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

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1. **Policy Statement**
   The IRB shall require a set of documents listed in a checklist for initial submission and re-submissions, 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 proponents 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. 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. This SOP begins with the receipt of study documents for initial review and determination of completeness of submission or resubmission and ends with the determination of type of review or action.

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***	***TIMELINE***
Step 1. Receive the initial protocol package for review and check the completeness of the documents	*Secretariat*	*To be done within 7 days from submission*
Step 2. Assign a permanent code to the protocol package	*Secretariat*	
Step 3. Give a duplicate copy of the review application form to the person submitting the package.	*Secretariat*	
Step 4. Determine the type of review and the primary reviewers *a. Expedited Review (SOP on Expedited Review (SOP#4.1)* *b. Full Review (SOP on Full Review (SOP#4.2)* *c. Exemption from Review (SOP on Communicating REC Decisions (SOP#6.2)*	*Chair/Member Secretary*	

Step 5. Prepare the protocol review package for distribution to the primary reviewers. For resubmissions, include Form 2.5: Resubmission form	*Secretariat*	
Step 6. Log the received protocol package in the Incoming Documents logbook and Protocol Data Base	*Secretariat*	
Step 7. File the initial protocol package in a properly labeled	*Secretariat*	

6. Description of Procedures

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

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

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

- 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).
- 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.

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

- The Chair/member secretary shall determine if the protocol warrants expedited or full

review. (See SOP on Review Procedures SOP #3). If the request for review is not be within the mandate of the IRB, the decision will be "Exempted from Review". In the latter case, the appropriate communication to the researcher should be sent (SOP on Communicating IRB Decisions SOP# 6.2).

- Protocols that are exempted from review:
  - Research about public behavior (voting trends, opinion surveys, etc.)
  - Evaluation of public programs by the agency itself
  - Quality control studies by the agency itself
  - Standard educational tests and curriculum development
  - Surveillance functions of DOH
  - Historical and cultural events
  - Research involving large statistical data without identifiers
  - Research not involving humans or human data

- The Chair/Member-Secretary designates at least two IRB members to be the primary reviewers of the protocol regardless of whether the type of review is expedited or full board.
- Primary reviewers are selected on the basis of expertise related to the protocol.
- If the IRB membership does 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. 1.2).

Step 5. Prepare the protocol review package for distribution to the primary reviewers

- The initial protocol 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 or approval from the technical review board
- The timeline from receipt of complete package to distribution to primary reviewers within 7 calendar days.
- For resubmitted protocols, Form 2.5 Resubmission Form should be completely filled up by the investigator indicating the IRB comments, and the revisions made

Step 6. Log the received protocol package in the Protocol Data Base

- After ensuring the completeness of the initial protocol package, log the pertinent data in the incoming documents logbook and electronic protocol database.
- As soon as subsequent data is available, complete the required protocol details in the protocol database.

Step 7. File the initial protocol package in a properly labeled

- File the initial protocol package in a properly labeled Protocol File folder and place it in the Active Study File cabinet (SOP #7.2)
- Write the IRB Protocol Code Number of the protocol on the side of the file binder. On the front cover of the protocol binder, write the following:
  - IRB Protocol Code Number
  - Full title of the research
  - Name of the Principal Investigator and Co-Investigator/s
  - Name of the Sponsor if applicable
  - File the properly-labeled protocol file folders sequentially 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.

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*	*SOP Team*	*FIRST DRAFT*
02	*December 14, 2019*	*SOP Team*	*Submission on or before 2nd Wed of the month will be reviewed (instead of on or before 3rd week of the month) Addition of Resubmission Form*

9. References:

- 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.
- National Ethical Guidelines for Health Research 2011 PNHRS
- Chong Hua Hospital Institution Review Board Standard Operating Procedures http://chonghua.com.ph/irb/SOP.html

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?	☐ **Yes**	☐ **No**
	Did you do consultancy or part time work for the sponsor?	☐ **Yes**	☐ **No**
	In the past year, did you receive any monetary consideration or gifts from the sponsor?	☐ **Yes**	☐ **No**
	Other ties with the sponsor	☐ **Yes**	☐ **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: _____