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Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
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DE LA SALLE MEDICAL AND HEALTH SCIENCES INSTITUTE
INDEPENDENT ETHICS COMMITTEE

Ground Floor, De La Salle Angelo King Medical Research Center
Governor D. Mangubat Avenue, City of Dasmariñas, Cavite, Philippines 4114
Contact No.: (046) 4818000 / (02) 89883100 local 1388/4000
Email: iec@dlsmhsi.edu.ph

1. POLICY STATEMENT

The **IEC** requires the submission of a complete set of pertinent documents for an application for ethical review. A **preliminary evaluation** determines whether a research proposal is exempted from review or requires ethical review, following the criteria outlined in the *2022 National Ethical Guidelines for Research Involving Human Participants (NEGRIHP 2022)* The Ethics Review Process. Protocols exempted from review must resubmit any amendments for reevaluation to confirm if the revised protocol still qualifies for exemption.

The **classification of protocol review** is based on the level of risk involved and adheres to the guidelines from the *2022 NEGRIHP*, *CIOMS (2016)*, and *Declaration of Helsinki (2013)*:

- **Exemption from Review:** Applies to protocols with minimal or no risk to participants. While exempted from standard review processes, these studies remain subject to ethical considerations.
- **Expedited Review:** Applies to protocols with minimal risk that do not include vulnerable groups or generate vulnerability.
- **Full-Board Review:** Required for protocols involving more than minimal risk, participation of vulnerable groups, or procedures that generate vulnerability.

This structured approach ensures that ethical review processes are proportionate to the level of risk posed by each research protocol.

2. OBJECTIVES

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

3. SCOPE

The IEC accepts the study protocols on health-related research dealing with human participants. Study protocols that may be accepted are as follows:

- Research conducted by members of DLSMHSI
- Research done in DLSMHSI by other institutions
- Research referred by the PNHRS, PHREB, DOH, industry organizations, or other academic institutions may be reviewed by the IEC, provided there is a formal agreement with the host hospital or institution where the research will be conducted. The host hospital or institution must explicitly accept the IEC's review and agree to adhere to its rules and regulations, which are based on PHREB and FERCAP standards. Additionally, other research sites involved must ensure a conducive environment for the safe and ethical conduct of the research. This includes

providing oversight, stewardship, and monitoring procedures as deemed necessary by the IEC. These conditions must be documented in a formal agreement signed by the participating hospitals or institutions acknowledging and accepting the IEC review.

- Protocols referred by the Single Joint Review Ethics Board (SJREB) to be submitted by Sponsor/Principal Investigator (PI) or its representative where the IEC is one of the sites of a multicenter research (Appendix 2: DOH Administrative Order No. 2017-0021).

This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database and filing of the original study protocol package in the Active Study File cabinet.

4. WORKFLOW

	ACTIVITY	RESPONSIBILITY
Step 1	*Receipt of study protocol package for initial screening*	IEC Staff
Step 2	*Assessment of the completeness and correctness of the protocol package and notifies the PI*	IEC Staff
Step 3	*Assignment of permanent code to the package*	IEC Staff and Member-Secretary
Step 4	*Logging the received protocol in the IEC database*	IEC Staff
Step 5	*Classifying the protocols into Exempt, Expedited, or Full-Board Review* ***(SOP 7: Exempt from Review; SOP 8: Expedited Review; SOP 9: Full-Board Review)***	IEC Chair, Co-chair, or Member-Secretary
Step 6	*Assignment of the primary reviewers*	IEC Chair, Co-chair, or Member-Secretary
Step 7	*Distribution of copies of the protocol package to the reviewers*	IEC Staff
Step 8	*Filing the original protocol package in a properly coded Protocol File folder and placing it in the Active Study File cabinet* ***(SOP 29: Management of Active Files)***	IEC Staff

5. DESCRIPTION OF PROCEDURES

5.1. Step 1 – Receipt of study package for initial screening.

5.1.1. The IEC staff receives one hard copy and one electronic copy (online) of the study protocol package for review.

5.1.2. All study protocols must obtain technical approval before proceeding to ethical review.

- For **DLSMHSI-initiated protocols**, the protocol package submitted to the IEC must include a certification of technical approval. This certification should be signed by the Chair of the Technical Review Committee (institutional or departmental) and/or the Director of Research Administration and Compliance, indicating that the protocol has been reviewed and approved.
- For **non-DLSMHSI-initiated protocols**, a document certifying that the research protocol has undergone and passed a technical review must be included with the submission for ethical review.

5.1.3. The PI submits protocol/proposal submission packages for review between the 1st and 15th day of each month, from 8:00 am to 5:00 pm.

5.1.4. Protocols must adhere to the standard protocol format and include a Protocol Submission Checklist (IEC Form 013/V3/2025).

5.1.5. The Protocol Review Application (IEC Form 014/V2/2025) must be signed by the Principal Investigator (PI). A copy of the completed application form is retained by the IEC, and a duplicate is provided to the PI or their representative.

5.1.6. Study protocols qualified for SJREB review are given instructions to submit to SJREB and given endorsement letter to SJREB.

5.1.7. A **Protocol Package** has to include the following:

Basic Documents (must submit for initial review)

- Protocol Review Application (IEC Form 014/V2/2025)
- Protocol Submission Checklist (IEC Form 013/V3/2025)
- Study Protocol (complete with relevant documents)
- Data Collection Forms (including Case Report Forms or CRFs)
- Protocol Synopsis and Diagrammatic workflow (IEC Form 016/V1/2025)
- Curriculum Vitae for Principal Investigators, the study team members, and the Adviser if applicable (IEC Form 015/V3/2025)
- Technical Review Certificate

Study-Specific Documents (submit as needed)

- Institutional Endorsement from the Vice Chancellor, Dean, or Medical Director (for research by students, faculty, staff, or medical residents)
- Investigator's Brochure (for Clinical Trials Phase I , II, III) or Basic Product Information Document (for Clinical Trial Phase IV)

- Informed Consent Form or ICF (for studies with human participants)
  - must include an English version and a Tagalog and/or other local language version/s
  - must have Version No., Date, Page No. in the footer
- Parent's Consent Form (for studies involving children/minor and relevant populations)
  - must include an English version and a Tagalog and/or other local language version/s
  - must have Version No., Date, Page No. in the footer Tagalog and/or other local version/s
- Assent Form (for studies involving minors and relevant populations deemed incompetent to sign an ICF)
  - must include an English version and a Tagalog and/or other local language version/s
  - must have Version No., Date, Page No. in the footer Tagalog and/or other local version/s
- Training Certificate in Health Research Ethics of PI, Co-investigator (Co-I), and the rest of the study team or Certificate of Good Clinical Practice (GCP) for clinical trials obtained within the last three years
- Recruitment advertisements (as needed by the study protocol)
- Other information or documents for participants (such as diaries, etc.)
- Certificate of Approval from the Institutional Biosafety Committee (for studies involving hazardous biological materials)
- Material Transfer Agreement (for any research involving transfer of biological specimens)
- Memorandum of Agreement or Terms of Reference (for collaborative studies)
- Grants Acquisition and Management (GAM)-endorsed Clinical Trial Agreement with approval from the Institutional Contract Review Committee (ICRC) (for sponsor-initiated clinical trials done in DLSMHSI)
- Site Resources Checklist (for clinical trials outside DLSMHSI done by DLSMHSI staff)
- Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
- National Commission for Indigenous People Clearance (for studies with indigenous populations) **can be processed while IEC review is ongoing*
- Insurance/Indemnity Policy
- Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)

5.2. **Step 2 – Assessment of the completeness and correctness of the protocol.** The IEC staff verifies the completeness and correctness of all documents submitted using the Protocol Submission Checklist (IEC Form 013/V3/2025) including the completeness of all required information in the application form. Incomplete submission and incomplete information in the application form will be returned to the PI indicating the reasons for rejection and possible corrective action or acknowledge the receipt of the protocol for those with complete and correct documents.

5.3. **Step 3 – Assignment of permanent code to the package.** If the documents are determined to be complete, the IEC staff with the supervision of the Member-Secretary assigns a permanent protocol code. 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 will always be indicated for easier referencing. All codes will follow the format: **Year submitted (e.g., 2025) – Assigned Protocol Number (e.g., 001) – Type of Research – Status of Research**.

5.3.1. Code for Type of Research
- 01 – Clinical Trial
- 02 – Epidemiological (Cohort/Case-Control/Cross-Sectional)
- 03 – Basic Science
- 04 – Behavioral
- 05 – Social Science
- 06 – Community
- 07 – Medical Devices
- 08 – Bioavailability/Bioequivalence Studies
- 09 – Health Economics
- 10 – Others

5.3.2. Code for Status of Research
- A – **Active** (Ongoing study, no close-out or final report notification)
- I – **Inactive** (Final study report approved, or no post-review response from PI more than 90 days, or no notification of termination)
- C – **Completed** (Close-out notification submitted or final report not yet approved)
- T – **Terminated** (Termination notification submitted before/during study implementation)

5.4. **Step 4 – Logging the received protocol in the IEC Database.** The protocol is logged in the DLSMHSI database and logbook. It is an official document that contains the receipt of a particular documents on a specific date and time. It includes information on (1) Title of the Study, (2) Name of Proponent, (3) Date of Submission, (4) Name of Receiver, and (5) Action. It is also good to include the name and signature of the individual who actually submitted the documents in case he/she is not the proponent.

5.5. **Step 5 – Classifying the protocols into Exempt, Expedited, or Full-board Review.** The IEC Chair, Co-chair, or Member-Secretary conducts a preliminary review of the protocol to determine level of ethical review: **Exempted from Review**, **Expedited Review**, or **Full-board Review.**

5.5.1. If the preliminary reviewer decides that the protocol is exempted from review, he/she directs the IEC staff to follow the procedure to communicate the decision to the researcher. *(Refer to **SOP 7: Exempt from Review**; **SOP 27: Communicating DLSMHSI-IEC Decisions**)*

5.5.2. If the preliminary reviewer determines that the protocol should undergo either Full or Expedited Review, then the IEC staff proceeds to follow either ***SOP 8: Expedited Review*** or ***SOP 9: Full-Board Review***.

5.6. **Step 6 – Assignment of primary reviewers.** The IEC Chair, Co-chair, or Member Secretary assigns the primary reviewers. Primary reviewers are selected based on expertise related to the protocol.

5.7. **Step 7 – Distribution of copies of the protocol package to the reviewers.** The IEC Staff prepares the copies of protocol package for distribution to the reviewers. Alternatively, they may simply email the electronic copy of the protocol package. Only reviewers requesting for hard copies will be provided with such and sent physically.

5.8. **Step 8 – Filing the original protocol package in a properly coded Protocol File folder and placing it in the Active Study File cabinet.** The IEC Staff compiles the original package in a properly coded Protocol File folder *(Refer to **SOP 29: Management of Active Files**)*. The complete Protocol File folder is filed for safekeeping in the Active Study File cabinet *(Refer to **SOP 29: Management of Active Files**)*. Electronic database is likewise updated as to the type of review and assigned primary reviewers.

6. GLOSSARY

6.1. **Amendment** – a change in or revision of the protocol made after its approval

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

6.3. **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

6.4. **Exempted from Review** – a decision made by the IEC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGRIHP 2022 or 2022 National Ethical Guidelines for Research Involving Human Participants

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

6.6. **Full Review or Full-board 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

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

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

6.9. **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

6.10. **Study Documents** – include all materials protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the IEC for review

7. FORMS

IEC Form 013/V3/2025	Protocol Submission Checklist
IEC Form 014/V2/2025	Protocol Review Application
IEC Form 015/V2/2025	Curriculum Vitae for Principal Investigators / Team Members (Template)
IEC Form 016/V2/2025	Protocol Synopsis and Diagrammatic Workflow

8. HISTORY

Version No.	Date	Authors	Main Revision
1	22 Oct. 2012	Dr. Melchor Victor G. Frias IV	
2	20 Jun 2016	Dr. Melchor Victor G. Frias IV Ms. Genevieve V. Bayas	
3	16 Oct 2019	Dr. Melchor Victor G. Frias IV Ms. Genevieve V. Bayas	
4	N/A	Dr. Melchor Victor G. Frias IV Ms. Aiza Jean B. Datu-dacula	
5	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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