Supersedes:	Previous SOPs
Prepared by:	SOP Team 2019
Reviewed by:	Dr. Manuel Emerson Donaldo
Reviewed Date:	December 14, 2018
Approved by:	Ma. Nona A. Velez, RN, MN
Date Approved	December 20, 2018
Date Effective:	January 2, 2019

TABLE OF CONTENTS

CONTENT	PAGE NO.
Table of Contents	2
Policy Statement	3
Objective	3
Scope	3
Responsibilities	3
Workflow	3
Description of Procedures	4
Forms	6
History	6
References	6
Annex	7

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***	***TIMELINE***
Step 1: Assignment of primary reviewers or Independent Consultant/s (SOP on Appointment of Independent Consultants (SOP#1.3)	*Chair*	4 weeks
Step 2: Notification of primary reviewers or Independent Consultants	*Secretariat*	
Step 3: Provision of protocol and protocol-related documents and assessment forms to reviewers	*Secretariat*	
Step 4: Presentation of review findings and	*Primary Reviewers*	

recommendations during a Committee meeting (SOP on Conduct of Meeting (SOP#5.3)		*4 WEEKS*
Step 5: Discussion of technical and ethical issues	*Committee members*	
Step 6: Summary of issues and resolutions	*Chair*	
Step 7: Committee action	*Committee members and Chair*	
Step 8: Documentation of Committee deliberation and action (SOP on Preparing the Meeting Minutes (SOP#6.1)	*Secretariat*	
Step 9: Communication of Committee Action to the researcher (SOP Communicating REC Decisions (SOP#6.2)	*Secretariat*	
Step 10: Filing of protocol-related documents	*Secretariat*	

6. Description of Procedures

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

- 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:*

- 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 Secretariat 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:*

- The Secretariat shall prepare and send the protocol review package to the primary reviewers within 7 calendar days from protocol submission.
- 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*:

- 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.

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

- Check the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements
- Consider whether study and training background of the principal investigator/s are related to the study to check for suitability of the PI.
- Look for disclosure or declaration of potential conflicts of interest or the lack of it.
- Non-physician principal investigators should be advised by a physician when necessary as a sub-investigator.
- If applicable, determine if the facilities and infrastructure at study sites can accommodate the study.
- 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
- 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*:

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

Step 7 - *Committee action*:

- 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 Secretariat 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 Secretariat 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

8. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
01	*Nov 16, 2016*	*IRB MEMBERS*	*FIRST DRAFT*
02	*May 3, 2018*	*IRB MEMBERS*	*Formatting; Annex / Forms included*

9. References

- International Ethical Guidelines for Health-related Research Involving Humans Council for International Organizations of Medical Sciences (CIOMS) 2016
- Philippine Health Research Ethics Board (PHREB) Workbook 2015
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1

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Review Application Form

Form 2.1

APPLICATION FORM FOR REVIEW

Sponsor Protocol Number:		IRB Protocol Number:	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Continuing Review ☐ Protocol Termination ☐ Final Report	
Submission Date:			
Protocol Title:			
Principal Investigator:			
Telephone number:		**Fax**	
E-mail:		Preferred Contact	
Institute:			
Investigator Initiated:			
Sponsor Initiated		Name of Sponsor	
Conflict of Interest Declaration (Relationship with sponsor)	Are you a regular employee of the sponsor? Did you do consultancy or part time work for the sponsor? In the past year, did you receive money or gifts from the sponsor? Other ties with the sponsor	☐ **Yes** ☐ **Yes** ☐ **Yes** ☐ **Yes**	☐ **No** ☐ **No** ☐ **No** ☐ **No**
PI Signature:			
Documents submitted: (Please Check)			
☐ Protocol summary ☐ Patient information form ☐ Informed consent form ☐ Advertisement ☐ Investigator brochure ☐ Protocol summary ☐ Case report forms (CRF) ☐ Research team list		☐ CVs ☐ GCP certificates ☐ Study budget ☐ Revised protocol ☐ Revised consent form ☐ Amendments ☐ Research team list ☐ Questionnaire	
Type of Research			
Phase of Study			
☐ Survey ☐ Social ☐ Medical ☐ Community Based ☐ Individual Based ☐ Screening ☐ Observational ☐ Epidemiology ☐ Interventional Study ☐ Clinical Trial: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Genetic Study ☐ Retrospective ☐ Prospective ☐ Others_____ ☐ Single center ☐ Multicenter ☐ Others_____			
Study Duration			
Received by:			
Primary Reviewer_____ Type of Review : ☐ Exempt ☐ Expedited ☐ Full Board :			

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Protocol Summary Sheet

Form 2.2

PROTOCOL SUMMARY SHEET

IRB Reference Number:		**Submitted date:**	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Continuing Review ☐ Study Termination ☐ Final Report	
Protocol Title:			
Principal Investigator:			
Telephone number/s:			
Sub Investigator:			
Telephone number/s:			
Fax :			
E-mail:		**Preferred Contact**	☐ Phone ☐ Fax ☐ E-mail
Department affiliated			
Documents submitted:	**Provide details (May include version number and date of submitted version)**		
☐ Protocol summary			
☐ Patient information form			
☐ Informed consent form			
☐ Advertisement			
☐ Investigator brochure			
☐ Protocol summary			
☐ Case report forms (CRF)			
☐ Amendments			
☐ CVs			
☐ Others			
Received by:	**Signature**		
	Full Name		
Date received:			
Note: *Please keep the duplicate copy of the form and submit the original with the package upon submission.*			
DO NOT FILL UP BEYOND THIS			
TYPE OF REVIEW			

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FORM 2.3:

PROTOCOL EVALUATION FORM

IRB REFERENCE NO.	I R B - -	
PRINCIPAL INVESTIGATOR (P.I.)	SPON SOR	DATE OF REVIEW
P.I. CONTACT NO.	P.I. EMAIL-ADDRESS	
PROTOCOL NO. & TITLE		

QUESTIONS		Comments/Remarks
1) Are the objectives clear?	Y☐ N☐	
2) Is there a need for human participants?	Y☐ N☐	
3) Is the background information sufficient?	Y☐ N☐	
4) Is the study design appropriate for the objectives?	Y☐ N☐	
• Are the control arms appropriate? (for clinical trials)	Y☐ N☐	
5) Is the approximate number of subjects involved in the trial specified?	Y☐ N☐	
• Are the inclusion criteria appropriate?	Y☐ N☐	
• Is the proposed subject population appropriate for the nature of the research?	Y☐ N☐	
• Has the IRB taken into account any special vulnerability among prospective subjects that might be relevant to evaluating the risk of participation?	Y☐ N☐	
• Are the exclusion criteria appropriate?	Y☐ N☐	
• 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☐	
6) Is the setting of the study clearly identified?	Y☐ N☐	
• Are the facilities and infrastructure of the participating sites adequate?	Y☐ N☐	
• Is the duration of the study specified?	Y☐ N☐	
7) Are the procedures to be done in the study clearly described and understandable?	Y☐ N☐	
• Are blood/tissue samples sent abroad?	Y☐ N☐	
8) Are research data recorded and maintained with strict confidentiality?	Y☐ N☐	

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FORM 2.3:

PROTOCOL EVALUATION FORM

9)	Considering the degree of risk, is the plan for monitoring the research appropriate and adequate in terms of timeliness and thoroughness?	Y☐	N☐	
10)	If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient?	Y☐	N☐	
11)	Is the mechanism for providing information to the IRB in the event that unexpected results are discovered appropriate?	A☐	N☐	
12)	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☐	
13)	Has due care been used to minimize risks and maximize the likelihood of benefits?	Y☐	N☐	
14)	Are there adequate provisions for a continuing reassessment of the balance between risks and benefits?	Y☐	N☐	
15)	Does the institution have a data and safety monitoring board?	Y☐	N☐	
	a. If so, should it be asked to monitor the project under review?	Y☐	N☐	
	b. 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☐	

Recommendations:

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

Primary Reviewer

_____
Name & Signature / Date

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FORM 2.4:

INFORMED CONSENT ASSESSMENT FORM

IRB REFERENCE NO.		
PRINCIPAL INVESTIGATOR	SPONSOR	DATE OF REVIEW
PROTOCOL NO. & TITLE		
Primary Reviewer:		Date:_____
☐ Applicable		☐ Not Applicable

QUESTIONS		Comments/Remarks
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☐	

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FORM 2.4:

INFORMED CONSENT ASSESSMENT FORM

QUESTIONS			Comments/Remarks
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?		N☐	
20) Is there a compensation and/or treatment available to the subject in the event of trial-related injury?	Y☐	N☐	
Is there a person to contact in the event of trial-related injury?	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?	Y☐	N☐	
Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion?	Y☐	N☐	
If privacy is to be invaded, does the importance of the research objective justify the intrusion?	Y☐	N☐	
What if anything, will the subject be told later?	Y☐	N☐	

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FORM 2.4:

INFORMED CONSENT ASSESSMENT FORM

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

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PROTOCOL RESUBMISSION FORM
FORM 2.5

IRB REF. NO.		DATE SUBMITTED	

Protocol Title:	
Document to be revised	☐ Protocol ☐ Informed Consent ☐ Advertisement ☐ Composition of Research Team ☐ Others _____
Study Duration	
Sponsor:	
Principal Investigator:	
Telephone Number:	Fax:
Email:	Preferred means of contact ☐ Phone ☐ Fax ☐ Email
Institution	

IRB Recommendations	Revision made by the PI

PI Name & Signature: _____ DATE: _____

Received by IRB Secretariat: _____ DATE: _____