conforme:

_____
Signature over printed name; Date

ANNEX 2

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

CURRICULUM VITAE

FORM 1.2

Personal Information		
(1 x 1 Picture)	Name:	
	Date of Birth:	
	Address:	
	Contact Number:	

Educational Background	
Post Graduate Degree:	
Graduate Degree:	
Bachelor's Degree:	
Other Qualifications and Specializations:	

IRB Membership Record			
Position:		Term of Office:	
Date of Appointment:		End of Term:	

Research Ethics Trainings	
Title of Trainings	***Date***

Work Experiences		
Company/Institution	*Position*	*Year*
Name and Signature of Member		
< write Full Name herein/Date>		

ANNEX 3

CIM-CVGH
INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

Confidentiality Agreement

FORM 1.3

CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT

Know all Men by these Presents:

In view of the appointment as a member of the (CIM - CVGH) IRB, and hereinafter referred to as the *Undersigned*, and Whereas: the *Undersigned* has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines; the appointment of the *Undersigned* as a member of the (CIM - CVGH)IRB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; the fundamental duty of an IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and the (CIM - CVGH) IRB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects; The following terms and conditions covering Confidentiality and Conflict of Interest arising in the discharge of said appointed IRB member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the IRB to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the *Undersigned* in conjunction with and/or in the course of the performance of his/her duties as a member/Independent Consultant of the (CIM - CVGH) IRB.

Any written information provided to the *Undersigned* that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.

As such, the *Undersigned* agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"). Moreover, the *Undersigned* agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be dis closed to any third party.

The *Undersigned* further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the *Undersigned* confirms that her performance of this agreement is consistent with (CIM - CVGH)'s policies and any contractual obligations owed to third parties.

performance of this agreement is consistent with (CIM - CVGH)'s policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the IRB to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the IRB that no member/consultant may participate in their view, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IRB.

The *Undersigned* will immediately disclose to the Chair of the (CIM - CVGH) IRB any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the IRB, and to abstain from any participation in discussions or recommendations in respect of such proposals .If an applicant submitting a protocol believes that an IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the IRB member(s) in question. The IRB may elect to investigate the applicant's claim of the potential conflict.

When a member/consultant has a conflict of interest, before any IRB meeting commences, the member should notify the Chairperson and may not participate in the IRB review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

- A member/consultant is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's/consultant's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

[*To the Undersigned:* Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the (CIM - CVGH) IRB. A copy will be given to you for your records.]

In the course of my activities as an INDEPENDENT CONSULTANT of the (CIM - CVGH) IRB, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to

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INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

Confidentiality Agreement

FORM 1.3

applicable legislation, not to disclose the confidential information to any person; not to use the Confidential Information for any purpose outside the Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an IRB member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____

(CIM - CVGH) IRB Chair Date

Conforme:

_____

Print Name & Sign: Date

ANNEX 4

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

Training Record of an IRB Member

FORM 1.4

TRAINING RECORD OF AN IRB MEMBER

Last name		First name	

BASIC COURSES	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. GCP Training				
2. Research Ethics				
3.IRBStandard Operating				

CONTINUING ETHICS EDUCATION : Research Ethics Workshops, Conferences, Meetings, Lectures	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. GCP Training				
2.				
3.				
4.				

1. Policy Statement

The CIM-CVGH IRB shall invite individuals with expertise in special areas to assist in the review of protocols that are not within the area of competence or expertise of the IRB members. He/she may or may not be affiliated with CIM or CVGH.

2. Objective

This SOP aims to ensure that the appointment of Independent Consultants conforms with institutional practice and complements the pool of expertise in the IRB.

3. Scope

This SOP begins with the creation and maintenance of a pool of Independent Consultants and ends with the filing of their appointment documents.

4. Duties of Independent Consultant

In assisting in the review of the research protocol, the Independent Consultant shall have the following duties:

1. Submit to the CIM-CVGH IRB Secretariat a completed protocol evaluation form for the protocol reviewed. This must be submitted at least one day prior to the IRB meeting when the reviewed research protocol will be deliberated;
2. Participate in the IRB meetings when invited. If the Independent Consultant cannot attend, he/she shall submit to the IRB Secretariat at least one day prior to the scheduled IRB meeting his/her extensive written evaluation and comments relevant to the protocol reviewed;
3. I Review, discuss, and consider related research proposals submitted according to his expertise including risks involved and the means of mitigating these risks;
4. Maintain confidentiality of the documents and deliberations of IRB meetings;
5. Declare any conflict of interest before assuming the duties as Independent Consultant; and
6. Conform at all times with the legal and ethical principles accepted by the CIM-CVGH IRB.

5. Workflow

ACTIVITY	*RESPONSIBILITY*
Step 1: *Create and maintain a pool of Independent Consultants from each specialty*	*Chair, Member- Secretary, Members*
Step 2: *Determine the need of an Independent Consultant to assist in the review of a research protocol*	*Chair*
Step 3: *Select and recommend list of Independent Consultants to the CIM Dean and CVGH Medical Director*	*Chair/Member-Secretary*
Step 4: *Invitation of the Independent Consultant*	*Chair*
Step 5: *Acceptance of invitation*	*Independent Consultant*
Step 6: *Appointment of Independent Consultant*	*CIM Dean and CVGH Medical Director*
Step 7: *Signing of Confidentiality and Conflict of Interest Agreement*	*Independent Consultant*
Step 8: *Filing of appointment documents (see SOP Managing Active Files(SOP#7.2)*	*IRB Administrative Support Staff*

6. Description of Procedures

6.1 Step 1**:** *Create and maintain a pool of Independent Consultants from each specialty*

The CIM-CVGH IRB will create and maintain a pool of potential Independent Consultants recruited from the different specialty departments of CIM, CVGH, and other medical education or medical institutions.

The Chair or the Member-Secretary will recruit the potential Independent Consultants. The Secretariat then compiles the list of Independent Consultants who are willing to form part of the pool.

From this pool, CIM-CVGH IRB will select and appoint an Independent Consultant who will assist in the review of protocols that are not within the area of competence or expertise of the IRB members. The Independent Consultant will be selected according to the expertise required by or relevant to the protocols reviewed.

6.2 Step 2: *Determine the need of an Independent Consultant to assist in the review of a research protocol*

Upon the receipt by the CIM-CVGH IRB Secretariat of a research protocol for review, the Chair shall determine the need to appoint an Independent Consultant to assist in the review.

6.3 Step 3: *Select and recommend list of Independent Consultants to the CIM Dean and CVGH Medical Director*

Once the Chair determines that the assistance of an Independent Consultant is needed, he/she or the Member-Secretary conducts a qualification review of the list.

From the pool and based on the expertise and availability criteria needed, the Chair will then prepare and finalize a list of the Independent Consultants most suitable for the review of the research protocol. This list together with a written request for the appointment of an Independent Consultant and the corresponding honorarium will be submitted to the Dean of CIM and the Medical Director.

Within five (5) working days after receiving the list and written request for appointment and honorarium, the Dean and the Medical Director will select from the list the Independent Consultant who will assist in the protocol review. They will then communicate in writing their selection to the Chair.

6.4 Step 4: *Invitation of the Independent Consultant*

After receiving the communication from the Dean and the Medical Director, the Chair shall write an Invitation Letter to the selected Independent Consultant informing the latter of the CIM-CVGH IRB's intention to appoint him/her to assist in the review of a research protocol. The purpose of the Invitation Letter is to verify and confirm the selected Independent Consultant's availability and willingness to assist in the protocol review.

6.5 Step 5: *Acceptance of invitation*

The Independent Consultant signifies his acceptance of the invitation by signing the Conforme in the Invitation Letter and by submitting his/her Curriculum Vitae (Form 1.2).

6.6 Step 6: *Appointment of Independent Consultant*

After receiving the Independent Consultant's acceptance of the invitation and CV, the Chair shall inform the Dean of CIM and the Medical Director of CVGH of the acceptance. The Dean and the Medical Director will then issue a Letter of Appointment of Independent Consultant (Form 1.1A) that will be sent to the selected Independent Consultant for his Conforme.

The Letter of Appointment shall clearly state the responsibilities of an Independent Consultant as mentioned in this SOP.

6.7 Step 7: *Signing of Confidentiality and Conflict of Interest Agreement*

Upon the appointment of the Independent Consultant, he/she shall sign the Confidentiality and Conflict of Interest Agreement. The Agreement shall cover all applications, meeting deliberations, information on research participants, and other related matters.

6.8 Step 8: *Filing of appointment documents*

The Secretariat shall file the documents and CVs of the Independent Consultants as provided in SOP 7.2

7.Forms

Annex 1: Form 1.1A Letter of Appointment of Independent Consultant
Annex 2: Form 1.2 Curriculum Vitae
Annex 3: Form 1.3 Confidentiality Agreement

8.History

Version No.	***Date***	***Authors***	***Main Change***
01	*December 14, 2018*	*SOP Team*	
02	*July 21, 2021*	*SOP Team*	- *Clarified the appointing officer for the Independent Consultant* - *Included responsibilities of the Independent Consultant in the appointment workflow* - The independent consultants are invited by the IRB according to the expertise relevant to the protocols reviewed

ANNEX 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

LETTER OF APPOINTMENT INDEPENDENT CONSULTANT FORM 1.1A

DATE _____

_____
_____
_____

Dear_____

I have the honor to appoint you as a _____ of the (CIM – CVGH) IRB for a period of _____ years, effective _____ until _____. As an independent consultant, you will have the following responsibilities:

- Responsibilities:
- Participate in the IRB meetings when invited. If the Independent Consultant cannot attend he/she shall provide a written document of his/her evaluation and comments relevant to the protocol prior to the set IRB meeting.
- Review discuss and consider related research proposals submitted according to his expertise including risks involved and how to mitigate them
- Maintain confidentiality of the documents and deliberations of IRB meetings
- Declare any conflict of interest
- Conform at all times with the legal and ethical principles accepted by the IRB

If you agree with the terms of this appointment, please sign on the space provided below, date your signature and return one copy of this letter to the (CIM – CV GH) IRB Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest agreement.

Very truly yours,
_____+
Dean

Conforme:
_____
Signature over printed name, Date

ANNEX 2

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

CURRICULUM VITAE

FORM 1.2

Personal Information			
(1 x 1 Picture)	Name:		
	Date of Birth:		
	Address:		
	Contact Number:		
Educational Background			
Post Graduate Degree:			
Graduate Degree:			
Bachelor's Degree:			
Other Qualifications and Specializations:			
IRB Membership Record			
Position:		Term of Office:	
Date of Appointment:		End of Term:	
Research Ethics Trainings			
Title of Trainings			*Date*
Work Experiences			
Company/Institution	*Position*		*Year*

Name and Signature of Member		
< write Full Name herein/Date>		

ANNEX 3

CIM-CVGH
INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

Confidentiality Agreement

FORM 1.3

CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT

Know all Men by these Presents:

In view of the appointment as an INDEPENDEN CONSULTANT of the **(CIM - CVGH) IRB**, and hereinafter referred to as the ***Undersigned***, and Whereas: the ***Undersigned*** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines; the appointment of the ***Undersigned*** as a member of the **(CIM - CVGH)IRB** is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; the fundamental duty of an IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and the **(CIM - CVGH) IRB** must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects; The following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed IRB member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the IRB to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the ***Undersigned*** in conjunction with and/or in the course of the performance of his/her duties as a member/Independent Consultant of the **(CIM - CVGH) IRB**.

Any written information provided to the ***Undersigned*** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.

As such, the ***Undersigned*** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"). Moreover, the ***Undersigned*** agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be dis closed to any third party.

The ***Undersigned*** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the ***Undersigned*** confirms that her

performance of this agreement is consistent with [CIM - CVGH]'s policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the IRB to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the IRB that no member/consultant may participate in their view, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IRB.

The *Undersigned* will immediately disclose to the Chair of the (CIM - CVGH) IRB any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the IRB, and to abstain from any participation in discussions or recommendations in respect of such proposals .If an applicant submitting a protocol believes that an IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the IRB member(s) in question. The IRB may elect to investigate the applicant's claim of the potential conflict.

When a member/consultant has a conflict of interest, before any IRB meeting commences, the member should notify the Chairperson and may not participate in the IRB review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

- A member/consultant is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's/consultant's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

[*To the Undersigned:* Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the (CIM - CVGH) IRB. A copy will be given to you for your records.]

In the course of my activities as an INDEPENDENT CONSULTANT of the [CIM - CVGH] IRB, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to

applicable legislation, not to disclose the confidential information to any person; not to use the Confidential Information for any purpose outside the Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an IRB member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____

(CIM - CVGH) IRB Chair Date

Conforme:

_____

Print Name & Sign: Date

1. Policy Statement

The IRB ensure that the members and staff of the Institutional Review Board are trained in the proper conduct of their duties as members and officers of the Board.

2. Objective

This activity aims to define the IRB procedures to ensure initial and continuing training of the IRB members and staff.

3. Scope:

This SOP describes the training requirements of IRB members and staff from initial training to continuing education to maintain and update IRB competence in the review of different types of protocols.

4. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: ***Require basic research ethics training for all members and staff.***	*Chair*
Step 2: ***Provide opportunities for continuing education for members and staff through participation in meetings conferences and training courses.***	*Chair, Member- Secretary, Members*
Step 3: ***Track member and staff participation in initial training and file the documents in the membership File***	*Member- Secretary, IRB Staff*

5. Description of Procedures:

IRB members should maintain competence by ensuring that they have updated knowledge of the following:

Good Clinical Practice (GCP)

- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc.
- International meetings and conferences

5.1 Step 1: *Require Basic Research Ethics Training for all members and staff*

5.1.1 All IRB members are required to have basic research ethics training that shall consist of research ethics principles, GCP, SOPs, etc. Upon appointment, a new member or staff undergoes orientation, individually or as a group, to cover the following:

5.1.1.1 Member's/Staff's responsibilities;

5.1.1.2 Confidentiality and Conflict of Interest Agreement; ○ IRB review process and use of Protocol and ICF Assessment forms; ○ And IRB SOPs.

5.1.2 The IRB Chair and Member-Secretary shall ensure that initial research ethics training is provided to all new members.

5.2 Step 2: Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses

5.2.1 The IRB Chair provides training opportunities to members/staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.

5.2.2 The IRB Chair and Secretariat plan the training activities for individual IRB members based on their training needs.

5.2.3 The IRB Chair and Secretariat track and facilitate IRB members and staff of specific training activities needed to ensure that each one gets training at least once a year.

5.2.4 The IRB Members who participate in research ethics training course or seminar-workshops either through personal or through IRB efforts/funding are encouraged to:

5.2.5 Share information with other members during IRB meetings; and

5.2.6 Distribute photocopies/e-copies of relevant materials to the other members

5.3 Step 3: *Track member and staff participation in initial and continuing ethics training and file the documents in the Membership File.*

5.3.1 For in-house training, the IRB Staff prepares attendance sheets with relevant information about the topic, duration, date and venue. They ask member-attendees to sign the attendance sheet and keeps a photocopy of the attendance in the membership files, if Training Certificate is not given.

5.3.2 All IRB Members and Staff should regularly update their Training Record. They should submit proof of attendance in relevant training or continuing professional education sessions conducted outside of the institution – e.g. certificates of training to the IRB Staff for filing.

5.3.3 Administrative Staff should update the Training Record of individual Member and Staff to reflect their attendance in training activities every time a photocopy of Training Certificate is submitted for filing.

6. Forms:

Form 1.4 Training Record of IRB Member and Staff

7. History

Version No.	***Date***	***Authors***	***Main Change***
01	*April 10, 2016*	*SOP Team*	*First Draft*
01	*July 2, 2019*	*SOP Team*	- *Formatted changed REC to IRB*
02	*July 21, 2021*	*SOP Team*	- *NONE*
03	*July 21, 2023*	*Dr. Cutillar*	- *Updated References*

ANNEX 1

Form 1.4 Training Record of IRB Member and Staff

To be summarized by the IRB Staff and checked by IRB member				
Last Name		**First Name**		
BASIC COURSES	**ORGANIZER**	**VENUE**	**DATE**	**FUNDING SOURCE**
1. GCP				
2. BRET				
3. IRB SOP Training				
4. Etc.				
Continuing Education include; **Workshops, conferences Meetings, Lectures**	**ORGANIZER**	**VENUE**	**DATE**	**FUNDING SOURCE**
1.				
2.				
3.				
4.				

1. **Policy Statement**

   This SOP describes how the CIM-CVGH IRB manages study protocol submission packages from initial submission including review classifications and panel review assignments.

   The IRB shall require a set of documents listed in a checklist for initial submission and only complete submissions shall be accepted. Only complete protocols submitted **on or before the 2nd Wednesday of the month** will be taken up during the IRB meeting which is scheduled every 3rd Wednesday of the month.

2. **Objective**

   This activity aims to ensure that study documents which are submitted by Principal Investigators for initial review are properly received, identified, recorded, and are complete.

3. **Scope:**

   This SOP begins with the receipt of study documents for initial review and ends with the distribution of the protocol to the primary reviewers.

4. **Workflow**

ACTIVITY	RESPONSIBILITY	Schedule of Accomplishment
Step 1. Receive the initial protocol package for review and check the completeness of the documents.	IRB Staff	Day 0
Step 2. Assign a permanent code to the protocol package		
Step 3. Give a duplicate copy of the review application form to the person submitting the package.		

Step 4. Determine the type of review Exemption from Review (SOP 2.2) Expedited Review (SOP on Expedited Review (SOP#2.3) Full Review (SOP on Full Review (SOP#2.4)	Chair/Member Secretary	Within 3 days from acceptance of protocol
Step 5. Assignment of primary reviewers		
Step 6. Prepare the protocol review package for distribution to the primary reviewers.	IRB Staff	The protocols are distributed to the reviewers not less than 1 week prior the monthly meeting

5. Description of Procedures

5.1. ***Step 1 Receive the initial protocol package for review and check the completeness of the documents***

5.1.1. The staff secretary shall receive on line protocol submissions as well as hard copies submitted in person by the Principal Investigator and/or Research Team

5.1.2. The Secretariat shall ensure that the Review Application Form (Form 2.1) and the Protocol Summary Sheet (Form 2.2) are completely filled up, signed and dated by the researcher including receipt for review fee if applicable.

5.1.3. Protocols should be accompanied by a letter signifying that it has undergone and passed technical review of the respective departments. The Technical Review Committee should have addressed the technical issues in the study protocol.\

5.1.4. Upon submission of the initial protocol for the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format.

5.1.5. Only complete protocols submitted on or before the 2nd Wednesday of the month will be taken up during the IRB meeting which is scheduled every 3rd Wednesday of the month

5.1.6. If so desired by the principal investigator a waiver of Informed Consent should be requested in writing and submitted together with the initial package. A request for waiver of consent should be accompanied by a justification.

5.2. ***Step 2 The Secretariat shall assign a permanent code to the protocol package***

5.2.1. For efficient file management, it is necessary to use a unique identifier to refer to this file, the Protocol Code Number. This code number is given as follows: CIM_CVGH IRB: YYYY (year) – mm (month) – number (chronological number based on order of receipt).

5.2.2. For example, if the protocol entitled "Comparison of Drug A versus Drug B in inducing remission rate of X" is the first protocol received in 2017, the code (Name of Hospital) CIM-CVGH IRB: 2017-01 – 01 should be used to identify this protocol. The code will be communicated to the researcher/principal investigator in all communications regarding the protocol

5.3. ***Step 3 Give a duplicate copy of the review application form to the author.***

5.3.1. A duplicate copy of the review application form, containing the Protocol Code Number, will be given to the person who submitted the protocol.

5.3.2. The author will use this Code Number to refer to the protocol submitted in all future re-submissions, and/or communications to the IRB.

5.4. ***Step 4 Determine the type of review***

5.4.1. The CIM-CVGH IRB Chair classifies the study protocol review pathway within 3 days from protocol acceptance. The review can be Expedited Review, Full Board Review or Exempt from Ethical Review, filtered through the following criteria for Expedited Review:

5.4.1.1. The research poses low risk.
5.4.1.2. The study does not involve vulnerable populations.
5.4.1.3. The study does not involve the collection of stigmatizing information.
5.4.1.4. The study uses anonymized or archived samples.
5.4.1.5. Continuing review of clinical trials that do not involve further recruitment of participants.
5.4.1.6. Continuing review of studies previously classified under expedited review.
5.4.1.7. Study protocol amendments that are administrative in nature and do not affect the study protocol.
5.4.1.8. Study protocol amendments that do not change the overall risk profile of study.

5.4.2. Research that qualifies for exemption from ethical review will be filtered through the criteria listed in the 2017 National Ethical Guidelines for Health and Health-related Research (NEGHHR 2017). See SOP 2.2

5.5. ***Step 5 Assignment of primary reviewers***

5.5.1. The Chair/Member secretary shall assign at least 2 primary reviewers, 1 medical to review the protocol and the ICF, and one non-medical to review the ICF.

5.5.2. The Primary reviewers shall be informed not later than 1 week before the meeting schedule

5.5.3. For protocols to be reviewed Full Board, all IRB members shall be given a copy of the protocol for review

5.6. ***Tep 6 Distribution of the protocol and evaluation form to the primary reviewers***

5.6.1. Electronic and/or hard copies of the protocol and the evaluation forms (protocol evaluation form #2.3 and ICF evaluation form #2.4 shall be provided to the reviewers once they are informed

6. Forms

Annex 1 – Form 2.1: Review Application Form
Annex 2 – Form 2.1A: Waiver of Informed Consent Form
Annex 3 – Form 2.2: Protocol Summary Sheet
Annex 4 – Form 2.3: Protocol Evaluation Form
Annex 5 – Form 2.4: Informed Consent Assessment Form
Annex 6 – Form 3 Review Exemption Application Form

7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*Nov 16, 2016*	*SOP Team*	*FIRST DRAFT*
02	June 21, 2021	SOP Team	Formatting changed
03	Aug 21, 2023	Dr. Cutillar	- Timeline included - Steps 5-7 (Filing of documents) were moved to other SOP - Updated References

STEPS FOR CIM CVGH IRB SUBMISSION

1. Fill up an application form for review (IRB Form 2.1) and submit to the IRB office.
2. Pay the appropriate IRB review fee.
3. IRB staff will screen the application for completeness. All protocols and Informed Consents submitted should reflect the protocol version number and date. The IRB reserves the right not to accept incomplete submission packages.
4. Applications will be accepted no later than 2 weeks prior to the scheduled monthly meeting (3rd Wednesday of each month). Applicants are encouraged to submit on the first week of the month.
5. IRB staff will assign an IRB reference number to the protocol submitted. Please use this reference number for future dealings with the IRB.
6. The investigator/representative may be invited to present during the board meeting to provide further information related to the study submitted for approval by the IRB.
7. IRB Decision letter will be available to the PI not later than 2 weeks from review.
8. Technical Review from Research Committee.
9. Submit Two (2) copies and send the soft copy at irbcimcvgh@gmail.com
10. Follow up inquiries will be entertained through tel nos. 09173204149 – e mail add irbcimcvgh@gmail.com

***** Please keep this copy for your guidance *****

ANNEX 1

APPLICATION FOR INITIAL REVIEW To be filled by Investigator				
Sponsor Protocol Number:			**IRB Protocol Number:**	
Submission Date:				
Protocol Title:				
Principal Investigator:				
Telephone number:			**Fax**	
E-mail:			**Preferred Contact**	
Institute:				
Investigator Initiated:	• Yes	• No		
Sponsor Initiated	• Yes	• No	**Name of Sponsor**	**N/A**
(Relationship with sponsor)				

Are you a regular employee of the sponsor?	• Yes	• No
Did you do consultancy or part time work for the sponsor?	• Yes	• No
In the past year, did you receive ≥ P250,000 or from the sponsor?	• Yes	• No
Other ties with the sponsor? If Yes pls Specify _____	• Yes	• No

No Conflict of Interest Declaration by Principal Investigator:

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

PI Signature:	
Name of Adviser/Mentor	

Documents submitted: (Please Check)

REQUIRED FOR ALL INITIAL SUBMISSIONS	OPTIONAL: only IF APPLICABLE TO PROTOCOL
• Protocol • Protocol summary (for clinical trials) • Informed consent form (when in use) • Research Team List • CVs & Research Ethics Training Certificates • Study budget	• Technical Review Certificate (for PI Initiated) • Questionnaire • Case report forms (CRF) • Investigator brochure (for Clinical Trials) • GCP certificates (for Clinical Trials) • Advertisement
ARE THE DOCUMENTS SUBMITTED COMPLETE:	• YES • NO

DO NOT ACCEPT INCOMPLETE PACKAGES

Type of Research/Phase of Trial

• Survey • Screening • Clinical trial • Genetic • Single Center	• Social • Observational • Phase I • Retrospective • Multicenter	• Medical • Epidemiologic • Phase II • Prospective • Others _____	• Community • Interventional • Phase III • Others____	• Individual Based • Phase IV

Study Duration:		**Received By:**		**Date:**	

FOR IRB USE ONLY

• Exempt	• Expedited	• Full Board
• Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols)	• Minimal risk protocols • Chart review • Survey of non-sensitive nature	• Protocols that entails more than minimal Risk • Protocols involving Vulnerable populations, particularly prisoners

• Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the IRB for exemption from review:
  • Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
  • Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
  • There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation;
  • The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.
• Protocols that involve the use of publicly available data or information.
	• Use of anonymous or anonymized laboratory/pathology samples or stored tissues or data	• Sensitive topics, including illegal behaviors
		• Research involving genetic testing
		• A complex research design requiring the expertise of multiple board members to evaluate

Type of Review: ☐ **Exempt** ☐ **Expedited** ☐ **Full Board**

Assigned Primary Reviewer:

Dr. Manuel Emerson Donaldo **IRB Chair/Member Secretary Name & Signature**	**DATE**

ANNEX 2

CIM-CVGH

WAIVER OF INFORMED CONSENT

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

IRB ref No. | | | | - | | | - | | |

Protocol Title:	
Principal Investigator:	

Please tick as appropriate:

- ☐ The research presents no more than minimal risk; including archival research involving publicly available documents that it is impractical to get an informed consent
- ☐ The waiver or amendment will not adversely affect the rights and welfare of the participants.
- ☐ The research cannot be practicably carried out without the waiver.
- ☐ The participants will be provided with additional pertinent information after their participation (debriefing whenever appropriate).
- ☐ Research that uses the method of naturalistic observation (often described as "covert" method) in data collection if all the following requirements are complied with:
  - ☐ Thorough justification for the use of naturalistic observation;
  - ☐ There is a plan for how the data collected will be used;
  - ☐ There is an assurance that risks to participants are unlikely;
  - ☐ There is an existing mechanism to ensure confidentiality and anonymity of observed individuals and their data (e.g., observations are recorded in such a way that the individuals involved are not identifiable).

Recommended IRB Decisions:

☐ Approved

☐ Disapproved

Chair IRB: _____ Date: _____

Application for waiving an informed consent:

A waiver of Informed consent should be applied for in writing by the Investigator addressed to the IRB. Informed consents may be waived only with the CIMCVGH IRB'S written consent.

The informed consent process may be waived in specific research contexts, such as:

- Archival research involving publicly available documents that it is impractical to get an informed consent
- Research that uses the method of naturalistic observation (often described as "covert" method) in data collection if all the following requirements are complied with:
    1. Thorough justification for the use of naturalistic observation;
    2. Plan for how the data collected will be used;
    3. Assurance that risks to participants are unlikely;
    4. There is an existing mechanism to ensure confidentiality and anonymity of observed individuals and their data (e.g., observations are recorded in such a way that the individuals involved are not identifiable).

Some or all the elements in the informed consent may be waived or amended (with prior approval of the REC) if all the following conditions are met:

1. The research presents no more than minimal risk.
2. The waiver or amendment will not adversely affect the rights and welfare of the participants.
3. The research cannot be practicably carried out without the waiver or alteration.
4. The participants will be provided with additional pertinent information after their participation (debriefing whenever appropriate).

ANNEX 3

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

PROTOCOL SUMMARY FORM

FORM 2.2

Date		**IRB REFERENCE NO.**					-			-		

Primary Investigator	
1. Study Title	
2. Study Category	☐ Research involving human participants ☐ Research involving non-human living vertebrateS ☐ Others (indicate):

3. TECHNICAL SYNOPSIS (TO BE FILLED UP BY THE PRIMARY INVESTIGATOR)		**Page**
a. Objectives/Expected output	.	
b. Research design	.	
c. Sampling design, sample size		
d. Inclusion criteria, exclusion criteria, withdrawal criteria		
e. Data collection and processing plan		
f. Specimen collection and processing plan	.	
g. Data analysis plan		
h. Duration of human participant involvement		
4. Ethical Considerations		
a. Protection of privacy and confidentiality of research information including data protection plan	.	
b. Vulnerability of research participants		
c. Risks of the study		
d. Benefits of the study		

e.Patient-related compensations/reimbursements/ entitlements		
5. Study Duration	(in months)	
6. Use of special populations or vulnerable groups	_____ Yes _____ No _____ Not Applicable	
7. Study Budget		
8. Previous ethics approval or clearance issued by other sites	☐ Name of Institutional Review Board or ERC ☐ Date of ethics approval: ☐ Date of expiration of ethics approval: ☐ Not applicable	
9. Principal Investigator Signature:		

ANNEX 4

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

PROTOCOL EVALUATION FORM

FORM 2.3

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	**SPONSOR**	**DATE OF REVIEW**

CATEGORY OF THE INVESTIGATOR:

☐ CIM Faculty ☐ CIM students Year Level _____ ☐ Residents-in-Training _____	☐ Fellows -in-training _____ ☐ Others _____

P.I. CONTACT NO.		**EMAIL-ADDRESS**	

PROTOCOL NO. & TITLE

QUESTIONS				**Recommendations**
1) Are the objectives clear?	Y☐	N☐	N.A.☐	
2) Is there a need for human participants?	Y☐	N☐	N.A.☐	
• Are the subjects vulnerable? (if yes- for full Board review)	Y☐	N☐	N.A.☐	
3) Is there an informed consent?	Y☐	N☐	N.A.☐	
4) Is the background information sufficient?	Y☐	N☐	N.A.☐	
5) Is the study design appropriate for the objectives?	Y☐	N ☐	N.A.☐	

• Are the control arms appropriate? (for clinical trials)	Y☐	N ☐	N.A.☐	

6) Is the approximate number of subjects involved in the trial specified?	Y☐	N☐	N.A.☐	
• Are the inclusion criteria appropriate?	Y☐	N ☐	N.A.☐	
• Is the proposed subject population appropriate for the nature of the research?	Y☐	N ☐	N.A.☐	
• Has the IRB taken into account any special vulnerability among prospective subjects that might be relevant to evaluating the risk of participation?	Y☐	N☐	N.A.☐	
• Are the exclusion criteria appropriate?	Y☐	N ☐	N.A.☐	
• Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research?	Y☐	N☐	N.A.☐	
7) Is the setting of the study clearly identified?	Y☐	N☐	N.A.☐	
• Are the facilities and infrastructure of the participating sites adequate	Y☐	N☐	N.A.☐	
• Is the duration of the study specified?	Y☐	N☐	N.A.☐	
8) Are the procedures to be done in the study clearly described and understandable?	Y☐	N☐	N.A.☐	
• Are blood/tissue samples sent abroad?	Y☐	N☐	N.A.☐	
9) Are research data recorded and maintained with strict confidentiality?	Y☐	N☐	N.A.☐	
10) Considering the degree of risk, is the plan for monitoring the research appropriate and adequate in terms of timeliness and thoroughness?	Y☐	N☐	N.A.☐	
11) Is the principal investigator competent to do the study? (by training, expertise or sub specialization)	Y☐	N☐	N.A.☐	
12) Is the principal investigator assessed for any Conflict of Interest for this study?	Y☐	N☐	N.A.☐	
13) If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient?	Y☐	N☐	N.A.☐	
14) Is the mechanism for providing information to the IRB if unexpected results are discovered appropriate?	Y☐	N☐	N.A.☐	
15) If the research involves the evaluation of a therapeutic procedure, have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?	Y☐	N☐	N.A.☐	

16) Has due care been used to minimize risks and maximize the likelihood of benefits?	Y☐	N☐	N.A.☐	
17) Are the subjects given incentives or compensation for study-related expenses?	Y☐	N☐	N.A.☐	
18) Are there adequate provisions for a continuing reassessment of the balance between risks and benefits?	Y☐	N☐	N.A.☐	
19) Is the research expected to have an impact on the community where the research occurs and/or to whom findings can be linked, including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study?	Y☐	N☐	N.A.☐	
20) Does the institution have a data and safety monitoring board?	Y☐	N☐	N.A.☐	
If so, should it be asked to monitor the project under review?	Y☐	N☐	N.A.☐	
If the institution does not have a data and safety monitoring board, should the IRB request or recommend that one be appointed, either by the institution or the sponsor, for this project?	Y☐	N☐	N.A.☐	

Recommendations:

- Approve
- Minor Modifications
- Major Modifications
- Disapprove
- Others

_____

_____

Primary Reviewer

_____

Name & Signature / Date

ANNEX 5

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

ICF EVALUATION FORM

FORM 2.4

IRB REFERENCE NO.					-			-	

RINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE OF REVIEW

PROTOCOL NO. & TITLE

PRIMARY REVIEWER

QUESTIONS		Comments	Recommendations
1) Is there a statement saying the study involves research?	Y☐ N☐		
2) Is the purpose of the trial clearly stated?	Y☐ N☐		
3) Is there an explanation to the subjects why they were included in the study?	Y☐ N☐		
4) Are there provisions ensuring that the subject's participation in the trial is voluntary?	Y☐ N☐		
5) Is the subject well-informed of his/her responsibilities? (*This includes providing health information including symptoms or any changes made in her regimen.)*	Y☐ N☐		
6) Is the language and presentation of the information to be conveyed appropriate to the subject population? *(Consider the level of complexity and the need for translation into a language other than English.)*	Y☐ N☐		
7) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained?	Y☐ N☐		
8) Is the expected duration of the subject's participation in the trial specified?	Y☐ N☐		

9) Is the approximate number of study subject stated?	Y☐ N☐		
10) For experimental studies is the nature of the experiment explained well?	Y☐ N☐		

11) For studies using placebo is the use of placebo ethically applicable?	Y☐ N☐		
12) Is detailed explanation of the procedures or tests that are new or not widely used or combinations/doses of drugs never tested before provided to the subject?	Y☐ N☐		
13) Are the proposed explanations of the research appropriate and adequate to provide the subject an accurate assessment of its risks and anticipated benefits?	Y☐ N☐		
14) Are the risks to the study participants disclosed?	Y☐ N☐		
15) Are the potential adverse events disclosed?	Y☐ N☐		
16) Are the possible benefits to the participants discussed?	Y☐ N☐		
17) Are the potential benefit to the Community discussed? 18) Are there lists of alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks?	Y☐ N☐		
19) Are these any anticipated expenses to the subject in the course of the study?	Y☐ N☐		
20) Is there a compensation and/or treatment available to the subject in the event of trial-related injury? Is there a person to contact in the event of trial-related injury?	Y☐ N☐ Y☐ N☐		
21) Is there a person to contact for further information regarding the trial and the rights of the trial subjects?	Y☐ N☐		
22) Do other groups of potential subjects have a greater need to receive any of the anticipated benefits?	Y☐ N☐		
23) Whether they finish the study or not, are the subjects compensated on a per visit basis for trial related expenses?	Y☐ N☐		
24) Will the subject or the subject's legally acceptable representative (LAR) be informed, in a timely manner, of any new available information which may be relevant to the subject's willingness to continue his/her participation?	Y☐ N☐		
25) Is the subject informed of his right to refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled?	Y☐ N☐		
26) Is the subject informed of any foreseeable events and or reasons which may cause his/her participation in the trial to be terminated?	Y☐ N☐		
27) In the event of any information that will affect the willingness of the subject to participate, is re-consenting necessary or provided for?	Y☐ N☐		

28) Are the withdrawal criteria made known to the subject?	Y☐ N☐		
29) If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver?	Y☐ N☐		
30) Are there provisions for medical / psychosocial support if applicable?	Y☐ N☐		
31) Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy? • Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion? • If privacy is to be invaded, does the importance of the research objective justify the intrusion? • What if anything, will the subject be told later?	Y☐ N☐		
32) Is there a mechanism for providing information to the IRB in the event that unexpected results are discovered? (Unexpected results may raise the possibility of unanticipated risks to subjects)	Y☐ N☐		
33) Is there a provision allowing consent from the subject for other monitors/ auditors/ IRB/IEC access to the subject's original medical record for verification purposes?	Y☐ N☐		
34) Are the records identifying the subject kept confidential and to the extent permitted by the applicable laws and/or regulations, not made available in public? • Should the trial be published, will the subject's identity remain confidential?	Y☐ N☐ Y☐ N☐		
35) For genetic studies is there a discussion on the precautions in place to prevent disclosure of results without the subject's permission	Y☐ N☐		
36) Is the subject informed of the possible direct or secondary use of subject's medical records & biological specimen in the course of clinical care	Y☐ N☐		
37) Are plans in place to destroy collected biological specimen at the end of the study or details of storage and possible future discussed with the patient?	Y☐ N☐		

Recommendations:

- ☐ Approve
- ☐ Minor Modifications
- ☐ Major Modifications
- ☐ Disapprove

Primary Reviewer

_____

Name & Signature / Date

ANNEX 6

CIM-CVGH

REVIEW EXEMPTION APPLICATION FORM

FORM 2.2A

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

IRB REFERENCE NO.		
PRINCIPAL INVESTIGATOR	SPONSOR	DATE OF REVIEW
PROTOCOL NO. & TITLE		

The following are protocols that may be exempted from review:

☐ Protocols that neither involves human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.

☐ Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the IRB for exemption from review:

- ☐ Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
- ☐ Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
  - ☐ There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and
  - ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

☐ Protocols that involve the use of publicly available data or information.

Note: SUBMIT THIS FORM TOGETHER WITH:

- Form 2.1 Application for review
- Form 2.2 Protocol summary Sheet

_____	_____ approved for exemption from review.
Signature of IRB Chair	_____ for expedited review
	_____ for full review

ANNEX 7

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

RESUBMISSION FORM

FORM 2.5

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED
INSTITUTION:	**P.I. CONTACT NO.**	**P.I. EMAILL ADDRESS**

PROTOCOL NO. & TITLE

DOCUMENTS SUBMITTED	
☐ Protocol ☐ Advertisement ☐ Informed Consent	☐ Composition of Research Team ☐ Others _____
PRIMARY REVIEWER	**DATE REVIEWED**

IRB RECOMMENDATION	PI RESPONSES PI to respond to IRB recommendations in this box	REVIEWER COMMENTS
PI Signature		
Received by IRB Staff		
Summary of Comments		
Primary Reviewer		

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
VERSION 3	**SOP 2.2 Exempt from Review**	Effective Date: JULY 21, 2023

1. Policy Statement

The CIM CVGH IRB shall ensure that all protocols submitted shall be provided the appropriate review to include those protocols that are deemed exempt and do not need to undergo full or expedited review after an initial assessment

2. Objective

This SOP discusses the process for exemption of a proposal from review. This applies to initial submissions on protocols which qualifies as exempt from review.

Protocols undergo an initial assessment by the chair before it is deemed exempt. The following are protocols that may be exempted from review

2.1. Protocols that neither involves human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.

2.2. Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the IRB for exemption from review:

2.2.1. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

2.2.2. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

2.2.2.1. There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and

2.2.2.2. The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

2.3. Protocols that involve the use of publicly available data or information.

3. Scope:

This SOP starts with the receipt of the study protocol applying for exemption from review and ends with filing of a copy of the documents in the protocol binder and update protocol database for exemption from review.

4. Workflow

ACTIVITY	*RESPONSIBILITY*	*Schedule of accomplishment*
Step 1: *Receive study protocol applying for exemption from review*	*IRB Staff*	*Day 0*
Step 2: *Classify a study protocol applying for exemption from review*	*Designated Member/ Chair*	*Within 1 week from acceptance of protocol*
Step 3: *Prepare a report of protocols that are exempt from review to full-board*	IRB Staff	
Step 4. *Communicate the IRB decision to the PI.*	IRB Staff	Within 3 days after the decision was made
Step 5: *File a copy of the documents in the protocol binder and update protocol database for exemption from review*	IRB Staff	

5. Description of Procedures

5.1. ***Step 1 Receive a study protocol applying for exemption from review***

5.1.1. The IRB Staff shall log the application for exemption

5.1.2. The IRB Staff inform the IRB chair of the application for exemption

5.2. ***Step 2 Classify a study protocol applying for exemption from review***

5.2.1. The IRB chair shall classify whether the protocol fulfills the criteria for exemption within 1 week from acceptance of the protocol package

5.2.2. If the protocol qualifies for exemption from review, the chair submits the results of the assessment to Secretariat for the IRB staff to prepare a Certificate of Exemption from Review.

5.2.3. If the protocol does not meet the Exemption Criteria, the Chair reclassifies the protocol for expedited or full-board review.

5.3. ***Step 3 Prepare a report of protocols that are exempt from review to full-board***

5.3.1. The IRB Staff prepares a report to the next full board meeting to include details of all protocols exempted from review.

5.4. ***Step 4 Communicate the IRB decision to the PI.***

5.4.1. The IRB Staff prepares Certificate of Exemption from Review and forwards to the Chair for signature.

5.4.2. The IRB Staff issues the Certificate of Exemption to the Principal investigator within 3 days after the decision was made

5.5. ***Step 5 File a copy of the documents in the protocol binder and update protocol database for exemption from review***

5.5.1. The IRB staff shall;

5.5.1.1. Prepare a binder to contain all protocols exempt from review.

5.5.1.2. File the properly-labeled binder in the appropriate shelf of the storage cabinet.

5.5.1.3. Update protocol database for exemption from review.

6. Forms

Form 2.1: Review Application Form

Form 2.2: Protocol Summary Sheet

Form 2.5: Certificate of Exemption from Review

Form 3.0: Review Exemption Application Form

7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*July 2019*	*SOP Team*	*New SOP*
02	*June 21, 2021*	*SOP Team*	*NONE*
03	*July 21, 2021*	*Dr Cutillar*	*Added timelines to Steps 2 & 4*

ANNEX 1

APPLICATION FOR INITIAL REVIEW
To be filled by Investigator

Sponsor Protocol Number:			**IRB Protocol Number:**	
Submission Date:				
Protocol Title:				
Principal Investigator:				
Telephone number:			**Fax**	
E-mail:			**Preferred Contact**	
Institute:				
Investigator Initiated:	• Yes	• No		
Sponsor Initiated	• Yes	• No	**Name of Sponsor**	**N/A**

(Relationship with sponsor)

Are you a regular employee of the sponsor?	• Yes	• No
Did you do consultancy or part time work for the sponsor?	• Yes	• No
In the past year, did you receive ≥ P250,000 or from the sponsor?	• Yes	• No
Other ties with the sponsor? If Yes pls Specify _____	• Yes	• No

No Conflict of Interest Declaration by Principal Investigator:

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

PI Signature:	
Name of Adviser/Mentor	

Documents submitted: (Please Check)

REQUIRED FOR ALL INITIAL SUBMISSIONS	**OPTIONAL: only IF APPLICABLE TO PROTOCOL**
• Protocol • Protocol summary (for clinical trials) • Informed consent form (when in use) • Research Team List • CVs & Research Ethics Training Certificates • Study budget	• Technical Review Certificate (for PI Initiated) • Questionnaire • Case report forms (CRF) • Investigator brochure (for Clinical Trials) • GCP certificates (for Clinical Trials) • Advertisement

ARE THE DOCUMENTS SUBMITTED COMPLETE:	• YES	• NO

DO NOT ACCEPT INCOMPLETE PACKAGES

Type of Research/Phase of Trial

• Survey	• Social	• Medical	• Community	• Individual Based
• Screening	• Observational	• Epidemiologic	• Interventional	• Phase IV
• Clinical trial	• Phase I	• Phase II	• Phase III	
• Genetic	• Retrospective	• Prospective	• Others____	
• Single Center	• Multicenter	• Others _____		

Study Duration:		**Received By:**		**Date:**	

FOR IRB USE ONLY

• **Exempt**	• **Expedited**	• **Full Board**

• Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols)
• Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the IRB for exemption from review:
  • Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
  • Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
  • There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation;
  • The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.
• Protocols that involve the use of publicly available data or information.
	• Minimal risk protocols
	• Chart review
	• Survey of non-sensitive nature
	• Use of anonymous or anonymized laboratory/pathology samples or stored tissues or data
		• Protocols that entails more than minimal Risk
		• Protocols involving Vulnerable populations, particularly prisoners
		• Sensitive topics, including illegal behaviors
		• Research involving genetic testing
		• A complex research design requiring the expertise of multiple board members to evaluate

Type of Review: ☐ **Exempt** ☐ **Expedited** ☐ **Full Board**

Assigned Primary Reviewer:

Dr. Manuel Emerson Donaldo **IRB Chair/Member Secretary Name & Signature**	**DATE**

ANNEX 2

CIM-CVGH

REVIEW EXEMPTION APPLICATION FORM

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

FORM 2.2A

IRB REFERENCE NO.		- -
PRINCIPAL INVESTIGATOR	SPONSOR	DATE OF REVIEW
PROTOCOL NO. & TITLE		

The following are protocols that may be exempted from review:

☐ Protocols that neither involves human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.

☐ Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the IRB for exemption from review:

- ☐ Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
- ☐ Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
  - ☐ There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and
  - ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

☐ Protocols that involve the use of publicly available data or information.

Note: SUBMIT THIS FORM TOGETHER WITH:

- Form 2.1 Application for review
- Form 2.2 Protocol summary Sheet

_____	_____ approved for exemption from review.
Signature of IRB Chair	_____ for expedited review
	_____ for full review

ANNEX 3

CIM-CVGH

CERTIFICATE OF EXEMPTION

FORM 2.2B

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

Certificate of Exemption from Ethics Review			
This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the CIM CVGH IRB for implementation			
EXPIRY of DATE OF APPROVAL			
IRB REF No.			
Sponsor Protocol No			
Sponsor			
Title:			
Principal Investigator/s:			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other documents submitted			
Responsibilities of the PI • *Submit any amendment, progress report that change the risk benefit ratio as well as final report once the study has been completed*			
REC Chair Person Name	Signature		Date

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL **INSTITUTIONAL REVIEW BOARD**	
VERSION 3	**SOP 2.3 Expedited Review**	Effective Date: July 21, 2023

1. **Policy Statement**

   An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, and (2) do not have study participants belonging to a vulnerable group, and (3) does not generate vulnerability. The results of the initial review shall be released to principal investigator within four weeks after the submission of all the required documents.

2. **Objective**

   This SOP discuss the processes of review of studies that do not entail more than minimal risk to the study participants, do not have study participants belonging to a vulnerable group, and does not generate vulnerability aims to demonstrate due diligence and high standards in the system of protection of human participants.

3. **Scope:**

   This SOP begins with the assignment of reviewers or independent consultant/s and ends with the inclusion of the review in the agenda of the next meeting.

4. **Workflow**

ACTIVITY	RESPONSIBILITY	***Timeline***
Step 1: *Assign primary reviewers (medical / scientific and a non-medical / nonscientific members).*	*M*ember-Secretary / Chair	*Within 2 days from the receipt of protocol*
Step 2: *Notification of the Primary Reviewers*	IRB Staff	
Step 3. *Provision of documents and evaluation form to reviewers:*	Member Secretary	*Within 7 days from the receipt of the protocol*
Step 4: *Reviewers review and assess the submitted documents using the assessment form/s*	Primary Reviewers	*Within 10 days from receipt of protocol.*
Step5: *Return the accomplished assessment forms to the Secretariat.*	Primary Reviewers	
Step 6: *Finalization of Review Results*	Primary Reviewers	
Step 7: *Communicate the IRB decision to the PI (SOP # 6.2)*	Member Secretary	*Within 2 days after submission of the approval*
Step 8: *Filing of documents in the protocol file (SOP on Management of Active Files – SOP #7.2)*	IRB Staff	

Agenda of	**Step 9:** Inclusion of the Review in the the next meeting (SOP on Preparing the Meeting Agenda – SOP #5.2)	Member Secretary	

5. Description of Procedures

5.1. *Step 1 Assign primary reviewers (medical / scientific and a non-medical / non-scientific members).*

5.1.1. The Chair/Member-Secretary designates at least two IRB members to be the primary reviewers for new protocols submitted. One (Medical/Scientific) reviewer for the Protocol Evaluation and another (lay or non-scientific/non-medical member) for the ICF Evaluation.

5.1.2. Primary reviewers are selected on the basis of expertise related to the protocol.

5.1.3. If the IRB membership does not have the needed expertise, the Chair/Member Secretary chooses from the roster of Independent Consultant. If none is available a consultant with the needed expertise is recruited as per SOP on Selection of Independent Consultant (SOP No. 1.3).

5.2. Step 2 Notification of Reviewers or Independent Consultant/s

5.2.1. *The IRB Staff shall inform the primary reviewers by phone call and text within two* days after the receipt of the complete protocol package. The reviewers shall determine his/her conflict of interest, availability, and suitability. The primary reviewers shall respond through call to IRB Staff within two days after notice.

5.3. Step 3 Provision of documents and evaluation form to reviewers:

5.3.1. The IRB Staff shall provide the primary reviewers with the initial protocol review package which consists of all the documents in the initial protocol package plus blank copies of the Study Evaluation Forms (Form 2.3: Protocol Evaluation Form, and Form 2.4: Informed Consent Evaluation Form), and letter or approval from the technical review board. For resubmissions under expedited, a completed Form 2.5 Resubmission Form should be included.

5.3.2. These documents will be hand carried and delivered to the Primary Reviewers by a messenger. An electronic copy may be emailed to the reviewer upon request. Electronic copies of the submitted protocol is provided to the other members for reference during discussion

5.3.3. The timeline from receipt of complete package to distribution to primary reviewers is within 7 calendar days.

5.4. Step 4 Reviewers review and assess the submitted documents using the assessment form/s

5.4.1. The reviewers will review the protocol and fill up the assessment form in a comprehensive manner and make appropriate recommendation.

5.4.2. For expedited review, accomplished evaluation forms are submitted on or before the scheduled meeting on the 3rd week of the month.

5.4.3. For Full board review, evaluation form is submitted after the meeting.

5.5. Step 5 Return the accomplished assessment forms to the Secretariat.

5.5.1. The medical primary reviewer should also evaluate the ICF besides the protocol.

5.5.2. The forms shall be returned to the Secretariat during the next IRB meeting for filing

5.6. Step 6 Finalization of Review Results

5.6.1. The review results of both the protocol assessment and the ICF assessment will be consolidated by the Member-Secretary to determine if there is agreement in the review/ decision. If there is agreement between primary reviewers with no dissenting opinions the decision can be communicated to the Principal Investigator. This shall be completed within 10 days after receipt of protocol.

5.6.2. The possible specific IRB actions include:
- 5.6.2.1. approval
- 5.6.2.2. minor modifications
- 5.6.2.3 major modifications
- 5.6.2.4 disapproval

5.6.3 The results of the expedited approval shall then be presented during the next IRB meeting as approved through expedited process.

5.6.4 Protocols that are disapproved, or elicited contesting opinions will be subjected to Full Review.

5.6.5 The IRB Staff prepares a list of protocols approved through expedited process and the Member Secretary presents them during the full board meeting.

5.7 Step 7 Communicate the IRB decision to the PI

5.7.1. Within 2 days after approval by expedited process, the decision can be communicated to the researcher

5.7.2 The IRB Staff communicates approval to the PI using the Approval Letter (Form 3.0).

5.8 Step 8 Filing of documents in the protocol file (SOP on Management of Active Files (SOP# 7.2)

5.9 Step 9 Inclusion of the Review in the Agenda of the next meeting (SOP on Preparing the Meeting Agenda – SOP #5.2)

5.9.1 Only approved protocols reviewed by expedited process are included in the agenda for reporting during the next full board meeting

6. Forms

Form 2.1: Review Application Form
Form 2.2: Protocol Summary Sheet
Form 2.3: Protocol Evaluation Form
Form 2.4: Informed Consent Assessment Form
Form 2.5: Resubmission Form

7.History of SOP

Version No.	Date	Authors	Main Change
01	Dec, 2018	SOP Team	-
02	June 21, 2021	SOP Team	Clarified that the Primary Reviewers will consolidate the review Defined Step 8 to report approved protocols in the next board meeting
03	June 21, 2023	SOP Team	Step 3 added distribution of protocol related documents to all members Step 4 added evaluation of protocols and ICF and filling up of the assessment form by the reviewer Step 6 added Types of decision Step 7 added once there is an approval by expedited process the decision can be communicated.

Annex 1

APPLICATION FOR INITIAL REVIEW

To be filled by Investigator

Sponsor Protocol Number:			**IRB Protocol Number:**	
Submission Date:				
Protocol Title:				
Principal Investigator:				
Telephone number:			**Fax**	
E-mail:			**Preferred Contact**	
Institute:				
Investigator Initiated:	• **Yes**	• **No**		
Sponsor Initiated	• **Yes**	• **No**	**Name of Sponsor**	**N/A**
(Relationship with sponsor)				

Are you a regular employee of the sponsor?	• **Yes**	• **No**
Did you do consultancy or part time work for the sponsor?	• **Yes**	• **No**
In the past year, did you receive ≥ P250,000 or from the sponsor?	• **Yes**	• **No**
Other ties with the sponsor? If Yes pls Specify _____		

No Conflict of Interest Declaration by Principal Investigator:

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

PI Signature:	
Name of Adviser/Mentor	

Documents submitted: (Please Check)

REQUIRED FOR ALL INITIAL SUBMISSIONS	**OPTIONAL: only IF APPLICABLE TO PROTOCOL**
• Protocol • Protocol summary (for clinical trials) • Informed consent form (when in use) • Research Team List • CVs & Research Ethics Training Certificates • Study budget	• Technical Review Certificate (for PI Initiated) • Questionnaire • Case report forms (CRF) • Investigator brochure (for Clinical Trials) • GCP certificates (for Clinical Trials) • Advertisement

ARE THE DOCUMENTS SUBMITTED COMPLETE:	• **YES**	• **NO**

DO NOT ACCEPT INCOMPLETE PACKAGES

Type of Research/Phase of Trial

• Survey • Screening • Clinical trial • Genetic • Single Center	• Social • Observational • Phase I • Retrospective • Multicenter	• Medical • Epidemiologic • Phase II • Prospective • Others _____	• Community • Interventional • Phase III • Others____	• Individual Based • Phase IV

Study Duration:		**Received By:**		**Date:**	

FOR IRB USE ONLY

• **Exempt**	• **Expedited**	• **Full Board**
• Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) • Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the IRB for exemption from review:	• Minimal risk protocols • Chart review • Survey of non-sensitive nature	• Protocols that entails more than minimal Risk • Protocols involving Vulnerable populations, particularly prisoners

• Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests; • Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met: • There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; • The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant. • Protocols that involve the use of publicly available data or information.	• Use of anonymous or anonymized laboratory/pathology samples or stored tissues or data	• Sensitive topics, including illegal behaviors • Research involving genetic testing • A complex research design requiring the expertise of multiple board members to evaluate

Type of Review: ☐ **Exempt** ☐ **Expedited** ☐ **Full Board**

Assigned Primary Reviewer:

Dr. Manuel Emerson Donaldo
IRB Chair/Member Secretary Name & Signature | **DATE**

CIM-CVGH

ANNEX 2

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

PROTOCOL SUMMARY FORM

FORM 2.2

Date		**IRB REFERENCE NO.**					-			-			

Primary Investigator	
10. Study Title	
11. Study Category	☐ Research involving human participants ☐ Research involving non-human living vertebrates ☐ Others (indicate):

12. TECHNICAL SYNOPSIS (TO BE FILLED UP BY THE PRIMARY INVESTIGATOR)		**Page**
b. Objectives/Expected output	.	
i. Research design	.	
ii. Sampling design, sample size		
iii. Inclusion criteria, exclusion criteria, withdrawal criteria		
iv. Data collection and processing plan		
v. Specimen collection and processing plan	.	
vi. Data analysis plan		
vii. Duration of human participant involvement		
13. Ethical Considerations		
b. Protection of privacy and confidentiality of research information including data protection plan	.	
b. Vulnerability of research participants		

ANNEX 3

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

PROTOCOL EVALUATION FORM

FORM 2.3

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	**SPONSOR**	**DATE OF REVIEW**

CATEGORY OF THE INVESTIGATOR:

☐ CIM Faculty ☐ CIM students Year Level _____ ☐ Residents-in-Training _____	☐ Fellows -in-training _____ ☐ Others _____

P.I. CONTACT NO.		**EMAIL-ADDRESS**	

PROTOCOL NO. & TITLE

QUESTIONS				**Recommendations**
21) Are the objectives clear?	Y☐	N☐	N.A.☐	
22) Is there a need for human participants?	Y☐	N☐	N.A.☐	
• Are the subjects vulnerable? (if yes- for full Board review)	Y☐	N☐	N.A.☐	
23) Is there an informed consent?	Y☐	N☐	N.A.☐	
24) Is the background information sufficient?	Y☐	N☐	N.A.☐	
25) Is the study design appropriate for the objectives?	Y☐	N ☐	N.A.☐	

• Are the control arms appropriate? (for clinical trials)	Y☐	N ☐	N.A.☐	

26) Is the approximate number of subjects involved in the trial specified?	Y☐	N☐	N.A.☐	
• Are the inclusion criteria appropriate?	Y☐	N ☐	N.A.☐	
• Is the proposed subject population appropriate for the nature of the research?	Y☐	N ☐	N.A.☐	
• Has the IRB taken into account any special vulnerability among prospective subjects that might be relevant to evaluating the risk of participation?	Y☐	N☐	N.A.☐	
• Are the exclusion criteria appropriate?	Y☐	N ☐	N.A.☐	
• Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research?	Y☐	N☐	N.A.☐	
27) Is the setting of the study clearly identified?	Y☐	N☐	N.A.☐	
• Are the facilities and infrastructure of the participating sites adequate	Y☐	N☐	N.A.☐	
• Is the duration of the study specified?	Y☐	N☐	N.A.☐	
28) Are the procedures to be done in the study clearly described and understandable?	Y☐	N☐	N.A.☐	
• Are blood/tissue samples sent abroad?	Y☐	N☐	N.A.☐	
29) Are research data recorded and maintained with strict confidentiality?	Y☐	N☐	N.A.☐	
30) Considering the degree of risk, is the plan for monitoring the research appropriate and adequate in terms of timeliness and thoroughness?	Y☐	N☐	N.A.☐	
31) Is the principal investigator competent to do the study? (by training, expertise or sub specialization)	Y☐	N☐	N.A.☐	
32) Is the principal investigator assessed for any Conflict of Interest for this study?	Y☐	N☐	N.A.☐	
33) If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient?	Y☐	N☐	N.A.☐	
34) Is the mechanism for providing information to the IRB if unexpected results are discovered appropriate?	Y☐	N☐	N.A.☐	
35) If the research involves the evaluation of a therapeutic procedure, have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?	Y☐	N☐	N.A.☐	

36) Has due care been used to minimize risks and maximize the likelihood of benefits?	Y☐	N☐	N.A.☐	
37) Are the subjects given incentives or compensation for study-related expenses?	Y☐	N☐	N.A.☐	
38) Are there adequate provisions for a continuing reassessment of the balance between risks and benefits?	Y☐	N☐	N.A.☐	
39) Is the research expected to have an impact on the community where the research occurs and/or to whom findings can be linked, including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study?	Y☐	N☐	N.A.☐	
40) Does the institution have a data and safety monitoring board?	Y☐	N☐	N.A.☐	
If so, should it be asked to monitor the project under review?	Y☐	N☐	N.A.☐	
If the institution does not have a data and safety monitoring board, should the IRB request or recommend that one be appointed, either by the institution or the sponsor, for this project?	Y☐	N☐	N.A.☐	

Recommendations:

- Approve
- Minor Modifications
- Major Modifications
- Disapprove
- Others

_____

_____

Primary Reviewer

_____

Name & Signature / Date

ANNEX 4

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

ICF EVALUATION FORM

FORM 2.4

IRB REFERENCE NO.					-			-	

PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE OF REVIEW

PROTOCOL NO. & TITLE

PRIMARY REVIEWER

QUESTIONS		Comments	Recommendations
38) Is there a statement saying the study involves research?	Y☐ N☐		
39) Is the purpose of the trial clearly stated?	Y☐ N☐		
40) Is there an explanation to the subjects why they were included in the study?	Y☐ N☐		
41) Are there provisions ensuring that the subject's participation in the trial is voluntary?	Y☐ N☐		
42) Is the subject well-informed of his/her responsibilities? (*This includes providing health information including symptoms or any changes made in her regimen.)*	Y☐ N☐		
43) Is the language and presentation of the information to be conveyed appropriate to the subject population? *(Consider the level of complexity and the need for translation into a language other than English.)*	Y☐ N☐		
44) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained?	Y☐ N☐		
45) Is the expected duration of the subject's participation in the trial specified?	Y☐ N☐		
46) Is the approximate number of study subject stated?	Y☐ N☐		
47) For experimental studies is the nature of the experiment explained well?	Y☐ N☐		

48) For studies using placebo is the use of placebo ethically applicable?	Y☐ N☐		
49) Is detailed explanation of the procedures or tests that are new or not widely used or combinations/doses of drugs never tested before provided to the subject?	Y☐ N☐		
50) Are the proposed explanations of the research appropriate and adequate to provide the subject an accurate assessment of its risks and anticipated benefits?	Y☐ N☐		
51) Are the risks to the study participants disclosed?	Y☐ N☐		
52) Are the potential adverse events disclosed?	Y☐ N☐		
53) Are the possible benefits to the participants discussed?	Y☐ N☐		
54) Are the potential benefit to the Community discussed? 55) Are there lists of alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks?	Y☐ N☐		
56) Are these any anticipated expenses to the subject in the course of the study?	Y☐ N☐		
57) Is there a compensation and/or treatment available to the subject in the event of trial-related injury? Is there a person to contact in the event of trial-related injury?	Y☐ N☐ Y☐ N☐		
58) Is there a person to contact for further information regarding the trial and the rights of the trial subjects?	Y☐ N☐		
59) Do other groups of potential subjects have a greater need to receive any of the anticipated benefits?	Y☐ N☐		
60) Whether they finish the study or not, are the subjects compensated on a per visit basis for trial related expenses?	Y☐ N☐		
61) Will the subject or the subject's legally acceptable representative (LAR) be informed, in a timely manner, of any new available information which may be relevant to the subject's willingness to continue his/her participation?	Y☐ N☐		
62) Is the subject informed of his right to refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled?	Y☐ N☐		
63) Is the subject informed of any foreseeable events and or reasons which may cause his/her participation in the trial to be terminated?	Y☐ N☐		
64) In the event of any information that will affect the willingness of the subject to participate, is re-consenting necessary or provided for?	Y☐ N☐		
65) Are the withdrawal criteria made known to the subject?	Y☐ N☐		
66) If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver?	Y☐ N☐		
67) Are there provisions for medical / psychosocial support if applicable?	Y☐ N☐		

68) Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy? • Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion? • If privacy is to be invaded, does the importance of the research objective justify the intrusion? • What if anything, will the subject be told later?	Y☐ N☐		
69) Is there a mechanism for providing information to the IRB in the event that unexpected results are discovered? (Unexpected results may raise the possibility of unanticipated risks to subjects)	Y☐ N☐		
70) Is there a provision allowing consent from the subject for other monitors/ auditors/ IRB/IEC access to the subject's original medical record for verification purposes?	Y☐ N☐		
71) Are the records identifying the subject kept confidential and to the extent permitted by the applicable laws and/or regulations, not made available in public? • Should the trial be published, will the subject's identity remain confidential?	Y☐ N☐ Y☐ N☐		
72) For genetic studies is there a discussion on the precautions in place to prevent disclosure of results without the subject's permission	Y☐ N☐		
73) Is the subject informed of the possible direct or secondary use of subject's medical records & biological specimen in the course of clinical care	Y☐ N☐		
74) Are plans in place to destroy collected biological specimen at the end of the study or details of storage and possible future discussed with the patient?	Y☐ N☐		

Recommendations:

- ☐ Approve
- ☐ Minor Modifications
- ☐ Major Modifications
- ☐ Disapprove

Primary Reviewer

Name & Signature / Date _____

ANNEX 5

CIM-CVGH

RESUBMISSION FORM

I INSTITUTIONAL REVIEW BOARD

79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

FORM 2.5

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	**SPONSOR**	**DATE SUBMITTED**
INSTITUTION:	**P.I. CONTACT NO.**	**P.I. EMAILL ADDRESS**

PROTOCOL NO. & TITLE

DOCUMENTS SUBMITTED

☐ Protocol ☐ Advertisement ☐ Informed Consent	☐ Composition of Research Team ☐ Others _____

PRIMARY REVIEWER	**DATE REVIEWED**

IRB RECOMMENDATION	**PI RESPONSES** **PI to respond to IRB recommendations in this box**	**REVIEWER COMMENTS**
PI Signature		
Received by IRB Staff		

Summary of Comments

Primary Reviewer

1. Policy Statement

A full review shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants. Such a protocol shall be deliberated and decided upon during a regular meeting, within 4 weeks after submission of required documents. Full review shall be conducted through a primary reviewer system.

2. Objective of the Activity

A full review aims to ensure compliance with technical and ethical standards in the conduct of researches involving human participants and identifiable human data and materials.

3. Scope

This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of protocol-related documents.

4. Workflow

ACTIVITY	RESPONSIBILITY	Timeline
Step 1: Assignment of primary reviewers or Independent Consultant/s (SOP on Appointment of Independent Consultants (SOP#1.3)	Chair	Within 2 days from the receipt of protocol
Step 2: Notification of primary reviewers or Independent Consultants	IRB Staff	
Step 3: Provision of protocol and protocol-related documents and assessment forms to reviewers	IRB Staff	Within 7 days from the receipt of the protocol
Step 4: Presentation of review findings and recommendations during a Board meeting (SOP on Conduct of Meeting (SOP#5.3)	Primary Reviewers	Every 3rd Wednesday of the month
Step 5: Discussion of technical and ethical issues	IRB members	
Step 6: Summary of issues and resolutions	Chair	

Step 7: Committee action	IRB members and Chair	
Step 8: Documentation of Committee deliberation and action (SOP on Preparing the Meeting Minutes (SOP#6.1)	Member Secretary	Within 5 days after the IRB meeting
Step 9: Communication of Committee Action to the researcher (SOP Communicating IRB Decisions (SOP#6.2)	Member Secretary	Within 7 days after the IRB meeting
Step 10: Filing of protocol-related documents	IRB Staff	

5. Description of Procedures

5.1. Step 1 – Assignment of primary reviewers or Independent Consultants.

5.1.1. The Chair/Member Secretary shall assign two or more CIM-CVGH IRB members (One (1) Medical member with related expertise to review the protocol and one (1) non-medical person to review the informed consent.) An independent consultant may be invited to provide expert opinion about a protocol (SOP # 1.3).

5.2. Step 2 – Notification of primary reviewers or Independent Consultants:

5.2.1. The Primary reviewers shall be informed thru text/call and email. The reviewers will acknowledge the acceptance of the assignment. If the designated primary reviewer/s is/are not available, the *IRB Staff* shall inform the Chair so the protocol shall be re-assigned to other reviewers.

5.3. Step 3 – Provision of protocol and protocol -related documents and assessment forms to reviewers:

5.3.1. The IRB Staff shall prepare and send the protocol review package to the primary reviewers within 7 calendar days from protocol submission.

5.3.2. Protocol related documents are likewise provided to all members prior to the scheduled meeting.

5.3.3. The review package consists of all the documents in the initial protocol package plus blank copies of the:

5.3.3.1. Study Assessment Forms (Form 2.3: Protocol Evaluation Form, and Form 2.4: Informed Consent Assessment Form), and

5.3.3.2. letter of approval from the technical review board

5.4. Step 4 – Presentation of review findings and recommendations during a committee meeting:

5.4.1. At least one primary reviewer should be present during the meeting. The protocol shall be projected using LCD projector for all the IRB members to see. The primary reviewer shall go through the review, guided by the assessment form. If the primary reviewer is absent, the review shall be postponed to the next IRB meeting, and then the primary reviewer will make a detailed documentation of his review of the protocol.

5.4.2. All other IRB members will be given access to the protocol related documents either electronic or hard copies prior to the meeting

5.5. Step 5 – Discussion of technical and ethical issues:

5.5.1. Check the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements
5.5.2. Consider whether study and training background of the principal investigator/s are related to the study to check for suitability of the PI.
5.5.3. Look for disclosure or declaration of potential conflicts of interest or the lack of it.
5.5.4. Non-physician principal investigators should be advised by a physician when necessary, as a sub-investigator.
5.5.5. If applicable, determine if the facilities and infrastructure at study sites can accommodate the study.
5.5.6. Use the Protocol Evaluation Form (Form 2.3) for the protocol and the Informed Consent Evaluation Form (Form 2.4) during the discussion to review the protocol and the consent form and make relevant comments
5.5.7. The medical primary reviewer also evaluates the ICF beside the protocol
5.5.8. Check the "Assent Form" if the protocol involves children ages 7-17 and "parental Informed Consent form for all minors as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedures to be done including risks and benefits should be explained to the child or vulnerable participant separately).

5.6. Step 6 – Summary of issues and resolutions:

5.6.1. Issues and recommendations will be recorded in real-time. Final decision will be done through consensus by the IRB.

5.7. Step 7 – Committee action:

5.7.1. The possible specific IRB actions include:

5.7.1.1. approval,
5.7.1.2. minor modifications,
5.7.1.3. major modifications, or
5.7.1.4. disapproval

5.8. Step 8 – Documentation of committee deliberation and action:

5.8.1. The CIM-CVGH IRB deliberation and action shall be documented in the Minutes of the Meeting. See SOP on Preparing the Meeting Minutes.

5.9. Step 9 – Communication of Committee Action to the researcher:

5.9.1. The Member Secretary shall prepare the communication of the decision to the researcher. See SOP on Communicating IRB Decisions (SOP#6.2)

5.10. Step 10 – Filing of protocol-related documents:

5.10.1. The IRB Staff shall file protocol-related documents. See SOP on Managing Active Files

6. Forms

Annex 1. Form 2.1: Review Application Form
Annex 2. Form 2.2: Protocol Summary Sheet
Annex 3. Form 2.3: Protocol Evaluation Form
Annex 4. Form 2.4: Informed Consent Assessment Form
Annex 5. Form 2.5: Resubmission Form
Annex 6. Form 2.8: Approval Letter

7. History of SOP

Version No.	Date	Authors	Main Change
01	Nov 16, 2016	IRB MEMBERS	FIRST DRAFT
01	May 3, 2018	IRB MEMBERS	Formatting; Annex / Forms included
02			NONE
03	June 21, 2023		Step 3 provide timelines Step 4 included all other members to receive access to protocol related documents Step 5 includes ICF to be reviewed by medical reviewer

ANNEX 1

APPLICATION FOR INITIAL REVIEW To be filled by Investigator				
Sponsor Protocol Number:			**IRB Protocol Number:**	
Submission Date:				
Protocol Title:				
Principal Investigator:				
Telephone number:			**Fax**	
E-mail:			**Preferred Contact**	
Institute:				
Investigator Initiated:	• **Yes**	• **No**		
Sponsor Initiated	• **Yes**	• **No**	**Name of Sponsor**	**N/A**
(Relationship with sponsor)				

Are you a regular employee of the sponsor?	• **Yes**	• **No**
Did you do consultancy or part time work for the sponsor?	• **Yes**	• **No**
In the past year, did you receive ≥ P250,000 or from the sponsor?	• **Yes**	• **No**
Other ties with the sponsor? If Yes pls Specify _____	• **Yes**	• **No**

No Conflict of Interest Declaration by Principal Investigator:

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

PI Signature:	
Name of Adviser/Mentor	

Documents submitted: (Please Check)

REQUIRED FOR ALL INITIAL SUBMISSIONS	**OPTIONAL: only IF APPLICABLE TO PROTOCOL**
• Protocol • Protocol summary (for clinical trials) • Informed consent form (when in use) • Research Team List • CVs & Research Ethics Training Certificates • Study budget	• Technical Review Certificate (for PI Initiated) • Questionnaire • Case report forms (CRF) • Investigator brochure (for Clinical Trials) • GCP certificates (for Clinical Trials) • Advertisement

ARE THE DOCUMENTS SUBMITTED COMPLETE:	• **YES**	• **NO**

DO NOT ACCEPT INCOMPLETE PACKAGES

Type of Research/Phase of Trial

• Survey	• Social	• Medical	• Community	• Individual Based
• Screening	• Observational	• Epidemiologic	• Interventional	• Phase IV
• Clinical trial	• Phase I	• Phase II	• Phase III	
• Genetic	• Retrospective	• Prospective	• Others____	
• Single Center	• Multicenter	• Others _____		

Study Duration:		**Received By:**		**Date:**	

FOR IRB USE ONLY

• **Exempt**	• **Expedited**	• **Full Board**
• Protocols that neither involve human participants nor identifiable human tissue,	• Minimal risk protocols • Chart review	• Protocols that entails more than minimal Risk

biological samples, and data (e.g., meta-analysis protocols)
• Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the IRB for exemption from review:
  • Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
  • Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
  • There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation;
  • The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.
• Protocols that involve the use of publicly available data or information.
	• Survey of non-sensitive nature
	• Use of anonymous or anonymized laboratory/pathology samples or stored tissues or data
		• Protocols involving Vulnerable populations, particularly prisoners
		• Sensitive topics, including illegal behaviors
		• Research involving genetic testing
		• A complex research design requiring the expertise of multiple board members to evaluate

Type of Review: ☐ **Exempt** ☐ **Expedited** ☐ **Full Board**

Assigned Primary Reviewer:

Dr. Manuel Emerson Donaldo **IRB Chair/Member Secretary Name & Signature**	**DATE**

ANNEX 2

CIM-CVGH

ANNEX 2

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

PROTOCOL SUMMARY FORM

FORM 2.2

Date		**IRB REFERENCE NO.**					-			-			

Primary Investigator		
14. Study Title		
15. Study Category	☐ Research involving human participants ☐ Research involving non-human living vertebrates ☐ Others (indicate):	
16. TECHNICAL SYNOPSIS (TO BE FILLED UP BY THE PRIMARY INVESTIGATOR)		**Page**
c. Objectives/Expected output	.	
viii. Research design	.	
ix. Sampling design, sample size		
x. Inclusion criteria, exclusion criteria, withdrawal criteria		
xi. Data collection and processing plan		
xii. Specimen collection and processing plan	.	
xiii. Data analysis plan		
xiv. Duration of human participant involvement		
17. Ethical Considerations		
c. Protection of privacy and confidentiality of research information including data protection plan	.	
b. Vulnerability of research participants		

ANNEX 3

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

PROTOCOL EVALUATION FORM

FORM 2.3

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	**SPONSOR**	**DATE OF REVIEW**

CATEGORY OF THE INVESTIGATOR:

☐ CIM Faculty ☐ CIM students Year Level _____ ☐ Residents-in-Training _____	☐ Fellows -in-training _____ ☐ Others _____

P.I. CONTACT NO.		**EMAIL-ADDRESS**	

PROTOCOL NO. & TITLE

QUESTIONS				**Recommendations**
41) Are the objectives clear?	Y☐	N☐	N.A.☐	
42) Is there a need for human participants?	Y☐	N☐	N.A.☐	
• Are the subjects vulnerable? (if yes- for full Board review)	Y☐	N☐	N.A.☐	
43) Is there an informed consent?	Y☐	N☐	N.A.☐	

44) Is the background information sufficient?	Y☐	N☐	N.A.☐	
45) Is the study design appropriate for the objectives?	Y☐	N ☐	N.A.☐	
• Are the control arms appropriate? (for clinical trials)	Y☐	N ☐	N.A.☐	

46) Is the approximate number of subjects involved in the trial specified?	Y☐	N☐	N.A.☐	
• Are the inclusion criteria appropriate?	Y☐	N ☐	N.A.☐	
• Is the proposed subject population appropriate for the nature of the research?	Y☐	N ☐	N.A.☐	
• Has the IRB taken into account any special vulnerability among prospective subjects that might be relevant to evaluating the risk of participation?	Y☐	N☐	N.A.☐	
• Are the exclusion criteria appropriate?	Y☐	N ☐	N.A.☐	
• Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research?	Y☐	N☐	N.A.☐	
47) Is the setting of the study clearly identified?	Y☐	N☐	N.A.☐	
• Are the facilities and infrastructure of the participating sites adequate	Y☐	N☐	N.A.☐	
• Is the duration of the study specified?	Y☐	N☐	N.A.☐	
48) Are the procedures to be done in the study clearly described and understandable?	Y☐	N☐	N.A.☐	
• Are blood/tissue samples sent abroad?	Y☐	N☐	N.A.☐	
49) Are research data recorded and maintained with strict confidentiality?	Y☐	N☐	N.A.☐	
50) Considering the degree of risk, is the plan for monitoring the research appropriate and adequate in terms of timeliness and thoroughness?	Y☐	N☐	N.A.☐	
51) Is the principal investigator competent to do the study? (by training, expertise or subspecialization)	Y☐	N☐	N.A.☐	
52) Is the principal investigator assessed for any Conflict of Interest for this study?	Y☐	N☐	N.A.☐	
53) If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient?	Y☐	N☐	N.A.☐	

54) Is the mechanism for providing information to the IRB if unexpected results are discovered appropriate?	Y☐	N☐	N.A.☐	
55) If the research involves the evaluation of a therapeutic procedure, have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?	Y☐	N☐	N.A.☐	
56) Has due care been used to minimize risks and maximize the likelihood of benefits?	Y☐	N☐	N.A.☐	
57) Are the subjects given incentives or compensation for study-related expenses?	Y☐	N☐	N.A.☐	
58) Are there adequate provisions for a continuing reassessment of the balance between risks and benefits?	Y☐	N☐	N.A.☐	
59) Is the research expected to have an impact on the community where the research occurs and/or to whom findings can be linked, including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study?	Y☐	N☐	N.A.☐	
60) Does the institution have a data and safety monitoring board?	Y☐	N☐	N.A.☐	
If so, should it be asked to monitor the project under review?	Y☐	N☐	N.A.☐	
If the institution does not have a data and safety monitoring board, should the IRB request or recommend that one be appointed, either by the institution or the sponsor, for this project?	Y☐	N☐	N.A.☐	

Recommendations:

- Approve
- Minor Modifications
- Major Modifications
- Disapprove
- Others

_____

_____

Primary Reviewer

_____

Name & Signature / Date

ANNEX 4

ICF EVALUATION FORM

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

FORM 2.4

IRB REFERENCE NO.					-			-		
RINCIPAL INVESTIGATOR (P.I.)						**SPONSO R**			**DATE OF REVIEW**	
PROTOCOL NO. & TITLE										
PRIMARY REVIEWER										

QUESTIONS		Commen :s	Recommendations
75) Is there a statement saying the study involves research?	Y☐ N☐		
76) Is the purpose of the trial clearly stated?	Y☐ N☐		
77) Is there an explanation to the subjects why they were included in the study?	Y☐ N☐		
78) Are there provisions ensuring that the subject's participation in the trial is voluntary?	Y☐ N☐		
79) Is the subject well-informed of his/her responsibilities? (*This includes providing health information including symptoms or any changes made in her regimen.)*	Y☐ N☐		
80) Is the language and presentation of the information to be conveyed appropriate to the subject population? *(Consider the level of complexity and the need for translation into a language other than English.)*	Y☐ N☐		

81) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained?	Y☐ N☐		
82) Is the expected duration of the subject's participation in the trial specified?	Y☐ N☐		
83) Is the approximate number of study subject stated?	Y☐ N☐		
84) For experimental studies is the nature of the experiment explained well?	Y☐ N☐		

85) For studies using placebo is the use of placebo ethically applicable?	Y☐ N☐		
86) Is detailed explanation of the procedures or tests that are new or not widely used or combinations/doses of drugs never tested before provided to the subject?	Y☐ N☐		
87) Are the proposed explanations of the research appropriate and adequate to provide the subject an accurate assessment of its risks and anticipated benefits?	Y☐ N☐		
88) Are the risks to the study participants disclosed?	Y☐ N☐		
89) Are the potential adverse events disclosed?	Y☐ N☐		
90) Are the possible benefits to the participants discussed?	Y☐ N☐		
91) Are the potential benefit to the Community discussed? 92) Are there lists of alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks?	Y☐ N☐		
93) Are these any anticipated expenses to the subject in the course of the study?	Y☐ N☐		
94) Is there a compensation and/or treatment available to the subject in the event of trial-related injury? Is there a person to contact in the event of trial-related injury?	Y☐ N☐ Y☐ N☐		
95) Is there a person to contact for further information regarding the trial and the rights of the trial subjects?	Y☐ N☐		
96) Do other groups of potential subjects have a greater need to receive any of the anticipated benefits?	Y☐ N☐		

97) Whether they finish the study or not, are the subjects compensated on a per visit basis for trial related expenses?	Y☐ N☐		
98) Will the subject or the subject's legally acceptable representative (LAR) be informed, in a timely manner, of any new available information which may be relevant to the subject's willingness to continue his/her participation?	Y☐ N☐		
99) Is the subject informed of his right to refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled?	Y☐ N☐		
100) Is the subject informed of any foreseeable events and or reasons which may cause his/her participation in the trial to be terminated?	Y☐ N☐		
101) In the event of any information that will affect the willingness of the subject to participate, is re-consenting necessary or provided for?	Y☐ N☐		
102) Are the withdrawal criteria made known to the subject?	Y☐ N☐		
103) If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver?	Y☐ N☐		
104) Are there provisions for medical / psychosocial support if applicable?	Y☐ N☐		
105) Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy? • Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion? • If privacy is to be invaded, does the importance of the research objective justify the intrusion? • What if anything, will the subject be told later?	Y☐ N☐		
106) Is there a mechanism for providing information to the IRB in the event that unexpected results are discovered? (Unexpected results may raise the possibility of unanticipated risks to subjects)	Y☐ N☐		
107) Is there a provision allowing consent from the subject for other monitors/ auditors/ IRB/IEC access to the subject's original medical record for verification purposes?	Y☐ N☐		

108) Are the records identifying the subject kept confidential and to the extent permitted by the applicable laws and/or regulations, not made available in public? • Should the trial be published, will the subject's identity remain confidential?	Y☐ N☐ Y☐ N☐		
109) For genetic studies is there a discussion on the precautions in place to prevent disclosure of results without the subject's permission	Y☐ N☐		
110) Is the subject informed of the possible direct or secondary use of subject's medical records & biological specimen in the course of clinical care	Y☐ N☐		
111) Are plans in place to destroy collected biological specimen at the end of the study or details of storage and possible future discussed with the patient?	Y☐ N☐		

Recommendations:

- ☐ Approve
- ☐ Minor Modifications
- ☐ Major Modifications
- ☐ Disapprove

Primary Reviewer

_____

Name & Signature / Date

ANNEX 5

CIM-CVGH

I INSTITUTIONAL REVIEW BOARD

79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

RESUBMISSION FORM

FORM 2.5

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED
INSTITUTION:	**P.I. CONTACT NO.**	**P.I. EMAILL ADDRESS**

PROTOCOL NO. & TITLE

DOCUMENTS SUBMITTED	
☐ Protocol ☐ Advertisement ☐ Informed Consent	☐ Composition of Research Team ☐ Others _____

PRIMARY REVIEWER	DATE REVIEWED

IRB RECOMMENDATION	PI RESPONSES PI to respond to IRB recommendations in this box	REVIEWER COMMENTS
PI Signature		
Received by IRB Staff		

Summary of Comments

Primary Reviewer

ANNEX 6

CIM-CVGH

APPROVAL LETTER FORM

FORM 2.8

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

APPROVAL LETTER

Date: _____

To: _____

Re:

Protocol Title: _____
IRB Ref No.: _____
Submission Type: Initial
IRB Review Date: MM/DD/YYYY
IRB Review Type: Expedited
IRB Review Action:
Approved

This is to inform you of the IRB decision related to your above referenced application for review. The CIMCVGH IRB met on MM/DD/YYYY and decided to approve the documents submitted effective MM/DD/YYYY. Please note that the approval is valid for 1 year and will expire on MM/DD/YYYY. The PI is advised to submit an annual Continuing Review Report 1 month before expiry date.

The approval covers the following submitted documents

1. _____ version no. ___ date
____ 2. _____ version no. ___

date ____ 3. _____ version no. ___ date ____
4. _____ version no. ___ date ____

Investigator's Responsibilities:

1. Faithfully follow the Protocol
2. Submit SAEs when applicable.
3. Any changes made to the protocol must be submitted as amendment and should not be carried until after IRB approval.
4. To submit continuing renewal review Reports/Progress Reports and obtain approval before the expiration date
5. Submit any Protocol Deviations / Violations/Final Report as applicable

The approval was done with the following members in attendance:

	Designation	Specialty
1. Dr. Manuel Emerson S. Donaldo	Chairman	Rheumatology
2. Dr. Corazon Tan-Meneses	Co-Chair	Academe(MHPEd)
3. Dr. Consolacion Cutillar	Secretary	Endocrinology

Truly yours,

Manuel Emerson S. Donaldo, M.D.
Chairman
CIM –CVGH- IRB

1. **Policy Statement**

   CIM CVGH IRB shall ensure that proposals recommended for resubmission is being reviewed and approved properly. A resubmission review shall be conducted when a proposed study has been recommended for minor or major modifications during initial and continuing review.

2. **Objectives**

   To describe the procedures of CIM CVGH IRB when the protocol resubmissions are received.

3. **Scope**

   This SOP begins with the receipt of the resubmitted protocol, and ends with filing of the protocol in the file folder.

4. **Workflow**

ACTIVITY	RESPONSIBILITY	Timeline
Step 1: Receive the resubmitted protocol package from the PI.	IRB Staff	Day 0
Step 2: Send the protocol package to the primary reviewers.	IRB Staff	Within 7 days from receipt of protocol
Step 3: Review if the resubmission complied with the required modifications	Primary Reviewers	Within 10 days from receipt of protocol
Step 4: Return the documents with a decision after expedited review or recommended a decision to full board review	Primary Reviewers	
Step 5: Discuss and decide on major modifications received during a full board meeting	Committee members	Every 3rd week of the month

Step 6: Accomplish the Certificate of Approval and communicate the IRB decision to the PI	IRB Staff	Within 7 days after the IRB meeting
Step 7: File copies of the documents in the protocol file folder and	IRB Staff	

5. Description of Procedures

5.1. ***Step 1 Receive the resubmitted protocol package from the Principal Investigator***

5.1.1. The IRB staff receives the resubmitted protocol documents from the PI.

5.2. Step 2 Send the protocol package to the primary reviewers:

5.2.1. The IRB staff sends the package to the primary reviewers who reviewed the protocol during initial review.

5.3. Step 3 Review if the resubmission complied with the required modifications:

5.3.1. The Chair/Member-Secretary or designated primary reviewers may review minor protocol modifications.

5.3.2. The primary reviewers review the resubmitted documents and compares it with the requirements for modification

5.3.3. Provide a summary of the comments in compliance to the recommendations for the resubmitted document/s

5.4. ***Step 4 Return the documents with a decision after expedited review or recommended a decision to full*** *board review*:

5.4.1. The primary reviewers return the resubmission package indicating their decision.

5.4.2. In expedited review, the primary reviewers approve the resubmitted documents if the PI has substantially complied with the required modifications.

5.4.3. Minor modifications recommended by full board should also go to expedited review.

5.5. ***Step 5*** *Discuss and decide on major modifications received during a full board meeting*:

5.5.1. Primary reviewers resend their assessment of major modifications during full board discussion and make a recommendation for approval.

5.5.2. IRB members vote to endorse or not to endorse the recommendation for approval.

5.6. ***Step 6*** *Accomplish the Certificate of Approval and communicate the IRB decision to the PI:*

5.6.1. For approved resubmitted protocols, the IRB staff prepares the Certificate of Approval that the Chair should sign.

5.6.2. The IRB decision is communicated to the PI.

5.7. ***Step 7*** *File copies of the documents in the protocol file folder and:*

5.7.1. The IRB Staff files copies of the approved documents in the protocol file folder.

5.7.2. Update the protocol file index of the protocol file folder.

5.7.3. The IRB Staff updates the protocol database.

6. Forms

Annex 1. Form 2.5: Resubmission Form

7. History of SOP

Version No.	Date	Authors	Main Change
01	December 2018	SOP Team	First draft-
02	June 21, 2021	SOP Team	Separated from Initial Submission Revised policy statement Revised Resubmission Form
03	July 21, 2023	Dr Cutillar	Updated References Appended Form

ANNEX 1

CIM-CVGH	RESUBMISSION FORM
INSTITUTIONAL REVIEW BOARD 79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127	**FORM 2.5**

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED
INSTITUTION:	**P.I. CONTACT NO.**	**P.I. EMAILL ADDRESS**

PROTOCOL NO. & TITLE

DOCUMENTS SUBMITTED	
☐ Protocol ☐ Advertisement ☐ Informed Consent	☐ Composition of Research Team ☐ Others _____
PRIMARY REVIEWER	**DATE REVIEWED**

IRB RECOMMENDATION	PI RESPONSES PI to respond to IRB recommendations in this box	REVIEWER COMMENTS
PI Signature		
Received by IRB Staff		

Summary of Comments

Primary Reviewer

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
VERSION 3	**SOP 2.6 Management of Appeal of Decision**	Effective Date: July 21, 2023

1. **Policy Statement**
   The IRB is open to appeal of its decision should the Investigating team request it. Letters of appeal must be filed with the IRB chair within 30 days of the final decision of the IRB. It should state the grounds upon which the appeal is filed.

2. **Objective of the Activity**
   Management of appeals ensures fairness, transparency and comprehensiveness of ethics review.

3. **Scope**
   This SOP provides instructions for the management of appeals of decisions made by the CIM CVGH IRB only. Starting from receipt of appeal request to filing of the appropriate document.

4. **Work Flow**

ACTIVITY	RESPONSIBILITY
Step 1: Receive an appeal request from investigators.	IRB Staff
Step 2: Submit appeal request from investigators to IRB Chair	IRB Staff/ IRB chair
Step 3: Schedule the appeal review for the next IRB board meeting	IRB Staff
Step 4: Discuss the merits of the appeal and make appropriate decision during the Board meeting.	IRB Chair/Members
Step 5: Communicate IRB decision to PI	IRB Staff
Step 6: Files and documents the appeal request	IRB Staff

5. **Description of Procedures**

5.1. Step 1 Receive an appeal request from investigators.

5.1.1. The IRB Staff receives an appeal request from investigators.

5.1.2. Letters of appeal must be received 30 days in advance of the next IRB Meeting

5.2. Step 2 Submit appeal request from investigators to IRB Chair

5.2.1. The IRB staff sends the appeal request from investigators to IRB Chair.

5.2.2. IRB chair assigns the review of the appeal to the primary investigator

5.3. Step 3 Schedule the appeal review for the next IRB board meeting.

5.3.1. The IRB Staff schedules the appeal review for the next IRB board meeting.

5.4. Step 4 Discuss the merits of the appeal and make appropriate decision during the Board meeting.

5.4.1. The primary reviewer/s discuss the merits of the appeal and make appropriate decision.

5.4.2. The board makes the appropriate decision.

5.5. Step 5 Communicate IRB decision to PI

5.5.1. IRB staff sends the communication to the PI about the decision on the appeal submitted within seven (7) Days from the board meeting

5.6. Step 6 Files and documents appeal

5.6.1. Appeal or other documents are filed by the IRB staff.

6. Forms (None)

7. History

Version No.	***Date***	***Authors***	***Main Change***
01	***July 2, 2019***	***SOP Team***	***New SOP***
02			***NONE***
03	June 21, 2023	Dr. Cutillar	– Added timelines for submission to Step 1

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 3	**SOP 2.7 Review of Medical Device**	Effective Date: July 21, 2023

1. Policy Statement

CIM CVGH IRB shall provide guidelines on procedures in the review and approval of medical device studies submitted to the IRB.

2. Objective

This SOP shall aim to describe the procedures in the review and approval of medical device studies submitted to the CIM CVGH IRB.

3. Scope

This SOP provides instructions on how the CIM-CVGH IRB review submitted proposals on medical devices. It starts with the receipt of the submitted documents and ends with the storage of the reviewed documents

4. **Process Flow/Steps**

ACTIVITY	***RESPONSIBILITY***
Step 1: *Receipt of submitted documents*	*IRB Staff*
Step 2: *Assignment of Primary Reviewer*	*Member-Secretary/ IRB Chair*
Step 3: *Reporting of Protocol assessment*	*Primary Reviewers*
Step 4: *Notification to the investigators*	*IRB Staff*
Step 5: *Storage of the documents*	*IRB Staff*

5. **Description of Procedures**

5.1 Step 1: *Receipt of submitted documents*

5.1.1 The IRB Staff received the new medical device study.

5.1.2 The CHH IRB Secretariat checks the submitted package for completeness.

5.1.3 The CHH IRB Secretariat document the checking procedure by completing a checklist form

5.2 Step 2: *Assignment of Primary Reviewer*

5.2.1 The Member-Secretary/ CHH IRB Chair to assign the primary reviewers to review the study, If available an independent Consultant with expertise on the reviewed a medical device is most appropriate as the primary reviewer.

5.2.2 According to the risk identified the study will be channeled to Expedited, Full Board or Exempted from Review.

5.2.3 Staff secretary prepares the documents for distribution to each CHH IRB member/ primary reviewer.

5.2.4 Include the new medical device study on the meeting agenda.

5.3 Step 3: *Reporting of Protocol assessment*

5.3.1 Primary Reviewers present a brief oral or written summary of the study design related to the level of risk

5.3.2 The Chairperson opens discussion about whether the study is SR or NSR (see examples in ANNEX 1).

5.3.2.1 The Chairperson leads discussion about each document under consideration (e.g. protocol, informed consent, investigators and site qualifications, advertisements).

5.3.2.2 The Chairperson calls for a decision by voting. The IRB decision points to either:

❑ Approve the study to start as presented with no modifications

❑ Require further clarifications and/or request further information to be resubmitted and subjected to review in the next full Board meeting.

❑ Disapprove the study and state the reason.

5.4 Step 4: *Notification to the investigators*

5.4.1 The Secretariat sends an action letter along with the approved documents to the investigator. (Refer to SOP on Communicating IRB Decision to PI)

5.4.2 If the Board votes not to approve the study, the IRB staff immediately notifies the investigator in writing of the decision and the reason for disapproving the study.

5.4.2.1 If the investigator wishes to appeal this decision, he or she may do so.

5.4.2.2 If the Board members votes to require modifications to any of the documents, the IRB Staff sends a written resubmission request of the specific changes to the investigator.

.

5.5 Step 5: *Storage of the documents*

5.5.1 IRB Staff files the properly-labeled protocol file folders in the appropriate shelf of the storage cabinet for active study files taking note of the sequence of protocol code numbers on the file binders.

6. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
03	*June 21, 2023*	*Dr. Donaldo*	• *New SOP*

1. Policy Statement

CIM CVGH IRB in compliance with the ADMINISTRATIVE ORDER NO. 2019 - 0044 NOV 05 2013 *shall participate in the single review of a multi-site researches.* ***(Please Refer to attached SOP on Single Joint Research Ethics Board SJREB STANDARD OPERATING PROCEDURES)***

2. Objective

This SOP describes the involvement of the CIM-CVGH IRB in the SIngle Joint REview of a common multi-center clinical Trial reviewed by the ***Single Joint Research Ethics Board****.*

3. Scope (Please Refer to attached SOP)

This procedure applies to all multi-site protocols submitted to the SJREB with CIM CVGH IRB as a participating site for initial ethics review.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt of submitted documents	***IRB Staff***
Step 2: Assignment of Primary Reviewer/s	***Member-Secretary/ IRB Chair***
Step 3: Attendance to SJREB Joint review	***Primary Reviewers/IRB Chair***
Step 4: CIM CVGH IRB Discussion of site specific details	***IRB members***
Step 5: Notification of decision to the investigators	***IRB Staff***
Step 6: Storage of the documents	***IRB Staff***

5. *Description of Procedures*

5.1 Step 1: Receipt of submitted documents

5.1.1 The IRB Staff receives the new protocol documents for review.

5.1.2 The CHH IRB Secretariat staff checks the submitted package for completeness.

5.1.3 The CHH IRB Secretariat staff document the checking procedure by completing a checklist form

5.2 Step 2: Assignment of Primary Reviewer

5.2.1. Member-Secretary/ CHH IRB Chair assigns the primary reviewer/s to review the study, according to the use of study assessment forms.

5.2.2 staff secretary provides copies of documents to each IRB member/ primary reviewer.

5.3 Step 3: Attendance to SJREB joint review

5.3.1. Primary Reviewers attend the SJREB review as scheduled

5.3.2. Primary Reviewer request copy of minutes of the SJREB for file

5.4 Step 4: CIM CVGH IRB Discussion of site-specific detail

5. 4.1 Primary Reviewers presents SJREB review

5.4.2. Primary Reviewer discusses local area site specific details of the study

5.4.3 Board determines decides for site specific issues

5.5 Step 5: Notification of decision to the investigators

5.5.1 IRB staff communicates to the Investigators the SJREB and the CIM CVGH IRB decision

5.6 Step 6: Storage of the documents

5.6.1. IRB Staff files the properly-labelled protocol file folders in the appropriate shelf of the storage cabinet for active study files taking note of the sequence of protocol code numbers on the file binders.

6. *History of SOP*

Version No.	*Date*	*Authors*	*Main Change*
03	*June 21, 2023*	*Dr. Donaldo*	· *New* · *Refer to annexed SOP on SJERB* · *Updated References*

1. Policy Statement

The IRB shall require the submission of an application for an amendment to an approved protocol and/or other related documents (e.g. Informed Consent Form) prior to the implementation of these changes.

2. Objective of the Activity

This activity provides instructions for the application for an amendment required by the CIM-CVGH IRB to be submitted by the PI to monitor conduct of the study and the safety of participants enrolled in the study.

3. Scope

This SOP begins with the receipt of the amendment package by the IRB staff and ends with the communication of IRB decision to the PI.

4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY	Timeline
Step 1: Receive and manage Amendment Package	IRB Staff	Day 0
Step 2: Refer Amendment Documents to original primary reviewers	IRB Staff	Within 7 days from receipt of protocol
Step 3: Review amendments and make a recommendation	Primary Reviewers	Within 10 days from receipt of protocol
Step 4: Review recommendations and determine if amendment should be referred to full board	Chair	
Step 5: Discuss at full board, if necessary and make a decision	Members, Member Secretary	Every 3rd week of the month
Step 6: Communicate CIM-CVGH IRB decision to PI	Member Secretary, IRB staff	Within 7 days after the IRB meeting
Step 7: Keep a copy of all amendment related documents in the protocol file	IRB Staff	

5. Description of Procedures

5.1. *Step 1 Receive and manage Amendment Package*

5.1.1. The IRB Staff checks the completeness of the amendment package

5.2. Step 2 Refer Amendment Documents to original primary reviewers

5.2.1. This will be done within 7 days from submission.

5.3. Step 3 Review amendments and make a recommendation

5.3.1. The primary reviewers shall check the amended documents if the changes would alter the risk/benefit ratio of the study.

5.3.2. Major amendments of full board protocols will be reviewed full board while minor amendments should be reviewed by expedited

5.3.3. Amendments are then classified into major amendments and minor amendments. Major protocol amendment which increases risk to study participants may include, but is not limited to the following:

5.3.3.1 change in study design
5.3.3.2 additional treatments or the deletion of treatments
5.3.3.3 any change in the inclusion/exclusion criteria
5.3.3.4 change in method of drug intake or route of drug intake (e.g. oral changed to intravenous)
5.3.3.5 significant change in the number of subjects (increase or decrease in sample size that alters the fundamental characteristics of the study)
5.3.3.6 significant decrease or increase in dosage amount

5.3.4. Otherwise, amendments are considered minor especially if they do not compromise the integrity of the research data or change the risk benefit ratio.

5.3.5. For amendments that will potentially affect the risk/benefit ratio, the protocol shall be subjected to full review.

5.3.6. Decision points may include
5.3.6.1. Approval
5.3.6.2. Require further information
5.3.6.3. Require further action
5.3.6.4. Disapproval

6. Communicate CIM-CVGH IRB decision to PI

i. CIM-CVGH IRB Staff shall communicate the decision to the PI (Communicating IRB Decisions – SOP 6.2)

7. Keep a copy of all amendment related documents in the protocol file

ii. CIM-CVGH IRB Staff shall keep a copy of all documents submitted in the protocol file.

8. Forms

Annex 1: Form 4.2A PROTOCOL AMENDMENT SUBMISSION FORM
Annex 2: Form 4.2B PROTOCOL AMENDMENT STANDARD TEMPLATE

9. History

Version No.	Date	Authors	Main Change
1	Nov. 8, 2017	SOP Team	First draft
02	June 21, 2021	SOP Team	NONE
03	June 21, 2023	Dr Donaldo	Added proper channeling to Step 3 Added decision Points to Step 5

ANNEX 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

PROTOCOL AMENDMENT SUBMISSION FORM FORM 4.1A

Any amendment to an approved protocol must be reviewed and approved by the IRB before the amendment is implemented. Such amendments could include changes to the study design, procedures, enrolment, methods of recruitment, personnel, funding source or the consent form/information sheet. This includes changes that appear to reduce risks to subjects. There are NO EXCEPTIONS to this rule.

IRB REFERENCE NO.			
PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED	
INSTITUTION:	P.I. CONTACT NO.	P.I. EMAIL ADDRESS	
PROTOCOL NO. & TITLE			
PRIMARY REVIEWER	DATE REVIEWED		

1. Describe each proposed amendment and provide the reason for such.

2. For each amendment listed above, explain whether the proposed amendment increases or decreases the level risk to participants (thereby changing the risk/benefit ratio) and, if so, describe. Please use page 2 attached

Does not change the risk/benefit ratio

Increase the risk to participants:

Decrease the risk to participants

Has the funding source or the status of funding changed since initial or last re-approval review?

YES ☐ NO

To the PI to fill		
Before Amendment	**After Amendment**	**Rationale**

TYPE OF REVIEW	☐ **Full Board** ☐ **Expedited**
Name and Signature Principal Investigato	**Date**

Recommended action

- ☐ **Approved**
- ☐ **Minor Modification subject to expedited review at the level of the chair**
- ☐ **Major Modification subject to full Board Review**
- ☐ **Disapproved**

FOR IRB USE ONLY			
Classification of Amendment			
☐ Major Amendment	☐ Minor Amendment		
Effects of Amendment on the Risk Benefit Ratio			
☐ Yes	☐ No		
Remarks			
IRB Decision			
☐ Approved	☐ Disapproved		☐ Require further Information
Reviewed by:		Date Reviewed:	
Chairman **CIM CVGH IRB**		**Date**	

1. **Policy Statement**

   To ensure the integrity of the data and continued safety of the participants the IRB shall require the submission of progress reports at a frequency based on the level of risk of the study. At the very least progress reports/continuing review reports are submitted yearly. This include early termination of the research to ensure adequate protection and welfare of subjects that had been recruited into the study.

2. **Objective of the Activity**

   This activity aims to provide instructions for the review of progress reports that are required by the CIM-CVGH IRB to be submitted by the PI to monitor the safety of participants enrolled in a study. This further ensures that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted.

3. **Scope**

   The annual and/or more frequent progress report as determined by the IRB becomes the basis for continuing review of protocols whose approval needs to be renewed every year.

   This SOP begins with the reminder to the PI to submit progress reports and ends with the communication of IRB decision to the PI.

4. **Work Flow**

ACTIVITY	RESPONSIBILITY
Step 1: Remind Pis to submit progress report 2 months before expiry date of approval	IRB Staff
Step 2: Receive progress reports within one month before expiry date of approval	IRB Staff
Step 3: Check whether the initial review was done full board or expedited	IRB Staff
Step 4: Check completeness of information in the report and forward to the primary reviewers for assessment/comments	IRB Staff
Step 5: Review the progress if it is in accordance with the approved protocol and related documents as well as changes in the benefit risk ratio.	Primary Reviewer

Step 6: Recommend approval or require more information or other action from the PI	Primary Reviewer
Step 7: Report approval/ other recommendations to full board	Primary Reviewer
Step 8: Discuss at full board and make a decision	Members, Member Secretary
Step 9: Communicate IRB decision to PI/Furnish a renewal of approval of the protocol with the new approval date and the date of subsequent expiry of approval stated	IRB Staff

5. Description of Procedures

5.1. ***Step 1:*** *Remind PIs to submit progress report two months before due date*

5.1.1. The IRB Staff checks the database and tracks due dates of progress reports of Study Protocols approved by the CIM-CVGH IRB.

5.1.2. The Secretariat prepares and sends reminder letter/notice addressed to the PI two Months before the *expiry date of approval*.

5.2. ***Step 2: Receive progress within one month before expiry date of approval***

5.2.1. The IRB staff will receive the progress report submitted to CIM-CVGH IRB within one month before *expiry date of approval*

5.3. ***Step 3: Check whether the initial review was done full board or expedited***

5.3.1. The IRB staff will check whether the initial review was done full board or expedited and schedules the discussion of the progress report accordingly

5.3.2. Expedited protocols will go to expedited, full board will go to full board

5.4. ***Step 4: Check completeness of information in the report and forward to the primary reviewers for assessment/comments***

5.4.1. The IRB Staff reviews the completeness of submitted report based on the items in Progress Report (Form 4.1) and forwards the report to the primary reviewers within three days from submission.

5.5. ***Step 5: Review the progress or final report if it is in accordance with the approved protocol and related documents***

5.5.1. The primary reviewers conduct continuing review of progress/ final report if they are in accordance with the protocol and related documents approved by the IRB.

5.5.2. The primary reviewer will assess for any changes in the risk/benefit ratio.

5.5.3. The primary reviewers refer to the protocol file to check compliance with approval given by the IRB during initial review and upon submission of continuing review reports.

5.6. ***Step 6: Recommend approval or require more information or other action from the PI***

5.6.1. The primary reviewers recommend approval of the progress/final report if there is no deviation or violation of IRB approvals.

5.6.2. If there is any issue of approvals given by the IRB, the primary reviewers recommend that appropriate action be taken by the PI (e.g. amendment of the protocol or consent form, etc for progress reports; explanation of deviation or violation for final reports, etc.)

5.7. ***Step 7: Report approval/ other recommendations to full board***

5.7.1. Approval or other recommendations by the primary reviewers of progress report is reported to the board meeting by the Secretariat.

5.8. ***Step 8: Discuss at full board and make a decision***

5.8.1. Related issues or recommendations related to progress reports are included in the agenda for discussion during the board meeting in order to arrive at a renewed approval or disapproval.

5.8.2. The board arrives at the appropriate decision which may be any of the following: follows

- Approval
- Require further information/action from PI
- Amendment of protocol (e.g. reconsent)
- Suspension of recruitment
- Site Visit

5.9. ***Step 9: Communicate IRB decision to PI***

5.9.1. The Member Secretary takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required. (SOP on Communicating IRB Decisions SOP #6.2)

6. Forms

Annex 1: Form 4.2 Progress Report Form

7. History

Version No.	*Date*	*Authors*	*Main Change*
01	***Nov. 8, 2017***	***SOP Team***	***First draft***
02	***Jun 21 2019***	***SOP Team***	– ***Separated Progress Report from Final Report*** – ***Change of IRB Secretariat to Staff***
03	***June 21, 2023***	***Dr Baking***	– ***Improved the Scope*** – ***Provided timeline for Step 2*** – ***Added Step 3 to Work flow*** – ***Revised Step 5*** – ***Defined decision points in Step 8***

Annex 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

PROGRESS REPORT FORM

FORM 4.2

IRB REFERENCE NO.					-			-		
PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED
INSTITUTION:	P.I. CONTACT NO.	P.I. EMAILL ADDRESS
TITLE		

1. ACTION REQUESTED:
   - ❑ Renew - New participant accrual to continue
   - ❑ Renew - Enrolled participant follow up only
   - ❑ Terminate - Protocol discontinued

2. AMENDMENTS SINCE THE LAST REVIEW?
   - ❑ NO
   - ❑ YES (Describe briefly in attached narrative)

3. PROTOCOL PARTICIPANTS SUMMARY:
   - _____ Accrual ceiling set by IRB
   - _____ New participants accrued since last review
   - _____ Total participants accrued since protocol began
   - _____ Number of participants who are lost to follow up
   - _____ Number of participants who experienced SAEs/SUSARs

4. ACCRUAL EXCLUSIONS
   - ❑ NONE
   - ❑ MALE
   - ❑ FEMALE
   - ❑ OTHER (specify):_____

5. IMPAIRED PARTICIPANTS
   - ❑ None
   - ❑ Physically
   - ❑ Cognitively
   - ❑ Both

6. HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?
   - ❑ NO
   - ❑ YES (Explain changes in attached narrative)

7. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
   - ❑ NO

9. IS THERE NEW INFORMATION FROM SIMILAR RESEARCH THAT MIGHT AFFECT THE RISK/BENEFIT RATIO OF THE HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?
   - ❑ NO
   - ❑ YES (Discuss in the attached narrative)

10. HAVE ANY UNEXPECTED COMPLICATIONS OR ADVERSE EVENTS BEEN NOTED SINCE LAST REVIEW?
   - ❑ NO
   - ❑ ?YES (Discuss in the attached narrative)

11. HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?
   - ❑ ?NO
   - ❑ ?YES (Discuss in the attached narrative)

12. HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?
   - ❑ NO
   - ❑ YES (Identify all changes in the attached narrative)

13. HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW?
   - ❑ NO
   - ❑ YES (Identify all changes and provide an explanation of changes in the attached narrative)

14. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST?
   - ❑ NO
   - ❑ YES (Append a statement of disclosure)

15. WERE THERE PROTOCOL DEVIATION/ VIOLATION REPORTS?
   - ❑ NO
   - YES (Summarize and what corrective actions were taken)

❑ YES (Explain changes in attached narrative) 8. CHANGE IN PRINCIPAL INVESTIGATOR? ❑ NONE ❑ DELETE:_____ ADD: _____	

1. Policy Statement

The CIM-CVGH IRB shall require the submission of reports of onsite SAEs and SUSARs as soon as possible, and no later than 7 calendar days after first knowledge of the investigator. The evaluation of the SAEs and SUSARs shall be conducted by the assigned Reviewers whose recommendation shall be submitted to the IRB Chair for final action.

2. Objective of the Activity

This activity of reviewing aims to ensure that the safety and welfare of human participants in the study are safeguarded and that information on SAEs and SUSARs are properly documented.

3. Scope

3.1. The IRB reviews such reports to determine appropriate action to protect the safety of participants in an approved study.

3.2. ICH-GCP E6 defines a serious adverse event (SAE) or a serious adverse drug reaction (ADR) as any untoward medical occurrence that at any dose

3.2.1. Results in death,
3.2.2. Is life threatening,
3.2.3. Requires hospitalization or prolongation of existing hospitalization,
3.2.4. Results in persistent or significant disability or incapacity, or
3.2.5. Results in a congenital anomaly or birth defect.

3.3. A suspected unexpected serious adverse reaction (SUSAR) is a serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics

4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Step 1: Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database	IRB Staff
Step 2: Retrieval of pertinent protocol file	IRB Staff
Step 3: Notification of Chair and SAE Reviewer	IRB Staff

Step 4: Review SAE and SUSAR reports and make a recommendation	Assigned member (for SAE review)
Step 5: Summarize and report to full board for appropriate action	IRB Staff
Step 6: Communication of IRB recommendation to the Principal Investigator/researcher (SOP on Communication of IRB Decisions SOP#6.2)	IRB Staff
Step 7: Filing of all related documents (SOP on Management of Active Files - SOP# 7.2)	IRB Staff

5. Description of Procedures

5.1. *Step 1 Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database*

5.1.1. The *IRB Staff* shall accept and document the submission of documents in the manual log book. The following information should be recorded: Date of occurrence of the SAE / SUSAR, date reported, title of the study, and the nature of the SAE/SUSAR as indicated in the FORM.

5.1.2. Report should use the specified IRB form (Form 3.1 SAE Forms, 3.2 USAE Form, Form 3.3 CIOMS) and to accomplish completely and properly.

5.1.3. Date of submission should be within the required timeline as mentioned in IRB Guidelines.

5.2. *Step 2: Retrieval of pertinent protocol file*

5.2.1. The IRB Staff shall retrieve the protocol from the Active Files to determine the identity of primary reviewers, and to check if there were earlier reports on SAEs and SUSARs

5.3. *Step 3: Notification of Chair and the Primary Reviewers*

5.3.1. The *IRB Staff* shall notify the designated SAE Reviewer. The secretariat staff will then notify the designate. Reviewer of the report through SMS and a phone call within 48 hours from submission.

5.4. *Step 4: Review SAE and SUSAR reports and make a recommendation*

5.4.1. The designated SAE Reviewer shall do a comprehensive review of all the SAE reports using the SAE Assessment Form (Form 3.4) and make a recommendation to the IRB Chair who will decide if there is a need for a full board review. Only onsite SAEs/SUSARs are reviewed while offsite reports are noted for significant trends.

5.4.2. After deliberation IRB decides on appropriate action as follows:

5.4.2.1. Request an amendment to the protocol or consent form

5.4.2.2. Request further information

5.4.2.3. Suspension of:

5.4.2.3.1. Enrolment of new research participants until further review by the IRB

5.4.2.3.2. All trial-related procedures (except those intended for the safety and well-being of the participants) until further review by the IRB

5.4.2.3.3. Termination of the study

5.4.2.3.4. Take note and continue monitoring

5.4.2.3.5. Conduct site visit

5.5. ***Step 5: Summarize and report to full board for appropriate action***

5.5.1. All SAEs/SUSARS are presented for FULL BOARD review the designated reviewer Shall prepare the report to be presented in the IRB meeting

5.6. ***Step 6: Communication of IRB recommendation to the Principal Investigator/researcher (SOP on Communication of IRB Decisions SOP#6.2)***

5.6.1. The I*RB Staff* takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required. (SOP on Communicating IRB Decisions SOP #6.2)

5.7. ***Step 7: Filing of all related documents (SOP on Management of Active Files - SOP# 7.2)***

5.7.1. The *IRB Staff* shall file all the documents, to include the submitted reports, and IRB decision in the Active File. (SOP on Managing Active Files SOP #7.2)

6. Form

Annex 1: Form 3.1 Serious Adverse Event Form
Annex 2: Form 3.2 Unexpected Serious Adverse Event Form
Annex 3: Form 3.3 CIOMS Form
Annex 4: Form 3.4 SAE Assessment Form

7. History

Version	Date	Authors	Main Change
1	November 8, 2018	IRB Members	First Draft
02	June 21, 2021	SOP Team	Revised step 3 to include notification of a particular member to review SAEs and SUSARS. Revised Step 4 and added decision points to Step 4
03	June 21, 2021	Dr Evasco	Updated References

ANNEX 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 P. RAMOS ST., CEBU CITY
Tel: 253-7403 Fax: (63-32) 253-9127

SERIOUS ADVERSE EVENT REPORT FORM

FORM 3.1

Principal Investigator:	Protocol No.:	IRB Reference No: ☐☐☐ ☐☐☐ ☐☐
Study Title:		
Name of the study medicine/device:	Report Date: ☐ initial ☐ follow-up	Onset date:
	Sponsor:	Date of first use:

Subject's initial/number:	Age:	☐ Male ☐ Female
Subject's history:	Laboratory findings:	
SAE:	Treatment: Outcome: ☐ resolved ☐ on-going	
Seriousness: ☐ Death ☐ Life Threatening ☐ Hospitalization – O initial O prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other	Relation to O Drug O Device O study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown	
Changes to the protocol recommended?		☐ No ☐ Yes , attach proposal
Changes to the informed consent form recommended?		☐ No ☐ Yes , attach proposal
Reviewed by:		Date:
Comment:		Action:

ANNEX 2

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

UNEXPECTED ADVERSE EVENT REPORT FORM

FORM 3.2

Principal Investigator:	Protocol No.:	IRB Reference No: ☐☐☐-☐☐☐☐-☐☐
Study Title:		
Name of the study medicine/device:	Report Date: ☐initial ☐follow-up	Onset date:
	Sponsor:	Date of first use:

Subject's initial/number:	Age:	☐Male ☐Female
Subject's history:	Laboratory findings:	
SAE:	Treatment: Outcome: ☐resolved ☐on-going	
Seriousness: ☐Death ☐Life Threatening ☐Hospitalization –O initial O prolong ☐Disability / Incapacity ☐Congenital Anomaly ☐Other	Relation to O Drug O Device O study ☐Not related ☐Possibly ☐Probably ☐Definitely related ☐Unknown	
Changes to the protocol recommended?	☐No ☐Yes , attach proposal	
Changes to the informed consent form recommended?	☐No ☐Yes , attach proposal	
Reviewed by:	Date:	
Comment:	Action:	

ANNEX 3

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

CIOMS FORM

FORM 3.3

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2.a AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTIONS (including relevant tests/lab data)										PATIENT DIED INVOLVED OR PROLONGED INPATIENT HOSPITALISATION INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? YES □ NO □ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCITON? YES □ NO □ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATE (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24A. NAME AND ADDRESS OF MANUFACTURER		26. REMARKS
	24b. MFR CONTROL NO.	25b. NAME AND ADDRESS OF REPORTER
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE STUDY □ LITERATURE HEALTHPROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE INITIAL □ FOLLOWUP	

ANNEX 4

IRB Reference No.	
Protocol No. & Title	

CIM-CVGH
INSTITUTIONAL REVIEW BOARD

SAE ASSESSMENT FORM
FORM 3.4

Site of reported SAE		Type of SAE (Number)		On-site SAEs					
On-Site (Site in the country)	Off – Site (Site in foreign countries)	SUSAR	Non-SUSAR	Date of SAE	Date reported to REC	Date presented in REC meeting	Relation to Investigational New Drug	Action taken	Reviewed By
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						

1. Policy Statement

The CIM CVGH IRB requires the submission of RNE reports, at the latest three (3) days after the event has come to the attention of the researcher. A special meeting shall be considered depending on the level of risk involved.

2. Objective of the Activity

Review of RNE reports aims to ensure that the safety and welfare of human participants and the research team are safeguarded and that information on RNEs are properly documented and evaluated.

3. Scope

This SOP begins with the receipt and documentation of submission of RNE report in the logbook and ends with the filing of all related documents and update of the protocol database.

4. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: *Receipt and documentation of submission of RNE report in the logbook.*	*IRB Staff*
Step 2: *Retrieval of pertinent protocol file*	*IRB Staff*
Step 3: *Notification of Chair*	*IRB Staff*
Step 4: *Call for a Special Meeting*	*Chair*
Step 5: *Deliberation on the RNE*	*REC members*
Step 6: *Communication of IRB action to the Principal Investigator/researcher and to the Institutional authority*	*IRB Staff*
Step 7: *Filing of all related documents*	*IRB Staff*

5. Detailed Instructions

5.1 Step 1 - Receipt and documentation of submission of the RNE report in the logbook/database: The Staff receives the accomplished RNE report form (Form ##) and

enters the submission into the logbook. The Staff notes whether the submission is within the required timeline.

5.2 Step 2 - Retrieval of pertinent protocol file:
The Staff retrieves the approved protocol file and checks the identity of the primary reviewers.

5.3 Step 3 - Notification of Chair:
The Staff notifies and sends the report and the retrieved documents to the Chair who may decide to call for a special meeting.
5.4 Step 4 - Call for a Special Meeting. The staff prepares for a special meeting The researcher and other members of the study team may be invited for a clarificatory meeting.

5.5 Step 5 - Conduct of the Special Meeting. The Chair leads the discussion of the special meeting, summarizes the RNE report and informs the IRB members regarding the presence of the research team for clarificatory meeting. The safety issues are evaluated, i.e., identification of risks to the participants / research team, nature and effectivity of preliminary interventions with or without the help of community constituents/authority, impact on integrity of data and completion of the research. The Research team is excused and the IRB members deliberate on possible options, as follows:

- recommend suspension of the study until risk is resolved. ○ withdrawal of ethical clearance ○ submission of a plan to mitigate risk/harm ○ require an amendment to the protocol
- uphold original ethical clearance

5.6 Step 6 - Communication of REC recommendation to the researcher: IRB staff prepares and send recommendations to the PI

5.7 Step 7 - Filing of all related documents and update of the protocol database: IRB staff files all related documents and updates the database

6. Form

7. History

Version	*Date*	*Authors*	*Main Change*
01	*June15, 2019*	*IRB Members*	*First Draft*
02	*June 21. 2021*	*SOP Team*	*NONE*
03	*July 21, 2023*	*Dr. Cutillar*	*Updated References*

1. Policy Statement

The IRB shall require Researchers to report protocol deviations and violations in the conduct of approved researches within a week of the event. Major protocol deviations and violations shall undergo a full review.

2. Objective of the Activity

This activity provides instructions for the review of protocol deviations and violations to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility of data is maintained.

3. Scope

This SOP begins with the receipt and documentation of report of protocol violations and deviations in the logbook/database and ends with the filing of all related documents

4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Step 1: Receipt and documentation of report of protocol violations and deviations in the logbook.	IRB Staff
Step 2: Retrieval of pertinent protocol file	IRB Staff
Step 3: Notification of Chair and Primary Reviewers	IRB Staff
Step 4: Determination of type of review: expedited (SOP on Expedited Review - SOP#4.1), full review (SOP on Full Review - SOP#4.2)	Primary Reviewer, Chair
Step 5: Inclusion of report in the agenda of the next IRB regular meeting (SOP on Preparing the Meeting Agenda (SOP#5.1)	Member Secretary, Chair
Step 6: Communication of decision to the Principal Investigator/researcher (SOP on Communicating IRB Decisions- SOP#6.2)	Member Secretary, Chair, IRB Staff
Step 7: Filing of all related documents (SOP on Managing Active Files (SOP#7.2)	IRB Staff

5. Detailed Instructions

5.1 Step 1: Receipt and documentation of report of protocol violations and deviations in the logbook.

5.1.1. The IRB Staff shall receive protocol violation/ deviation reports from investigators and Other parties related to any event that is not in compliance with the previously IRB approved protocol.

5.1.2. The IRB Staff shall obtain full information about the event and document the submission the log books.

5.2. Step 2: Retrieval of pertinent protocol file

5.2.1. The IRB Staff shall retrieve the protocol from the Active Files to determine the identity of primary reviewers, and to check if there were earlier records of protocol deviation

5.3. Step 3: Notification of Chair and the Primary Reviewers

5.3.1. The IRB Staff shall notify the Chair and the Primary Reviewers of the report through SMS and a phone call within48 hours from submission.

5.4. **Step 4: Determination of type of review: expedited (SOP on Expedited Review – SOP#3.1), full review (SOP on Full Review-SOP#3.2)**

5.4.1. The Primary Reviewers shall do a comprehensive review of the report and make a recommendation if for Expedited or a Full Review.

5.5. **Step 5: Inclusion of report in the agenda of the next IRB regular meeting (SOP on Preparing the Meeting Agenda-SOP#5.1)**

5.5.1. If a full board review is needed, the member secretary shall prepare the report to be presented in the IRB meeting

5.6. Step 6: Communication of decision to the Principal Investigator/researcher (SOP on Communicating IRB Decisions- SOP#6.2)

5.6.1. The Member Secretary/IRB staff shall take note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required. (SOP on Communicating IRB Decisions SOP #6.2)

5.6.2. Possible decisions include one or several of the following:

- Submission of additional information
- Submission of corrective action / preventive action
- Clarificatory interview with Principal Investigator/researcher
- Site visit
  - Suspension of recruitment
  - Suspension of the study

5.7. Step 7: Filing of all related documents (SOP on Management of Active Files - SOP# 7.2)

5.7.1. The IRB shall file all the documents, to include the submitted reports, and IRB decision in the Active File. (SOP on Managing Active Files SOP #7.2)

6. Forms

FORM 3.5: Protocol Deviation/Violation Report Form

7. History

Version No.	Date	Authors	Main Change
01	December 2018	SOP Team	FNA

02	JUNE 21, 2021	SOP Team	Changed REC to IRB Appended Forms Corrected SOP No.
03	July 21, 2023	Dr Gravador	Updated References

Annex 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

PROTOCOL DEVIATION VIOLATION REPORT

FORM 3.5

Protocol Violation Deviation Report for:		
Date:	**IRB Ref No.:**	
Investigator:	**Contact No.:**	
Sponsor:	**Contact NO.:**	
Title		
☐ **Deviation from Protocol** ○ **Major** ○ **Minor**	☐ **Violation**	
Description:		
Found By:	**Reported by:**	
Actions Taken	**Outcome:**	
Primary reviewer Name	**Signature**	**Date**
CIMCVGH IRB Chairman Name	**Signature**	**Date**

1. **Policy Statement**

   The IRB shall require the submission of final reports to signify the end of the research submitted for approval to the CIM CVGH IRB. Submission of a final report shall be within a month after completion of the research and when approved by the IRB becomes the basis for initiation of the archiving procedure.

2. **Objective of the Activity**

   This activity aims to describe the CIM CVGH IRB review procedures for final reports.

3. **Scope**

   This SOP begins with the receipt of the final report and ends with the communication of IRB decision to the PI.

4. **Work Flow**

ACTIVITY	RESPONSIBILITY
Step 1: Receive the final report package and check its completeness	IRB Staff
Step 2: Identify primary reviewers	IRB Chair/Member - Secretary
Step 3: Forward final/closure report to primary reviewers for review	IRB Staff, Primary/Reviewers
Step 4: Final reports of expedited reviewed protocols shall undergo expedited review, final report of full reviewed protocols shall undergo full review.	IRB Members, Chair/Secretary
Step 5: Communicate IRB decision to PI	IRB Secretariat, Chair
Step 6: File documents & update protocol file index and protocol database	IRB Staff

5. Description of Procedures

5.1. ***Step 1*** *Receive the progress report package and check its completeness*

5.1.1. *The IRB staff receives the of Final / Closure Report of Study Protocols approved by the CIM-CVGH IRB.*

5.1.2. *For Investigator (students and residents) Initiated Protocols that are submitted to the Research Committee, PIs are required to clear with the CIM CVBH IRB and fill up final report Form or submit Certificate of Completion from the CIM Research Committee before clearance is signed for promotion to next year level.*

5.1.3. *For Sponsor Initiated Protocols the submission shall only include the accomplished Final Report forms.*

5.1.4. *The IRB Staff verifies the completeness of the submission and whether the Protocol Code* No. and the forms used are correct.

5.2. ***Step 2 Identify primary reviewers***

5.2.1. *The IRB Staff identifies the Primary Reviewers of the protocol from the protocol database.*

5.2.2. *If the Primary Reviewer is not available, the review is done either by the IRB Chair/Member-Secretary, or qualified Member/s designated by the Chair/Member-Secretary.*

5.3. ***Step 3 Forward final/closure report to primary reviewers for review***

5.3.1. *The IRB Staff records the Final Report/Closure package together with the Notice of Review and a copy of the latest version of the protocol in the Log of Outgoing Documents.*

5.3.2. *The of Final / Closure Report package is forwarded to the primary reviewer/s at least 7 days before the full board meeting.*

5.3.3. *The Primary Reviewer/s accomplish the review by commenting and recommending appropriate action on the of Final / Closure Report form to include review of relevant information pertinent to the study in compliance with IRB requirements (included in the Final Report Form)*

5.3.4. *The primary reviewers does expedited review and recommend approval of the Final / Closure Report if there is no deviation or violation of IRB approvals.*

5.3.5. *Primary Reviewer signs and dates the form and returns the of Final / Closure Report package to the IRB Staff.*

5.4. ***Step 4 Final reports of expedited reviewed protocols shall undergo expedited review, final report of full reviewed protocols shall undergo full review.***

5.4.1. *The Primary Reviewer presents the results of the protocol during IRB meeting*

5.4.1.1. Final reports of expedited reviewed protocols shall undergo expedited review, final report of full reviewed protocols shall undergo full review

5.4.2. *The IRB decision can be any of the following:*

5.4.2.1. Acknowledged/Accepted

5.4.2.2. Request for further information, specify

5.4.2.3. Recommend further action, specify

5.5. *Step 5: Communicate IRB decision to PI*

5.5.1. *The IRB Staff takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required.*

5.5.2. *The IRB Staff prepares Notification of IRB Decision on the Review of Final / Closure Report for signature of the IRB Chair.*

5.5.3. *The IRB Staff sends the notification to the PI*

5.6. *Step 6: File documents & update protocol file index and protocol database*

5.6.1. *The IRB Staff files the accomplished, signed and dated Closure/Final Report and other related document in the protocol file folder and updates the protocol file index.*

5.6.2. *Upon approval of the of Final / Closure Report, the study protocol is classified as inactive, the Protocol Code No. is updated and the protocol file folder re-labeled and transferred to storage cabinet for inactive files*

5.6.3. *IRB Staff updates the protocol database.*

6. Forms

Annex 1: Form 4.3A Final Report Form
Annex 2: Form 4.3B Certificate of Completion

7. History

Version No.	Date	Authors	Main Change
02	June 21, 2021	SOP Team	New SOP Separated from the Progress Report
03	July 21, 2023	Dr Evasco	Submission of a final report shall be within a month after completion of the research and when approved by the IRB becomes the basis for initiation of the archiving procedure. The Primary Reviewer/s accomplish the review by commenting and recommending appropriate action on the of Final / Closure Report form to include review of relevant information pertinent to the study in compliance with IRB requirements (included in the Final Report Form) The primary reviewers does expedited review and recommend approval of the of Final / Closure Report if there is no deviation or violation of IRB approvals.

ANNEX 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

FINAL REPORT
FORM 4.3A

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED
STUDY SITE:	**P.I. CONTACT NO.**	**P.I. EMAILL ADDRESS**

PROTOCOL NO. & TITLE

PRIMARY REVIEWER	PROTOCOL APPROVAL DATE

1. Study Arms:

2.Summary of Recruitment

_____Accrual ceiling set by IRB

_____ New participants accrued since last review

_____ Total number of participants accrued since protocol began

_____ No. of participants who are lost to follow up

_____ No. of participants withdrawn from the study

_____ No. of participants who experienced SAEs/ SUSARs

_____ Number of participants who completed the study

3. Amendments to the original protocol (including dates of approval):

4. Summary of onsite SAEs reported:

5. Summary of participants' complaints or grievances documented regarding conduct of study:

6. Summary of benefits to participants:
7. Summary of indemnifications of study related injury (If Applicable):
8. If terminated early, specify reason for termination:
9. Progress reports submitted (with dates of approval):
10. Duration of the study (months):
11. Informed consent form used (with version no./date) and attach most recent version:
12. Study objectives and summary of results:
Date of Last Review:
_____ **Name and Signature of Primary Investigator**

Annex 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

CERTIFICATE OF COMPLETION
FORM 4.3B

FORM 4.3B **CERTIFICATE OF COMPLETION**	
IRB REF No.	
Title:	
Principal Investigator/s:	
This is to certify that the above-mentioned research paper has been completed and submitted to the Research Committee **Secretary** **Research Committee**	
FOR IRB USE ONLY	
Recommended Action: _____ Approve _____ Request further information, specify _____ Recommend further action, specify _____ (e.g. Require protocol/ ICF amendment, re-consent) to address concerns about patient safety) Other Comments: Primary Reviewer: Signature: Date:	

1. Policy Statement

The CIM CVGH IRB shall form a "site visit" committee to conduct visits to selected sites of submitted or approved protocols.

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2. Objective of the Activity

Site visits shall be used as a mechanism to enable the CIM CVGH IRB to monitor compliance of the study to approved protocols. It will also be an opportunity to assess reasons for increases in reported risks.

3. Scope

This SOP begins with the selection of site to visit and ends with the draft of the site visit report and presentation of the report during a meeting and discussions for recommendation.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Selection of site to visit*	*IRB Members*
Step 2: *Notification of Primary Researcher*	*IRB Staff*
Step 3: *Creation of Site Visit Team*	*IRB Chair*
Step 4: *Preparation of Documents for Site Visit*	*IRB Staff*
Step 5: *Conduct of Site Visit*	*IRB Members and Chair*
Step 6: *Draft and presentation of report*	*IRB Chair / Member Secretary*
Step 7: *Discussion and Formulation of Recommendation*	*IRB Chair and Members*
Step 8: *Filing of Documents*	*IRB Staff*

5. Detailed Instructions

5.1 Step 1: Selection of site to visit

Selection of which sites to visit will be based on review of protocols falling within the following criteria:

5.1.1 new study sites /new researcher
5.1.2 reports of remarkable serious adverse events
5.1.3 major protocol noncompliance iv. reports of complaints from study participants
5.1.4 failure to submit continuing review requirements
5.1.5 high risk studies
5.1.6 studies requiring a large study population

5.2 Step 2: ***Notification of Primary Researcher***

5.2.1. A letter of notification will be sent to the primary researcher 2 weeks prior to a site visit. The letter will contain the reason for the site visit, and request for any additional documents, if any. It will also contain the members involved in the site visit and their travel arrangements.

5.3 Step 3: Creation of Site Visit Team

5.3.1 The Committee that will become the site visit team will be created by the IRB members from among its roster. The IRB Chair may appoint a Committee Chair who will in turn choose a secretary. Review of the protocol in line for a site visit will be done with the rest of the IRB members. Familiarization with documents necessary for the site visit will be done the Committee members.

5.4 Step 4: Preparation of Documents for Site Visit

5.4.1. The IRB Staff shall prepare the documents needed for the site visit including documents requested from the primary researcher.

5.5 Step 5: Conduct of Site Visit

5.5.1 During the site visit, the committee will review with the researcher the following points:

- validity of study protocol
- informed consent in its most recently approved version
- random check that the same consent is signed by subjects of the study ○ post – approval documents and verification of its approval ○ facilities in the study site
- determination of the protection of the rights, safety and welfare of human participants in the study

5.6 Step 6: Draft and presentation of report

5.6.1 A site visit checklist and report form will be used by the Committee members. A consensus of all the report forms will be collated by the Committee secretary and submitted to the Chair.

5.6.2 A draft of the overall report will be prepared by the Chair within one week of the site visit for presentation to the IRB in the next scheduled meeting.

5.7 Step 7: Discussion and Formulation of Recommendation

5.7.1 The report from the Committee Chair will be up for discussion on a scheduled IRB meeting. The course of action on the points reviewed during the site visit will be discussed and a consensus of the recommended changes will be determined in compliance to the IRB – approved protocol.

5.7.2 The final report and recommendations will be relayed to the primary researcher in a formal letter.

5.8 Step 8: Filing of Documents

5.8.1 All documents and forms will be filed by the IRB member in charge for documentation. A logbook of the site visits done, reports given and actions taken will be kept.

6. Form: Checklist for Site Monitoring **(See Annex 3)**

7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*November 22, 2016*	*CIM-CVGH-IRB MEMBERS*	*First Draft*
01	*April 13, 2019*	*SOP Team*	*Formatting; Forms added*
02	*June 21, 2021*	*SOP Team*	*Included high risk in selection criteria*
03	*July 21, 2023*	*Dr. Donaldo*	*Updated References*

ANNEX 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 E. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-5127

SITE VISIT REPORT FORM

FORM 4.4

IRB Ref. No.		Date of the Visit:	
Study Title:			
Principal Investigator:		Phone:	
Sponsor		Site	
Reason for site visit		Persons interviewed	
Total number of expected subjects:		Total subjects enrolled:	

	YES	NO	COMMENTS
Are site facilities appropriate?			
Is confidentiality of documents maintained (e.g. cabinets with lock and keys)?			
Are the test articles properly kept and maintained?			
Are informed Consent Forms complete?			
Are approved ICF versions used?			
Are copies of the approved versions of the protocol documents kept in the site?			
Are files of all communication with the IRB found in the site?			
Does the site keep copies of all communication with the IRB in the site?			
Are copies of adverse event reports kept?			
Are investigator functions properly delegated to qualified research personnel?			
Is there appropriate documentation of qualifications of personnel?			
Are all Case Record Forms up to date?			
Are copies of protocol deviation/ violation reports kept in the site?			
Is there evidence of appropriate corrective action taken as recommended by the IRB?			

Summary of findings:

Recommendations:

Duration of visit: (hours)		Starting form:		Finish:
Name of IRB Member Visitors:				
Reported by:		Date:		
Signature				

1. Policy Statement

CIM CVGH shall address all Queries and complaints from clients, patients, or research participants and that it shall be done promptly and appropriately while exercising due diligence.

2. Objective of the Activity

To describe the CIM-CVGH IRB procedures related to requests, queries, and complaints of research participants and other interested parties. Managing queries and complaints aims to promote public trust and confidence in the institution.

3. Scope

This SOP begins with the classification of the IRB documents which are confidential, and ends with the logging of access of the documents concerned.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Receive the complaint or inquiry*	*IRB Staff*
Step 2: *Review the complaint/inquiry*	*IRB Chair and Member Secretary*
Step 3: *Discuss in convened meeting or report the decision/action taken to full board*	*IRB Chair and members*
Step 4: *Communicate IRB's response*	*Member Secretary and Chair*
Step 5: *File pertinent documents*	*IRB Staff*

5. Detailed Instructions

5.1 Step 1: Receive the complaint or inquiry

5.1.1 The request, query, or complaint related to research participation or research protocols may come from research participants or other interested parties.

5.1.2 The CIM-CVGH IRB Staff receives and studies the request, query, or complaint.

5.1.3 The IRB Staff may assist to put the request, query, or complaint in writing especially if the complainant or inquiring party is a research participant.

5.1.4 The IRB Staff responds to the request, query, or complaint, if it is within his/her authority to do so, or refers this to the Chair/Member-Secretary for appropriate action.

5.1.5 The IRB Staff records the submitted document in the Log of Incoming Communications

5.2 Step 2: Review the complaint/inquiry

5.2.1 The CIM-CVGH IRB Chair or Member-Secretary reviews the request, query, or complaint.

5.2.3 The PI maybe contacted to provide clarification or further information.

5.3 Step 3: Discuss in convened meeting or report the decision/action taken to full board

5.3.1 The CIM-CVGH IRB Chair presents serious requests, queries, or complaints to full board for discussion.

5.3.2 A request, query, or complaint is considered serious if it may have an adverse effect on the integrity and reputation of the CIM-CVGH IRB or any of its members.

5.3.3 The IRB members discuss to take appropriate actions.

5.4 Step 4: Communicate IRB's response

5.4.1. The CIM-CVGH Member secretary prepares the formal written response to the request, query, or complaint. The response must be communicated to the participant or requesting party within 7days from the time of receipt of the request, query, or complaint.

5.5 Step 5: File pertinent documents

5.5.1 The CIM-CVGH IRB Staff files the accomplished Form 3.6 in the protocol file folder together with the letter of request, inquiry, or complaint and the excerpts of the meeting minutes when this matter was deliberated or reported.

5.5.2 The IRB Staff updates the protocol file index.

6. Form

Annex 1: Communication Record Form Form 4.5

7. History of SOP

Version No.	*Date*	*Authors*	*Main Change*
01	*Nove 13, 2019*	*SOP TEAM*	*First Draft*
02	*June 21, 2021*	*SOP TEAM*	*NONE*
03	*July 21, 2023*	*Dr Cutillar*	*Updated References*

Annex 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

COMMUNICATION REPORT

FORM 4.5

Date							
Means of Contact:	☐ **Telephone**	☐ **Facsimile**	☐ **E-mail**	☐ **In-person**			
Person contacted:	☐ **Reviewer**	☐ **CIM CVGH Member**	☐ **Investigator**	☐ **Media**			
	☐ **Secretariat**	☐ **CIM CVGH Chairperson**	☐ **Subject**	☐ **Sponsor**			
Name:							
Contact No.:			**E-mail:**				
Protocol No.:			**IRB Ref No.:**				
Title							
Communication Issues/<u>Reasons for making contact</u>:							
Follow up action	☐ **Return call**	☐ **Send written communication**	☐ **None**				
Summary of Communication:							
Recorded by:							

1. Policy Statement

To ensure consistency of the IRB functions the CIM-CVGH IRB shall conduct regular meetings once a month on the 3rd Wednesday of each month. If monthly meeting falls on a holiday, the meeting shall be held within a + 2day window period from the original schedule. Special meetings may be held to resolve issues that require immediate attention.

The meetings shall be held at the CIM – CVGH IRB Conference room (unless a written prior notice for it to be held somewhere else), and/or through remote communication which shall include, but not limited to, teleconferencing, video conferencing, and the like.

2. Objective of the Activity

This activity discusses the processes of preparations to contribute to a smooth, orderly, and efficient conduct of meetings.

3. Scope

This SOP begins with the preparation of the agenda and ends with the notification of IRB Members and confirmation of attendance.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Preparation of the agenda (SOP on Preparing the Meeting Agenda - SOP#5.2)*	*IRB Staff*
Step 2: *Assembly of materials and documents needed for the meeting*	*IRB Staff*
Step 3: *Preparation of logistics for the meeting*	*IRB Staff*
Step 4: *Notification of IRB Members and confirmation of attendance*	*IRB Staff*

5. Description of Procedures

5.1 Step 1: *Preparation of the agenda (SOP on Preparing the Meeting Agenda - SOP#5.2)*

5.1.1 The IRB Staff shall encode the items to be discussed in the Meeting to include submissions for initial and continuing review using Form 5.2 Meeting Agenda.

5.2 Step 2: *Assembly of materials and documents needed for the meeting*

5.2.1 The IRB Staff shall collect all the documents needed during the full board meeting. These will include, but not limited to, the following:

5.2.1.1 Meeting Agenda (See SOP# 5.2)
5.2.1.2 Attendance sheet
5.2.1.3 At least 2 hard copies, and an electronic copy of all submissions on or before the 2nd Wednesday of the month.
5.2.1.4 Electronic copies of the minutes of the previous meeting
5.2.1.5 Folders of individual IRB member
5.2.1.6 Administrative documents, if any
5.2.1.7 Letters / Communications, 1 hard and soft copy
5.2.1.8 For online meetings, electronic copies of necessary documents shall be sent via
5.2.1.9 email at least a week prior to the scheduled meeting

5.3 Step 3: *Preparation of logistics for the meeting*

5.3.1 All meetings shall be held at the IRB Office located at the second floor of Cebu Institute of Medicine. ii. The IRB Staff shall coordinate with the CIM Technician to prepare the overhead projector, screen.

5.3.2 *Meetings are scheduled at 12noon – 2 PM. Lunch will be provided for the members.*

5.3.3 *The IRB members who attended shall file a Daily Time Record which will be submitted to the Accounting Dept. immediately after the meeting.*

5.3.4 *For online meetings, the link shall be sent to the IRB members at least a day prior to schedule*

5.3.5 *The IRB Secretariat will send a reminder thru text to all members the day before, and in the morning prior to the meeting.*

5.4 ***Step 4****: Notification of IRB Members and confirmation of attendance*

5.4.1 The IRB members shall be notified through email and SMS at least a week before the meeting.

5.4.2 *The members should confirm their attendance at least 3 days before the meeting schedule. iii. Members attending online can log in thru the link at least 5 minutes prior to start of the meeting.*

6. Forms:

None

7. History

Version No.	***Date***	***Authors***	***Main Change***
01	April 6, 2016	IRB members	First draft
01	*June 21, 2019*	*SOP Team Members*	– *Changed RERC to IRB*
02	*June 21, 2021*	*SOP Team Members*	– *Revised Policy Statement*
03	*July 21, 2023*	*Dr Donaldo, Dr Cutillar*	– *Included more details to Policy Statement re meeting schedule windows& venue of meeting* – *Added more details to Step 3* – *Updated References*

1. Policy Statement

The meeting agenda shall be based on the submissions received on or before the 2nd Wednesday of the month, or at least one week prior to the scheduled regular meetings. Special meetings may be held to resolve issues that require immediate attention. Both regular and special meetings shall follow the established template for meeting agenda. This agenda ensures readiness of the needed documents and the staff in preparation for the meeting

2. Objective of the Activity

The SOP defines the process of preparation of the meeting agenda aims to ensure a smooth, orderly, inclusive, and efficient conduct of meetings.

3. Scope

This SOP begins with the preparation of the draft meeting agenda and ends with the filing of the final meeting agenda.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Preparation of the draft meeting agenda* ***(Form 5.1)***	*IRB Staff*
Step 2: *Preparation of the provisional meeting agenda*	*Chair*
Step 3: *Distribution of the provisional meeting agenda (SOP on Preparing for a Meeting - SOP#4.1)*	*IRB Staff*
Step 4: *Approval of the provisional meeting agenda*	*Members*
Step 5: *Filing of the final meeting agenda (SOP on management of Active Files - SOP#4.7)*	*IRB Staff*

5. Detailed Instructions

5.1 Step 1: Preparation of the agenda (SOP on Preparing the Meeting Agenda - SOP#5.2)

5.1.1 The IRB Staff shall encode the items to be discussed in the Meeting to include submissions for initial and continuing review using **Form 5.1 Meeting Agenda**. Only documents submitted on or before the 3rd Wednesday of the month (at least 7 days before the meeting) will be included in the agenda. The IRB Secretariat will email the Form 5.1 to the Chair and Member Secretary 6 days before the meeting. The IRB Staff shall inform the Chair and the Member Secretary of the said email thru text.

5.2 Step 2: Preparation of the provisional meeting agenda

5.2.1 The Chair shall review Form 5.1, and make the necessary modifications and email the provisional meeting agenda to the IRB Staff 5 days before the meeting.

5.3 Step 3: Distribution of the provisional meeting agenda

5.3.1 The IRB Staff will forward the provisional agenda to all the IRB members at least 3 days before the scheduled meeting.

5.4 Step 4: Approval of the provisional meeting agenda

5.4.1 The IRB members will approve the provisional agenda during the meeting

5.5 Step 5: Filing of the final meeting agenda

5.5.1 The IRB Staff will file the meeting agenda after the meeting (SOP on management of Active Files – SOP#7.2)

6. Forms

Meeting Agenda Template Form 5.1

7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*April 7, 2016*	*IRB Members*	*First Draft*
02	*June 21, 2021*	*SOP Team*	– *Revised Steps Policy Statement and Steps 1 , 2, 3* – *Changed IRB Secretariat to IRB Staff*
03	*July 21, 2023*	*Dr Cutillar*	– *Updated References*

ANNEX 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

MEETING AGENDA TEMPLATE

FORM 5.1

DATE			VENUE:	CIM CONFERENCE ROOM	
	IRB MEMBERS	**POSITION**			**ATTENDANCE**
1)	Dr. Manuel Emerson Donaldo	Chairman	Affiliated	Medical	( ) present ( ) absent
2)	Dr. Corazon Tan-Meneses	Co-Chairman	Affiliated	Medical	( ) present ( ) absent
3)	**Dr. Consolacion Cutillar**	Secretary	Affiliated	Medical	( ) present ( ) absent
4)	**Dr. Rudy Amatong**	Member	Affiliated	Medical	( ) present ( ) absent
5)	Mdm. Charito Calumpang	Member	Non affiliated	Non Medical	( ) present ( ) absent
6)	**Fr. Raphael Catane, SHF**	Member	Non affiliated	Non Medical	( ) present ( ) absent
7)	**Dr. Irelan A. Evasco**	Member	Affiliated	Medical	( ) present ( ) absent
8)	**Atty. Terence Fernandez**	Member	Affiliated	Non Medical	( ) present ( ) absent
9)	**Dr. Saleshe Tracy Anne Fernandez**	Member	Affiliated	Medical	( ) present ( ) absent
10)	**Dr. Nerissa Sanchez**	Member	Affiliated	Medical	( ) present ( ) absent
11)	**Dr. Christina Gravador**	Member	Affiliated	Medical	( ) present (/) absent

Meeting No.: 2019-00			
☐ **Regular** ☐ **Emergency Meeting**			
MEETING CHAIRED BY:		**Designation**	
Announcement of formal start of meeting		**Time started**	
Determination of a duly constituted quorum by the Secretary to proceed with the meeting.		Quorum (out 0 11 members) Affiliated – Non affiliated	
COI Disclosures			

Approval of Provisional Agenda

II. Review and approval of the previous minutes:

III. Business or matters arising from the minutes:

IV. Review of Protocols

A. INITIAL REVIEW

(A.1) IRB Reference No.:		
Protocol No.		
Study Title		
Principal Investigator		
Sponsor		
Independent Consultant		
Technical Reviewer		
Primary Reviewer PROTOCOL		
Expertise		
Primary Reviewer ICF		
Expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

B. RESUBMISSION

(B.1) IRB Reference No.	**NONE**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	

Primary Reviewer PROTOCOL		
Expertise		
Primary Reviewer ICF		
Expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

C. PROTOCOL AMENDMENTS

(C.1) IRB Reference No.		
Protocol No.		
Study Title		
Principal Investigator		
Sponsor		
Primary Reviewer Protocol		
expertise		
Primary Reviewer ICF		
expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

D. PROGRESS REPORTS / CONTINUING REVIEW REPORTS

(D.1) IRB Reference No.:	**N O N E**	
Protocol No.		
Study Title		
Principal Investigator		
Sponsor		
Primary Reviewer Protocol		
expertise		
Primary Reviewer ICF		
expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

REMINDER LETTER DUE FOR DISPATCH

Protocol No.	Study Title
1.	
2.	
3.	
4.	
5.	
6.	

E. SAE/SUSARS

(E.1) IRB Reference No.:	**N O N E**

Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Summary of Recommendations/Actions Taken	
IRB DECISION	

F. PROTOCOL DEVIATIONS

(F.1) IRB Reference No.:	**N O N E**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Summary of Recommendations/Actions Taken	
IRB DECISION	

G. COMMUNICATIONS/NOTIFICATIONS

(G.1) IRB Reference No.	**N O N E**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	

H. FINAL REPORTS

(H.1) IRB Reference No.	**None**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Summary of Recommendations/Actions Taken	
IRB DECISION	

I. Protocols Exempted from Review

(V.1) IRB Reference No.:	**NONE**
Study Title	
Principal Investigator	
Decision	

J. Protocol Approved by Expedited Process

(VI.1) IRB Reference No.:	**None**
Study Title	
Principal Investigator	
Primary Reviewer	
Decision	

K. Other Matters:

Prepared by:	**NOTED BY:**	**APPROVED BY:**
Gina Lord	**DR. CONSOLACION CUTILLAR**	**DR. MANUEL EMERSON S. DONALDO**
IRB Staff	**Member Secretary- CIMCVGH IRB**	**CHAIR- CIMCVGH IRB**

1. Policy Statement

Meetings shall be presided by the chair or designated substitute, shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the communication of protocols for review.

2. Objective of the Activity

Meetings are conducted to provide an opportunity for the IRB to arrive at collegial decisions regarding study protocols and IRB operations.

3. Scope

This SOP begins with the distribution of meeting materials and ends with the collection, storage, and disposal of meeting materials.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Distribution of meeting materials*	*IRB Staff*
Step 2: *Determination of quorum (formal start)*	*Chair or Member Secretary*
Step 3: *Approval of the provisional agenda*	*IRB Members*
Step 4: *Declaration of conflict of interest (COI)*	*IRB Chair and Members*
Step 5: *Approval of minutes of the previous meeting*	*IRB Members*
Step 6: *Discussion of "business arising from the minutes*	*IRB Chair and Members*
Step 7: *Review of protocols and protocol-related submissions (SOP on Full Review - SOP#4.1)*	*IRB Chair and Members*
Step 8: *Report of results of expedited review (SOP on Expedited Review - SOP# 4.2)*	*Designated Reviewers*
Step 9: *Discussion of operations-related matters*	*IRB Chair and Members*
Step 10: *Adjournment*	*Chair*
Step 11: *Collection, storage, and disposal of meeting materials*	*IRB Staff*

5. Description of Procedures

5.1 Step 1: Distribution of meeting materials

5.1.1 The IRB Staff shall prepare the attendance form, and other pertinent documents to be distributed at the start of the meeting. For submissions that are for full board review, 1 hard copy shall be given to the Chair.

5.1.2 For online attendees, electronic copies of documents shall be sent by email at least 7 days prior to the meeting

5.2 Step 2: *Determination of quorum (formal start)*

5.2.1 The member secretary shall declare upon formal request of the Chair if there is a quorum. There must be 7 out of the 13 IRB members present (face to face or online) with the presence of a non-affiliate/non-institutional, non-medical member, with adequate gender representation or any other member as indicated by the protocol (advocate or subject representative) before a quorum can be declared.

5.3 Step 3: *Approval of the provisional agenda*

5.3.1. The provisional agenda will be projected in the big screen and the Chair shall invite the members to examine the provisional agenda and to propose changes / approval of the agenda.

5.5 ***Step 4:*** *Declaration of conflict of interest (COI)*

5.4.1 The IRB members will declare any conflict of interest. The Chair shall ensure that only those IRB members who are independent of the investigator and sponsor of the trial will vote on the research-related matters.

5.5.2 The conflicted member shall step out of the room and does not participate in the decision-making process. The time when the member steps out of the room and rejoins the meeting after deliberation shall be included in the meeting minutes.

5.5 Step 5: *Approval of minutes of the previous meeting*

5.5.1 The Member Secretary shall project the minutes of the previous meeting and gives the members time to review. Corrections will be noted and recorded in real time. Approval of the minutes shall be done by two members.

5.6 Step 6: *Discussion of "business arising from the minutes*

5.6.1 The Chair shall lead the discussion on the business arising from the previous meeting. Issues shall be resolved by voting if necessary.

5.7Step 7: *Review of protocols and protocol-related submissions*

5.7.1 The Primary Reviewers shall present and discuss the submitted papers and the members shall give their inputs. The comments will be recorded in real time. The primary authors may be invited during the presentations for clarification.

5.7.2 Discussion is structured as follows: technical issues, ethical issues, and informed consent process/form issues. The primary reviewers should be guided by the assessment form in their presentations. Independent consultants shall be invited if needed (See SOP on Review procedures SOP#3) but they cannot participate in the voting.

5.7.3 The chair summarizes the points raised and notes different views among members that should be resolved. Quorum shall be checked prior to IRB decision. The Chair asks for consensus on the ff decision points;

5.7.4 Approval (no further revision of the documents is required)

5.7.5 Minor Modification

- Major Modification,
- Disapproval

5.7.6 If there are differences in opinion, voting will be done.

5.8 Step 8: *Report of results of expedited review* o The Primary Reviewers shall report the submissions for expedited review *(SOP on Expedited Review - SOP# 3.1)*.

5.9 Step 9: *Discussion of operations-related matters* ○ The Chair shall discuss operation-related matters that include, but not limited to: internal and external communications, training programs, accreditation, membership concerns.

5.10 Step 10: *Adjournment* ○ Meeting must be adjourned after all items in the agenda have been discussed and/or resolved. The Chair shall declare the adjournment of the meeting.

5.11 Step 11: *Collection, storage, and disposal of meeting materials* ○ The IRB staff shall collect all the documents distributed during the meeting put them on file (SOP on Managing Active Files SOP #7.2).

6 Forms

NONE

7 History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*April 10*	*IRB Members*	*First Draft*
02	*JUNE 21, 2021*	*SOP Team*	- *Expanded the definition of quorum*
03	*July 21, 2023*	*Dr Donaldo , Dr Cutillar*	- *Included online attendees to Step 1* - *Updated quorum definition to Step 2* - *Step 3 defines process for documentation of management of COI in IRB member* - *Updated References*

1. Policy Statement

The meeting minutes shall be based on the approved agenda and shall be the basis of the decision letter on protocols.

2. Objective of the Activity

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in an IRB meeting.

3. Scope

This SOP begins with the entry of preliminary information on the minutes template and ends with the storage of the approved minutes.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Entry of preliminary information on the minutes template*	IRB Staff
Step 2: *Preparation of the draft minutes*	IRB Staff
Step 3: *Approval of the minutes in the next IRB meeting*	*IRB Chair and Members*
Step 4: *Storage of the approved minutes (SOP on Managing Active Files SOP#7.2)*	*IRB Staff*

5. Description of Procedures

5.1 Step 1: Entry of preliminary information on the minutes template

5.1.1. The IRB Staff shall fill up the minutes template (Form 6.1) based on the submitted documents/protocol-related information, and other matters ahead of time.

5.2 Step 2: Preparation of the draft minutes

5.2.1 During the meeting, the IRB Staff shall record all board opinions and proceedings in accordance with the agenda. Recording shall be done by real time / note taking while the minute template is projected on screen.

5.2.2 Comments and recommendations on the scientific issues, ethical issues, and informed consent form issues shall likewise be recorded. The opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members.

5.2.3 The member secretary reviews the proceedings prepared by the IRB Staff during the meeting and verifies that it contains the following sections:

- Date and venue of meeting
- Member attendance (members present and absent) to determine quorum
- Time when the meeting was called to order
- Presiding officer
- Conflict of interest declaration by IRB members
- Discussion of items based on the Meeting Agenda
- Decisions and recommendations arrived at during the meeting
- Name and signature of person who prepared the Minutes

5.2.4 An electronic copy of the draft minutes will be sent to the IRB Chair within 5 days after the meeting

5.3 Step 3: Approval of the minutes in the next IRB meeting

5.3.1 The draft minutes shall be presented in the next IRB meetings for comments and/or corrections.

5.3.2 The approval of the minutes is done through a formal motion from any member of the committee and seconded accordingly.

5.3.3 See SOP on conduct of meeting

5.4 Step 4: Storage of the approved minutes

5.4.1 Both hard and electronic copies of the approved minutes will be saved

5.4.2 See SOP on Managing Active Files (SOP #7)

6. Forms

Annex: Minutes Template Form 6.1

7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*March 3, 2017*	*IRB Members*	*First draft*
02	*June 21, 2021*	*SOP Team*	- *Harmonized Detailed Instructions with Agenda template on person in charge of Meeting minutes*
03	*July 21, 2023*	*Dr. Cutillar*	- *Updated References*

Annex 1

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

MEETING MINUTES TEMPLATE

FORM 5.2

DATE			VENUE:	CIM CONFERENCE ROOM	
	IRB MEMBERS	**POSITION**			**ATTENDANCE**
1)	Dr. Manuel Emerson Donaldo	Chairman	Affiliated	Medical	( ) present ( ) absent
2)	Dr. Corazon Tan-Meneses	Co-Chairman	Affiliated	Medical	( ) present ( ) absent
3)	**Dr. Consolacion Cutillar**	Secretary	Affiliated	Medical	( ) present ( ) absent
4)	**Dr. Rudy Amatong**	Member	Affiliated	Medical	( ) present ( ) absent
5)	Mdm. Charito Calumpang	Member	Non affiliated	Non Medical	( ) present ( ) absent
6)	**Fr. Raphael Catane, SHF**	Member	Non affiliated	Non Medical	( ) present ( ) absent
7)	**Dr. Irelan A. Evasco**	Member	Affiliated	Medical	( ) present ( ) absent
8)	**Atty. Terence Fernandez**	Member	Affiliated	Non Medical	( ) present ( ) absent
9)	**Dr. Saleshe Tracy Anne Fernandez**	Member	Affiliated	Medical	( ) present ( ) absent
10)	**Dr. Nerissa Sanchez**	Member	Affiliated	Medical	( ) present ( ) absent
11)	**Dr. Cristina Gravador**	Member	Affiliated	Medical	( ) present (/) absent

Meeting No.: 2019-00			
☐ **Regular** ☐ **Emergency Meeting**			
MEETING CHAIRED BY:		**Designation**	
Announcement of formal start of meeting		**Time started**	
Determination of a duly constituted quorum by the Secretary to proceed with the meeting.		Quorum (out 0 11 members) Affiliated – Non affiliated	
COI Disclosures			

I. Approval of Provisional Agenda

II. Review and approval of the previous minutes:

III. Business or matters arising from the minutes:

IV. Review of Protocols

A. INITIAL REVIEW

(A.1) IRB Reference No.:		
Protocol No.		
Study Title		
Principal Investigator		
Sponsor		
Independent Consultant		
Technical Reviewer		
Primary Reviewer PROTOCOL		
Expertise		
Primary Reviewer ICF		
Expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

B. RESUBMISSION

(B.1) IRB Reference No.	**NONE**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	

Primary Reviewer PROTOCOL		
Expertise		
Primary Reviewer ICF		
Expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

C. PROTOCOL AMENDMENTS

(C.1) IRB Reference No.		
Protocol No.		
Study Title		
Principal Investigator		
Sponsor		
Primary Reviewer Protocol		
expertise		
Primary Reviewer ICF		
expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

D. PROGRESS REPORTS / CONTINUING REVIEW REPORTS

(D.1) IRB Reference No.:	**N O N E**	
Protocol No.		
Study Title		
Principal Investigator		
Sponsor		
Primary Reviewer Protocol		
expertise		
Primary Reviewer ICF		
expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

E. REMINDER LETTERS DUE FOR DISPATCH

Protocol No.	Study Title
1.	
2.	
3.	
4..	
5.	
6.	

F. SAE/SUSARS

(E.1) IRB Reference No.:	**N O N E**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Summary of Recommendations/Actions Taken	
IRB DECISION	

G. PROTOCOL DEVIATIONS

(F.1) IRB Reference No.:	**N O N E**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Summary of Recommendations/Actions Taken	
IRB DECISION	

H. COMMUNICATIONS/NOTIFICATIONS

(G.1) IRB Reference No.	**N O N E**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	

Recommendations/Actions Taken	

I. FINAL REPORTS

(H.1) IRB Reference No.	**None**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Summary of Recommendations/Actions Taken	
IRB DECISION	

J. Protocols Exempted from Review

(V.1) IRB Reference No.:	**NONE**
Study Title	
Principal Investigator	
Decision	

K. Protocol Approved by Expedited Process

(VI.1) IRB Reference No.:	**None**
Study Title	
Principal Investigator	
Primary Reviewer	
Decision	

Other Matters:

L. Adjournment:

Prepared by:	**NOTED BY:**	**APPROVED BY:**
Gina Lord	**DR. CONSOLACION CUTILLAR**	**DR. MANUEL EMERSON S. DONALDO**
IRB Staff	**Member Secretary- CIMCVGH IRB**	**CHAIR- CIMCVGH IRB**

1. **Policy Statement**

   The IRB shall communicate its decisions to the researcher within 2 weeks after the IRB meeting. The communication shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the IRB and signed by the chair.

2. **Objective**

   2.1. This aims to ensure that all stakeholders (ex: sponsors, primary investigators) are appropriately, accurately and promptly informed of the results of deliberations of the REC.

   2.2. To ensure an efficient tracking system

3. Scope

This SOP begins with the finalization of recommendations of the committee or the reviewers and ends with the filing of the decision document in the protocol file.

4. **Process Flow/Steps**

ACTIVITY	***RESPONSIBILITY***
Step 1: Finalization of recommendations of the Board	Chair
Step 2: Transfer of information from minutes or reports to IRB decision forms or templates	IRB Staff
Step 3: Approval of the IRB decision document	Chair
Step 4: Dispatch of IRB decision document to researcher/ Principal Investigator	IRB Staff
Step 5: Storage of the decision document in the protocol file (SOP on Managing Active Files (SOP# 7.2)	IRB Staff

5. **Detailed Instructions**

5.1. ***Step 1*** *Finalization of recommendations of the committee*

5.1.1. Finalization of recommendations of reviewers (in case of full review see SOP on Full Review: SOP#3.2)

5.1.2. Finalization of recommendations of the committee (in case of expedited review see SOP on Expedited Review (SOP#3.1)

5.2. ***Step 2*** *Transfer of information from minutes or reports to IRB decision forms or templates*

5.2.1. The record should contain, but is not limited to, the following information

5.2.1.1. Date of communication

5.2.1.2. Study information, i.e., sponsor, protocol number, investigator, etc.

5.2.1.3. Name of person contacted

5.2.1.4. Contact address, telephone number, e-mail, fax, in person

5.2.1.5. Summary of the communications made

5.2.1.6. Notation of any follow-up if necessary

- Signature of the individual responsible for the recording of the communication

5.3. ***Step 3 Approval of the IRB decision document***

5.3.1. The Chair shall review and approve the document within 1 week after the IRB Board meeting.

5.4. ***Step 4 Dispatch of IRB decision document to researcher***

5.4.1. An electronic copy of the IRB decision document will be sent to the investigators within 1 week after the IRB meeting. In the same email, they will be informed that a printed copy of the document can be obtained upon request from the IRB Secretariat.

5.5. ***Step 5*** *Storage of the decision document in the protocol file (SOP on Managing Active Files (SOP# 7.2)*

6. Forms (None)

7. History of SOP

Version No.	Date	Authors	Main Change
01	March 17, 2019	SOP Team	First draft
02	June 21, 2021	SOP Team	Deleted form 6.2 Change REC to IRB
02	July 21, 2023	Dr Fernandez	Revised Objectives Updated References

1. Policy Statement

CIM CVGH ensures that Incoming and outgoing communications shall be recorded promptly and accurately in an electronic logbook or database.

2. Objective of the Activity

This aim of this SOP is to describe the procedure for recording incoming and outgoing documents and ensuring an appropriate IRB response.

3. Scope

This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Sorting of incoming/outgoing communications*	*IRB Staff*
Step 2: *Recording of incoming/outgoing communications*	*IRB Staff*
Step 3: *Acting on communications*	*Chair and Member Secretary*
Step 4: *Storing or filing of incoming/outgoing communications (SOP on Managing Active Files SOP#4.7)*	*IRB Staff*

5. Description of Procedures

5.1 Step 1: Sorting of incoming/outgoing communications vi. IRB communications refer to documented communications to and from the IRB in the form of hard copy letters or emails.

5.1.1 All IRB communications shall have a subject to facilitate sorting and documentation of all actions, instructions, and even responses to queries. Sorting shall be done by the IRB staff.

5.2 Step 2: Recording of incoming/outgoing communications

5.2.1 Both hard copies of the communications will be classified and saved. The IRB Staff shall record all communications in a "Communications Logbook" as they come, in chronological order.

The following data shall be included:

- Date received/sent
- Subject
- Person who sent the communication with signatures
- Person who received the communication with signature
- Action taken

5.3 Step 3: Acting on communications

5.3.1 Communications shall be acted upon by the Chair if applicable. The IRB secretary may also be tasked by the Chair to draft responses to the communications. All communications shall have the approval of the Chair.

5.4* Step 4: Storing *or filing of incoming/outgoing communications (SOP on Managing Active Files SOP#7.2)

5.4.1 Hard copies of the communications shall be filed by the IRB staff in their respective folders (Protocol-related communications; administrative communications, etc.)

5.4.2 See SOP on Managing Active Files (SOP #7)

6. Forms (None)

7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*April 6, 2019*		*First Draft*
03	*July 21, 2023*	*Dr Cutillar*	- *Updated References*

1. Policy Statement

CIMCVGH ensures that all files are protected in their confidentiality and the use of the same is subjected to the data privacy Act. Active files shall be kept in a secured cabinet, arranged in an orderly manner that shall allow easy identification and retrieval. Access to the active files shall be governed by SOP on Managing Access to Confidential Files (SOP# 7.4).

2. Objective of the Activity

To provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the CIM-CVGH IRB.

To provide easy retrieval of files through proper documentation, labeling and filing system. To ensure protection of confidential files in the IRB office.

3. Scope

This SOP provides instructions related to the management of active study files that include protocol submissions, all documents that reflect all actions taken by the IRB before completion of the study. It also provides instructions for the maintenance and storage of other IRB documents that include SOPs, IRB membership files, agenda and meeting minutes, relevant international and national regulations and guidelines, etc.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Design a standard coding system for all protocols submitted to the IRB for review*	*CIM-CVGH IRB*
Step 2: *File all submitted documents in an orderly sequence in a protocol folder*	*IRB Staff*
Step 3: U*pdating and organization of active study files*	*IRB staff*
Step 4: *Storage of Active Protocol Files*	*IRB Staff*

5. Description of Procedures

5.1 Step 1: Design a standard coding system for all protocols submitted to the IRB for review

5.1.1 Protocol files of CIM-CVGH IRB - approved protocols are considered active from the moment the protocol files are received for review until such time they are inactivated either by completion or termination. It is necessary to use a unique identifier or code to refer to protocol file for efficient file management and retrieval.

5.1.2 Color code for Active files: GREEN. Completed files: YELLOW. Terminated files: RED. Inactive files: GREY. STICKERS will be used to identify such files in their binders

5.1.3 Protocol files are considered active from the moment the protocols are received for initial review until such time they are in activated either by its completion or termination or its withdrawal from the review process. Active protocol files are either those undergoing IRB review process or IRB - approved ongoing studies. It is necessary to use a unique identifier or code to refer to protocol file for efficient file management and retrieval

5.1.4 Code active study files as follows: CIM-CVGH IRB – yyyy (year) –number (chronological number based on order of receipt). Protocol Code No. given by the IRB as described in SOP 2.1 on Management of Initial Submission ○ For example, if Protocol entitled "First Clinical Drug Trial on Pediatric Patients" is the first protocol received in 2016, the code (CIM-CVGH IRB 2016-01) is the code that should be used to identify this protocol.

5.1.5. Study Protocols are identified using a unique identification number known as Protocol Code No. given by the IRB as described in SOP 2.0 on Management of Initial submission.

5.1.5.1 File protocol documents in sturdy file folders-binder, using one folder-binder per study protocol title. The protocol file folder is to be labeled (Protocol code no., title of the protocol, name of PI, sponsor on the front cover of the file binder.

5.2 Step 2: File all submitted documents in an orderly sequence in a protocol folder

5.2.1 The protocol file folder contains the following documents arranged chronologically in an organized manner according to the Protocol File Index per type of submission (e.g. initial submission, protocol amendment, progress report, SAE Reports, Protocol Violation/Deviation, etc.):

5.2.1.1 All versions of study protocol

5.2.1.2 Related documents that came with the study protocol (ICF, CRF, recruitment materials, patient diary, IB, etc.)

5.2.1.3 Principal investigator and co-investigators' CVs and ((other similar documents)) a valid GCP Training Certificate, if required

5.2.1.4 Reviewers' assessment forms

5.2.1.5 Amendment reports

5.2.1.6 Continuing review applications

5.2.1.7 Serious Adverse Event Reports or Safety Notifications

5.2.1.8 Non-compliance (Deviation or Violation) reports

5.2.1.9 Participant Queries/ Complaints, if any

5.2.1.10 Site Visit Reports, if any

5.2.1.11 Notifications of IRB Decision

5.2.1.12 Approval letters Decision letters (notification letters or approval letter/s initial and renewal)

5.2.1.13 Post-approval submissions (protocol amendment, progress report, SAE report, protocol deviation/violation report, early termination report) and corresponding reviewers' assessment and IRB decision letters (Notifications of IRB Decision)

5.2.1.14 Miscellaneous communication related to the protocol

5.1.2.15 Final report

5.3 Step 3: Update and organize active study files

5.3.1 Update the active protocol files regularly by chronologically organizing the contents of the active study files according to time of receipt.

5.3.2 Ensure that all updates and organization are recorded in the database

5.3.3 Combine related documents of the approved study files appropriately. Attach an identity Label to the package.

5.4 Step 4: Store active Protocol Files.

5.4.1 Keep the active protocol files in the Active File Cabinet in the office.

5.4.2 Keep all active study files in a secure filing cabinet, with access limited only to IRB Chair and Secretariat. The IRB Staff keeps the keys of file storage cabinets.

5.4.3 Store the closed study files for at least 5 years after the study closure.

5.4.4 For studies with multiple study sites, the Secretariat should maintain the files to allow cross-referencing without unnecessary duplications.

5.4.5 Place the protocol file binders in the shelf in vertical position and sequentially arranged according to their Protocol Code No.

5.4.6 Label the storage cabinet with the year when the protocols were submitted.

6. Forms (none)

7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*November 16, 2018*	*IRB Members*	*First draft*
03	*June 21, 2023*	*Dr. Evasco*	- *Added Objective* - *Shortened titles of Steps 3 & 4*

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
VERSION 3	**SOP 4.8. Archiving Inactive Files**	Effective Date: July 21, 2023

1. Policy Statement

Archiving inactive protocol files ensures efficient and effective retrieval of information for reference and compliance with national and international guidelines. including storage, access and confidentiality.

2. Objective of the Activity

To describe IRB procedures related to archiving of completed, terminated and inactive studies.
To provide easy retrieval of files through proper documentation, labeling and filing system. To ensure protection of confidential files in the IRB office.

3. Scope

This SOP begins with the acceptance of final or early termination reports and ends with the reclassification of the file as inactive file.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Selection of Files for archiving*	*Member secretary*
Step 2: *Management for Archived Files*	*IRB Chair, Members and Member Secretary*
Step 3: *Sorting of Archived Files*	*IRB Staff*
Step 4: *Storing the Protocol Documents*	*IRB Staff*
Step 5: *Management of file retrievals*	*IRB Staff*

5. Description of Procedures

5.1 Step 1*: Selection of Files for archiving*

5.1.1 Inactive Protocol Files (Completed/Terminated/ Closed) are defined as:

5.1.1.1 Study protocols that have been completed with CIM-CVGH-IRB-Approved Final Reports

5.1.1.2 Study protocols declared “Inactive” by the CIM-CVGH IRB after six (6) months period of no communication.

5.1.1.3 Study protocols that have been terminated or closed

5.2 Step 2: Management for Inactive Files

5.2.1 Upon receipt of CIM-CVGH-IRB Final Report Form, IRB reviews it in accordance with SOP on Final Reports ii. An archive number is assigned to the protocol adding the (year of archiving) as a suffix to the original protocol code. For example, if the Final Report of Protocol CIM-CVGH IRB 201002 was archived in 2016, the archiving code is CIM-CVGHIRB 2010-02/2016.

5.3 Step 3: Sorting of Archived Files

5.3.1 Sorting is done once at the end of the year after the documents have been Completed/Terminated/Inactive for 6 months ii. Sorting is done chronologically

5.4 Step 4: Storing the Protocol Documents

5.4.1 Documents are stored in the cabinets for archived files after they have been sorted with the CIM-CVGH IRB document identifier duly logged in the protocol data base.

5.4.2 After they have been kept in the active file's cabinet for 6 months the files will be transferred to the archived files cabinet.

5.4.3 Database will be updated to indicate protocol files that will be transferred to archive.

5.5 Step 5: Disposal of Archived Files

5.5.1 Disposal of archived files will be through shredding of documents after 5 years of being stored as Archived Files.

5.6 Step 6: Management of file retrievals

5.6.1. See SOP on Managing Access to Confidential Files (SOP #7.4)

6. Forms: None

7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*April 6, 2019*	*CIM-CVGH IRB*	*First Draft*
02	*JUNE 19, 2021*	*SOP Team*	- *Highlighted definition of Inactive files*
03	*July 21, 2023*	*Dr Evasco*	- *Improved Policy Statement* - *Added objectives on retrieval and confidentiality of files* - *Added Step on disposal of archived files* - *Updated References*

1. Policy Statement

Documents submitted to the CIM-CVGH IRB are considered confidential. Management of requests for access to confidential files helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the IRB.

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2. Objective of the Activity

This SOP provides instructions to the Secretariat related to the protection of confidentiality of all study files as well as documents of the IRB

3. Scope

This SOP begins with the classification of the IRB documents which are confidential, and ends with the logging of access of the documents concerned.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Classification of the IRB documents which are confidential*	*Member Secretary*
Step 2: *Receipt and logging of request for access to confidential files*	*IRB Members, Chair, Member Secretary*
Step 3: *Approval of requests for access and retrieval of documents*	*IRB Chair*
Step 4: *Supervision of use of retrieved document*	*IRB Staff*
Step 5: *Return of document to the files*	*IRB Staff*
Step 6: *Logging of access*	*IRB Staff*

5. Description of Procedures

5.1 Step 1: Classification of the IRB documents which are confidential

Study files submitted to the CIM-CVGH IRB and related documents are considered confidential, such as:

5.1.1. Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews) IRB documents (Minutes of the meeting or decisions), Correspondence (experts, auditors, study participants, etc.)

5.2 Step 2: Receipt and logging of request for access to confidential files

Access to IRB confidential documents is subject to the following limitations:

5.2.1 IRB members and staff with a signed Confidentiality Agreement and Conflict of Interest Disclosure can access confidential documents outside of regular protocol review access upon request.

5.2.2 Non-members can access specific documents by submitting a written formal request. The Secretariat will provide a copy of the Agreement Form for Non-members requesting for copies of IRB Documents to be accomplished by the person making the request to be signed by the Chair.

5.2.3 Regulatory authorities have full access to IRB documents provided it is within their mandate (e.g. FDA), and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. FDA Director).

5.2.4 The request will be logged in the incoming/outgoing communications book.

5.3 Step 3: Approval of requests for access and retrieval of documents

5.3.1 The request for document retrieval shall be discussed in the IRB meeting and shall be approved by the members.

5.4 Step 4: Supervision of use of retrieved document **Recording of copies made of from confidential documents**

5.4.1 The IRB Staff records the retrieval of IRB documents. The following data shall be recorded in the log of request (Annex 3).

5.4.1.1 Study File Code
5.4.1.2 Date borrowed
5.4.1.3 Number of borrowers
5.4.1.4 Name and Signature of borrower upon retrieval
5.4.1.5 Signature of IR Secretariat upon return
5.4.1.6 Document copied
5.4.1.7 Number of copies made ○
5.4.1.8 Number of copies received

5.4.2 All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.

5.4.3 The IRB Staff makes only the exact number of copies requested.

5.4.4 Upon receipt of the copies, the person who requested the copies will sign the Log of Request Form

5.5 ***Step 5: Return of document to the files***

5.5.1 Access to CIM-CVGH IRB documents is generally room use only but any request to make copies can be accommodated only on a case-to-case basis.

5.5.2 The IRB Staff records the retrieval of CIM-CVGH IRB documents.

6. Forms-

Annex 1 – FORM 5.3 FILE REQUEST LOG

7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*April 13, 2019*	*CIM-CVGH-IRB MEMBERS*	*First Draft*
02	*June 21, 2021*	*SOP Team*	*NONE*
03	*July 21, 2023*	*Dr. Evasco*	*Updated References*

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL **INSTITUTIONAL REVIEW BOARD**	
VERSION 3	**SOP 5.1 Writing and Revising SOP**	Effective Date: July 21, 2023

1. Policy Statement

CIM CVGH shall provide a standardized format for writing and revising SOPs to provide clear, unambiguous instructions for all the related activities in the institutional review board.

2. Objective

This SOP shall define the process for writing and revising SOPs used by the CIM-CVGH Institutional Review Board (IRB).

3. Scope

It begins with the organization of an SOP team, and end with the filing and distribution of the approved SOP to the board members.

4. Process Flow/Steps

ACTIVITY	***RESPONSIBILITY***
Step 1: *Organize an SOP Team*	*Chair*
Step 2: *Design the format, layout, identifier of SOP*	*SOP Team*
Step 3: *Write a new SOP and submit to Chair*	*SOP Team*
Step 4: *Review new SOP in full board meeting*	*IRB Members*
Step 5: *Approve new SOP*	*Chairman of the Board*
Step 6: *Distribute approved SOPs and keep copies in the IRB files.*	*IRB Staff*
Step 7: *Review and request for a revision of an existing SOP*	*IRB Chair, Members*
Step 8: *Training on SOP*	*IRB Members*
Step 9: *Manage and archive superseded SOPs*	*IRB Staff*

5. Description of Procedures

5.1 Step 1: Organize an SOP Team

5.1.1 The Chair assigns members and non-members, as needed, to be part of the SOP Team to include at least the following

1. Chair
2. Member Secretary
3. Staff secretary
4. Other members assigned by the IRB chair

5.1.2 The SOP Team receives an orientation from the Chair regarding duties and responsibilities

5.1.3 The Chair can organize SOP Team workshops to facilitate the drafting of SOPs.

5.2 Step 2: Design the format, layout, identifier of SOP

5.2.1. An SOP is written according to the following format:

5.2.1.1 Number and version

5.2.1.2 Title o Policy ○ Objectives

5.2.1.3 Scope which includes description and purpose of the SOP

5.2.1.4 A flowchart, when necessary,

5.2.1.5 Detailed instructions

5.2.1.6 Forms (if applicable)

5.2.2 The layout of a typical SOP uses a header with the following elements:

5.2.2.1 Institutional seal or logo of both CIM and CVGH

5.2.2.2 Name of Institutional Review Board

5.2.2.3 SOP identifier

5.2.2.4 SOP title

5.2.2.5 Version number

5.2.2.6 Effectivity date

5.3 Step 3: Write a new SOP and submit to Chair

5.3.1. The SOP Team makes a draft of the SOP based on the design and format detailed above. The SOP Team submits completed draft to the Chair. The SOPs should contain details under the following main topics ○ Introduction – contains a statement of ethical principles that will guide the IRB ○ Structure and Composition of the IRB – describes the composition of IRB membership with specific review functions

5.3.2 Initial Review Procedures – describe types of review and initial review procedures

5.3.2.1 Monitoring Procedures – describe how the IRB monitor implementation of approved protocols

5.3.3 Management of Meetings, Documentation and Archiving – describe administrative procedures that support the review functions

5.3.4 Writing and Revising SOPs – describes how to draft and revise SOPs

5.4 Step 4: Review new SOP in full board meeting

5.4.1 The Chair submits the draft to full board review where IRB members deliberate on the draft

5.4.2 Upon full board approval, the Chair submits the approved draft to the CIM CVGH President for final approval.

5.5 Step 5: Approve new SOP

5.5.1 The CIM-CVGH President of CIM CVGH approves the SOP by signing in the appropriate section in the cover page.

5.5.2 The approved SOPs will be implemented from the date of approval by the Medical Director.

5.6 Step 6: Distribute approved SOPs and keep copies in the IRB files

5.6.1. Distribute approved SOPs and keep copies in the IRB files. ii. Upon approval of CIM-CVGH Medical Director, the IRB Staff distributes SOP to CIMCVGH IRB members, and publishes the SOP through the School/Hospital website. iii. The IRB Staff distributes the printed copy of the approved SOPs to the CIM-CVGH IRB members and staff; with an electronic copy published through the School/Hospital website.

5.6.2. The IRB Staff retains one complete originally signed SOPs copy.

5.7 Step 7: Review and request for a revision of an existing SOP

5.7.1 IRB member request for revision of an existing SOP

5.7.2 IRB chair assigns a member to revise the SOP.

5.7.8 Assigned member submits revised SOP for circulation.

5.8 Step 8: Training on SOP

5.8.1 New SOPs are circulated for self-reading to the members and the secretariat

5.8. 2 Training is documented in the training log sheet (Refer to Annex 4)

5.9 Step 9: Manage and archive superseded SOPs

5.9.1. Superseded SOPs should be retained and clearly marked “superseded” and archived in the historical file by the Secretariat.

6. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*November 14, 2018*	*SOP Team*	*First Draft*
02	*June 21, 2021*	*SOP Team*	– *Corrected layout* – *Defined the approver of the SOP as the President of CIM CVGH*
03	*July 21, 2023*	*Dr. Gravador*	– *Corrected the scope and Responsibility sections – Defined SOP Team* – *Updated References*

FORMS

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

LETTER OF APPOINTMENT IRB MEMBER FORM 1.1

DATE _____

_____
_____

Dear_____

I have the honor to appoint you as a _____ of the (CIM – CVGH) IRB for a period of _____ years, effective _____ until _____. As a member, you will have the following duties and responsibilities:

- Duties
- Willingness to make public his/her full name, profession, and affiliation as an IRB member
- Members shall disclose all financial accountability related to their work in the IRB that may record and publicly disclose its financial records upon request
- Members shall sign the Confidentiality and Conflict of Interest Agreements. The agreement should cover all applications, meeting deliberations, information on research participants and related matters.
- Responsibilities:
- Participate in CIM-CVGH IRB meetings
- Review, discuss and consider research proposals submitted for evaluation. • Review progress reports and monitor ongoing studies as appropriate
- Evaluate final reports.
- Assess serious adverse event reports for onsite and do trending of offsite SAE and SUSARS and recommend appropriate action if assigned by the Chair.
- Maintain confidentiality of the documents and deliberations during IRB meetings • Participate in continuing education activities in health research and ethics
- Declare any conflict of interest.
- Update CV and training record every time appointment is renewed
- Conform at all times with the legal and ethical principles accepted by the IRB • Attend basic and continuing education on Research Ethics at least once a year.
- Perform other tasks requested by the IRB Chair.

If you agree with the terms of this appointment, please sign on the space provided below, date your signature and return one copy of this letter to the (CIM – CV GH) IRB Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest agreement.
Very truly yours,

_____+
Dean
Conforme:

_____
Signature over printed name, Date

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-9127

LETTER OF APPOINTMENT INDEPENDENT CONSULTANT FORM 1.1A

DATE _____

_____
_____
_____

Dear_____

I have the honor to appoint you as a _____ of the (CIM – CVGH) IRB for a period of _____ years, effective _____ until _____. As an independent consultant, you will have the following responsibilities:

- Responsibilities:
- Participate in the IRB meetings when invited. If the Independent Consultant cannot attend he/she shall provide a written document of his/her evaluation and comments relevant to the protocol prior to the set IRB meeting.
- Review discuss and consider related research proposals submitted according to his expertise including risks involved and how to mitigate them
- Maintain confidentiality of the documents and deliberations of IRB meetings
- Declare any conflict of interest
- Conform at all times with the legal and ethical principles accepted by the IRB

If you agree with the terms of this appointment, please sign on the space provided below, date your signature and return one copy of this letter to the (CIM – CV GH) IRB Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest agreement.

Very truly yours,
_____+
Dean

Conforme:

_____
Signature over printed name, Date

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CURRICULUM VITAE
FORM 1.2

Last Name		**First Name**	
Position in the IRB		**Address**	
Date of 1st Appointment		Contact No.	
Educational Background:			
Research and Ethics Training/s:			
WORK EXPERIENCE			
A. Previous work Experience			
B. Present work Experience			
C. Researchrelated Experience			

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CONFIDENTIALITY AGREEMENT and CONFLICT OF INTEREST FORM
FORM 1.3

CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT

Know all Men by these Presents:

In view of the appointment as a member of the **(CIM - CVGH) IRB**, and hereinafter referred to as the ***Undersigned***, and Whereas: the ***Undersigned*** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines; the appointment of the ***Undersigned*** as a member of the **(CIM - CVGH)**IRB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; the fundamental duty of an IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and the **(CIM - CVGH) IRB** must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects; The following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed IRB member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the IRB to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the ***Undersigned*** in conjunction with and/or in the course of the performance of his/her duties as a member/Independent Consultant of the **(CIM - CVGH) IRB**.

Any written information provided to the ***Undersigned*** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.

As such, the ***Undersigned*** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information").Moreover, the ***Undersigned*** agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be dis closed to any third party.

The ***Undersigned*** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the ***Undersigned*** confirms that her performance of this agreement is consistent with **(CIM - CVGH)'s** policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the IRB to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the IRB that no member/consultant may participate in their view, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IRB.

The ***Undersigned*** will immediately disclose to the Chair of the **(CIM - CVGH) IRB** any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the IRB, and to abstain from any participation in discussions or recommendations in respect of such proposals .If an applicant submitting a protocol believes that an IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the IRB member(s) in question. The IRB may elect to investigate the applicant's claim of the potential conflict.

When a member/consultant has a conflict of interest, before any IRB meeting commences, the member should notify the Chairperson and may not participate in the IRB review or approval except to provide information requested by the Board. Examples of conflict of interest cases may include but is not limited to any of the following:

- A member/consultant is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's/consultant's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

[*To the Undersigned:* Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the **(CIM - CVGH)** IRB. A copy will be given to you for your records.]

In the course of my activities as a member of the **(CIM - CVGH) IRB**, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the confidential information to any person; not to use the Confidential Information for any purpose outside the Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an IRB member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

MANUEL EMERSON DONALDO, M.D.
(CIM - CVGH) IRB Chair Date

Conforme:
Print Name & Sign: Date

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TRAINING RECORD
FORM 1.4

Last name		**First name**		
BASIC COURSES	**ORGANIZER**	**VENUE**	**DATE**	**FUNDING SOURCE**
1. GCP Training				
2. Research Ethics				
3.IRB SOP Training				
CONTINUING ETHICS EDUCATION*:	**ORGANIZER**	**VENUE**	**DATE**	**FUNDING SOURCE**
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				
17.				
18.				
*** Research Ethics Workshops, Conferences, Meetings, Lectures**				

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APPLICATION FOR INITIAL REVIEW FORM FORM 2.1

APPLICATION FOR INITIAL REVIEW To be filled by Investigator				
Sponsor Protocol Number:			**IRB Protocol Number:**	
Submission Date:				
Protocol Title:				
Principal Investigator:				
Telephone number:			**Fax**	
E-mail:			**Preferred Contact**	
Institute:				
Investigator Initiated:	☐ Yes	☐ No		
Sponsor Initiated	☐ Yes	☐ No	**Name of Sponsor**	

(Relationship with sponsor)		
Are you a regular employee of the sponsor?	☐ Yes	☐ No
Did you do consultancy or part time work for the sponsor?	☐ Yes	☐ No
In the past year, did you receive ≥ P250,000 or from the sponsor?	☐ Yes	☐ No
Other ties with the sponsor? If Yes pls Specify _____	☐ Yes	☐ No

No Conflict of Interest Declaration by Principal Investigator:

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

PI Signature:	
Name of Adviser/Mentor	

Documents submitted: (Please Check)

REQUIRED FOR ALL INITIAL SUBMISSIONS	OPTIONAL: only IF APPLICABLE TO PROTOCOL
☐ Protocol	☐ Technical Review Certificate (for PI Initiated)
☐ Protocol summary (for clinical trials)	☐ Questionnaire
☐ Informed consent form (when in use)	☐ Case report forms (CRF)
☐ Research Team List	☐ Investigator brochure (for Clinical Trials)
☐ CVs & Research Ethics training Certificates	☐ GCP certificates (for Clinical Trials)
☐ Study budget	☐ Advertisement

ARE THE DOCUMENTS SUBMITTED COMPLETE:	☐ YES	☐ NO

DO NOT ACCEPT INCOMPLETE PACKAGES

Type of Research/Phase of Trial

☐ Survey ☐ Social ☐ Medical ☐ Community ☐ Individual Based
☐ Screening ☐ Observational ☐ Epidemiologic ☐ Interventional
☐ Clinical trial ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV
☐ Genetic ☐ Retrospective ☐ Prospective ☐ Others____
☐ Single Center ☐ Multicenter ☐ Others _____

Study Duration:		**Received By:**		**Date:**	

Assigned Primary Reviewer_____

Exempt	**Expedited**	☐ **Full Board**
☐ ols that neither involves human participants nor able human tissue, biological samples, and data (e.g., s protocols) ☐ meta- d that the following do not involve more than l risks or harms, these protocols may be considered B for exemption from review: b ☐ Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests; ☐ Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met: ☐ There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant. ☐ ols that involve the use of publicly available data or information.	☐ Minimal risk protocols ☐ Chart review ☐ Survey of non-sensitive nature ☐ Use of anonymous or anonymized laboratory/pathology samples or stored tissues or data	☐ Protocols that entails more than minimal Risk ☐ Protocols involving Vulnerable populations, particularly prisoners ☐ Sensitive topics, including illegal behaviors ☐ Research involving genetic testing ☐ A complex research design requiring the expertise of multiple board members to evaluate

Type of Review: ☐ **Exempt** ☐ **Expedited** ☐ **Full Board**

IRB Chair/Member Secretary Name & Signature **DATE**

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Waiver of Informed Consent Form

Requested for the following Protocol:

IRB ref No.	2 0 2 - -
Protocol Title:	
Principal Investigator:	

Please tick as appropriate:

- The research presents no more than minimal risk; including archival research involving publicly available documents that it is impractical to get an informed consent
- The waiver or amendment will not adversely affect the rights and welfare of the participants.
- The research cannot be practically carried out without the waiver.
- The participants will be provided with additional pertinent information after their participation (debriefing whenever appropriate).
- Research that uses the method of naturalistic observation (often described as "covert" method) in data collection if all the following requirements are complied with:
  - Thorough justification for the use of naturalistic observation;
  - There is a plan for how the data collected will be used;
  - There is an assurance that risks to participants are unlikely;
  - There is an existing mechanism to ensure confidentiality and anonymity of observed individuals and their data (e.g., observations are recorded in such a way that the individuals involved are not identifiable).

Recommended IRB Decisions:

- Approved
- Disapproved

Chair IRB: _____ Date: _____

Application for waiving an informed consent:

A waiver of Informed consent should be applied for in writing by the Investigator addressed to the IRB. Informed consents may be waived only with the CIMCVGH IRB'S written consent.

The informed consent process may be waived in specific research contexts, such as:

- Archival research involving publicly available documents that it is impractical to get an informed consent
- Research that uses the method of naturalistic observation (often described as "covert" method) in data collection if all the following requirements are complied with:
    1. Thorough justification for the use of naturalistic observation;
    2. Plan for how the data collected will be used;
    3. Assurance that risks to participants are unlikely;
    4. There is an existing mechanism to ensure confidentiality and anonymity of observed individuals and their data (e.g., observations are recorded in such a way that the individuals involved are not identifiable).

Some or all the elements in the informed consent may be waived or amended (with prior approval of the REC) if all the following conditions are met:

1. The research presents no more than minimal risk.
2. The waiver or amendment will not adversely affect the rights and welfare of the participants.
3. The research cannot be practicably carried out without the waiver or alteration.
4. The participants will be provided with additional pertinent information after their participation (debriefing whenever appropriate).

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PROTOCOL SUMMARY SHEET
FORM 2.2

Date		IRB REFERENCE NO.					-			-		

Primary Investigator	
18. Study Title	
19. Study Category	☐ Research involving human participants ☐ Research involving non-human living vertebrates ☐ Others (indicate):

20. TECHNICAL SYNOPSIS (TO BE FILLED UP BY THE PRIMARY INVESTIGATOR)		**Page**
d. Objectives/Expected output	.	
i. Research design	.	
ii. Sampling design, sample size		
iii. Inclusion criteria, exclusion criteria, withdrawal criteria		
iv. Data collection and processing plan		
v. Specimen collection and processing plan	.	
vi. Data analysis plan		
vii. Duration of human participant involvement		
21. Ethical Considerations		
d. Protection of privacy and confidentiality of research information including data protection plan	.	
b. Vulnerability of research participants		

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REVIEW EXEMPTION APPLICAITION FORM
FORM 2.2A

IRB REFERENCE NO.		- -
PRINCIPAL INVESTIGATOR	SPONSOR	DATE OF REVIEW
PROTOCOL NO. & TITLE		

The following are protocols that may be exempted from review:

☐ Protocols that neither involves human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.

☐ Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the IRB for exemption from review:

- ☐ Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;
- ☐ Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
  - ☐ There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and
  - ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

☐ Protocols that involve the use of publicly available data or information.

Note: SUBMIT THIS FORM TOGETHER WITH: •
Form 2.1 Application for review
- Form 2.2 Protocol summary Sheet

_____ **Signature of IRB Chair**	_____ approved for exemption from review. _____ for expedited review _____ for full review

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CERTIFICATE OF EXEMPTION

FORM 2.2B

Certificate of Exemption from Ethics Review			
This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the CIM CVGH IRB for implementation			
EXPIRY of DATE OF APPROVAL			
IRB REF No.			
Sponsor Protocol No			
Sponsor			
Title:			
Principal Investigator/s:			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other documents submitted			
Responsibilities of the PI • *Submit any amendment, progress report that changes the Risk and benefit ratio and final report once the study has been completed*			
REC Chair Person Name	Signature		Date

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PROTOCOL EVALUATION FORM FORM 2.3

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE OF REVIEW

CATEGORY OF THE INVESTIGATOR:

☐ CIM Faculty ☐ CIM students Year Level _____ ☐ Residents-in-Training _____	☐ Fellows -in-training _____ ☐ Others _____

P.I. CONTACT NO.		EMAIL-ADDRESS	

PROTOCOL NO. & TITLE

QUESTIONS				Recommendations
61) Are the objectives clear?	Y☐	N☐	N.A.☐	
62) Is there a need for human participants?	Y☐	N☐	N.A.☐	
• Are the subjects vulnerable? (if yes- for full Board review)	Y☐	N☐	N.A.☐	
63) Is there an informed consent?	Y☐	N☐	N.A.☐	
64) Is the background information sufficient?	Y☐	N☐	N.A.☐	
65) Is the study design appropriate for the objectives?	Y☐	N ☐	N.A.☐	
• Are the control arms appropriate? (for clinical trials)	Y☐	N ☐	N.A.☐	

66) Is the approximate number of subjects involved in the trial specified?	Y☐	N☐	N.A.☐	

• Are the inclusion criteria appropriate?	Y☐	N ☐	N.A.☐	
• Is the proposed subject population appropriate for the nature of the research?	Y☐	N ☐	N.A.☐	
• Has the IRB taken into account any special vulnerability among prospective subjects that might be relevant to evaluating the risk of participation?	Y☐	N☐	N.A.☐	
• Are the exclusion criteria appropriate?	Y☐	N ☐	N.A.☐	
• Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research?	Y☐	N☐	N.A.☐	
67) Is the setting of the study clearly identified?	Y☐	N☐	N.A.☐	
• Are the facilities and infrastructure of the participating sites adequate	Y☐	N☐	N.A.☐	
• Is the duration of the study specified?	Y☐	N☐	N.A.☐	
68) Are the procedures to be done in the study clearly described and understandable?	Y☐	N☐	N.A.☐	
• Are blood/tissue samples sent abroad?	Y☐	N☐	N.A.☐	
69) Are research data recorded and maintained with strict confidentiality?	Y☐	N☐	N.A.☐	
70) Considering the degree of risk, is the plan for monitoring the research appropriate and adequate in terms of timeliness and thoroughness?	Y☐	N☐	N.A.☐	
71) Is the principal investigator competent to do the study? (by training, expertise or subspecialization)	Y☐	N☐	N.A.☐	
72) Is the principal investigator assessed for any Conflict of Interest for this study?	Y☐	N☐	N.A.☐	
73) If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient?	Y☐	N☐	N.A.☐	
74) Is the mechanism for providing information to the IRB if unexpected results are discovered appropriate?	Y☐	N☐	N.A.☐	
75) If the research involves the evaluation of a therapeutic procedure, have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?	Y☐	N☐	N.A.☐	
76) Has due care been used to minimize risks and maximize the likelihood of benefits?	Y☐	N☐	N.A.☐	

77) Are the subjects given incentives or compensation for study-related expenses?	Y☐	N☐	N.A.☐	
78) Are there adequate provisions for a continuing reassessment of the balance between risks and benefits?	Y☐	N☐	N.A.☐	
79) Is the research expected to have an impact on the community where the research occurs and/or to whom findings can be linked, including issues like stigma or draining of local capacity, sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study?	Y☐	N☐	N.A.☐	
80) Does the institution have a data and safety monitoring board?	Y☐	N☐	N.A.☐	
If so, should it be asked to monitor the project under review?	Y☐	N☐	N.A.☐	
If the institution does not have a data and safety monitoring board, should the IRB request or recommend that one be appointed, either by the institution or the sponsor, for this project?	Y☐	N☐	N.A.☐	

Recommendations:

- Approve
- Minor Modifications
- Major Modifications
- Disapprove
- Others

_____

_____

Primary Reviewer

_____

Name & Signature / Date

CIM-CVGH

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INFORMED CONSENT FORM EVALUATION FORM
FORM 2.4

IRB REFERENCE NO.					-			-		
PRINCIPAL INVESTIGATOR (P.I.)					**SPONSOR**			**DATE OF REVIEW**		
PROTOCOL NO. & TITLE										
PRIMARY REVIEWER										

QUESTIONS		Comments	Recommendations
1) Is there a statement saying the study involves research?	Y☐ N☐		
2) Is the purpose of the trial clearly stated?	Y☐ N☐		
3) Is there an explanation to the subjects why they were included in the study?	Y☐ N☐		
4) Are there provisions ensuring that the subject's participation in the trial is voluntary?	Y☐ N☐		
5) Is the subject well-informed of his/her responsibilities? (*This includes providing health information including symptoms or any changes made in her regimen.)*	Y☐ N☐		
6) Is the language and presentation of the information to be conveyed appropriate to the subject population? *(Consider the level of complexity and the need for translation into a language other than English.)*	Y☐ N☐		
7) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained?	Y☐ N☐		
8) Is the expected duration of the subject's participation in the trial specified?	Y☐ N☐		
9) Is the approximate number of study subject stated?	Y☐ N☐		

10) For experimental studies is the nature of the experiment explained well?	Y☐ N☐		
11) For studies using placebo is the use of placebo ethically applicable?	Y☐ N☐		
12) Is detailed explanation of the procedures or tests that are new or not widely used or combinations/doses of drugs never tested before provided to the subject?	Y☐ N☐		
13) Are the proposed explanations of the research appropriate and adequate to provide the subject an accurate assessment of its risks and anticipated benefits?	Y☐ N☐		
14) Are the risks to the study participants disclosed?	Y☐ N☐		
15) Are the potential adverse events disclosed?	Y☐ N☐		
16) Are the possible benefits to the participants discussed?	Y☐ N☐		
17) Are the potential benefit to the Community discussed? 18) Are there lists of alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks?	Y☐ N☐		
19) Are these any anticipated expenses to the subject in the course of the study?	Y☐ N☐		
20) Is there a compensation and/or treatment available to the subject in the event of trial-related injury? Is there a person to contact in the event of trial-related injury?	Y☐ N☐ Y☐ N☐		
21) Is there a person to contact for further information regarding the trial and the rights of the trial subjects?	Y☐ N☐		
22) Do other groups of potential subjects have a greater need to receive any of the anticipated benefits?	Y☐ N☐		
23) Whether they finish the study or not, are the subjects compensated on a per visit basis for trial related expenses?	Y☐ N☐		
24) Will the subject or the subject's legally acceptable representative (LAR) be informed, in a timely manner, of any new available information which may be relevant to the subject's willingness to continue his/her participation?	Y☐ N☐		
25) Is the subject informed of his right to refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled?	Y☐ N☐		
26) Is the subject informed of any foreseeable events and or reasons which may cause his/her participation in the trial to be terminated?	Y☐ N☐		
27) In the event of any information that will affect the willingness of the subject to participate, is re-consenting necessary or provided for?	Y☐ N☐		

28) Are the withdrawal criteria made known to the subject?	Y☐ N☐		
29) If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver?	Y☐ N☐		

30) Are there provisions for medical / psychosocial support if applicable?	Y☐ N☐		

31) Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy? • Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion? • If privacy is to be invaded, does the importance of the research objective justify the intrusion? • What if anything, will the subject be told later?	Y☐ N☐ Y☐ N☐ Y☐ N☐		
32) Is there a mechanism for providing information to the IRB in the event that unexpected results are discovered? *(Unexpected results may raise the possibility of unanticipated risks to subjects)*	Y☐ N☐		
33) Is there a provision allowing consent from the subject for other monitors/ auditors/ IRB/IEC access to the subject's original medical record for verification purposes?	Y☐ N☐		
34) Are the records identifying the subject kept confidential and to the extent permitted by the applicable laws and/or regulations, not made available in public? • Should the trial be published, will the subject's identity remain confidential?	Y☐ N☐ Y☐ N☐		
35) For genetic studies is there a discussion on the precautions in place to prevent disclosure of results without the subject's permission	Y☐ N☐		
36) Is the subject informed of the possible direct or secondary use of subject's medical records & biological specimen in the course of clinical care	Y☐ N☐		
37) Are plans in place to destroy collected biological specimen at the end of the study or details of storage and possible future discussed with the patient?	Y☐ N☐		

Recommendations:

- ☐ Approve
- ☐ Minor Modifications
- ☐ Major Modifications
- ☐ Disapprove

Primary Reviewer

_____

Name & Signature / Date

CIM-CVGH

RESUBMISSION FORM

I INSTITUTIONAL REVIEW BOARD

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FORM 2.5

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED
INSTITUTION:	**P.I. CONTACT NO.**	**P.I. EMAILL ADDRESS**

PROTOCOL NO. & TITLE

DOCUMENTS SUBMITTED	
☐ Protocol ☐ Advertisement ☐ Informed Consent	☐ Composition of Research Team ☐ Others _____

PRIMARY REVIEWER	DATE REVIEWED

IRB RECOMMENDATION	PI RESPONSES PI to respond to IRB recommendations in this box	REVIEWER COMMENTS
PI Signature		
Received by IRB Staff		

Summary of comments

Primary Reviewer

[Title of Study]

Introduction

You are invited to participate in a research study conducted by [PI name or names], a [title] in [the Department Name] at Cebu Institute of Medicine OR Cebu Velez General Hospital. The purpose of this research is to [describe the purpose of the study in lay terms]. Your participation is entirely voluntary.

This form includes detailed information on the research to help you decide whether to participate. Please read it carefully and ask any questions you have before you agree to participate.

Procedures

Your participation will involve [please give a detailed description of what participants will be asked to do, taking care to use easily understandable terms. Ensure that you include a task-by-task and total time estimate (e.g. "you will participate in three separate surveys which should each take 15 minutes. Your total participation in this project is expected to be 45 minutes")]. If you agree to participate, the researchers will also collect [discuss any data about the participant that you will gather that you are not receiving directly from them, as well as the source (e.g. "collect information about your ACT scores, high school GPA, college major, and completed courses from the Registrar's Office at your institution")]. We anticipate that [#] people will participate in this research study [at this site, and that a total of # people will participate among all # sites]. *Bracketed information in that last sentence is only required if this is a multi-site study.*

If your procedures are experimental or making use of waitlists, you must identify exactly which procedures are experimental and/or the probability of being placed in a control/waitlist group. If you do not want to reveal all of those details to your participants, please be sure that you apply for an alteration of the requirements for informed consent, which allows you to reveal those details later if all of the appropriate criteria are met.

If you collected screening information prior to obtaining informed consent, please include this paragraph, indicating what you will do with that data, e.g. Before you read this form, [you responded to some questions regarding *eligibility description* OR we collected information from *third party/system* regarding your eligibility for this study, including *list information you collected here*. Researchers will [maintain/destroy] that data once you agree to enter the full study.

If your study deals with biospecimens, you must include the following information; you may delete this paragraph otherwise. The study team [will/will not] return clinically relevant information to you. *If you will return clinically relevant research results, you must describe the circumstances under which you will do so (e.g. participants scoring less than X will discuss their results with the research team and be encouraged to seek additional medical care).* This research [will/will not] include whole genome sequencing.

If your procedures are experimental or require you to interface with participants and non-participants in the same setting, please include this header. If not, you may delete the entire Alternative Procedures subsection.

Alternative Procedures

Rather than participate in this research, you might prefer alternatives such as [list any appropriate alternatives here].

Risks

This is a minimal risk research study. That means that the risks of participating are no more likely or serious than those you encounter in everyday activities. **OR** This study is greater than minimal risk, meaning that the risks are [slightly/significantly] higher than those you encounter in everyday activities. The foreseeable risks or discomforts include [list all foreseeable risks here, and ensure it is consistent with the prompt in your protocol, recalling that loss of confidentiality is nearly always a risk in research studies]. In order to minimize those risks and discomforts, the researchers will [list what the research team is doing to minimize those risks, and ensure it is consistent with the prompt in your protocol]. [*If the nature of the research is experimental and you believe it carries unforeseeable risks, please add this phrase:* This research may involve risks that are not yet known.] If you have a bad research-related experience, please [contact PERSON]. *If your protocol is greater than minimal risk, you must explicitly state whether compensation and/or medical treatment is available if there is an injury and where to go or who to contact for compensation/treatment. For greater than minimal risk protocols or if you feel it is applicable*: If you are injured in any way, [compensation/medical treatment] [is/is not] available. Please [contact PERSON/go to RESOURCE] immediately if you are injured so that further information can be provided.

If physical injury or mental health risks are present, please add a sentence stating whether and the extent to which the research-related injuries will receive treatment from the research team or from the research team's resources.

Benefits

Although you will not directly benefit from this study, it has been designed to learn more about [insert purpose or topic]. **OR** Participation in this study may directly benefit you by [list benefits, e.g. "exposing you to a math intervention that has helped others"]. We cannot guarantee that you will directly benefit from this study [but it has been designed to learn more about *insert purpose or topic]*. *Please note that it is incredibly common not to have direct benefits to participants, so please do not go out of your way to overstate direct benefits.*

Confidentiality

The researchers will make every effort to ensure that the information you provide as part of this study remains confidential. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study. [However, it may be possible for someone to recognize your particular story/situation/response (particularly applicable in focus group/ethnographic/oral history research projects).] *If you are doing research in a group setting, please add a statement that:* While we will ask all group members to keep the information they hear in this group confidential, we cannot guarantee that everyone will do so.

We will collect your information through [video recordings, audio recordings, interviews, email… whatever mechanism(s) you are using to collect it, including indirect ones like seeking the information from a third party]. *If you will collect or store data online,* Online activities always carry a risk of a data breach, but we will use systems and processes that minimize breach opportunities. [This information or Data] will be securely stored [in a restricted-access folder, an encrypted, cloud-based storage system [and/or] in a locked drawer in a restricted-

access office. *If you have data where identifiers can be separated and destroyed, please state the timeframe for doing so. If your data is necessarily identifying (e.g. videos, extensive demographic data, etc.) please state the timeframe for destruction of that data and what, if anything, will be kept.* This form will be kept for three years *three is the minimum* after the study is complete, and then it will be destroyed.

It is unlikely, but possible, that others (Cebu Institute of Medicine, [funding sponsor,] or government officials) may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so.

Voluntary Participation & Withdrawal

Your participation in this research is completely voluntary. If you agree to participate now and change your mind later, you may withdraw at any time by [please provide instructions on how a participant should withdraw once they have initiated research participation]. If you choose to withdraw after we have already collected information about you, [state what you will do with that information, or the extent to which withdrawal is possible (e.g. completely anonymous participation cannot be withdrawn, as you will be unable to determine whose data is whose)]. *If participant is already or may in the future receive services from your clinic/department/unit*, If you decide not to participate, the services you receive from [researcher clinic/department/unit] will not be affected in any way. The researchers may choose to terminate your participation in this research study if [state any circumstances that would lead to termination of a participant's continued participation. Also state whether and how they will be notified if this happens].

Payment or **Compensation [& Costs]**

For your participation in this research study, you will receive [amount and type of payment. This must be concrete before your submission]. *State whether compensation will occur if participation is incomplete, either due to their withdrawal or your termination of their participation, including whether compensation can occur in increments. If the compensation is in the form of extra credit, you must ensure that there is an alternative, nonresearch related extra credit opportunity available, and you must state what that alternative is here. If you are giving SONA credits for participation, you must state how many credits participants are eligible to receive – note that in-person lab components are often able to award more credit than online procedures.*

If biospecimens are collected as a part of this research project will be used for the research team or institution's commercial profit, you must disclose: Your biospecimens, even once de-identified, may be used for the [research team's, sponsor's, institution's, etc.] commercial profit. You [will/will not] share in that commercial profit.

Your participation may require that you incur additional costs, including [include any additional costs here, such as parking fees to come to campus, any procedures that may not be covered by health insurance, etc. If none, delete this whole sentence].

Findings [& Future Participation]

<u>If your procedures are experimental, please include this paragraph:</u> If the researchers learn anything new during the course of this research study that might affect your willingness to continue participation, you will be contacted about those findings. This might include changes in procedures, changes in the risks or benefits of participation, or any new alternatives to participation that the researchers learn about. *You may delete this paragraph if your procedures are not experimental and only the next two are relevant. Please note that if you learn about something*

study-related that results in increased risks to participants, you must notify them, whether you include this section or not.

You must include one of these statements if you collect identifying information/biospecimens: Identifiers may be removed from your [information/biospecimens]. These de-identified [data/biospecimens] may be used or distributed for future research without additional consent from you. If you do not wish for us to use your [information/biospecimens] in this way, please state so below. **OR** Your [information/biospecimens], identified or de-identified, will not be used or distributed for future research studies, even if all of the identifying information has been removed.

If you plan to share your findings with the participants once the study has concluded once the research study is complete, the researchers will [email you, mail you, call you with, etc.] the findings of the study, including [aggregate, individual, etc.] results relating to your participation. *If you do this, please ensure you are capturing adequate contact information at the end of this document to follow up on this commitment.*

*If you would like to be able to contact this participant about future studies of yours, t*he researchers would like to keep your contact information in order to invite you to participate in future research studies. If you would like them to keep your contact information, please initial here: _____. This information will be entered into [please detail how the information will be maintained] that is completely separated from anything to do with this research study and maintained for [time period you plan to keep this information]. You can contact the Principal Investigator at any time to be removed from this list.

IRB Review

The Institutional Review Board (IRB) for the protection of human research participants at Cebu Institute of Medicine has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at [phone number] or [email address]. If you have questions about your rights or would simply like to speak with someone *other* than the research team about questions or concerns, please contact the IRB Chair at (+63) 917-3204149 or cimcvghirb@gmail.com. *The signature blocks below look funny now but will sort themselves out once information is filled in and deleted.*

Please replace this line with an electronic signature, if you would like.

[Principal Investigator Name]

Principal Investigator

((XXX) XXX-XXXX email@usu.edu

[Co-Investigator or Student Researcher Name]

Co-Investigator OR Student Investigator

(XXX) XXX-XXXX; email address

Informed Consent

By signing below, you agree to participate in this study. You indicate that you understand the risks and benefits of participation, and that you know what you will be asked to do. You also agree that you have asked any questions you might have, and are clear on how to stop your participation in the study if you choose to do so. Please be sure to retain a copy of this form for your records.

_____ _____ _____

Participant's Signature Participant's Name, Printed Date

☐ I do **not** agree to allow my de-identified information/biospecimens to be used or shared for future research. *You may delete this if, above, you decided that you would not de-identify and store data for potential future research use.*

Please be sure that if you need to collect additional information in order to recontact with new findings, study results, or future research purposes, you do so here. If you are using any kind of differential consent procedures (e.g. allowing participants to consent or not consent to video recordings while still participating in the study) please add those initial or check boxes in this area of the consent form as well.

You can ask any questions you have, now or later. Your parents know about this research study, and they have said you can participate, if you want.

If you would like to be in this study, please sign your name and write the date.

_____ _____ Name

Date

You should also feel free to develop a separate assent document using this template – it does not need to be appended to the informed consent document. In all cases working with minors, please do be sure that the consent form is written to the parents/guardians, and not the child themselves – only the assent should be addressed directly to the children.

The IRB strongly recommends the development of separate consent forms where you have both minors and adults as direct participants.

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INSTITUTIONAL REVIEW BOARD
79F. RAMOS ST., CEBU CITY
Tel. 2537413 Fax(6332) 2539127

NOTIFICATION LETTER TEMPLATE FORM 2.7

NOTIFICATION LETTER
(for initial and continuing review)

Date _____

To:

Name of PI_____
Contact No._____
Protocol Title_____
Version No. and Date: _____
ICF Version No. and Date _____
IRB REF. No. _____
Sponsor Protocol No_____

Type of Submission

☐ Initial Review
☐ Amendment
☐ Final Report
☐ Resubmission
☐ Progress Report
☐ Others

This is to inform you of the IRB decision related to your above referenced documents submitted.

Type of Review	IRB Decision
☐ Expedited ☐ Full board ☐ Exempt Date of Review: _____	☐ Approved ☐ Minor revisions required ☐ Major revisions required ☐ More information required ☐ Others

ITEMS FOR REVISION	REVISIONS/INFORMATION REQURIED FROM THE PRINCIPAL INVESTIGATOR
Protocol	
Informed Consent	
Others	

Please submit the revised documents within 30 days from receipt of this notice.

Name and Signature
IRB Chair

Date

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APPROVAL LETTER TEMPLATE FORM 2.8

APPROVAL LETTER

Date: _____

To: _____

Re:

Protocol Title: _____
IRB Ref No.: _____
Submission Type: Initial
IRB Review Date: MM/DD/YYYY
IRB Review Type: Expedited
IRB Review Action: Approved

This is to inform you of the IRB decision related to your above referenced application for review. The CIMCVGH IRB met on MM/DD/YYYY and decided to approve the documents submitted effective MM/DD/YYYY. Please note that the approval is valid for 1 year and will expire on MM/DD/YYYY. The PI is advised to submit an annual Continuing Review Report 1 month before expiry date.

The approval covers the following submitted documents

5. _____ version no. ___ date ____ 6.
_____ version no. ___ date ____ 7.
_____ version no. ___ date ____
8. _____ version no. ___ date ____

Investigator's Responsibilities:

1. Faithfully follow the Protocol
2. Submit SAEs when applicable.
3. Any changes made to the protocol must be submitted as amendment and should not be carried until after IRB approval.
4. To submit continuing renewal review Reports/Progress Reports and obtain approval before the expiration date
5. Submit any Protocol Deviations / Violations/Final Report as applicable

The approval was done with the following members in attendance:

	Designation	Specialty
1. Dr. Manuel Emerson S. Donaldo	Chairman	Rheumatology
2. Dr. Corazon Tan-Meneses	Co-Chair	Academe (MHPEd)
3. Dr. Consolacion Cutillar	Secretary	Endocrinology

Truly yours,

Manuel Emerson S. Donaldo, M.D.
Chairman
CIM –CVGH- IRB

CIM-CVGH

INSTITUTIONAL REVIEW BOARD
79 P. RAMOS ST., CEBU CITY
Tel. 253-7403 Fax (63-32) 253-9127

SERIOUS ADVERSE EVENT REPORT FORM

FORM 3.1

Principal Investigator:	Protocol No.:	IRB Reference No: ☐☐☐☐ ☐☐☐ ☐☐
Study Title:		
Name of the study medicine/device:	Report Date: ☐ initial ☐ follow-up	Onset date:
	Sponsor:	Date of first use:

Subject's initial/number:	Age:	☐ Male ☐ Female
Subject's history:	Laboratory findings:	
SAE:	Treatment: Outcome: ☐ resolved ☐ on-going	
Seriousness: ☐ Death ☐ Life Threatening ☐ Hospitalization – O initial O prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other	Relation to O Drug O Device O study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown	
Changes to the protocol recommended?	☐ No ☐ Yes , attach proposal	
Changes to the informed consent form recommended?	☐ No ☐ Yes , attach proposal	
Reviewed by:	Date:	
Comment:	Action:	

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UNEXPECTED ADVERSE EVENT REPORT FORM

FORM 3.2

Principal Investigator:	Protocol No.:	IRB Reference No: ☐☐☐-☐☐☐☐-☐☐
Study Title:		
Name of the study medicine/device:	Report Date: ☐ initial ☐ follow-up	Onset date:
	Sponsor:	Date of first use:

Subject's initial/number:	Age:	☐ Male ☐ Female
Subject's history:	Laboratory findings:	
SAE:	Treatment: Outcome: ☐ resolved ☐ on-going	
Seriousness: ☐ Death ☐ Life Threatening ☐ Hospitalization – ○ initial ○ prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other	Relation to ○ Drug ○ Device ○ study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown	
Changes to the protocol recommended?		☐ No ☐ Yes , attach proposal
Changes to the informed consent form recommended?		☐ No ☐ Yes , attach proposal
Reviewed by:		Date:
Comment:		Action:

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CIOMS FORM

FORM 3.3

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2.a AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTIONS (including relevant tests/lab data)										PATIENT DIED INVOLVED OR PROLONGED INPATIENT HOSPITALISATION INVOLVED PERSISTENCE OF SIGNINFICANT DISABILITY OR INCAPACITY LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? YES □NO □NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCITON? YES □NO □NA
17. INDICATION(S) FOR USE		
18. THERAPY DATE (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24A. NAME AND ADDRESS OF MANUFACTURER		26. REMARKS
	24b. MFR CONTROL NO.	25b. NAME AND ADDRESS OF REPORTER
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE STUDY □ LITERATURE HEALTHPROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE INITIAL □ FOLLOWUP	

IRB Reference No.	
Protocol No. & Title	

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SAE ASSESSMENT FORM

FORM 3.4

Site of reported SAE		Type of SAE (Number)		On-site SAEs					
On-Site (Site in the country)	Off – Site (Site in foreign countries)	SUSAR	Non-SUSAR	Date of SAE	Date reported to REC	Date presented in REC meeting	Relation to Investigational New Drug	Action taken	Reviewed By
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						
☐	☐	☐	☐						

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PROTOCOL DEVIATIONVIOLATION REPORT

FORM 3.5

Protocol Violation Deviation Report for:		
Date:	**IRB Ref No.:**	
Investigator:	**Contact No.:**	
Sponsor:	**Contact NO.:**	
Title		
☐ **Deviation from Protocol** ○ **Major** ○ **Minor**	☐ **Violation**	
Description:		
Found By:	**Reported by:**	
Actions Taken	**Outcome:**	
Primary reviewer Name	**Signature**	**Date**
CIMCVGH IRB Chairman Name	**Signature**	**Date**

FORM 4.0 REMINDER LETTER OF CONTINUING REVIEW

Dear Doctor,

This is to remind you that the study with **IRB REF NO**, _____: with Protocol Title_____.
is due to expire on _____.

Please submit the Continuing Review Report/Annual Progress Report not later than 30 days prior to date of expiry.

Very truly yours,

Dr. Manuel Emerson Donaldo

Chair

CIM CVGH IRB

CIM-CVGH

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79 F. RAMOS ST., CEBU CITY
Tel. 253-7413 Fax.(63-32) 2539127

PROTOCOL AMENDMENT SUBMISSION FORM
FORM 4.1

Any amendment to an approved protocol must be reviewed and approved by the IRB before the amendment is implemented. Such amendments could include changes to the study design, procedures, enrolment, methods of recruitment, personnel, funding source or the consent form/information sheet. This includes changes that appear to reduce risks to subjects. There are NO EXCEPTIONS to this rule.

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED
INSTITUTION:	**P.I. CONTACT NO.**	**P.I. EMAILL ADDRESS**

PROTOCOL NO. & TITLE	
PRIMARY REVIEWER	**DATE REVIEWED**

1. Describe each proposed amendment and provide the reason for such.

2. For each amendment listed above, explain whether the proposed amendment increases or decreases the level risk to participants (thereby changing the risk/benefit ratio) and, if so, describe. Please use page 2 attached

☐ **Does not change the risk/benefit ratio**

☐ Increase the risk to participants:

_____

☐ Decrease the risk to participants

4. Has the funding source or the status of funding changed since initial or last re-approval review?

☐ YES ☐ NO

To the PI to fill

Section	Before Amendment	After Amendment	Rationale

TYPE OF REVIEW	☐ Full Board ☐ Expedited
Name and Signature Principal Investigator	Date

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PROGRESS REPORT FORM 4.2

IRB REFERENCE NO.					-			-		
PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED
INSTITUTION:	P.I. CONTACT NO.	P.I. EMAILL ADDRESS
TITLE		

ACTION REQUESTED:

Renew - New participant accrual to continue

Renew - Enrolled participant follow up only

Terminate - Protocol discontinued

AMENDMENTS SINCE THE LAST REVIEW?

NO

YES (Describe briefly in attached narrative)

PROTOCOL PARTICIPANTS SUMMARY:

_____ Accrual ceiling set by IRB

_____ New participants accrued since last review

IS THERE NEW INFORMATION FROM SIMILAR RESEARCH THAT MIGHT AFFECT THE RISK/BENEFIT RATIO OF THE HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?

NO

YES (Discuss in the attached narrative)

10. HAVE ANY UNEXPECTED COMPLICATIONS OR ADVERSE EVENTS BEEN NOTED SINCE LAST REVIEW?

NO

YES (Discuss in the attached narrative)

HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?

_____ Total participants accrued since protocol began _____ Number of participants who are lost to follow up _____ Number of participants who experienced SAEs/SUSARs ACCRUAL EXCLUSIONS NONE MALE FEMALE OTHER (specify):_____ IMPAIRED PARTICIPANTS None Physically Cognitively Both HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW? NO YES (Explain changes in attached narrative) HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW? NO YES (Explain changes in attached narrative)	☐ NO ☐ YES (Discuss in the attached narrative) HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW? NO YES (Identify all changes in the attached narrative) HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW? NO YES (Identify all changes and provide an explanation of changes in the attached narrative) HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST? NO YES (Append a statement of disclosure) WERE THERE PROTOCOL DEVIATION/ VIOLATION REPORTS? NO YES (Summarize and what corrective actions were taken)

CHANGE IN PRINCIPAL INVESTIGATOR? NONE DELETE:____ ADD: _____	

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FINAL REPORT FORM
FORM 4.3A

IRB REFERENCE NO.					-			-		

PRINCIPAL INVESTIGATOR (P.I.)	SPONSOR	DATE SUBMITTED
STUDY SITE:	**P.I. CONTACT NO.**	**P.I. EMAILL ADDRESS**

PROTOCOL NO. & TITLE

PRIMARY REVIEWER	PROTOCOL APPROVAL DATE

1. Study Arms:

2.Summary of Recruitment

_____Accrual ceiling set by IRB

_____ New participants accrued since last review

_____ Total number of participants accrued since protocol began

_____ No. of participants who are lost to follow up

_____ No. of participants withdrawn from the study

_____ No. of participants who experienced SAEs/ SUSARs

_____ Number of participants who completed the study

3. Amendments to the original protocol (including dates of approval):
4. Summary of onsite SAEs reported:
5. Summary of participants' complaints or grievances documented regarding conduct of study:
6. Summary of benefits to participants:
7. Summary of indemnifications of study related injury (If Applicable):
8. If terminated early, specify reason for termination:
9. Progress reports submitted (with dates of approval):
10. Duration of the study (months):
11. Informed consent form used (with version no./date) and attach most recent version:
12. Study objectives and summary of results:
Date of Last Review:
_____ **Name and Signature of Primary Investigator**

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Tel. 2537413 Fax.(63-32)253-9127

CERTIFICATE OF COMPLETION FORM 4.3B

FORM 4.3B CERTIFICATE OF COMPLETION	
IRB REF No.	
Title:	
Principal Investigator/s:	

This is to certify that the above-mentioned research paper has been completed and submitted to the Research Committee

Secretary
Research Committee

FOR IRB USE ONLY

Recommended Action:
_____ Approve
_____ Request further information, specify
_____ Recommend further action, specify
_____ (e.g. Require protocol/ ICF amendment, re-consent) to address concerns about patient safety)
Other Comments:

Primary Reviewer: Signature: Date:

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79 E. RAMON ST., CEBU CITY
Tel. 253-7413 Fax. (63-32) 253-5127

STUDY SITE VISIT REPORT FORM

FORM 4.4

IRB Ref. No.		Date of the Visit:	
Study Title:			
Principal Investigator:		Phone:	
Sponsor		Site	
Reason for site visit		Persons interviewed	
Total number of expected subjects:		Total subjects enrolled:	

	YES	NO	COMMENTS
Are site facilities appropriate?			
Is confidentiality of documents maintained (e.g. cabinets with lock and keys)?			
Are the test articles properly kept and maintained?			
Are informed Consent Forms complete?			
Are approved ICF versions used?			
Are copies of the approved versions of the protocol documents kept in the site?			
Are files of all communication with the IRB found in the site?			
Does the site keep copies of all communication with the IRB in the site?			
Are copies of adverse event reports kept?			
Are investigator functions properly delegated to qualified research personnel?			
Is there appropriate documentation of qualifications of personnel?			
Are all Case Record Forms up to date?			
Are copies of protocol deviation/ violation reports kept in the site?			
Is there evidence of appropriate corrective action taken as recommended by the IRB?			

Summary of findings:

Recommendations:

Duration of visit: (hours)		Starting form:	Finish:
Name of IRB Member Visitors:			
Reported by:		Date:	
Signature			

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F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

COMMUNICATION REPORT

FORM 4.5

Date					
Means of Contact:	☐ **Telephone**	☐ **Facsimile**	☐ **E-mail**		☐ **In-person**
Person contacted:	☐ **Reviewer**	☐ **CIM CVGH Member**	☐ **Investigator**	☐ **Media**	
	☐ **Secretariat**	☐ **CIM CVGH Chairperson**	☐ **Subject**	☐ **Sponsor**	
Name:					
Contact No.:		**E-mail:**			
Protocol No.:		**IRB Ref No.:**			
Title					
Communication Issues/<u>Reasons for making contact</u>:					
Follow up action	☐ **Return call**	☐ **Send written communication**		☐ **None**	
Summary of Communication:					
Recorded by:					

CIM-CVGH

INSTITUTIONAL REVIEW BOARD

79 F. RAMOS ST., CEBU CITY
Tel. 2537413 Fax.(63-32) 2539127

MEETING AGENDA TEMPLATE FORM 5.1

DATE			VENUE:	CIM CONFERENCE ROOM	
	IRB MEMBERS	**POSITION**			**ATTENDANCE**
1)	Dr. Manuel Emerson Donaldo	Chairman	Affiliated	Medical	( ) present ( ) absent
2)	Dr. Corazon Tan-Meneses	Co-Chairman	Affiliated	Medical	( ) present ( ) absent
3)	**Dr. Consolacion Cutillar**	Secretary	Affiliated	Medical	( ) present ( ) absent
4)	**Dr. Rudy Amatong**	Member	Affiliated	Medical	( ) present ( ) absent
5)	Mdm. Charito Calumpang	Member	Non affiliated	Non Medical	( ) present ( ) absent
6)	**Fr. Raphael Catane, SHF**	Member	Non affiliated	Non Medical	( ) present ( ) absent
7)	**Dr. Irelan A. Evasco**	Member	Affiliated	Medical	( ) present ( ) absent
8)	**Atty. Terence Fernandez**	Member	Affiliated	Non Medical	( ) present ( ) absent
9)	**Dr. Saleshe Tracy Anne Fernandez**	Member	Affiliated	Medical	( ) present ( ) absent
10)	**Dr. Nerissa Sanchez**	Member	Affiliated	Medical	( ) present ( ) absent
11)	**Dr. Cristina Gravador**	Member	Affiliated	Medical	( ) present (/) absent
Meeting No.: 2019-00					

☐ **Regular**		☐ **Emergency Meeting**	
MEETING CHAIRED BY:		**Designation**	
Announcement of formal start of meeting		**Time started**	
Determination of a duly constituted quorum by the Secretary to proceed with the meeting.		Quorum (out 0 11 members) Affiliated – Non affiliated	
COI Disclosures			

I. Approval of Provisional Agenda

II. Review of the previous minutes:

III. Business or matters arising from the minutes:

IV. Review of Protocols

A. INITIAL REVIEW

(A.1) IRB Reference No.:	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Independent Consultant	
Technical Reviewer	
Primary Reviewer PROTOCOL	

Expertise		
Primary Reviewer ICF		
Expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

B. RESUBMISSION

(B.1) IRB Reference No.	**NONE**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer PROTOCOL	
Expertise	
Primary Reviewer ICF	
Expertise	
Submitted Documents	
Discussion	

Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

C. PROTOCOL AMENDMENTS

(C.1) IRB Reference No.		
Protocol No.		
Study Title		
Principal Investigator		
Sponsor		
Primary Reviewer Protocol		
expertise		
Primary Reviewer ICF		
expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

D. REMINDER LETTER DUE FOR DISPATCH

(D.1) IRB Reference No.:	**N O N E**	
Protocol No.		
Study Title		
Principal Investigator		
Sponsor		
Primary Reviewer Protocol		
expertise		
Primary Reviewer ICF		
expertise		
Submitted Documents		
Discussion		
Summary of Recommendations/Actions Taken		
QUORUM CHECK	☐ QUORUM MAINTAINED	☐ QUORUM NOT MAINTAINED
IRB DECISION		

E. SAE/SUSARS

(E.1) IRB Reference No.:	**N O N E**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Summary of Recommendations/Actions Taken	
IRB DECISION	

F. PROTOCOL DEVIATIONS

(F.1) IRB Reference No.:	**N O N E**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Summary of Recommendations/Actions Taken	
IRB DECISION	

G. COMMUNICATIONS/NOTIFICATIONS

(G.1) IRB Reference No.	**N O N E**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	

H. FINAL REPORTS

(H.1) IRB Reference No.	**None**
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Summary of Recommendations/Actions Taken	
IRB DECISION	

I. Protocols Exempted from Review

(V.1) IRB Reference No.:	**NONE**
Study Title	
Principal Investigator	
Decision	

J. Protocol Approved by Expedited Process

(VI.1) IRB Reference No.:	**None**
Study Title	
Principal Investigator	
Primary Reviewer	
Decision	

K. Other Matters:

Prepared by:	**NOTED BY:**	**APPROVED BY:**
Gina Lord	**DR. CONSOLACION CUTILLAR**	**DR. MANUEL EMERSON S. DONALDO**
IRB Staff	**Member Secretary- CIMCVGH IRB**	**CHAIR- CIMCVGH IRB**

APPENDIX 1

1. References

i. ADMINISTRATIVE ORDER NO. 2019 - 0044 NOV 05 2013 SUBJECT: Guidelines for the Operationalization of the Single Joint Ethics Review Process for Multi-Site Researches in the Department of Health

ii. **Single Joint Research Ethics Board SJREB STANDARD OPERATING PROCEDURES** Department of Health Policy Development and Planning Bureau Health Research Division Department of Health 2021 Published by Health Policy Development and Planning Bureau Department of Health San Lazaro Compound Rizal Avenue, Sta. Cruz Manila 1003, Philippines Philippine Health Research Ethics Board (PHREB) SOP Workbook 2020

iii. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2002.

iv. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011.

v. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

vi. International Conference on Harmonization, E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) 2018.

vii. International Ethical Guidelines for Health-related Research Involving Humans (Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) 2016

viii. National Ethical Guidelines for Health Research 2022 PNHRS Prepared by the Philippine Health Research Ethics Board Ad Hoc Committee for Updating the National Ethical Guidelines

ix. RA 10173 Data Privacy Act of 2012

x. PNHRS ACT OF 2013

xi. CHED Memorandum Order No. 34 ser 2007

xii. DOST AO No. 001 series 2008

xiii. FDA Circular No 2012 – 007

xiv. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001

xv. NCIP AO 01-2012

APPENDIX II

CIM-CVGH

ACRONYMS
UNIFIED
GLOSSSARY

NSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
253-7413 Fax. (63-32) 253-9127

ACRONYMS

ADR	Adverse Drug Reaction
AE	Adverse Effects
CHED	Commission on Higher Education
CIOMS	Council for International Organizations of Medical Sciences
COI	Conflict of Interest
CRF	Case Report Form
CRO	Contract Research Organization
CV	Curriculum Vitae
DOH	Department of Health
DOST	Department of Science and Technology
DSMB	Data Safety Monitoring Board
FDA	Food and Drug Administration
GCP	Good Clinical Practice
IB	Investigator Brochure
ICF	Informed Consent Form
ICHGCP	International Conference on the Harmonization of Good Clinical Practice
MREB	Multi–Site Research Ethics Board
PCHRD	Philippine Council for Health Research and Development
PHIC	Philippine Health Insurance Corporation
PHREB	Philippine Health Research Ethics Board

PI	Principal Investigator
PNHRS	Philippine National Health Research System
IRB	Institutional Review Board
RNE	Reportable Negative Events
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TOR	Terms of Reference
WHO	World Health Organization

UNIFIED ACRONYMS AND GLOSSARY

Adverse Drug	All noxious or unintended responses to a new medicinal product or an already marketed product which shows that there is a causal relationship between the product and the adverse event
Adverse event	Any unintended unfavorable sign or experience associated with the use of the investigational product, whether or not related to the product
Affiliated member	Member who have official appointment with UP Manila.
Agenda	A list of items to be taken up at a meeting
Alternative members	Alternative members attend IRB meetings replacing a specified Primary member.
Amendments	Change/changes from a previously approved study protocol requested by the Principal Investigator

Approved Protocols	Protocols that have been reviewed by the UPMREB and approved without conditions or approved after recommendations have been fulfilled
Archives	A designated place/section used for storage for completed protocols, inactive files or terminated studies
Assent Form	A form used to explain the study related procedures to minors or research volunteers who lack the capacity to give consent in order to get their agreement to join the study. It is a supplementary form to the informed consent given by the guardian or the legally acceptable representative
Assessment Form	A form used by reviewers to evaluate the scientific and ethical merits of the protocol and the consent forms
Audit	A systematic and independent examination of approval activities and documents related to a research study or clinical trial to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements
Case Report Form	A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant
Clinical Trial/Study	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s), with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Collaborative studies	Studies that are carried out by researchers in collaboration with other universities or institutions, in the Philippines or in other countries, which are not necessarily the sponsor of the study
Comparator (Product)	An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.
Completed study	A study that was accomplished according to the study protocol and where a final report of the study had been submitted and approved
Compliance	Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.
Confidentiality	Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.
Confidentiality Agreement / Secrecy or Nondisclosure Agreement	An agreement between the CIM-CVGH IRB and an individual who has been invited to be a member of the IRB, or someone invited to attend an IRB meeting, in order to maintain confidentiality and protect trade secrets, protected information, and other proceedings and files and documents.
Conflict of Interest	Conditions in which professional judgment concerning a primary interest (such as patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)
Coordinating Investigator	Refers to the point person identified by the sponsor or study team that will facilitate all communications with SJREB
Deviation/ Non – compliance/ Violation	Any event that is not in accordance with regulations or approval given by the IRB

Documentation	All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken and includes all actions or decisions given by the IRB.
Epidemiological research	Population-based investigations that lead to improved understanding of risk factors for disease or for progression of diseases
Exempt from Review	A protocol with negligible risk that does not require IRB review
Expedited Review	A review process done by two or more designated IRB members for study protocols determined to be minimal risk and subsumed within the criteria
Full Board Review	Review and deliberation on a study on a study protocol determined to be more than minimal risk, and discussed during a panel meeting, thus subject to quorum requirements
Funding Institution	Refers to the institution which provided funding for the research project
Guideline	A written suggestion, rule, etc., intended as a guide for specific practice or action
Independent	An expert who gives advice(s), comment(s) and suggestion(s)

Consultant	upon review of the study protocols with no affiliation to the institute(s) or investigator(s) proposing the research proposal
Informed consent form (ICF)	A written, signed, and dated form confirming a competent participant's willingness to voluntarily participate in a particular trial or research, after having been informed of all aspects that are relevant to the participant's decision to participate and given time to reflect on the decision.
Home Institution	Refers to the institution where the coordinating investigator comes from
Inactive Protocol files	Study protocols that have been completed with CIM-CVGH-IRB-Approved Final Reports Study protocols declared "Inactive" by the CIM-CVGH IRB after a six (6) months period of no communication. Study protocols that have been terminated or closed
Informed Consent	A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
Initial Review	The review of a protocol for the first time to assess its scientific soundness and compliance with ethical principles
Institution	Any public or private entity or agency where research is conducted.

Inspection	The act by regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO) facilities, Office of Ethics, or at other establishments deemed appropriate by the regulatory authorities
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Sub investigator.
Investigator-initiated research	Refers to researches that are funded by the investigator.
Investigator Brochure	A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects
Legally Acceptable Representative	An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.
Majority Vote	A vote by one – half plus One of IRB members attending a

	formal meeting that meets the quorum requirements
Medical member	Member with education and training related to the degree of Doctor of Medicine (e.g. physician, dentist).
Members	Individuals serving as regular or alternate members in the IRB
Member Secretary	IRB member who heads the secretariat
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations
More than minimal risk	Occurs when the participants in the course of the research would be exposed to more than a remote possibility of a “substantial or prolonged pain, discomfort, distress” or “clinically significant deterioration of a medical condition”
Monitoring	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Multi-site/center Study	A study conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator. Sites may either be hospital or community based.

Non-Medical, Non-Scientific Member	IRB member with a lay person's perspective about protocols being reviewed by the ethics committee
On – site SAE	Serious adverse events that happen within the institution
Off – site SAE	Serious adverse events that happen outside the institution
Phase I study	Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses
Phase II study	A study of drug metabolism, structure – activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease process
Phase III study	A study expanded to controlled and uncontrolled trials performed after preliminary evidence suggesting efficacy of the drug has been obtained. They are intended to gather the additional information about efficacy and safety that is needed to evaluate the overall benefit – risk relationship of the drug to provide an adequate basis for physician labeling.
Phase IV study	A study of a medical product conducted after marketing

	authorization approval to provide continuing safety evidence of the product when it is available for use of the general population
Primary Reviewer	Point person given the primary task of evaluating the protocol and/or ICF with the use of assessment form
Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.
Protocol Package	Study protocol plus accompanying communications, registration forms, and other documents relevant to the protocol
Protocol Amendment	A written description of a change(s) to, or formal clarification of a protocol
Protocol Deviation/Violation	Any change during protocol implementation that does not comply with IRB approved version.
Quorum	The number of present members required to act on any motion presented for action during a full board meeting, in addition to types of members required to be present based on international

	and national guidelines and regulations
Randomization	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
Regulatory Authorities	Bodies having the power to regulate. In the ICH GCP Guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities
Research Ethics Committee	An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Respondent	Person or group of persons answering or replying to research questions or providing the data that are collected during the research
Resubmission	Protocols that were not yet approved by IRB and were resubmitted after being revised in accordance with IRB recommendations

Scientific member	Member who has education, training, or extensive experience in the Biomedical or Behavioral/Social Sciences.
Scientists	Professionals with advanced training and expertise in the medical or non – medical areas of science
Secretariat	Group of persons providing administrative support to the operations of the IRB
Standard of Care or Treatment	healthcare intervention or regimen that is generally accepted by health practitioners and experts as beneficial to an individual needing such care.
Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)	Any untoward medical occurrence that at any dose: - results in death, - is life-threatening, - requires inpatient hospitalization or prolongation of existing hospitalization, - results in persistent or significant disability/incapacity, or - is a congenital anomaly/birth defect (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

Single Joint Ethics Review	Refers to a joint review for the purpose of approving multi-site research, that is participated in by the identified sites where the protocol will be conducted.
Site Visit	An action taken by IRB members or representatives which involves going to a study site to assess how the investigators are conducting a trial or research and maintaining proper documentation for an IRB approved protocol
Site Representative	Refer to participants from hospital research ethics committees (REC) of sites included in the study
Sponsor	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Sponsor Initiated Research	Refers to researches that are funded by a local or international funding agency.
Standard of Care or Treatment –	healthcare intervention or regimen that is generally accepted by health practitioners and experts as beneficial to an individual needing such care.
Standard Operating Procedure (SOP)	Detailed, written instructions, in a certain format, describing all activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function.
Stigma	The negative regard (e.g., shame and dishonor) of the community or society to particular groups because of disability, illness, occupation, poverty, among others, as dictated by culture
Study Site	An institution, hospital, clinic or any community where

	participants for a study are recruited and where the actual study is conducted
Sub-investigator	Any individual member of the study team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator
Subject	An individual who participates in a research or a clinical trial as a recipient of an investigational product or an intervention.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).
Trial Site	The location(s) where trial-related activities are actually conducted.
Technical Review	The process of examining, assessing or evaluating a research

	protocol by technical experts, seasoned researchers, statisticians, and other relevant specialist or authority to ensure the scientific soundness and appropriateness of the objectives and design of the study and the qualifications of the investigator(s).
Terminated Study	A study approved by the Ethics Committee that is being recommended for termination before its scheduled completion
Vulnerability	the state of being relatively or absolutely incapable of deciding for oneself whether or not to participate in a study, for reasons such as physical and mental disabilities, poverty, asymmetric power relations, and marginalization, among others. It also refers to the increased likelihood of being wronged or of incurring additional harm
Vulnerable Persons or Groups	individuals or groups which require special protection because of certain characteristics or situations that render them relatively or absolutely incapable of deciding for themselves whether or not to participate in a study.

References:

1. International Conference on the Harmonisation of Good Clinical Practice,1997
2. Integrated Addendum to ICHE6(R1): Guideline for Good Clinical Practice E6(R2),2016
3. Standard Operating Procedures UP Manila Research Ethics Board (UPMREB),2012

APPENDIX lll

Single Joint Research Ethics Board

SJREB

STANDARD OPERATING PROCEDURES

SJREB Single Joint Research Ethics Board

STANDARD

OPERATING PROCEDURES

Department of Health
Health Policy Development and Planning Bureau Health Research Division

Published by

Health Policy Development and Planning Bureau
Department of Health
San Lazaro Compound
Rizal Avenue, Sta. Cruz
Manila 1003, Philippines

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INTRODUCTION

The Single Joint Research Ethics Board (SJREB) was institutionalized in the Department of Health through the issuance of *Administrative Order (AO) No. 2017-0021* in October 2017. This initiative has been put in place to streamline the ethics review process within the Department and contribute in the improvement of the research ethics governance system in the country.

SJREB has started its operations in March 2018. Its primary role is to host and serve as a platform for joint review of multi-site research studies sponsored by DOH and/or to be implemented across various DOH hospitals. In 2019, with the Board's commitment to further improve its processes and promote transparency, SJREB underwent joint accreditation from PHREB and the Forum for Ethical Review Committees MR%WMEERHXLI;IWXIVR4EGM5G*)6'%4 8LMWEGGVIHMXEXMSR then led to the issuance of the revised *AO No. 2019-0049: Guidelines for the Operationalization of the Single Joint Ethics Review Process for Multi-Site Researches in the Department of Health* in November 2019 which addresses the issues and KETW MHIRXM5IH MR MXW TVII\MWXMRK TVSGIHYVIW ERH VIMXIVEXIW the processes and procedures in the adoption of the single joint review system in the DOH. Further, recognizing the capacity and core functions of the SJREB, the *Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals* was also institutionalized in which the Board's primary responsibility is to assist DOH hospitals research ethics committees in MHIRXMJ]MRKERHQEREKMRKGSR5MGXSJMRXIVIWXERHSXLIVWXYH] related complaints.

The SJREB's oversight applies to all DOH units including Centers for Health Development (CHDs), Ministry of Health – Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM), hospitals, and attached agencies with research ethics committees. It also covers private research ethics committees who have agreed to participate in the single joint ethics review process. And with its recent designation by the Sub Technical Working Group (TWG) on Vaccine Development and in accordance with PHREB Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal, SJREB shall facilitate the ethics review of all COVID-19 vaccine trials to be implemented in the country following the prescribed process 5S[WIXJSVXLF]XLIZEGGMRII\TIVXWTERIP

This SOPs have been developed based on the DOH harmonized research ethics committee SOPs, PHREB and FERCAP standards, and other relevant local and international guidelines on health research ethics such as:

a. *National Ethical Guidelines for Health and Health Related Research (NEGHHRR)*
   - This PHREB document acknowledges the conduct of a joint review of a group of PHREB accredited ethics committees provided that the review abides by a standard operating procedures (SOPs) approved by PHREB

b. *Council for International Organizations of Medical Sciences (CIOMS)*
   - This international guideline highlights the conduct of single review of multi-site research in one jurisdiction (country) by one ethics committee to avoid lengthy procedures and ensure quality of the review.

8LI HSGYQIRX GSRXEMRW 5ZI MQTSVXERX GLETXIVW WYGL EW Authority, composition, and structure of SJREB; (2) Joint review process for initial submission; (3) Consolidated post-approval TVSGIHYVIW (SGYQIRXEXMSR ERH EVGLMZMRK ERH ;VMXMRK ERH revising SOPs. This SOP will be periodically reviewed and revised to address new issues and gaps that may arise over time. Also, this document will be updated as new local and international regulations, policies and guidelines are published. Meanwhile, the SJREB encourages stakeholders to send feedback and questions through S5GMEP7.6)&IQEMPEXWNVIFHSL$KQEMPGSQ

ETHICAL FRAMEWORK OF THE SINGLE JOINT RESEARCH ETHICS BOARD

The Single Joint Research Ethics Board is guided by in its review, recommendations, and decisions by the following ethical principles:

1. **Respect for Persons –** principle that states that individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
2. **&IRI5GIRGI** – principle that requires investigators to protect participants from harm and secure their well-being.
3. **Justice** – principle that refer to the sense of "fairness in distribution" and "what is deserved".

Source: *Belmont Report, 1979*

A. SJREB is guided and informed by the ethical principles, processes and procedures embedded in the following international guidelines:
   - Declaration of Helsinki (2013 and its subsequent revisions)
   - International Conference on the Harmonization of Good Clinical Practice (ICH-GCP) R2
   - Council for International Organizations of Medical Sciences (CIOMS) Guidelines 2016
   - Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011) by the World Health Organization (WHO)

B. 7.6)& WLEPP JYRGXMSR MR EGGSVHERGI [MXL XLI I\MWXMRK REXMSREP laws, policies, regulations, and guidelines such as:
   - National Ethical Guidelines for Health Research set forth by the Philippine Health Research Ethics Board (PHREB)
   - Policy issuances (i.e., Administrative Orders, Department Orders, etc.) from the Department of Health, Philippine Food and Drug Administration (FDA) and other relevant agencies such as:
   - Administrative Order No. 2019-0049
   - Department Order No. 2019-0063

C. SJREB adopts its own standard operating procedures (SOP) based on:
   - Operational Guidelines for Ethics Committees that review Biomedical Research (2000) by the WHO
   - DOH-REC SOP Templates
   - FERCAP-SOP Templates
   - PHREB SOP Workbook 2020

D. In evaluating protocols and ethical issues, SJREB is cognizant of the diversity of the laws, cultures, and practices governing health research in various local sites and countries around the world.

E. SJREB is strictly aware and abide by the relevant Philippine laws in terms of the conduct of various types of research.

F. SJREB attempts to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a proposed research is being considered.

G. SJREB will take the initiative to be informed, as appropriate, by current state-of-the art researches and publications of the impact of the research that it has approved.

SOPA. 1 STRUCTURE AND COMPOSITIONSJREB

1.1 Purpose

1.1.1. To describe the authority, composition and structure of the Single Joint Research Ethics Board (SJREB) related to the ethics review of multi-site researches.

1.1.2. SJREB is organized by the Department of Health (DOH) Health Policy Development and Planning Bureau (HPDPB) with the following objectives:

1.1.2.1. To streamline the review process of health-related protocols to be conducted in multiple sites in the Philippines.

1.1.2.2. To shorten the turn-around time of ethics review of multi-site protocols.

1.1.2.3. To harmonize the results of ethics review among various site RECs through joint review.

1.1.2.4. To strengthen the ethics review capacity of PHREB accredited RECs to review different types of protocols that are conducted at their sites.

To serve as DOH central ethics committee who shall review DOH funded research.

1.2 Scope of Authority

1.2.1. SJREB is a joint review mechanism for multi-site protocols to be implemented at various sites and as adopted by duly accredited PHREB Research Ethics Committees (RECs).

1.2.1.1. It serves as a common review platform for all DOH RECs that will sign a letter of intent to participate and accept its review.

1.2.1.2. It also covers the non-DOH hospital RECs from both the public and the private sectors that will sign a letter of intent to participate and accept its review.

1.2.2. SJREB conducts joint review of study protocols to be implemented in at least three (3) sites in the Philippines.

1.2.2.1. All DOH funded research studies shall be reviewed by SJREB.

1.2.2.2. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB.

1.2.2.2.1. At least one site is a Level 3 PHREB-accredited hospital with letter of intent.

1.2.2.3. It accepts multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED and other local organizations, including industry organizations and other foreign entities.

1.2.2.4. SJREB also accepts and reviews multicenter researches that are community-based.

1.2.3. SJREB requires the site RECs to agree and abide with the procedures that SJREB follows. All research sites should agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study.

1.2.4. SJREB facilitates the ethics review of all COVID-19 vaccine trials to be conducted in the country in compliance with its designation by the Sub-Technical Working Group for Vaccine Development and PHREB's Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal.

-X WIVZIW EW E 'IRXVEP 6)' XS VIZMI[(3, 'IRXVEP 3ŝGI funded researches. It invites all site RECs to participate in the review of DOH protocols. However, SJREB may also review the following; (a) for DOH hospital RECs that lack the required level of PHREB accreditation; and, (b) have lost or have pending reaccreditation according to the following procedures:

The site REC shall receive submissions and reports JVSQXLIWMXI4-WVIZMI[XLIMWWYIWXLVSYKLI\TIHMXIH or full board as prescribed in their SOPs, and arrive at a recommended decision. There should be an interim agreement between SJREB and the site;

The site REC should forward their recommended decision and attach relevant documents (PI submission, site REC assessment forms, minutes, etc.) to SJREB together with a request for SJREB review and oversight.

The SJREB secretariat shall receive the request, determine the appropriate review channels and procedures.

SJREB shall review the issues and arrive at an appropriate decision to be forwarded to the site REC which in turn will forward the decision to the site investigator.

1.2.6. 7.6)&QE]EPWSFIMRZSPZIHMRVIWSPZMRKGSRŝMGXSJMRXIVIWX issues and other study-related complaints implicating E (3, 6)' XLEX QE] FI GSRWXVEMRIH XS JYP5PP MXW IXLMGEP mandate. SJREB may intervene and recommend the course of action to be implemented by the DOH research unit and/ or REC in accordance with Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH Hospitals.

1.3 Structure of the Single Joint Research Ethics Board

1.3.1. Organizational Structure. The Single Joint Research Ethics Board shall be placed directly under the Health Policy (IZIPSTQIRX ERH 4PERRMRK &YVIEY,4(4& 3ŝGI SJ XLI Director to ensure independence of the board. This Bureau has the responsibility to set-up and support the SJREB SŝGI ERH WIGVIXEVMEX XS EWWMWX XLI &SEVHW MR MXW HE]XSHE] operations. See Figure 1 for the Organogram of the SJREB.

1.3.2. HPDPB Roles and Responsibilities 1.3.2.1. Administrative support to the Board.

1.3.2.1.1. It ensures the independence of the decision making of SJREB.

1.3.2.1.2. It approves the SJREB Standard operating procedures to ensure that it is in agreement with policies of DOH.

1.3.2.1.3. It ensures that SJREB provides a mechanism to educate its reviewers and staff, including site RECs to develop the necessary knowledge, skills and practice to improve the review of various types of protocols submitted.

1.3.2.1.4. It requires progress report from SJREB to assess performance as basis for continuous quality improvement. -X TVSZMHIW WYŝGMIRX WXEJJ XS WYTTSVX XLI SJREB operations.

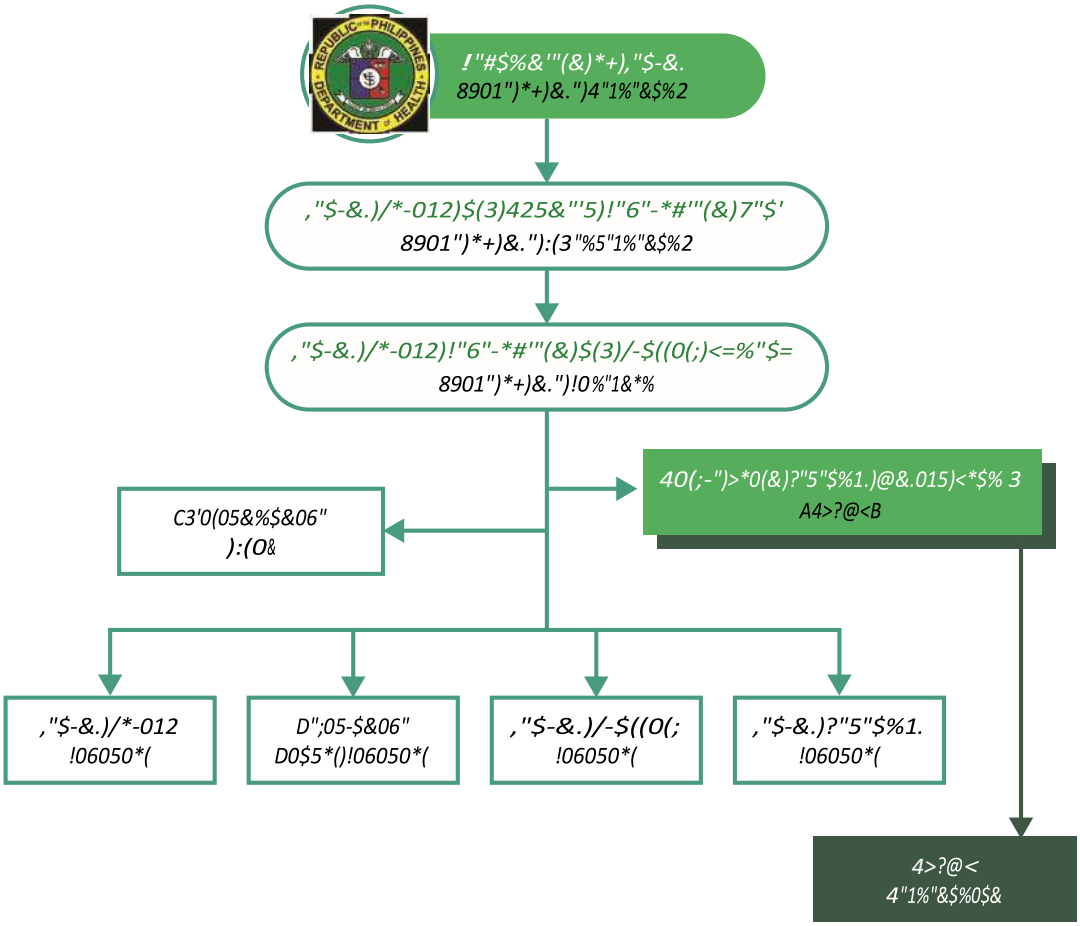
1.3.2.1.6. -X EPPSGEXIW WTEGI SŝGI IUYMTQIRX -8 infrastructure and all the necessary logistical support to enable SJREB to conduct its joint VIZMI[JYRGXMSRWIŝGMIRXP]ERHIJJIGXMZIP]

1.3.2.1.7. It provides a budget for annual update training to SJREB Members and all DOH RECs and non-DOH RECs that submitted an LOI to the Board.

1.3.2.1.8. It screens nominees and recommends SJREB members to the Secretary of Health.

***MKYVI3VKERSKVEQSJ7.6)&**

***MKYVI3VKERSKVEQSJ7.6)&**



1.3.3. 4VSGIWWŝS[ERH7XITWJSV%TTSMRXQIRXSJ7.6)&QIQFIVW

8EFPI4VSGIWWŝS[ERH7XITWJSV%TTSMRXQIRXSJ7.6)&QIQFIVW

NO.	ACTIVITIES	PERSON/S RESPONSIBLE

1	Nomination and Selection of SJREB Members	SJREB Chair and permanent members
2	Screening of Nominees and Recommendations	HPDPB Director
3	Appointment of the SJREB members	Secretary of Health

1.3.4. 2SQMREXMSR4VSGIWW

1.3.4.1. The permanent REC members, secretariat, and all participating REC members with an active LOI may nominate potential SJREB members.

1.3.4.2. 8LI MHIRXM5IH PMWX SJ RSQMRIIW WLEPP FI TVIWIRXIH to the SJREB members during a regular full board
QIIXMRKJSVXLI&SEVHXS5REPM^IWYGLEPMWX

1.3.4.3. The list of nominees will then be endorsed by XLI 7.6)& 'LEMV XS XLI ,4(4& (MVIGXSV JSV 5REP screening.

1.3.5. 7GVIIRMRKSJ2SQMRIIWERH6IGSQQIRHEXMSRW The HPDPB Director, upon receipt of the list of nominees for SJREB membership from the SJREB Chair, shall assess the submitted documents and VIGSQQIRHW XLI 5REP PMWX SJ TVSTSWIH RI[WIX SJ SJREB members to the Secretary of Health (SOH).

The HPDPB Director has the prerogative to recommend the Chair based on his/her knowledge of the competence and capacity of such nominee. This privilege is guided by the common understanding that despite the nature of such recommendation, the independence of the decision making of the Board WLSYPHWXMPPFIWXVMGXP]SFWIVZIHERHI\IVGMWIHEXEPP times.

A formal endorsement of the HPDPB's recommendation for the SJREB membership shall be
JSV[EVHIHXSXLI3ŝGISJXLI7IGVIXEV]JSVETTVSZEP

After the approval of the of the SOH, the SJREB Secretariat shall prepare the necessary documentary requirements to formalize appointment of the new SJREB members.

1.3.6. %TTSMRXQIRX4VSGIWW

1.3.6.1. The SJREB Secretariat shall ensure that the appointment documents are completed prior to engaging the SJREB members as described below.

1.3.6.2. SJREB Members

1.3.6.2.1. The Secretary of Health appoints an appropriate number of persons to form the SJREB membership to manage the SJREB operations. It may appoint consultants with relevant skills to help SJREB perform its review functions.

1.3.6.2.2. It appoints the SJREB Chair with a three-

]IEV XIVQ SJ SŧGI JVSQ TEVXMGMTEXMRK 6)'W -X IRWYVIW XLEX XLI 'LEMV LEW WYŧGMIRX FEGOKVSYRHXVEMRMRKERHI\TIVMIRGIMRIXLMGW review of various types of protocols.

1.3.6.2.3. -X ETTSMRXW E RSRQIHMGEPRSRWGMIRXM5G member, depending on the type of review, shall review the informed consent forms (ICF) and provide inputs from the community/ people's perspective.

1.3.6.2.4. -XIRWYVIWXLEXXLIVIMWERSREŧPMEXIHQIQFIV (i.e representative not coming from any of the LSWTMXEPWMXIWWTIGM5IHMRXLIVIWIEVGLFIMRK reviewed) during the SJREB meetings.

It invites the Philippine Health Research Ethics Network (PHREN) to nominate its VITVIWIRXEXMZI [MXL E 5\IH XIVQ TVIJIVEFP] from the private sector.

1.3.6.2.6. It appoints an appropriate number of HIWMKREXIH WYFNIGX I\TIVXWMRHITIRHIRX consultants who can assist SJREB review of multi-site protocols.

1.3.6.2.7. It ensures that a representative from a DOHspecialty hospital (e.g. Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.) is invited to attend review meetings related to XLIMVI\TIVXMWI

1.3.6.2.8. It shall aim for adequate representation of men and women members in order to promote gender sensitivity in its review procedures.

1.3.6.2.9. It shall have representatives from ages below]IEVWSPHERHEFSZI]IEVWSPH

1.3.6.2.10. In order to ensure continuity of functions, at least half of the SJREB shall be retained/reappointed for at least one (1) year before a new set shall be appointed.

1.3.7. 7.6)&1IQFIVWLMTERH7IGVIXEVMEX

1.3.7.1. SJREB Membership. The SJREB membership is composed of seven (7) permanent and nonpermanent members as indicated below. Independent consultants are also engaged for the review of specialized protocols.

1.3.7.1.1. 4IVQERIRX1IQFIVW

1.3.7.1.1.1. The **Chair** is a dedicated individual JVSQ ER 6)' [MXL I\TIVMIRGI XS VIZMI[HMJJIVIRX X]TIW SJ VIWIEVGLIW [MXL 5\IH term of three (3) years as stipulated in the joint review SOPs.

1.3.7.1.1.2. A **Vice Chair** may be assigned from the I\MWXMRKTIVQERIRXQIQFIVW

1.3.7.1.1.3. The **1IQFIV7IGVIXEV]** shall oversee the protocols being reviewed by the Board and ensure the accuracy of the minutes of the meeting. He/she is a plantilla staff EŧPMEXIH[MXLXLI(3,

1.3.7.1.1.4. Designated **Philippine Health Research)XLMGW2IX[SVO4,6)2 6ITVIWIRXEXMZI** JVSQ E TVMZEXI MRWXMXYXMSR [MXL E 5\IH term of three (3) years as stipulated in the joint review SOPs.

The **RSRQIHMGEP SV RSRWGMIRXM5G QIQFIV**, depending on the type of protocol submission, shall review the informed consent forms (ICF) and provide inputs from the community/ people's perspective.

1.3.7.1.1.6. 7YFNIGXQEXXIVI\TIVXW71) on Health Systems, Ethics, Social science, and Public Health.

1.3.7.1.2. 2SR4IVQERIRX1IQFIVW

1.3.7.1.2.1. The **participating site REC VITVIWIRXEXMZIW** EVI MHIRXM5IH TSMRX TIVWSRW SV WYFNIGX QEXXIV I\TIVX JVSQ the sites who are knowledgeable on the study protocols being reviewed

1.3.7.1.2.2. 7YFNIGX 1EXXIV)\TIVX 71) 2SR QIHMGEP QIQFIV JVSQ XLI WTIGMEPX] hospitals who is a designated representative from the DOH specialty hospitals to review a multi-site research i.e., Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.

1.3.7.1.3. Independent consultant is an individual who has the specialization that is not present on the permanent members assigned to review a multi-site protocol.

1.3.7.2. Secretariat 1.3.7.2.1. 1IQFIV 7IGVIXEV] MW ER E‡PMEXIH TPERXMPPE technical staff who sits as a permanent member of the Board and ensures compliance with the SOP during the entire review process.

1.3.7.2.2. ,IEH SJ 7IGVIXEVMEX,S7 is a plantilla

technical staff who shall supervise the day-today operations of the Board

1.3.7.2.3. %HQMRMWXVEXMZI7XEJJ is a dedicated staff who provides support to the HoS and Member Secretary in the administrative and clerical management of the SJREB.

1.3.8. Roles and Functions

1.3.8.1. 7.6)&1IQFIVW

1.3.8.1.1. The SJREB Chair presides over full board meetings and ensures appropriate review of protocol related documents in accordance with international and national guidelines and regulations. He/she may designate the Vice Chair or a representative from an accredited REC to preside over a meeting that he/ she cannot attend.

1.3.8.1.2. The SJREB members shall evaluate and QEREKI GSR‡MGX SJ MRXIVIWX XLEX GERRSX FI resolved at the institutional level especially for hospitals within the purview of the Department following the processes and procedures in the Department Order No. 2019-0163: Guidelines on the Implementation of Clinical Research Policy in DOH hospitals

1.3.8.2. SJREB Secretariat

1.3.8.2.1. 1IQFIV7IGVIXEV]

1.3.8.2.1.1. Oversees the conduct of the full board meeting and ensures that the review process is in accordance with the SOP

1.3.8.2.1.2. Conducts ethical review of assigned protocols as primary reviewer and TVIWIRXW VIZMI[HYVMRK I\TIHMXIH SV JYPP board meeting

1.3.8.2.2. Head of Secretariat

1.3.8.2.2.1. Manages the day-to-day activities of 7.6)&XSMRGPYHIS‡GITVSGIHYVIW

1.3.8.2.2.2. Conducts ethical review of assigned protocols as primary reviewer and TVIWIRXW VIZMI[HYVMRK I\TIHMXIH SV JYPP board meeting

1.3.8.2.2.3. 'SRHYGXW WGVIIRMRK ERH MHIRXM5IW X]TI of review of initial protocol submissions and post approval submissions

1.3.8.2.2.4. 6IGSQQIRHW I\IQTXMSR JSV VIZMI[XS the Chair

Reviews all technical and administrative documents relative to SJREB operations to include but not limited to agenda of the meeting, minutes of the meeting, RSXM5GEXMSR SJ ETTVSZEPQSHM5GEXMSRW and other post approval communication letters and documents

1.3.8.2.3. %HQMRMWXVEXMZI7XEJJ

1.3.8.2.3.1. Communicates with various clients and stakeholders, and ensuring appropriate REC and site representation during the conduct of review.

1.3.8.2.3.2. Invites reviewers from RECs of sites selected by the sponsor or researcher to conduct the study.

1.3.8.2.3.3. Ensures completeness of protocols package submitted by the Coordinating PI for SJREB review.

1.3.8.2.3.4. Checks the site REC's level of PHREB accreditation. Only level 3 REC representatives can vote during full board review of clinical trial protocols intended for FDA registration, while both levels 2 and 3 REC representatives can vote during the review of public health protocols and clinical research not intended for FDA registration. Further, it ensures fair representation in terms of the counts of votes; only one (1) vote per site.

Invites observers from study sites, without RECs or RECs with a level of accreditation not appropriate for the type of protocol being reviewed, provided that they are listed in the protocol submitted for review.

1.3.8.2.3.6. Prepares the meeting agenda and minutes of all SJREB meetings for approval of the Chair.

1.3.8.2.3.7. Checks completeness of all assessment forms accomplished by the designated primary reviewers.

1.3.8.2.3.8. Issues an appropriate decision document (i.e. Notice of Approval, Notice SJ 4VSXSGSP 1SHM5GEXMSR 'IVXM5GEXI SJ)\IQTXMSR 2SXM5GEXMSR 0IXXIV XS all participating site RECs as reviewed and approved by the HoS and Member Secretary and duly signed by the SJREB Chair.

1.3.8.2.3.9. Ensures that Letter of Intent to participate in SJREB are secured prior to attendance to any SJREB meetings.

1.3.8.3. SJREB Participating Sites

1.3.8.3.1. DOH Hospital RECs and non-DOH RECs need to submit a Letter of Intent (LOI) to SJREB to participate in joint review when their sites are selected by the sponsor for the conduct of multi-site researches. The LOI shall apply for the entire duration of participation of the RECs in the single joint ethics review. In any given circumstances, the REC may opt to withdraw any time from participation in the review process by submitting a letter of withdrawal to the SJREB Secretariat. Should an REC wish to participate in the joint review after withdrawal, they should submit a new LOI to SJREB.

1.3.8.3.2. All DOH Hospital RECs and non-DOH RECs EVI I\TIGXIH XS EGGITX XLI VIWYPXW SJ 7.6)& VIZMI[[LIVIUYEPM5IHWMXI6)'WTEVXMGMTEXIH in the deliberations and decision making

I\GITX [LIR XLIVI EVI WXVSRK IXLMGEP MWWYIW ERHSVWMXIWTIGM5GGSRGIVRWXLEXGERRSXFI addressed. For non-DOH hospitals, their RECs retain the option to accept or reject SJREB decision.

1.3.8.3.3. All RECs participating in joint review agree to share their review responsibilities with SJREB as follows:

1.3.8.3.3.1. Authority is shared by a duly accredited site REC with SJREB to conduct joint review with representatives from site RECs of multi-site researches. Joint review by SJREB is done only for initial review and renewal of approval. SJREB conducts full board review of clinical trials for investigational medicinal products intended for FDA registration. All participating sites are invited to send a representative to join the deliberations and arrive at a joint decision. Low risk TVSXSGSPWQE]FII\IQTXIHJVSQVIZMI[SV QE] KS XLVSYKL I\TIHMXIH VIZMI[procedures.

1.3.8.3.3.2. All RECs who will participate in joint review should submit their membership list with their CVs and they should MHIRXMJ] VITVIWIRXEXMZIW UYEPM5IH XS HS WGMIRXM5G ERH IXLMGEP VIZMI[JSV ZEVMSYW types of protocols commonly submitted for review.

1.3.8.3.3.3. All DOH Hospital RECs and non-DOH 6)'WEVII\TIGXIHXSEGGITXXLIVIWYPXW SJ 7.6)& VIZMI[[LIVI UYEPM5IH WMXI RECs participated in the deliberations ERH HIGMWMSR QEOMRK I\GITX [LIR there are strong ethical issues and/ SV WMXI WTIGM5G GSRGIVRW XLEX GERRSX be addressed. All site RECs will issue a 'IVXM5GEXISJ%TTVSZEPXSKIXLIV[MXLXLI Notice of Decision from SJREB.

1.3.8.3.3.4. The site REC retains its review functions related to protocol amendments, SAE reports, protocol deviation and violation VITSVXW ERH 5REP VITSVXW EPP SJ [LMGL MRZSPZIIZIRXWEXWTIGM5GWMXIW8LIWMXI REC, meanwhile, has the prerogative to elevate protocol deviation to SJREB and provide corrective actions. The site REC maintains active collaboration and communication with SJREB for joint review to achieve its WXEXIHSFNIGXMZIWERHJSVQYXYEPFIRI5X of improving the research environment in the Philippines.

1.3.8.3.3.6. For site RECs that have lost or pending accreditation, the REC should still conduct review of the protocol. The REC then has the responsibility to submit the result of the review to SJREB for any further discussion or approval.

1.4 7.6)&0IXXIVSJ-RXIRXERH3ZIVWMKLX*YRGXMSR

1.4.1. Purpose

To describe the process of engaging participating sites in the NSMRXIXLMGWVIZMI[TVSGIWWERHHI5RIXLISZIVWMKLXJYRGXMSR of the SJREB

1.4.2. Scope

The Letter of Intent (LOI) is an agreement between the participating site(s) and SJREB whereby the site acknowledges and agrees to participate in the joint review process being conducted by the SJREB and abide by all its policies and guidelines set forth in this SOP and other relevant issuances.

1.4.3. Responsibility

1.4.3.1. It is the responsibility of the participating sites to submit a letter of intent (See SJREB Form 12) to 7.6)&XLVSYKLMXW7IGVIXEVMEXI\TVIWWMRKXLIMRXIVIWX to participate in the joint review process

1.4.3.2. The SJREB Secretariat shall receive and facilitate the necessary documents to formalize such engagement. The LOI shall then be endorsed to the Director of the HPDPB for conforme.

1.4.3.3. *SV WMXIW [LS LEZI FIIR MHIRXM5IH XS TEVXMGMTEXI MR a clinical trial but do not have the required PHREB accreditation level, the SJREB may assume oversight functions following the conditions below:

1.4.3.3.1. Adopt the SJREB standard operating procedures as part of the REC's SOPs in compliance with AO no. 2019-0049;

1.4.3.3.2. Attend SJREB meetings when the indicated protocol is being discussed.

1.4.3.3.3. Accept the decision of the SJREB for implementation at the site.

1.4.3.3.4. Submit results of the REC review of the protocol to SJREB.

Monitor the study implementation and submit the REC's recommendations to SJREB about action on reports submitted by the PI.

1.4.3.3.6. Inform SJREB at any time that the REC has been given its PHREB accreditation.

1.4.4. 4VSGIWW*PS[7XITW

8EFPI4VSGIWWsS[ERH7XITWJSV03-ERH3ZIVWMKLX*YGXMSR		
NO.	**ACTIVITIES**	**PERSON/S RESPONSIBLE**
1	Submit LOI to SJREB Secretariat	Participating site(s)
2	Receive and process documents formalizing engagement	Secretariat
3	Issue conforme letter to the participating site	HPDPB Director, Secretariat

1.4.5. Detailed instructions

Submit LOI to SJREB Secretariat

The participating site shall prepare the LOI duly signed by their respective REC Chairperson using SJREB Form 12.

The signed LOI shall be submitted to the SJREB Secretariat for approval of the HPDPB Director.

Receive and process documents

The SJREB Secretariat shall acknowledge and process the necessary documents

to formalize the engagement with the participating site.

Issue conforme letter to the participating sites

The signed conforme letter from the HPDPB Director shall be provided and issued to the participating site by the SJREB Secretariat

1.5 8VEMRMRKSJ7.6)&1IQFIVWERH7XEJJ

1.5.1. Purpose

To describe **SJREB** procedures to ensure initial and continuing training of members and staff

1.5.2. Scope

The SJREB recognizes the importance of training and continuing professional development. This SOP describes the training requirements of SJREB members and staff from initial training to continuing education to maintain and update competence in the review of different types of protocols.

1.5.3. Responsibility It is the responsibility of the SJREB members and staff to have themselves educated and trained regularly.

It is the responsibility of the SJREB Chair along with the Secretariat to assess the training needs and prepare a training plan for all members, Independent Consultants, and staff. The chair may assign a permanent member to lead capacity building related activities.

The Secretariat keeps track of the training records of all members, Independent Consultants, and staff in accordance with the training plan.

1.5.4. 4VSGIWW*PS[7XITW

8EFPI4VSGIWW5S[ERH7XITWJSV03-ERH3ZIVWMKLX*YGXMSR

NO.	ACTIVITIES	PERSON/S RESPONSIBLE	TIMELINE
1	Require basic research ethics training for all members and staff	Chair	Needs assessment to be done at the beginning of the year
2	Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses	Chair, Secretariat	

3	Track member and staff participation initial and continuing Members, IXLMGWXVEMRMRKERH5PI Secretariat the documents in the Membership File	

1.5.5. Detailed instructions REC members should maintain competence by ensuring that they have updated knowledge of the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc.
- International meetings and conferences

Require Research Ethics Training for all members and staff

All members are required to have basic research ethics training that shall consist of research ethics principles, GCP, SOPs, etc. Upon appointment, a new member or staff undergoes orientation, individually or as a group, to cover the following:

Member's/Staff's responsibilities; 'SR5HIRXMEPMX] ERH 'SR5MGX SJ -RXIVIWX Agreement;

Review process and use of Protocol and ICF Assessment forms; and, SOPs.

The Chair and Member-Secretary shall ensure that initial research ethics training is provided to all new members.

Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses

The Chair provides training opportunities to members/staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.

The Chair and Secretariat plan the training activities for individual members based on their training needs.

The Chair and Secretariat track and facilitate EXXIRHERGISJQIQFIVWERHWXEJJSJWTIGM5G training activities needed to ensure that each one gets training at least once a year.

The members who participate in research ethics training course or seminar-workshops either through personal or through REC efforts/funding are encouraged to:

Share information with other members during meetings; and,
Distribute photocopies/e-copies of relevant materials to the other members.

Track member and staff participation in initial and
GSRXMRYMRKIXLMGWXVEMRMRKERH5PIXLIHSGYQIRXWMR the Membership File

For in-house training, the SJREB Staff prepares attendance sheets with relevant information about the topic, duration, date and venue. They ask member-attendees to sign the attendance sheet and keeps a photocopy SJXLIEXXIRHERGIMRXLIQIQFIVWLMT5PIWMJ 8VEMRMRK'IVXM5GEXIMWRSXKMZIR

All members and staff should regularly update their Training Record. They should submit proof of attendance in relevant training or continuing professional education sessions conducted outside of the institution – e.g.

GIVXM5GEXIW SJ XVEMRMRK XS XLI 6)' 7XEJJ JSV 5PMRK

Administrative Staff should update the Training Record of individual Member and 7XEJJ XS VI5IGX XLIMV EXXIRHERGI MR XVEMRMRK activities every time a photocopy of Training 'IVXM5GEXIMWWYFQMXXIHJSV5PMRK

The joint review process shall serve as an avenue for FYMPHMRK GETEGMX] SJ XLI 6)'W F] I\TSWMRK XLIQ XS wide variety of protocols and best review practices JVSQI\TIVXTVMQEV]VIZMI[IVW7.6)&QE]EPWSMRZMXI observers from study sites without RECs or RECs with a level of accreditation not appropriate for the type of protocol being reviewed, provided that they are listed in the protocol submitted for review.

B. SOP 2 JOINT REVIEW OF PROTOCOLS

2.1 Purpose

To describe the Single Joint Research Ethics Board (SJREB) requirements and procedures in conducting initial and continuing review of multi-site protocol related documents, vis-a-vis the site RECs.

2.2 Scope

This procedure applies to all multi-site protocols submitted to the SJREB for initial ethics review.

2.2.1. Sponsors and investigators may submit a protocol to SJREB if it's one of the following:

2.2.1.1. Sponsored or funded by the Department of Health

2.2.1.2. Multi-site protocol to be conducted in at least 3 sites
[MXLEXPIEWXSRI WMXIMHIRXM5IHEWWMXI[MXLXLIJJ
UYEPM5GEXMSRW

2.2.1.2.1. Level 3 hospital

2.2.1.2.2. At least one (1) site with a Letter of Intent
03- [LMGLWTIGM5IWXLEX

2.2.1.2.2.1. SJREB reviews the country protocol
2.2.1.2.2.2. PIs shall submit to both SJREB and the sites
2.2.1.2.2.3. Sites accept the SOPs of SJREB for the joint review of protocols
2.2.1.2.2.4. 3RP] WMXI WTIGM5G QSHM5GEXMSRW WLEPP FI EPPS[IH 2S QSHM5GEXMSRW XS XLI approved country protocol shall be required by the participating sites.
Site accepts the decision of SJREB unless there is compelling ethical, legal SV WGMIRXM5G GSRGIVRW 6IEWSRW JSV WMXI disapproval shall be submitted to SJREB ERHQYWXFINYWXM5IH
2.2.1.2.2.6. Disapproval of protocol shall mean that the site is opting out as a site for the study.

2.2.2. SJREB requires an LOI to regularly participate in joint review from all Research Ethics Committees when their sites are selected by the sponsors as a study. The LOI shall be effective unless a withdrawal of the intent to participate is submitted in writing.
2.2.3. SJREB requires the site RECs to agree and abide with the procedures of SJREB
2.2.4. All research sites agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study.
In sites with no REC or has a functional REC with PHREB accreditation that is not appropriate for the type of protocol being reviewed, SJREB may either assume the oversight function of the site or choose to assign a PHREB-accredited REC to do the review and oversight. The determination will depend on the type and nature of the protocol to be implemented. The designated oversight REC shall issue
XLI GIVXM5GEXI SJ ETTVSZEP ERH EWWYQI WXI[EVHWLMT ERH monitoring functions.

2.3 Responsibility

2.3.1. The permanents members, independent consultant, and participating sites representatives act as primary reviewers and attend board meeting
2.3.2. The members review and decide make decisions on the protocol
2.3.3. The SJREB Secretariat manages all protocol submissions to the SJREB.

2.4 8]TIWSJ6IZMI['PEWWM5GEXMSRSJ4VSXSGSPW 7YFQMXXIHJSV-RMXMEP6IZMI[

7.6)&GPEWWM5IWTVSXSGSPWMRXSX]TIWXSHIXIVQMRIXLIETTVSTVMEXI type of review of multi-site protocols. The Head of Secretariat makes a preliminary assessment of protocols and recommends the type of VIZMI[XSXLI'LEMV[LSETTVSZIWXLIGPEWWM5GEXMSR

2.4.1. (IXEMPIHTVSGIHYVIWJSVXLIXLVIIVIZMI[X]TIW

2.4.1.1.)\IQTXMSRJVSQ)XLMGW6IZMI[

2.4.1.1.1. The Head of Secretariat makes a preliminary assessment of the protocol using the SJREB *SVQ 'LIGOPMWX JSV)\IQTXMSR JVSQ *YPP Ethical Review Form to determine if it meets XLII\IQTXMSRGVMXIVMEEWJSPPS[W

2.4.1.1.2. Protocols that neither involve human TEVXMGMTERXW RSV MHIRXM5EFPI LYQER XMWWYI biological samples, and data (e.g. metaanalysis protocols)

2.4.1.1.3. Protocols that involve human participants or MHIRXM5EFPILYQERXMWWYIFMSPSKMGEPWEQTPIW and data provided that the following do not involve more than minimal risks or harm:

2.4.1.1.3.1. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

2.4.1.1.3.2. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

2.4.1.1.3.3. No disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or FI HEQEKMRK XS XLIMV 5REP WXERHMRK employability, or reputation; and

2.4.1.1.3.4. Information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through MHIRXM5IVWPMROIHXSXLITEVXMGMTERX

Protocols that involve the use of publicly availaďůĞĚłĂŽđŝŶĨŽđŵĂΘŽŶ

2.4.1.1.4. The Head of Secretariat and a senior member of the board reviews the protocol and makes E HIXIVQMREXMSR JSV I\IQTXMSR -R GIVXEMR GMVGYQWXERGIWI\IQTXMSRQE]FIHMWGYWWIH MR ER I\TIHMXIH QIIXMRK 8LI TVSXSGSP JSV I\IQTXMSRWLEPPFIVITSVXIHMRXLIJYPPFSEVH review for the information of the Board. The reviewer(s) submits the SJREB Form 4: 'LIGOPMWX JSV)\IQTXMSR XS XLI 7IGVIXEVMEX seven (7) calendar days before the full board meeting.

7.6)& MWWYIW E 'IVXM5GEXI SJ)\IQTXMSR (SJREB Form 4.1) signed by the Chair within seven (7) calendar days after the decision.

2.4.1.1.6. Should there be any major protocol change EJXIV XLI MWWYERGI SJ XLI 'IVXM5GEXI SJ)\IQTXMSR XLI 'SSVHMREXMRK 4- WLEPP WYFQMX an amendment to SJREB to make a decision EFSYXGLERKISJGPEWWM5GEXMSR

2.4.1.2.)\TIHMXIH6IZMI[

2.4.1.2.1. The Head of Secretariat makes a preliminary assessment of the protocol and determines UYEPM5GEXMSR JSV I\TIHMXIH VIZMI[FEWIH SR the following criteria:

2.4.1.2.1.1. Does not involve more than minimal risks or harm but does not qualify for I\IQTXMSR

2.4.1.2.1.2. About a topic that should not result in causing social stigma

2.4.1.2.1.3. Does not involve vulnerable populations

2.4.1.2.1.4. Retrospective studies using anonymized data from medical records
Studies using simple questionnaires
[MXLSYXMHIRXM5IVW 2.4.1.2.1.6. Proposals such as:

2.4.1.2.1.6.1. Chart review
2.4.1.2.1.6.2. Survey of non-sensitive nature
2.4.1.2.1.6.3. Use of anonymous or anonymized laboratory/pathology samples or stored tissue or data

2.4.1.2.2. The Head of Secretariat recommends the type of review to the Chair who approves the GPEWWM5GEXMSR

2.4.1.2.3. 8LI ,IEH SJ 7IGVIXEVMEX MHIRXM5IW X[S SV more primary reviewers from the permanent members and/or participating sites to conduct MRMXMEP VIZMI[XLVSYKL I\TIHMXIH TVSGIHYVIW SJREB may also call for a meeting of the sites XSI\TIHMXIXLIVIZMI[

2.4.1.2.4. The primary reviewer(s) should review within seven (7) calendar days using appropriate SJREB assessment forms. The primary VIZMI[IVW QE] VIGSQQIRH QSHM5GEXMSRW and decide on the approval of the protocol documents.

If any of the PR recommends disapproval, it is automatically elevated to full board.

2.4.1.2.6. The Head of Secretariat may recommend to LSPH ER I\TIHMXIH QIIXMRK [LIR RIGIWWEV] with the attendance of the secretariat and XLITVMQEV]VIZMI[IVW8LII\TIHMXIHVIZMI[VITSVX WLEPP FI 5REPM^IH F] XLI 1IQFIV Secretary for reporting in the full board meeting.

2.4.1.2.7. The SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the Coordinating Principal Investigator (PI) within fourteen (14) calendar days after protocol submission.

2.4.1.2.8. The SJREB secretariat endorses the decision of SJREB to participating sites. SJREB I\TIGXW XLI TEVXMGMTEXMRK WMXIW XS EGGITX MXW HIGMWMSR)EGL WMXI QE] EHH WMXI WTIGM5G recommendation to SJREB Decision.

2.4.1.2.9. The site REC isƐƵĞƐĂĞđΘĮĐĂłĞŽĬĐĐđŽ|Ăů

2.4.1.3. *YPP&SEVH6IZMI[

2.4.1.3.1. The Head of Secretariat makes a preliminary EWWIWWQIRX SJ XLI TVSXSGSP ERH MHIRXM5IW more than minimal risk protocols for full board review.

2.4.1.3.2. The Head of Secretariat assigns primary reviewers from site RECs or invites independent consultants to review the protocol and the ICF.

2.4.1.3.3. The SJREB secretariat informs the site RECs of its receipt of protocols for full board joint review. Participating RECs conduct a preliminary assessment of the protocol and prepare comments/ recommendations on the protocol to be presented during the full board review.

2.4.1.3.4. The assigned primary reviewers shall prepare their comments using appropriate SJREB assessment forms and lead the discussion about the protocol during the board meeting. Other SJREB and participating sites representatives contribute to the discussion.

The SJREB Secretariat schedules the date of the full board meeting, prepares the meeting agenda and informs the members of the board, the site REC representatives, the assigned primary reviewers, as well as SME JVSQRIGIWWEV]5IPHWSJI\TIVMIRGIXSEXXIRH the meeting.

2.4.1.3.6. The Coordinating PI shall be invited for a GPEVM5GEXSV]MRXIVZMI[XSERW[IVUYIVMIWEFSYX the protocol.

2.4.1.3.7. The board adopts one of the following decisions during joint review:

2.4.1.3.7.6.1. Approval
2.4.1.3.7.6.2. 1MRSVQSHM5GEXMSRVIUYMVIH
2.4.1.3.7.6.3. 1ENSVQSHM5GEXMSRVIUYMVIH
2.4.1.3.7.6.4. Disapproved

2.4.1.3.8. The SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the Coordinating PI and to all the participating sites within fourteen (14) calendar days after the Full Board meeting.

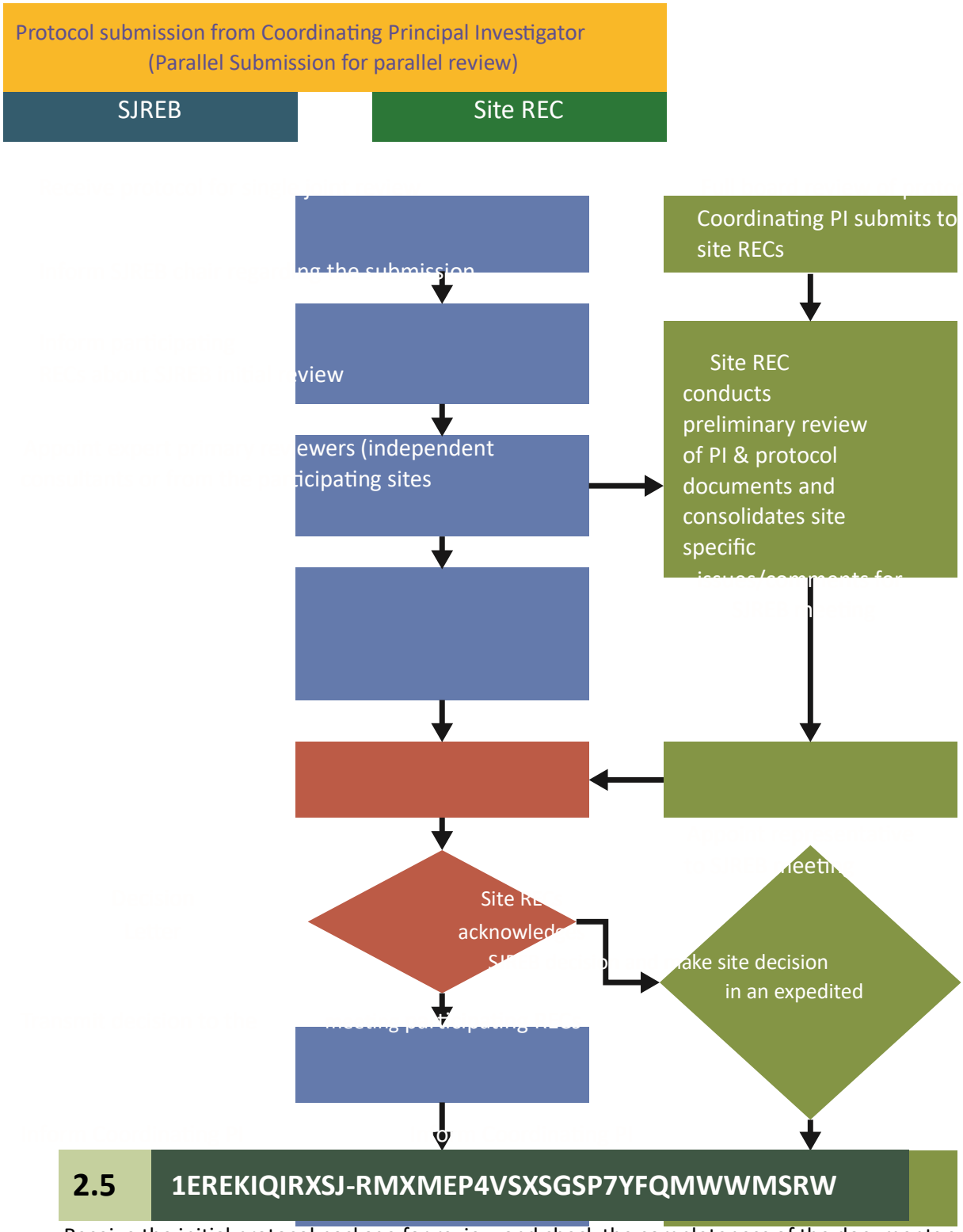
2.4.1.3.9. For protocols with recommendations for QSHM5GEXMSR XLI 'SSVHMREXMRK 4- MW KMZIR 5JXIIR GEPIRHEVHE]WXSWYFQMXEVIZMWIH protocol.

2.4.1.3.10. Site RECs acknowledges SJREB decision and QEOI WMXIWTIGM5G HIGMWMSRW MR ER I\TIHMXIH meeting.

2.4.1.3.11. All DOH Hospital RECs and non-DOH RECs [MXL 03- EVI I\TIGXIH XS EGGITX XLI VIWYPXW SJ 7.6)& VIZMI[[LIVI UYEPM5IH WMXI 6)'W participated in the deliberations and decision QEOMRKI\GITX[LIRXLIVIEVIWXVSRKIXLMGEP MWWYIW ERHSV WMXI WTIGM5G GSRGIVRW XLEX cannot be addressed. Each site REC shall MWWYIE'IVXM5GEXISJ%TTVSZEPSVERSXMGISJ its decision clearly stating the ethical issues, if it chooses to disapprove the protocol.

2.4.1.3.12. The site in general can no longer introduce QENSV QSHM5GEXMSR SR XLI GSYRXV] TVSXSGSP However, the site RECs can disapprove the protocol only when they think that there EVI WXVSRK IXLMGEP MWWYIW SV WMXI WTIGM5G concerns that were not addressed. Reasons for disapproval should always be stated in the decision letter. Meanwhile, the ICF may be revised in any manner the site REC requires.

*MKYVI-RMXMEPERH%RRYEP6IRI[EPSJ%TTVSZEP6IZMI[4VSGIHYVIW



2.5 1EREKIQIRXSJ-RMXMEP4VSXSGSP7YFQMWWMSRW

Receive the initial protocol package for review and check the completeness of the documents submitted

SJREB Secretariat ensures that SJREB Form 1: Application for SJREB Initial Review and SJREB Form 1.2: Protocol 7YQQEV]7LIIXEVIGSQTPIXIP]5PPIHSYXWMKRIHERHHEXIHF] the Coordinating PI submitting the protocol documents.

The following documents should be submitted in the initial protocol package:

Basic Documents:

Application Form [SJREB Form 1 - Application Form]
Protocol Summary Sheet [SJREB Form 1.2 - Protocol Summary Sheet]
Study Protocol
Informed Consent Forms
Recruitment and Advertisement Materials Data Collection Forms
Curriculum vitae of principal investigators
Study Budget
Technical Clearance
Proof of submission to at least three (3) study sites

7XYH]WTIGM5G(SGYQIRXWWYFQMXEWRIIHIH FDA Approval/ Proof of submission (for clinical trials)

Patient Information Sheet (for clinical trials) Investigator Brochure (for clinical trials) &EWMG6IWIEVGL)XLMGW8VEMRMRK'IVXM5GEXIWSJ PIs (for non-clinical trials)

+'4GIVXM5GEXIWSJ4-WJSVGPMRMGEPXVMEPW
Other protocol-related documents

SJREB may require Coordinating PI to submit to SJREB WTIGM5G TVSXSGSPVIPEXIH HSGYQIRXW WYFQMXXIH XS XLI PSGEP RECs.

SJREB requires proof of submission of protocol to at least three (3) sites, with at least one (1) DOH hospital or a level 3 6)'[MXL03-MHIRXM5IHEWWMXITVMSVXSEGGITXERGIJSVIXLMGW review.

3RI LEVHGST]ERHWSJXGST]WIRXIMXLIVZMEIQEMPƽEWL drive, or CD) of the above documents shall be submitted to the SJREB.

The SJREB full board meeting is scheduled every second Wednesday of the month. The deadline for protocol submission for full board meeting is fourteen (14) calendar days prior (last Wednesday of the preceding month) to the RI\XQIIXMRK

Assign a permanent code to the protocol package

*SV IƺGMIRX 5PI QEREKIQIRX MX MW RIGIWWEV] JSV 7.6)&WXEJJXSYWIEYRMUYIMHIRXM5IVXSVIJIVXSXLMW 5PI XLI 4VSXSGSP 'SHI 2YQFIV 8LMW GSHI RYQFIV is given as follows: SJREB-yyyy (year) –number (chronological number based on order of receipt).

*SV I\EQTPI MJ XLI TVSXSGSP IRXMXPIH ƈ'PMRMGEP (VYK 8VMEPSJ<=>SR4IHMEXVMG4EXMIRXWĐMWXLI5VWXTVSXSGSP received in 2017, the code SJREB-2017-01 should be used to identify this protocol. The code shall be used on all communications regarding the protocol.

Determine the Type of Review and assign primary reviewers The Head of Secretariat makes a determination about the appropriate type of review and seeks approval of XLI'LEMVSRXLIVIZMI[GPEWWM5GEXMSR

8LI ,IEH SJ 7IGVIXEVMEX MHIRXM5IW SRI TVSXSGSP reviewer and one (1) as ICF reviewer from the permanent members or from members of TEVXMGMTEXMRK WMXI 6)'W JSV JYPP FSEVH ERH I\TIHMXIH protocols.

Distribute the Initial Protocol Documents to the Primary Reviewers

The SJREB Staff sends copies of protocol documents together with the SJREB Form 2: Protocol Assessment Form and SJREB Form 3: Informed Consent Assessment Form, with the transmittal letter to the primary reviewers.

The initial protocol documents should be distributed to the Primary Reviewers seven (7) calendar days before the full-board meeting.

2.6 *YPP&SEVH6IZMI[4VSGIHYVIW

2.6.1. Before Full-Board Meeting

2.6.1.1. The Coordinating PI submits the multi-site protocol HSGYQIRXW XS XLI MHIRXM5IH WMXIW EX PIEWX X[S weeks prior to submission to SJREB.

2.6.1.2. The site RECs conduct their preliminary review of the protocol documents and identify a representative who will participate in the discussion during the Full&SEVH 7.6)& QIIXMRK XS VI5IGX XLI ZMI[W SJ XLIMV own REC.

2.6.1.3. The SJREB staff schedules the Joint Review meeting and checks the availability of the regular SJREB members, independent consultants, and representatives of the participating RECs to determine if quorum will be met. Quorum requires attendance SJEXPIEWX5ZI 7.6)&ZSXMRKQIQFIVWMRGPYWMZI of the presence of at least 4 out of 7 permanent members and at least one (1) participating site representative. Further, there should be at least one QIQFIV [LS MW RSRQIHMGEPRSRWGMIRXM5G ERH EXPIEWXSRI QIQFIV[LSMWRSRE‡PMEXIHJVSQE non-DOH site).

2.6.1.4. Attendance of members through video conference is allowed.

The SJREB secretariat prepares and sends the agenda to all participating sites. Prior to dissemination, the HoS should review the prepared agenda of the QIIXMRKXSGLIGOMJMXIQWEVITVSTIVP]GPEWWM5IHERH presented. The agenda should include information about the following: a. date, time, and venue of the joint SJREB full-board meeting, b. full details about the protocol (number, title, sponsor, coordinating PI, sites) for initial review and renewal of approval.

2.6.1.6. The SJREB full board meeting is regularly scheduled on the second Wednesday of the month or more frequently depending on the volume of protocol submissions. An emergency meeting may also be conducted to facilitate review of urgent protocols 7II %TTIRHM\ & +YMHIPMRIW JSV VIZMI[TVSGIHYVIW during a public health emergency or during an epidemic) and critical issues needing the Board's immediate decision.

2.6.2. During Full-Board Meeting

2.6.2.1. A full-board SJREB meeting is convened to discuss and recommend a decision about the protocol and related documents. The SJREB members attending the full board meeting have to review and comment on the following:

2.6.2.1.1. Protocol;
2.6.2.1.2. Informed Consent;
2.6.2.1.3. PI and research team;
2.6.2.1.4. Study sites covered by the application; Advertisements, etc.

2.6.2.2. Designated primary reviewers shall submit the accomplished and signed SJREB Form 2: Protocol Assessment Form and SJREB Form 3: Informed Consent Assessment Form during the full-board meeting.

2.6.2.3. The SJREB secretariat invites the Coordinating PI XS EXXIRH XLI QIIXMRK JSV GPEVM5GEXSV] MRXIVZMI[XS answer questions about the protocol.

2.6.2.4. The SJREB members discuss protocol documents ERH ZSXI SR WTIGM5G MXIQW XS EVVMZI EX E HIGMWMSR as follows (voting requirements are discussed in Chapter 1):

2.6.2.4.1. %TTVSZEP[LIRRSJYVXLIVQSHM5GEXMSRMW required)

2.6.2.4.2. 1MRSV QSHM5GEXMSR VIUYMVIW QMRSV changes in the documents such as typographical errors, administrative MWWYIWEHHMXMSREPI\TPEREXMSRWIXG

2.6.2.4.3. 1ENSV QSHM5GEXMSR VIUYMVIW VIZMWMSR of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)

2.6.2.4.4. Disapproval (due to ethical, legal or WGMIRXM5G GSRGIVRW 6IEWSRW JSV ZSXI of disapproval should be noted in the minutes and coŵŵƵŶŝĐĂŧĞĚŧŽŧŚĞW/

If the study is approved, SJREB determines the frequency of continuing review. All meeting deliberations and decisions regarding a protocol shall be noted in the meeting minutes.

2.6.2.6. Copies of meeting minutes and SJREB decision TIVXEMRMRKXSXLIWTIGM5GTVSXSGSPEVIWIRXXSXLIWMXI RECs for their information.

2.6.2.7. Site RECs shall submit to SJREB copies of their 'IVXM5GEXISJ%TTVSZEP2SXMGISJ(IGMWMSR

2.6.3. After the Full-Board Meeting

2.6.3.1. The SJREB secretariat communicates the notice of QSHM5GEXMSRHIGMWMSRXSXLI'SSVHMREXMRK4-

2.6.3.2. Once the SJREB board approves the protocol related documents, the decision of SJREB is communicated to the Coordinating PI and all the participating site RECs.

2.6.3.3. Investigators may appeal the decision of SJREB by writing a letter requesting for reconsideration with reasons clearly stated and submission of a new protocol. Any appeal shall be taken up at full board meeting.

2.6.3.4. All DOH Hospital RECs and non-DOH RECs with an 03- EVI I\TIGXIH XS EGGITX XLI VIWYPXW SJ 7.6)& VIZMI[[LIVIUYEPM5IHWMXI6)'WTEVXMGMTEXIHMRXLI HIPMFIVEXMSRW ERH HIGMWMSR QEOMRK I\GITX [LIR XLIVI EVI WXVSRK IXLMGEP MWWYIW ERHSV WMXI WTIGM5G concerns that cannot be addressed. The site REC GSRHYGXW ER I\TIHMXIH VIZMI[SJ XLI ETTVSZIH TVSXSGSPXSEHHVIWWWMXIWTIGM5GGSRGIVRWERHMRJSVQ the PI of the local site of the outcome of the SJREB review as well as the outcome of the local REC review. All site REC decisions should be reported to SJREB and copy of decisions should be provided to the SJREB Secretariat.

The SJREB secretariat prepares the Minutes of the SJREB Full-Board Meeting as follows:

8LI 7.6)& WIGVIXEVMEX 5PPW SYX XLI FEWMG information about each protocol submission for review in the SJREB Meeting Minutes template with identifying information (Protocol number, title, PI, sponsor, etc.) before the meeting date.

As the SJREB meeting proceeds, the SJREB Secretariat takes minutes of the meeting on real time according to the prescribed format and projects this on the multimedia screen to enable the SJREB Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by XLI 7.6)& 'LEMV 4VIWMHMRK 3ŧGIV 8LI SJREB decisions and

recommendations are GSPPIGXMZIMRREXYVI2SEXXVMFYXMSRXSWTIGM5G SJREB member is stated in the minutes. The meeting minutes should include the following items:

Date and venue of the meeting
4VIWMHMRK3ŧGIV
Attendance of REC representatives
QIHMGEPWGMIRXM5G RSRQIHMGEPRSR WGMIRXM5G RSREŧPMEXIH [MXL XLI WXYH] site)
Attendance of independent consultants
Attendance of coordinating PI and guests or observers, if any
Time when the meeting was called to order
Status of quorum at the start of the meeting and before every decision making
Discussion of items based on the order in the meeting agenda
Summary of technical and ethical discussion points and recommendations
SJREB decision and voting results according to decision categories, abstention and votes for disapproval with reasons given.

If the review decision (for initial and continuing reviews) is “approved”, the frequency of submission of progress reports are determined.

If the review decision is disapproved, the reasons for the disapproval are stated.

If the review decision (for initial and continuing reviews) is “for QSHM5GEXMSRĐ XLI MXIQW XS FI VIZMWIH EVI MHIRXM5IH ERH XLI X]TI of review for the resubmission is HI5RIH

Attach the list of protocols for I\IQTXMSR ERH TVSXSGSPW ETTVSZIH XLVSYKL I\TIHMXIH VIZMI[VITSVX JSV XLI information of the board. Name and signature of the person who prepared the minutes

Name and signature of the Chair who approved the minutes with the date of approval

2.6.3.6. The SJREB secretariat sends the draft meeting minutes to the SJREB Members for their review and comments within 7 calendar days before the succeeding meeting. Prior to dissemination of the minutes of the meeting, the secretariat shall seek approval from the HoS for the release of the document.

2.6.3.7. (YVMRKXLIRI\XJYPPFSEVHQIIXMRKXLI'LEMVEWOWXLI members to approve the Minutes.

2.6.3.8. 8LI7.6)&7XEJJ5PIWETTVSZIHQIIXMRKQMRYXIWMRXLI online database of Meeting Minutes.

2.7 'SRXMRYMRK6IZMI[4VSGIHYVIW

2.7.1. The following documents shall be submitted to SJREB for continuing review:

2.7.1.1. Amendment of the country protocol
2.7.1.2. Progress report
2.7.1.3. Final report
2.7.1.4. Protocol violation/ deviation
Early termination report

2.7.2. The SJREB secretariat keeps the continuing review application package together with the review comments of the primary reviewer/s and the SJREB decision in the protocol 5PIJSPHIVERHYTHEXIWXLI3RPMRI(EXEFEWISJ%GXMZI7XYH] Files.

2.7.3. Detailed Procedures

2.7.3.1. Amendment of the country protocol

2.7.3.2. The Coordinating PI submits to SJREB any amendments to the previously approved protocol documents.

2.7.3.3. The Head of Secretariat makes a preliminary assessment of the amendment and determines the type of review necessary.

2.7.3.4. Amendments that may potentially alter the risk/ FIRI5X VEXMS MW VIJIVVIH XS JYPP FSEVH VIZMI[JSV discussion, including but not limited to the following:

2.7.3.4.1. Change in study design

2.7.3.4.2. Change in the number of subjects

2.7.3.4.3. 'LERKI MR XLI MRGPYWMSR SV I\GPYWMSR criteria

2.7.3.4.4. Addition or removal of treatments

Change in the method or route of drug administration

2.7.3.4.6. Change in drug dosage

Minor changes that does not potentially alter the VMWOFIRI5X VEXMS MW VIJIVVIH XS XLI SVMKMREP 4VMQEV] Reviewers.

2.7.3.6. The SJREB secretariat sends the amendment report to the primary reviewers at least seven (7) calendar days before full-board meeting.

2.7.3.7. 8LI7.6)&WIGVIXEVMEXRSXM5IWEPPWMXI6)'WEFSYXXLI amendment application.

2.7.3.8. Approval of amendment application reviewed by XLI 4VMQEV] 6IZMI[IVW F] I\TIHMXIH TVSGIHYVI MW reported to the board meeting.

2.7.3.9. The SJREB staff communicates the decision of the SJREB to the Sponsor/ Coordinating PI, and local RECs.

2.7.3.10. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if JYVXLIV EGXMSR MW VIUYMVIH ERH TVITEVIW 2SXM5GEXMSR of SJREB Decision – Progress/Annual Report for signature of SJREB Chair.

2.7.4. Progress report

2.7.4.1. Progress reports shall be submitted annually unless an earlier or more frequent schedule is decided by the board.

2.7.4.2. The SJREB secretariat communicates to the Sponsor/ Coordinating PI about the need to submit TVSKVIWWVITSVXGEPIRHEVHE]WFIJSVIXLII\TMV]SJ the Notice of Approval.

2.7.4.3. The Coordinating PI submits to SJREB the latest versions of the Investigator

2.7.4.4. Brochure (IB), current versions of the protocol, informed consent forms (ICF) and other relevant documents, along with a summary of all protocol amendments, protocol deviations/ violations and on-site SAEs/SUSARs etc., as well as participant recruitment since the last SJREB approval.

8LI7.6)&WIGVIXEVMEXRSXM5IWEPPWMXI6)'WEFSYXXLI continuing review submissions. The Site RECs collect WTIGM5G MRJSVQEXMSR JVSQ XLIMV WMXI EFSYX TVSXSGSP amendments, protocol deviations/ violations and local SAEs/ SUSARS, including participant recruitment data to provide inputs during joint review.

2.7.4.6. The SJREB secretariat sends the progress report package to the primary reviewers at least seven (7) calendar days before full-board meeting.

2.7.4.7. Primary reviewers refer to the progress report document to determine whether they contain updated information related to patient safety. Review comments should consider the following:

2.7.4.7.1. Risk Assessment: the risks to the subjects are minimized; the risks to the subjects are VIEWSREFPIMRVIPEXMSRXSERXMGMTEXIHFIRI5XW if any, and the importance of the knowledge XLEXQE]FII\TIGXIHXSFIKEMRIHJVSQXLI study.

2.7.4.7.2. Adequacy of Informed Consent: Informed consent/Assent forms current (most recent); ETTVSTVMEXI RI[WMKRM5GERX 5RHMRKW WMRGI the last continuing review that may be related to the subjects' willingness to continue participation provided to enrolled subjects IK MQTSVXERX XS\MGMX] SV EHZIVWI IZIRX information)

2.7.4.7.3. Local Issues: Changes in the investigator's WMXYEXMSR SV UYEPM5GEXMSRWIK WYWTIRWMSR of hospital privileges, medical license; involvement in numerous clinical trials); Evaluation, investigation and resolution of complaints related to the research, if any; Changes in the acceptability of the proposed research in terms of institutional GSQQMXQIRXWIK TIVWSRRIP ERH 5RERGMEP resources, adequacy of facilities) and regulations, applicable national law, or standards of professional conduct of practice.); Report from third party observation of the research (including the informed consent process) carried out; Investigator concerns about trial conduct at the local site (e.g., study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent document required by institutional policies), if any.

2.7.4.7.4. Trial Progress: Start date of the study and I\TIGXIH HYVEXMSR 8SXEP WYFNIGX IRVSPPQIRX I\TIGXIH IRVSPPQIRX EGXYEP IRVSPPQIRX enrollment issues), subject withdrawal (number of subjects who withdrew, lost to follow-up, summary of reasons for withdrawal at local site)

2.7.4.8. Progress report of protocols reviewed through full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

2.7.4.8.1. Renew approval
2.7.4.8.2. Request additional information
2.7.4.8.3. 6IGSQQIRHQSHM5GEXMSR
2.7.4.8.4. Suspend:
Enrollment of new subjects
2.7.4.8.6. Research procedures in currently enrolled subjects
2.7.4.8.7. Entire study
2.7.4.8.8. Disapprove renewal

2.7.4.9. Approval of progress report reviewed by the Primary 6IZMI[IVWF]I\TIHMXIHTVSGIHYVIMWVITSVXIHXSXLI board meeting.

2.7.4.10. SJREB staff communicates the decision of the SJREB to the Sponsor/ Coordinating PI, and local RECs.

2.7.4.11. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if JYVXLIV EGXMSR MW VIUYMVIH ERH TVITEVIW 2SXM5GEXMSR of SJREB Decision – Progress/Annual Report for signature of SJREB Chair.

2.7.5. Final report Final reports shall be submitted by the Coordinating PI upon completion of the study using SJREB Form 'PSWYVI*MREP6ITSVX*SVQ8LI5REPVITSVXWLEPP contain consolidated information from all the sites included in the study.

The SJREB secretariat communicates to the Coordinating PI about the need to submit progress VITSVX GEPIRHEV HE]W FIJSVI XLI I\TMV] SJ XLI Notice of Approval.

8LI 7.6)& LIEH SJ WIGVIXEVMEX GPEWWM5IW XLI

WYFQMWWMSREWIMXLIVJSVJYPPFSEVHSVJSVI\TIHMXIH review based on the original protocol review

GPEWWM5GEXMSR

8LI7.6)&WIGVIXEVMEXWIRHWXLI5REPVITSVXTEGOEKI to the primary reviewers at least seven (7) calendar days before the full-board meeting.

4VMQEV]VIZMI[IVWVIJIVXSXLI5REPVITSVXHSGYQIRX to determine whether they are in accordance with the protocol and related documents approved by the SJREB during initial review and review of amendments, as applicable.

Final report of protocols reviewed through full board shall be included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

%TTVSZI 5REP VITSVX ERH GPEWWMJ] XLI protocol as inactive
Request additional information from the coordinating PI

Approval of progress report reviewed by the Primary

6IZMI[IVWF]I\TIHMXIHTVSGIHYVIMWVITSVXIHHYVMRK the board meeting.

The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required

The SJREB Secretariat prepares the Notice of Approval for signature of SJREB Chair.

The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

2.7.6. 4VSXSGSP:MSPEXMSR(IZMEXMSR

2.7.6.1. Protocol violation or deviation, whether minor or major, from any of the sites included in the study shall be reported to the SJREB by the coordinating PI through the Progress Report Form including relevant HSGYQIRXW RIIHIH XS I\TPEMR SV TVSZMHI HIXEMPW JSV the information indicated in the report.

2.7.6.2. 8LI,IEHSJ7IGVIXEVMEXGPEWWM5IWXLIWYFQMWWMSREW IMXLIVJSVJYPPFSEVHSVJSVI\TIHMXIHVIZMI[

2.7.6.3. Minor Protocol Deviation- are non-systematic protocol noncompliance with minor consequences to the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature

2.7.6.4. Major Protocol Deviation or Protocol Violation - are persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk

The SJREB secretariat sends the protocol noncompliance report package to the primary reviewers at least seven (7) calendar days before the full-board meeting.

2.7.6.6. Primary reviewers refer to the protocol noncompliance report package to determine the appropriate course of action depending on the seriousness of the non-compliance.

2.7.6.7. 2SRGSQTPMERGI MHIRXM5IH JSV JYPP FSEVH WLEPP FI included in the agenda for discussion in the full board meeting where members arrive at any of the following decisions:

2.7.6.7.1. Uphold Original Approval
2.7.6.7.2. Request Further Information
2.7.6.7.3. Suspension of Ethical Clearance
2.7.6.7.4. Cancellation of Ethical Clearance
Deferred Action pending major
GPEVM5GEXMSR

2.7.6.8. Non-compliance report reviewed by the Primary 6IZMI[IVWF]I\TIHMXIHTVSGIHYVIMWVITSVXIHHYVMRK

the board meeting.

2.7.6.9. The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required

2.7.6.10. 8LI7.6)&7IGVIXEVMEXTVITEVIWXLI2SXM5GEXMSRSJ Decision for signature of SJREB Chair.

2.7.6.11. The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

2.7.7.)EVP]8IVQMREXMSR

2.7.7.1. Early termination of protocol implementation shall be reported to the SJREB by the coordinating PI through the Early Termination Application Form (SJREB Form 11).

2.7.7.2. The SJREB secretariat sends the early termination report to the primary reviewers at least seven (7) calendar days before the full-board meeting.

2.7.7.3. Primary reviewers refer to the early termination application to determine the appropriate recommendations

2.7.7.4. Early termination application shall be included in the agenda for discussion in the full board meeting to determine the early termination's implication to the participants and arrive at recommendations for continued protection of study participants including follow-up plan to those who are still actively enrolled.

The SJREB Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required

2.7.7.6. 8LI 7.6)& 7IGVIXEVMEX TVITEVIW XLI 2SXM5GEXMSR SJ Decision for signature of SJREB Chair.

2.7.7.7. The SJREB staff communicates the decision of the SJREB to the Coordinating PI and site RECs.

C. DOCUMENTATION

SOP 3 AND ARCHIVING

3.1 Purpose

3.1.1. To describe the Single Joint Research Ethics Board (SJREB) procedures in documenting all protocol submissions and archiving completed and inactive studies.

3.2 Scope

3.2.1. This procedure applies to documentation and archiving of all protocols submitted to SJREB for ethics review.

3.3 4VSGIWW*PS[ERH4VSGIHYVIWJSV(SGYQIRXEXMSR

8EFPI4VSGIWW*PS[ERH4VSGIHYVIWJSV(SGYQIRXEXMSR

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Input of protocol submission in the online database	Secretariat staff
2	Input digital and hard copy of TVSXSGSPVIPEXIH5PIWMRXLIMV respective storage areas	Secretariat staff

3.4 (SGYQIRXEXMSR

8LIWIGVIXEVMEXWXEJJQEMRXEMRWETVSXSGSP5PIXSGSRXEMREPP submissions and action taken on protocols submitted for SJREB review.

3.4.1. Online database

3.4.1.1. The secretariat staff It maintains an online database that contains complete and updated information about all protocol submissions.

3.4.1.2. The database should contain the following information:

3.4.1.2.1. Protocol code
3.4.1.2.2. Protocol title
3.4.1.2.3. Type of protocol 3.4.1.2.4. Sponsor
Study sites
3.4.1.2.6. Coordinating investigator
3.4.1.2.7. Submission date
3.4.1.2.8. Type of review
3.4.1.2.9. Primary reviewers
3.4.1.2.10. Date of meeting
3.4.1.2.11. Review decision
3.4.1.2.12. Date of issuance of decision
3.4.1.2.13. Resubmission date
3.4.1.2.14. Date of decision of resubmission
Approval date
3.4.1.2.16.)\TMVEXMSRHEXI
3.4.1.2.17. Due date for progress report
3.4.1.2.18. Date of submission of progress report
3.4.1.2.19. Submission of amendment report
3.4.1.2.20. Date of approval of amendment report
3.4.1.2.21. 7YFQMWWMSR SJ 5REP VITSVX (EXI SJ ETTVSZEPSJ5REPVITSVX
3.4.1.2.22. Other reports (SAEs, protocol violations, etc.)

3.4.1.3. All protocol submissions should be logged in the database.

3.4.2. (MKMXEP ERH LEVH GSTMIW SJ TVSXSGSP VIPEXIH 5PIW WLSYPH FI submitted to the secretariat staff.

3.4.2.1. All protocol submissions should be properly labeled with protocol code (Refer to chapter 2 on proper labelling, *see 2.5.8*).

3.4.2.2. Digital copies are stored in their separate google drive folders that are password protected.

3.4.2.3. Hard copies are kept in separate folders in the cabinet with locks and keys

3.4.2.3.1. All protocol submission should be stored in separate folders.

3.4.2.3.2. Folders should be properly labeled with their protocol code. For protocols with multiple folders, the label format should be: Protocol Code + letter (in chronological order based on XLISPHIWX5PIW

3.4.2.3.3. Folders should be stored in cabinets properly labeled with active or inactive status. All cabinets should be secured by a lock and key. Only the secretariat staff should have the key and its duplicate.

3.4.2.3.4.)EGL JSPHIV WLSYPH GSRXEMR ER MRHI\ EX XLI FIKMRRMRK SJ XLI 5PI XS MHIRXMJ] XLI TVSXSGSP documents found in the folder

3.4.2.4. Any document submitted by the investigator is added XSXLITVSXSGSP5PIW

3.5 4VSGIWW*PS[ERH4VSGIHYVIWJSV%VGLMZMRK

8EFPI4VSGIWW*PS[ERH4VSGIHYVIWJSV%VGLMZMRK

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	-HIRXMJ]MREGXMZITVSXSGSPW5PIW	Secretariat staff
2	Update protocol database	Secretariat staff
3	%ŝ\ETTVSTVMEXIPEFIPXS5PIW for archiving	Secretariat staff
4	8VERWJIV5PIWXSXLITVSTIV cabinet	Secretariat staff

3.6 %VGLMZMRK

The secretariat staff will follow the following procedures: 3.6.1. Studies are considered to be completed and inactive when XLIGPSWYVI5REPVITSVXSJXLIWXYH]LEWFIIRVIZMI[IHERH approved by SJREB.

3.6.2. -RGSQTPIXIWXYHMIWEVIGPEWWM5IHEWMREGXMZI[LIRRSJYVXLIV communication or submission has been received by SJREB after two years. Studies that are terminated earlier before GSQTPIXMSR[MPPEPWSFIGPEWWM5IHEWMREGXMZI5PIW

3.6.3. 3RGIXLI5REPVITSVXLEWFIIRETTVSZIHXLI7IGVIXEVMEXWXEJJ marks the database as completed.

3.6.4. (MKMXEP5PIJSPHIVWEVIQEVOIH[MXLER-SV'XSMRHMGEXIXLEX they are incomplete and complete respectively. Hard copy folders are marked with a red sticker to indicate that they are inactive.

At the end of the year, the secretariat staff transfers all completed/inactive protocol folders to the archive.

3.6.6. Protocols are archived for 3 years. After 3 years in the archive, XLITVSXSGSP5PIWQE]FIXVERWJIVVIHXSETEWW[SVHTVSXIGXIH SpMRILEVHHMWO

3.7 4VSGIWW*PS[ERH4VSGIHYVIWJSV6IXVMIZEPSJ(SGYQIRXW

8EFPI4VSGIWW*PS[ERH4VSGIHYVIWJSV6IXVMIZEPSJ(SGYQIRXW

NO.	ACTIVITIES	PERSON/S RESPONSIBLE
1	Receive requests to access SJREB protocol documents	Secretariat staff
2	Approve and input all requests and transaction in the database	Secretariat staff
3	Supervise the use of retrieved documents	Secretariat staff
4	Return of document to the TVSXSGSP5PIJSPHIV	Secretariat staff

3.8 6IXVMIZEP

The secretariat staff will follow the following procedures:

3.8.1. Receive requests to access SJREB protocol documents.

3.8.1.1. %GGIWW XS 7.6)& 5PIW MW WYFNIGX XS XLI JSPPS[MRK limitations:

3.8.1.1.1. Participating site members with a signed 'SR5HIRXMEPMX] %KVIIQIRX ERH 'SR5MGX SJ Interest Disclosure can access documents outside of regular protocol review access, upon request.

3.8.1.1.2. 2SRQIQFIVW GER EGGIWW WTIGM5G documents by submitting a formal request. The secretariat staff will require a signed 'SR5HIRXMEPMX] %KVIIQIRX ERH 'SR5MGX SJ Interest Disclosure. This request needs to be approved by the Member Secretary.

3.8.1.1.3. Regulatory authorities (e.g. Philippine FDA) can have full access to SJREB documents provided it is within their mandate and within a VIEWSREFPIRSXMGIXSQEOIXLI5PIWEZEMPEFPI

3.8.2. Approve and input all requests and transaction in the database.

3.8.2.1. All requests are put into the online database. The following information should be included:

3.8.2.1.1. Protocol code
3.8.2.1.2. Date borrowed
3.8.2.1.3. Name of borrower
3.8.2.1.4. Document requested or copied
Number of copies made
3.8.2.1.6. Date returned of borrowed documents

3.8.3. Supervise the use of retrieved documents.

3.8.3.1. Access to SJREB documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.

3.8.3.2. 8LIWIGVIXEVMEXWXEJJQEOIWSRP]XLII\EGXRYQFIVSJ copies requested.

3.8.4. 6IXYVRHSGYQIRXXSXLITVSXSGSP5PIJSPHIV

3.8.4.1. The secretariat staff is responsible for returning the HSGYQIRXW MR XLI TVSXSGSP 5PI JSPHIV MR XLI GEFMRIX after making sure that all documents are complete as TIVTVSXSGSP5PIMRHI\

SOP 4 REVISING STANDARD OPERATING PROCEDURES/WRITING AND

4.1 Writing SOPs

4.1.1. Purpose

To describe the procedure for writing and revising SOPs used by the Single Joint Research Ethics Board

4.1.2. Scope

This SOP provides instructions on how the new SJREB SOPs are prepared.

4.1.3. Responsibility

4.1.3.1. It is the responsibility of the Chair of SJREB to organize an SOP Team to formulate the SOPs of the REC.

4.1.3.2. The SOP Team is an ad hoc committee composed of designated SJREB members and invited resource persons. The team is responsible for drafting new
734W ERH VIZMWMRK I\MWXMRK 734W [LIR RIGIWWEV] 8LI XIEQ QYWX JSPPS[I\MWXMRK MRWXMXYXMSREP procedures when drafting SOPs in consultation with the Secretariat and Chair. The team submits the draft SOPs to the Chair.

4.1.3.3. The Chair convenes an SJREB meeting to review and 5REPM^I XLI HVEJX 734W ERH IRWYVIW XLEX EPP 7.6)& members have an access to current versions of SOPs to guide them in the performance of their functions.

4.1.4. 4VSGIWW*PS[

8EFPI4VSGIWW*PS[JSV;VMXMRK734W		
NO.	ACTIVITIES	PERSON/S RESPONSIBLE

1	Organize an SOP Team	SJREB Chair
2	Identify reference templates with corresponding layout	SOP Team
3	Draft revised SOPs and submit to Chair	SOP Team
4	6IZMI[ERH5REPM^IVIZMWIH734 in an SJREB meeting and submit to the HPDPB Director	Chair, SJREB Members
	Approve and sign revised SOPs	HPDPB Director
6	Distribute approved SOPs and OIITGSTMIWMRXLI7.6)&5PIW	Secretariat

4.1.5. Detailed Instructions

4.1.5.1. 3VKERM^IHER7348IEQ HPDPB Director assigns members of the SOP Team, and invites resource persons as needed.

The SOP Team receives an orientation from the Chair regarding its duties and responsibilities.

The Chair may organize a SOP Team workshops to facilitate the drafting of SOPs.

4.1.5.2. -HIRXMJ] VIJIVIRGI XIQTPEXIW [MXL GSVVIWTSRHMRK layout

Identify reference templates with corresponding layout from SOPs of other RECs to guide the SOP Team in drafting new SOPs.

An SJREB SOP have the following format:

SOP Number
Title
Purpose of the SOP
7GSTI [LMGL HI5RIW XLI I\XIRX SJ coverage of the SOP and its limitations
6IWTSRWMFMPMX] MHIRXM5IW XLI TIVWSRW
EWWMKRIH XS TIVJSVQ WTIGM5G XEWOW during SOP implementation
Process Flow/ Steps
Detailed instructions which elaborates
XLIWXITWSYXPMRIHMRXLITVSGIWW5S[
Standard forms and checklist to be used Glossary
References
List of Acronyms

Each SOP should be given a number and
E XMXPI XLEX MW WIPJI\TPEREXSV] ERH MW IEWMP] understood.

The SOP Document History describes the different versions of the document by version no., version date, and description of main changes. This is attached with the SOP
1EWXIV5PI

The typical SOP uses a header with the following elements

Institutional seal or logo

Name of institution
734-HIRXM5IV
SOP Title
Effectivity date
Page number

4.1.5.3. (VEJXRI[734WERHWYFQMXXSXLI'LEMV The SJREB SOPs should contain details under the following main topics:

Introduction - contains a statement of ethical principles that will guide SJREB Authority, Composition, and Structure of SJREB - describes the composition of
7.6)&1IQFIVWLMT[MXLWTIGM5GVIZMI[functions

Joint Review of Initial Submission - describes types of review and initial review procedures
Continuing Review Procedures - describes how SJREB conducts postapproval review procedure
Documentation, and Archiving - describes administrative procedures that support the review functions
Writing and Revising SOPs - describes how to draft and revise SOPs

The SOP Team submits completed SOP draft to the Chair.

4.1.5.4. 6IZMI[ERH5REPM^IRI[734WMRER7.6)&QIIXMRK ERHWYFQMXXSXLI,4(4&(MVIGXSV

The SJREB Chair or any permanent member presents the draft SOPs during an SJREB meeting for the member to discuss and
5REPM^IXLIHVEJX
The SJREB Chair submits the approved draft to the Director of HPDPB for approval.

4.1.5.5. %TTVSZIERHWMKRRI[734W The HPDPB Director reviews and approves the SOPs by signing in the designation section.

The approved SOPs will be implemented after approval by the HPDPB Director.

4.1.5.6. (MWXVMFYXI ETTVSZIH 734W ERH OIIT GSTMIW MR XLI 7.6)&5PIW

The SJREB Secretariat distributes the new SJREB SOPs to all SJREB Members, participating site RECs with active LOI, and 7XEJJERH5PIWXLISVMKMREPGST]MRXLI7.6)& storage cabinet.

The SOP Manual with downloadable forms are uploaded on the SJREB website for the use of and guidance of researchers.

APPENDICES AND FORMS

APPENDIX A

%TTIRHM\%	
SJREB FORM 1	Application for SJREB Initial Review
SJREB FORM 1.2	Protocol Summary Sheet
SJREB FORM 2	Protocol Assessment Form
SJREB FORM 3	Informed Consent Assessment Form
SJREB FORM 4	'LIGOPMWXSJ)\IQTXMSR
SJREB FORM 4.1	'IVXM5GEXISJ)\IQTXMSRJVSQ)XLMGW Review
7.6)&*361	2SXMGIJSV4VSXSGSP1SHM5GEXMSR
7.6)&*361	Protocol Resubmission Form
SJREB FORM 6	Notice of Approval
SJREB FORM 7	Progress or Annual Report for Philippine Sites
SJREB FORM 7.1	Progress Report for Government Funded Protocols
SJREB FORM 8	Protocol Amendment Application Form
SJREB FORM 9	Closure or Final Report Form
SJREB FORM 9.1	Early Study Termination Application
SJREB FORM 10	2SXMGIJSV4SWX%TTVSZEP1SHM5GEXMSR
SJREB FORM 11	Onsite Serious Adverse Event Report
SJREB FORM 12	Protocol Violation_Deviation Report
SJREB FORM A	(IGPEVEXMSRSJ'SR5MGXSJ-RXIVIWX

APPENDICES AND FORMS

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%TTIRHM\%	
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SJREB FORM 4	'LIGOPMWXSJ)\IQTXMSR
SJREB FORM 4.1	'IVXM5GEXISJ)\IQTXMSRJVSQ)XLMGW Review
7.6)&*361	2SXMGIJSV4VSXSGSP1SHM5GEXMSR
7.6)&*361	Protocol Resubmission Form
SJREB FORM 6	Notice of Approval
SJREB FORM 7	Progress or Annual Report for Philippine Sites
SJREB FORM 7.1	Progress Report for Government Funded Protocols
SJREB FORM 8	Protocol Amendment Application Form
SJREB FORM 9	Closure or Final Report Form
SJREB FORM 9.1	Early Study Termination Application
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SJREB FORM 11	Onsite Serious Adverse Event Report
SJREB FORM 12	Protocol Violation_Deviation Report
SJREB FORM A	(IGPEVEXMSRSJ'SR5MGXSJ-RXIVIWX

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 1
APPLICATION FOR SJREB INITIAL REVIEW

To be filled up by the Coordinating Investigator

SJREB Protocol Number *(to be filled-up by secretariat staff)*:	

Sponsor Protocol Number:		Submission Date:			

Protocol Title:	

Type of Research:	☐	Clinical Research	☐ Clinical Trial	☐	Laboratory Research
	☐	Genetic Research	☐ Socio-behavioral	☐	Public health
	☐	Others (*specify*): _____			

Study Duration:	

Sponsor:	

Coordinating Investigator: *(Please assign one person only)*	

Sites and Site Principal Investigators: *(List all sites and site investigators)*	

Telephone number:		Email	

Institution:	

Declaration of Conflict of Interest (COI)				
Are you an employee of the sponsor/s?	x	Yes	x	No
Did you do consultancy or part time work for the sponsor/s?	x	Yes	x	No

In the past year, did you receive P500,000 or more from the sponsor/s?	x	Yes	x	No
Other ties with the sponsor:				
Ethical Responsibility and COI Statement I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI).				

CI Signature:	

Documents submitted: *(Please check the documents submitted)*

Basic documents:	
	Application Form [SJREB FORM 1 – APPLICATION FORM]
	Protocol Summary Sheet [SJREB Form 1.2 – Protocol Summary Sheet]
	Informed Consent Forms (in English and in local language)
	Recruitment and Advertisement Materials
	Data Collection Forms
	CVs of PIs
	Study Budget
	Study Protocol
	Technical Clearance
	Proof of parallel submission to at least three (3) study sites

Study-specific Documents (submit as needed):	
	FDA Approval/Clearance (for clinical trials)
	Patient Information Sheet (for clinical trials)
	Investigator Brochure (for clinical trials)
	GCP Certificates of PIs (for clinical trials)
	Other protocol-related documents (please specify):

Received by:

(SJREB Secretariat)

Date:

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

FORM 1.2 PROTOCOL SUMMARY SHEET

SJREB Protocol No.	Protocol Title

Coordinating Investigator	Sponsor

Rationale	
Objectives	
Study Design/Methodology	
Inclusion Criteria	
Exclusion Criteria	
Data Analysis Plan	
Study Outcomes	

Ethical Consideration	

SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 2 PROTOCOL ASSESSMENT FORM

To be filled up by primary reviewer

Instructions: Please do literature search to update your knowledge about this protocol

SJREB Protocol No.:		Date (D/M/Y.):	

Protocol Title:	

Coordinating Investigator:	

Institution:	

Total No. of Participants:		No. of Study Sites:	
Expected no. from Philippine sites:			

Sponsor:	

Duration of the Study:		Status:		New		For Renewal of Approval

Reviewers:	

	Intervention		Epidemiology		Observational study
	Document review		Case study	Genetic	
	Social Survey		Others *(specify):*		

Exempted | Review Type: | Full Board | Expedited

Description of the Study in brief: Mark whatever applies to the tudy. s					
	Randomized		Drug		Use of Genetic Materials
	Double-blind		Medical Device		Multicenter Study
	Single-blind		Vaccine		Global Protocol
	Open-label		Diagnostics		Sponsor-initiated
	Observational		Questionnaire		Investigator-initiated

A. PROTOCOL DOCUMENT REVIEW (*please put an X before your choice and N/A on the comments if there are no further comments)*

Questions				Comment/s:
1. Objectives of the study				
	Clear		Not clear	
2. Need for human participants				
	Clear		Not clear	
3. Background information				
	Sufficient		Not sufficient	
4. Methodology				
	Clear		Not clear	
5. Sufficient number of participants				
	Yes		No	
6. Control arms (placebo, if any)				
	Yes		No	
7. Data analysis plan				
	Appropriate		Not Appropriate	

8. Study outcomes Defined / Incomplete / Not defined	
9. Level of risk Low / Medium / High	
10. Risk mitigation in the protocol Appropriate / Not Appropriate	
11. Benefits of the participants in the protocol Appropriate / Not Appropriate	
12. Inclusion criteria Appropriate / Not Appropriate	
13. Exclusion criteria Appropriate / Not Appropriate	
14. Withdrawal criteria	

Appropriate / Not Appropriate	
15. Involvement of vulnerable participants Yes / No	
16. Protection of vulnerable participants Appropriate / Not Appropriate	
17. Voluntary, non-coercive recruitment of participants Yes / No	
18. Are the qualifications and experience of the coordinating investigators/participating investigators, research team appropriate? Yes / No	

19. Disclosure of potential conflicts of interest						
	Yes		No			
20. Facilities and infrastructure of participating sites						
	Yes		No			
21. Community consultation						
	Yes		No		N/A	
22. Involvement of local researchers and communities in the protocol preparation and implementation						
	Yes		No		N/A	
23. Contribution to local capacity building						
	Yes		No		N/A	
24. Benefit to local community						
	Yes		No		N/A	
25. Sharing of study results						
	Yes		No		N/A	
26. Are blood or tissue samples sent abroad						
	Yes		No		N/A	

B. RECOMMENDATION

Decision:		Approval		Minor Revision
		Major Revision		Disapproval

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	

Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 3 INFORMED CONSENT ASSESSMENT FORM

To be filled up by primary reviewer

SJREB Protocol No.		Date (D/M/Y):	

Protocol Title:	

Coordinating Investigator:	

A. INFORMED CONSENT DOCUMENT REVIEW (*please put an X before your choice and*
N/A on the comments if there are no further comments)

Questions				Comment/s:
1. Does the Informed Consent document state that the procedures are primarily intended for research?				
	Yes		No	
2. Are procedures for obtaining Informed Consent appropriate?				
	Yes		No	
3. Does the Informed Consent document contain comprehensive and relevant information?				
	Yes		No	
4. Is the information provided in the protocol consistent with those in the consent form?				

	Yes		No	
5. Are study related risks mentioned in the consent form?				
	Yes		No	
6. Is the language in the Informed Consent document understandable?				
	Yes		No	
7. Is the Informed Consent translated into the local language/dialect?				
	Yes		No	
8. Are there vulnerable participants?				
	Yes		No	
9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants?				
	Appropriate		Not appropriate	
10. Are names and contact numbers from the research team and the REC in the informed consent?				
	Yes		No	
11. Does the ICF provide privacy & confidentiality protection?				
	Yes		No	
12. Is there any undue inducement for participation?				
	Yes		No	
13. Is there provision for medical/psychosocial support?				
	Yes		No	N/A
14. Is there provision for treatment of study-related injuries				
	Yes		No	N/A
15. Is the amount paid to participants stated?				
	Yes		No	N/A

B. RECOMMENDATION

Decision:		Approval		Minor Revision
		Major Revision/ Resubmission		Disapproval

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 4 CHECKLIST FOR EXEMPTION FROM FULL ETHICAL REVIEW FORM

To be filled up by primary reviewer

SJREB Protocol No.		Date (D/M/Y):	

Protocol Title:	

Coordinating Investigator:	

A. Protocol Assessment

Questions	Comment/s:
1. Does this research involve human participants? ☐ Yes ☐ No	
2. Does this research involve use of nonidentifiable human tissue/ biological samples? ☐ Yes ☐ No	
3. Does this research involve use of nonidentifiable publicly available data? ☐ Yes ☐ No	
**Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGHHR 2017)*	
4. Does this research involve interaction with human participants ☐ Yes ☐ No	
5. Type of research (*please tick appropriate box)*	
a. Institutional quality assurance ☐ Yes ☐ No	

b. Evaluation of public service program				
	Yes		No	
c. Public health surveillance				
	Yes		No	
d. Educational evaluation activities				
	Yes		No	
e. Consumer acceptability test				
	Yes		No	
**These 5 have been identified in the NEGHHR as exemptible, as long as it does not involve more than minimal risk.*				
6. What is/are the method/s of data collection *(please tick appropriate box)*				
a. Surveys and/or questionnaire				
	Yes		No	
b. Interviews or focus group discussion				
	Yes		No	
c. Public observations				
	Yes		No	
d. Research which only uses existing data				
	Yes		No	
e. Audio/video recordings				
	Yes		No	
**These 5 have been identified in the NEGHHR as exemptible, as long as anonymity and/or confidentiality is maintained.*				
7. Will the collected data be anonymized or identifiable?				
	Anonymized		Identifiable	
	De-identified			
8. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHRR 2017) **Please refer to section B. Risk Assessment, prior to answering this item*				
	Yes		No	
**If YES, then this protocol does not qualify for exemption*				

B. Risk Assessment

Questions	Comment/s
1. Does this research involve the following: *(please check all that applies)*	
a. Any vulnerable groups?	
☐ Yes ☐ No	
b. Sensitive topics that may make participants feel uncomfortable *(i.e. sexual behaviour, illegal activities, racial biases, etc.*	
☐ Yes ☐ No	
c. Use of drugs	
☐ Yes ☐ No	
d. Invasive procedure (e.g. blood sampling)	
☐ Yes ☐ No	
e. Physical stress/distress, discomfort	
☐ Yes ☐ No	
f. Psychological/mental stress/distress	
☐ Yes ☐ No	
g. Deception of/or withholding information from subjects	
☐ Yes ☐ No	
h. Access to data by individuals or organizations other than the investigators	
☐ Yes ☐ No	
i. Conflict of interest issues	
☐ Yes ☐ No	
j. Or any other ethical dilemmas	
☐ Yes ☐ No	
k. Is there any blood sampling involved in the study	
☐ Yes ☐ No	

C. RECOMMENDATION

Decision:		Qualified for Exemption
		Unqualified for Exemption

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 4.1 CERTIFICATE OF EXEMPTION FROM ETHICS REVIEW

Date:

This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the SJREB for implementation

SJREB Protocol No.:		Sponsor Protocol No.:	

Coordinating Investigator:		Sponsor:	

Title:	

Protocol Version No.:		Version Date:	

ICF Version No.:		Version Date:	
Other Documents:			

This protocol is exempted from review for the following reasons: *(check the NEGHHR)*

1.

SJREB Chair	Signature	Date

NOTE: x Final/Closure Reports should be submitted at the end of the study.

x Any amendment to the protocol should be submitted to SJREB for re-evaluation of exemption.

Received by:

Name: _____

Signature: _____ Date: _____

Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 5 NOTICE OF PROTOCOL MODIFICATION

Date: 2020

To *(name of PI)*: _____

Contact Details: _____

Protocol Title: _____

SJREB Protocol Code _____

Sponsor Protocol No. _____

Protocol Version No. and Version Date: _____

ICF Version No. and Version Date _____

Type of Submission
- ☐ Initial Submission
- ☐ Resubmission
- ☐ Others

This is to inform you of the SJREB decision related to the documents you have submitted:

ITEMS FOR REVISION	REVISION/INFORMATION REQUIRED FROM THE PRINCIPAL INVESTIGATOR
Protocol	
Informed Consent Form	
Others	

Please submit the revised documents on or before _____

Type of review	SJREB Decision

	Exempted		Minor revisions required		Approved
	Expedited		Major revisions required		Others:
	Full Board		More information required		

Meeting Date:	

SJREB Chair	Signature	Date
Dr. Jacinto Blas Mantaring III		

Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD SJREB FORM 5.1

PROTOCOL RESUBMISSION FORM

To be filled by investigator

SJREB Protocol Number	

Sponsor Protocol Number		Submission Date	

Protocol Title:	

Documents revised		Protocol (*latest version number and date*)		ICF (*latest version number and date*)
		Others (specify):		

Type of Initial Review		Exempted		Expedited		Full Board

Channel of review for resubmission		Expedited		Full Board

Coordinating PI		Sponsor	

Contact Numbers		Email	

Institution	

REC Recommendations	Revisions made by the PI	Reviewer Comments *(to be filled up by primary reviewers)*

Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

Co-PI Signature:	Date:
Received by SJREB Secretariat:	Date:

FOR REC USE:	
Summary of comments:	

Recommendations:	
	Approve
	Request for further information/modification
	Others

Name of reviewer:		Signature:		Date:	

Final Decision:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 6 NOTICE OF APPROVAL

Date:

This is to certify that the following protocol and related documents have been granted approval by the SJREB for implementation in accordance with the International Conference on the Harmonization of Good Clinical Practice and the National Ethical Guidelines on Health and Health-related Research

SJREB Protocol No.:		Sponsor Protocol No.:	

Coordinating Investigator:		Sponsor:	

Title:	

Protocol Version No.:		Version Date:	

ICF Version No.:		Version Date:	
Other Documents:			
Members of research team:			
Study sites:			

Type of Review:	☐ Expedited ☐ Full Board Meeting date:	Duration of Approval From – To *(date)* December 28, 2018 to December 28, 2019	Frequency of continuing review Annual

SJREB Chair	Signature	Date

Investigator Responsibilities after Approval:

x Submit country protocol amendments to the SJREB and site REC for approval before implementing them; x Submit site-specific amendments to site REC for approval before implementing them; x Submit annual report for renewal of approval to SJREB; x Submit SAE and SUSAR reports to the site REC within 7 days; x Submit progress report every 12 months; x Submit final report after completion of protocol procedures at the study site; x Report protocol deviation/violation to the REC study sites; x Comply with all relevant international and national guidelines and regulations; and x Abide by the principles of good clinical practice and ethical research

Received by:

Name: _____

Signature: _____ Date: _____

Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 7 PROGRESS/ANNUAL REPORT FOR PHILIPPINE SITES

SJREB Protocol No.:		Initial Approval Date:	

Protocol Title:	

Coordinating Investigator:		Sponsor:	

Any amendment since the last review? Describe briefly.		Yes		No
Any change in participant population, recruitment or selection criteria since the last review? Explain the changes.		Yes		No
Any change in the Informed Consent process or documentation since the last review? Please explain.		Yes		No
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? Summarize.		Yes		No
		Yes		No

Any unexpected complication or side effect noted since the last review? Summarize.	

Were there protocol deviation/ violation reports? Summarize. What corrective actions were taken?		Yes		No
Any new investigator that has been added to or removed from the research team since the last review? Please identify them and submit the CVs of new investigators.		Yes		No

Summary of recruitment:	
	Accrual ceiling set by REC
	New participants accrued since last review
	Total participants accrued since protocol began
	No. of participants who are lost to follow up
	No. of participants withdrawn from the study
	No. of participants who experienced SAEs/ SUSARs

Questions:	**Yes**	**No**	**Comments:**
Do the risks to the study participants remain reasonable in relation to anticipated benefits?			

Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent?			

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.		Yes		No

---

FOR SJREB USE

Name of Primary Reviewer	

Assessment by the Primary Reviewer:

Is there need to revise the ICF?			
Is there need to re-consent subjects enrolled in the study?			
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety?			
Are there concerns about patient safety, inability to comply with the protocol, high dropout rate that affect study implementation?			

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol deviation/ violation, etc.) submitted by the PI

Recommended Action:	
	Approve
	Request further information, *specify*
	Recommend further action, *specify*
Other comments:	

Primary Reviewer:	Signature:	Date:

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 7.1 PROGRESS REPORT FOR GOVERNMENT FUNDED PROTOCOLS

SJREB Protocol No.:		Initial Approval Date:	

Protocol Title:	

Coordinating Investigator:		Sponsor:	

Summary of Accomplishments			
Objectives	Activities (for each objective)	Targets	Accomplishments

Results and Discussion (Detailed discussion of outputs / findings for the period based on target activities)

Problems / Difficulties Encountered (Obstacles/hurdles met and experienced during implementation, explanatory notes for deviation(s) in targets and accomplishments, changes in dates of implementation, etc.)

Proposed or Suggested Solutions (Proposed action(s) to solve problems encountered)

Please submit an endorsement letter from the end-user/sponsor that they have fully received and accept the progress of the study

FOR SJREB USE

Name of Primary Reviewer	

Assessment by the Primary Reviewer:

Recommended Action:	
	Approve
	Request further information, *specify*
	Recommend further action, *specify*
Other comments:	

Primary Reviewer:	Signature:	Date:

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 8 PROTOCOL AMENDMENT APPLICATION FORM

Date of submission	SJREB Protocol No.	Sponsor Protocol No
Principal Investigator	**Email/ Mobile No.**	**Sponsor**

Title of Study	

Study Site/s:		Date of Initial Approval	
		Type of Initial Review: *(Full Board, Expedited, Exempted)*	

Items to be Amended	List of Amendments	Reasons

Signature of PI:	
Date:	

FOR REC USE:				
Assessment of Primary Reviewers	1. Type of amendments:			
		Minor		Major
	Comment/s:			
	2. Does the amendment decrease the risks to participants			
		Yes		No
	Comment/s:			
	3. Does the amendment decrease the benefits to participants?			
		Yes		No
	Comment/s:			
	4. Is there favorable benefit/ risk ratio?			
		Yes		No

	Comment/s:

Recommendations:	
	Approve
	Request for further information/modification
	Others

Type of review	
	Expedited
	Exempted
	Full Board

Name of reviewer:		Signature:		Date:	

Final Decision:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

FORM 9 CLOSURE/FINAL REPORT FORM

(Consolidated report from all sites included in the study)

PROTOCOL CODE:			
PROTOCOL TITLE:			
(INITIAL) APPROVAL DATE:			
COORDINATING INVESTIGATOR:			
Email:		**Mobile:**	
STUDY SITES:			
SPONSOR:			
SPONSOR CONTACT PERSON:		**Email:**	
1. Study Arms:			
2. Summary of Recruitment:			
Accrual ceiling set by REC			
x New participants accrued since last review			
x Total number of participants accrued since protocol began			
x No. of participants who are lost to follow up			
x No. of participants withdrawn from the study			
x No. of participants who experienced SAEs/SUSARs			
3. Number of participants who completer the study:			

4. Amendments to the original protocol (including dates of approval):	
5. Summary of onsite SAEs reported:	
6. Summary of participants' complaints or grievances documented regarding conduct of study:	

7. Summary of benefits to participants:	
8. Summary of indemnifications of study related injury (If Applicable):	
9. If terminated early, specify reason for termination:	
10. Progress reports submitted (with dates of approval):	
11. Duration of the study (months):	
12. Informed consent form used (with version no./date) and attach most recent version:	
13. Study objectives and summary of results:	

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SIGNATURE OF PI:	
DATE:	

RECEIVED BY:	
REPORT SUBMISSION DATE: (to be filled out by REC)	

FOR REC USE ONLY:
COMMENTS OF PRIMARY REVIEWER (i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study)

Recommendations:	
	Approve
	Request for further information/modification
	Others

Type of review	
	Expedited
	Exempted
	Full Board

Name of reviewer:		Signature:		Date:	

Final Decision:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 9.1 EARLY STUDY TERMINATION APPLICATION

(Consolidated report from all sites included in the study)

SJREB PROTOCOL CODE:			
PROTOCOL TITLE:			
(INITIAL) APPROVAL DATE:			
COORDINATING INVESTIGATOR:			
Email:		**Mobile:**	
STUDY SITES:			
SPONSOR:			
SPONSOR CONTACT PERSON:		**Email:**	
TERMINATION DATE:			

1. No. of participants	
2. No. of enrolled	
3. Reason/s for early termination	
4. Summary of results	
Accrual data	
x How many have completed the study?	
x How many are still active?	
x What are the plans for those who are still active in the study?	

SIGNATURE OF PI:	
DATE:	
RECEIVED BY:	

REPORT SUBMISSION DATE: (to be filled out by REC)	

FOR REC USE ONLY:
COMMENTS OF PRIMARY REVIEWER (i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study)

Recommendations:	
	Approve
	Request for further information/modification
	Others

Type of review	
	Expedited
	Exempted
	Full Board

Name of reviewer:		Signature:		Date:	

Final Decision:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 10 NOTICE OF POST-APPROVAL MODIFICATION

Date:

To *(name of PI)*:

Contact Details:

Protocol Title:

SJREB Protocol Code

Sponsor Protocol No.

Protocol Version No. and Version Date:

ICF Version No. and Version Date

Initial Approval Date

Type of Submission Amendment ☐ Annual Progress Report ☐ Final Report

This is to inform you of the SJREB decision related to the documents you have submitted:

ITEMS FOR REVISION	REVISION/INFORMATION REQUIRED FROM THE PRINCIPAL INVESTIGATOR
Protocol	
Informed Consent Form	
Others	

Please submit the revised documents on or before _____

Type of review		SJREB Decision			
☐	Exempted	☐	Minor revisions required	☐	Approved

☐	Expedited	☐	Major revisions required	☐	Others
☐	Full Board	☐	More information required		

Meeting Date:	

SJREB Chair	Signature	Date

Republic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 11 ONSITE SERIOUS ADVERSE EVENT REPORT

Seriousness:		Relation to:					
	Life Threatening		Drug		Device		Study
	Death		Not related				
	Hospitalization		Possibly				

	Disability/Incapacity		Probably
	Congenital Anomaly		Definitely related

Coordinating Principal Investigator:	
SJREB Protocol Code:	
Study Title:	
Sponsor:	
Name of Study Medicine:	
Report Date:	
Onset Date:	
Date of First Use:	

Patient Number	Age	Sex

Patient's History:	
Laboratory Findings:	
SAE:	
Treatment Outcome:	
Management of Adverse Reaction:	

Please check the ones applicable:

	Others (please specify)		Unknown

*Please attach standard CIOMS r

FOR REC USE

Reviewer's Name	Signature	Date

Changes in the protocol recommended?		Yes	Comments:
		No	
Changes to the informed consent form recommended?		Yes	Comments:
		No	

REC Final Action	
	Request an amendment to the protocol or the consent form
	Request further information
	Suspend enrollment of new research participants
	Suspend all trial-related procedures
	Termination of study
	Take note and continue monitoring
	Conduct study site visits
	Others (please specify)

Republic of the Philippines
Department of Health
SINGLE JOINT RESEARCH ETHICS BOARD

SJREB FORM 12
PROTOCOL VIOLATION/DEVIATION REPORT

Coordinating Principal Investigator:	
SJREB Protocol Code:	
Study Title:	
Sponsor:	
Date of Submission:	
Reported by:	

Protocol deviation:	
Corrective measures done:	

FOR REC USE

Reviewer's Name	Signature	Date

Please check the ones applicable:

Deviation from the protocol:		Participant non-compliance:	
	Minor		Yes
	Major		No

		N/A

REC Recommendation:	
	Noted (no further action needed)
	Correction action needed
	Site visit needed
	Others (please specify)

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SINGLE-JOINT RESEARCH ETHICS BOARDRepublic of the Philippines
Department of Health

SINGLE JOINT RESEARCH ETHICS BOARD SJREB FORM A DECLARATION OF CONFLICT OF INTEREST

Coordinating Principal Investigator:	
SJREB Protocol Code:	
Study Title:	
Sponsor:	

Declaration of Conflict of Interest				
Are you an employee of the sponsor/s?		Yes		No
Have you done consultancy or part time work for the sponsor/s in the past?		Yes		No
In the past year, did you receive P500,000 or more from the sponsor/s?		Yes		No

Other information	
Do you have other financial or non-financial ties with the sponsor (e.g. employment of relative to the 4th level of consanguinity)	

Are you a member of a policy-determining/recommendatory body that is convened by the DOH, DOST, and other national agencies who lead on COVID-19 response?	

List of all studies you are currently managing			
Title of study	**Sponsor**	**Status of implementation**	**% of time allotted for the study**

Ethical Responsibility and COI Statement

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI)

SIGNATURE	**DATE**

APPENDICES AND FORMS

APPENDIX B

%TTIRHM\&	
	Guidelines for Review of Protocols during Emergency Outbreak

APPENDIX B. +YMHIPMRIWJSV6IZMI[SJ4VSXSGSPW HYVMRK)QIVKIRG]3YXFVIEO

Adapted from the WHO Guidelines for Rapid Review of COVID-19 Research

&EGOKVSYRH

To date, there are no approved treatments or prophylactic products known to be safe and effective for COVID 19, which is similar to previous outbreaks such as Ebola, Zika, or Lassa fever. Consequently, conducting research on new medications or vaccines during this pandemic is essential. Research conducted during pandemics or outbreaks, while in the best interests of communities that are presently affected or could be affected in the future, raises many unique ethical issues.

Different countries will be in different stages of readiness to review epidemic-relevant research. Regardless of preparatory work that has been done so far, there are things that ethics committees can and should do now to prepare for rapid review of COVID-19 protocols. It is necessary that research ethics committees be prepared to rapidly review COVID-19 research.

There have been many articles and reports published after the 2014 Ebola outbreak that address ethical issues in research during outbreaks and research ethics governance. Of note, issues were raised about time sensitivity and the balance between the quality and time to review and ensuring the protection of participants in clinical trials, many of whom are in desperate need for any management protocols, lest they lose their lives.

Recently, two workshops were held to address important issues in
XLMW GSRXI\X c)XLMGW TVITEVIHRIWWĐ *EGMPMXEXMRK *Ethics Review During Outbreaks*, organized by ALERRT[6] (**A**frican coa**L**ition for **E**pidemic **R**esearch, **R**esponse and **T**raining)& WHO (World Health Organization) in Dakar, Senegal in March 2018, and 2) "*Ethics review of research on Lassa & other infectious disease outbreaks*", organized by WHO in Abuja, Nigeria in October 2018. These workshops provided recommendations for addressing how National/Institutional (Research) Ethics Committees (N(R)ECs) and other research review committees should prepare for changes that may be necessary to their Standard Operating Procedures (SOPs) in order to respond IŝGMIRXP]HYVMRKXLMWTERHIQMG

7TIGM5G+YMHIPMRIW

To facilitate the rapid or time-sensitive reviews, the following
EHHMXMSRW SV GLERKIW XS XLI IXLMGW GSQQMXXIIWb I\MWXMRK WXERHEVH operating procedures are being recommended.

-XMWMQTSVXERXXSRSXIXLEXXLMWKYMHERGIWLSYPHGSQIMRXS EGXMSR SRGI ER SYXFVIEO MW HIGPEVIH EW E TYFPMG LIEPXL IQIVKIRG] 8LMW HIGPEVEXMSR [MPP GSQI JVSQ XLI TYFPMG LIEPXLEYXLSVMX]SJXLIGSYRXV]8SWTIIHYTXMQIXSWXEVX XLI VIWIEVGL QER] TVSGIWWIWIK HVEJXMRK HSGYQIRXW XVERWPEXMSRW ETTVSZEPW IXG [MPP FI LETTIRMRK MR TEVEPPIP VEXLIVXLERWIUYIRXMEPP]EWMWXLIGEWIMRRSRIQIVKIRGMIW

When a protocol is being considered for submission in a language different from that in which the review is conducted, the synopsis, plan, documents of consent/assent, and data collection tools/ JSVQW EX E QMRMQYQ WLSYPH FI WYFQMXXIH MR

XLI S‡GMEP PERKYEKI of the country where the review will take place. Other documents in the reviewing country's language should be submitted as soon as possible.

(SGYQIRXEV]6IUYMVIQIRXW

A checklist including the following items should be included in addition to the ethics review form (if used by the research ethics committee):

An option to identify the research as epidemic/outbreak-related in order to facilitate fast-tracking;

An opportunity to describe whether prior research data about the HMWIEWII\MWXW

Inclusion of at least one PI or co-PI of the country where research and review is taking place;

5YEPM5GEXMSRSJOI]MRZIWXMKEXSVWMRGPYHMRKEHIWGVMTXMSRSJTVIZMSYW track record with outbreak-relevant research among the research group; and,

An indication whether the protocol is part of a multicenter trial. If yes, an opportunity should be provided to describe the status of ethics approval of the master protocol or the ethics approval of the sponsoring country.

Apart from the basic documents submitted for review (Protocol, CVs, etc.), the following should also be submitted:

Letter of collaboration in the form of a Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA) with sponsor institution(s) and the funder(s) of the research along with HIGPEVEXMSRWSJ'SR‡MGXSJ-RXIVIWX[LIRTSWWMFPI

Monitoring and safety management plan for the project, as provided by the study sponsor;

Both data sharing and material transfer agreements (MTA) for data and human biological material, especially if samples are being I\TSVXIHSYXSJXLIGSYRXV][LMPILSRSVMRKXLIPE[WSJXLIPERHE draft may be submitted initially);

'PIEV TVSGIWWIW ERH TVSGIHYVIWI\TIGXEXMSRW JSV JSPPS[YT dissemination and publication, co-authorship, co-presentation, and Intellectual Property Rights;

4VSGIHYVIWJSVHMWWIQMREXMSRSJ5RHMRKWXSXLIEJJIGXIHGSQQYRMX] (important to ensure maintaining contact and upholding trust of the affected populations, especially research participants); and, May include local requirements on insurance policies, particularly on trials/interventions.

[1] World Health Organization (WHO). Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. WHO 2016. ISBN 978 92 4 154983 7

[2] Schopper D, Ravinetto R, Schwartz L, et al. Research Ethics Governance in Times of Ebola. Public Health Ethics 2016; doi: 10.1093/phe/phw039 First published online: November 1, 2016. 1XIĆHOG&RXQFLORI%LRHWKLFV&RQGXFWLQJUHVHDUFKDQGLQQRYDWLRQLQWKHFRQWH[WRIJOREDOKHDOWK emergencies: what are the ethical challenges? Notes of workshop held on 9 December 2016:
å%HGIRUG6TXDUH/RQGRQ:&%-6
8SVKXU5)XOOHU-5DQGRPL]HGFRQWUROOHGWULDOVLQWKH:HVW$IULFDQ(ERODYLUXVRXWEUHDN &OLQLFDO7ULDOV'2,

[3] The Challenge of Timely, Responsive and Rigorous Ethics Review of Disaster Research: Views of Research Ethics Committee Members. Matthew Hunt, Catherine M. Tansey, James Anderson, Renaud F. Boulanger, Lisa Eckenwiler, John Pringle, Lisa Schwartz. PLOS ONE | DOI:10.1371/journal.pone.0157142 June 21, 2016.

[4] Abha Saxena, Peter Horby, John Amuasi, Nic Aagaard, Johannes Köhler, Ehsan Shamsi *RRVKNL(PPDQXHOOH'HQLV$QGUHDV$5HLV7KH$/(557:+2:RUNVKRSDQG5D□DHOOD Ravinetto. Ethics preparedness: facilitating ethics review during outbreaks - recommendations from an expert panel. BMC Medical Ethics 2019; 20:29

1IIXMRK6IUYMVIQIRXWERH4VSGIHYVIW

Considerations

To prepare for the review of COVID-19 research, RECs should agree on a process for rapid review and communicate this to researchers (and communicate any anticipated delays for non-COVID-19 research).

Also, practical aspects like: identify surge capacity for review, set up systems for remote discussions (which software platform, does everybody who needs it have access and know how to use it, what will you do if internet isn't functioning etc.)

Membership and Quorum

-XMWIWWIRXMEPXLEXEGIVXEMRRYQFIVSJQIQFIVWFITVIMHIRXM5IH[LS will share the major burden of review. These members would require WTIGMEPM^IHXVEMRMRKSVIUYMZEPIRXI\TIVMIRGI MRVIZMI[MRKVIWIEVGL in outbreaks so that they are able to rapidly review research proposals without compromising the ethics. Additional members should be MHIRXM5IHERHGEPPIHJSVVIZMI[EXXMQIW[LIRHIQERHMRGVIEWIW Once an outbreak is imminent or ongoing, the chair or the secretary of the review committee should alert members and ascertain which members would be available for the rapid review.

-HIRXM5GEXMSR EW [IPP EW GSRXEGXMRK MR EHZERGI WYFNIGX I\TIVXW (technical) and people with strong knowledge of ethics (both incountry and abroad) willing to serve as ad hoc or co-opted members during outbreaks, as there is a likelihood of receiving multiple projects that need to be reviewed in a short time.

The quorum shall abide by the ICH-GCP requirements.

-JTVIMHIRXM5IH6)'QIQFIVWYFQMXWXLIMVVIZMI[FYXMWYREFPIXS join the meeting, they should be considered as part of the quorum requirement.

Procedures

The new SOPs should be circulated to all members of the review committee.

The review meetings could be virtual or electronic especially if the risk of face-to-face meeting in highly infectious outbreak like COVID-19 may be risky to the members.

Protocol submission **should** be done electronically to save time with submission of the hard copy, which if mandatory can follow. PIs should contact RECs as soon as possible to communicate their intention to submit as well as a high-level overview of research (is it a trial of new medicine, vaccine, observational study, survey, etc.) so that RECs are aware of protocols that may be forthcoming. Face to face meetings with the PIs should not be mandatory and if necessary electronic and or virtual venues may be adopted.

Timelines

Protocols should be sent to reviewers within **LSYVWSJWYFQMWWMSR**.)EGLVIZMI[IVWLSYPHGSQTPIXIXLIMVVIZMI[W[MXLMREWTIGM5IHTIVMSH of time (usually **3 calendar days** MWWY$GMIRXERHETTVSTVMEXIHYVMRK an outbreak).

Consolidated review and suggestions (or approval) should be GSQQYRMGEXIH XS XLI 4- [MXLMR E WTIGM5IH TIVMSH SJ XMQIYWYEPP] **[MXLMRGEPIRHEVHE]W**).

The complete review process until issuance of approval should not I\GIIH**14 calendar days**.

'SQQYRMGEXMSR

Electronic or telephonic communication with PIs **should** be initiated

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The PI **should** respond to the review within 48-hour

Focal points/persons for communication in respective institutions ERH 6)'W2)'W WLSYPH FI MHIRXM5IH EW IEVP] MR XLI TVSGIWW EW possible.

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All communications **should** be documented and archived following the research ethics committee's standard operating procedures.

SINGLE-JOINT RESEARCH ETHICS BOARD !"#$% 101

Department of Health
Health Policy Development and Planning Bureau
Health Research Division