CEBU DOCTORS UNIVERSITY HOSPITAL
Osmeña Boulevard, Cebu City, 6000 Philippines

"We Lead to Serve and We Serve so that Others May Live"

CEBU DOCTORS UNIVERSITY HOSPITAL
RESEARCH ETHICS COMMITTEE

CDUHREC
Standard Operating Procedures
2024

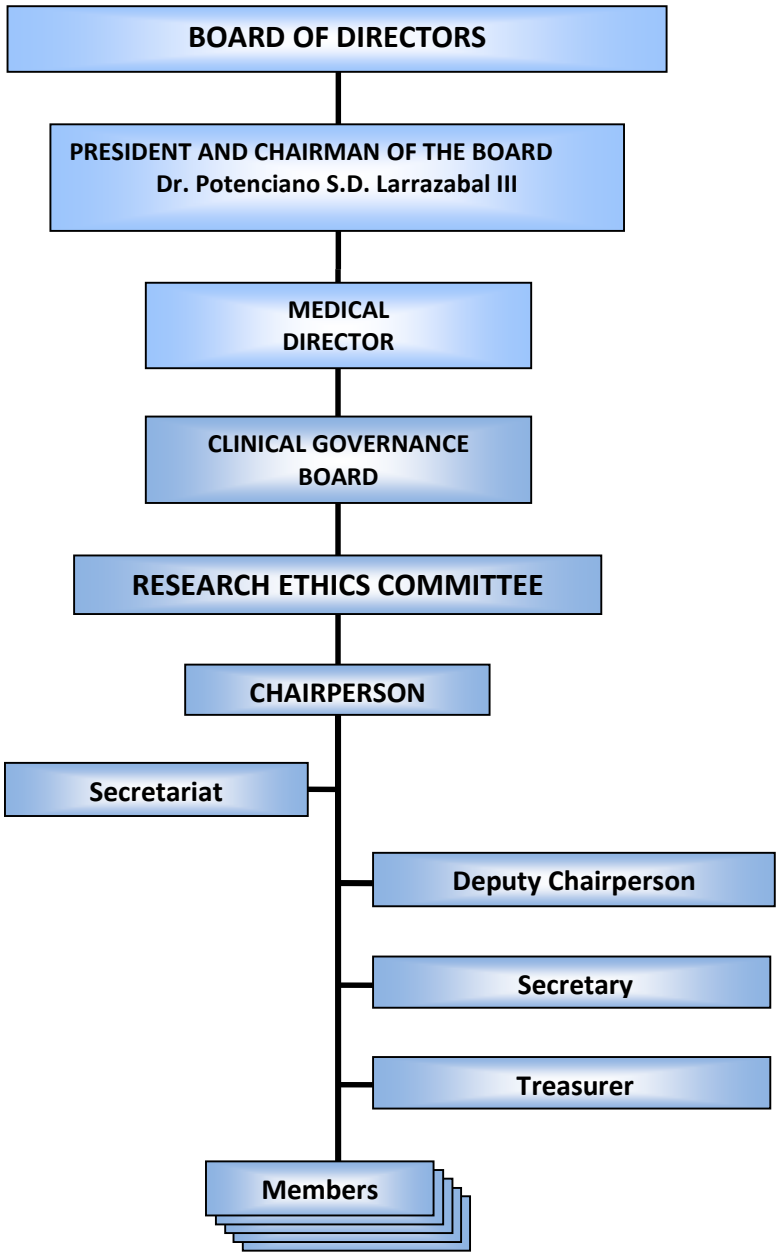
Supersedes	SOP Version 7 (21 November 2024)	
Authored	CDUHREC (Adapted from WHO, ICH-GCP, PNHRS, CIOMS 2009)	
Effective Date	21 November 2024	
Reviewed by	Enrico B. Gruet, MD Chairman, CDUHREC	Date Signed
Approved by	Jose Antonio Quitevis, MD Asst. Medical Director Potenciano SD Larrazabal III, MD President and Chairman of the Board	
Approval Date	21 November 2024	

Cebu Doctors University Hospital
Research Ethics Committee
(CDUHREC)

Table of Contents

Cebu Doctors University Hospital
Research Ethics Committee
(CDUHREC)

Organizational Chart



Cebu Doctors University Hospital
Research Ethics Committee
(CDUHREC)

List of Members

The members of the Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC) effective 01 January 2024 until 31 December 2025:

1. Dr. Enrico B. Gruet	Chair; Medical Doctor Contact no. +63 32 416 9341
2. Dr. Ma. Noemi A. Uy	Deputy Chair; Medical Doctor Contact no. +63 32 416 9341
3. Atty. Allan Orvien P. Geotina	Committee Secretary; Lawyer; Non Scientific member; Independent from the institution
4. Mrs. Lani B. Arcenal	Treasurer; Nurse; Independent from the institution
5. Dr. Lamberto M. Garcia Jr.	Medical Doctor
6. Dr. Helen V. Madamba	Medical Doctor
7. Mr. Nimrod Nazarito L. Quiñones	Journalist; Lay member; Independent from The institution
8. Rev. Fr. Jayson B. Facunla	Priest; Non-scientific member; Independent from the institution
9. Ms. Fabiana G. Sunit	Teacher; Lay member; Independent from the institution
10. Ms. Mae Quenie T. Pontanar	Pharmacist; Independent from the institution
11. Dr. Florencia T. Miel	Medical Doctor
12. Dr. Joseph Lester A. Hernandez	Medical Doctor

CDUHREC Office Secretary: Noime A. Ramones

Office Hours:
Mondays to Fridays 8:00 am to 12:00 noon; 1:00 pm to 5:00 pm
Office Address:
Ground Floor, CDUH Administrative Offices Building
Cebu Doctors University Hospital
Gov. M. Roa St. corner Don Jose Avila St.
6000 Cebu City, Philippines
Office Telefax: +63 (32) 416-9341
Email: cduhrec@gmail.com

Cebu Doctors University Hospital
Research Ethics Committee
(CDUHREC)

Institutional Authority, Vision, Mission and Functions

I. Institutional Authority

The CDUHREC is a part of and operates under the authority of the Cebu Doctors' University Hospital (CDUH) Clinical Governance Board. It is responsible for the review and final approval of the human subject studies that would be conducted at Cebu Doctors' University Hospital, South General Hospital, North General Hospital, Mactan Doctors' Hospital, San Carlos Doctors' Hospital, Ormoc Doctors' Hospital and CDG Bohol Doctors Hospital.

II. Vision

A responsive, globally recognized center of excellence upholding the highest ethical standards in all researches involving human subjects.

III. Mission

Protect the psychological and physical welfare, rights, dignity and safety of participants in research, through efficient and effective review processes to promote ethical standards of human research. Review research in accordance with National Ethical Guidelines for Research Involving Human Participants 2022, ICH GCP, CDUH policies and local regulatory laws

IV. Functions

1. To provide independent, competent and timely review of research projects involving human subjects with respect to their ethical acceptability;
2. To provide ethical oversight, monitoring and advice for research projects involving human subjects following the institutional guideline (Appendix A9)
3. To prescribe the principles and procedures that govern research projects involving human subjects, human tissue and/or personal records.

Document History:

Version No.	Date	Authors	Main Change
01	01 Jun 2012		
02	11 Sep 2024	CDUHREC members	Changed to National Ethical Guidelines for Research Involving Human Participants 2022 in Mission section.
03	21 November 2024	CDUHREC members	Changed vision to A responsive, globally recognized center of excellence upholding the highest ethical standards in all researches involving human subjects and mission to Protect the psychological and physical welfare, rights, dignity and safety of participants in research, through efficient and effective review processes to promote ethical standards of human research. Review research in accordance with National Ethical Guidelines for Research Involving Human Participants 2022, ICH GCP, CDUH policies and local regulatory laws.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Selection and Appointment of CDUHREC Members	SOP No.	01
		Version No.	08
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The selection of the CDUHREC members shall be through a nomination process that ensures proper representation of different disciplines (scientific and non- scientific, medical and non-medical, lay or non-lay members), sectors (male and female) and by affiliation (affiliated and non-affiliated with the institution). There shall be at least 5 regular members with each serving a period of 2 years but may be renewed for an indefinite number of terms. Members must have the necessary experience, training, knowledge to perform their duties.

II. Objective

The purpose of this section is to ensure that the composition of the REC complies with the provisions of the WHO Operational Guidelines/CIOMS Guidelines and the National Ethical Guidelines on the composition of ethics review committees.

III. Scope

This Standard Operating Procedure of CDUHREC applies specifically to the selection of members of the REC. This SOP begins with the call for nominations and ends with the filing of appointment documents and CVs of REC members in the membership file.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Call for nominations	*Chair*
Step 2: Receipt of nominations	*CDUHREC office secretary*
Step 3: Finalization of the list of nominees for appointment	*Chair*
Step 4: Approval of the appointment of members	*Medical Director of CDUH*
Step 5: Receipt of Appointment of new members	*Chair*

Step 6: Forwarding of Appointment papers to the new members	*CDUHREC office secretary*
Step 7: Signing of conforme, conflict of interest disclosure and confidentiality agreement	*CDUHREC New Member/s*
Step 8: Filing of appointment documents and CVs in the membership file (SOP on Managing Active Files (SOP# 24)	*CDUHREC office secretary*

V. **Description of Procedures**

Step 1 - Call for nominations: *The Chair informs the Medical Director of CDUH regarding the need for new member/s. The call for nominations should be based on qualifications and requirements stated in the international, national and institutional policies. It shall require accomplishment of a nomination form (Form A2) and submission of other documents, e.g. CV (Form A1) and acceptance of nomination (Form A2). The call of nominations is coursed through the head of the institution and sent to the heads of units or other entities that the authorities deemed to be concerned.*

Step 2 - Receipt of nominations: *The nominated submits the nomination form (Form A2) and other required documents including CVs and acceptance of nomination to the REC Office. The CDUHREC office secretary checks the completeness of the nominations, e.g. CVs of the nominees, Ethics training record, endorsement of the unit/department, etc."*

Step 3 – Finalization of the List of nominees for appointment: *The CDUHREC Chair prepares a final list of the nominees for appointment based on requirements and qualifications.*

Step 4 – Approval of the appointment of members – *The CDUH Medical Director upon receipt of the final list of nominees and after due verification and deliberation shall approve the nominated members by signing the appointment letters.*

Step 5 - Receipt of Appointment papers of new members: *The CDHUREC office secretary receives the appointment papers from the CDUHREC Medical Director and informs the Chair accordingly. The appointment papers already specifies the conditions of the appointment including the roles and responsibilities.*

Step 6 - Forwarding of Appointment papers to the new members: *The CDUHREC Chair instructs the CDUHREC office secretary to forward the documents to the concerned new member/s.*

Step 7- Signing the conforme, and the conflict of interest disclosure and confidentiality agreement: *The new CDUHREC member/s sign the conforme, confidentiality and conflict of interest disclosure agreements (Form D1).*

Step 8 - Filing of appointment documents and CVs and signed Agreements in the membership file: All appointment documents are stored in the Membership Folder.

VI. Training of REC Members

All members must undergo introductory research ethics training and must have specific GCP training every 3 years. The chair, member secretary and staff secretary shall have training on SOP writing and revision. All orientation and continuing trainings will be documented and placed on file.

VII. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Scientific Members – individuals whose formal education is at least a Master's degree in a scientific discipline, e.g., medicine or any of the allied sciences, etc.

Non-scientific Members - individuals whose primary interest is not in any of the scientific disciplines but must have at least college level education

Medical Members – individuals with academic degrees in the medical profession or a Master's in the nursing profession

Non-medical Members – individuals without academic degrees in the medical profession nor a Master's degree in the nursing profession

Affiliated Members – regular members who are in the roster of personnel or staff of CDUH. They are employees of CDUH or receive regular salary or stipend from CDUH.

Non-affiliated Members – regular members who are not in the roster of personnel or staff of CDUH. They are not employees of CDUH nor do they receive regular salary or stipend from CDUH.

Lay members – individuals who are non-affiliated, literate, who have not pursued a medical science/health-related career in the last 5 years

Regular Members – members constituting the Research Ethics Committee, who receive official appointments from the CDUH Medical Director with specific terms and responsibilities including review of research proposals and attendance of meetings

Conflict of Interest – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties

Confidentiality – the duty to not freely disclose private/research information entrusted to an individual or organization

VIII. Forms

Form A2: Nomination Form

Form A1: CV Template

Form A2: Acceptance of Nomination

Form B1: Appointment Letter Template

Form D1: Confidentiality and Conflict of Interest Disclosure Agreements

IX. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012		
02	02 Feb 2013	CDUHREC members	Change of format
03	09 Jul 2015	CDUHREC members	Changed title from Institutional Authority, Objective & Functions of CDUHREC to Membership
04	15 Dec 2015	CDUHREC members	Changed title from Membership to Structure & Composition
05	10 Jan 2020	CDUHREC members	Changed formatting to PHREB format as well as introduced new amendments as shown in the underscored portions
06	23 Apr 2021	CDUHREC members	First Draft/ Formerly Part of Old SOP#1
07	31 Jul 2024	CDUHREC members	Change Policy to include number of regular members, qualifications Added definition of affiliated and lay members in the Glossary Added section on Training of REC Members
08	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

X. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors University Hospital Research Ethics Committee (CDUHREC)		
	Designation of CDUHREC Officers and Office Secretary	SOP No.	02
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC Chair shall be appointed by the CDUH Medical Director. The Chair shall then call for a special meeting to elect the Deputy Chair, Member-Secretary and Treasurer among the members of the committee. The CDUHREC office secretary must be knowledgeable of the functions and responsibility including the confidential nature of the work.

II. Objective

This activity aims to ensure that the CDUHREC officers are qualified and are selected in a transparent manner in conformity with institutional policy and practice.

III. Scope

The scope of this SOP includes the selection of Chair, Deputy Chair, Committee Secretary and Treasurer. It starts from the special meeting called by the initial Chair duly appointed by the CDUH Medical Director to elect the other officers then another special meeting to elect the concerned officers after the initial term of 2 years and ends with the filing of appointment documents of the officers.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Appointment of the Chair	*CDUH Medical Director*
Step 2: Signing of the conforme	*Chair*
Step 3: Appointment of specific officers	*Chair*
Step 4: Approval of the appointed officers	CDUH Medical Director
Step 5: Signing of the conforme by the appointed officers	*Deputy Chair, Member Secretary and Treasurer*
Step 6. Receipt of Appointment of new officers	*CDUHREC office secretary*

V. Description of Procedures

Step 7: Filing of appointment documents (SOP on Managing Active Files (SOP #24))	*CDUHREC office secretary*

Step 1 – Appointment of the Chair: *The CDUH Medical Director appoints the Chair by signing the appointment letter. The appointment papers will include the roles and responsibilities of the Chair.*

Step 2 – Signing of the conforme: *The appointed Chair signs the conforme in the appointment letter and submits it to the CDHUREC office secretary for filing.*

Step 3 – Appointment of specific officers: *The Chair appoints the Deputy Chair, Member Secretary and Treasure among the CDUHREC members.* The appointment papers will include the roles and responsibilities of each officer.

Step 4 – Approval of the appointed officer: The CDUH Medical Director shall approve the appointed officers by signing the appointment letters.

Step 5: Signing of the conforme of the appointed officers: *The appointed Deputy Chair, Member Secretary and Treasurer signs the conforme in the appointment letter and submits it to the CDHUREC office secretary for filing.*

Step 6: Receipt of the Appointment of new officers: *The CDUHREC Office receives the appointment papers of the elected officers that contain the role and responsibilities of the specific officers and the corresponding term of office.*

Step 7: Filing of appointment documents: *The CDUHREC Staff secretary files the appointment papers accordingly (see SOP for Management of Active Files (SOP 24).*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as*:*

Term of office – the specified length of time that a person serves in a particular designation /role.

Conforme – acceptance of or agreement to an assignment or designation.

VII. Forms

Form B1: Appointment Letter

VIII. Document History

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.
03	10 Oct 2024	CDUHREC members	Added the statement "The CDUHREC office secretary must be knowledgeable of the functions and responsibility including the confidential nature of the work" Changed of Title "and Office Secretary"

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

I. Policy

The CDUHREC shall invite an independent consultant whose expertise is not represented in the current membership but is needed in a study under review. He/she need not be affiliated with the CDUH.

II. Objective

This activity aims to ensure that the appointment of independent consultants conforms with institutional practice and complements the pool of expertise in the CDUHREC.

III. Scope

This SOP specifically pertains to the selection and designation of independent consultants in the review of research protocols of the CDUHREC. This SOP begins with the identification of the study that requires an independent consultant and ends with the inclusion of the name of the Independent Consultant in the pool of consultants.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Identification of the external experts	*Chair*
Step2: Invitation of the external experts	*Chair*
Step 3: Receipt of the acceptance of invitation	*CDUHREC office secretary*
Step 4: Furnishing of appointment letter, conflict of interest disclosure, and confidentiality agreement to the external experts	*CDUHREC office secretary*
Step 5: Signing of conforme, conflict of interest disclosure and confidentiality agreement	*External expert*
Step 6: Receipt of the signed appointment letter, signed conflict of interest disclosure and confidentiality agreement	*External expert*
Step 7: Inclusion of the appointee in the pool of external experts	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Identification of the external experts: *The Chair identifies from the roster of specialists in CDUH potential external experts who may be called upon to review research protocols whose subject matter is outside of the expertise of the CDUHREC regular members. The Chair instructs the CDUHREC office secretary to prepare the letters of invitation.*

Step 2 - Invitation of the independent consultant: *The CDUHREC office secretary prepares an Appointment of External Expert (Form B3) containing the Terms of Reference with attached Confidentiality Agreement and Conflict of Interest Disclosure (Form D1) for signature of the Chair and sends it to the identified expert. The letter of invitation contains a section for acceptance of the invitation.*

Step 3 - Receipt of the acceptance of invitation: *The CDUHREC office secretary receives the acceptance of invitation.*

Step 4 - Furnishing of appointment letter, conflict of interest disclosure, and confidentiality agreement to the external experts: *Upon receipt of the acceptance of the invitation, the CDUHREC office secretary prepares a letter of appointment (Form A1) for signature of the Chair and sends the appointment to the external experts together with the Conflict of Interest Disclosure and Confidentiality Agreement.*

Step 5 - Signing of conforme, conflict of interest disclosure and confidentiality agreement: *The external experts affix their signatures as conforme on the documents.*

Step 6 - Receipt of the signed appointment letter, signed conflict of interest disclosure and confidentiality agreement: *The CDUHREC office secretary receives the signed documents from the external experts and they are then considered part of the pool of external experts.*

Step 7 - Inclusion of the appointee in the pool of external experts: *The CDUHREC office secretary enters the names of the newly-appointed external experts in the appropriate database and files their signed documents.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

External expert - a resource person who is not a member of the CDUHREC, whose expertise is needed in the review of a research protocol and who may be invited to attend a committee meeting but are non-voting during the deliberations.

Expertise – a proficiency, skill or know-how possessed by experts in a certain professional field.

Database – a structured/organized collection of information so that the data can easily be accessed, managed and updated.

VII. Forms

Form B3: Appointment of External Expert

Form D1: Confidentiality and Conflict of Interest Disclosure Agreement Form

VIII. Document History

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.
03	23 Sep 2024	CDUHREC members	Changed Form A1 to B3 and added Form D1

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

I. Policy

An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study subjects, (2) do not have study subjects belonging to a vulnerable group, (3) the study procedures do not generate vulnerability, (4) minor informed consent changes, (5) case reports and (6) retrospective studies with minimal risk to study subjects. Expedited review refers to the number of CDUHREC members doing the actual review rather than the length of time it requires. The Chair and the lead reviewer shall make a decision regarding the study and release to the principal investigator the decision as soon as it is made even before the next regular committee meeting. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular committee meeting.

II. Objective

Expedited Review aims to demonstrate due diligence and high standards in the system of protection of human participants.

III. Scope

This SOP applies to initial review of protocols and post-approval submissions which do not entail more than minimal risk to study subjects, whose subjects do not belong to vulnerable groups, and where vulnerability issues do not arise. 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.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Assignment of Lead Reviewer or External Expert (SOP#3 Appointment of External Experts)	*Chair*
Step 2: Notification of Lead Reviewer or External Expert	*CDUHREC office secretary*
Step 3: Provision of study documents and evaluation forms (Form F1) to reviewers	*CDUHREC office secretary*
Step 4: Accomplishment and submission of evaluation forms	*Assigned Reviewer*
Step 5: Finalization of review results	*Chair*
Step 6: Communication of review results to the Principal Investigator (SOP# 22 Communicating REC Decisions)	*Chair and CDUHREC office secretary*

Step 7: Filing of documents in the protocol file	*CDUHREC office secretary*
Step 8: Inclusion of the Review in the Agenda of the next regular meeting	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Assignment of Lead Reviewer or External Expert: *The Chair shall determine the kind of review whether it will be a full review, expedited review or exempted review. After determining the type of review and if the study protocol meets any of the following criteria: (1) do not entail more than minimal risk to the study subjects, and (2) do not have study subjects belonging to a vulnerable group, (3) the study procedures do not generate vulnerability, the Chair shall then subject the said study protocol for expedited review and then choose the necessary expertise of the Lead Reviewer. An External Expert may be assigned. (see SOP on Appointment of External Experts (SOP#3).*

Step 2 – Notification of Lead Reviewer or External Expert: *The CDUHREC office Secretary shall then promptly notify the assigned lead reviewer or External Expert when applicable, in order to provide an opportunity to assess conflict of interest, availability, and suitability of reviewers. Usually, the response from the assigned reviewers should be received within two days after notice.*

Step 3 - Provision of documents and evaluation form to reviewers: *The CDUHREC office secretary gathers the pertinent documents (for example, for initial submissions: the complete submission package; for post approval submissions: the pertinent information from the retrieved protocol and the report itself). After gathering, the said pertinent documents shall be delivered personally to the assigned reviewers.*

Step 4 - Accomplishment and Submission of Evaluation forms: *The assigned reviewer shall submit his completed assessment forms in a most comprehensive and informative matter to the CDUHREC office not later than 5 days prior to the next committee meeting.*

Step 5 - Consolidation and Finalization of the review results: *The Chair upon being notified by the CDUHREC office secretary of the filing and submission of the completed assessment forms by the assigned reviewer, he/she shall then consolidate (if 2 or more were assigned) and finalize the review results prior to the next committee meeting.*

Step 6 - Communication of review results to the principal investigator: *See SOP on Communicating CDUHREC Decisions (SOP# 22)*

Step 7 - Filing of documents in the protocol file: *See SOP on Managing Active Files (SOP# 24)*

Step 8 - Inclusion of the Review in the Agenda of the next REC regular meeting: *See SOP on Preparing the Meeting Agenda (SOP# 19)*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Decision – the result of the deliberations of the CDUHREC in the review of a protocol or other submissions.

Exempt from Review – a decision made by the CDUHREC Chair or designated member of the committee regarding a submitted study proposal based on criteria in NEGRIHP 2022. This means that the protocol will not undergo an expedited nor a full review.

Expedited Review – the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Full Review – the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage.

Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

More than Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in a research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Lead Reviewer – a regular member of the Research Ethics Committee who is assigned to assess a study protocol, the Informed Consent, and other research-related submissions based on ethical criteria established by the committee.

External Expert – resource person who is not a member of the CDUHREC, whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but is non-voting during the deliberations.

VII. Forms

Form F1: Protocol Evaluation Worksheet
Form E2: Informed Consent Evaluation Worksheet
Form C1: Decision letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 Apr 2013	CDUHREC members	Editorial change
04	09 Jul 2015	CDUHREC members	Changed title from Meetings to The Review Process for New Applications
05	15 Dec 2015	CDUHREC members	Rephrased Item No. 3 of the Review Process
06	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC Members	First Draft/ Formerly Part of Old SOP#3
08	11 Sep 2024	CDUHREC Members	Changed NEGHHR 2017 to NEGRIHP 2022 and removed "The Research Ethics Review Process Guideline 3.1" in the glossary. Changed as reference NEGHHR 2017 to NEGRIHP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

I. Policy

A full review shall be conducted when a study protocol entails more than minimal risk to study subjects or when study subjects belong to vulnerable groups or when a study generates vulnerability to participants. CDUHREC adopts the primary reviewer system for the full review of a study protocol. If necessary, external experts and/or the Principal Investigators shall be invited during the meeting to clarify certain issues. Barring any issues that may be noted by the committee, the decision shall be communicated to the Principal Investigator within two to seven weeks after submission of required documents. A decision letter shall be released to the principal investigator within seven days after the decision is made during a regular committee meeting.

II. Objective

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

III. Scope

This SOP applies to initial, resubmissions and post-approval submissions which are classified as entailing more than minimal risk to study subjects or whose participants belong to vulnerable groups. This SOP begins with the assignment of lead reviewers or external expert/s and ends with the filing of protocol-related documents.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Assignment of lead reviewers or External Expert/s (SOP on Appointment of External Experts (SOP# 3)	*Chair*
Step 2: Notification of lead reviewers or External Experts	*CDUHREC office secretary*
Step 3: Provision of protocol and protocol-related documents and assessment forms to reviewers	*CDUHREC office secretary*
Step 4: Provision of protocol and protocol-related documents to the rest of the committee members	*CDUHREC office secretary*
Step 5: Presentation of review findings and recommendations during a committee meeting (SOP on Conduct of Meeting (SOP# 20)	*Lead Reviewer*
Step 6: Discussion of ethical issues	*Committee members*
Step 7: Summary of issues and resolutions	*Chair*

Step 8: Committee action	*Committee members and Chair*
Step 9: Communication of review results to the Principal Investigator (SOP# 22) Communicating REC Decisions)	*Chair and CDUHREC office secretary*
Step 10: Filing of documents in the protocol file	*CDUHREC office secretary*
Step 11: Inclusion of the Review in the Agenda of the next regular meeting	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Assignment of primary reviewers or External Experts. *The Chair assigns members who have the necessary expertise as lead reviewers (designates an external expert in case such expertise is not present among the members) including a non-scientific member to review the Informed Consent Process and Form.*

Step 2 - Notification of primary reviewers and/or External Experts: *The CDUHREC office secretary notifies the assigned lead reviewers and/or External Experts about their assignment by email with a request that they confirm their acceptance and availability within 3 days*

Step 3 - Provision of protocol and protocol-related documents and assessment forms to primary reviewers/External Experts: *Upon receipt of confirmation/acceptance,* the CDUHREC office secretary *prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery to the lead reviewers and/or External Experts no less than 10 days before the next scheduled committee meeting.*

Step 4 - Provision of protocol and protocol-related documents to the rest of the committee members: *The CDUHREC office secretary provides the rest of the members of the committee with the study protocol including the assessment forms at least one week before the committee meeting, at the latest.*

Step 5 - Presentation of review findings and recommendations during a committee meeting: *The lead reviewers submit their findings and recommendations using (Form I1 Checklist for the Assessment of the Clinical Trial Protocol and Protocol Amendment(s), Form I2 Checklist for the Assessment of the Informed Consent and Form I3 Checklist for the Assessment of the Risk/Benefit) to the chair 3 days before the meeting and present these during the actual meeting. If a lead reviewer cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the lead reviewer so that the meeting can proceed. If necessary, and upon due notice when there is a need for clarification of issues, the CDUHREC requires the principal investigator to make a presentation. For any other instance, the lead reviewer will take charge (SOP#19 Conduct of Meetings).*

Step 6 - Discussion of ethical issues: *The chair leads the discussion of the ethical issues using Form I1, Form I2 and Form I3 as guides for an orderly exchange of ideas.*

Step 7 - Summary of issues and resolutions: *The Chair summarizes the ethical issues that were identified, the issues that were resolved or not resolved, including the recommendations for the issues that were not resolved.*

Step 8 - Committee action: Final decisions *(e.g., approval, minor modifications, major modifications, disapproval)* on the reviewed study protocols are done by consensus such that as long as there is an objection, the deliberation continues until everyone is convinced. Approval protocol is good only for a period of 1 year. Thereafter, Annual Progress Report must be submitted at least 4 weeks before expiry date of approval.

Step 9 - Documentation of committee deliberation and action: See SOP on Preparing the Meeting Minutes (SOP# 21).

Step 10 - Communication of Committee Action to the researcher: The committee through its chair would send out the comment/approval to the researcher using form C4/C5. See SOP on Communicating REC Decisions (SOP# 22)

Step 11 - Filing of protocol-related documents and Updating of the Protocol Database: See SOP on Managing Active Files (SOP# 24)

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Full Review – the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the CDUHREC, in the presence of a quorum, using established ethical criteria.

Vulnerable Groups – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage.

Minimal Risk – term used when the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

More than Minimal Risk - term used when the probability and magnitude of harm or discomfort anticipated in a research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

External Expert - resource person who is not a member of CDUHREC, whose expertise is needed in the review of a study protocol and who may be invited to attend a committee meeting but is non-voting during the deliberations.

Lead Reviewer – a member of the CDUHREC (usually a medical doctor) assigned to do an in-depth evaluation of the study protocol using ethical criteria established by the committee. The non-scientist member shall focus on the review of the Informed Consent process and form and reflect on community values, culture and tradition in order to recommend acceptance, non-acceptance or improvement of the informed consent process and form. The lead reviewers shall present their findings and recommendations during the meeting for discussion.

Major Modification – a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria,

collection of data statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.

Minor Modification - a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g., incomplete documentation, incomplete IC elements, unsatisfactory IC format)

Resubmissions - revised study protocols that are submitted after the initial review.

Protocol-related Documents - all other documents aside from the study protocol itself that required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions,

Decision – the result of the deliberations of the CDUHREC in the review of a study protocol or other submissions.

Voting – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.

Consensus – a collective agreement.

VII. Forms

Form I1: Checklist for the Assessment of the Clinical Trial Protocol and Protocol Amendment(s)
Form I2: Checklist for the Assessment of the Informed Consent
Form I3: Checklist for the Assessment of the Risk/Benefit)
Form C4: Comment Letter Template
Form C5: Approval Letter Template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 Apr 2013	CDUHREC members	Editorial change
04	09 Jul 2015	CDUHREC members	Changed title from Meetings to The Review Process for New Applications
05	15 Dec 2015	CDUHREC members	Rephrased Item No. 3 of the Review Process
06	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC members	First Draft/ Formerly Part of Old SOP#3
08	29 Aug 2024	CDUHREC members	Inserted Form I1- Checklist for the Assessment of the Clinical Trial Protocol and Protocol Amendment(s) and Form I2- Checklist for the Assessment of the Informed Consent
09	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.
10	02 Oct 2024	CDUHREC members	Inserted Form I3 and added the statement "The committee through its chair would send out the comment/approval to the researcher using form C4/C5" in Step 10 and changed deadline from 2 weeks to 4 weeks in Step 8.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Exempted Review	SOP No.	06
		Version No.	08
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

An exempted review is the term used to denote that a protocol does not need to undergo either full or expedited review after a preliminary assessment by a designated member of the CDUHREC. "Exempt from Review" is a decision made by CDUHREC.

II. Objective

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

III. Scope

This SOP applies to initial, resubmissions and post-approval submissions which are classified as exempt from review as detailed in National Ethical Guidelines for Research Involving Human Participants 2022 item 47 and 48 with sub sections (pages 48-49). This SOP begins with the assignment of a lead reviewer or external expert and ends with the filing of protocol-related documents.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Assignment of lead reviewer or external expert (SOP on Appointment of External Expert (SOP# 3)	*Chair*
Step 2: Notification of lead reviewer or external expert	*CDUHREC office secretary*
Step 3: Provision of protocol and protocol-related documents and assessment forms to the reviewer	*CDUHREC office secretary*
Step 4: Presentation of review findings and recommendations during a Committee meeting (SOP on Conduct of Meeting (SOP# 20)	*Lead Reviewer*
Step 5: Committee action	*CDUHREC members and Chair*
Step 6: Communication of review results to the Principal Investigator (SOP# 22 Communicating REC Decisions)	*Chair and CDUHREC office secretary*
Step 7: Filing of documents in the protocol file	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Assignment of lead reviewer or external expert. *The Chair assigns a member who has the necessary expertise as lead reviewer or designates an external expert in case nobody among the members has such expertise.*

Step 2 - Notification of lead reviewer or external expert: *The CDUHREC office secretary notifies the assigned lead reviewer or external expert about their assignment by email with a request that they confirm within 3 days their acceptance to review the protocol and availability to attend the next regular committee meeting.*

Step 3 - Provision of protocol and protocol-related documents and assessment forms to lead reviewer or external expert: *Upon receipt of confirmation/acceptance,* the CDUHREC office secretary *prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery to the lead reviewer or the external expert.*

Step 4 - Presentation of review findings and recommendations during a Committee meeting: *The lead reviewer will report to the CDUHREC members during a regular meeting his findings and recommendations why the said study protocol falls under Exempt from Review.*

The following protocols fall under the category Exempt from Review:

a. *Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols).*

b. *Protocols that do not involve more than minimal risks or harms, such as:*

b.1. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

b.2. Research that only includes interactions involving survey procedures, interview procedures, or observations of public behavior (including visual or auditory recording) if the following criteria are met:

b.2.1. There will be no disclosure of the human participant's 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

b.2.2. The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

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

Step 5 – Committee action: *The CDUHREC en banc notes the said report and the Chair instructs the CDUHREC office secretary to include the said report in its annual report which will be submitted to the PHREB.*

Step 6 - Communication of Committee Action to the principal investigator: See SOP on Communicating REC Decisions (SOP# 22)

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

External expert - resource person who is not a member of CDUHREC, whose expertise is needed in the review of a study protocol and who may be invited to attend a committee meeting but is non-voting during the deliberations.

Lead Reviewer – a member of the CDUHREC (usually a medical doctor) assigned to do an in-depth evaluation of the study protocol using ethical criteria established by the committee.

VII. Forms

Form C1: Decision letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 Apr 2013	CDUHREC members	Editorial change
04	09 Jul 2015	CDUHREC members	Changed title from Meetings to The Review Process for New Applications
05	15 Dec 2015	CDUHREC members	Rephrased Item No. 3 of the Review Process
06	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC members	First Draft/ Formerly Part of Old SOP#3
08	11 Sep 2024	CDUHREC members	Changed NEGHHR 2017 to NEGHRIP 2022 in Scope. Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Management of Initial Submissions	SOP No.	07
		Version No.	08
		Version Date	29 Aug 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC shall require the submission of a set of pertinent documents for an application for ethical review to be accepted. A preliminary evaluation shall determine whether a study protocol is exempted from or needs to undergo ethical review based on the NEGRIHP 2022. Subsequent amendments to a protocol that was exempted from review shall be submitted for a preliminary evaluation to determine whether the revised protocol can still be "exempted from review". New protocols should be submitted at least 14 calendar days prior to the scheduled review meeting.

II. Objective

Management of Initial Submissions ensures that study documents are complete, properly recorded, and properly evaluated to determine appropriate action or type of review.

III. Scope

The CDUHREC shall accept for initial review only study protocols of new applications, extension studies and researches that would be conducted at Cebu Doctors University Hospital, South General Hospital, North General Hospital, Mactan Doctors Hospital, San Carlos Doctors Hospital, Ormoc Doctors Hospital and CDG Bohol Doctors Hospital. This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database. The number of hard copies to be submitted must be equal to the total membership of the committee. A soft copy must be emailed to the official CDUHREC email address.

IV. Workflow

ACTIVITY	*RESPONSIBILITY*
Step 1: Receipt of study protocols for initial review and determination of completeness of submission.	*CDUHREC office secretary*
Step 2: Recording of entry into the logbook	*CDUHREC office secretary*
Step 3: Coding	*CDUHREC office secretary*
Step 4: Determination of type of Action/ Type of Review *a. Exemption from Review* *b. Expedited Review (SOP on Expedited Review (SOP# 4)*	*Chair*

c. Full Review (SOP on Full Review (SOP# 5)	
Step 5: Preparation of a protocol folder	*CDUHREC office secretary*
Step 6: Entry into the database	*CDUHREC office secretary*

V. **Description of Procedures**

Step 1 - Receipt of study documents for initial review and determination of completeness of submission: *The CDUHREC office is open from 8:00 AM to 5:00 PM (with noon break) during which the CDUHREC office secretary accepts study documents. The CDUHREC office secretary checks completeness of the documents based on the checklist (Form F1 for clinical trials, Form E1.1 for residents' studies, Form E2 Informed Consent Checklist, Form I1 for Checklist for the Assessment of the Clinical Trial Protocol and Protocol Amendment(s) and Form I2 Checklist for the Assessment of the Informed Consent.) If incomplete, the CDUHREC office secretary informs the Principal Investigator of the missing documents. All application forms should be signed and dated.*

Step 2 – Acknowledging and recording of entry into the logbook: All submitted study protocols shall be entered into the CDUHREC logbook where all documents, either received or sent out, are recorded including the specific date and time. It shall have the following information: (1) title of the study, (2) name of Principal Investigator, (3) date of submission, (4) name of the submitting entity, (5) name of the receiver and (6) action.

Step 3 - Coding: If the documents are determined to be complete, the CDUHREC office secretary assigns a protocol code which includes information on the year of submission and series number, for example, Dr. ABC submitted a protocol on COVID-19 in 2021 and it was the 3rd study protocol received for the year, then the code for the documents will be 2021-03. This code is the ID number of the protocol and cannot be assigned to any other protocol. When referring to the protocol in communications or presentations, the code is lengthened to include the Principal Investigator and topic as follows, 2021-03 – ABC - COVID-19, to become more informative.

Step 4 - Determination of type of Review/Action: The Chair conducts a preliminary review of the study protocol to determine whether it is for Full Review, Expedited Review, or Exempted from Review. The Review Fees (Appendix A10).

If the Chair decides that the protocol is exempted from review, s/he directs the CDUHREC office secretary to follow the procedure to communicate the decision to the Principal Investigator (SOP # 22 Communicating REC Decisions).

If the Chair determines that the protocol should undergo either Full or Expedited review, then the CDUHREC office secretary proceeds to follow either SOP # 4 Expedited Review or SOP # 5 Full Review.

Step 5 - Preparation of a Protocol Folder: The CDUHREC office secretary files the protocol documents in a protocol folder and labels it accordingly (SOP # 24 Managing Active Files).

Step 6 - Entry into the database: The new submission will be entered in a database as described in SOP # 24 Managing Active Files.

IV. **Glossary**

The terms/abbreviations used in this SOP are understood and defined as:

Initial Submission – a set of documents consisting of the full proposal and other study-related documents that need to be submitted so that review can be conducted.

Study Documents - include all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the REC for review.

Initial Review – ethical review conducted on the initially-submitted study documents. It may be expedited or full.

Amendment – a change in /revision of the protocol made after its approval.

Coding - a unique number assigned to a protocol indicating the year and series it was received.

Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Principal Investigator, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action taken.

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

Exemption from Review – a decision made by the CDUHREC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGRIHP 2022.

Full Review – is the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established ethical criteria.

Expedited Review – is the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

V. **Forms**

Form F1: Application Form for Clinical trials

Form E1.1: Application Form for Residents' and Fellows' Studies

Form E2: Informed Consent Checklist

Form I1: Checklist for the Assessment of the Clinical Trial Protocol and Protocol Amendment(s)

Form I2 Checklist for the Assessment of the Informed Consent.

Logbook

VI. **Document History**

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 Apr 2013	CDUHREC members	Editorial change
04	09 Jul 2015	CDUHREC members	Changed title from Meetings to The Review Process for New Applications
05	15 Dec 2015	CDUHREC members	Rephrased Item No. 3 of the Review Process
06	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC members	First Draft/ Formerly Part of Old SOP#3
08	29 Aug 2024	CDUHREC members	Changed NEGHHR 2017 to NEGRIHP 2022. Removed "The Research Ethics Review Process Guideline Process 3.1." Added deadline for initial submissions, indicated application forms, indicated number of copies to be submitted and editorial changes. Inserted Form E2, I1 and I2 in Step 1. Inserted the word "Acknowledging and" in Step 2. Added the statement "All application forms must be signed and dated." Changed as reference NEGHHR 2017 to NEGRIHP 2022.

VII. **References**

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Management of Resubmissions	SOP No.	08
		Version No.	09
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC shall require a resubmission of a study protocol that requires either minor or major modification/s not later than 4 weeks after receipt of the Decision Letter. Minor modifications shall undergo expedited review while major modifications shall undergo full review. For amendments it should be submitted at least 14 calendar days prior to the scheduled review meeting.

II. Objective

Management of resubmission ensures that the principal investigator addressed the required modifications before approval of the study protocol.

III. Scope

This SOP pertains to the resubmission of revised or modified study protocols that have been previously reviewed by the CDUHREC. The procedure begins with the receipt of the revised study protocol documents and ends with filing of the documents in the protocol file and the entry of the submission into the protocol database.

IV. Workflow

ACTIVITY	***RESPONSIBLE PERSONS***
Step 1: Receipt and Entry into the Logbook	*CDUHREC office secretary*
Step 2: Coding of Resubmitted Protocol Documents	*CDUHREC office secretary*
Step 3: Evaluation by the Chair or Notification of the Lead Reviewers	*Chair and CDUHREC office secretary*
Step 4: Review of the Resubmission *a. Expedited Review (SOP# 4 Expedited Review)* *b. Full Review (SOP# 5 Full Review)*	*Assigned Lead Reviewers*
Step 5: Communication of Decision	*CDUHREC office secretary*
Step 6: Filing of Documents in the Protocol File and Update of the database	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and Entry into the Logbook: *The CDUHREC office secretary receives the study protocol documents, checks the nature of the document and ensures that the submission is properly logged.*

Step 2 - Coding of Resubmitted Protocol Documents: *The CDUHREC office secretary stamps/indicates the code assigned to the study protocol when it was initially submitted and the date of receipt on all the documents.*

Step 3 - Notification of the Chair and Reviewers: *The CDUHREC office secretary retrieves the Decision Letter (Form C1) that pertains to the original study protocol and informs the Chair about the resubmission and about the nature of the modifications required from the Principal Investigator. Given the necessary information, the Chair either evaluates the resubmitted protocol at his/her level or directs the CDUHREC office secretary to inform the Lead Reviewer concerned and to forward to him/her the necessary documents.*

Step 4 - Review of the Resubmission: *The assigned Lead Reviewer conducts review of the resubmitted study protocol documents by referring to the resubmission form noting the different recommendations made by the CDUHREC and evaluating whether these were satisfactorily addressed in the resubmitted study protocol documents. The Lead Reviewer submits the report to the Chair for inclusion in the next regular meeting.*

Step 5 - Communication of Decision: *For Resubmissions approved at the level of the Chair, the Chair dictates his/her decision to CDUHREC office secretary for preparation of the draft letter, finalization and sending to the Principal Investigator. For the resubmissions that underwent Full Review, please see to SOP # 22 Communicating Committee Decisions.*

Step 6 - Filing of Documents in the Protocol Folder and update of the database: *The CDUHREC office secretary gathers all the pertinent documents related to the resubmission (revised protocol, assessment forms, excerpts of minutes, approval letter) and enters the relevant information on resubmission in the appropriate protocol database.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Initial Submission – the first (initial) package of study protocol forwarded to the CDUHREC for review.

Resubmission – the revised study protocol that is re-forwarded to the CDUHREC following the recommendations from the initial review.

Study Protocol Documents – all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the CDUHREC for a comprehensive review.

Initial Review – the ethical assessment of the first complete set of study protocol documents submitted to the CDUHREC so that review can be conducted

Coding - a unique number assigned to a study protocol indicating the year and series it was received.

Logbook – a real-time chronological record of incoming study protocols that includes the Date/Time of Receipt, Title of the Document, Name of the Principal Investigator, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.

Protocol Database – significant information about study protocols that are organized systematically so that these can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

Full Review – is the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the CDUHREC en banc, in the presence of a quorum, using established ethical criteria.

Expedited Review – is the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

VII. Forms

Form C1: Decision Letter
Form F2: Resubmission Form
Form C1: Approval Letter

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	09 Jul 2015	CDUHREC members	Changed title from The Review Process for New Applications to Continuing Review
04	15 Dec 2015	CDUHREC members	Changed title from Continuing Review to Post Approval Review
05	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC members	First Draft/Formerly part of Old SOP#4
08	29 Aug 2024	CDUHREC members	Added deadline for amendment submissions
09	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Review of Progress Report	SOP No.	09
		Version No.	08
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC shall require a submission of progress reports at a frequency based on the level of risk of the study. This requirement shall be explicitly stated in the Approval Letter.

II. Objective

This activity aims to ensure that the conduct of the study is in compliance with the approved study protocol and that the safety and welfare of study subjects are promoted.

III. Scope

This SOP applies to the management and review of progress submitted by the Principal Investigator while the study is on-going or has ended. This SOP begins with the receipt and entry to logbook of incoming documents and the protocol database and ends with filing of progress report and committee decision in the protocol file.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and entry into the logbook of the progress report (SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*
Step 2: Retrieval of pertinent protocol file	*CDUHREC office secretary*
Step 3: Notification of Chair and Lead Reviewers	*CDUHREC office secretary*
Step 4: Determination of type of review: expedited (SOP on Expedited Review (SOP# 4) or full review (SOP on Full Review (SOP# 5)	*Chair and Lead Reviewers*
Step 5: Communication of committee action (SOP on Communication REC Decisions (SOP# 22)	*Chair*
Step 6: Filing of Progress report and decision letter and update of the protocol database. SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and entry into the logbook: *The CDUHREC office secretary receives the progress report written in the Progress Report Form F4 and enters the date and pertinent information into the logbook of incoming documents (See SOP 21: Management of Active files).*

Step 2 - Retrieval of pertinent protocol file: *The CDUHREC office secretary retrieves the corresponding protocol file for reference and guidance of the Chair and Lead Reviewer.*

Step 3 - Notification of Chair and Lead Reviewer: *Within three days after receipt of the progress report, the CDUHREC Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Lead Reviewer.*

Step 4 - Determination of type of review: expedited or full review: *The Chair and the Lead Reviewer, together, decide the type of review and proceed accordingly. For Expedited review, see SOP #4: and for Full review, see SOP #5.*

***Step 5 - Communication of committee decision**: The CDUHREC communicates the committee action, see SOP #22: Communicating REC Decisions. For progress reports, the committee action may be "approved" or "additional information required" or "specific action/s required from the researcher". CDUHREC office secretary prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chair signs the decision letter as follows: Approval, request for additional information or specific action/s.*

Step 6 – Filing of Progress Report and committee decision and update of the database: *The CDUHREC office secretary files the progress report and a copy of the committee decision in the appropriate protocol folder. S/he proceeds to update the pertinent protocol database.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Progress Report – description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form F4. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the CDUHREC based on the level of risk.

Lead Reviewer – a member of the CDUHREC (usually a medical doctor) assigned to do an in-depth evaluation of the study protocol documents using ethical criteria established by the committee.

Expedited Review – the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Full Review – the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the CDUHREC en banc, in the presence of a quorum, using established ethical criteria.

Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Principal Investigator, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.

Database – a collection of information (e.g., regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

VII. Forms

Form F4: Progress Report Form
Form C1: Decision Letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	09 July 2015	CDUHREC members	Changed title from The Review Process for New Applications to Continuing Review
04	15 Dec 2015	CDUHREC members	Changed title from Continuing Review to Post Approval Review
05	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC members	First Draft/Formerly part of Old SOP#4
08	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Review of Amendments	SOP No.	10
		Version No.	08
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC shall require a submission of proposed amendments for review and approval before their implementation. This requirement shall be explicitly stated in the Approval Letter.

II. Objective

This activity aims to ensure that the conduct of the study is in compliance with the approved study protocol such that any change, such as amendments, does not impact safety and welfare of study subjects.

III. Scope

This SOP applies to the management and review of study protocol amendments submitted by the Principal Investigator while the study is on-going. This SOP begins with the receipt and entry into the logbook of incoming documents and the protocol database and ends with filing of progress reports and committee decisions in the protocol file.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and recording of entry into the logbook of the submission of amendments (SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*
Step 2: Retrieval of pertinent protocol file	*CDUHREC office secretary*
Step 3: Notification of Chair and Lead Reviewer	*CDUHREC office secretary*
Step 4: Determination of type of review: expedited (SOP on Expedited Review (SOP# 4) or full review (SOP on Full Review (SOP# 5)	*Chair and Lead Reviewer*
Step 5: Communication of committee action (SOP on Communication REC Decisions (SOP# 22)	*Chair*
Step 6: Filing of amendments and decision letter and update of the protocol database. SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and recording of entry into the logbook: *The CDUHREC office secretary receives the Application for Review of Amendments and enters the date and pertinent information into the logbook of incoming documents (See SOP 21: Management of Active files).*

Step 2 - Retrieval of pertinent protocol file: *The CDUHREC office secretary retrieves the corresponding protocol file for reference and guidance of the Chair and Lead Reviewer.*

Step 3 - Notification of Chair and Lead Reviewer: *Within three days after receipt of the Application for Review of Amendments, the CDUHREC Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Lead Reviewer.*

Step 4 - Determination of type of review: expedited or full review: *The Chair and the Lead Reviewer, together, decide the type of review and proceed accordingly. For Expedited review, see SOP 4: and for Full review, see SOP 5.*

Step 5 - Communication of committee decision: The CDUHREC communicates the committee action, see SOP #22: Communicating REC Decisions. For amendments, the committee action may be "approved" or "additional information required" or "specific action/s required from the researcher". *CDUHREC office secretary prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The Chair signs the decision letter as follows: Approval, request for additional information or specific action/s.*

Step 6 - Filing of amendments and committee decision and update of the protocol database: *The CDUHREC office secretary files the amendment and a copy of the committee decision in the appropriate protocol folder. S/he proceeds to update the pertinent protocol database.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Amendment – any change or revision in the study protocol made after its approval.

Lead Reviewer – a member of the CDUHREC (usually a medical doctor) assigned to do an in-depth evaluation of the study protocol documents using ethical criteria established by the committee.

Expedited Review – the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Full Review – the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the CDUHREC en banc, in the presence of a quorum, using established ethical criteria.

Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Principal Investigator, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.

Database – a collection of information (e.g., regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

VII. Forms

Form F3: Application for Amendment Form
Form C1: Decision Letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	09 Jul 2015	CDUHREC members	Changed title from The Review Process for New Applications to Continuing Review
04	15 Dec 2015	CDUHREC members	Changed title from Continuing Review to Post Approval Review
05	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC members	First Draft/Formerly part of Old SOP#4
08	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Management of Protocol Deviation and Violation Report	SOP No.	11
		Version No.	3
		Version Date	10 Oct 2024
		Effective Date	10 Oct 2024

I. Policy

The CDUHREC shall require that Principal Investigators must report protocol deviations and violations in the conduct of approved study protocols within 4 weeks from the detection of the protocol violation/deviation. Major protocol violations undergo full review.

II. Objective

To ensure that the safety and welfare of study subjects as well as the credibility and integrity of data are maintained, protocol deviations and violations must be reviewed by the CDUHREC.

III. Scope

This SOP applies to the management and review of study protocol deviations/violations while the study is on-going. This SOP begins with the receipt and entry into the logbook of the reported protocol violations and deviations and ends with filing of progress report and committee decision in the protocol file.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and recording of entry into the logbook of the reported protocol violations and deviations (SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*
Step 2: Retrieval of pertinent protocol file	*CDUHREC office secretary*
Step 3: Notification of Chair and Lead Reviewer	*CDUHREC office secretary*
Step 4: Determination of type of review: expedited (SOP on Expedited Review (SOP# 4) or full review (SOP on Full Review (SOP# 5)	*Chair and Lead Reviewer*
Step 5: Inclusion of report in the agenda of the next CDUHREC regular meeting (SOP on Preparing the Meeting Agenda (SOP# 18); SOP on Conduct of Meeting (SOP# 20)	*CDUHREC office secretary and Chair*
Step 6: Communication of decision to the Principal Investigator (SOP on Communicating CDUHREC Decisions (SOP# 22)	*CDUHREC office secretary and Chair*
Step 7: Filing of all related documents and update of the protocol database (SOP on Managing Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and recording of entry into the logbook: *The CDUHREC office secretary receives the report on protocol deviation or violation in the appropriate report form (Form F4) and enters the date and pertinent information into the logbook of incoming documents (See SOP #24: Management of Active files).*

Step 2 - Retrieval of pertinent protocol file: *The CDUHREC office secretary retrieves the corresponding protocol file for reference and guidance of the Chair and Lead Reviewer.*

Step 3 - Notification of Chair and Lead Reviewer: *Within three days after receipt of the Report on Protocol Deviation or Violation, the CDUHREC office secretary notifies and sends the pertinent protocol file to the Chair and the previously assigned Lead Reviewer.*

Step 4 - Determination of type of review: expedited or full review: *The Chair and the Lead Reviewer, together, decide the type of review and proceed accordingly. For Expedited review, see SOP #4: and for Full review, see SOP #5.*

Step 5 - Inclusion of report in the agenda of the next CDUHREC regular meeting. *The Chair includes the report on protocol deviation and violation in the Agenda of the next meeting if it is for Full review or the decision report if Expedited review.*

Step 6 - Communication of committee decision: The CDUHREC communicates the committee action, see SOP #22: Communicating REC Decisions. *CDUHREC office secretary prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting in the full board review. The Chair signs the decision letter which includes one or several of the following: (1) submission of additional information, (2) submission of corrective action, (3) invitation to a clarificatory interview, (4) requirement for an amendment (5) site visit, (6) suspension of recruitment, and (7) withdrawal of ethical clearance.*

Step 7 – Filing of all related documents and update of the protocol database: *The CDUHREC office secretary collates and files the retrieved protocol documents, the report on protocol deviation and violation and the decision letter in the appropriate protocol folder. S/he proceeds to update the pertinent protocol database.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Protocol Deviation – non-compliance with the approved protocol that does not increase risk or decrease benefit to study subjects or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

Protocol Violation - non-compliance with the approved protocol that increases risk or decreases benefit to study subjects or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

Principal Investigator - the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.

Sponsored Clinical Trials – clinical studies on investigational drugs.

Clinical Monitor - an individual who oversees the progress of a clinical trial.

Clinical Auditor – an individual who systematically and independently examines trial related activities and documents at a particular period.

Regular Meeting – a periodically scheduled assembly of the CDUHREC.

Drug or device – health product used for diagnosis or treatment.

Protocol File – an organized physical or electronic compilation of all documents related to a Protocol

Full Review - the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the CDUHREC en banc, in the presence of a quorum, using established ethical criteria.

Expedited Review - the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Site Visit – an activity of the CDUHREC during which an assigned team goes to the research site or office for specific monitoring purposes.

Clarificatory Interview/meeting – a meeting or consultation of the CDUHREC with the Principal Investigator for the purpose of obtaining explanations or clarifications regarding some research issues identified by the CDUHREC.

VII. Forms

Form F5: Protocol Deviation/Violation Report Form

Form C1: Decision Letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.
03	10 Oct 2024	CDUHREC Members	Changed the time of reporting to 4 weeks.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

I. Policy

The CDUHREC shall require the submission of Reportable Negative Events Reports (RNE) at the latest three (3) days after the event has come to the attention of the Principal Investigator. A special meeting shall be considered depending on the level of risk involved.

II. Objective

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

III. Scope

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

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and documentation of submission of the RNE report in the logbook/database (SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*
Step 2: Retrieval of pertinent protocol file	*CDUHREC office secretary*
Step 3: Notification of Chair	*CDUHREC office secretary*
Step 4: Call for a Special Meeting	*Chair*
Step 5: Deliberation on the RNE	*CDUHREC members*
Step 6: Communication of decision to the Principal Investigator (SOP on Communicating CDUHREC Decisions (SOP# 22)	*CDUHREC office secretary and Chair*
Step 7: Filing of all related documents and update of the protocol database (SOP on Managing Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and documentation of submission of the RNE report in the logbook/database: *The CDUHREC office secretary receives the accomplished RNE report form (Form F6) and enters the submission into the logbook. The CDUHREC office secretary notes whether the submission is within the required timeline.*

Step 2 - Retrieval of pertinent protocol file: *The CDUHREC office secretary retrieves the approved protocol file and checks the identity of the Lead Reviewer.*

Step 3 - Notification of Chair: *The CDUHREC office secretary 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 CDUHREC office secretary prepares for a special meeting (SOP# 18). The Principal Investigator and other members of the study team, if any, 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 CDUHREC members regarding the presence of the research team for a clarificatory meeting. The safety issues are evaluated, i.e., identification of risks to the study subjects/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 CDUHREC en banc will then 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 CDUHREC recommendation to the Principal Investigator: See SOP# 22 on Communicating REC decisions.

Step 7 - Filing of all related documents and update of the protocol database: See SOP# on Managing Active Files (SOP# 24).

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

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

Reportable Negative Events (RNE) - occurrences in the study site that indicate risks or actual harms to study subjects, members of the research team and to integrity of data. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.

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

Clarificatory Meeting/Interview – a face-to-face meeting or consultation of the CDUHREC with the Principal Investigator for the purpose of obtaining explanations or clarity regarding some research issues identified by the CDUHREC

VII. Forms

Form F6: RNE Report
Form G1: Notice of Meeting
Form C: Decision Letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

I. Policy

The CDUHREC shall require the submission of reports of SAEs/AEs within 24 hours, center specific SUSARs within 2 weeks and SUSARs within 4 weeks after the event has come to the attention of the Principal Investigator. The evaluation of the SAEs and SUSARs shall be conducted by the assigned CDUHREC member, preferably a pharmacist, whose recommendation shall be submitted to the CDUHREC for final action.

II. Objective

Review of SAE and SUSAR reports aims to ensure that the safety and welfare of the study subjects in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated.

III. Scope

This SOP applies to the review of reports of SAEs in various studies and SUSARs in clinical trials. This SOP begins with the receipt and documentation of submission of report of SAEs and SUSARs in the logbook and ends with the filing of all related documents and update of the protocol database.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and documentation of submission of the SAE/SUSARs report in the logbook/database (SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*
Step 2: Retrieval of pertinent protocol file	*CDUHREC office secretary*
Step 3: Notification of Chair	*CDUHREC office secretary*
Step 4: Submission of report to the assigned CDUHREC member	*CDUHREC office secretary*
Step 5: Inclusion of report of the assigned CDUHREC member in the agenda of the next regular CDUHREC meeting	*CDUHREC office secretary and Chair*
Step 6: Communication of decision to the Principal Investigator (SOP on Communicating CDUHREC Decisions (SOP# 22)	*CDUHREC office secretary and Chair*
Step 7: Filing of all related documents and update of the protocol database (SOP on Managing Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and documentation of submission of the SAE/SUSARs report in the logbook/database: *The CDUHREC office secretary receives the accomplished SAE/SUSARs report forms (Form F11) and enters the submission into the logbook. The CDUHREC office secretary notes whether the submission is within the required timeline.*

Step 2 - Retrieval of pertinent protocol file: *The CDUHREC office secretary retrieves the approved protocol file, checks the identity of the Lead Reviewer and a tabulation of earlier SAE/SUSAR reports.*

Step 3 - Notification of Chair: *The CDUHREC office secretary notifies and sends the report and the retrieved documents to the Chair.*

Step 4 – Submission of report to the assigned CDUHREC member. *The Chair directs the CDUHREC office secretary to forward the report and pertinent documents to the assigned CDUHREC member for action which should not be later than 3 days prior to the next committee meeting.*

Step 5 – Inclusion of report of the assigned CDUHREC member in the CDUHREC meeting agenda. *The suggested action/decision of the assigned CDUHREC member is included in the agenda of the next meeting (see SOP on Preparing the Meeting Agenda) for ratification or discussion and final decision. Possible actions include: notation with no further action required, further information or action required or suspension of recruitment.*

Step 6 - Communication of CDUHREC recommendation to the Principal Investigator: See SOP# 22 on Communicating REC decisions.

Step 7 - Filing of all related documents and update of the protocol database: See SOP# on Managing Active Files (SOP# 24).

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

SAE (Serious Adverse Events) - an event observed during the implementation of a study whether or not it is related to the study intervention where the outcome is any of the following:

- Death
- Life-threatening event
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage (devices)
- Other serious (important medical) events

SUSAR (Suspected Unexpected Serious Adverse Reactions) - a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert

Principal Investigator - the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial

Sponsor - an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial

Researcher-initiated Studies – research activities whose conceptualization, protocol development and implementation are done by a researcher or group of individuals who may request for external funding support

Sponsored-clinical Trials – a systematic study of pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization, protocol development and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities

VII. Forms

Form F11: SAE/SUSAR Report
Form F11: Evaluation of SAE/SUSAR Reports
Form C1: Decision Letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	09 July 2015	CDUHREC members	Changed title from The Review Process for New Applications to Continuing Review
04	15 Dec 2015	CDUHREC members	Changed title from Continuing Review to Post Approval Review
05	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC members	First Draft/Formerly part of Old SOP#4
08	10 Aug 2023	CDUHREC members	Changed Of submission reports of SAEs and SUSARs
09	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.
10	10 Oct 2024	CDUHREC Members	Added "center specific SUSARs within 2 weeks and AEs and Changed title."

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Management of An Application for Continuing Review	SOP No.	13
		Version No.	08
		Version Date	02 Oct 2024
		Effective Date	10 Oct 2024

I. Policy

The CDUHREC shall require the submission of an application for Continuing Review at least 4 weeks before the expiration of the ethical clearance of a protocol. Protocols that underwent Full Review in its initial submission shall undergo Full Review in its application for Continuing review. Similarly, protocols that underwent Expedited Review shall undergo Expedited Review in its application for Continuing review. (Form F7) Application for Continuing Review will be used.

II. Objective

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study subjects are promoted and the integrity of data protected beyond the period of initial ethical clearance and up to the end of the study.

III. Scope

This SOP applies to the management of an application for Continuing review submitted by the Principal Investigator proponent while the study is still on-going but whose ethical clearance is about to expire. This SOP begins with the receipt of an application for continuing review and ends with the recording of the entry into the logbook and protocol database.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and documentation of the application for continuing review in the logbook/database (SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*
Step 2: Retrieval of pertinent protocol file	*CDUHREC office secretary*
Step 3: Notification of Chair and Lead Reviewer	*CDUHREC office secretary*
Step 4: Determination of type of review: Expedited (SO# 4 Expedited Review) or Full review (SOP# 5 Full Review)	*Chair and Lead Reviewer*
Step 5: Communication of decision (SOP on Communicating CDUHREC Decisions (SOP# 22)	*CDUHREC office secretary and Chair*
Step 6: Filing of all related documents and update of the protocol folder (SOP on Managing Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and documentation of the application for continuing review in the logbook/database: *The CDUHREC office secretary receives, logs and enters into the protocol database the information included in the application for Continuing review (Form F7 Application for Continuing Review)*

Step 2 - Retrieval of pertinent protocol file: *The CDUHREC office secretary retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports, report of negative events (RNEs) and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.*

Step 3 - Notification of Chair and Lead Reviewer: *The CDUHREC office secretary notifies the Chair and the Lead Reviewer regarding the submission and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance.*

Step 4 – Determination of type of review: expedited or full review: *The Chair shall determine the type of review based on the policy that study protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, study protocols that underwent Expedited review shall undergo Expedited review in its application for Continuing review (see SOP#4: Expedited Review and SOP#5: Full Review)*

Step 5 - Communication of CDUHREC action: The CDUHREC office secretary prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair finalizes and signs the decision letter (Form C1). Possible decisions include but is not limited to the following: Approval, Additional information required, submission of an explanation for failure to submit required reports or disapproval, withdrawal of the ethics approval.

Step 6 - Filing of all related documents and update of the protocol folder: The CDUHREC office secretary files the application for Continuing Review, the recommendations of the Lead Reviewer and decision letter in the appropriate protocol folder.

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Continuing Review - the decision of the CDUHREC to extend the ethical clearance of a study based on an assessment that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.

Progress Report – a description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form F4. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the CDUHREC based on the level of risk.

Amendment – a change in or revision of the protocol made after it has been approved.

Protocol Deviation – non-compliance with the approved protocol that does not increase risk or decrease benefit to study subjects or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

Protocol Violation - non-compliance with the approved protocol that increases risk or decreases benefit to the study subjects or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

SAE – Serious Adverse Event – an event whether or not it is related to the study intervention where the outcome observed in a study is any of the following:

- Death
- Life-threatening event
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/ birth defect
- Required intervention to prevent permanent impairment or damage (devices)
- Other serious (important medical) events

SUSAR – Suspected Unexpected Serious Adverse Reaction – a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert

RNE – an occurrence in the study site that indicates risks or actual harms to participants and to members of the research team. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.

Lead Reviewer – a member of the CDUHREC (usually a medical doctor) assigned to do an in-depth evaluation of the research-related documents using ethical criteria established by the committee.

Expedited Review – the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Full Review – the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established ethical criteria.

Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Principal Investigator, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.

Database – a collection of information (e.g,. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

VII. Forms

Form F7: Continuing Review Application For

Form C1: Decision Letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	09 Jul 2015	CDUHREC members	Changed title from The Review Process for New Applications to Continuing Review
04	15 Dec 2015	CDUHREC members	Changed title from Continuing Review to Post Approval Review
05	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC members	First Draft/Formerly part of Old SOP#4
08	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.
09	02 Oct 2024	CDUHREC members	Added Form F7 in Policy. Inserted the statement "but is not limited to" and "withdrawal of the ethics approval in Step 5

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Review of Final Report	SOP No.	14
		Version No.	08
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC shall require the submission of the final report not later than 8 weeks after the end of the study. Final reports shall undergo either expedited or full review.

II. Objective

This activity aims to ensure that the conduct of the study was in compliance with the approved protocol and that the safety and welfare of study subjects were promoted and the integrity of data protected until the end of the study.

III. Scope

This SOP applies to the management and review of final reports submitted by proponents at the end of the study. This SOP begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and documentation of the Final Report in the logbook/database (SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*
Step 2: Retrieval of pertinent protocol file	*CDUHREC office secretary*
Step 3: Notification of Chair and Lead Reviewer	*CDUHREC office secretary*
Step 4: Determination of type of review: Expedited (SOP# 4 Expedited Review) or Full review (SOP# 5 Full Review)	*Chair and Lead Reviewer*
Step 5: Communication of decision (SOP on Communicating CDUHREC Decisions (SOP# 22)	*CDUHREC office secretary and Chair*
Step 6: Filing of the Final Report and all related documents and update of the protocol folder (SOP on Managing Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and documentation of the Final Report in the logbook/database: *The CDUHREC office secretary receives, logs and enters into the logbook the Final Report.*

Step 2 - Retrieval of pertinent protocol file: *The CDUHREC office secretary retrieves the corresponding protocol file as reference in the review of the Final Report.*

Step 3 - Notification of Chair and Lead Reviewers: *The CDUHREC office secretary notifies the Chair and the Lead Reviewer regarding the receipt of the Final Report.*

Step 4 – Determination of type of review: expedited or full review: *The Chair shall determine the type of review based on the policy that study protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, study protocols that underwent Expedited review shall undergo Expedited review (see SOP#4: Expedited Review and SOP#5: Full Review)*

Step 5 - Communication of CDUHREC action: The CDUHREC office secretary prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair finalizes and signs the decision letter (Form C1). Possible decisions include the following: Acceptance or to require resubmission with corrections.

Step 6 - Filing of the Final Report and all related documents and update of the protocol folder: The CDUHREC office secretary files the Final Report and related documents in the appropriate protocol folder and updates the protocol database.

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Final Report – a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The CDUHREC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Lead Reviewer – a member of the CDUHREC (usually a medical doctor) assigned to do an in-depth evaluation of the research-related documents using ethical criteria established by the committee.

Risks – summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol

Benefits – summary of probable positive or favorable outcomes ranging from benefit to the community (or society), indirect gains such as education, or direct therapeutic value

Status of study subjects – summary of what happened to (condition of) study subjects (participants) recruited to the study, including those that completed the study, those that dropped out, or those withdrawn for specific reasons in accordance with the protocol

Full Review - the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the CDUHREC en banc, in the presence of a quorum, using established ethical criteria.

Expedited Review - the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".

Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Principal Investigator, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

VII. Forms

Form F10: Final Report Form
Form C1: Decision Letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	09 Jul 2015	CDUHREC members	Changed title from The Review Process for New Applications to Continuing Review
04	15 Dec 2015	CDUHREC members	Changed title from Continuing Review to Post Approval Review
05	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 April 2021	CDUHREC members	First Draft/Formerly part of Old SOP#4
08	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Review of Early Termination Reports	SOP No.	15
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	11 Sep 2024

I. Policy

When a decision for early termination of the research has been made, the well-being and safety of study subjects that have already been recruited shall be a primary consideration and the plan for termination shall reflect this concern. Early termination reports shall undergo full review.

II. Objective

Review of early termination reports aims to ensure that the decision takes into consideration the safety and welfare of study subjects that have already been recruited and that there is adherence to the principle of fairness to all concerned.

III. Scope

This SOP applies to the review of early termination reports. This SOP begins with the receipt and entry of the early termination reports into the logbook and ends with an update of the protocol database.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and documentation of the Early Termination Report in the logbook/database (SOP on Management of Active Files (SOP# 24)	*CDUHREC office secretary*
Step 2: Retrieval of pertinent protocol file	*CDUHREC office secretary*
Step 3: Notification of Chair and Lead Reviewers	*CDUHREC office secretary*
Step 4: Full Review (SOP on Full Review (SOP# 5)	*Lead Reviewers*
Step 5: Communication of CDUHREC decision (SOP on Communicating CDUHREC Decisions (SOP# 22)	*CDUHREC office secretary and Chair*
Step 6: Filing of the Early Termination Report and all related documents and update of the protocol folder (SOP on Managing Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and documentation of the Early Termination Report in the logbook/database: *The CDUHREC office secretary receives the early termination report and logs and enters the appropriate information into the logbook.*

Step 2 - Retrieval of pertinent protocol file: *The CDUHREC office secretary retrieves the corresponding protocol file and summarizes the documents that have been submitted.*

Step 3 - Notification of Chair and Lead Reviewer: *The CDUHREC office secretary notifies the Chair and the Lead Reviewer regarding the receipt of the Early Termination Report and the summary of documents that have been submitted.*

Step 4 – Full Review: *The CDUHREC office secretary, upon the instruction of the Chair, shall include the report in the agenda of the next meeting and ensure that the Lead Reviewer is given the necessary documents so that s/he can prepare the presentation (SOP # Full Review). The review should tackle the implication of the early termination on the rights, safety, and welfare of the study subjects in the form of a termination package with a set of procedures. The procedures may include adopting specific provisions so the study subjects shall have continued access to protective mechanisms and information.*

Step 5 - Communication of CDUHREC action: The CDUHREC office secretary prepares the draft decision based on the minutes of the meeting in the full review. The Chair finalizes and signs the decision letter (Form C1). Possible decisions include the following: Acceptance of the decision with no further action; to request for additional information; or requirement for further action.

Step 6 - Filing of all related documents and update of the protocol folder: The CDUHREC office secretary files the Early Termination Report and related documents in the appropriate protocol folder and updates the protocol database.

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Early Termination - the decision of the Principal Investigator, Sponsor, or the institution to end the implementation of a study before its completion.

Termination package - entitlements of study subjects in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness to all concerned

Lead Reviewer – a member of the CDUHREC (usually a medical doctor) assigned to do an in-depth evaluation of the research-related documents using ethical criteria established by the committee.

Full Review - the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the CDUHREC en banc, in the presence of a quorum, using established ethical criteria.

Logbook – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Principal Investigator, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.

Database – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

VII. Forms

Form F10: Final Report Form
Form C1: Decision Letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Management of Appeals	SOP No.	16
		Version No.	08
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC shall consider the perspective of the Principal Investigator/Sponsor regarding the feasibility and acceptability of CDUHREC recommendations including its disapproval. Appeals shall undergo full review and shall be resolved within six weeks (24 working days) upon receipt of the fully documented appeal.

II. Objective

Management of appeals ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the Principal Investigator/Sponsor.

III. Scope

This SOP covers CDUHREC actions related to the handling of an appeal made by a principal investigator or a sponsor regarding a CDUHREC decision. It begins with the receipt of the appeal recording of pertinent information into the logbook and ends with an update of the protocol database.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt of an appeal	*CDUHREC office secretary*
Step 2: Retrieval of pertinent protocol file	*CDUHREC office secretary*
Step 3: Notification of Chair and Lead Reviewer	*CDUHREC office secretary*
Step 4: Inclusion in Agenda of the next regular committee meeting	*Chair and Lead Reviewer*
Step 5: Deliberation of the appeal	*Chair and CDUHREC members*
Step 6: Communication of committee action (SOP# 22 on Communicating CDUHREC Decisions)	*Chair*
Step 7: Filing of documents and updating of the protocol database (SOP on Managing Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt of an Appeal: *The CDUHREC office secretary receives the letter of appeal and enters the pertinent information into the logbook.*

Step 2 - Retrieval of pertinent protocol file: *The CDUHREC office secretary retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.*

Step 3 - Notification of Chair and Lead Reviewer: *The CDUHREC office secretary notifies the Chair and the lead reviewer about the letter of appeal and awaits further instructions.*

Step 4 - Inclusion in the Agenda of the next regular meeting: *The Chair instructs the CDUHREC office secretary to include the appeal in the agenda of the next regular meeting to ensure that the retrieved protocol and related documents are available during the meeting and to inform the principal investigator to be available on the scheduled meeting in case there is a need for further clarification.*

Step 5 - Deliberation of the Appeal: *The lead reviewer summarizes the protocol and the previous discussion of the issues in the protocol as a background of the appeal. The Chair presents the contents of the appeal and leads the discussion. The lead reviewer may be called for further clarification of issues. The principal investigator is asked to step out of the meeting room after the committee has taken up the issues for clarification. The committee then decides (by consensus) whether to accept any or all of the points raised in the appeal.*

Step 6 - Communication of Committee Action: *Based on the deliberations, the Chair summarizes the decision points and instructs the CDUHREC office secretary to prepare the draft decision letter (Form C1 Decision Letter Template) for his/her finalization and forwarding to the Principal Investigator. (SOP# 22 Communicating REC Decisions).*

Step 7 - Filing of Documents and Update of Protocol Database: *The CDUHREC office secretary files all the documents into the appropriate folder and updates the protocol database accordingly.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Appeal – a request of a principal investigator for a reconsideration of the CDUHREC decision.

Lead reviewer – a member of the CDUHREC (usually a medical doctor) who is assigned to do an in-depth evaluation of research-related documents using ethical criteria established by the committee.

Protocol File/Folder – an organized compilation of all documents (in physical or electronic form) related to a study.

Protocol database - a collection of information (e.g., regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

VII. Forms

Form C1: Decision Letter template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 June 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 April 2013	CDUHREC members	Editorial change
04	09 July 2015	CDUHREC members	Changed title from Meetings to The Review Process for New Applications
05	15 Dec 2015	CDUHREC members	Rephrased Item No. 3 of the Review Process
06	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 April 2021	CDUHREC members	First draft/Formerly Part of Old SOP#3
08	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Conduct of Site Visits	SOP No.	17
		Version No.	08
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHERC shall conduct visits of selected sites of approved protocols that fall within the following established criteria for such visits: (a) high risk studies, (b) receipt of significant number of protocol violations, (c) receipt of complaints from study subjects and families, (d) non-receipt of required after-approval reports from the Principal Investigator, and (e) multiple studies conducted by a Principal Investigator.

II. Objective

Site visits are mechanisms by which the CDUHREC monitors compliance with approved protocols, the ICF process and continuing protection and promotion of study subject's dignity, rights and well-being.

III. Scope

This SOP covers the procedures in conducting visits to study sites for reasons set by the CDUHREC. It begins with the selection of the site to be visited and ends with the filing of Site Visit Reports in the protocol folder and updating of the protocol database.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Selection of the Site to be visited	*CDUHREC members*
Step 2: Notification of the Principal Investigator	*CDUHREC office secretary*
Step 3: Creation of the Site Visit Team	*Chair*
Step 4: Conduct of the Site Visit	*Site Visit Team members*
Step 5: Draft of report and presentation of report during the meeting and discussion for recommendations	*Site Visit Team members*
Step 6: Transmittal of Final Report to the Principal Investigator	*CDUHREC office secretary and Chair*
Step 7: Filing of the Site Visit Reports in the protocol folder and update of the protocol folder (SOP on Managing Active Files (SOP# 24)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Selection of the site to visit: *The CDUHREC decides which site to visit based on the following criteria: (a) high risk studies, (b) consistent non-submission or failure to submit after-approval submission requirements, (c) reports of major protocol non-compliance, (d) significant number of serious adverse events, and (e) reports of complaints from study subjects or their family. The decision is likewise made by consensus.*

Step 2 - Notification of the Principal Investigator: *The CDUHREC office secretary will notify the Principal Investigator through a letter at least 5 days prior to the conduct of the Site Visit. The letter will state the reasons of the Site Visit.*

Step 3 - Creation of the Site Visit Team: *The Chair designates who will constitute the Site Visit Team from among the CDUHREC members. The team shall not be less than 3 where one is a medical doctor and will be designated as the Team Leader.*

Step 4 - Conduct of the Site Visit: *The following important points shall serve as guide in the conduct of the site visit:*

- *Study protocol version*
- *Informed consent documents: verify if the site is using the most recently approved version*
- *Post-approval documents: verify if these have been submitted to and approved by the CDUHREC.*
- *Security, privacy, and confidentiality of the documents at the study site*
- *Facilities in the study site*
- *Determination of the protection of the rights, safety, and welfare of human participants in the study*

Step 5 - Draft of report and presentation of report during meeting and discussion for recommendations: *The team shall discuss among themselves after the Site Visit their findings and recommendations in order for the Team Leader to collate and use such data to fill out the Site Visit Report Form which will then be submitted to the CDUHREC office not later than 3 days from the conduct of the Site Visit. The CDUHREC office secretary shall then include the said Site Visit Report in the agenda of the next regular meeting of the committee. The Team Leader will present the Site Visit Team's findings and recommendation to the CDUHREC en banc. The CDUHREC members will then decide on the proposed recommendation by consensus.*

Step 6 - Transmittal of the Final Report to the Principal Investigator:*The CDUHREC office secretary prepares a summary of the findings and recommendations of the CDUHREC based on the deliberations during the meeting. The Chair finalizes the report for transmittal to the Principal Investigator. (SOP# 22 Communicating REC Decisions)*

Step 7 - Filing of the Site Visit documents and update of the Protocol database: *The CDUHREC office secretary files the Site Visit Report in the appropriate folder and updates the protocol database accordingly. (SOP# 24 Management of Active Files)*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Site Visit - an activity of the CDUHREC (based on established criteria) in which an assigned team goes to the research site or office for specific monitoring purposes.

After-approval reports – reports, e.g., progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the CDUHREC for submission by the Principal Investigator after the study has been approved for implementation.

Protocol Violation - non-compliance with the approved protocol that may result in an increased risk or decreased benefit to study subjects or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

High Risk Studies – research where harm or danger resulting from the study intervention is very likely to occur for participants.

Lead Reviewer – a member of the CDUHREC (usually a medical doctor) assigned to do an in-depth evaluation of the research-related documents using ethical criteria established by the committee.

Full Review – the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established ethical criteria.

Decision - the result of the deliberations of the CDUHREC in the review of a protocol or other submissions.

Protocol File/Folder – an organized compilation of all documents (physical or electronic form) related to a study.

Protocol Database- a collection of information regarding protocols that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

VII. Forms

Form F8: Site Visit Report Form

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	
02	02 Feb 2013	CDUHREC members	Changed Format
03	09 Jul 2015	CDUHREC members	Changed title from The Review Process for New Applications to Continuing Review
04	15 Dec 2015	CDUHREC members	Changed title from Continuing Review to Post Approval Review
05	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
07	23 Apr 2021	CDUHREC members	First draft/Formerly part of Old SOP#4
08	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Preparing for a Meeting	SOP No.	18
		Version No.	09
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC shall have a regular schedule of meetings every 2nd Thursday of the month. All meetings shall be held within the premises of Cebu Doctors University Hospital. Special meetings shall be held to resolve issues that require immediate attention, e.g., safety of study subjects, protocol violations that impact research integrity.

II. Objective

Preparing for a meeting aims to contribute to a smooth, orderly, and efficient conduct of meetings.

III. Scope

This SOP covers all activities prior to the conduct of a CDUHREC meeting. This SOP begins with the preparation of the agenda and ends with the notification of CDUHREC Members and confirmation of attendance.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Preparation of the agenda (SOP# 19 Preparing the Meeting Agenda)	*Member Secretary and CDUHREC office secretary*
Step 2: Coordination with the venue in-charge	*CDUHREC office secretary*
Step 3: Assembly of materials and documents needed for the meeting	*CDUHREC office secretary*
Step 4: Preparation of presentation and recording equipment and food arrangement for the meeting	*CDUHREC office secretary and Treasurer*
Step 5: Notification of CDUHREC Members and confirmation of attendance	*Member Secretary and CDUHREC office secretary*

V. Description of Procedures

Step 1 - Preparation of the agenda: *The CDUHREC office secretary upon the instruction of the Member Secretary shall include in the agenda all submissions made not later than 2 weeks before the scheduled meeting. It includes the following: Study Protocols for initial Review; Resubmissions or Study Protocols for Modifications; Study Protocol Amendment Applications/ICF Revisions; Protocols with Expedited Approval; Withdrawal of Study Protocol Applications; Study Protocol for Notification and Updates; Continuing Review Applications;*

Final Reports; Serious Adverse Events/Adverse Events Reports; Site Visit Reports; Study Protocol Non-Compliance (Deviation or Violation) Reports; Early Study Termination

Applications; Queries or Complaints; Safety Reports (SUSAR Notifications); and Other matters.

Step 2 – Coordination with the venue in-charge: *In the event the meeting room in the CDUHREC office will not be available or appropriate to maintain social distancing, the CDUHREC office secretary will coordinate with the venue in-charge of the CDUH Conference Room regarding the upcoming meeting of the CDUHREC (date, time, appropriate conference room) one week before the schedule.*

Step 3 – Assembly of materials and documents needed for the meeting:*The CDUHREC office secretary gathers the documents and materials for the meeting based on the provisional agenda, e.g., copies of the provisional agenda, provisional minutes of the previous meeting, protocols and related documents submitted at least 2 weeks before the meeting, post-approval reports, expedited review reports, administrative memos, etc.*

Step 4 – Preparation of presentation and recording equipment and food arrangement for the meeting: *The CDUHREC office secretary ensures that the following are prepared and available for the meeting: computer, projector and screen, microphones, adequate food and drinks depending on the expected duration of the meeting. In coordination with the Treasurer, the honoraria for the committee members should also be prepared.*

Step 5 – Notification of CDUHREC Members and confirmation of attendance:*The member secretary supervises the CDUHREC office secretary in the preparation of the Notice of Meeting (Form G1) that includes the provisional agenda. The CDUHREC office secretary sends the notice of meeting to the members of the committee at least two weeks before the schedule and follows-up the confirmation of attendance to ensure a quorum. In case, a quorum cannot be met, the CDUHREC office secretary informs the Chair and the member secretary for appropriate action.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Quorum – the minimum number (i.e., majority of the members) and type of members of the CDUHREC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 7 regular members including the non-affiliated and the non-scientific members and there must be a mix of genders.

CDUHREC office secretary – institutional personnel assigned by administration to assist in the REC office operations.

Regular Meeting - a periodically scheduled assembly of the CDUHREC

Special Meeting - an assembly of the Committee outside of the regular schedule of

meetings for a specific purpose, usually to decide on an urgent matter like selection of an officer, approval of a revised or new SOP, report of critical research problems that require immediate action

Administrative Documents – documents that pertain to the operations of the CDUHREC and are not directly related to a study or protocol.

Honorarium - monetary payment for specific professional services.

Venue-in-charge – employee of Cebu Doctors University Hospital who is in charge of the maintenance and use of physical facilities.

Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".

VII. Forms

Form G1: Notice of Meeting
Form G4: Attendance Confirmation Form
Form G2: Agenda Template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012		
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 Apr 2013	CDUHREC members	Increased honorarium and revised Criteria for Removal members
04	01 Feb 2014	CDUHREC members	Increased honorarium
05	09 Jul 2015	CDUHREC members	Changed title from Membership to Meetings
06	15 Dec 2015	CDUHREC members	Changed schedule of regular meetings
07	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
08	23 Apr 2021	CDUHREC members	First draft/Formerly part of Old SOP#2
09	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Preparing the Meeting Agenda	SOP No.	19
		Version No.	09
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The meeting agenda shall be based on the submissions received, at the latest, two (2) weeks before the scheduled regular meeting. It shall follow an established template for meeting agenda. The provisional agenda shall be included in the Notice of Meeting.

II. Objective

The preparation of the meeting agenda aims to ensure a smooth, orderly, inclusive, and efficient conduct of meetings.

III. Scope

This SOP describes how the CDUHREC determines what items are to be included in the agenda of 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.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Preparation of the draft meeting agenda	*Member Secretary and CDUHREC office secretary*
Step 2: Preparation of the provisional meeting agenda	*Chair*
Step 3: Distribution of the provisional meeting agenda (SOP# 19 Preparing for a Meeting)	*CDUHREC office secretary*
Step 4: Approval of the provisional meeting agenda	*CDUHREC Members*
Step 5: Filing of the final meeting agenda (SOP# 24 on Management of Active Files)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Preparation of the draft meeting agenda: *The CDUHREC office secretary under the supervision of the Member Secretary prepares the draft agenda two (2) weeks before the scheduled meeting, using the Meeting Agenda Template (Form G2). The agenda includes the following:*

1. *Call to Order*
2. *Declaration of Quorum*
3. *Approval of the Provisional Agenda*
4. *Disclosure of Conflict of Interest*
5. *Review and Approval of the Minutes of the Previous Meeting*
6. *Business Arising from the Minutes*
7. *New Business:*
    - *7.1. Study Protocols for initial Review;*
    - *7.2. Resubmissions or Study Protocols for Modifications;*
    - *7.3. Study Protocol Amendment Applications/ICF Revisions;*
    - *7.4. Protocols with Expedited Approval;*
    - *7.5. Withdrawal of Study Protocol Applications;*
    - *7.6. Study Protocol for Notification and Updates;*
    - *7.7. Continuing Review Applications;*
    - *7.8. Final Reports;*
    - *7.9. Serious Adverse Events/Adverse Events Reports;*
    - *7.10. Site Visit Reports;*
    - *7.11. Study Protocol Non-Compliance (Deviation or Violation) Reports;*
    - *7.12. Early Study Termination Applications;*
    - *7.13. Queries or Complaints;*
    - *7.14. Safety Reports (SUSAR Notifications);*
8. *Other Matters*

Step 2 - Preparation of the provisional meeting agenda: *The Chair reviews the draft agenda (within 2 days) as the basis for preparing the provisional agenda for inclusion in the Notice of Meeting.*

Step 3 - Distribution of the provisional meeting agenda: The provisional meeting agenda are sent to the CDUHREC members via electronic mail. *The provisional agenda is included in the Notice of Meeting (SOP# 19 Preparing for a Meeting).*

Step 4 - Approval of the provisional meeting agenda: *The CDUHREC members approve the provisional agenda during the meeting.* (SOP# 20 Conduct of Meeting).

Step 5 - Filing of the final meeting agenda: *The CDUHREC office secretary files the final (approved) meeting agenda in a special folder that contains all meeting agenda in chronological order. See SOP# 24 Managing Active Files).*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Draft Meeting Agenda – the order of business that includes the list of topics or items recommended for discussion in a meeting. This is endorsed to the CDUHREC Chair for his/her approval.

Provisional Meeting Agenda – the order of business that includes the list of topics or items approved for discussion in a meeting by the CDUHREC Chair.

Final Meeting Agenda - the order of business that includes the list of topics or items approved for discussion in a meeting by the CDUHREC Members in a regular or special meeting.

Quorum – the minimum number (i.e., majority of the members) and type of members of the CDUHREC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 7 regular members including the non-affiliated and the non-scientific members and there must be a mix of genders.

Conflict of Interest - a situation in which aims or concerns of two (primary and secondary) different roles or duties are not compatible such that decisions may adversely affect the official/primary duty.

Protocols for Full Review – Study protocols that require an en banc ethical assessment because they entail more than minimal risks to the study subjects and/or that participation generates vulnerability issues.

Exemption Report – a list of protocols submitted for review that were deemed not to require the conduct of either expedited or full review. This report is presented during a regular committee meeting or as required by the institutional authority.

Expedited Review Reports – an enumeration of protocols (including title, code number, proponent, submission date, names of reviewers and decisions) that underwent expedited review for information of the CDUHREC members and for record viewers.

Post-approval Reports – accounts of the ongoing implementation of an approved study (e.g., progress report, amendment, safety report, protocol deviation/violation, early termination, final report, or application for continuing review) that are required to be submitted by the Principal Investigator to the CDUHREC for monitoring purposes.

Administrative Issuances – official communications or announcements from institutional authorities.

VII. Forms

Form G2: Meeting Agenda Template
Form G1: Notice of Meeting

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012		
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 Apr 2013	CDUHREC members	Increased honorarium and revised Criteria for Removal members
04	01 Feb 2014	CDUHREC members	Increased honorarium
05	09 Jul 2015	CDUHREC members	Changed title from Membership to Meetings
06	15 Dec 2015	CDUHREC members	Changed schedule of regular meetings
07	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
08	23 Apr 2021	CDUHREC members	First draft/Formerly part of Old SOP#2
09	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Conduct of Meetings	SOP No.	20
		Version No.	10
		Version Date	02 Oct 2024
		Effective Date	10 Oct 2024

I. Policy

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. The meeting depending on the exigency of the situation can be conducted either on-site or off-site via Zoom, Google Meet, Microsoft Teams or any other available platform.

II. Objective

Meetings are conducted to provide an opportunity for the CDUHREC to arrive at collegial decisions regarding study protocols and CDUHREC operations and to be informed of pertinent administrative matters.

III. Scope

This SOP describes the manner by which the CDUHREC conducts all its meetings. It covers CDUHREC actions and activities from the time the meeting is called to order and quorum is declared 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.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Distribution of meeting materials	*CDUHREC office secretary*
Step 2: Declaration of quorum (formal start)	*Member Secretary*
Step 3: Approval of the provisional agenda	*CDUHREC Members*
Step 4: Declaration of conflict of interest (COI) (Form D1)	*CDUHREC Members (who have COI)*
Step 5: Approval of minutes of the previous meeting	*CDUHREC Members*
Step 6: Discussion of "Business arising from the minutes"	*CDUHREC Members*
Step 7: Review of protocols and protocol-related submissions (SOP on Full Review (SOP# 5)	*CDUHREC Chair and Members*
Step 8: Report of results of expedited review (SOP on Expedited Review (SOP# 4)	*Designated Lead Reviewers*

Step 9: Discussion of operations-related matters	*CDUHREC Chair and Members*
Step 10: Adjournment	*Chair*
Step 11: Collection, storage, and disposal of meeting materials	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Distribution of meeting materials: *The CDUHREC office secretary distributes the hard copies or the soft copies of the Provisional Agenda, Minutes of the Previous Meeting and Study protocols at least 2 weeks before the meeting.*

Step 2 – Declaration of quorum: *The Chair asks the Member secretary if there is a quorum and the latter manifests before the en banc of such fact or lack thereof before the meeting would proceed.*

Step 3 - Approval of the provisional agenda: *The Chair invites the members to examine the provisional agenda and to propose addition or deletion of items. The provisional agenda had already been sent in advance through electronic mail. After deliberation, the provisional agenda is approved by consensus and after due motion.*

Step 4 - Declaration of Conflict of Interest: *The Chair asks the members if there is a conflict of interest. Any declaration of COI will be duly noted and the policy on conflict-of-interest management shall be implemented (e.g., conflicted member stepping out of the room and non-participation in the decision-making process).*

Step 5 - Approval of minutes of previous meeting: *The Chair invites the members to examine the Minutes of the Previous Meeting and notes any questions or objections about the minutes. The minutes had already been sent in advance through electronic mail. After deliberation, the Minutes of the Previous Meeting is approved by consensus and after due motion.*

Step 6 - Discussion of "Business arising from the minutes": *The Chair asks the en banc for any "business arising from the minutes". All issues on "business arising from the minutes" are discussed among the members and its resolution including the discussion is duly recorded in the minutes of the meeting.*

Step 7 - Review of protocols and protocol-related submissions: *If necessary and upon due notice when there is a need for clarification of issues, the CDUHREC requires the Principal Investigators to make a presentation. For any other instance, the Lead Reviewer will take charge. The Lead Reviewer may be a member of the CDUHREC or an External Expert.*

The sequence of review and discussion is structured in the following order: a cursory comment on the technical issues of the study protocol, ethical issues, and informed consent process/form issues. The Lead Reviewers are guided by the assessment form in their presentations. See SOP# 5 Full Review.

After deliberation, the CDUHREC arrives at a decision by consensus.

Step 8 - Report of results of expedited review: *The Chair presents the results of the expedited review for information of the members as well as for the documentation of the review results.*

Step 9 - Discussion of operations-related matters: *The Chair invites the attention of the members on issues relating to GCP Trainings, Updates on SOP, including administrative/operation related matters.*

Step 10 - Adjournment: *Meetings are adjourned after all items in the agenda have been discussed and/or resolved. A member moves for the adjournment of the meeting, and seconded, for it to be declared.*

Step 11 - Collection, storage, and disposal of meeting materials:*The CDUHREC office secretary sorts the documents distributed during the meeting which now includes the study protocols and protocol related documents furnished in advance to the members prior to the meeting. See SOPs on Managing Active Files (SOP# 24) and SOP# 19 Preparation of Agenda*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Quorum – the minimum number (i.e., majority of the members) and type of members of the CDUHREC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 7 regular members including the non-affiliated and the non-scientific members and there must be a mix of genders.

Conflict of Interest - a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.

Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".

Adjournment – formal closure of the meeting. Motion for adjournment and record of the time are minuted.

Consensus – the process of arriving at a decision without voting but by generating the overall sentiment of a group such that deliberations continue until no more strong objection is registered.

Collegial Decision – a course of action arrived at after a group deliberation where members were considered of equal authority such that the course of action is considered a group action and is not ascribed to any one member.

Meeting Minutes - the official narration and record of the proceedings of the assembly of CDUHREC Members, based on the agenda.

CDUHREC Operations - the overall activities of the CDUHREC that reflect performance of its functions and responsibilities.

Protocol – documentation of the study proposal that includes a presentation of the rationale and significance of the study, background and review of literature, study objectives, study design and methodology, data collection, dummy tables, plan for analysis of data, ethical consideration, and dissemination plan.

Protocol-related submissions – other documents that are included (required) in the submission of the protocol, e.g., Informed Consent Forms, study tools (Interview guide, survey questionnaire, FGD guide) and CVs of the proponents and certificates of training.

Business Arising from the Minutes – matters generated from the discussions in the previous meeting that need continuing attention and require reporting.

Operations-related Matters – items included in the agenda that are not directly related to any protocol under review.

VII. Forms

Form G4: Attendance Sheet
Form F1: Protocol Assessment Form
Form E2: ICF Assessment Form
Form C1: CDUHREC Decision Form
Form D1: Confidentiality Agreement

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012		
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 Apr 2013	CDUHREC members	Increased honorarium and revised Criteria for Removal members
04	01 Feb 2014	CDUHREC members	Increased honorarium
05	09 Jul 2015	CDUHREC members	Changed title from Membership to Meetings
06	15 Dec 2015	CDUHREC members	Changed schedule of regular meetings
07	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
08	23 Apr 2021	CDUHREC members	First draft/Formerly part of Old SOP#2
09	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022. Added Form D1 in Step 4.
10	02 Oct 2024	CDUHREC members	Added the statements "the soft copies" and "study protocols at least 2 weeks before the meeting" in Step 1, and "before the meeting would proceed" in Step 2.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Preparation of the Minutes of Meetings	SOP No.	21
		Version No.	09
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

All discussions, deliberations and decisions on all matters listed in the agenda and taken up during the meeting shall be reduced into writing by the Member Secretary as Minutes of the Meeting, which are projected to a screen so that all members will see what is being written while the meeting is ongoing.

II. Objectives

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in the CDUHREC meeting.

III. Scope

This SOP includes CDUHREC actions related to the documentation of the proceedings of a 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 filing of the approved minutes.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Entry of preliminary information on the minutes template	*CDUHREC office secretary*
Step 2: Preparation of the draft minutes	*Member Secretary and CDUHREC office secretary*
Step 3: Notation of the draft minutes	*Chair*
Step 4: Approval of the minutes in the next CDUHREC meeting	*Chair and Members*
Step 5: Filing of the approved minutes (SOP on Managing Active Files (SOP# 24)	*CDUHREC Staff*

V. Description of Procedures

Step 1- Entry of preliminary information on the minute's template: *The CDUHREC has a minutes template where all preliminary information are entered by the CDUHREC office secretary. Preliminary or relevant information includes but is not limited to protocol-related information and other matters.*

Step 2 - Preparation of the draft minutes: *Upon the supervision of the Member Secretary, the CDUHREC office secretary prepares the draft minutes. During the meeting, the Member Secretary, with the assistance of the CDUHREC office secretary, is tasked with documentation of proceedings in accordance with the agenda and the assessment checklist (forms) . The documentation is done through note-taking and sound recording in real time while the meeting is ongoing. The CDUHREC en banc will know that all documents and discussions are recorded as the soft copy is projected on a screen for everyone to see all entries. All information (e.g., comments and recommendations) are entered including the discussions of all issues.*

Step 3 - Notation of the draft minutes: *The draft minutes will be sent through electronic mail at least 2 weeks prior to the scheduled regular meeting to the Chair for notation. In general, the following items are included in the minutes of the meeting:*

- *Date and venue of meeting*
- *Members attendance (members present and absent)*
- *Presence of external experts, principal investigators, guests, and observers (if any)*
- *Time when the meeting was called to order*
- *Declaration of Quorum*
- *Name of Presiding officer*
- *Conflict of Interest (COI) declaration*
- *Items discussed, issues raised, and resolutions*
- *CDUHREC decisions and recommendations*
- *Name and signature of person who prepared the minutes*
- *Name and signature of the Chair and date of notation*

Step 4 - Approval of the minutes in the next CDUHREC meeting: *The draft minutes are sent in advance to all members through electronic mail. During the meeting, the Chair invites the attention of the members to go over it and approval of the minutes is done through a formal motion from any member of the committee and seconded accordingly.*

Step 5 - Storage of the approved minutes: *The CDUHREC office secretary compiles all approved minutes of the meeting and stores them in a central file of all meeting minutes by year to facilitate retrieval.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Meeting Agenda- the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".

Draft Meeting Minutes – proceedings of the meeting prepared by the CDUHREC office secretary under the supervision of the Member Secretary.

Provisional Meeting Minutes – proceedings of the meeting that have been noted or approved by the Chair.

Final Meeting Minutes – proceedings of the meeting that have been approved by the CDUHREC en banc.

Real-time Recording – the process of documenting the minutes of the meeting while the meeting is ongoing.

Conflict of Interest – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.

VII. Forms

Form G3: Minutes Template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012		
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 Apr 2013	CDUHREC members	Increased honorarium and revised Criteria for Removal members
04	01 Feb 2014	CDUHREC members	Increased honorarium
05	09 Jul 2015	CDUHREC members	Changed title from Membership to Meetings
06	15 Dec 2015	CDUHREC members	Changed schedule of regular meetings
07	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
08	23 Apr 2021	CDUHREC members	First draft/Formerly part of Old SOP#2
09	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Communicating CDUHREC Decisions	SOP No.	22
		Version No.	10
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC shall communicate its decisions to the Principal Investigator within 8 weeks after receipt of the complete set of submission documents. The communication document shall include clear instructions/recommendations for guidance of the Principal Investigator, must be written on an official stationery of the CDUHREC and signed by the Chair.

II. Objective

The management of communicating CDUHREC decisions ensures that all stakeholders are appropriately, accurately and promptly informed of the results of deliberations of the CDUHREC.

III. Scope

This SOP covers CDUHREC actions related to communicating CDUHREC decisions (e.g., actions to applications submitted to the CDUHREC). This SOP begins with the finalization of recommendations of the committee or the lead reviewers and ends with the filing of the decision document in the protocol file.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Finalization of recommendations of the committee (in case of full review) (SOP # 5 Full Review) or Finalization of recommendations of lead reviewers (in case of expedited review) (SOP # 4 Expedited Review)	*Chair*
Step 2: Transfer of information from meeting minutes or reports to CDUHREC decision forms or templates	*Member Secretary and CDUHREC office secretary*
Step 3: Approval of the CDUHREC decision document	*Chair*
Step 4: Transmittal of CDUHREC decision to Principal Investigator	*CDUHREC office secretary*
Step 5: Filing of the decision document in the protocol file (SOP # 24 Managing Active Files) and Update of Protocol Database	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Finalization of recommendations of the committee (in case of full review) or reviewers (in case of expedited review): *For finalization of Committee's Recommendations See SOP#5 on Full Review or for finalization of Reviewers' Recommendations, see SOP #4 Expedited Review). The Chair finalizes the recommendations proposed by the committee en banc.*

Step 2 - Transfer of information from meeting minutes to CDUHREC decision forms: *Upon approval of the draft minutes, or finalization of the lead reviewers' recommendations, the CDUHREC relays the information to the Principal Investigator through an Approval Letter or Notification Letter either through electronic mail or hard copy. The transfer is done by the CDUHREC office secretary with the supervision of the Member Secretary.*

Step 3 - Approval of the CDUHREC decision document: *The Chair reviews and approves the decision documents by signing on the Approval Letter (Form C5) or Notification Letter (Form C1) within 5 days from the last committee meeting.*

Step 4 - Transmittal of CDUHREC decision to Principal Investigator: *The CDUHREC office secretary transmits the CDUHREC decision to the Principal Investigator either through electronic mail or hand-delivered. This is done a week after the approval by the Chair.*

Step 5 - Filing of the decision document in the protocol file and Update of the Protocol Database: *The CDUHREC maintains all protocol-related decisions or actions in the protocol folder to facilitate retrieval including updating of the protocol database.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Expedited Review - the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

Full Review – the ethical evaluation of a study protocol and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established ethical criteria.

Protocol Index – a chronological record of the documents in the protocol file. The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking,

Protocol Database - a collection of information about protocols that is structured and organized for easy access, management, interpretation, analysis and updating. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

Active Files – documents pertaining to protocols which are currently being assessed, managed or monitored by the CDUHREC. For easy monitoring, the CDUHREC maintains a white board indicating all active studies.

VII. Forms

Form C1: Notification Letter
Form C4: Approval Letter

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012		
02	02 Feb 2013	CDUHREC members	Changed Format
03	01 Apr 2013	CDUHREC members	Increased honorarium and revised Criteria for Removal members
04	01 Feb 2014	CDUHREC members	Increased honorarium
05	09 Jul 2015	CDUHREC members	Changed title from Membership to Meetings
06	15 Dec 2015	CDUHREC members	Changed schedule of regular meetings
07	10 Jan 2020	CDUHREC members	Changed format to PHREB format as well as introduced new amendments as shown in the underscored portions
08	23 Apr 2021	CDUHREC members	First draft/Formerly part of Old SOP#2
09	29 Aug 2024	CDUHREC members	Inserted Form C1 and C4 in the Description of Procedures
10	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Management of Incoming and Outgoing Communications	SOP No.	23
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

All communications shall be recorded accurately and appropriately in a physical logbook and electronic database. Protocol-related communications are separated from administrative communications. Incoming communications shall be acted upon promptly.

II. Objective

The management of CDUHREC incoming and outgoing documents/communications aims to establish accountability and an efficient and effective tracking system.

III. Scope

This SOP covers CDUHREC actions related to organizing incoming and outgoing documents and ensuring an appropriate CDUHREC response. This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Sorting of incoming/outgoing communications	*CDUHREC office secretary*
Step 2: Recording of incoming/outgoing communications	*CDUHREC office secretary*
Step 3: Acting on incoming communications	*Chair*
Step 4: Filing of incoming/outgoing communications and Updating of respective Databases	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Sorting of incoming/outgoing communications: *All kinds of communications are received by the CDUHREC office (e.g., letters, official memoranda, or emails). The CDUHREC office secretary then sorts out the said communications depending on the source (e.g., Principal Investigators, Sponsors, Regulators, study subjects, Family/kin of study subjects or Institutions) All sorted out communications are organized and addressed in a relevant and timely manner (e.g., separating protocol-related from process-related communication).*

Step 2 - Recording of incoming/outgoing communications: *The CDUHREC adopts a system of recording of incoming/outgoing communications that documents the date received, source (person who sent communication), subject, person who received the communication, action taken (with details of who received it from the CDUHREC). The CDUHREC office secretary is responsible for recording the communications in a logbook.*

Step 3 - Acting on communications: *The Chair is responsible for initiating response for incoming communications and sending outgoing communications.*

Step 4 - Storing or filing of incoming/outgoing communication: *The CDUHREC has in place a storage system for all incoming/outgoing communications. The practice of the CDUHREC is that all protocol-related communications are filed in the study protocol file while non-protocol-related documents are filed in the appropriate administrative file. All files are properly indexed and entered in the logbook and updated in the protocol database.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Incoming Communications – documents which are directed to and received at the CDUHREC office.

Outgoing Communications – documents related to the operations of the CDUHREC generated within the CDUHREC office intended for individuals or offices.

Administrative Documents - documents that pertain to the operations of the CDUHREC and not directly related to a study or protocol. Examples include the SOPs, Membership files, Agenda and minutes files, administrative issuances.

Protocol-related File/Documents - all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of the proponent, advertisements, In-depth Interview Guide Questions, and Indexing System.

VII. Forms

Form H3: Index of Protocol File

VIII. Document History

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Management of Active Files	SOP No.	24
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

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# 24). Relevant and essential office equipment are provided which includes but is not limited to computer and printer, internet connection and shredder.

II. Objective

The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality.

III. Scope

This SOP covers procedures done related to protocols accepted for review, undergoing review, or have been approved by the CDUHREC. This SOP begins with the classification and coding of active files and ends with the periodic updating of the file.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Classification and coding of Active Files	*Member Secretary and CDUHREC office secretary*
Step 2.: Preparation of the Protocol Folder	*CDUHREC office secretary*
Step 3: Periodic updating of the Protocol File	*Member Secretary and CDUHREC office secretary*

V. Description of Procedures

Step 1. Classification and coding of active files: *The CDUHREC office secretary under the supervision of the Member Secretary classifies active files as follows:*

- *Initial Submission*
- *Resubmission*
- *Progress Report*
- *Amendment*
- *Protocol Deviation*
- *Protocol Violation*
- *SAE - Serious Adverse Event*

- *SUSAR – Suspected Unexpected Serious Adverse Reaction*
- *Early Termination*
- *Continuing Review*
- *Final Report/ Close Out Report*

The CDUHREC office secretary assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. The code consists of the year and the serial number that indicates the sequence order of receipt. For example, a protocol received in 2019 as the 10th submission in that year will be coded as 2019-010.

Step 2. Preparation of the Protocol Folder: *The CDUHREC office secretary files all documents pertaining to a study in a vertical folder that is labelled on the front cover and along the spine with: Protocol Code - Study Title – Principal Investigator's Family Name - Sponsor or Funding Agency. The CDUHREC office secretary attaches a protocol index on the inside front cover that indicates the contents of the folder.*

Step 3. Periodic Updating of the Protocol File: *The CDUHREC office secretary ensures that the documents are filed in chronological order such that the most recent documents are topmost. These documents include the following:*

- *Protocol (Original and Revised) versions*
- *Informed consent (Original and Revised) versions*
- *Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final, Amendment, Early Termination, Site Visit Reports*
- *Assessment Forms for each of the submitted and reviewed reports which should be signed and dated*
- *Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda*
- *Decision and Approval Letters*
- *Communications*

The office secretary updates the protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness.

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Initial Submission - a set of documents consisting of the full proposal and other study-related documents that is received by the CDUHREC so that ethical review can be done.

Resubmission - the revised study proposal that is forwarded to the CDUHREC in response to the recommendations given during the initial review.

Progress Reports- a systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form #. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the CDUHREC based on the level of risk.

Amendment - a change in or revision of the protocol made after it has been approved.

Protocol Deviation – non-compliance with the approved protocol that does not increase risk nor decrease benefit to participants and does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

Protocol Violation - non-compliance with the approved protocol that may result in an increased risk or decreased benefit to participants or significantly affect their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

Serious Adverse Event (SAE) – an event observed during the implementation of a study where the outcome is any of the following

- *Death*
- *Life-threatening event*
- *Hospitalization (initial or prolonged)*
- *Disability or permanent damage*
- *Congenital anomaly/birth defect*
- *Required intervention to prevent permanent impairment or damage (devices)*
- *Other serious (important medical) events whether or not it is related to the study intervention.*

Suspected Unexpected Serious Adverse Reaction (SUSAR) - a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert.

Early Termination - ending the implementation of a study before its completion. This is a decision made by the sponsor or a regulatory authority and/or recommended by the Data Safety Monitoring Board or Principal investigator in consideration of participant safety, funding issues, protocol violations, and data integrity issues.

Continuing Review - the decision of the CDUHREC to extend ethical clearance of a study beyond the initial period of effectivity based on an appreciation that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.

Final Reports/Close Out Reports – a summary of the outputs and outcomes of the study upon its completion. The CDUHREC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Protocol Index - a chronological record of the documents in the protocol file. The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed it and an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking.

Assessment Form – evaluation tool accomplished by the lead reviewers when appraising the protocol or the Informed Consent Form.

VII. Forms

Form H3: Index of Protocol File

VIII. Document History

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.
03	10 Oct 2024	CDUHREC members	Added the statement "Relevant and essential office equipment are provided which includes but is not limited to computer and printer, internet connection and shredder".

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Archiving	SOP No.	25
		Version No.	08
		Version Date	10 Oct 2024
		Effective Date	10 Oct 2024

I. Policy

Files of studies which have been terminated or completed or declared inactive shall be kept in a separate storage for 3 years. Studies of Principal Investigators who have not resubmitted their study protocols within 3 months after receiving the Notification Letter (Form C) shall be considered inactive. The prescriptions of the WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethical Guidelines are followed, including security of file storage and access, document control, and document tracking.

II. Objective

Archiving inactive, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines.

III. Scope

This SOP includes procedures related to storage and retrieval of protocols that are classified as inactive, terminated or completed. This SOP begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Acceptance of Final or Early Termination Reports (SOP# 14 on Review of Final Reports, SOP# 15Review of Early Termination Reports, and Identification of a Study Protocol as Inactive.	*CDUHREC Members, Chair*
Step 2: Updating of corresponding protocol folder	*CDUHREC office secretary*
Step 3: Transfer of the protocol folder in the archives and Update of the Protocol Database	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Acceptance of Final or Early Termination Reports and Identification of an Inactive File: *The CDUHREC members approve or accept the final report or early termination report during a meeting (SOP#14 Review of Final, Report; SOP#15 Review of an Early Termination Report). In the identification of an Inactive File, the CDUHREC office secretary informs the Member Secretary of the failure of a concerned Principal Investigator to respond to the recommendations of the CDUHREC in the last 3 months during which time the Principal Investigator has been appropriately reminded of the requirement. This is included in the agenda of the next meeting where the protocol is declared inactive.*

Step 2 – Updating of the corresponding active file: *The CDUHREC office secretary files the Comment Letter C4, Approval Letter C5, Notification Letter C1, Ethical Clearance Template C2, Certificate of Exemption Template C3, Checklist for the Assessment of the Clinical Trial Protocol I1. Checklist for the Assessment of the Informed Consent I2, Checklist for the Assessment of the Risk/Benefit I3, Final or Early termination report in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.*

Step 3 - Transfer of the Protocol Folder in the Archives and Update of the Protocol Database: *The CDUHREC office secretary checks whether the documents listed in the protocol file index are complete and removes extraneous documents. Thence, the CDUHREC office secretary transfers the folder to the archive section and updates the protocol database.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Final Report – a summary of the outputs and outcomes of the study upon its completion. The CDUHREC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Early Termination - ending the implementation of a study before its completion.

Inactive Study – a study whose principal investigator has not communicated with the CDUHREC with regard to issues pertaining to the approval or implementation of the study within a period of 3 months.

Active Study – an ongoing study, implementation of which is within the period covered by ethics clearance.

Archiving - the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, or terminated or declared inactive.

Confidentiality of Documents – the recognition and awareness that certain documents that have been entrusted or submitted to the CDUHREC must not be freely shared or disclosed.

Controlled document – a document that has been entrusted or submitted to the CDUHREC and which must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored, and appropriately recorded.

VII. Forms

Form H4: Borrower's Log

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 June 2012		
02	01 Feb 2013	CDUHREC members	Changed Format
03	09 July 2015	CDUHREC members	Changed title from Office Secretary to Review Fees
04	15 Dec 2015	CDUHREC members	Changed title from Review Fess to Writing and Revising SOPs
05	10 Jan 2020	CDUHREC members	Change format to PHREB format
06	23 April 2021	CDUHREC members	First draft/Formerly part of Old SOP6
07	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.
08	10 Oct 2024	CDUHREC members	Added "Comment Letter C4, Approval Letter C5, Notification Letter C1, Ethical Clearance Template C2, Certificate of Exemption Template C3, Checklist for the Assessment of the Clinical Trial Protocol I1. Checklist for the Assessment of the Informed Consent I2, Checklist for the Assessment of the Risk/Benefit I3" in Step 2

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Management of Access to Confidential Files	SOP No.	26
		Version No.	02
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

It is the responsibility of the CDUHREC to keep particular documents in its custody confidential. This is to protect the intellectual property rights of research proponents and to protect REC members from unnecessary scrutiny and pressure from non-authorized individuals. In the Philippines, personally identifiable documents entered into a database system are subject to protections under the Data Privacy Act of 2012, emphasizing the need to lay down policies authorizing access to such documents. Confidential files include study protocol-related documents (e.g., protocols, case report forms, informed consent documents, scientific documents, expert opinions or reviews), meeting minutes, decisions, action letters/notification of committee decision, approval letters, and study protocol-related communications.

Access to the CDUHREC confidential files shall be regulated and limited to CDUHREC members and staff. Other persons with legitimate interest in these files (e.g., institutional authorities, regulatory agencies, sponsors) shall be allowed to access specific files with proper justification. Principal Investigators shall be allowed access only to their own protocol files upon request.

II. Objective

Management of access to confidential files helps protect the intellectual property rights of Principal Investigators, their study subjects as well as the data and enhances the credibility and integrity of the REC.

III. Scope

This SOP consists of procedures for accessing confidential files including document handling and distribution. This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt and logging of request for access to confidential files	*CDUHREC office secretary*
Step 2: Approval of requests for access and retrieval of documents	*Chair*
Step 3: Supervision of use of retrieved document	*CDUHREC office secretary*
Step 4: Return of document to the files	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt and logging of request for access to confidential files: *The CDUHREC office secretary receives the request (Form H6) to access specific files and refers this to the Chair. The said request is entered into the logbook for record purposes stating all pertinent information.*

Step 2 - Approval of requests for access and retrieval of documents: *The Chair examines the authority of the requesting individual and the reason for the request. If the Chair finds the reason satisfactory, such is approved. The CDUHREC office secretary asks the* individual *requesting to sign the Confidentiality Agreement and proceeds to retrieve the pertinent document.*

Step 3 - Supervision of use of retrieved document: *The CDUHREC office secretary asks the user to sign the logbook, enforces the room-use restriction and limits photocopying to principal investigators or requesting party.*

Step 4 - Return of document to the files: *After use, the CDUHREC office secretary returns the retrieved files to the protocol file. The fact of return is also entered in the logbook.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Confidentiality - the duty to refrain from freely disclosing private/research information entrusted to an individual or organization.

Study-related Communications – documents that refer to an exchange of information or opinions regarding a study, usually between the CDUHREC and the Principal Investigator.

Sponsor - an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.

Intellectual property – intangible creations of the human mind (such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce, that are considered as owned by the one who thought of it. Intellectual property includes information and intellectual goods.

Intellectual property right – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.

Meeting Minutes – narration of the proceedings of the assembly of CDUHREC members.

Regulatory Authorities – government agencies or institutions that have oversight or control over the conduct of research, e.g., Department of Health, Food and Drug Administration, Research Institutions.

Conflict of Interest - a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.

Room-use Restriction – the rule that limits the use of a document within the designated premises.

VII. Forms

Form H6: Request Form
Form H6: Log of Requests
Form H7: Log of Access

VIII. Document History

Version No.	Date	Authors	Main Change
01	23 April 2021	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Management of Queries and Complaints	SOP No.	27
		Version No.	02
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

Queries and complaints from study subjects or their legal representative shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the CDUHREC office secretary or referred to the lead reviewer of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the lead reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the CDUHREC en banc with the lead reviewer facilitating the discussion.

II. Objective

Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the CDUHREC and ensures that the rights and well-being of the study subjects are protected and attended to.

III. Scope

This SOP is limited to queries and complaints of study subjects, or their legal representative, in studies that have been issued an ethical approval by the CDUHREC. This SOP begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the next CDUHREC meeting.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Receipt, logging, and acknowledgement of queries and complaints (SOP on Managing CDUHREC Incoming and Outgoing Communications)	*CDUHREC office secretary*
Step 2: Referral of query or complaint to competent authority. *2.1 Referral of protocol-related query to the lead reviewer.* *2.2. Referral of all complaints to the Chair*	*CDUHREC office secretary and Chair*
Step 3: Formulation of response *3.1. Protocol-related queries* *3.2. Minimal-risk complaints* *3.3. More than minimal risk complaints*	 *Lead Reviewer* *Lead Reviewer* *Chair and CDUHREC members*

Step 4: Communication of response (SOP on Communicating CDUHREC Decisions (SOP# 22)	*CDUHREC office secretary*
Step 5: Logging of the response (SOP on Managing CDUHREC Incoming and Outgoing Communications (SOP# 23) and inclusion in the agenda of the CDUHREC meeting (SOP on Preparing the Meeting Agenda (SOP# 19)	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Receipt, logging, and acknowledgement of queries and complaints:*All queries and complaints from study subjects or their legal representative are received in the CDUHREC office. The CDUHREC office secretary records into the logbook the following information: date, time, name of concerned party, specific study, nature of query or complaint.*

Step 2 - Referral of query or complaint to competent authority: *Upon receipt of the queries or complaints, the CDUHREC office secretary informs the Chair and the latter will decide to whom it will be referred to.*

2.1. The office secretary refers queries related to specific protocols approved by the CDUHREC to the lead reviewers.

2.2. On the other hand, the CDUHREC office secretary refers all complaints to the CDUHREC Chair who determines the level of risk effected by the issue.

2.2.1. Minimal risk complaints are referred to the lead reviewer of the concerned protocol.

2.2.2. Complaints that involve more than minimal risk are referred to the CDHUREC en banc through a special meeting that shall be called within 48 hours. The CDUHREC office secretary notifies the concerned lead reviewer that s/he will facilitate the discussion such that pertinent materials are provided to him/her as reference.

Step 3 - Formulation of response: *The CDUHREC has a special form for documenting responses to queries and complaints.*

3.1. For queries, the lead reviewer accomplishes the Form G5 Query Reply.

3.2. For minimal risk complaints, the lead reviewer accomplishes Form G6 Complaints Resolution.

3.3. For more than minimal risk, the committee may choose any of the following options:

3.3.1. Constitute a Site Visit Team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.

3.3.2. Designate the lead reviewer to meet with the complainants and the Principal Investigator (preferably separately) for clarification of issues and obtain suggestions for resolution.

3.3.3. Formulate recommendations if satisfied with the adequacy of information –

- *request for explanation/justification from researcher*
- *accept request/demand of participant*
- *suspension of further recruitment*
- *amendment of protocol and re-consent of participants*
- *others*

Step 4 - Communication of response: *The CDUHREC office secretary shall communicate the response to the person who posed a query or complaint. The CDUHREC has a special form for communicating the response to queries and complaints. If the responder is the Lead Reviewer, the response will be signed by the Lead Reviewer and noted by the Chair. In all other instances, the Chair signs the CDUHREC response.*

Step 5 – Logging of the response and inclusion in the agenda of the next CDUHREC meeting: *The response of the CDUHREC shall be entered in the logbook and included in the agenda of the next CDUHREC meeting.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Query – the act of asking for information or clarification about a study.
Complaint – the act of expressing discontent or unease about certain events or arrangements in connection with a study.
Legal representative – one who represents or stands in the place of the study subject under authority recognized by law
Regular Meeting – a periodically scheduled assembly of the CDUHREC.
Special Meeting - an assembly of the Committee for a specific purpose outside of the regular schedule of meetings.
Competent Authority – designated officer or member of the CDUHREC with the authority to respond to queries and complaints regarding studies approved by the CDUHREC.
Lead Reviewer – a member of the Research Ethics Committee (usually a medical doctor) assigned to do an in-depth evaluation of the research-related documents using ethical criteria established by the committee.
Site Visit Team – members of the REC (2-4 members) assigned by the Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of study subjects and protection of integrity of data.

VII. Forms
Form G5: Query/Complaint Form
Form G6 Query/Complaint Response Form
Form H7: Log of Access

VIII. Document History

Version No.	Date	Authors	Main Change
01	23 April 2021	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Writing and Revising SOPs	SOP No.	28
		Version No.	08
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The CDUHREC shall designate a team to annually review its set of SOPs to determine its continuing relevance and effectiveness to its operations.

II. Objective

Writing and revising SOPs ensures continuing quality assurance of CDUHREC functions.

III. Scope

This SOP applies to all CDUHREC activities involved in the development of its SOPs and their revisions as published and distributed by the institution. This SOP begins with the proposal and approval for revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

IV. Workflow

ACTIVITY	***RESPONSIBILITY***
Step 1: Proposal and approval for revision or writing of a new SOP	*Any CDUHREC Member*
Step 2: Designation of the SOP Team	*Chair*
Step 3: Drafting of the revision or new SOP	*SOP Team*
Step 4: Review and finalization of SOP	*CDUHREC Members*
Step 5. Submission of finalized SOP to the institutional authority	*CDUHREC office secretary and Chair*
Step 6: Inclusion of the new or revised SOP in the SOP Manual and its dissemination	*CDUHREC office secretary*

V. Description of Procedures

Step 1 - Proposal for a revision of an SOP or a new SOP and its approval: *Any CDUHREC Member can propose for a revision of an SOP or a new SOP is needed to due exigencies of the time. The proposal can be made upon motion in a regular meeting or through a completed Request for Creation/Revision of an SOP.*

Step 2 - Designation of the SOP Team: *The Chair shall choose the members of the SOP Team to spearhead the revision or the drafting of a new SOP.*

Step 3 - Drafting of the revision or new SOP: *Using the CDUHREC SOP template, the SOP Team can be guided on the procedure of the revision or drafting of a new SOP. The template contains the following:*

(a) *Title, which is descriptive of contents*
(b) *Policy statement*
(c) *Objective/s of the activity, which defines the purpose and intended outcome*
(d) *Scope, which defines the extent of coverage of the SOP and its limitations*
(e) *Workflow provides the essential steps to implement the SOP and the responsible person for each step.*
(f) *Description of Procedures, which elaborates the steps listed in the workflow*
(g) *Glossary – acronyms and terms which need to be defined*
(h) *Forms, documents to be accomplished by different parties as required by the SOP*
(i) *Document history, which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes*
(j) *References, which lists the instruments used to draft the Guideline such as other SOPs, guidelines, or policies*

The SOPs are coded according to the Number and the Version with the first SOP assigned the number 01.

Step 4 - Review and approval of SOP: *Once the draft version is ready, it is submitted to the CDUHREC office secretary so that the matter will be included in the agenda of the next regular meeting. The review, deliberation, and approval are done by consensus. The approval of the revision or new SOP is done within five days after the meeting. If during the deliberation, there are some objections, the same will again be referred to the SOP Team for redrafting.*

Allnew or revised SOPs shall take effect immediately upon its approval. The approval shall be recorded in the Minutes of the Meeting.

Step 5 – Submission of the SOP to the institutional authority: *All approved SOPs whether new or revised shall be submitted by the CDUHREC office secretary upon instruction of the Chair to the CDUH Medical Director. A proper transmittal letter shall be used as cover letter to the submission.*

Step 6 - Inclusion of the new or revised SOP in the SOP Manual and its dissemination: *The new or revised SOP shall be made available in soft copy or hard copy within 15 days from date of receipt of the CDUH Medical Director. The CDUHREC office secretary is the custodian of the official approved copy. The old versions are then retired or stored separately which can still be retrieved at any time.*

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Standard Operating Procedures - the step-by-step description of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for ethical review to ensure quality and consistency.

Coding – unique number assigned to a particular SOP that reflects its serial position among the SOPs and version number to indicate the number of times it has been revised.

Format - general style or layout of the document
Date of Effectivity – date when the guidelines shall be enforced.

VII. Forms
Form G7: Request for Creation/Revision of an SOP
Form G8: SOP Template

VIII. Document History

Version No.	Date	Authors	Main Change
01	01 June 2012		
02	01 Feb 2013	CDUHREC members	Changed Format
03	09 July 2015	CDUHREC members	Changed title from Office Secretary to Review Fees
04	15 Dec 2015	CDUHREC members	Changed title from Review Fess to Writing and Revising SOPs
05	10 Jan 2020	CDUHREC members	Change format to PHREB format
07	23 April 2021	CDUHREC members	First draft/Formerly part of Old SOP#7
08	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	PROCEDURES COVID-19 AND OTHER PANDEMICS DURING	SOP No.	29
		Version No.	02
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

I. Policy

The current COVID-19 pandemic is affecting clinical research activities in most parts of the world. The focus on developing a vaccine for SARS-COV-2 and the treatment of COVID-19 is, in fact, disrupting many upcoming and/or ongoing clinical trials on other diseases around the world. So as to mitigate the crippling effect of the COVID-19 as well as other future health pandemic on the clinical studies reviewed by CDUHREC, the foregoing procedure will be adopted.

II. Objective

The purpose of this section is to serve as guide for procedures that will be implemented during COVID-19 or other pandemics to ensure that the safety and welfare of study subjects and the research team will be safeguarded.

III. Scope

This SOP applies specifically to the procedures that will be adopted during COVID-19 and other pandemics.

IV. Workflow

ACTIVITY	*RESPONSIBILITY*
Step 1: Determination of the application of the SOP on Procedures during COVID-19 and Other Pandemics	*Chair*
Step 2: Notification to all CDUHREC members en banc as well as all the principal investigators who have ongoing clinical trials	*CDUHREC office secretary*

V. Description of Procedures

Step 1- Determination of the application of the SOP on Procedures during COVID-19 and Other Pandemics: *The Chair determines whether the foregoing SOP will be applied after considering the prevailing health situation in the country or the locality.*

Step 2- Notification to all CDUHREC members en banc as well as all the principal investigators who have ongoing clinical trials: *The CDUHREC office secretary upon instruction of the Chair will notify all committee members as well as all the principal investigators who have ongoing clinical trials. The foregoing shall then be observed:*

a. Receiving of Documents or Protocols

1. To ensure the safety of the CDUHREC office secretary, all submissions must comply with the minimum standard health protocols.

b. Meetings

1. Due to the physical restrictions brought about by the COVID-19 or other pandemics, meetings can be done remotely through video conferencing (e.g., Zoom, Google Meet or Microsoft Teams).

c. Conduct of Research

1. To limit the possibility of infection, aside from complying with the minimum health protocols, all Principal Investigators or Sub Investigators are encouraged to monitor their patients remotely or institute infection prevention control measures during face-to-face encounters with subjects.

2. Sponsors and clinical research monitors should comply with minimum health protocols while on physical visits to monitor conduct of research.

3. In the event that the research subject tests positive for COVID-19 or any of the viruses causing a pandemic, the principal investigator is responsible for reporting such to the CDUHREC within 24 hours from its recognition.

d. Protocol Amendment

1. The research protocol should reflect interventions to mitigate infection transmission among researchers and study subjects in the conduct of the research.

VI. Glossary

The terms/abbreviations used in this SOP are understood and defined as:

Lead Reviewer – a member of the Research Ethics Committee (usually a medical doctor) assigned to do an in-depth evaluation of the research-related documents using ethical criteria established by the committee.

Principal Investigator - the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.

VII. Forms

Form G9: Notification letter

VIII. Document History

Version No.	Date	Authors	Main Change
01		CDUHREC members	First Draft
02	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.

IX. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Curriculum Vitae **Template**	CDUHREC FORM	A1
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

Curriculum Vitae

Surname:	Name:
Position: Date of 1st Appointment: Term of Office:	Address:
Educational Background	
Post-graduate degree	
Graduate degree	
Bachelor's degree	
Other qualifications and specializations	
Work Experience	
Present Work Experience	
Previous Work Experience	

CDUHREC Member Signature:

Date:

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Nomination Form	CDUHREC FORM	A2
		Version No.	1
		Version Date	23 April2021
		Effective Date	23 April 2021

1. General Information			
Name of Nominee			
Affiliation:	Name of Department:	Name o Institution:	
Position:			
Highest Educational Attainment :	Name of Institution:	Year/s attended:	Course/Degree:
Research Related Trainings including Research Ethics:	Name of Course: 1.	Offered by:	Year:

Acceptance of Nomination: Signature of Nominee Date:
Name and signature of Nominator: Date: Position: Institution:

Received by: _____

Date: _____

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Appointment of Member Template	CDUHREC FORM	B1
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date

NAME

Department and Position

Institutional Affiliation

Subject: Appointment as _____

Dear ***Name:***

You are hereby appointed as _____ of the Research Ethics Committee (REC) effective (from) to (to). As member/ independent consultant, your responsibilities are as follows:

(As member)

1. Attend REC meetings consistently.
2. Participate in the ethical review of research proposals and other related reports. The non-scientific member shall give special attention to the Informed Consent Form and process to ensure that these are comprehensible by ordinary persons and are considerate of community values.
3. Participate in the after-review activities, e.g., continuing review, site visits, etc.
4. Declare any conflict of interest (COI) in the review of research proposals.
5. Maintain confidentiality of the documents and deliberations of the REC meetings.
6. Attend continuing ethics education and other related activities.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be the member / Independent Consultant of the Research Ethics Committee. Kindly signify your acceptance by signing the conforme below.

Very truly yours,

INSTITUTIONAL AUTHORITY

Conforme:

_____

Name and signature of Appointee

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Appointment of REC Officer Template	CDUHREC FORM	B2
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date

NAME

Department and Position

Institutional Affiliation

Subject: Appointment as Chair/Vice Chair/Member Secretary_____

Dear ***Name:***

You are hereby appointed as Chair/Vice Chair/Member Secretary of the Research Ethics Committee (REC) effective (from) to (to). As Chair/Vice Chair/Member Secretary, your responsibilities are as follows:

(As Chair)

Over and above duties as a Member, the Chair shall have the following responsibilitie:

1. Represent the REC in internal and external meetings and conferences.
2. Preside over REC Meeting.
3. Oversee review of protocols.
4. Assign Primary Reviewers of protocols based on expertise and experience.
5. Supervise development and revisions of SOPs.
6. Prepare and submit annual budget of the REC.
7. Prepare and submit annual report of the REC to the office of the Institutional Authority and to PHREB.
8. Ensure initial and continuing research ethics trainings of members and staff.

(As Vice Chair)

Over and above duties as a Member, the Vice Chair shall have the following responsibilities:

1. Perform duties of Chair in his/her absence.
2. Perform tasks assigned by Chair Participate in the review of research proposals and other related reports when requested.

(As Secretary)

Over and above duties as a Member, the Member Secretary shall have the following responsibilities:

1. Supervise the administrative Staff in the daily operations of the REC.
    a. Receipt of protocol documents
    b. Preparation of protocol files and folders
    c. Preparation of draft of communications
    d. Preparation of draft Agenda and Minutes
    e. Updating of records
2. Assist the Chair in assigning Primary Reviewers.
3. Assist the Chair in the preparation of the Agenda, Annual Report, and budget.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be the Chair/Vice Chair/Member Secretary of the Research Ethics Committee. Kindly signify your acceptance by signing the conforme below.

Very truly yours,

INSTITUTIONAL AUTHORITY

Conforme:

_____

Name and signature of Appointee

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Appointment/Terms of Reference of External Expert Template	CDUHREC FORM	B3
		Version No.	2
		Version Date	23 Sep 2024
		Effective Date	10 Oct 2024

Date

NAME

Department and Position

Institutional Affiliation

Subject: Appointment as External Expert

Dear ***Name:***

You are hereby appointed as External Expert of the Research Ethics Committee (REC) effective (from) to (to). As member/ independent consultant, your responsibilities are as follows:

1. Attend REC meeting when requested.
2. Participate in the review of research proposals and other related reports when requested.
3. Declare any conflict of interest (COI) in the review of research proposals.
4. Maintain confidentiality of the documents and deliberations of the REC meetings.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be the member / External Expert of the Research Ethics Committee. Kindly signify your acceptance by signing the conforme below.

Very truly yours,

INSTITUTIONAL AUTHORITY

Conforme:

_____

Name and signature of Appointee

Document History:

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	Original Version
02	23 Sep 2024	CDUHREC members	Changed Title

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Notification Letter Template	CDUHREC FORM	C1
		Version No.	2
		Version Date	29 Aug 2024
		Effective Date	12 Sep 2024

(Date)

(NAME OF PROPONENT)

(Designation)

(Institution)

(Address)

RE: (Title of project/study)

REC code:

Subject: (Nature of action requested, e.g. ethical clearance extension, acceptance of report, etc.)

Dear ***(Name of proponent)***:

This is to acknowledge receipt of your request and the following supporting documents dated_____.

- _
- _
- _
- _
- _

The above documents underwent full/expedited review which generated the following:

(List of findings)

(List of recommendations)

(Specific instructions to the proponent, if any)

Very truly yours,

(Signature)

(Name)
Chair

Document History:

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	Original Version
02	29 Aug 2024	CDUHREC members	Changed Title

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Ethical Clearance Template	CDUHREC FORM	C2
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

(Date)

(NAME OF PROPONENT/RESEARCHER)

(Designation)

(Institution)

(Address)

RE: (Title of project/study)

REC code:

Subject: Ethical Clearance

Dear ***(Name of proponent)***

(Acknowledgment of request (date of letter) and submitted documents with version numbers and dates)

- _
- _
- _
- _
- _

(Information on type of review and date of meeting, if full review)

(Validity of ethical clearance)

(Provisions for post-approval submissions)

Very truly yours,

(Signature)

(Name)

Chair

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Certificate of Exemption from Review Template	CDUHREC FORM	C3
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

(Date)

(NAME OF PROPONENT)

(Designation)

(Institution)

(Address)

RE: (Title of project/study)

EC code:

Subject: Certificate of Exemption from Review

Dear ***(Title and Family name of proponent)***

This is to acknowledge submission of the following documents (include version numbers and dates)

- _
- _
- _
- _
- _

After a preliminary review of the above documents, the Research Ethics Committee deemed it appropriate that the above proposal be EXEMPTED FROM REVIEW.

This means that the study may be implemented without undergoing an expedited or full review. Neither will the proponents be required to submit further documents to the committee as long as there is no amendment nor alteration in the protocol that will change the nature of the study nor the level of risk involved.

Very truly yours,

(Signature)

(Name)

Chair

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Comment Letter	CDUHREC FORM	C4
		Version No.	1
		Version Date	10 Oct 2024
		Effective Date	10 Oct 2024

Date:

Principal Investigator:

Protocol Code:
Protocol Title:

Dear Dr.:

The Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC) reviewed the above-mentioned protocol on 12 September 2024. The committee noted the following issue/s in the Informed Consent Form:

The decision of the committee regarding the application for review of this study will be communicated to you once all issues have been resolved.

Should you have any questions or comments, please feel free to contact the undersigned at +63 32 416 9341.

Thank you very much.

Respectfully yours,

Enrico B. Gruet, MD
Chairman, CDUH Research Ethics Committee

ACKNOWLEDGEMENT RECEIPT		
PRINTED NAME	SIGNATURE	DATE

Document History:

Version No.	Date	Authors	Main Change
01	10 Oct 2024	CDUHREC members	Original Version

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Approval Letter	CDUHREC FORM	C5
		Version No.	3
		Version Date	02 Oct 2024
		Effective Date	10 Oct 2024

Date:

Principal Investigator:

Protocol Code:
Protocol Title:

Dear Dr.,

The Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)reviewed and approved the following documents:

The review and approval had been in accordance with the principles of the International Conference on Harmonization (ICH) Good Clinical Practice (GCP), the National Ethical Guidelines for Health Research (2022), and the Standard Operating Procedures of CDUHREC.

During the conduct of this study, the investigator must comply with the following:

a) Report serious and/or unexpected adverse event(s) (SAEs, suspected unexpected serious adverse reactions (SUSARs)) that may occur on a study participant. This must be done within 24 hours from site's initial knowledge of the event.
b) Report of SAEs from other study sites or centers (i.e., CIOMS, expedited safety reports) must be submitted to CDUHREC within one (1) month from the site's receipt of the report.
c) Submit any changes or amendments to the approved protocol and informed consent document. These shall require another review and approval by CDUHREC.
d) Notify the committee of any protocol deviations and violations.
e) Report to the CDUHREC any new information that may affect adversely the safety of the subjects or the conduct of the trial.
f) Submit progress report at least once a year from date of approval of the clinical study.
g) Notify the committee for actual date of study start and study closure or termination.
h) Prepare for possible CDUHREC site visit. The site will be notified 30 days prior to a CDUHREC site visit.

The following CDUHREC members took part in the review of Protocol Code:

Lead Reviewer; Medical Doctor

Medical Doctor

Medical Doctor

Medical Doctor

Medical Doctor

Medical Doctor

Nurse; Independent from the institution

Lawyer; Non-scientific member; Independent from the institution

Priest; Non-scientific member; Independent from the institution

Pharmacist; Independent from the institution

Lay member; Independent from the institution

Lay member; Independent from the institution

IMPORTANT: NO CHANGES IN THE PROTOCOL SHOULD BE IMPLEMENTED WITHOUT PRIOR WRITTEN CDUHREC APPROVAL.

Date of Approval:

Respectfully yours,

Enrico B. Gruet, MD
Chairman, CDUH Research Ethics Committee

ACKNOWLEDGEMENT RECEIPT		
PRINTED NAME	SIGNATURE	DATE

Document History:

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	Original Version
02	29 Aug 2024	CDUHREC members	Updated NEGHR edition to 2022 including the list who took part in the review with their qualifications
03	02 Oct 2024	CDUHREC members	Added the statement "Important: No changes in the protocol should be implemented without prior written CDUHREC approval," added the statement "Report to the CDUHREC any new information that may affect adversely the safety of the subjects or the conduct of the trial" in letter (e) and made editorial changes.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Review Notification Form	CDUHREC FORM	C6
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date:

Principal Investigator:

Protocol No.:
Protocol Title:

REVIEW NOTIFICATION

Dear Dr.,

Should you have any questions or comments, please feel free to contact the undersigned at +63 32 416 9341.

Thank you very much.

Respectfully yours,

Enrico B. Gruet, MD
Chairman, CDUH Research Ethics Committee

ACKNOWLEDGEMENT RECEIPT		
PRINTED NAME	SIGNATURE	DATE

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Checklist for Ethical Considerations	CDUHREC FORM	C7
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Short title of research: _____ Protocol version: _____

Principal investigator: _____ Date of submission: _____

For RETROSPECTIVE/PROSPECTIVE data collection

Heading	**Ethical Issues**	**Ethical considerations portion of Methodology**
Ethics review	Whose permission will you ask for before doing the research? (e.g., approval of an ethics committee, permission of departments involved, etc.)	
Privacy	Will you contact participants through phone calls or home visits?	
Confidentiality	What researchers will do to maintain privacy and confidentiality a. what measures will be taken to anonymize data b. how will you keep the data and for how long c. how will you discard/dispose of the data d. who can access data	
Extent of use of study data	Are there plans to use of data other than to answer the objectives stated in the protocol? Are there plans to digitally store the data or make the data available to others?	
Authorship and contributorship	Authorship and contributorship issues a. Who are the authors or contributors to the present paper? b. Acknowledgement of original data collectors c. Written consent of original data collectors that the data can be used for further research	
Conflicts of interest	Declaration of conflicts of interest among authors and contributors	
Publication	Publication issues and plans	
Funding	Source of study funds	

SAMPLE TEMPLATE:

Ethics review

The protocol of this research will be submitted for approval to the Cebu Doctors University Hospital Research Ethics Committee (CDUH-REC). Transmittal letters will be sent to the Medical Director, the Department Chairperson, and the Head of the Medical Records to ask permission to conduct the study and to gather data from the medical records.

Privacy

As a researcher, I will not contact any participants through phone calls or home visits since the data I will receive are already anonymized nor will I divulge any of the patients' identities in this research.

Confidentiality

The data will be in both hard and soft copies. The hard copies will be discarded once the research has been finalized while the soft copies will be kept in the records of the Department of (department) for 5 years.

Under the Data Privacy Act of 2012, information of all the subjects will be held confidential. Data collection sheets will be secured in an envelope and will be stored in a secure cabinet and this will not be made available to the public. Subject identity will not be known. Instead, the hospital PIN will be used as patient identifier. The data collected will only be used for this study. After gathering and analyzing of the data, the data collection sheets will be discarded through paper shredding.

Extent of use of the study

There are no plans to use the data other than to answer the objectives stated in my protocol. There are no plans to make the data available to the general public.

Authorship and Contributorship

I will be the first author and Dr. (co-author) will be my consultant co-author.

The medical records personnel who gave the data will contribute to the paper by providing the data. They will be acknowledged in the final write up of this paper and in any output of this research.

Objectives of this research will be presented to the CDUH Medical Director and the consent will be secured to use data from the Medical Records section to answer the objectives of this research. A written consent to use the data will be obtained from the Section Chairperson, Dr. (department chairperson).

Conflicts of Interest (COI)

Dr. (co-author) is the co-author of this study. I, the principal investigator, declare no conflict of interest.

Funding

I, the principal investigator, will be the source of study funds.

Contact details

For any questions regarding the conduct of this research, I can be contacted through my mobile number 0917xxxxxxx or through my email address xxxxxxxxx@xxxxxxx.com.

Assessed by:

Noted by:

.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Confidentiality Agreement and Conflict of Interest Disclosure (For Members, Observers or Guests of the Cebu Doctors' University Hospital Research Ethics Committee)	CDUHREC FORM	D1
		Version No.	2
		Version Date	23 Sep 2024
		Effective Date	10 Oct 2024

Confidentiality Agreement and Conflict of Interest Disclosure

Know all Men by these Presents:

In view of the appointment of as a member/external expert/guest of the Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC) 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 an external expert of CDUHREC 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 external expert is to independently review both scientific and ethical aspects of research protocols involving human subjects, including adverse events occurring during the conduct of researches, and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the CDUHREC 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 function of an appointed external expert of CDUHREC are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the CDUHREC 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 an external consultant of the CDUHREC.

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 CDUHREC.

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 disclosed 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 his/her performance of this agreement is consistent with the policies of Cebu Doctors University Hospital (CDUH) 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 CDUHREC 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 CDUHREC that no member/external expert may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the CDUHREC.

The ***Undersigned*** will immediately disclose to the CDUHREC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in recommendations and voting with respect to such proposals.

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

- □ A member is involved in a potentially competing research program.
- □ Access to funding or intellectual information may provide an unfair competitive advantage.
- □ A member'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 CDUHREC. A copy will be given to you for your records.]

In the course of my activities as a member of the CDUHREC, 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 Committee'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 Committee duties) to the Chairperson upon termination of my functions as a Committee 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.

_____
Printed Name and Signature of Member

Date: _____

Noted:

Enrico B. Gruet, M.D.
CDUHREC CHAIR
Date: _____

Document History:

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	Original Version
02	23 Sep 2024	CDUHREC members	Changed Title, adding external expert/guest in the 1st paragraph of the form, editorial changes

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Disclosure of Conflict-of-Interest Agreement (For Members and Consultants of the Research Ethics Committee)	CDUHREC FORM	D2
		Version No.	3
		Version Date	09 Jul 2015
		Effective Date	09 Jul 2015

Confidentiality Agreement and Conflict of Interest Disclosure

Know all Men by these Presents:

In view of the appointment of as an external expert of the Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC) 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 an external expert of CDUHREC 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 external expert is to independently review both scientific and ethical aspects of research protocols involving human subjects/ adverse events occurring during the conduct of researches involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the CDUHREC 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 function of an appointed external expert of CDUHREC are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the CDUHREC 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 an external consultant of the CDUHREC.

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 CDUHREC.

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 disclosed 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 the policies of Cebu Doctors' University Hospital (CDUH) 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 CDUHREC 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 CDUHREC that no member/external expert may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the CDUHREC.

The ***Undersigned*** will immediately disclose to the CDUHREC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for r review by the Committee, and to abstain from any participation in recommendations and voting in respect of such proposals.

When an external consultant has a conflict of interest, he/she should not notify the Committee.

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

- □ An external consultant is involved in a potentially competing research program.
- □ Access to funding or intellectual information may provide an unfair competitive advantage.
- □ An external expert'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 CDUHREC. A copy will be given to you for your records.]

In the course of my activities as an external expert of the CDUHREC, 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 Committee'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 Committee duties) to the Chairperson upon termination of my functions as a Committee 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.

_____
Printed Name and Signature of External Expert
Date:_____

Noted:

Enrico B. Gruet, M.D.
CDUHREC CHAIR
Date: _____

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Protocol Reviewer Worksheet	0C0DUHREC FORM	E1
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Title of Study				
REC Code		Type of Review		
Project Leader		Institution		
Reviewer		Date Received	Primary reviewer	☐ Yes ☐No
Guide questions for reviewing the proposal / protocol				
Does the study have social value? ☐ Unable to Assess ☐ Yes ☐ No Comment: (e.g. scientific value, relevance to national /community needs)				
Is the study background adequate? ☐ Unable to Assess ☐ Yes ☐ No Comment:				
Are the research questions supported by the Review of Literature? ☐ Unable to Assess ☐ Yes ☐ No Comment:				
Are the study objectives Specific, Measurable, ☐ Unable to Assess ☐ Yes				

☐ No

Attainable, Realistic, Time-bound?

Comment:

Is the research design appropriate?

- Is the population identified and defined? ☐ Unable to Assess ☐ Yes ☐ No
- Is the selection of study participants described? ☐ Unable to Assess ☐ Yes ☐ No
- Is the sample size justified? ☐ Unable to Assess ☐ Yes ☐ No
- Is the plan for data analysis described? ☐ Unable to Assess ☐ Yes ☐ No
  Are there dummy tables?

Comment:

Does the research need to be carried out with human☐ Unable to Assess ☐ Yes ☐ No

participants?

Comment:

Does the study have a vulnerability issue? ☐ Unable to Assess ☐ Yes ☐ No

Comment:

Are appropriate mechanisms/interventions in place to address the vulnerability issue/s?

☐ Unable to Assess ☐ Yes ☐ No

Comment:

Are there risks/ probable harms to the human participants in the study?

☐ Unable to Assess ☐Yes ☐ No

Comment:

Are there measures to mitigate the risks? ☐ Unable to Assess ☐ Yes ☐ No Comment:
Is the informed consent procedure / form ade☐ Unable to Assess ☐ Yes ☐ No and culturally appropriate? Comment:
Is/are the investigator/s adequately trained and do ☐ Unable to assess ☐ Yes ☐ No they have sufficient experience to undertake the study? Comment:
Is there a disclosure of conflict of interest? ☐ Unable to assess ☐ Yes ☐ No Comment:
Are the research facilities adequate? ☐ Unable to assess ☐ Yes ☐ No Comment:
Are there any other concerns in the study?

Recommendation: ☐Approved

☐Minor revision/s required

_____

_____

☐Major revision/s required

_____

_____

☐Disapproved

Reasons for disapproval:

_____

_____

_____ _____

Name and Signature of Reviewer Review Date

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Checklist for Initial Submission for New Application for Review **Resident/Fellow-Initiated**	CDUHREC FORM	E1.1
		Version No.	3
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

Date of Submission:		
STUDY PROTOCOL Number:		
STUDY PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
STUDY COORDINATOR:		
Email:	**Telephone:**	**Mobile:**
Date of Review: (To be filled up by CDUHREC secretary):		

Checklist for Initial Submission for New Application for Review

Document	Number of Copies Received	Signature CDUHREC	Comment
1. Application letter for review from the PI			
2. Signed protocol and amendments (if any) including the following: a. project summary and flow chart of the protocol b. statement of agreement with ethical principles set out in relevant guidelines c. ethical considerations in the study			
3. Transmittal Letters with Signatures			
4. Study Information and Consent/Assent Forms (English and Cebuano Versions)			
5. Study tools (questionnaires, patient diaries, posters/ advertisements for recruitment) in English and Cebuano version			
6. Case report forms			
7. Curriculum vitae of principal investigator			
8. Information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, if any			
9. Certificate of GCP Training of PI			

Received By:_____ Date:_____
Printed Name and Signature

Document History:

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	First draft
02	29 Aug 2024	CDUHREC members	Changed Title
03	11 Sep 2024	CDUHREC members	Added the statement "including the following: a. project summary and flow chart of the protocol b. statement of agreement with ethical principles set out in relevant guidelines c. ethical considerations in the study" in item number 2.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Informed Consent Checklist	CDUHREC FORM	E2
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

Study Protocol/ICF Amendment Submission Form

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *A study protocol amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the CDUHREC that issued the ethical clearance or approval prior to the implementation of an amendment. Please fill out the form and submit together with your cover letter and documents.*

INSTRUCTIONS TO THE CDUHREC OFFICE SECRETARY: *The original form should be forwarded to the Chair and/or lead reviewer for the type of review. For documents requiring full board review, the accomplished form should be photocopied and provided to each committee member with the documents for review.*

STUDY PROTOCOL Number:

INITIAL APPROVAL DATE:

PRINCIPAL INVESTIGATOR:

AMENDMENT SUBMISSION DATE: (to be filled out by CDUHREC Secretary)

1. **NO. OF AMENDMENT/S**:

2. **STATE NATURE OF STUDY PROTOCOL/ICF AMENDMENT** (Cite study protocol section and page where amendment is found. Include a statement describing any compensation for study participants. For amended ICF, please make sure that all amendments in the ICF have been highlighted prior to submission to CDUHREC for review. Additional sheet may be used if necessary.)

Signature of Principal Investigator: **Date of Signature:**

Section E – ANNUAL RISK/BENEFIT ASSESSMENT

3. **TYPE OF REVIEW**:

3.1.☐EXPEDITED REVIEW

3.2.☐FULL BOARD REVIEW

Comments from Lead Reviewer:

Risk Benefit Assessment:

Recommended Action

- ☐ APPROVAL
- ☐ MINOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO EXPEDITED REVIEW AT THE LEVEL OF THE PANEL CHAIR
- ☐ MAJOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO FULL PANEL REVIEW
- ☐ DISAPPROVAL

Lead Reviewer	Signature	
		PRINTED NAME
Chairman		

Document History:

Version No.	Date	Authors	Main Change
01	22 Nov 2018	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Added the statement "Include a statement describing any compensation for study participants" in item number 2.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Protocol Reviewer Worksheet (For STEM Cell Research)	CDUHREC FORM	E3
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Title of the Study	

NEC Code

Type of Review

Proponent

Institution

Has an ERC/IRB? ____yes ____no

Sponsor

Funding Agency

Name of Reviewer

Primary Reviewer ____yes ____no

GUIDE QUESTIONS

Is there comprehensive literature review and information?

that describes the development of the stem cell therapy

in this study? _____ yes _____ no

Comment:

Nature of Stem Cell Use: ____ Clinical Trial ___ Phase 1 ____ Phase 2 ____ Phase 3

____ Experimental Therapy

____ Established Therapy for new indications/formulation

Source of Stem Cells: ____ Human (adult) ____ autologous ____ allogeneic

____ Human (embryonic)

____ cellular reprogramming

____ Animal (pls. identify_____)

____ Plant (pls. identify _____)

____ Others (pls. describe _____)

Will the stem cells be directly transplanted to the human recipient? _____yes _____no

If YES, where? _____ outside the Philippines, pls specify _____

_____ locally, pls. specify _____

If NOT, will the stem cells be

stored? ____yes ____no _____not indicated

processed? ____yes ____no _____not indicated

cultured? ____yes ____no _____not indicated

expanded? ____yes ____no _____not indicated

or genetically modified? ____yes ____no _____not indicated

Is the laboratory GMP/GLP certified? _____ yes _____ no ____not indicated

Is the hospital accredited by the DOH Bureau of Health

Facilities and Services (DOH-BHSF) for stem cell use? _____ yes _____ no ____not indicated

Will animal serum/feeder cells be used? _____ yes _____ no ____not indicated

Are release criteria described/indicated? _____ yes _____ no ____not indicated

Which stem cell markers will be used?

_____

Comment:

What is the route of administration/transplantation?

_____ intravenous

_____ intrathecal

_____ subdermal

_____ intramuscular

_____ direct to the target organ , _____

Are indicators of clinical efficacy described?

Are there homing indicators? _____ yes _____ no

Are there functional indicators? _____ yes _____ no

Are there persistence indicators? _____ yes _____ no

Comment:

Does the study design address the study objectives? _____ yes _____ no

Comment:

Is the selection of patients fair and equitable? _____ yes _____ no

Comment

Do the participants/ subjects belong to vulnerable groups? _____ yes _____ no

Is vulnerability addressed? _____ yes _____ no

Comment:

Are the benefits adequately described? _____ yes _____ no

Comment:

Will surrogate markers for good outcomes be used? _____ yes _____ no ____ not indicated

What are these?

Are the risks identified? _____ yes _____ no

Comment:

Do the benefits outweigh the risks? _____ yes _____ no

Comment:

Is the process for obtaining informed consent described?

in the protocol? _____ yes _____ no

Who will obtain the informed consent? _____ attending physician _____ project leader

_____ principal investigator _____ nurse

_____ others, pls. identify _____

Will standard health care be provided? _____ yes _____ no ____ not indicated

Comment:

Are financial arrangements reasonable and fair? _____ yes _____ no ____ not indicated

Comment:

Is there a potential conflict of interest? _____ yes _____ no

Comment:

Is the training and practice of the researcher/principal/

investigator adequate and appropriate to ensure safe and

competent conduct of the study and care of the participants? _____ yes _____ no

Comment:

Is there a commitment to publish study results? _____ yes _____ no _____ not indicated

Comment:

Recommendation: ☐Approved
☐Minor revisions required

_____

_____

☐Major revisions required

_____

_____

_____

☐Disapproved

Reasons for disapproval:

_____

_____

_____ _____

Name and Signature of Reviewer Review Date

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Informed Consent Checklist (For STEM Cell Research)	CDUHREC FORM	E4
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Title of the Study	

REC Code Type of Review

Proponent

Name of Reviewer Primary Reviewer ____yes
____no

GUIDE QUESTIONS

Is there a separate document for patient information and informed consent?

_____ yes _____ no

Comment:

Is the participant/patient provided with sufficient information

with regard to each of the following items?

- Purpose of the study _____ yes _____ no
- Unproven and experimental aspects of cell-based intervention _____ yes _____ no
- Clarification of therapeutic misconception _____ yes _____ no
- Expected duration of participation _____ yes _____ no
- Permanency of stem cell therapy _____ yes _____ no
- Discomforts and inconveniences _____ yes _____ no

- Alternative care _____ yes _____ no
- Risks (nature and likelihood) _____ yes _____ no
- Benefits (nature and likelihood) _____ yes _____ no
- Confidentiality / Protection of Privacy _____ yes _____ no
- Voluntary withdrawal _____ yes _____ no
- Financial arrangements _____ yes _____ no
- Compensation _____ yes _____ no
- Provision of standard of care _____ yes _____ no
- Contact information of person/s in-charge _____ yes _____ no

Comments:

Recommendation: ☐**Approved**
☐**Minor revisions required**

_____

_____

_____

☐**Major revisions required**

_____

_____

_____

_____

☐**Disapproved**

Reasons for disapproval:

_____

_____

_____

_____

_____

_____

Name and Signature of Reviewer **Review Date**

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Application for Ethics Review of a New Protocol	CDUHREC FORM	F1
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

Date of Submission:		
STUDY PROTOCOL Number:		
STUDY PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
STUDY COORDINATOR:		
Email:	**Telephone:**	**Mobile:**
Date of Review: (To be filled up by CDUHREC secretary):		

Checklist for Initial Submission for New Application for Review

Document	Number of Copies Received	Signature CDUHREC	Comment
1. Application letter for review from the PI			
2. Signed protocol and amendments (if any) including the following: a. project summary and flow chart of the protocol b. statement of agreement with ethical principles set out in relevant guidelines c. ethical considerations in the study			
3. Investigator Brochure			
4. Study Information and Consent/Assent Forms (English and Cebuano Versions)			
5. Study tools (questionnaires, patient diaries, posters/ advertisements for recruitment) in English and Cebuano version			
6. Case report forms			
7. Curriculum vitae of principal investigator			
8. Information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, if any			
9. Insurance/Indemnity statement			
10. Evidence of submission to regulatory authority			
11. Certificate of GCP Training of PI			

Received By:_____ Date:_____
Printed Name and Signature

Document History:

Version No.	Date	Authors	Main Change
01	22 Nov 2018	CDUHREC members	First draft
02	11 Sep 2024	CDUHREC members	Added the statement "including the following: a. project summary and flow chart of the protocol b. statement of agreement with ethical principles set out in relevant guidelines c. ethical considerations in the study" in item number 2.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Resubmission Form	CDUHREC FORM	F2
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

General Information			
*Title of Study			
Version number/date			
*REC Code (To be provided by NEC)		*Study Site	
*Name of Researcher		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher/s (if any)			Fax No:
			*Email:
*Institution of researcher			
*Address of Institution			

REC Recommendations	Response of Researcher	Section and page number of revisions

Signature of Researcher: _____

Date: _____

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Application for Ethics Review of Amendments	CDUHREC FORM	F3
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

General Information			
*Title of Study			
Version number/date of the EC approved protocol			
*EC Code (To be provided by EC)		*Study Site	
*Name of Researcher		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher/s (if any)			Fax No:
			*Email:
*Institution of researcher			
*Address of Institution			
Effective period of ethical clearance	From	To	

Procedure/provisions to be amended (Use additional sheets if necessary)	Original Procedure/Provision	Proposed Amendment/s	Justification

Signature of Researcher: _____

Date: _____

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Application for Ethics Review of Progress Reports	CDUHREC FORM	F4
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked below (in Section 3. Checklist of Documents).

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
*Date of Initial Approval			
Ethical clearance effectivity period			

Progress Report
1. Start of study (date)
2. Expected end of Study (date)
3. Number of enrolled participants
4. Number of required participants
5. Number of participants who withdrew
6. Any amendment since last review? If yes, please explain.
7. Any deviations from the approved protocol? If yes, please state the details
8. Any new information (literature or in the conduct of the study) that may significantly change the risk-benefits ratio since last review? If yes, please state the details.
9. Any issues/problems encountered since last review? If yes, please elaborate.
10. Any change in the ICF process since last review? If yes, please elaborate

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Progress/Annual Report for Philippine Sites	SOP No.	F4-1
		Version No.	01
		Version Date	21 Nov 2024
		Effective Date	21 Nov 2024

To be filled up by coordinating principal investigator

Submission Date	
CDUHREC Protocol Code	
Study Title	
Initial Approval Date	
Approval date of ethical clearance extension (if applicable)	
Sponsor	
CRO (if applicable)	
Coordinating Principal Investigator	
Signature	
Date	

Latest APPROVED Documents (with version number and version date)	
Country/General Protocol	
Country/General Informed Consent Forms	

List of active study sites	Site Principal Investigator	Site REC Oversight

Questions	Yes	No	Remarks
1. Any amendments since the last review? Describe briefly and indicate CDUHREC approval date (attach approval letters).			
2. Any change in participant population, recruitment or selection criteria since last review? Explain changes.			
3. Any change in the Informed Consent process or documentation since last review? Please explain.			
4. Is there any new information in recent literature or similar research that may change			

the risk/benefit ratio for participants in this study? Summarize.			
5. Any unexpected complications or side effects noted since the last review? Summarize.			
6. Were there protocol deviation/violation reports? Please explain and provide justification.			
7. Any new investigator that has been added to or removed from the research team since the last review? Please identify them and submit the CVs of new investigators.			
8. Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.			

NOTE:

- *For <u>Number 1, 7 and 8</u>: please submit **CDUHREC Amendment Application Form** if these changes not yet been approved by CDUHREC.*
- *For <u>Number 6</u>: please submit **CDUHREC Protocol Deviation/Violation Report** if not yet been reported to CDUHREC. Please note that protocol deviation/violation should be submitted 4 weeks from the detection of the protocol violation/deviation.*

Summary of Recruitment:	
	Accrual ceiling set by CDUHREC (total numbers of participants approved at initial review)
	New participants accrued since last review
	Total participants accrued since protocol began
	No. of participants who are **lost to follow up**
	No. of participants **withdrawn** from the study
	No. of participants who **experienced SAEs/SUSARs**
	No. of **protocol deviations** since last review
	No. of **protocol violations** since last review
	No. of participants still **active** in the study

**Please accomplish this table comprehensively. Indicate N/A if not applicable. CDUHREC will not accept incomplete information*

To be filled up by primary reviewer

Questions	Yes	No	Comments
Do the risk to the study participants remain reasonable in relation to anticipated benefits?			
Are there new findings in the IB or literature (e.g. important toxicity or adverse event information) that need to be included in the informed consent?			
Is there need to revise the ICF?			
Is there need to re-consent subjects enrolled in the study?			
Are there concerns about conduct of research team (e.g. suspension of medical license, frequent protocol violation, patient or third-party complaints, etc.) or institutional commitment that may affect the patient safety?			
Are there concerns about patient safety, inability to comply with the protocol, high dropout rate			

that affect study implementation?			

**Check the protocol file to ensure the consistency of the progress report with actual reports (SAE, protocol deviation/violation, etc.) submitted by the Co-PI*

Summary of Comments

Decision	
	Renew approval/extend ethical approval
	Request for further information
	Submit SAE reports **Site IRB to review workload of PI "handling multiple trials"**
	Suspend/terminate the study

Name of the Reviewer	
Signature	
Date	

Version No.	Date	Authors	Main Change
01	21 Nov 2024	CDUHREC members	Original Version

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Protocol Violation/Deviation Report	CDUHREC FORM	F5
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
Date of Submission			

Protocol Violation/Deviation Report
1. Start of study (date)
2. Expected end of study
3. Number of enrolled participants
4. Number of required participants
5. Number of participants who withdrew
6. Protocol Deviation/Violation (state details)
7. Impact of deviation/violation on participants' risk/harms and integrity of data
8. Actions taken to prevent future deviation/violation

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Reportable Negative Event Report	CDUHREC FORM	F6
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
RNE Report			
1. Start of study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	

5. Description of Negative (harms, risks) Events a. Involving Participants b. Involving members of the Study Team c. Involving Data safety and integrity	6. Actions taken to prevent future RNEs, interventions and Outcomes
7. Recommendations	

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Application for Continuing Review	CDUHREC FORM	F7
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No: *Mobile No:
*Co-researcher (if any)			Fax No: *Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
Progress Report			
1. Start of study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	

5. Number of participants who withdrew	
6. Deviations from the approved protocol	7. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio
8. Issues/problems encountered	
9. Justification for application for Continuing Review	

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Site Visit Report	CDUHREC FORM	F8
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
Site Visit Report			
1. Start of study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	

5. Reasons for Site Visit	6. Person/s present during visit
7. Findings	8. Recommendations

Site Visit Team

1. -
2. -
3. -

Report submitted by:

_____

Name and signature

Date:

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Early Termination Report	CDUHREC FORM	F9
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
Recommended by:	(e.g. Sponsor, Funding Agency, Data Safety Monitoring Board, Researcher/Proponent)		

Early Termination Report	
1. Start of study	2. Expected end of study
3. Number of enrolled participants	4. Number of required participants
5. Reason/s for termination	6. Support mechanisms/Interventions for Enrolled Participants
7. Post-Termination Actions	

_____

Name and signature of Proponent

Date:

Received by:

Date:

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Final Report Form	CDUHREC FORM	F10
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

General Information			
*Title of Study			
Version number/date of the EC approved protocol			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher/s (if any)			Fax No:
			*Email:
*Institution of researcher			
*Address of Institution			
Effective period of ethical clearance	From:	To:	

Final Report	
1. Start of study	2. End of study
3. Number of enrolled participants	4. Number of required participants
5. Number of participants who withdrew	
6. Deviations from the approved protocol	7. Issues/problems encountered
8. Summary of findings:	
9. Conclusions:	
10. Actions for dissemination of study results:	

Signature of Researcher: _____

Date: _____

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	SAE/SUSARs Report Forms	CDUHREC FORM	F11
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC)		*Study Site	
*Name of Researcher)		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
SAE/SUSARS Report			
1. Start of study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	

5. Number of participants who withdrew	
6. SAE/SUSARS from the approved protocol	7. Explanation for SAE/SUSARS
8. Impact of SAE/SUSARS on participants' risks/harms and integrity of data	9. Actions taken to prevent future SAE/SUSARS

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Sample Template for Transmittal Letters **Resident Initiated**	CDUHREC FORM	F12
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

TEMPLATE FOR TRANSMITTAL LETTER

Date

Addressee

Medical Director/Department Chairperson

CDUH

Subject: Transmittal Letter

Dear Dr.Xxxxxxx,

I am submitting herewith my research protocol, "TITLE", as a requirement by the Department of (department). Most of the data for the research will be from patients admitted under the Department of (department) and will be obtained from the CDUH Medical Records.

In line with this, I would like to ask for your permission to allow me to retrieve the necessary data from the Medical Records Section. Rest assured, I will keep all information confidential as stated under the Data Privacy Act of 2012. Also, once allowed, I will only start retrieval of the data once I have been granted approval by the CDUH Research Ethics Committee.

Hoping for your kind consideration. Thank you very much!

Respectfully,

name of principal investigator

received and approved by:

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Notice of Meeting	CDUHREC FORM	G1
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date of Notice:
Date of Meeting:
Venue:
Time:

Itemsfor Discussion:

1. Full Review of New Proposals (Initial)
   1.1. REC Code - Title
   1.2. REC Code - Title
2. Report on Expedited Review of Proposals
   2.1. REC Code - Title
   2.2. REC Code - Title
3. Updates on Full Review of Proposals (Resubmission)
   3.1. REC Code - Title
   3.2. REC Code - Title
4. Updates on Expedited Review of Proposals (Resubmissions)
   4.1. REC Code - Title
   4.2. REC Code - Title
5. Updates on Approved, Ongoing Researches
   5.1. REC Code - Title
   5.2. REC Code - Title
6. Other Matters

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Provisional Agenda	CDUHREC FORM	G2
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Venue:	
Date:	Time:

1. Call to Order
2. Declaration of Quorum
3. Disclosure of Conflict of Interest
4. Approval of the Provisional Agenda
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising
7. New Business
8. Full Review of New Proposals (Initial)
   8.1. REC Code - Title
   8.2. REC Code - Title
9. Report on Expedited Review of Proposals
   9.1. REC Code - Title
   9.2. REC Code - Title
10. Updates on Full Review of Proposals (Resubmission)
    10.1. REC Code - Title
    10.2. REC Code - Title
11. Updates on Expedited Review of Proposals (Resubmissions)
    11.1. REC Code - Title
    11.2. REC Code - Title
12. Updates on Approved, Ongoing Researches
    12.1. REC Code - Title
    12.2. REC Code - Title
13. Other Matters
14. Adjournment

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Minutes of the Meeting	CDUHREC FORM	G3
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Venue:	
Date:	Time:

1. Call to Order
2. Determination of Quorum
3. Disclosure of Conflict of Interest
4. Reading and Approval of the Agenda
5. Reading and Approval of the Minutes of the last meeting
6. Business Arising from the Minutes of the previous meeting
7. Protocol Review
   7.1. Study Protocols for Initial Review
   7.2. Resubmissions or Study Protocols for Modifications
   7.3. Study Protocol Amendment Applications/ICF Revisions
   7.4. Protocols with Expedited Approval
   7.5. Withdrawal of Study Protocol Applications
   7.6. Study Protocol for Notification and Updates
   7.7. Continuing Review Applications
   7.8. Final Reports
   7.9. Serious Adverse Events/ Adverse Events Reports
   7.10. Site Visit Reports
   7.11. Study Protocol Non-Compliance (Deviation or Violation) Reports
   7.12. Early Study Termination Applications
   7.13. Queries or Complaints

8. **Safety Reports**
   8.1. SUSAR Notification:
   8.2. Safety Reports reported by Ms. Mae Quenie T. Pontanar

9. **Other Matters**
   Adjournment:

Prepared by: DATE:	CDUHREC Office Secretary
Corrected by: DATE:	CDUHREC Member Secretary
Noted by: DATE:	CDUHREC Chairman

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Attendance of the Meeting	CDUHREC FORM	G4
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Cebu Doctors University Hospital Research Ethics Committee(CDUHREC)

Cebu Doctors' University Hospital
Date of Meeting:
Venue:

Name	Signature	Comment
Enrico B. Gruet, MD		
Ma. Noemi Alsay-Uy, MD		
Lamberto Garcia Jr., MD		
Joseph Lester A. Hernandez, MD		
Helen V. Madamba, MD		
Lani B. Arcenal, MAN, MAHAd		
Fabiana G. Sunit, EdD		
Mr. Nimrod Nazarito L. Quiñones		
Ms. Mae Quenie T. Pontanar, RPh		
Florencia T. Miel, MD		
Atty. Allan Orvien Geotina		
Rev.Fr. Jayson B. Facunla		

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Query Form Template	CDUHREC FORM	G5
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

(Date)

(NAME OF CHAIR

(Designation)

(Institution)

(Address)

RE: (Title of project/study)

REC code:

Subject: Query

Dear ***(Name of Chair)***:

I am _____ the (study subject/family member of the study subject). I would like CDUHREC to answer the following questions/queries:

(state queries)

- _
- _
- _
- _
- _

I am fully aware that your answers is purely confidential is any applicable to me.

I will await for your usual prompt attention on the matter.

Very truly yours,

(Signature)

(Name)
Chair

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Complaint Form Template	CDUHREC FORM	G6
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

(Date)

(NAME OF CHAIR

(Designation)

(Institution)

(Address)

Subject: Complaints

Dear ***(Name of Chair)***:

I am _____ the (study subject/family member of the study subject). I would like CDUHREC to look in to the matter:

(state complaint/s)

- _
- _
- _
- _
- _

I would highly appreciate your prompt attention in to the matter.

I will await for your usual prompt attention on the matter.

Very truly yours,

(Signature)

(Name)
Chair

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Request for Creation/Revision of an SOP Form Template	CDUHREC FORM	G7
		Version No.	1
		Version Date	23 April 2021
		Effective Date	

(Date)

(NAME OF CHAIR

(Designation)

(Institution)

(Address)

Subject: Revision/Creation of an SOP

Dear ***(Name of Chair)***:

I am _____ a member of CDUHREC. I would like CDUHREC to request for the revision/creation of an SOP pertaining to(subject matter):

Thank you.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	SOP Template	SOP No.	G8
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

I. **Policy**

II. **Objective**

III. **Scope**

IV. **Workflow**

ACTIVITY	***RESPONSIBILITY***

V. **Description of Procedures**

VI. **Glossary**

VII. **Forms**

VIII. **Document History**

Version No.	Date	Authors	Main Change

IX. **References**

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Notification Letter	CDUHREC FORM	G9
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date:

Principal Investigator:

Protocol No.:
Protocol Title:

NOTIFICATION LETTER

Dear Dr.,

Should you have any questions or comments, please feel free to contact the undersigned at +63 32 416 9341.

Thank you very much.

Respectfully yours,

Enrico B. Gruet, MD
Chairman, CDUH Research Ethics Committee

ACKNOWLEDGEMENT RECEIPT		
PRINTED NAME	SIGNATURE	DATE

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Logbook of Outgoing Communications	CDUHREC FORM	H1
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date	Nature of document (Decision letter, Approval letter, Invitation, Notice of Meeting, etc.)	Signatory	Addressee	Received by (Name and Signature of Recipient)	Delivered by (Name and Signature)
1.					
2.					

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Logbook of Protocol Submission	CDUHREC FORM	H2
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

YEAR: _____

Date of Submission	Code Number	Title	Proponent	Submitted by (Name and Signature)	Received by (Name and Signature)	Action
1.						
2.						

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Protocol Folder Index	CDUHREC FORM	H3
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date of Filing	Nature of document (Initial Submission of Protocol and related documents version number, Excerpts of Minutes, Protocol and ICF Assessment, Decision letter, Approval letter, Post-Approval submissions, Communications from Researchers, Final Report, etc.)	Name and signature of Filer	Date Document Withdrawn	Name and Signature of Staff Member-in-charge
1.				
2.				

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Borrowers Log	CDUHREC FORM	H4
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date of Borrowed	Name of the Item	Name who Borrow	Signature who Borrow	Received by (Name and Signature)
1.				
2.				

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Request Form Template	CDUHREC FORM	H5
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

(Date)

(NAME OF CHAIR

(Designation)

(Institution)

(Address)

RE: (Title of project/study)

REC code:

Subject: REQUEST FOR CONFIDENTIAL FILES

Dear ***(Name of Chair)***:

I am _____ the (study subject/family member of the study subject). I am requesting for the study files for the following reasons:

(state reason/s)

- _
- _
- _
- _
- _

I am fully aware that I must respect the confidential nature of the files and will not be allowed to make a photocopy, take a picture, remove the files in the folder or remove the folder out of the CDUHREC office.

I will await for your usual prompt attention on the matter.

Very truly yours,

(Signature)

(Name)
Chair

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Log of Request	CDUHREC FORM	H6
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date of Request	Name what request of forms/items	Name who Request	Signature who Request	Received by (Name and Signature)
1.				
2.				

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Log of Access	CDUHREC FORM	H7
		Version No.	1
		Version Date	23 April 2021
		Effective Date	23 April 2021

Date of Access	Name who Access	Signature who Access	Received by (Name and Signature)
1.			
2.			

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Checklist for the Assessment of the Clinical Trial Protocol and Protocol Amendment(s)	CDUHREC FORM	I1
		Version No.	6
		Version Date	02 Oct 2024
		Effective Date	10 Oct 2024

STUDY PROTOCOL Number:
STUDY PROTOCOL TITLE:
PRINCIPAL INVESTIGATOR:
Date of Initial Review:
CDUHREC Reviewer: (Printed name, signature and date)

Checklist for the Assessment of the Clinical Trial Protocol and Protocol Amendment(s)

(Based on ICH-GCP Current *Step 4* version dated 10 June 1996)

The contents of a trial protocol should generally include the following topics. However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol referenced documents, such as an Investigator's Brochure.

Are the following included in the study protocol?

6.1 General Information

	Yes	**No**	**Comment**
1. Protocol title, protocol identifying 2. number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).			
3. Name and address of the sponsor and monitor (if other than the sponsor).			
4. Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.			

5. Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.			
6. Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).			
7. Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).			
8. Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.			

6.2 Background Information

	Yes	**No**	**Comment**
1. Name and description of the investigational product(s).			
2. A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.			
3. Summary of the known and potential risks and benefits, if any, to human subjects.			
4. Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).			
5. A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).			

6. Description of the population to be studied.			
7. References to literature and data that are relevant to the trial, and that provide background for the trial.			

6.3 Trial Objectives and Purpose

	Yes	No	Comment
A detailed description of the objectives and the purpose of the trial.			

6.4 Trial Design

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design, should include:

	Yes	No	Comment
1. A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.			
2. A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages			
3. A description of the measures taken to minimize/avoid bias, including: (a) Randomization. (b) Blinding.			
4. A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labelling of the investigational product(s).			
5. The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.			

6. A description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial and entire trial.			
7. Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.			
8. Maintenance of trial treatment randomization codes and procedures for breaking codes.			
9. The identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data.			

6.5 Selection and Withdrawal of Subjects

	Yes	No	Comment
1. Subject inclusion criteria.			
2. Subject exclusion criteria.			
3. Subject withdrawal criteria (i.e. terminating investigational product treatment/trial treatment) and procedures specifying: a. When and how to withdraw subjects from the trial/ investigational product treatment. b. The type and timing of the data to be collected for withdrawn subjects. c. Whether and how subjects are to be replaced. d. The follow-up for subjects withdrawn from investigational product treatment/trial treatment.			

6.6 Treatment of Subjects

	Yes	No	Comment
1. The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.			
2. Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.			
3. Procedures for monitoring subject compliance.			
4. Procedure for making the study product available to research participants following the research, if applicable.			

6.7 Assessment of Efficacy

	Yes	No	Comment
1. Specification of the efficacy parameters.			
2. Methods and timing for assessing, recording, and analyzing of efficacy parameters.			

6.8 Assessment of Safety

	Yes	No	Comment
1. Specification of safety parameters.			
2. The methods and timing for assessing, recording, and analysing safety parameters.			
3. Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.			
4. The type and duration of the follow-up of subjects after adverse events.			

5. Monitoring and auditing the conduct of the research, including the constitution of a data safety and monitoring board (DSMB).			

6.9 Statistics

	Yes	No	Comment
1. A description of the statistical methods to be employed, including timing of any planned interim analysis(ses).			
2. The number of subjects planned to be enrolled. In multicentre trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.			
3. The level of significance to be used.			
4. Criteria for the termination of the trial.			
5. Procedure for accounting for missing, unused, and spurious data.			
6. Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).			
7. The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects).			

6.10 Direct Access to Source Data/Documents

	Yes	No	Comment
1. The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/ institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.			

6.11 Quality Control and Quality Assurance

	Yes	No	Comment
A description of how QC and QA are monitored.			

6.12 Ethics

	Yes	No	Comment
Description of ethical considerations relating to the trial.			

6.13 Community Impact

	Yes	No	Comment
Description of the impact and relevance of the research on the local community from which the research participants come from.			
Description of the steps taken to consult with the concerned communities during the course of designing the research.			
Description of the influence of the community on the consent of the individuals			
Description of the proposed community consultation during the course of the research.			
Description of the extent to which research contributes to capacity building within the community.			
Description of the availability and affordability of any successful study product to the concerned communities following the research.			

6.14 Data Handling and Record Keeping

	Yes	No	Comment
A description of data handling and record keeping.			

6.15 Financing and Insurance

	Yes	No	Comment
Financing and insurance if not addressed in a separate agreement.			

6.16 Publication Policy

	Yes	No	Comment
Publication policy, if not addressed in a separate agreement.			

6.17 Supplements

	Yes	No	Comment

Notes and Comments from Reviewer:

Document History:

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	Original Version
02	01 Feb 2014	CDUHREC members	Changed Format
03	09 Jul 2015	CDUHREC members	Changed to PHREB Format
04	29 Aug 2024	CDUHREC members	Changed Form to I1
05	23 Sep 2024	CDUHREC members	Added "Monitoring and auditing the conduct of the research, including the constitution of a data safety and monitoring board (DSMB)" in section 6.8
06	02 Oct 2024	CDUHREC members	Added "Procedure for making the study product available to research participants following the research, if applicable" in section 6.6, added the whole table 6.13 Community Impact and made editorial changes

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Checklist for the Assessment of the Informed Consent	CDUHREC FORM	I2
		Version No.	7
		Version Date	02 Oct 2024
		Effective Date	10 Oct 2024

STUDY PROTOCOL Number:
STUDY PROTOCOL TITLE:
ICF Version and Date:
Date of Initial Review:
CDUHREC Reviewer: (Printed name, signature and date)

Checklist for the Assessment of the Informed Consent Form

(Based on National Ethical Guidelines for Research Involving Human Participants 2022 and on ICH-GCP Current *Step 4* version dated 10 June 1996)

Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

Are the following included in the written information provided to the subjects?

	Yes	**No**	**Comment**
1. That the trial involves research.			
2. The purpose of the trial.			
3. The trial treatment(s) and the probability for random assignment to each treatment.			
4. The trial procedures to be followed, including all invasive procedures.			
5. The subject's responsibilities.			

6. Those aspects of the trial that would be experimental.			
7. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.			
8. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.			
9. The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.			
10. The compensation and/or treatment available to the subject in the event of trial related injury.			
11. The anticipated prorated payment, if any, to the subject for participating in the trial.			
12. The anticipated expenses, if any, to the subject for participating in the trial.			
13. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at anytime, without penalty or loss of benefits to which the subject is otherwise entitled.			
14. That the monitor(s), the auditor(s), the EC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.			

15. That the records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.			
16. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.			
17. The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.			
18. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.			
19. The expected duration of the subject's participation in the trial.			
20. The approximate number of subjects involved in the trial.			
21. Is the informed consent form written in a language understandable to the participants?			
22. Does the informed consent form describe how the informed consent will be obtained?			
23. Does the informed consent process ensure that it is voluntary?			
24. Is the person responsible for obtaining informed consent identified?			
25. Is the person responsible for receiving and responding to queries and complaints			

from participants/representatives during the research identified?			
26. Does it provide protection of privacy and confidentiality of the research participant during and after the completion of the research?			

Comments and Notes of Lead Reviewer

Document History:

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	Original Version
02	01 Feb 2014	CDUHREC members	Changed Format
03	09 Jul 2015	CDUHREC members	Changed to PHREB Format
04	29 Aug 2024	CDUHREC members	Changed Form to I2
05	11 Sep 2024	CDUHREC members	Changed as reference NEGHHR 2017 to NEGHRIP 2022.
06	23 Sep 2024	CDUHREC members	Added "Is the person responsible for obtaining informed consent identified?", and "Is the person responsible for receiving and responding to queries and complaints from participants/representatives during the course of the research identified?"
07	02 Oct 2024	CDUHREC members	Added "Does it provide protection of privacy and confidentiality of the research participant during and after the completion of the research?"

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Checklist for the Assessment of the Risk/Benefit	CDUHREC FORM	I3
		Version No.	5
		Version Date	10 Oct 2024
		Effective Date	10 Oct 2024

STUDY PROTOCOL Number:
Principal Investigator:
Date of Review:
CDUHREC Reviewer: (Printed name, signature and date)

Risk/Benefit Assessment

Note: This form is for use as guidance by the reviewer to consider regulatory requirements for minimizing risks to participants and balancing risks with benefits.

Section A – Conducting Risk-Benefit Assessment

1. Identify and distinguish risks associated with:
   a) Procedures performed solely for research

   b) Procedures or therapies subjects would receive even if not in research

   c) Procedures that are experimental or investigational

2. Identify the context in which research procedures are performed:
   d) Are research procedures added to conventional (standard) care?

3. Consider the subject population.
   e) Age, health status?

   f) Are they more sensitive or vulnerable to risks posed by the research?

   g) How are they identified and recruited?

   h) Should additional protection be in place to minimize risks and maximize benefits?

4. Minimal risk or greater than minimal risk?
   a) Do the risks of procedure meet the definition of minimal risk?

Section B – RISKS

Definition of minimal risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(i)).

When evaluating the minimal risk standard, the criteria shall be applied based on the experience of a population that is considered healthy and in the prevailing environment. The standard would therefore not to be applied using, for example, the normal harm and discomfort experienced by HIV-positive women ages 15-40 in developing countries, but to women ages 15-40 in a stable and healthy environment.

Check appropriate risk category:

1. _____The research involves no more than minimal risk to subjects.

2. _____The research involves more than minimal risk to subjects.

   _____The risk(s) represents a minor increase over minimal risk, **OR**

   _____The risk(s) represents more than a minor increase over minimal risk.

3. _____ If the risk represents greater than minimal risk, please describe what measures have been taken to minimize risk to the participant. Evaluate research methods that might be less risky, if any. Consider whether any diagnostic, therapeutic, or other procedures already performed on the participant could be used to gather the data needed. Consider whether risks have been minimized by using procedures that are consistent with sound research practices and that do not unnecessarily expose participants to risk.

4. _____If the risk represents greater than minimal risk, indicate plans for detecting research-related harm promptly, and plans for mitigating potential harms.

Section C - BENEFITS

Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is <u>not</u> considered to be a benefit, but rather compensation for research-related inconveniences. A study participant is entitled to receive at least Php1,500 per visit to defray the cost of transportation.

Check appropriate benefit category:

- ❑ The research involves the prospect of direct benefit to individual participants.
- ❑ The research involves no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the subject's disorder or condition.

Section D – JUSTIFICATION OF STUDY RISK

The Common Rule requires that risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. When research involves vulnerable populations, additional safeguards may be required.

Check appropriate

- ❑ The study population is not considered vulnerable. Based on the above criteria, risks to participants are reasonable compared to expected benefits.
- ❑ Participants belong to vulnerable populations. For children, prisoner, or pregnant women populations, submit additional checklist for the population involved. Otherwise, explain what safeguards will be implemented for the study's vulnerable population.

Document History:

Version No.	Date	Authors	Main Change
01	01 Jun 2012	CDUHREC members	Original Version
02	01 Feb 2014	CDUHREC members	Changed Format
03	09 Jul 2015	CDUHREC members	Changed to PHREB Format
04	11 September	CDUHREC members	Changed Form to I3
05	10 Oct 2024	CDUHREC members	Added "A study participant is entitled to receive at least Php1,500 per visit to defray the cost of transportation" in Section C.

CEBU DOCTORS' UNIVERSITY HOSPITAL RESEARCH ETHICS COMMITTEE

Date : 12 August 2021
Venue : CDUH Conference Room A
Time : 12:00 noon

CDUHREC Members presents:

1. Enrico B. Gruet, MD - Medical Doctor
2. Atty. Allan Orvien P. Geotina - Lawyer; Non-scientific member; independent from the institution
3. Fabiana G. Sunit, EdD - Lay member; independent from the institution
4. Joseph Lester A. Hernandez, MD - Medical Doctor
5. Florencia T. Miel, MD - Medical Doctor
6. Mr. Nimrod Nazarito L. Quiñones - Lay member; independent from the institution
7. Rev. Fr. Jayson Bantilan Facunla - Lay member; independent from the institution

CDUHREC Members absent:

1. Ma. Noemi A. Uy, MD - Medical Doctor
2. Lani B. Arcenal, MAN, MAHAd - Nurse; independent from the institution
3. Mae Quenie T. Pontanar, RPh - Pharmacist; independent from the institution
4. Helen V. Madamba, MD - Medical Doctor
5. Lamberto Garcia Jr., MD - Medical Doctor

MINUTES OF THE MEETING

1. Call to Order: Dr. Enrico B. Gruet called this regular meeting to order at 10:35 pm
2. Determination of Quorum: A quorum was declared with the presence of 10 members, inclusive of the presence of 5 scientific members and 5 lay members, 4 of whom are non-affiliated as confirmed by the CDUHREC Secretary Atty. Allan Orvien P. Geotina.

3. Disclosure of Conflict of Interest: NONE
4. Reading and Approval of the Agenda: On Motion made by Ms. Sunit and duly seconded by Mr. Quiñones, the agenda was approved
5. Reading and Approval of the Minutes of the last meeting: On Motion made by Ms. Sunit and duly seconded by Dr. Alsay-Uy, the minutes was approved
6. Business Arising from the Minutes of the previous meeting: None
7. Protocol Review

7.1. Study Protocols for Initial Review:

7.1.1.

CDUHREC CODE	
PROTOCOL NO.	
DATE OF RECEIPT	
PROTOCOL TITLE	
PRINCIPAL INVESTIGATOR	
LEAD REVIEWER	
DOCUMENTS SUBMITTED	
ASSESSMENT OF SCIENTIFIC SOUNDNESS AND ETHICAL ISSUES	-
RECOMMENDED ACTIONS	

7.2. Resubmissions or Study Protocols for Modifications: None

7.3. Study Protocol Amendment Applications/ICF Revisions: None

7.4. Protocols with Expedited Approval: None

7.5. Withdrawal of Study Protocol Applications: None

7.6. Study Protocol for Notification and Updates:

7.6.1.

CDUHREC CODE	
PROTOCOL NO.	
DATE OF RECEIPT	
PROTOCOL TITLE	
PRINCIPAL INVESTIGATOR	
LEAD REVIEWER	
DOCUMENTS SUBMITTED	
ACTIONS TAKEN	

7.7. Continuing Review Applications: None

7.8. Final Reports: None

7.9. Serious Adverse Events/ Adverse Events Reports: None

7.10. Site Visit Reports: None

7.11. Study Protocol Non-Compliance (Deviation or Violation) Reports:

7.11.1

CDUHREC CODE	
PROTOCOL NO.	
DATE OF RECEIPT	
PROTOCOL TITLE	
PRINCIPAL INVESTIGATOR	
LEAD REVIEWER	
Summary of Deviations	
ACTIONS TAKEN	

7.12. Early Study Termination Applications: None

7.13. Queries or Complaints: None

8. Safety Reports

8.1. SUSAR Notification:

8.1.1.

CDUHREC CODE	
PROTOCOL NO.	
DATE OF RECEIPT	
PROTOCOL TITLE	
PRINCIPAL INVESTIGATOR	
LEAD REVIEWER	
DOCUMENTS SUBMITTED	
ACTIONS TAKEN	

8.1.2.

CDUHREC CODE	
PROTOCOL NO.	
DATE OF RECEIPT	
PROTOCOL TITLE	
PRINCIPAL INVESTIGATOR	
LEAD REVIEWER	
DOCUMENTS SUBMITTED	
ACTIONS TAKEN	

8.2. Safety Reports by Ms. Mae Quenie T. Pontanar

9. Other Matters:

10. Adjournment

11. Next Schedule:

Prepared by: DATE: 12 August 2021	Ms. Noime A. Ramones CDUHREC Office Secretary
Corrected by: DATE: 12 August 2021	Atty. Allan Orvien P. Geotina CDUHREC Member Secretary
Noted by: DATE: 12 August 2021	Enrico B. Gruet, M.D. CDUHREC Chairman

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	PROTOCOL CHECKLIST FOR RETROSPECTIVE STUDIES **Resident Initiated**	CDUHREC FORM	I4
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

Full title of research:

_____

Principal investigator: _____

Date of submission: _____

(*Note: Incomplete submissions will NOT be processed or scheduled for review.*)

Heading	Present [Yes/No]	Comments
INTRODUCTION	----	
"Topic background" and/or “What is the topic all about?”		
"Research question/s" and/or “What is not yet known about the topic?”		
"Significance of the study" and/or “What will healthcare be if the answer/s to the research question/s will be known?”		
"Review of related literature” and/or “What is already known about the topic?”		
"Objective/s" and/or “What will this study do?”		
METHODOLOGY	----	
Research design		
Setting		
Participants		
Inclusion criteria		

Exclusion criteria		
Sampling procedures		
Interventions and comparisons		
Randomization		
Data gathering		
Independent variables		
Main outcome measures and other dependent variables		
Sample size computation		
Data handling and analysis		
Ethical considerations		
DUMMY TABLES with dummy data		
REFERENCES (follow APA format)		
ANNEXES or APPENDICES	----	
Signed Transmittal Letter to Medical Director		
Signed Transmittal Letter to Department Chairperson		
Transmittal Letter to Ethics Chairperson		
Signed Transmittal Letter to Head of Medical Records		
Endorsement Letter from Technical Committee		
Sample case report form		
Protocol Brief (2 copies)		
Budget		
Timetable		
Certificate of recent Good Clinical Practice		
CV of Primary Investigator		

RISK-BENEFIT ASSESSMENT	
NOTES FROM LEAD REVIEWERS (STUDY PROTOCOL AND ICF)	
ACTION(S) TAKEN	
RECOMMENDATIONS	

Note: (After submission is verified complete by CDUH-REC Administrative Staff)

Please see template of Transmittal Letter for Retrospective Studies

For protocols that qualify for expedited review:

PI must submit**?**

- **3** hardcopies

For protocols that qualify for convened review:

PI must submit **?**

- **3** hardcopies

For RETROSPECTIVE data collection

Heading	Ethical Issues	Ethical considerations portion of Methodology	Comments
Ethics review	Whose permission will you ask for before doing the research? (e.g., approval of an ethics committee, permission of departments involved, etc.)		
Privacy	Will you contact participants through phone calls or home visits?		
Confidentiality	What researchers will do to maintain privacy and confidentiality a. what measures will be taken to anonymize data b. how will you keep the data and for how long c. how will you discard/dispose of the data d. who can access data		
Extent of use of study data	Are there plans to use of data other than to answer the objectives stated in the protocol? Are there plans to digitally store the data or make the data available to others?		
Authorship and contributorship	Authorship and contributorship issues a. Who are the authors or contributors to the present paper? b. Acknowledgement of original data collectors c. Written consent of original data collectors that the data can be used for further research		
Conflicts of interest	Declaration of conflicts of interest among authors and contributors		
Publication	Publication issues and plans		
Funding	Source of study funds		

Assessed by

Document History

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	Original Version
02	11 Sep 2024	CDUHREC members	Changed the phrase "Dummy results with Dummy numbers" to "Dummy Tables with Dummy Data" and Changed Form to I4.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Sample Template for Transmittal Letters Retrospective Study **Resident Initiated**	CDUHREC FORM	I5
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

Date

Addressee

Medical Director/Department Chairperson

CDUH

Subject: Transmittal Letter

Dear Dr.Xxxxxxx,

I am submitting herewith my research protocol, "TITLE", as a requirement by the Department of (department). Most of the data for the research will be from patients admitted under the Department of (department) and will be obtained from the CDUH Medical Records.

(Reason for undertaking the study.)

In line with this, I would like to ask for your permission to allow me to retrieve the necessary data from the Medical Records Section. Rest assured, I will keep all information confidential as stated under the Data Privacy Act of 2012. Also, once allowed, I will only start retrieval of the data once I have been granted approval by the CDUH Research Ethics Committee.

Hoping for your kind consideration. Thank you very much!

Respectfully,

name of principal investigator

received and approved by:

Document History:

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	Original Version
02	11 Sep 2024	CDUHREC members	Changed Form to I5.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	PROTOCOL CHECKLIST FOR PROSPECTIVE STUDIES **Resident Initiated**	CDUHREC FORM	I6
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

Full title of research:

_____

Principal investigator: _____

Date of submission: _____

(*Note: Incomplete submissions will NOT be processed or scheduled for review.*)

Heading	Present [Yes/No]	Comments
INTRODUCTION	----	
"Topic background" and/or “What is the topic all about?”		
"Research question/s" and/or “What is not yet known about the topic?”		
"Significance of the study" and/or “What will healthcare be if the answer/s to the research question/s will be known?”		
"Review of related literature” and/or “What is already known about the topic?”		
"Objective/s" and/or “What will this study do?”		
METHODOLOGY	----	
Research design		
Setting		
Participants		

Inclusion criteria		
Exclusion criteria		
Sampling procedures		
Interventions and comparisons		
Randomization		
Data gathering		
Independent variables		
Main outcome measures and other dependent variables		
Sample size computation		
Data handling and analysis		
Ethical considerations		
DUMMY RESULTS with dummy numbers		
INFORMED CONSENT* (English)		
INFORMED CONSENT* (Cebuano)		
INFORMED ASSENT* (English)		
INFORMED ASSENT* (Cebuano)		
REFERENCES (follow APA format)		
ANNEXES or APPENDICES	----	
Signed Transmittal Letter to Medical Director		
Signed Transmittal Letter to Department Chairperson		
Transmittal Letter to Ethics Chairperson		
Endorsement Letter from Technical Committee		
Sample case report form		
Protocol Brief (2 copies)		
Budget		

Timetable			
Certificate of recent Good Clinical Practice			
CV of Primary Investigator			
RISK-BENEFIT ASSESSMENT			
NOTES FROM LEAD REVIEWERS (STUDY PROTOCOL AND ICF)			
ACTION(S) TAKEN			
RECOMMENDATIONS			

Note: (After submission is verified complete by CDUH-REC Administrative Staff)

Please see template of Transmittal Letter for Retrospective Studies

For protocols that qualify for expedited review:

PI must submit**?**

- **3** hardcopies

For protocols that qualify for convened review:

PI must submit **?**

- **3** hardcopies

For PROSPECTIVE data collection

Heading	Ethical Issues	Ethical considerations portion of Methodology	Informed Consent Form	Comments
Ethics review	Whose permission will you ask for before doing the research? (e.g., approval of an ethics committee, permission of departments involved, etc.)			
Informed consent – [Form]	What form of informed consent will be obtained from participants or their representatives? (e.g., written, audiotaped, video-recorded, etc)			
Informed consent – [Signatory]	Who may give informed consent Will you require a signature to formalize the consent? Will you allow thumbmarks in lieu of a signature?			
Informed consent – [Witness]	Will you require a witness?			
Informed consent – [Proxy consent]	Will you allow proxy consent?			
Informed assent	Will you obtain informed assent for participants less than 18 years old or for those who cannot legally decide for themselves?			
Informed consent – [Process]	What is the process of obtaining informed consent? (e.g., the potential participant will be invited to listen to a 10-minute presentation of the study objectives, procedures; questions from the potential participant will be entertained anytime during the presentation, etc.)			
Informed consent – [Timing]	When will informed consent be obtained			
Informed consent – [Venue]	Where will informed consent be obtained			
(Disclosure of) study	What information will be given to participants or legal guardians			

objectives, risks, benefits and procedures	a. study objectives b. why study must be done c. who will benefit from the findings of the study d. procedures will be done as part of the study e. what participants are expected to do What study risks will be declared What study risks will not be declared			
Remuneration, reimbursement and other benefits	What benefits will be given to participants			
Confidentiality	What researchers will do to maintain privacy and confidentiality a. what measures will be taken to anonymize data b. how will you keep the data and for how long c. how will you discard/dispose of the data d. who can access data			
Investigator's responsibility during adverse events	What researchers will do if there are adverse events What measures will be taken in order to monitor the incidence of adverse events			
Specimen handling	Does your study involve retaining tissue samples for genetic studies? How will specimens be disposed of			
Voluntariness	What participants' rights will be declared (e.g., right to refuse, right to withdraw)			
Alternative options	What researchers will do if invited parties refuse to participate			
Privacy	Will you contact participants through phone calls or home visits?			
Information on study results	How and when will patients be informed of individual and study results?			
Extent of use of study data	Are there plans to use of data other than to answer the objectives stated in the protocol?			

	Are there plans to digitally store the data or make the data available to others?			
Authorship and contributorship	Authorship and contributorship issues			
Conflicts of interest	Declaration of conflicts of interest among authors and contributors			
Publication	Publication issues and plans			
Funding	Source of study funds			
Duplicate copy of informed consent form	That the participant will be provided a copy of the informed consent form			
Questions and concerns regarding the study	That participants will be allowed to ask questions or voice out their concerns			
Contact details	Who to contact if participants have questions or concerns and their contact details			

Assessed by

Document History:

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	Original Version
02	11 Sep 2024	CDUHREC members	Changed Form to I6.

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Sample Template for Transmittal Letters Prospective Study **Resident Initiated**	CDUHREC FORM	I7
		Version No.	2
		Version Date	11 Sep 2024
		Effective Date	12 Sep 2024

Date

Addressee

Medical Director/Department Chairperson

CDUH

Subject: Transmittal Letter

Dear Dr.Xxxxxxx,

I am submitting herewith my research protocol, "TITLE", as a requirement by the Department of (department). Most of the data for the research will be from patients under the Department of (department).

(Reason for undertaking the study.)

In line with this, I would like to ask for your permission to allow me to pursue with my study and retrieve the necessary data from the patients. Rest assured, I will keep all information confidential as stated under the Data Privacy Act of 2012. Also, once allowed, I will only start collecting data once I have been granted approval by the CDUH Research Ethics Committee.

Hoping for your kind consideration. Thank you very much!.

Respectfully,

name of principal investigator

received and approved by:

Document History:

Version No.	Date	Authors	Main Change
01	23 Apr 2021	CDUHREC members	Original Version
02	11 Sep 2024	CDUHREC members	Changed Form to I7.

METHODS OF BIRTH CONTROL

I. Policy

1. Women in their reproductive years who will undergo investigational drug trials or procedures should be advised against getting pregnant and should be given options regarding contraception methods.
2. CDUH does not allow the use of intrauterine devices and intrauterine systems methods of contraception.

II. The CDUH acceptable forms of contraception include:

1. True abstinence (When this is in line with the preferred and usual lifestyle of the subject. [Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.
2. Barrier methods of contraception: Implanted hormonal methods, surgical sterilization, Condom or Occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/film/cream/suppository;

RISK BENEFIT ASSESSMENT

III. Policy

The procedures conducted by CDUHREC are based on the provisions of CDUH, national and international guidelines (WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethics Guidelines)

IV. Responsibility

The CDUHREC is responsible for evaluating the potential risks and weighing the probability of the risk occurring and the magnitude of harm that may result among clinical trial participants. The Committee must then judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies asking any person to undertake the risks. The Committee cannot approve research in which the risks are judged unreasonable in relation to the anticipated benefits.

V. Definitions

- Benefit: a valued or desired outcome; an advantage
- Risk: the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study
- A characteristic of ethical research is that:
    1. the study is designed so that the risks to subjects are minimized and;
    2. the potential benefits of the research justify the potential risks.

VI. Conducting Risk-Benefit Assessment

- The Committee's assessment of risks and anticipated benefits of each study involves a series of steps. In reviewing a research protocol, the Committee is required to:

1. Identify the risks associated with the research. In biomedical studies, it is required to identify the risks associated with the research as distinguished from the risks of therapies the subjects would receive even if not participating in research.
2. Determine that the risks to subjects will be minimized:
    a. By using procedures that are consistent with sound research design and that did not unnecessarily expose participants to risk.
    b. When appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

This responsibility also includes evaluating the probability, magnitude, and duration of the risks involved. The Committee is required to consider the physical pain or discomfort as well as the psychological, emotional, economic, legal, or sociological harm, including invasion of privacy, loss of confidentiality, harassment, and lessening of an individual's dignity. Inconveniences such as loss of time or pay must also be evaluated. The Committee is required to consider the potential risks as well as the precautions that will be taken to avoid or minimize potential risks.

3. Identify the probable benefits to be derived from the research. The benefits of research fall into two major categories: benefits to subjects and benefits to society.

   Frequently, the research subjects are undergoing treatment for an illness or abnormal condition. This kind of research often involves evaluation of a procedure that may benefit the subject by providing a better understanding of their disorder. Patients or healthy individuals may also agree to participate in research that is either not related to any illnesses they might have or that is related to their conditions but not designed to provide any diagnostic or therapeutic benefit. Such research is designed principally to increase understanding and store of knowledge about human physiology and behavior. Research that has no immediate therapeutic intent may, nonetheless, benefit society as a whole. These benefits take the form of increased knowledge, improved safety, technological advances, and better health. The Committee is required to determine that the anticipated benefits to research subjects and the knowledge researchers expect to gain are clearly identified.

4. Determine that the risks to subjects are reasonable in relation to the anticipated benefits to subjects, if any, and the importance of the knowledge that may be expected to result.
5. Determine if there are 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. In addition, determine whether there are procedures for identifying such individuals.
6. Determine if there are adequate plans to exclude subjects who are vulnerable to injury during the period of withdrawal of active and effective therapy, if that is part of the research design.
7. Ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.
8. Determine intervals of periodic review [at which time risks and benefits will be reassessed] and whether there should be a data and safety monitoring board.

VII. Checklist for Risk-Benefit Assessment

1. The risk-benefit assessment shall be done by the committee during the initial review and during continuing review (annual/progress report review).
2. The principal investigator (PI) shall submit to the committee a risk-benefit assessment using the Checklist for the Assessment of the Risk/Benefit Version No. 3 dated 09 Jul 2015 (Appendix A5).
3. The lead reviewer shall also complete the Checklist for the Assessment of the Risk/Benefit Version No. 3 dated 09 Jul 2015 (Appendix A5) and this shall be discussed during the committee review.

PEDIATRIC POPULATION

VIII. General Guidelines

1. Pediatric population would include persons below 18 years of age.
2. Research involving the pediatric population should follow general guidelines and SOPs of CDUHREC and this would include National Ethical Guidelines for Research Involving Human Participants 2022.
3. A child or minor may only participate in a research after his/her parent or legal representative has given permission. In default of parents or judicially declared guardians, this order of authority shall be followed:
    a. grandparents;
    b. oldest sibling over 21 years of age, unless unfit or disqualified;
    c. actual custodian over 21 years of age, unless unfit or disqualified.
4. Where the parents are both of minor age or themselves incapacitated to enter contracts giving consent to their children's participation in research, the guidelines on medical treatment of such children may be followed, where the parents as well as a legally capacitated third party both give consent (e.g. the child's grandparents, physician, or the hospital administrator, as in emergency cases).
5. The child should express assent to participate in the research study in oral and written form.
6. The child's assent should be obtained without coercion.
7. A child's refusal to participate or continue in the research study should be respected.
8. If the child is 7 to 13 years old, he/she will sign an Assent Form which is different from the informed consent form which would be signed by the parents or guardians.
9. The assent form should be reviewed and approved by CDUHREC prior to utilization.
10. If a child is at least 14 years old, he/she can sign on the same informed consent documents signed by his/her parents. Both parent and child must sign.
11. If a child is less than 7 years old, no assent is needed but a sign of dissent on the part of the child must be respected and documented.
12. At any age, any signs of dissent must be observed, and such children who dissent must not be recruited to the study except when they will directly benefit from the research, and the parents consent.
13. Information on the study to which the child's participation is sought and terms such as "research," "study design," "procedures," "adverse effect," "voluntary" should be explained in a manner and language the child understands for purposes of assent and dissent.

INFORMED CONSENT PROCESS

IX. Policy:

Informed consent is mandatory for all clinical trials involving human beings. The consent process must respect the patient ability to make decisions and adhere the individual hospital rules for clinical studies. An IRB may waive informed consent if certain conditions are met. Paramount to this is that there be "minimal risk" to the research participants. Informed consent is a continuing process, and the mental health researcher must base their assessment of the decisional capacity of the potential participant on established tools and instruments.

During emergency cases, the following guidelines must be observed:

1. The well-being or safety of the critically ill patient shall be **of** paramount consideration in the emergency room or ICU setting. No research shall stand in the way of **administering the standard of care** to critically ill patients.
2. In cases where the research participant, by the nature of his disease, is unable to give consent (e.g., research participant has delirium or the sensorium is impaired), consent must be obtained from the research participant's LAR before enrollment in the clinical study.
3. When the LAR is unavailable when the research participant is brought to the hospital, the principal investigator must exhaust all means to locate the LAR and document this process within the therapeutic window.
4. The protocol shall describe appropriate procedures to inform the LAR of the participant's inclusion in the study and their right to discontinue participation in the research at the earliest feasible opportunity.
5. Once the research participant's sensorium improves during management and can give informed consent, the researcher or investigator should seek consent from the research participant themselves on whether to continue with the study. If the research participant decides not to continue, they shall receive the standard treatment due to them.
6. In rare instances, the REC may grant exemption or waiver of the informed consent requirement, provided all the following conditions exist:
   6.1. The research participant has a life-threatening condition for which available treatments are unproven, lacking, or unsatisfactory;
   6.2. Prospect of direct benefit to the research participants;
   6.3. When research participants are unable to give consent (e.g., impaired sensorium), and no LAR is present or cannot be located;
   6.4. The risks associated with the investigation are reasonable in relation to what is known about the emergent condition; and
   6.5. Where to be effective, the intervention under investigation must be given right away upon admission to the emergency room or ICU or within the specified therapeutic window.

DATA PRIVACY ACT

X. **Policy:**

In 2012 The Philippines passed the Data Privacy Act of 2012, a legislation "to protect the fundamental human right of privacy, of communication while ensuring free flow of information to promote innovation and growth".

Responsibility:

The CDUHREC is fully aware of the sensitive nature of the research process. Thus, to ensure compliance of the data privacy law of the country, the CDUHREC must see to it that the Informed Consent must contain sufficient safeguards for the privacy and protection of the subjects of the study.

Document History:

Version No.	Date	Authors	Main Change
01	01 Jun 2012		
02	11 Sep 2024	CDUHREC members	Changed to National Ethical Guidelines for Research Involving Human Participants 2022 in the General Guidelines of Pediatric Population.
03	23 Sep 2024	CDUHREC members	Added a new section entitled "Informed consent process"

	Cebu Doctors' University Hospital Research Ethics Committee (CDUHREC)		
	Review, Institutional and Other Fees	CDUHREC FORM	I9
		Version No.	07
		Version Date	10 Oct 2024
		Effective Date	10 Oct 2024

I. Policy Statement

The procedures conducted by CDUHREC are based on the provisions of CDUH, national and international guidelines (WHO Operational Guidelines/CIOMS Guidelines/ICH GCP and the National Ethics Guidelines)

II. Objective

The purpose of this SOP is to define the review, institutional and other fees.

III. Scope

This Standard Operating Procedure of CDUHREC applies to review, institutional and other fees.

IV. Review Fees

1. CDUHREC is implementing the following review fees effective 10 October 2024:
   a. New application – Php60,000.00
   b. Major/Substantial Amendment – Php15,000.00
   c. Annual continuing review fee – Php15,000.00
   d. Undergraduate & Residents in Training – Php2,000.00
   e. Pharmacokinetic fee – Php30,000.00
   f. SJREB review fee – Php5,000.00
2. All CDUHREC Review Fees shall be net of tax.
3. The principal investigator will receive a billing statement from CDUHREC.
4. The principal investigator or study sponsor will issue a check in favor of Cebu Doctors' University Hospital.
5. All review fees shall be paid directly to the CDUH cashier.
6. An official receipt reflecting the payment of the review fee shall be issued by CDUH.

V. Institutional Fees

The institutional fee is a one-time charge for all clinical trials conducted at the hospital. This fee helps support the hospital's research programs. The funds collected will be used to create and maintain a Center for Medical Research, which will manage and oversee all clinical trials at CDUH. The funds will also support research activities in the hospital's residency and fellowship programs.

The fee is Php60,000 and should be settled prior to start of the clinical trial.

VI. Document History

Version No.	Date	Authors	Main Change
01	01 Jun 2012		
02	01 Feb 2013	CDUHREC members	Changed Format
03	09 Jul 2015	CDUHREC members	Changed title from Continuing Review to Review fees
04	04 Jan 2018	CDUHREC members	Update Fees
05	10 Jan 2020	CDUHREC members	Changed format to PHREB as well as introduced new amendments as shown in the underscored portions format
06	10 Aug 2023	CDUHREC members	Update Fees
07	10 Oct 2024	CDUHREC members	Added Institutional Fee including its purpose, SJREB fees and editorial changes.