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.

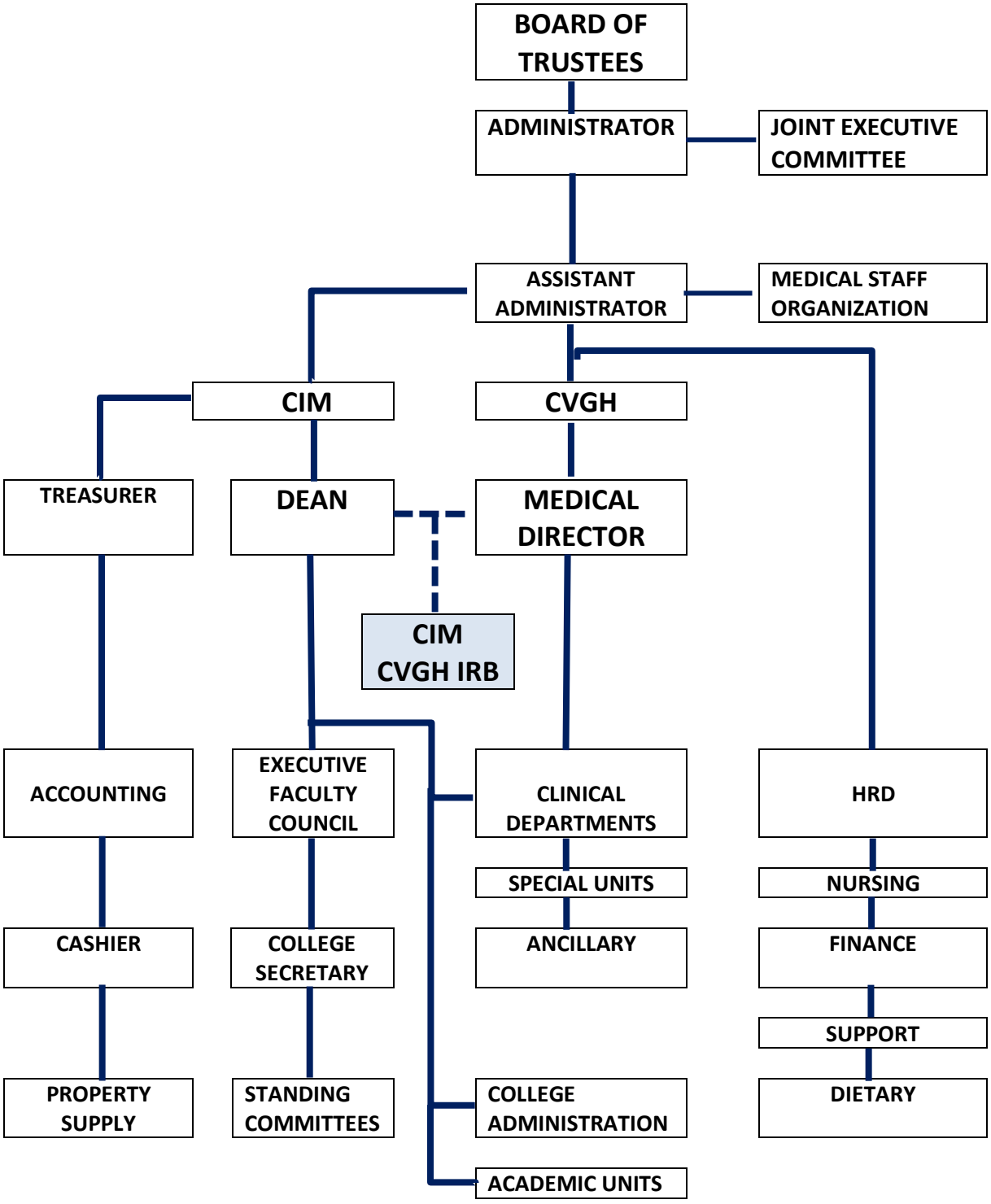
The Cebu Velez General Hospital (CVGH) is the main training hospital of the Cebu Institute of Medicine (CIM). CVGH shares with CIM its clinical and teaching departments which include the departments of Internal Medicine, Surgery, Paediatrics, Family Medicine, OB-GYN and Ophthalmology, and ENT. Similarly, 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 CIM-CVGH 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. Zamoria, 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. Culson, MD
Ophthalmology
Jolene 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
Gina V. Lord
IRB-STAFF

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**.

Joint Memorandum of Circular No. 01, Series of 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, appoint, and supervise 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 applies specifically to the selection and appointment of members and staff of the CIM-CVGH IRB. 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. Responsibilities

It is the responsibility of the IRB members, officers, and secretariat to understand and implement this SOP of the CIM-CVGH IRB.

5. 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*

6. Description of Procedures

Step 1: *Define the composition of the membership of the IRB*

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:

i. The CIM-CVGH IRB shall be composed of at least 9 members.
ii. 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.
iii. 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.
iv. 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.
v. A member's relevant expertise may include medicine and research, social or behavioral sciences, law, philosophy, environmental science, and public health.
vi. 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.
vii. The CIM-CVGH IRB shall aim for adequate representation of men and women members to promote gender sensitivity in its review procedures.
viii. The CIM-CVGH IRB shall have representatives from both the older and younger generations.
ix. 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)

Step 2: *Call for nominations*

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.

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.

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

Step 3: *Submission of nominations*

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.

Step 4: *Shortlisting of nominees*

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.

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.

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.

Step 5: *Invitation to and confirmation of interest of the nominees*

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.

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

i. 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;
ii. The term of office of three (3) years, renewable for several consecutive terms depending on their performance; and
iii. The period for the chosen nominee to accept the nomination, which must not be longer than five (5) working days.

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.

Step 6: *Appointment of members*

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.

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:

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

(b) Duties: These include —

i. Consent to the IRB to make public his/her full name, profession, and affiliation as an IRB member;
ii. 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
iii. Willingness to sign the Confidentiality and Conflict of Interest Agreement (Form 1.4).

Responsibilities: These include —

i. Participating in CIM-CVGH IRB meetings;
ii. Reviewing, discussing, and considering research proposals submitted for evaluation;
iii. Reviewing progress reports and monitoring ongoing studies as may be appropriate;
iv. Evaluating final reports;
v. Maintaining confidentiality of the documents and deliberations during IRB meetings;
vi. Participating in continuing education activities in health research and ethics;
vii. Declaring any conflict of interest;
viii. Updating CV and training record every time appointment is renewed;
ix. Conforming at all times with the legal and ethical principles accepted by the IRB;
x. Attending basic and continuing education on Research Ethics at least once a year; and
xi. Performing other tasks requested or assigned by the IRB Chair.
xii. For medical Member; Perform ethics review of protocols submitted for review, including reviewing the ICF of the same
xiii. For non-medical Member; Perform ethical review of the ICF of protocols submitted for review
xiv. 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;
xiii. For member secretary; To oversee and supervise the staff secretary;

Step 7: *Completion of membership documents and signing of Confidentiality and Conflict of Interest Agreement*

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. 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.

Step 8: *Filing of appointment documents and CVs in the membership file*

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

7. 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

8. 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	*July 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001

xvii. NCIP AO 01-2012

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		
(1 x 1 Pic ture)	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

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 for the selection of officers is specific for the IRB of CIM-CVGH. This SOP begins with the call for a meeting and ends with the filing of appointment documents.

4. Responsibilities

It is the responsibility of the IRB members, officers, and secretariat to understand and implement this SOP of the CIM-CVGH IRB.

Officers of the CIM-CVGH IRB

The officers of the CIM-CVGH IRB are the **Chair**, the **Vice Chair**, and the **Member-Secretary**.

The Chair will be appointed by the Dean of CIM while the Vice Chair and the Member-Secretary will only be appointed after being nominated and voted upon by the current members of the IRB.

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;
I 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:

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).

5. 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*

6. Description of Procedures

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.

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.

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.

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.

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

7. Forms

Annex 1: Form 1.1 Appointment Letter
Annex 2: Form 1.2 Curriculum Vitae
Annex 3: Form 1.3 Confidentiality Agreement

8. 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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 Pic ture)	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

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 specifically pertains to the selection and designation of Independent Consultants in the review of research protocols of the IRB. This SOP begins with the creation and maintenance of a pool of Independent Consultants and ends with the filing of their appointment documents.

4. Responsibilities

It is the responsibility of the IRB members, officers, Member-Secretary and Independent Consultants to understand and implement this SOP of the CIM-CVGH IRB.

5. Duties of Independent Consultant

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

i. 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;
ii. 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;
iii. I Review, discuss, and consider related research proposals submitted according to his expertise including risks involved and the means of mitigating these risks;
iv. Maintain confidentiality of the documents and deliberations of IRB meetings;
v. Declare any conflict of interest before assuming the duties as Independent Consultant; and
vi. Conform at all times with the legal and ethical principles accepted by the CIM-CVGH IRB.

6. 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*

7. Description of Procedures

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.

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.

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.

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.

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).

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.

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.

Step 8: *Filing of appointment documents*

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

8. 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

9. 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

10. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001

xvii. NCIP AO 01-2012

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 Pic ture)	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

CIM-CVGH
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

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:

The IRB recognizes the importance of training and continuing professional development. 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. Responsibilities

It is the responsibility of the IRB officers, members and staff to have themselves educated and trained regularly.

It is the responsibility of the IRB Chair along with the Secretariat to assess the training needs and prepare a training plan for all members, Independent Consultants, and staff.

The IRB Staff and Member Secretary keeps track of the training records of all members, Independent Consultants, and staff in accordance with the training plan.

5. 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*

6. 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

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

- 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:
    - Member's/Staff's responsibilities;
    - Confidentiality and Conflict of Interest Agreement;
    - IRB review process and use of Protocol and ICF Assessment forms;
    - And IRB SOPs.
- The IRB Chair and Member-Secretary shall ensure that initial research ethics training is provided to all new members.

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

- 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.
- The IRB Chair and Secretariat plan the training activities for individual IRB members based on their training needs.
- 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.
- The IRB Members who participate in research ethics training course or seminar-workshops either through personal or through IRB efforts/funding are encouraged to:
    - Share information with other members during IRB meetings; and
    - Distribute photocopies/e-copies of relevant materials to the other members

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

- 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.
- 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.

- 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.

7. Forms:
Form 1.4 Training Record of IRB Member and Staff

8. 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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 procedure applies to all protocols submitted to the IRB for ethical review. This SOP begins with the receipt of study documents for initial review and determination of completeness of submission or resubmission and ends with the distribution of the protocol to the primary reviewers.

4. **Responsibilities**
   It is the responsibility of the IRB Staff to screen, manage, log-in and process study protocol IRB registration and package submission. The IRB Staff determines the paper to be included in the review of the next board meeting according to the cut-off date (2ND Wednesday of the month).

5. Workflow

ACTIVITY	*RESPONSIBILITY*
*Step 1. Receive the initial protocol package for review and check the completeness of the documents. 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*	*IRB Staff*
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 *a. Expedited Review (SOP on Expedited Review (SOP#2.3)* *b. Full Review (SOP on Full Review (SOP#2.4)* *c. Exemption from Review (SOP 2.2)*	*Chair/Member Secretary*
Step 5. Assignment of primary reviewers	
Step 6. Prepare the protocol review package for distribution to the primary reviewers.	*IRB Staff*

6. Description of Procedures

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

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

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.

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.\

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.

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

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.

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

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).

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

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

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.

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.

Step 4. Determine the type of review

4.1. The CIM-CVGH IRB Chair classifies the study protocol review pathway as either Expedited Review, Full Board Review or Exempt from Ethical Review filtered through the following criteria for Expedited Review:

4.1.1. The research poses low risk.

4.1.2. The study does not involve vulnerable populations.

4.1.3. The study does not involve the collection of stigmatizing information.

4.1.4. The study uses anonymized or archived samples.

4.1.5. Continuing review of clinical trials that do not involve further recruitment of participants.

4.1.6. Continuing review of studies previously classified under expedited review.

4.1.7. Study protocol amendments that are administrative in nature and do not affect the study protocol.

4.1.8. Study protocol amendments that do not change the overall risk profile of study.

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

Step 5. Assignment of primary reviewers

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.

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

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

Step 6. Distribution of the protocol and evaluation form to the primary reviewers

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

7. 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

8. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*Nov 16, 2016*	*SOP Team*	*FIRST DRAFT*
02	July 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

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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

CIM-CVGH

APPLICATION FOR INITIAL REVIEW

FORM 2.1

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

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
☐ Protocols that neither involves 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**

IRB Chair/Member Secretary Name & Signature **DATE**

ANNEX 2

WAIVER OF INFORMED CONSENT FORM 2.1A

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

Waiver of Informed Consent Form

Requested for the following Protocol:

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 Ethics Review Committee: ☐ 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 subspecialization)	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	Y☐	N☐	N.A.☐	

cultural traditions, and involvement of the community in decisions about the conduct of study?				
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

ICF EVALUATION FORM

FORM 2.4

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

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☐		
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

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

RESUBMISSION FORM

INSTITUTIONAL REVIEW BOARD
F. RAMOS ST., CEBU CITY
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

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.

3. Scope:

This SOP 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

i. 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.

ii. 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:

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

   b. 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:

      i. 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

      ii. 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.

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

The IRB, in its annual report submitted to the PHREB, shall include a list of all proposals or protocols that were exempted from review.

4. Responsibilities

It is the responsibility of the IRB members, officers, and secretariat to understand and implement this SOP of the CIM-CVGH IRB.

5. Workflow

ACTIVITY	*RESPONSIBILITY*
Step 1: *Receive study protocol applying for exemption from review*	*IRB Staff*
Step 2: *Classify a study protocol applying for exemption from review*	*Designated Member/ Chair*
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
Step 5: *File a copy of the documents in the protocol binder and update protocol database for exemption from review*	IRB Staff

6. Description of Procedures

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

i. The IRB Staff shall log the application for exemption
ii. The IRB Staff inform the IRB chair of the application for exemption

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

i. The IRB chair shall classify whether the protocol fulfills the criteria for exemption within 1 week from acceptance of the protocol package
ii. 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.
iii. If the protocol does not meet the Exemption Criteria, the Chair reclassifies the protocol for expedited or full-board review.

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

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

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

i. The IRB Staff prepares Certificate of Exemption from Review and forwards to the Chair for signature.
ii. The IRB Staff issues the Certificate of Exemption to the Principal investigator 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*

i. The IRB staff shall;
    - Prepare a binder to contain all protocols exempt from review.
    - File the properly-labeled binder in the appropriate shelf of the storage cabinet.
    - Update protocol database for exemption from review.

7. 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

8. History of SOP

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

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

ANNEX 1

CIM-CVGH

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

APPLICATION FOR INITIAL REVIEW

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
☐ Protocols that neither involves 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**

IRB Chair/Member Secretary Name & Signature **DATE**

ANNEX 2

CIM-CVGH

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

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

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

ANNEX 3

CIM-CVGH

CERTIFICAE OF EXEMPTION

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

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 change the risk benefit ratio as well as final report once the study has been completed*			
REC Chair Person Name	**Signature**	**Date**	

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 applies to initial and post-approval submissions on protocols which have been classified as not involving more than minimal risk to study participants, whose participants do not belong to vulnerable groups, and whose study situations does not generate vulnerability to participants. 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. Responsibilities

It is the responsibility of the IRB members, officers, and secretariat to understand and implement this SOP of the CIM-CVGH IRB.

5. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: *Assign primary reviewers (medical / scientific and a non-medical / nonscientific members).*	*Member- Secretary / Chair*
Step 2: *Notification of the Primary Reviewers*	*IRB Staff*
Step 3. *Provision of documents and evaluation form to reviewers:*	*Member Secretary*
Step 4: *Reviewers review and assess the submitted documents using the assessment form/s*	*Primary Reviewers*
Step5: *Return the accomplished assessment forms to the Secretariat.*	
Step 6: *Finalization of Review Results*	*Primary Reviewers*
Step 7: *Communicate the IRB decision to the PI (SOP # 6.2)*	*Member Secretary*
Step 8: *Filing of documents in the protocol file (SOP on Management of Active Files – SOP #7.2)*	*IRB Staff*
Step 9: *Inclusion of the Review in the Agenda of the next meeting (SOP on Preparing the Meeting Agenda – SOP #5.2)*	*Member Secretary*

6. Description of Procedures

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

i. 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 nonscientific/non-medical member) for the ICF Evaluation.
ii. Primary reviewers are selected on the basis of expertise related to the protocol.
iii. 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).

Step 2: *Notification of Reviewers or Independent Consultant/s*

i. 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.

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

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

Step 4: *Reviewers review and assess the submitted documents using the assessment form/s*

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

Step 5: *Return the accomplished assessment forms to the Secretariat.*

i. The medical primary reviewer should also evaluate the ICF besides the protocol.
ii. The forms shall be returned to the Secretariat during the next IRB meeting for filing

Step 6: *Finalization of Review Results*

i. 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
ii. The possible specific IRB actions include:
    1) approval
    2) minor modifications

3) major modifications
4) disapproval

iii. The results of the expedited approval shall then be presented during the next IRB meeting as approved through expedited process. Difference of/or contesting opinion will be entertained. Should there be a need of further discussion the protocol will then be discussed under full board.

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

Step 7: *Communicate the IRB decision to the PI*

i. Once there is an approval by expedited process the decision can be communicated to the researcher.

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

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

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

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

7. 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

8. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*Dec, 2018*	*SOP Team*	-
02	*July 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	*July 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.

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

ANNEX 1

CIM-CVGH

APPLICATION FOR INITIAL REVIEW

FORM 2.1

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

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
☐ Protocols that neither involves 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**

IRB Chair/Member Secretary Name & Signature **DATE**

ANNEX 2

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	
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 subspecialization)	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	Y☐	N☐	N.A.☐	

cultural traditions, and involvement of the community in decisions about the conduct of study?				
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.					-			-		
RINCIPAL 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 applies to initial, resubmissions and post-approval submissions on protocols which have been classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups. This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of protocol-related documents.

4. Responsibilities

It is the responsibility of the Secretariat to manage the document submission, send protocol documents to the primary reviewers, refer the protocol to full board meeting for discussion and decision, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry in the IRB database. It is the responsibility of the primary reviewers to review the protocol and related documents by using the assessment forms, present the protocol for discussion during the full board meeting and make a recommendation for appropriate action based on the discussion of the IRB.

5. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Assignment of primary reviewers or Independent Consultant/s (SOP on Appointment of Independent Consultants (SOP#1.3)	*Chair*
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*
Step 4: Presentation of review findings and recommendations during a Board meeting (SOP on Conduct of Meeting (SOP#5.3)	*Primary Reviewers*
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*
Step 9: Communication of Committee Action to the researcher (SOP Communicating IRB Decisions (SOP#6.2)	*Member Secretary*
Step 10: Filing of protocol-related documents	*IRB Staff*

6. Description of Procedures

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

i. 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).

Step 2 – *Notification of primary reviewers or Independent Consultants:*

i. 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.

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

i. The IRB Staff shall prepare and send the protocol review package to the primary reviewers within 7 calendar days from protocol submission.
ii. Protocol related documents are likewise provided to all members prior to the scheduled meeting.
iii. The review package consists of all the documents in the initial protocol package plus blank copies of the:
    - Study Assessment Forms (Form 2.3: Protocol Evaluation Form, and Form 2.4: Informed Consent Assessment Form), and
    - letter of approval from the technical review board

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

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

Step 5 – *Discussion of technical and ethical issues*:

i. Check the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements
ii. Consider whether study and training background of the principal investigator/s are related to the study to check for suitability of the PI.
iii. Look for disclosure or declaration of potential conflicts of interest or the lack of it.
iv. Non-physician principal investigators should be advised by a physician when necessary as a sub-investigator.
v. If applicable, determine if the facilities and infrastructure at study sites can accommodate the study.
vi. 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
vii. The medical primary reviewer also evaluates the ICF beside the protocol
viii. 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).

Step 6 – *Summary of issues and resolutions*:

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

Step 7 – *Committee action*:

i. The possible specific IRB actions include:

    1) approval,
    2) minor modifications,

3) major modifications, or
4) disapproval

Step 8 – *Documentation of committee deliberation and action*:

The CIM-CVGH IRB deliberation and action shall be documented in the Minutes of the Meeting. See SOP on Preparing the Meeting Minutes (SOP# 6.1).

Step 9 – *Communication of Committee Action to the researcher*:

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

Step 10 – *Filing of protocol-related documents*:

The IRB Staff shall file protocol-related documents. See SOP on Managing Active Files (SOP# 7.2)

7. 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 3.1: Approval Letter

8. 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	*July 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

ANNEX 1

CIM-CVGH

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

APPLICATION FOR INITIAL REVIEW

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**

☐ Protocols that neither involves 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**		
IRB Chair/Member Secretary Name & Signature		**DATE**

ANNEX 2

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	
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	Y☐	N☐	N.A.☐	

cultural traditions, and involvement of the community in decisions about the conduct of study?				
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

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**
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

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		

ANNEX 6

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

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITIONAL REVIEW BOARD	
VERSION 3	**SOP 2.5 Resubmission Review**	Effective Date: JULY 21, 2023

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 applies to the IRB review and approval of study protocols recommended for minor or major modifications during initial and continuing review.

4. **Responsibilities**

   It is the responsibility of the IRB Chair/ Member Secretary to classify resubmitted protocols for expedited or full board review.

   It is the responsibility of primary reviewers to review the resubmitted documents to determine if they have complied with the required modifications before granting approval during expedited review or to recommend approval of protocols with major modification to full board.

   It is the responsibility of IRB members to approve resubmitted protocols with major modification after discussion.

5. **Workflow**

ACTIVITY	***RESPONSIBILITY***
Step 1: Receive the resubmitted protocol package from the PI.	*IRB Staff*
Step 2: Send the protocol package to the primary reviewers.	*IRB Staff*
Step 3: Review if the resubmission complied with the required modifications	*Primary Reviewers*
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*
Step 6: Accomplish the Certificate of Approval and communicate the IRB decision to the PI	*IRB Staff*
Step 7: File copies of the documents *in the protocol file folder and*	*IRB Staff*

6. Description of Procedures

Step 1 – *Receive the resubmitted protocol package from the Principal Investigator*

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

Step 2 – *Send the protocol package to the primary reviewers:*

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

Step 3 – *Review if the resubmission complied with the required modifications:*

i. The Chair/Member-Secretary or designated primary reviewers may review minor protocol modifications.
ii. The primary reviewers review the resubmitted documents and compares it with the requirements for modification
iii. Provide a summary of the comments in compliance to the recommendations for the resubmitted document/s

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

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

ii. In expedited review, the primary reviewers approve the resubmitted documents if the PI has substantially complied with the required modifications.
iii. Minor modifications recommended by full board should also go to expedited review.

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

i. Primary reviewers resend their assessment of major modifications during full board discussion and make a recommendation for approval.
ii. IRB members vote to endorse or not to endorse the recommendation for approval.

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

ii. For approved resubmitted protocols, the IRB staff prepares the Certificate of Approval that the Chair should sign.
iii. The IRB decision is communicated to the PI.

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

- The IRB Staff files copies of the approved documents in the protocol file folder.
- Update the protocol file index of the protocol file folder.
- The IRB Staff updates the protocol database.

7. Forms

Annex 1. Form 2.5: Resubmission Form

8. 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 providing a summary of comments*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

ANNEX 1

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

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL **INSTITIONAL 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

This activity aims to describes the process of appeal of an IRB decision.

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. Responsibility

It is the responsibility of the CIM-CVGH IRB Staff to receive an appeal request from investigators regarding decisions made earlier and make appropriate action.

5. 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*

6. Description of Procedures

Step 1: *Receive an appeal request from investigators.*

i. The IRB Staff receives an appeal request from investigators.
   - Letters of appeal must be received 30 days in advance of the next IRB Meeting

Step 2: *Submit appeal request from investigators to IRB Chair*

i. The IRB staff sends the appeal request from investigators to IRB Chair.
ii. IRB chair assigns the review of the appeal to the primary investigator

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

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

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

i. The primary reviewer/s discuss the *merits of the appeal and make appropriate decision*.
ii. The board *makes the appropriate decision*.

Step 5: *Communicate IRB decision to PI*

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

Step 6: *Files and documents appeal*

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

7. Forms (None)

8. 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

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITIONAL REVIEW BOARD	
VERSION 3	**SOP 3.1 Review of Amendments**	Effective Date: July 21, 2023

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. Responsibility

It is the responsibility of the CIM-CVGH IRB Secretariat to manage protocol amendment package submitted by the PI. It is the responsibility of preferably the original primary reviewers to review the amendments and recommend appropriate action. It is the responsibility of the CIM-CVGH IRB Chair to determine whether the amendment goes for expedited or full board review. The CIM-CVGH IRB approves the final decision for amendments submitted by the PI to the IRB.

5. **Process Flow/Steps**

ACTIVITY	***RESPONSIBILITY***
Step 1: *Receive and manage Amendment Package*	*IRB Staff*
Step 2: *Refer Amendment Documents to original primary reviewers*	*IRB Staff*
Step 3: *Review amendments and make a recommendation*	*Primary Reviewers*
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*
Step 6: *Communicate CIM-CVGH IRB decision to PI*	*Member Secretary, IRB staff*
Step 7: *Keep a copy of all amendment related documents in the protocol file*	*IRB Staff*

6. Description of Procedures

Step 1: *Receive and manage Amendment Package*

ii. The IRB Staff checks the completeness of the amendment package submitted by the Investigator.

Step 2: *Refer Amendment Documents to original primary reviewers*

i. The IRB Staff refers the amendment package preferably to the original primary reviewers within 7 days from submission.

Step 3: *Review amendments and make a recommendation*

- The original primary reviewers (preferably) shall check the amended documents and compare them with the previously IRB approved documents in the protocol files. They decide if the amendments would alter the risk/benefit ratio of the study, and make appropriate recommendations
- Major amendments of full board protocols will be reviewed full board while minor amendments should be reviewed by expedited
- For amendments that will potentially affect the risk/benefit ratio, a full board for discussion shall be conducted using the amendment review form.

Step 4: *Review recommendations and determine if amendment should be referred to full board*

i. The Chair shall review the recommendations by the Primary Reviewer and decide if the study needs a full board review.

Step 5: *Discuss at full board, if necessary and make a decision*

i. Amendments that may potentially alter the risk/benefit ratio of a study are referred to full board for discussion. Members shall make a decision.

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

iii. a change in study design
    1. additional treatments or the deletion of treatments
    2. any change in the inclusion/exclusion criteria
    3. change in method of drug intake or route of drug in take (e.g. oral changed to intravenous)
    4. significant change in the number of subjects (increase or decrease in sample size that alters the fundamental characteristics of the study)
    5. significant decrease or increase in dosage amount

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

v. Decision points may include
    i. Approval
    ii. Major Modification
    iii. Minor Modification
    iv. Disapproval

Step 6: *Communicate CIM-CVGH IRB decision to PI*

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

Step 7: *Keep a copy of all amendment related documents in the protocol file*

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

7. Forms

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

8. History

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

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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

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

☐ YES ☐ NO

Recommended action

☐ **Approved**

☐ **Minor Modification subject to expedited review at the level of the chair**

☐ **Major Modification subject to full Board REview**

☐ **Disapproved**

To the PI to fill			
Section	**Before Amendment**	**After Amendment**	**Rationale**
TYPE OF REVIEW		☐ **Full Board** ☐ **Expedited**	
Name and Signature **Principal Investigator**		**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. Responsibility

It is the responsibility of the CIM-CVGH IRB Staff to remind investigators to submit the progress report and forward the reports to the primary reviewers for review comments, to communicate with the investigators if there is need for further information or action and to submit to full board a list of progress and final reports for approval.

It is the responsibility of the primary reviewers to review the reports to check completeness of information and ensure that the data are in accordance with the protocols and other related documents approved by the IRB.

5. 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*

6. Description of Procedures

Step 1: *Remind Pis to submit progress report two months before due date*

i. The IRB Staff checks the database and tracks due dates of progress reports of Study Protocols approved by the CIM-CVGH IRB.
ii. The Secretariat prepares and sends reminder letter/notice addressed to the PI *two months* before the *expiry date of approval*.

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

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

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

i. The IRB staff will check whether the initial review was done full board or expedited and schedules the discussion of the progress report accordingly
ii. Expedited protocols will go to expedited, full board will go to full board

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

i. 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.

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

i. 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.
ii. The primary reviewer will assess for any changes in the risk/benefit ratio.
iii. 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.

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

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

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

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

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

i. 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.

ii. 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

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

iv. 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)

7. Forms

Annex 1: Form 4.2 Progress Report Form

8. 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	***July 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***

9. References:

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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
   - ❑ YES (Explain changes in attached narrative)

8. CHANGE IN PRINCIPAL INVESTIGATOR?
   - ❑ NONE
   - ❑ DELETE:_____

ADD: _____

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)

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

This SOP applies to the review of SAE and SUSAR reports submitted by investigators and sponsors to the CIM-CVGH IRB. The IRB reviews such reports to determine appropriate action to protect the safety of participants in an approved study.

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

i. Results in death,
ii. Is life threatening,
iii. Requires hospitalization or prolongation of existing hospitalization,
iv. Results in persistent or significant disability or incapacity, or
v. Results in a congenital anomaly or birth defect.

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. Responsibility

It is the primary responsibility of the CIM-CVGH IRB to receive and review SAE and SUSAR reports from its own site and to take the necessary action to ensure the safety of participants in the study. These are categorized as Onsite SAEs/SUSARs

In multicenter studies, the IRB also receives SAE and SUSAR reports from other sites within and outside the country. These are categorized as offsite SAEs/SUSARs. It is the responsibility of the CIM-CVGH IRB to be updated of trends of safety issues of studies that it has approved.

The CIM-CVGH IRB has the authority to suspend or terminate approval of research at its site when the safety of participants is no longer assured. When CIM-CVGH IRB takes such action, it is required to provide the reasons for its action and to promptly report such decision to the investigator, the sponsor, the institution and relevant regulatory authorities.

5. **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*

6. Description of Procedures

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

i. 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.
ii. 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.
iii. Date of submission should be within the required timeline as mentioned in IRB Guidelines.

Step 2: *Retrieval of pertinent protocol file*

i. 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

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

i. 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.

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

i. 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.

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

- Request an amendment to the protocol or consent form
- Request further information
- Suspension of:
  - Enrollment of new research participants until further review by the IRB

        - All trial-related procedures (except those intended for the safety and well-being of the participants) until further review by the IRB
    - Termination of the study
    - Take note and continue monitoring
    - Conduct site visit

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

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

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

i. 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)

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

i. 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)

7. 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

8. 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	*July 21, 2023*	*Dr Evasco*	– *Updated References*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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 – ○ 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:

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 –○ 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:

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, allergics, 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 SAE ASSESSMENT FORM
INSTITUTIONAL REVIEW BOARD
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*

4. Detailed Instructions

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.

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

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.

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.

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

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

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

6. Glossary

Study Site - physical location of where the study is being conducted, e.g., community,institutional facility.

Reportable Negative Events (RNE) - are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data.

Special meeting – an assembly of the Committee outside of the regular schedule of meetings fora specific purpose, usually to decide on an urgent matter like selection of officer,approval of a revised or new SOP, report of critical research problem that requires immediate action

Clarificatory Meeting/ Interview – is a face-to-face meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.

8. Form

NONE

9. 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*

10. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
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x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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 applies to the review of reports of protocol deviations or violations in the conduct of previously approved studies. This 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. Responsibility

The Principal Investigator/researcher reports major protocol violations and deviations at the time specified in approval letter. The IRB Staff receives and documents the report, retrieves the pertinent protocol file and notifies the Chair. The Chair determines the type of review and ensures inclusion of the report in the agenda of the next IRB meeting. The concerned reviewers evaluate the report of protocol violations/deviations. The members of IRB finalize the decision regarding the report.

5. **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*

6. Detailed Instructions

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

i. 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.

ii. The IRB Staff shall obtain full information about the event and document the submission in the log book.

Step 2: *Retrieval of pertinent protocol file*

i. 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

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

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

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

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

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

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

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

i. 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)

ii. Possible decisions include one or several of the following:
   - Submission of additional information
   - Submission of corrective action
   - Clarificatory interview with Principal Investigator/researcher
   - Site visit
     - Suspension of recruitment
     - Suspension of the study

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

i. 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)

7. Forms

FORM 3.5: Protocol Deviation/Violation Report Form

8. 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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 provides instructions for the review of of Final / Closure Reports that are required by the IRB to be submitted by the principal investigator when the approved study is completed or when the study site is closed.

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

4. Responsibility

It is the responsibility of the IRB Staff to receive final reports when submitted.
It is the responsibility of the Primary Reviewers to review the reports to check completeness of information and to ensure that the data are in accordance with the protocol and other related documents approved by the IRB.

5. 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: *Approve the final/closure report during IRB full board meeting*	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*

6. Description of Procedures

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

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

v. 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.

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

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

Step 2: *Identify primary reviewers*

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

ii. 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.

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

i. 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 .

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

iii. 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)

iv. 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.

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

Step 4: *Approve the final/closure report during* IRB

i. The Primary Reviewer presents the results of the review during full board.

ii. The IRB decision can be any of the following:

- Acknowledged/Accepted
- Request for further information, specify
- Recommend further action, specify

Step 5: *Communicate IRB decision to PI*

i. 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.
ii. The IRB Staff prepares Notification of IRB Decision on the Review of Final / Closure Report for signature of the IRB Chair.
iii. The IRB Staff sends the notification to the PI

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

i. 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.
ii. 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
iii. IRB Staff updates the protocol database.

7. Forms

Annex 1: Form 4.3A Final Report Form
Annex 2: Form 4.3B Certificate of Completion

8. 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. – Updated References

9. References:

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
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xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

ANNEX 1

CIM-CVGH

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

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**

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 includes the processes followed in conducting site visits for reasons set by the IRB. 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. Responsibility

The CIM CVGH IRB will select from among its members a team to compose the Site Visit Committee. The committee will have a designated Chair, Secretary and staff to facilitate the processes of the activity.

5. **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*

6. Detailed Instructions

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:

i. new study sites /new researcher
ii. reports of remarkable serious adverse events
iii. major protocol non compliance
iv. reports of complaints from study participants
v. failure to submit continuing review requirements
vi. high risk studies
vii. studies requiring a large study population

Step 2: *Notification of Primary Researcher*

i. 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.

Step 3: *Creation of Site Visit Team*

i. 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.

Step 4: *Preparation of Documents for Site Visit*

i. The IRB Staff shall prepare the documents needed for the site visit including documents requested from the primary researcher.

Step 5: *Conduct of Site Visit*

i. 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

Step 6: *Draft and presentation of report*

i. 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.
ii. 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.

Step 7: *Discussion and Formulation of Recommendation*

i. 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.
ii. The final report and recommendations will be relayed to the primary researcher in a formal letter.

Step 8: *Filing of Documents*

i. 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.

7. Form: Checklist for Site Monitoring**(See Annex 3)**

8. 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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. Responsibility

A designated member of the CIM-CVGH IRB Staff is responsible for receiving requests, queries, and complaints of research participants and other interested parties related to the participation in the research and research protocols and refers relevant issues to the CIM-CVGH IRB Chair for appropriate action. The IRB Staff keeps records of all actions taken by the CIM-CVGH IRB.

5. **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*

6. Detailed Instructions

Step 1: *Receive the complaint or inquiry*

i. The request, query, or complaint related to research participation or research protocols may come from research participants or other interested parties.
ii. The CIM-CVGH IRB Staff receives and studies the request, query, or complaint.
iii. 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.

iv. 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.
v. The IRB Staff records the submitted document in the Log of Incoming Communications

Step 2: *Review the complaint/inquiry*

i. The CIM-CVGH IRB Chair or Member-Secretary reviews the request, query, or complaint.
ii. The PI maybe contacted to provide clarification or further information.

Step 3: *Discuss in convened meeting or report the decision/action taken to full board*

i. The CIM-CVGH IRB Chair presents serious requests, queries, or complaints to full board for discussion.
ii. 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.
iii. The IRB members discuss to take appropriate actions.

Step 4: *Communicate IRB's response*

i. 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.

Step 5: *File pertinent documents*

iii. 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.
iv. The IRB Staff updates the protocol file index.

7. Form

Annex 1: Communication Record Form Form 4.5

8. 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*

9. References:

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
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x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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/Reasons for making contact:								
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 covers all activities prior to the conduct of an IRB meeting. This SOP begins with the preparation of the agenda and ends with the notification of IRB Members and confirmation of attendance.

4. Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Secretary-Member, to compile all documents/ information submitted to the IRB within a given period to include them in the next full board meeting agenda for discussion or information of the RERC members.

5. **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*

6. Description of Procedures

Step 1: *Preparation of the agenda (SOP on Preparing the Meeting Agenda - SOP#5.2)*

i. 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.

Step 2: *Assembly of materials and documents needed for the meeting*

i. The IRB Staff shall collect all the documents needed during the full board meeting. These will include, but not limited to, the following:

- Meeting Agenda (See SOP# 5.2)
- Attendance sheet
- At least 2 hard copies, and an electronic copy of all submissions on or before the 2nd Wednesday of the month.
- Electronic copies of the minutes of the previous meeting
- Folders of individual IRB member
- Administrative documents, if any
- Letters / Communications, 1 hard and soft copy
- For online meetings, electronic copies of necessary documents shall be sent via
- email at least a week prior to the scheduled meeting

Step 3: *Preparation of logistics for the meeting*

i. 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.

iii. Meetings are scheduled at 12noon – 2 PM. Lunch will be provided for the members.

iv. The IRB members who attended shall file a Daily Time Record which will be submitted to the Accounting Dept. immediately after the meeting.

v. For online meetings, the link shall be sent to the IRB members at least a day prior to schedule

vi. The IRB Secretariat will send a reminder thru text to all members the day before, and in the morning prior to the meeting.

Step 4*: Notification of IRB Members and confirmation of attendance*

i. The IRB members shall be notified through email and SMS at least a week before the meeting.

ii. 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.

7. Forms:

None

8. 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) Workbook 2015
ii. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
iii. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
iv. International Conference on Harmonization, E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) 2018.
v. National Ethical Guidelines for Health Research 2011 PNHRS
vi. National Ethical Guidelines for Health Research 2017 PNHRS
vii. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
viii. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2020
ix. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2002.
x. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011.
xi. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
xii. International Conference on Harmonization, E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) 2018.
xiii. 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
xiv. National Ethical Guidelines for Health Research 2011 PNHRS
xv. National Ethical Guidelines for Health Research 2017 PNHRS
xvi. 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
xvii. RA 10173 Data Privacy Act of 2012
xviii. PNHRS ACT OF 2013
xix. CHED Memorandum Order No. 34 ser 2007
xx. DOST AO No. 001 series 2008
xxi. FDA Circular No 2012 – 007
xxii. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xxiii. NCIP AO 01-2012

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 describes how the IRB determines what items are included in the agenda of the regular and special meetings. This SOP begins with the preparation of the draft meeting agenda and ends with the filing of the final meeting agenda.

4. Responsibility

It is the responsibility of IRB Staff, under the supervision of the Secretary-Member, and Chair to draft and prepare the provisional meeting agenda.

5. 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*

6. Detailed Instructions

Step 1: *Preparation of the agenda (SOP on Preparing the Meeting Agenda - SOP#5.2)*

- 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.

Step 2: *Preparation of the provisional meeting agenda*

i. 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.

Step 3: *Distribution of the provisional meeting agenda*

i. The IRB Staff will forward the provisional agenda to all the IRB members at least 3 days before the scheduled meeting.

Step 4: *Approval of the provisional meeting agenda*

- The IRB members will approve the provisional agenda during the meeting

Step 5: *Filing of the final meeting agenda*

i. The IRB Staff will file the meeting agenda after the meeting (SOP on management of Active Files - SOP#7.2)

7. Forms

Meeting Agenda Template Form 5.1

8. 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS

x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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. 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			

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. PROGRESS REPORTS / CONTINUING REVIEW REPORTS DUE IN 30 DAYS

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	

L. 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 discussion 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 describes the manner by which the IRB conducts all its meetings. It covers IRB actions and activities from the time quorum is confirmed to the time the meeting is adjourned. This SOP begins with the distribution of meeting materials and ends with the collection, storage, and disposal of meeting materials.

4. Responsibility

It is the responsibility of IRB Chair to chair and ensure an orderly conduct of the meeting, and the IRB members to attend, participate in the discussion/deliberation, and vote if the need arise. In his absence he may designate the Vice Chair or in the absence of the vice chair any member to chair the meeting

5. **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*

6. Description of Procedures

Step 1: *Distribution of meeting materials*

i. 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.

ii. For online attendees, electronic copies of documents shall be sent by email at least 7 days prior to the meeting

Step 2: *Determination of quorum (formal start)*

i. 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.

Step 3: *Approval of the provisional agenda*

i. 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.

Step 4: *Declaration of conflict of interest (COI)*

i. 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.

ii. 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.

Step 5: *Approval of minutes of the previous meeting*

i. 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.

Step 6: *Discussion of "business arising from the minutes*

i. The Chair shall lead the discussion on the business arising from the previous meeting. Issues shall be resolved by voting if necessary.

Step 7: *Review of protocols and protocol-related submissions*

i. 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.

ii. 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.

iii. 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;

- Approval (no further revision of the documents is required)
- Minor Modification
- Major Modification,
- Disapproval

iv. If there are differences in opinion, voting will be done.

Step 8: *Report of results of expedited review*

- The Primary Reviewers shall report the submissions for expedited review *(SOP on Expedited Review - SOP# 3.1)*.

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.

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.

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).

7. Forms

NONE

8. 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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 covers IRB actions related to the documentation of a full board meeting, the final output of which is the minutes of the meeting. This SOP begins with the entry of preliminary information on the minutes template and ends with the storage of the approved minutes.

4. Responsibility

It is the responsibility of the IRB members, officers, and secretariat to understand and implement this SOP of the CIM-CVGH IRB.

5. **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*

6. Description of Procedures

Step 1: *Entry of preliminary information on the minutes template*

i. 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.

Step 2: *Preparation of the draft minutes*

i. 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.

ii. 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.

iii. 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

iv. An electronic copy of the draft minutes will be sent to the IRB Chair within 5 days after the meeting.

Step 3: *Approval of the minutes in the next IRB meeting*

i. The draft minutes shall be presented in the next IRB meetings for comments and/or corrections.
ii. The approval of the minutes is done through a formal motion from any member of the committee and seconded accordingly.
iii. See SOP on conduct of meeting

Step 4: *Storage of the approved minutes*

i. Both hard and electronic copies of the approved minutes will be saved
ii. See SOP on Managing Active Files (SOP #7)

7. Forms

Annex: Minutes Template Form 6.1

8. 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

Annex 1

CIM-CVGH

MEETING MINUTES TEMPLATE

FORM 5.2

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

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. PROGRESS REPORTS / CONTINUING REVIEW REPORTS DUE IN 30 DAYS

Protocol No.	Study Title
7.	
8.	
9.	
10.	
11.	
12.	

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	

L. Other Matters:

M. 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**

a. This aims to ensure that all stakeholders are appropriately, accurately and promptly informed of the results of deliberations of the REC.
b. To ensure an efficient tracking system

3. Scope

This SOP covers IRB actions related to the communicating IRB decisions (e.g. actions to applications submitted to the IRB). 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. Responsibility

It is the responsibility of the Chair and the Board members as well as the secretariat to complete a written communication record for telephone or interpersonal discussions related to the past, present and/or future studies and/or processes involving the IRB.

5. **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*

6. Detailed Instructions

Step 1: *Finalization of recommendations of the committee*

iii. Finalization of recommendations of reviewers (in case of full review see SOP on Full Review: SOP#3.2)
iv. Finalization of recommendations of the committee (in case of expedited review see SOP on Expedited Review (SOP#3.1)

Step 2: *Transfer of information from minutes or reports to IRB decision forms or templates*

v. The record should contain, but is not limited to, the following information:
- Date of communication
- Study information, i.e., sponsor, protocol number, investigator, etc.
- Name of person contacted
- Contact address, telephone number, e-mail, fax, in person
- Summary of the communications made
- Notation of any follow-up if necessary
- Signature of the individual responsible for the recording of the communication

Step 3: *Approval of the IRB decision document*

ii. The Chair shall review and approve the document within 1 week after the IRB Board meeting.

Step 4: *Dispatch of IRB decision document to researcher*

v. 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.

Step 5: *Storage of the decision document in the protocol file (SOP on Managing Active Files (SOP# 7.2)*

7. Forms (None)

8. 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*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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

xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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 covers IRB actions related to all incoming and outgoing documents that are submitted to and sent out from the IRB. This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

4. Responsibility

It is the responsibility of the IRB staff and IRB secretary to handle the processing of the communications, and the Chair to approve the outgoing documents.

5. **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*

6. Description of Procedures

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.

vii. 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.

Step 2: *Recording of incoming/outgoing communications*

i. 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.

ii. The following data shall be include:

- Date received/sent
- Subject
- Person who sent the communication with signatures
- Person who received the communication with signature
- Action taken

Step 3: *Acting on communications*

i. 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.

Step 4: *Storing or filing of incoming/outgoing communications (SOP on Managing Active Files SOP#7.2)*

vi. Hard copies of the communications shall be filed by the IRB staff in their respective folders (Protocol-related communications; administrative communications, etc.)

vii. See SOP on Managing Active Files (SOP #7)

7. Forms (None)

8. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*April 6, 2019*		*First Draft*
03	*July 21, 2023*	*Dr Cutillar*	*- Updated References*

9. References

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015

ii. 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 2011 PNHRS

ix. National Ethical Guidelines for Health Research 2017 PNHRS

x. 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

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. Responsibility

It is the responsibility of IRB Secretariat to manage all protocol submissions and documents that reflect all IRB. Actions and organize them in an orderly manner. The IRB Secretariat also manages the maintenance and storage of all IRB documents and records.

5. **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*

6. Description of Procedures

Step 1: *Design a standard coding system for all protocols submitted to the IRB for review*

i. 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.

ii. 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
iii. 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
iv. 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.
v. 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.
vi. 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.

Step 2: *File all submitted documents in an orderly sequence in a protocol folder*

i. The protocol file folder contains the following documents arranged chronologically in an organized manner according to the Protocol File Index per type of submission (eg. initial submission, protocol amendment, progress report, SAE Reports, Protocol Violation/Deviation, etc.):

    i. All versions of study protocol
    ii. Related documents that came with the study protocol (ICF, CRF, recruitment materials, patient diary, IB, etc.)
    iii. Principal investigator and co-investigators' CVs and ((other similar documents))a valid GCP Training Certificate, if required
    iv. Reviewers' assessment forms
    v. Amendment reports
    vi. Continuing review applications
    vii. Serious Adverse Event Reports or Safety Notifications
    viii. Non-compliance (Deviation or Violation) reports
    ix. Participant Queries/ Complaints, if any
    x. Site Visit Reports, if any
    xi. Notifications of IRB Decision
    xii. Approval letters Decision letters (notification letters or approval letter/s initial and renewal)
    xiii. 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)
    xiv. Miscellaneous communication related to the protocol
    xv. Final report

***Step 3: U**pdate and organize active study files*

i. Update the active protocol files regularly by chronologically organizing the contents of the active study files according to time of receipt.
ii. Ensure that all updates and organization are recorded in the database
iii. Combine related documents of the approved study files appropriately. Attach an identity Label to the package.

***Step 4**: Store active Protocol Files.*

i. Keep the active protocol files in the Active File Cabinet in the office.
ii. 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.
iii. Store the closed study files for at least 5 years after the study closure.
iv. For studies with multiple study sites, the Secretariat should maintain the files to allow cross-referencing without unnecessary duplications.
v. Place the protocol file binders in the shelf in vertical position and sequentially arranged according to their Protocol Code No.
vi. Label the storage cabinet with the year when the protocols were submitted.

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*

8. *Forms (none)*

9. References:

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS

x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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 includes IRB actions related to storage of protocols that are classified as inactive either by termination or completion. This SOP begins with the acceptance of final or early termination reports and ends with the reclassification of the file as inactive file.

4. Responsibility

It is the responsibility of IRB Staff, under the supervision of the Member- Secretary, to archive in an orderly manner all protocol files that have been completed, terminated, or are no longer active. They are kept together in a designated place in the institution where confidentiality and security of the documents can be maintained.

5. **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*

6. Description of Procedures

Step 1: *Selection of Files for archiving*

i. Inactive Protocol Files (Completed/Terminated/ Closed) are defined as:
   - 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

Step 2: *Management for Inactive Files*

i. 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 by adding the (year of archiving) as a suffix to the original protocol code. For example, if the Final Report of Protocol CIM-CVGH IRB 2010-02 was archived in 2016, the archiving code is CIM-CVGHIRB 2010-02/2016.

Step 3: *Sorting of Archived Files*

i. 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

Step 4: *Storing the Protocol Documents*

i. 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.
ii. After they have been kept in the active files cabinet for 6 months the files will be transferred to the archived files cabinet.
iii. Database will be updated to indicate protocol files that will be transferred to archive.

Step 5: Disposal of Archived Files

i. Disposal of archived files will be through shredding of documents after 5 years of being stored as Archived Files.

Step 6: *Management of file retrievals*

i. See SOP on Managing Access to Confidential Files (SOP #7.4)

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*

8. Forms: none

9. References:

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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. Responsibility

It is the responsibility of the IRB Secretariat under the supervision of the Member Secretary to ensure that confidentiality is maintained in the management of all study files and records.

5. **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*

6. Description of Procedures

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:

i. 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.)

Step 2: *Receipt and logging of request for access to confidential files*

Access to IRB confidential documents is subject to the following limitations:

i. 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.
ii. 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.
iii. 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).
iv. The request will be logged in the incoming/outgoing communications book.

Step 3: *Approval of requests for access and retrieval of documents*

i. The request for document retrieval shall be discussed in the IRB meeting and shall be approved by the members.

Step 4: *Supervision of use of retrieved document* Recording of copies made of from confidential documents

ii. The IRB Staff records the retrieval of IRB documents. The following data shall be recorded in the log of request (Annex 3).
   - Study File Code
   - Date borrowed
   - Number of borrower
   - Name and Signature of borrower upon retrieval
   - Signature of IRB Secretariat upon return
   - Document copied
   - Number of copies made
   - Number of copies received
iii. All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.
iv. The IRB Staff makes only the exact number of copies requested.
v. Upon receipt of the copies, the person who requested the copies will sign the Log of Request Form

Step 5: *Return of document to the files*

i. 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.
ii. The IRB Staff records the retrieval of CIM-CVGH IRB documents.

7. Forms-

Annex 1 – FORM 5.3 FILE REQUEST LOG

8. 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*

9. **References:**

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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

This SOP provides instructions on how the CIM-CVGH IRB Standard Operating procedures are prepared, written approved and distributed. Also included in this SOP are the instructions on how the revisions and updates are written. 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. Responsibility

It is the responsibility of the assigned Board members as aided by the secretariat to draft new or revise and update current SOPs.

5. **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*

6. Description of Procedures

Step 1:*Organize an SOP Team*

i. 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

ii. The SOP Team receives an orientation from the Chair regarding duties and responsibilities
iii. The Chair can organize SOP Team workshops to facilitate the drafting of SOPs.

Step 2:*Design the format, layout, identifier of SOP*

i. An SOP is written according to the following format:
   - Number and version
   - Title
   - Policy
   - Objectives
   - Scope which includes description and purpose of the SOP
   - A flowchart when necessary
   - Detailed instructions
   - Forms (if applicable)

ii. The layout of a typical SOP uses a header with the following elements:

   - Institutional seal or logo of both CIM and CVGH
   - Name of Institutional Review Board
   - SOP identifier
   - SOP title
   - Version number
   - Effectivity date

Step 3: *Write a new SOP and submit to Chair*

i. 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
   - Initial Review Procedures – describe types of review and initial review procedures
   - Monitoring Procedures – describe how the IRB monitor implementation of approved protocols
   - Management of Meetings, Documentation and Archiving – describe administrative procedures that support the review functions
   - Writing and Revising SOPs – describes how to draft and revise SOPs

Step 4: *Review new SOP in full board meeting*

i. The Chair submits the draft to full board review where IRB members deliberate on the draft
ii. Upon full board approval, the Chair submits the approved draft to the CIM CVGH President for final approval.

Step 5: *Approve new SOP*

i. The CIM-CVGH President of CIM CVGH approves the SOP by signing in the appropriate section in the cover page.

ii. The approved SOPs will be implemented from the date of approval by the Medical Director.

Step 6: *Distribute approved SOPs and keep copies in the IRB files*

i. Distribute approved SOPs and keep copies in the IRB files.
ii. Upon approval of CIM-CVGH Medical Director, the IRB Staff distributes SOP to CIM-CVGH 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.
iv. The IRB Staff retains one complete originally signed SOPs copy.

Step 8: *Training on SOP*

i. New SOPs are circulated for self-reading to the members and the secretariat
ii. Training is documented in the training log sheet (Refer to Annex 4)

Step 9: *Manage and archive superseded SOPs*

i. Superseded SOPs should be retained and clearly marked "superseded" and archived in the historical file by the Secretariat.

7. 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*

8. References:

i. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
ii. 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 2011 PNHRS
ix. National Ethical Guidelines for Health Research 2017 PNHRS
x. 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
xi. RA 10173 Data Privacy Act of 2012
xii. PNHRS ACT OF 2013
xiii. CHED Memorandum Order No. 34 ser 2007
xiv. DOST AO No. 001 series 2008
xv. FDA Circular No 2012 – 007
xvi. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xvii. NCIP AO 01-2012

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 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

Step 1*: Receipt of submitted documents*

i. The IRB Staff received the new medical device study.
ii. The CHH IRB Secretariat check the submitted package for completeness.
iii. The CHH IRB Secretariat document the checking procedure by completing a checklist form

Step 2: *Assignment of Primary Reviewer*

i. It is the responsibility of the Member-Secretary/ CHH IRB Chair to assign the primary reviewers to review the study, according to the use of study assessment forms (refer to SOP/005/06).
ii. Staff secretary prepares the documents for distribution to each CHH IRB member/ primary reviewer.
iii. Include the new medical device study on the meeting agenda.

Step 3: *Reporting of Protocol assessment*

i. Primary Reviewers present a brief oral or written summary of the study design related to the level of risk
ii. The Chairperson opens discussion about whether the study is SR or NSR (see examples in ANNEX 1).
iii. The Chairperson leads discussion about each document under consideration (e.g. protocol, informed consent, investigators and site qualifications, advertisements).
iv. 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.

Step 4: *Notification to the investigators*

i. The Secretariat sends an action letter along with the approved documents to the investigator. (Refer to SOP on Communicating IRB Decision to PI)
ii. 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.
iii. If the investigator wishes to appeal this decision, he or she may do so.
iv. 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.

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Step 5: *Storage of the documents*

i. 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	*July 21, 2023*	*Dr. Donaldo*	– *New SOP*

7. References:

i. Code of Federal Regulation (CFR) 21, Volume 8, Part 812, April 2003, Food and Drug Administration, U.S. Government Printing Office via GPO Access
ii. ASEAN Agreement on Medical Device Directive Jakarta: ASEAN Secretariat, September 2015
iii. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
iv. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2020
v. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2002.
vi. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011.
vii. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

viii. International Conference on Harmonization, E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) 2018.
ix. 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
x. National Ethical Guidelines for Health Research 2011 PNHRS
xi. National Ethical Guidelines for Health Research 2017 PNHRS
xii. 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
xiii. RA 10173 Data Privacy Act of 2012
xiv. PNHRS ACT OF 2013
xv. CHED Memorandum Order No. 34 ser 2007
xvi. DOST AO No. 001 series 2008
xvii. FDA Circular No 2012 – 007
xviii. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xix. NCIP AO 01-2012

ANNEX 1

EXAMPLES OF DEVICE STUDIES ACCORDING TO RISK

NON-SIGNIFICANT RISK DEVICE STUDIES

EXAMPLES:

- Bio-stimulation Lasers for treatment of pain

- Caries Removal Solution

- Daily Wear Contact Lenses and Associated Cleaners and Solutions

- Dental Filling Materials, Cushions or Pads made from traditional materials

and designs

- Denture Repair Kits and Re-aligners

- Gynecologic Laparoscope and Accessories at power levels established prior to May 28, 1976 (excluding use in female sterilization)

- Externally worn Monitor for Insulin Reactions

- Jaundice Monitor for Infants

- Magnetic Resonance Imaging (MRI) Devices within specified physical parameters

- Menstrual Pads

- Menstrual Tampons of “old” materials (used prior to May 28, 1976)

- Non-implantable Male Reproductive Aids

- Ob/Gyn Diagnostic Ultrasound (within specified parameters)

- Transcutaneous Electric Nerve Stimulation (TENS) Devices for treatment of pain

- Wound Dressings, excluding absorbable hemostatic devices and dressings

SIGNIFICANT RISK DEVICE STUDIES

General Medical Use

Catheters:

- Cardiology – diagnostic, treatment, transluminal coronary angioplasty, intra-aortic balloon with control system
- Gastroenterology and Urology – biliary and urologic
- General Hospital – long-term percutaneous, implanted, subcutaneous and intravascular
- Neurology – cerebrovascular, occlusion balloon
- Collagen Implant Material for use in ear, nose and throat, orthopedics and plastic surgery
- Lasers for use in Ob/Gyn, cardiology, gastro-enterology, urology, pulmonary, ophthalmology and neurology
- Tissue Adhesives for use in neurology, gastro-enterology, ophthalmology, general and plastic surgery, and cardiology

Anesthesiology

- Respiratory Ventilators
- Electro-anesthesia Apparatus
- Gas Machines for Anesthesia or Analgesia
- High Frequency Jet Ventilators greater than 150 BPM

Cardiovascular

- **Arterial Embolization Device**
- **Artificial Heart, permanent implant and short term use**

- **Cardiac Bypass Systems: oxygenator, cardiopulmonary blood pump, ventricular assist devices**
- **Cardiac Pacemaker/Pulse Generator: implantable, external transcutaneous, antitachycardia, esophageal**
- **Cardiovascular/Intravascular Filters**
- **Coronary Artery Retroperfusion System**
- **DC-Defibrillators**
- **Implantable Cardioverters**
- **Laser Coronary Angioplasty Device**

Pacemaker Programmer

- Percutaneous Conduction Tissue Ablation Electrode
- Replacement Heart Valve
- Vascular and Arterial Graft Prostheses

Dental

- Endosseous Implant

Ear, Nose and Throat

- Cochlear Implant
- Total Ossicular Prosthesis Replacement
- Gastroenterology and Urology
- Anastomosis Device
- Endoscope and/or Accessories
- Extracorporeal Hyperthermia System
- Extrocorporeal Photophersis System
- Extracorporeal Shock-Wave Lithotriptor
- Kidney Perfusion System

- Mechanical/Hydraulic Impotence and Incontinence Devices
- Implantable Penile Prosthesis
- Peritoneal Shunt

General and Plastic Surgery

- Absorbable Hemostatic Agents
- Artificial Skin
- Injectable Silicone
- Implantable Prostheses: chin, nose, cheek, ear
- Sutures

General Hospital

- Infusion Pumps: Implantable and closed-loop, depending on infused drug
- Implantable Vascular Access Devices

Neurology

- Hydrocephalus Shunts
- Implanted Intracerebral/Subcortical Stimulator
- Implanted Intracranial Pressure Monitor
- Implanted Spinal Cord and Nerve Stimulators and Electrodes

Obstetrics and Gynecology

- Cervical Dilator
- Chorionic Villus Sampling Catheter, phase II (pregnancy continued to term)
- Contraceptive Devices: tubal occlusion, cervical cap, diaphragm, intrauterine device (IUD) and introducer, and sponge

Ophthalmics

- Extended Wear Contacts Lens
- Intraocular Lens (investigations subject to 21 CFR 813)
- Eye Valve Implant
- Retinal Reattachment Systems: sulfur hexafluoride, silicone oil, tacks, perfluoropropane

Orthopedics

- Implantable Prostheses: ligament, tendon, hip, knee, finger
- Bone Growth Stimulator
- Calcium Tri-Phosphate/Hydroxyapatite Ceramics
- Xenografts

Radiology

- Hyperthermia Systems and Applicators

1. Policy Statement

CIM CVGH IRB in compliance with the *National Ethical Guidelines for Health and Health Related Research (NEGHHRR) and Council for International Organizations of Medical Sciences (CIOMS)* shall adopt the mechanism of a single review of multi-site research. We adopt the **SOP on Single Joint Research Ethics Board SJREB STANDARD OPERATING PROCEDURES. (Please Refer to attached SOP)**

2. Objective

This SOP shall 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.

3. Scope (Please Refer to attached SOP)

This procedure applies to all multi-site protocols submitted to the SJREB for initial ethics review. Sponsors and investigators may submit a protocol to SJREB if it's one of the following:
Sponsored or funded by the Department of Health 2.2.1.2. Multi-site protocol to be conducted in at least 3 sites

ii. Level 3 hospital
iii. At least one (1) site with a Letter of Intent (LOI)which specifies that
   - SJREB reviews the country protocol
   - Pls submit to both SJREB and the sites
   - Sites accept the SOPs of SJREB for the joint review of protocols
   - Only site specific modifications shall be allowed. NO modifications to the approved country protocol shall be required by the participating sites.
   - Sites accepts the decision of the SJREB unless there is compelling ethical, legal or scientfici concerns. Reasons for site disapproval shall be submitted to SJREB and must be justified
   - Disapproval of protocol shall mena that the site is opting out as a site for the study

iv. 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.
v. SJREB requires the site RECs to agree and abide with the procedures of SJREB.
vi. 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.
vii. 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 the certificate of approval and assume stewardship and monitoring functions.

4. Responsibility (Please Refer to attached SOP)

i. The permanents members, independent consultant, and participating sites representatives act as primary reviewers and attend board meeting
ii. The members review and decide make decisions on the protocol
iii. The SJREB Secretariat manages all protocol submissions to the SJREB.

5. **Process Flow/Steps (Please Refer to attached SOP)**

6. Description of Procedures (Please Refer to attached SOP)

7. History of SOP

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

8. 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 Healt 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
iii. Code of Federal Regulation (CFR) 21, Volume 8, Part 812, April 2003, Food and Drug Administration, U.S. Government Printing Office via GPO Access
iv. ASEAN Agreement on Medical Device Directive Jakarta: ASEAN Secretariat, September 2015
v. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2015
vi. Philippine Health Research Ethics Board (PHREB) SOP Workbook 2020
vii. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2002.
viii. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011.
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x. International Conference on Harmonization, E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) 2018.

xi. 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
xii. National Ethical Guidelines for Health Research 2011 PNHRS
xiii. National Ethical Guidelines for Health Research 2017 PNHRS
xiv. 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
xv. RA 10173 Data Privacy Act of 2012
xvi. PNHRS ACT OF 2013
xvii. CHED Memorandum Order No. 34 ser 2007
xviii. DOST AO No. 001 series 2008
xix. FDA Circular No 2012 – 007
xx. DOST, DOH, CHED, UPM Joint M. O. 2012 – 001
xxi. NCIP AO 01-2012

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

Agenda	A list of items to be taken up at a meeting
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.
Comparator (Product)	An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.
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.
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.
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 protocols 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 Consultant	An expert who gives advice(s), comment(s) and suggestion(s) upon review of the study protocols with no affiliation to the institute(s) or investigator(s) proposing the research proposal
Home Institution	Refers to the institution where the coordinating investigator comes from
Inactive Protocol files	a. Study protocols that have been completed with CIM-CVGH-IRB-Approved Final Reports b. Study protocols declared "Inactive" by the CIM-CVGH IRB after a six (6) months period of no communication. c. 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	A compilation of the clinical and nonclinical data on the

Brochure	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
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
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 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.
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
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 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.
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

Vulnerable Subjects	Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

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

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

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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. Research-related 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**

☐ Protocols that neither involves 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**		
IRB Chair/Member Secretary Name & Signature		**DATE**

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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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CERTIFICAE 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	Y☐	N☐	N.A.☐	

cultural traditions, and involvement of the community in decisions about the conduct of study?				
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

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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		

[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, non-research 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]

If your procedures are experimental, please include this paragraph: 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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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.**

10. **To submit continuing renewal review Reports/Progress Reports and obtain approval before the expiration date**
11. **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

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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 – ○ 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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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, allergics, 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 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**

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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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 a mendments 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
FORM 4.2

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

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

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

11. 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

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

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

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

15. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
- ❑ NO
- ❑ YES (Explain changes in attached narrative)

16. CHANGE IN PRINCIPAL INVESTIGATOR?
- ❑ NONE
- ❑ DELETE:_____

ADD: _____

10. 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)

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

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

18. 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)

19. 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)

20. WERE THERE PROTOCOL DEVIATION/ VIOLATION REPORTS?
- ❑ NO

YES (Summarize and what corrective actions were taken)

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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**

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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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/Reasons for making contact:							
Follow up action	☐	**Return call**	☐	**Send written communication**	☐	**None**	
Summary of Communication:							
Recorded by:							

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MEETING AGENDA TEMPLATE
FORM 5.1

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

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. 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. PROGRESS REPORTS / CONTINUING REVIEW REPORTS DUE IN 30 DAYS

Protocol No.	Study Title
13.	
14.	
15.	
16.	
17.	
18.	

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	

L. 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**