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Supersedes:	None
Version:	1
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Effective date:	January 2025
Approved by:	
Approval date:	Pending

DE LA SALLE MEDICAL AND HEALTH SCIENCES INSTITUTE
INDEPENDENT ETHICS COMMITTEE

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1. POLICY STATEMENT

The IEC protocol review is conducted through the primary review system. Primary reviewers are selected on the basis of expertise related to the protocol. Research proposals are given to both medical and non-medical, institutional and non-institutional members for review. The medical members evaluate the scientific and ethical procedures in the protocol while the non-medical and non-institutional members focus their assessment on the informed consent form as well as the ethical procedures in the conduct of the study.

2. OBJECTIVES

This SOP describes the process of the assignment of Primary Reviewers for study protocols received for ethical review.

3. SCOPE

This SOP begins with the receipt of the IEC Chair, Co-chair, or Member-Secretary of the complete initial protocol package that underwent checking for its completion by the IEC Staff, and ends with submission of the protocol package to the assigned Primary Reviewers, and Independent Consultant, if any.

4. WORKFLOW

ACTIVITY		RESPONSIBILITY
Step 1:	*Submission of protocol package to IEC Chair, Co-chair, or Member-Secretary*	IEC Staff
Step 2:	*Conduct of Preliminary Review of the Protocol for Classification and Assignment of Primary Reviewers*	IEC Chair, Co-chair, or Member-Secretary
Step 3	*Preparation of copies of protocol package for distribution*	IEC Staff

5. DESCRIPTION OF PROCEDURES

5.1. **Step 1 – Submission of protocol package to IEC Chair, Co-chair, or Member-Secretary.** After verifying the completeness of the protocol package, the IEC staff forwards the entire package to the IEC Chair. In the Chair's absence, the package is submitted to the Co-Chair or Member-Secretary for preliminary review.

5.2. **Step 2 – Conduct of Preliminary Review of the Protocol for Classification and Assgnment of Primary Reviewers.** Upon receiving the protocol package, the IEC Chair (or, if unavailable, the Co-Chair or Member-Secretary) conducts a preliminary review to determine the type of review required. Additionally, the Chair assigns Primary Reviewers for the protocol and evaluates whether the involvement of an Independent Consultant is necessary. *(Refer to **SOP 3: Appointment of Independent Consultants and Assignment of Protocols**)*.

5.2.1. Each protocol is assigned at least two Primary Reviewers:
- One medical reviewer (affiliated or non-affiliated) assesses the scientific soundness and ethical considerations of the protocol.
- One non-medical reviewer (affiliated or non-affiliated) evaluates the informed consent process and forms.

5.2.2. Primary Reviewers are selected based on their expertise and experience related to the protocol, while also ensuring a fair distribution of workload among members.

5.2.3. After the preliminary review, the Protocol Review Application (IEC Form 014/V2/2025) and Protocol Assessment Form (IEC Form 017/V4/2025) are completed, and the full protocol package is returned to the IEC staff for further processing.

5.3. **Step 3 – Preparation of copies of protocol package for distribution.** The IEC staff receives the complete protocol package, including the signed and completed forms for classification and assignment of Primary Reviewers. The classification and assignments are logged into the IEC protocol database.

5.3.1. The DLSMHSI Staff then prepares and distributes copies of the protocol package as follows:
- **For expedited review**: Copies are sent to the assigned Primary Reviewers.
- **For full review**: Copies are distributed to all member reviewers.

5.3.2. If an independent consultant is required, the IEC staff prepares and sends an invitation letter along with the confidentiality agreement to the identified consultant.

6. GLOSSARY

6.1. **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

6.2. **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

6.3. **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

6.4. **Independent Consultant** – an external expert invited to provide specialized knowledge or insight on a protocol when expertise is not available within the ethics committee.

6.5. **Preliminary Review** – an initial assessment conducted by the Chair (or their delegate) to determine the type of review required for the protocol (e.g., full board, expedited). It also involves identifying potential reviewers and evaluating whether external expertise is needed.

6.6. **Primary Reviewers** – members of the ethics committee assigned to evaluate specific aspects of a protocol in detail. A **primary medical reviewer** focuses on the scientific validity and ethical issues related to the study design, methodology, and potential risks. A **primary non-medical reviewer** examines the informed consent process and forms for clarity, voluntariness, and adequacy of information provided to participants.

6.7. **Protocol Database** – a secure system used to log and track protocols submitted for ethical review. This database facilitates efficient monitoring and record-keeping, ensuring transparency and accountability in line with *ICH-GCP* and *NEGRIHP (2022)* standards.

6.8. **Protocol Package** – a set of documents submitted for ethical review, typically including the study protocol, informed consent forms, investigator's qualifications, study design, and relevant supporting documents.

7. FORMS

IEC Form 014/V2/2025	Protocol Review Application
IEC Form 017/V4/2025	Protocol Assessment Form

8. HISTORY

Version No.	Date	Authors	Main Revision
1	10 Jan 2025	Sigfredo Mata	First draft as independent SOP

9. REFERENCES

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