

ST GENERU
(28))
191 Hand

Version 1

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





Version 1

SOP3Review Procedures 3.2 Full Review

Effective Date: January 02, 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





SOP3Review Procedures 3.2 Full Review

Effective Date: January 02, 2019

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	
Step 2: Notification of primary reviewers or Independent Consultants	Secretariat	4 weeks
Step 3: Provision of protocol and protocol-related documents and assessment forms to reviewers	Secretariat	1
Step 4: Presentation of review findings and	Primary Reviewers	





Version 1

SOP3Review Procedures 3.2 Full Review

Effective Date: January 02, 2019

recommendations during a Committee meeting (SOP on Conduct of Meeting (SOP#5.3)		
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	4 WEEKS
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



SOP3Review Procedures 3.2 Full Review



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 subinvestigator.
- 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).





Version 1

SOP3Review Procedures 3.2 Full Review

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	01 Nov 16, 2016 IRB MEMB		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 ٠
- 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.





Version 1

SOP3Review Procedures 3.2 Full Review



Number: Number: Type of Submission: Initial Review Continuing Review Resubmission for re-review Protocol Termination Protocol Amendments Final Report Protocol Title: Protocol Title: Principal Investigator: Fax Frail: Preferred Contact Institute: Preferred Contact Investigator Initiated: Are you a regular employee of the sponsor? Did you do consultancy or part time work for the sponsor? Yes Did you do consultancy or part time work for the sponsor? In the past year, did you receive money or gifts from the	IOS ST., CEBU CITY 413 Fax. (63-32) 253-9127				Form 2.1
Number: Number: ype of Submission: Initial Review Continuing Review Protocol Termination Protocol Termination Protocol Title: Protocol Termination Principal Investigator: Fax redephone number: Fax		APPLICATION FORM	1 FOR REVIEW		
ype of Submission: Initial Review Continuing Review Resubmission for re-review Protocol Termination Within the sponsor Final Report Protocol Title: Preferred Contact Principal Investigator: Fax "redictor filte: Preferred Contact struct: Preferred Contact novestigator Initiated: Preferred Contact poposer Initiated Name of Sponsor Conflict of Interest Are you a regular employee of the sponsor? Did you do consultancy or part time work for the sponsor? Yes No Yes Sponsor! In the past year, did you receive money or gifts from the sponsor? Other ties with the sponsor Yes Other ties with the sponsor Yes Patient information form GCP certificates Informed consent form Revised consent form Patient information form Revised consent form Investigator brochure Revised consent form Protocol summary Questionnaire Type of Research Phase of Study Phase of Study Medical Community Based Individual Based	Sponsor Protocol				
Resubmission for re-review Protocol Termination Protocol Amendments Final Report submission Date: Protocol Title: Protocol Title: Principal Investigator: elephone number: Fax e-mail: Preferred Contact institute: nvestigator Initiated: nvestigator Initiated: Name of Sponsor Conflict of Interest Are you a regular employee of the sponsor? Did you do consultancy or part time work for the sponsor? Yes In the past year, did you receive money or gifts from the sponsor? Yes Other ties with the sponsor Yes Notocol Summary Protocol summary CVs Yes Notocol Summary Protocol summary CVs Study budget Namedments Advertisement Revised protocol Revised consent form Revised consent form Protocol summary Questionnaire Questionnaire Ype of Research team list Questionnaire Ype of Research team list Questionnaire Survey Social Beidemiology_Interventional Study Phase IV Survey Social Medical Community Based Individual Bas		Initial Review			
Protocol Amendments Final Report Jubmission Date: Protocol Title: Principal Investigator: Preferred Contact iselephone number: Fax	Type of outprintenent.		-	n	
aubmission Date: Protocol Title: Preferred Investigator: Trincipal Investigator: Preferred Contact Institute: Investigator Initiated: In the past year, did you receive money or gifts from the sponsor? Other ties with the sponsor In the past year, did you receive money or gifts from the sponsor? Other ties with the sponsor? Other ties with the sponsor? Other ties with the sponsor Yes No Yes					
Principal Investigator: Fax i=lephone number: Fax i=rmail: Preferred Contact institute: Preferred Contact institute: Name of Sponsor investigator Initiated: Preferred Contact interpretation Reverse prosor? Other ties with the sponsor Preferred Contact Protocol summary CVs Protocol summary CVs Protocol summary Revised protocol Investigator brochure Revised consent form Investigator brochure Revised consent form Protocol summary Questionnaire Protocol summary Questionnaire Protocol summary Questionnaire Protocol summary Questionnaire Screeni	Submission Date:		· · ·		
elephone number: Fax i-mail: Preferred Contact institute: Preferred Contact institute: Name of Sponsor investigator Initiated Name of Sponsor inthe past year, did you receive money or gifts from the sponsor? Yes in the past year, did you receive money or gifts from the sponsor? Yes Other ties with the sponsor Yes No Prosocol summary CVs Yes No ignature: Yes No Occurrents submitted: (Please Check) Yes No Patient information form GCVs Yes No Informed consent form Revised protocol No No Investigator brochure Revised consent form Revised consent form Amendments	Protocol Title:				
imail: Preferred Contact institute: institute: institute: Name of Sponsor investigator Initiated Name of Sponsor Conflict of Interest Are you a regular employee of the sponsor? Did you do consultancy or part time work for the sponsor? Yes Relationship with In the past year, did you receive money or gifts from the sponsor? Other ties with the sponsor Yes Other ties with the sponsor Yes Potocol summary CVs Protocol summary GCP certificates Informed consent form Study budget Advertisement Revised protocol Investigator brochure Revised consent form Protocol summary Questionnaire Protocol summary Questionnaire Fype of Research Questionnaire Study Study Survey Social Medical Study Individual Based Screening Observational Epidemiology_ Interventional Study Clinical Trial: Prospective Prospective Contact Protopective Others	Principal Investigator:				
nstitute:	Telephone number:				
nvestigator Initiated:			Preferred Contact		
Ipponsor Initiated Name of Sponsor Conflict of Interest Declaration Are you a regular employee of the sponsor? Yes Did you do consultancy or part time work for the sponsor? Yes No Did you do consultancy or part time work for the sponsor? Yes No Ponsor? Other ties with the sponsor? Yes No Other ties with the sponsor? Yes No Other ties with the sponsor? Yes No Patient information form GCVs Yes No Patient information form Study budget Amendments Informed consent form Revised protocol Revised consent form Informed consent form Questionnaire Questionnaire Protocol summary Questionnaire Questionnaire Study budget Amendments Questionnaire Study Social Medical Community Based Individual Based Screening Observational Epidemiology_Interventional Study Phase II Phase II Study Phase I Phase II Phase II Phase IV					
Conflict of Interest Declaration 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 No 2 Yes No 3 Yes Sudy budget 3 Amendme	<u> </u>		No		
Did you do consultancy or part time work for the sponsor? In the past year, did you receive money or gifts from the sponsor? Relationship with ponsor) In the past year, did you receive money or gifts from the sponsor? Yes Other ties with the sponsor Yes No Isignature: Image: Sponsor? Yes No Occuments submitted: (Please Check) Image: Sponsor? Yes No Patient information form GCP certificates Image: Study budget No Advertisement Revised protocol Image: Study budget Amendments Case report forms (CRF) Research team list Questionnaire Pype of Research Image: Sponsor Image: Sponsor Survey Social Medical Community Based Individual Based Streening Observational Epidemiology_Interventional Study Image: Prospective Others		Annual and the second sec			
Relationship with ponsor) In the past year, did you receive money or gifts from the sponsor? Yes No Other ties with the sponsor Yes No Other ties with the sponsor Yes No Pl Signature: Yes No Occuments submitted: (Please Check) CVs Yes Patient information form GCP certificates Study budget Advertisement Revised protocol Revised consent form Informed consent form Revised consent form Amendments Protocol summary Amendments Case report forms (CRF) Research team list Research team list Questionnaire Yes Yes Survey Social Medical Community Based Individual Based Screening Observational Epidemiology_Interventional Study Phase IV Genetic Study Phase II Phase II Phase IV		, , ,	•		
Other ties with the sponsor Ites Ites Ites Other ties with the sponsor Ites Ites Ites Ites Image: Submitted: (Please Check) Image: Study Submitted: (Please Check) Image: Study Submitted: (Please Check) Image: Study Submitted: (Please Check) Image: Protocol summary Image: Study Submitted: (Please Check) Image: Study Submitted: (Please Check) Image: Protocol summary Image: Study Submitted: (Please Check) Image: Study Submitted: (Please Check) Image: Protocol summary Image: Study Sudget Image: Study Sudget Image: Study Sudget Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary Image: Protocol summary </td <td>(Relationship with</td> <td></td> <td></td> <td>🗆 Yes</td> <td>🗆 No</td>	(Relationship with			🗆 Yes	🗆 No
Yes No Pl Signature:	sponsor)			☐ Yes	🗆 No
Pl Signature:		Other ties with the sponsor		Vec	
Documents submitted: (Please Check) Protocol summary CVs Patient information form GCP certificates Informed consent form Study budget Advertisement Revised protocol Investigator brochure Revised consent form Protocol summary Amendments Case report forms (CRF) Research team list Vase of Study Questionnaire Vase of Study Screening Observational Epidemiology_Interventional Study Clinical Trial: Phase II Phase IV Others	Dic'				
Protocol summary CVs Patient information form GCP certificates Informed consent form Study budget Advertisement Revised protocol Investigator brochure Revised consent form Protocol summary Amendments Case report forms (CRF) Research team list Vase of Study Questionnaire Vase of Study Social Survey Social Streening Observational Epidemiology Interventional Study Clinical Trial: Phase II Phase IV Others	-	 Riazza Chack)			
Patient information form GCP certificates Informed consent form Study budget Advertisement Revised protocol Investigator brochure Revised consent form Protocol summary Amendments Case report forms (CRF) Research team list Questionnaire Questionnaire Phase of Study Study Survey Social Study Individual Based Screening Observational Epidemiology Interventional Study Clinical Trial: Phase II Phase IV Others		,			
Informed consent form Study budget Advertisement Revised protocol Investigator brochure Revised consent form Protocol summary Amendments Case report forms (CRF) Research team list Research team list Questionnaire Phase of Study Individual Based Screening Observational Epidemiology_Interventional Study Clinical Trial: Phase II Phase IV Genetic Study Others				5	
Investigator brochure Revised consent form Protocol summary Amendments Case report forms (CRF) Research team list Research team list Questionnaire Ype of Research Valuestionnaire *hase of Study Screening Observational Survey Social Medical Community Based Screening Observational Epidemiology_Interventional Study Clinical Trial: Phase II Phase IV Genetic Study Prospective Others					
Protocol summary Amendments Case report forms (CRF) Research team list Questionnaire Ype of Research hase of Study Survey Social Medical Community Based Screening Observational Epidemiology Interventional Study Clinical Trial: Phase I Phase I Phase IV Genetic Study	Advertisement		Revised protoc	ol	
Case report forms (CRF) Research team list Questionnaire Ype of Research Asse of Study Survey Social Medical Community Based Screening Observational Epidemiology Interventional Study Clinical Trial: Phase I Phase II Phase IV Genetic Study	0			t form	
Research team list Questionnaire Questi					
Survey Social Medical Community Based Individual Based Screening Observational Epidemiology Interventional Study Clinical Trial: Phase II Phase III Genetic Study Prospective Others				list	
Phase of Study		ISL			
Survey Social Medical Community Based Individual Based Screening Observational Epidemiology Interventional Study Clinical Trial: Phase II Phase III Phase IV Genetic Study Retrospective Others					
Screening Observational Epidemiology Interventional Study Clinical Trial: Phase II Phase III Phase III Genetic Study Retrospective Prospective Others	These of secury		I		
	Screening Obse Clinical Trial: Phase I Genetic Study Retro	rvationalEpidemiologyInterventi Phase IIPhase III spectiveProspectiveOther	onal Study	idual Based	
itudy Duration					





Version 1

SOP3Review Procedures 3.2 Full Review



IRB Reference Number: Type of Initial Revie Submission: Resubmissio Protocol Am	PROTOCOL	SUMMARY SHEET Submitted date:	Form 2.2		
53-7413 Fax. (63-32) 253-9127 IRB Reference Number: Type of Submission: Resubmissio					
Number: Type of Initial Review Submission: Resubmission Protocol Am					
Number: Type of Initial Review Submission: Resubmission Protocol Am	w	Submitted date:			
Submission: Resubmission	w				
Protocol Am		Continuing Review	v		
	on for re-review	Study Termination	1		
Protocol Title:	nendments	Final Report			
Principal Investigator: Telephone number/s:					
Sub Investigator:					
Telephone number/s:					
Fax :					
E-mail:		Preferred Contact	Phone Fax E-mail		
Department affiliated	Drouido dotaila (NA)	u include version numb	or and data of submitted version)		
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 of	copy of the form and	d submit the original wit	h the package upon submission.		
	DO NOT FILL UP B	EYOND THIS			
TYPE OF REVIEW					





Version 1

SOP3Review Procedures 3.2 Full Review

INSTITUTIONAL REVIE 79 F. RAMOS ST., CEBU CITY TeL 032-416-2764 Fax. (63-32) 253		J	PROT	VI 2.3: FOCOL LUATION VI
	IRB REFERENCE NO.			
PRINCIPAL INVESTIGATOR (P.L)	SPON SOR	DATE OF REV	iew.	
P.L CONTACT ND.	P.L. EMAIL-ADDRESS			
QUE 1) Are the objectives clear?	STIONS	Y	ND	Comments/Remarks
2) Is there a need for human parti	dpants?	ΥD	ND	
Is the background information :	sufficient?	ΥD	ND	
 Is the study design appropriate 	for the objectives?	Υ□	ND	
 4) Is the study design appropriate Are the control arms appropriate 	for the objectives? opriate? (for clinical triak)	Y		
 4) Is the study design appropriate Are the control arms appro 5) Is the approximate number of s 	for the objectives? priate? (for clinical triak) subjects involved in the trial specified?	Y D		
 4) Is the study design appropriate Are the control arms appro 5) Is the approximate number of s Are the inclusion criteria approximate approximate	for the objectives? priate? (for clinical triak) subjects involved in the trial specified?	Y D Y D Y D Y D		
 Are the control arms appropriate Are the control arms appropriate Is the approximate number of s Are the inclusion criteria appropriate subject populate the research? Has the IRB taken into account 	for the objectives? opriate? (for clocal track) subjects involved in the trial specified? opropriate? pulation appropriate for the nature of sunt any special vulnerability among			
 Are the control arms appropriate Are the control arms appro 5) Is the approximate number of s Are the inclusion criteria approximate number of s Is the proposed subject popthe research? Has the IRB taken into accord prospective subjects that no of participation? 	for the objectives? opriate? (for clocal triak) subjects involved in the trial specified? opropriate? pulation appropriate for the nature of sunt any special vulnerability among night be relevant to evaluating the risk			
 4) Is the study design appropriate Are the control arms appro 5) Is the approximate number of s Are the inclusion criteria ag Is the proposed subject pothe research? Has the IRB taken into accorprospective subjects that not participation? Are the exclusion criteria ag 	for the objectives? opriate? (for clocal track) subjects involved in the trial specified? oppropriate? pulation appropriate for the nature of sunt any special vulnerability among night be relevant to evaluating the risk ppropriate?			
 4) Is the study design appropriate Are the control arms appropriate Are the control arms appropriate S the approximate number of s Are the inclusion criteria appropriate Is the proposed subject populate the research? Has the IRB taken into accord prospective subjects that no of participation? Are the exclusion criteria appropriate the exclusion criteriappropriate the exc	for the objectives? opriate? (for clinical triak) subjects involved in the trial specified? opropriate? pulation appropriate for the nature of ount any special vulnerability among night be relevant to evaluating the risk ppropriate? ople who might be more susceptible ne study and who therefore ought to			
 4) Is the study design appropriate Are the control arms appro 5) Is the approximate number of s Are the inclusion criteria approximate number of s Are the proposed subject populate the research? Has the IRB taken into accord prospective subjects that no of participation? Are the exclusion criteria approximate to the risks presented by the excluded from the research? 	for the objectives? opriate? (for clinical triak) subjects involved in the trial specified? opropriate? pulation appropriate for the nature of ount any special vulnerability among night be relevant to evaluating the risk ppropriate? ople who might be more susceptible he study and who therefore ought to arch?			
 4) Is the study design appropriate Are the control arms appro 5) Is the approximate number of s Are the inclusion criteria approximate number of s Are the proposed subject popthe research? Has the IRB taken into accorprospective subjects that no of participation? Are the exclusion criteria approximate to the risks presented by the excluded from the research? 6) Is the setting of the study clear of the study	for the objectives? opriate? (for clinical triak) subjects involved in the trial specified? opropriate? pulation appropriate for the nature of ount any special vulnerability among night be relevant to evaluating the risk ppropriate? ople who might be more susceptible he study and who therefore ought to arch?			
 4) Is the study design appropriate Are the control arms appropriate Are the inclusion criteria appropriate Is the approximate number of s Are the inclusion criteria appropriate Is the proposed subject poppretive subjects that no appropriate into according and the research? Has the IRB taken into according according and the appropriate into according and the second of the research? Are the exclusion criteria appropriate and the risks presented by the excluded from the research? Is the setting of the study clear Are the fadilities and infrast adequate? Is the duration of the study 	for the objectives? spriate? (for clinical triak) subjects involved in the trial specified? purpopriate? pulation appropriate for the nature of sunt any special vulnerability among night be relevant to evaluating the risk ppropriate? ople who might be more susceptible ne study and who therefore ought to arch? ly identified? tructure of the participating sites y specified?			
 4) Is the study design appropriate Are the control arms appro 5) Is the approximate number of s Are the inclusion criteria approximate number of s Are the proposed subject population of participation? Has the IRB taken into according participation? Are the exclusion criteria approximate number of participation? Are there any groups of petto the risks presented by the excluded from the research? 6) Is the setting of the study clear and an an	for the objectives? spriate? (for clinical trials) subjects involved in the trial specified? ppropriate? pulation appropriate for the nature of ount any special vulnerability among night be relevant to evaluating the risk ppropriate? ople who might be more susceptible ne study and who therefore ought to arch? ly identified? tructure of the participating sites / specified? in the study clearly described and			
Is the study design appropriate Are the control arms appro- Is the approximate number of s Are the inclusion criteria ap- Is the proposed subject po- the research? Has the IBB taken into acco- prospective subjects that no of participation? Are the exclusion criteria a Are there any groups of pe- to the risks presented by th be excluded from the resear- Is the setting of the study clean Are the facilities and infras- adequate? Is the duration of the study Are the procedures to be done understandable?	for the objectives? spriate? (for clinical trials) subjects involved in the trial specified? ppropriate? pulation appropriate for the nature of ount any special vulnerability among night be relevant to evaluating the risk ppropriate? ople who might be more susceptible ne study and who therefore ought to arch? ly identified? tructure of the participating sites / specified? in the study clearly described and			





Version 1

SOP3Review Procedures 3.2 Full Review



CIM-CVGH COM-CV	No.	PROTOCOL EVALUATION FORM
) Considering the degree of risk, is the plan for monitoring the research appropriate and adequate in terms of timeliness and thoroughness?	Υ□	N
0) If the principal investigator is other than full-time on the project, is the oversight and monitoring time sufficient?	Υ□	N
 Is the mechanism for providing information to the IRB in the event that unexpected results are discovered appropriate? 	A	N□
2) 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?	Υ□	N□
 Has due care been used to minimize risks and maximize the likelihood of benefits? 	Υ□	N□
4) Are there adequate provisions for a continuing reassessment of the balance between risks and benefits?	ΥΠ	N
5) Does the institution have a data and safety monitoring board?	Υ□	N
a. If so, should it be asked to monitor the project under review?	Υ□	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?	Υ□	N□
Recommendations: Approve Minor Modifications Major Modifications Disapprove		
Primary Reviewer	nature ,	/ Date





Version 1

SOP3Review Procedures 3.2 Full Review

Effective Date: January 02, 2019

CIMECVEH COMPCTORE C	INFO CONS		NT FORM
IRB REFERENCE	TE NO.		
	E OF REVIE	N	
Primary Reviewer:	Date Not Ap	e:	
QUESTIONS			Comments/Remarks
 Is there a statement saying the study involves research? 	ΥD	ND	
2) Is the purpose of the trial clearly stated?	ΥD	ND	
	ΥΠ	ND	
3] Is there an explanation to the subjects why they were included in the study?	_		
 Are there provisions ensuring that the subject's participation in the trial is 	Y	N□	
 Are there provisions ensuring that the subject's participation in the trial is voluntary? Is the subject well-informed of his/her responsibilities? 			
 4) Are there provisions ensuring that the subject's participation in the trial is voluntary? 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	ND	
 4) Are there provisions ensuring that the subject's participation in the trial is voluntary? 5) Is the subject well-informed of his/her responsibilities? (This includes providing health information including symptoms or any changes made in her regimen.) 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 			
 Are there provisions ensuring that the subject's participation in the trial is voluntary? Is the subject well-informed of his/her responsibilities? (This includes providing health information including symptoms or any changes made in her regimen.) Is the language and presentation of the information to be conveyed appropriate 	Y	ND	
 Are there provisions ensuring that the subject's participation in the trial is voluntary? Is the subject well-informed of his/her responsibilities? (<i>This includes providing health information including symptoms or any changes made in her regimen.</i>) Is the language and presentation of the information to be conveyed appropriate to the subject population? (<i>Consider the level of complexity and the need for translation into a language other than Inglish.</i>) For clinical trials, are the trial treatment(s) and the probability for random 	Y Y		
 4) Are there provisions ensuring that the subject's participation in the trial is voluntary? 5) Is the subject well-informed of his/her responsibilities? (<i>This includes providing health information including symptoms or any changes made in her regimen.</i>) 6) Is the language and presentation of the information to be conveyed appropriate to the subject population? (<i>Consider the level of complexity and the need for translation into a language other than English.</i>) 7) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained? 	Y Y Y Y		
 Are there provisions ensuring that the subject's participation in the trial is voluntary? Is the subject well-informed of his/her responsibilities? (This includes providing health information including symptoms or any changes made in her regimen.) 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.) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained? Is the expected duration of the subject's participation in the trial specified? 	Y Y Y Y Y		
 Are there provisions ensuring that the subject's participation in the trial is voluntary? Is the subject well-informed of his/her responsibilities? (<i>This helades providing health information helading symptoms or any changes made in her regimen.</i>) Is the language and presentation of the information to be conveyed appropriate to the subject population? (<i>Consider the level of complexity and the need for translation into a language other than liquids</i>). For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained? Is the expected duration of the subject's participation in the trial specified? Is the approximate number of study subject stated? For experimental studies is the nature of the experiment explained well? 			
 4) Are there provisions ensuring that the subject's participation in the trial is voluntary? 5) Is the subject well-informed of his/her responsibilities? (This includes providing health information including symptoms or any changes made in her regimen.) 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.) 7) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained? 8) Is the expected duration of the subject's participation in the trial specified? 9) Is the approximate number of study subject stated? 			
 4) Are there provisions ensuring that the subject's participation in the trial is voluntary? 5) Is the subject well-informed of his/her responsibilities? (This includes providing broth information including symptoms or any changes made in her regimen.) 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 transition into a language other than logith.) 7) For clinical trials, are the trial treatment[s] and the probability for random assignment to each treatment arm explained? 8) Is the approximate number of study subject stated? 9) Is the approximate number of study subject stated? 10) For experimental studies is the nature of the experiment explained well? 11) For studies using placebo is the use of placebo ethically applicable? 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? 			
 4) Are there provisions ensuring that the subject's participation in the trial is voluntary? 5) Is the subject well-informed of his/her responsibilities? (<i>This helades providing health information helading symptoms or any changes made in her regimen.</i>) 6) Is the language and presentation of the information to be conveyed appropriate to the subject population? (<i>Consider the level of complexity and the need for translation into a language other than legistary</i>.) 7) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained? 8) Is the expected duration of the subject's participation in the trial specified? 9) Is the approximate number of study subject stated? 10) For experimental studies is the nature of the experiment explained well? 11) For studies using placebo is the use of placebo ethically applicable? 12) Is detailed explanation of the procedures or tests that are new or not widely used 			
 Are there provisions ensuring that the subject's participation in the trial is voluntary? Is the subject well-informed of his/her responsibilities? (<i>This heldes providing health information including symptoms or any changes made in her regimen.</i>) Is the language and presentation of the information to be conveyed appropriate to the subject population? (<i>Consider the level of complexity and the need for translation lists a language other than English.</i>) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained? Is the approximate number of study subject stated? For experimental studies is the nature of the experiment explained well? For studies using placebo is the use of placebo ethically applicable? Is detailed explanation of the procedures or tests that are new or not widely used or combination/does of drugs never tested before provided to the subject? Are the proposed explanations of the research appropriate and adequate to 			
 4) Are there provisions ensuring that the subject's participation in the trial is voluntary? 5) Is the subject well-informed of his/her responsibilities? (This includes providing health information including symptoms or any changes made in her regimen.) 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.) 7) For clinical trials, are the trial treatment(s) and the probability for random assignment to each treatment arm explained? 8) Is the expected duration of the subject's participation in the trial specified? 9) Is the approximate number of study subject stated? 10) For experimental studies is the nature of the experiment explained well? 11) For studies using placebo is the use of placebo ethically applicable? 12) Is detailed explanation of the procedures or tests that are new or not widely used or combination/doses of drugs never tested before provided to the subject? 13) Are the proposed explanations of the research appropriate and adequate to provide the subject an accurate assessment of its risks and anticipated benefits? 			





Version 1

SOP3Review Procedures 3.2 Full Review



CIMECVGH	CONS	RMED SENT	NT 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?	Υ□	N□	
19) Are these any anticipated expenses to the subject in the course of the study?		ND	
20) Is there a compensation and/or treatment available to the subject in the event of trial-related injury?	Y۵	N□	
Is there a person to contact in the event of trial-related injury?	YD	ND	
21) Is there a person to contact for further information regarding the trial and the rights of the trial subjects?	Y	ND	
22) Do other groups of potential subjects have a greater need to receive any of the anticipated benefits?	ΥD	N□	
23) Whether they finish the study or not, are the subjects compensated on a per visit basis for trial related expenses?	Υ□	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?	YD	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?	Υ□	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?	ΥD	ND	
27) In the event of any information that will affect the willingness of the subject to participate, is re-consenting necessary or provided for?	ΥD	N□	
28) Are the withdrawal criteria made known to the subject?	ΥD	ND	
29) If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver?	ΥD	ND	
30) Are there provisions for medical / psychosocial support if applicable?	ΥD	ND	
31) Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy?	ΥD	N□	
Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion?	YD	Nロ	
If privacy is to be invaded, does the importance of the research objective justify the intrusion?	۲D	N□	
What if anything, will the subject be told later?	YD	Nロ	



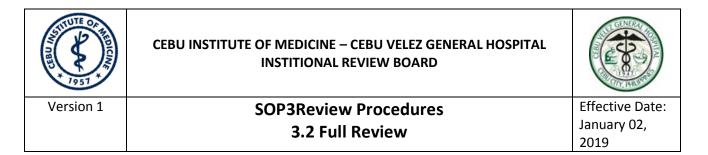


Version 1

SOP3Review Procedures 3.2 Full Review



79 F. RAN	CIM-CVGH	INFO CONS	M 2.4: RMED SENT SSMEI	RM	
	P.				
unexpecte	mechanism for providing information to the IRB in the event that d results are discovered? (Unexpected results may raise the possibility of ed risks to subjects)	Υ□	N□		
33) Is there a p auditors/ I purposes?	provision allowing consent from the subject for other monitors/ RB/IEC access to the subject's original medical record for verification	ΥD	N□		
34) Are the rec	cords identifying the subject kept confidential and to the extent by the applicable laws and/or regulations, not made available in public?	۲D	N□		
Should the	trial be published, will the subject's identity remain confidential?	YΠ	ND		
annorate the					
35) For genetic	c studies is there a discussion on the precautions in place to prevent	ΥD	ND		
35) For genetic disclosure	of results without the subject's permission	_			
35) For genetic disclosure 36) Is the subje		Y 🗆			
 35) For genetic disclosure 36) Is the subject medical re 37) Are plans i 	of results without the subject's permission ectinformed of the possible direct or secondary use of subject's	_			
 For genetic disclosure Sthe subje medical re Are plans i study or de 	of results without the subject's permission ect informed of the possible direct or secondary use of subject's cords & biological specimen in the course of clinical care in place to destroy collected biological specimen at the end of the etails of storage and possible future discussed with the patient?	Y	ND		
 For genetic disclosure Sthe subjemedical re Are plans i study or de 	of results without the subject's permission ect informed of the possible direct or secondary use of subject's cords & biological specimen in the course of clinical care in place to destroy collected biological specimen at the end of the etails of storage and possible future discussed with the patient?	Y	ND		
 For genetic disclosure disclosure Sthe subjemedical resolution of the subjemedical resolution of the study or description of the study or description. 	of results without the subject's permission ect informed of the possible direct or secondary use of subject's cords & biological specimen in the course of clinical care in place to destroy collected biological specimen at the end of the etails of storage and possible future discussed with the patient?	Y	ND		
35) For genetic disclosure 36) Is the subje medical re 37) Are plans i study or de	of results without the subject's permission ect informed of the possible direct or secondary use of subject's cords & biological specimen in the course of clinical care in place to destroy collected biological specimen at the end of the etails of storage and possible future discussed with the patient? Indations: Approve Minor Modifications	Y	ND		
35) For genetic disclosure 36) Is the subje medical re 37) Are plans i study or de	of results without the subject's permission ect informed of the possible direct or secondary use of subject's cords & biological specimen in the course of clinical care in place to destroy collected biological specimen at the end of the etails of storage and possible future discussed with the patient? Indations: Approve Minor Modifications Major Modifications	Y	ND		
35) For genetic disclosure 36) Is the subje medical re 37) Are plans i study or de	of results without the subject's permission ect informed of the possible direct or secondary use of subject's cords & biological specimen in the course of clinical care in place to destroy collected biological specimen at the end of the etails of storage and possible future discussed with the patient? Indations: Approve Minor Modifications	Y	ND		
35) For genetic disclosure 36) Is the subje medical re 37) Are plans i study or de	of results without the subject's permission ect informed of the possible direct or secondary use of subject's cords & biological specimen in the course of clinical care in place to destroy collected biological specimen at the end of the etails of storage and possible future discussed with the patient? Indations: Approve Minor Modifications Major Modifications Disapprove	Y	ND		



			PROTO RESUBMISS FORM	SION FORM				
IRB REF. NO.		DATE SUBMIT	TED					
Protocol Title:								
Document to be rea	vised Protocol Advertisement Others		formed Consent omposition of Research T	eam				
Study Duration								
Sponsor:								
Principal Investigat	or:							
Telephone Number			Fax:					
Email:		Preferred means of contact] Phone 🔲 Fax	Email				
Institution								
IRB Reco	ommendations		Revision made by the PI					
PI Name & Signature	e:		DATE:					
	retariat:		DATE					