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	IX. FULL-BOARD REVIEW	

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INDEPENDENT ETHICS COMMITTEE

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1. POLICY STATEMENT

A Full-Board Review (Full Review) shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants.

Only complete protocols submitted during the first 15 calendar days of the month, or for at least two weeks before a scheduled meeting may be considered to be included in the agenda for full-board review. This shall be conducted through a primary review system. If necessary, independent consultants and/or the proponents shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the proponent within five working days following the adjournment of the full-board meeting in which the protocol was discussed.

Criteria for protocols to be classified as subject to Full-Board Review, after initial submission, are as follows:

- Clinical trials about investigational new drugs, biologics, or device in various phases (Phase 1, 2, and 3)
- Phase 4 intervention research involving drugs, biologics, or device
- Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g., related sexual preferences, etc., or about sensitive issues that may cause social stigma) and may cause psychological, legal, economic, and other social harm
- Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority group, homeless persons, nomads, refugees, minors, and those incapable of giving consents) that require additional protection from the IEC during review
- Protocols that involve collection of identifiable biological specimen for research
- Protocols referred by the Single Joint Research Ethics Board (SJREB) classified as for Full Review by the IEC (*Refer [SOP 10: SJREB Protocol Review](#)*)

In addition, the criteria for Full-Board Review of Resubmissions, Amendments, and Reports are as follows:

- Protocols initially classified for full-board review and resubmitted after having major revisions of the protocol and informed consent (*Refer to [SOP 13: Management of Resubmission](#)*)
- Protocols, regardless of initial review classification, having post-approval major amendments resulting in major changes in the inclusion/exclusion criteria, safety issues, and risk/benefit assessment, as well as deviations from previously approved protocols, or any violations incurring in the implementation of the study
- Protocols having on-site SAEs/SUSARs that may require protocol amendment or re-consent of participants (*Refer to [SOP 13: Management of Resubmission](#)*)

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- Progress Reports and Continuing Review Applications if initial classification was likewise full-board review
- Reportable Negative Events and Early Termination Application, regardless of initial review classification

Initial Review shall commence no later than 10 working days after submission of the complete protocol package and inclusion in the meeting agenda.

SOP 25: Preparation and Conduct of Meetings outlines the procedures for the conduct of meetings, whether online or face-to-face. The IEC Chair, Co-chair, or Member-Secretary will decide on the type of platform used.

2. OBJECTIVES

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

3. SCOPE

This SOP applies to initial review and resubmissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups. This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of protocol-related documents.

4. WORKFLOW

	ACTIVITY	RESPONSIBILITY
Step 1:	<i>Assignment of Reviewers and Independent Consultant/s (SOP 6: Selection of Primary Reviewers and SOP 3: Appointment of Independent Consultants and Assignment of Protocols)</i>	IEC Chair, Co-chair, or Member-Secretary
Step 2:	<i>Notification of Primary Reviewers and Independent Consultant/s</i>	IEC Staff

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ACTIVITY	RESPONSIBILITY
Step 3: <i>Provision of study documents and assessment forms to the Primary Reviewers, Independent Consultants, and the rest of the committee members</i>	IEC Staff
Step 4: <i>Presentation of review findings and recommendations during a committee meeting (SOP 25: Preparation and Conduct of Meetings)</i>	Primary Reviewers
Step 5: <i>Discussion of technical and ethical issues</i>	Primary Reviewers and the rest of IEC Members
Step 6: <i>Summary of issues and resolutions</i>	IEC Chair
Step 7: <i>Committee action</i>	IEC Chair and Members
Step 8: <i>Documentation of committee deliberation and action (SOP 26: Preparation of the Minutes of the Meeting)</i>	IEC Member-Secretary and Staff
Step 9: <i>Communication of committee action to the researcher (SOP 27: Communicating the DLSMHSI-IEC Decisions)</i>	IEC Chair and Staff
Step 10: <i>Filing of protocol-related documents and updating of the protocol database</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Assignment of Reviewers and Independent Consultant/s.** Once the protocol was determined for full board review, the IEC Chair, Co-Chair and/or Member Secretary assigns two or three IEC members to be the Primary Reviewers of the protocol.
 - 5.1.1. Primary reviewers, at a minimum, should preferably be composed of a medical member (affiliated or non-affiliated) with related expertise to the study protocol and a non-medical, non-scientific, lay member (affiliated or non-affiliated).
 - 5.1.2. If there are no members with the field of expertise to adequately review the scientific aspect of the study protocol, an Independent Consultant may be invited to join the protocol review. (Refer to **SOP 3: Appointment of Independent Consultants and Assignment of Protocols**)

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- 5.2. **Step 2 – Notification of Primary Reviewers and Independent Consultant/s.** The IEC Staff notifies the assigned Primary Reviewers and/or Independent Consultant/s about their assignment by email with a request to confirm their acceptance and availability within three working days.
- 5.3. **Step 3 – Provision of study documents and assessment forms to the Primary Reviewers, Independent Consultants, and the rest of the committee members.** The IEC staff prepares the pertinent documents: for initial submissions, the complete protocol package; for post-approval submissions, the pertinent information from the retrieved protocol and the report itself. The IEC staff send out copies of the protocol and/or protocol-related documents and assessment forms, either physical or electronic copies to the primary reviewers, independent consultants, if any, and the rest of the committee members at least ten working days prior to the next IEC full board meeting.
- 5.4. **Step 4 – Presentation of review findings and recommendations during a committee meeting.** The Primary Reviewers review the protocol and other documents and submit their findings and recommendations [Protocol Assessment Form (IEC Form 017/V4/2025) and Informed Consent Form (ICF) Assessment Form (IEC Form 021/V3/2025)] to the IEC Chair at least one day before the scheduled meeting and present these during the actual meeting (*Refer to SOP 25: Preparation and Conduct of Meetings*). If a primary reviewer cannot attend the meeting, the IEC Chair shall present the findings.
- 5.4.1. The Primary Reviewers shall make sure that all required information are completely filled-out. Assessment forms may be submitted either as hard copies, duly signed and dated by the Primary Reviewers and Independent Consultants, or as electronic copies with e-signatures. If electronic copies are submitted, the IEC staff will print and file them as part of the official documentation.
- 5.4.2. When additional information is needed or recommendations require clarification, the Primary Reviewers may request a clarificatory meeting or dialogue with the PI. During this meeting, the PI may provide further explanations or address specific concerns raised by the reviewers. The Primary Reviewers may communicate the outcomes of such discussions, including any relevant updates, during the full board review meeting, upon request.
- 5.5. **Step 5 – Discussion of technical and ethical issues.** The Primary Reviewers lead the discussion of the technical and ethical issues using the Protocol Assessment Form (IEC Form 017/V4/2025) and the Informed Consent Form (ICF) Assessment Form (IEC Form 021/V3/2025) for an orderly exchange of ideas.
- 5.5.1. Some major points to be considered during the discussion are the following:
- The protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness.
 - In assessing the degree of risk against the benefit, determine whether the risk is reasonable in relation to anticipated benefits; and/or if the risks can be minimized.



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- Study participants are selected equitably especially if randomization is not to be used. Study participant's information sheet should be clear, complete and written in understandable language.
- There is voluntary, non-coercive recruitment of study participants
- The Informed Consent is adequate, easy to understand and properly documented.
- There should be a translation of the Informed Consent document into local dialect which should be comprehensible by general public.
- The procedure for getting the Informed Consent is clear and unbiased.
- The persons who are responsible for getting the Informed Consent are named and they introduce themselves to the study participants.
- The research plan makes adequate provision for monitoring data collection to ensure the safety of the study participants, where appropriate.
- There are adequate provisions to protect the privacy of study participants and to maintain the confidentiality of data, where appropriate.
- There is a provision for compensation to study participants. There should be reasonable provision for medical/psychosocial support: treatment for study related injuries, as well as compensation for participation to cover expenses like transport and lost wages because of participation.
- There are appropriate safeguards included to protect vulnerable study participants.
- Contact person with address and phone number are included in the Informed Consent.
- There is clear justification for the use of biological materials and a separate consent form for use of biological specimens.
- There are appropriate contracts or memoranda of understanding especially in collaborative studies.

5.5.2. The review and assessment should also include:

- Checking the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements.
- Considering whether the study and training background of the principal investigator/s are related to the study.
- Looking for disclosure or declaration of potential conflict of interest (i.e., if a member declares conflict of interest on a study for review, he/she may be asked to leave the meeting during the discussion of the associated study)
- Non-physician principal investigators should be advised by a physician when necessary.
- Determining if the facilities and infrastructure at study sites can accommodate the study.



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- Checking the “Assent Form” if the protocol involves children or other vulnerable groups as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedure to be done should be explained to the child or vulnerable participant separately).
- Examining community involvement and impact benefit of the study to the community and/or the institution. If relevant, the reviewer looks for the following in the protocol:
 - Community consultation described and planned with community leaders
 - Involvement of local researchers and institutions in the protocol design analysis and publication of the results
 - Contribution to development of local capacity for research and treatment as among the benefits to local communities
 - Sharing of study results with the participants/community

5.6. **Step 6 – Summary of issues and resolutions.** The IEC Chair summarizes the technical and ethical issues that were identified, the issues that were resolved/not resolved, and the recommendations for the issues that were not resolved.

5.7. **Step 7 – Committee Action.** The IEC Chair facilitates the voting process to determine the board's action on a protocol.

5.7.1. Decisions are made based on majority vote or consensus, which is then adopted as the official resolution. In cases of strong objections, deliberations may continue until the concerns of the objecting member are addressed. If necessary, a clarificatory interview with the PI may be conducted to resolve outstanding issues.

5.7.2. The committee's decision may fall into one of the following categories:

5.7.2.1. Approved if there are no ethical issues identified in the protocol.

5.7.2.2. Minor or Major Modification Required if there are findings that can be resolved through revision or modification of the protocol.

- **Minor Modification** – a recommended revision applying to protocols found to have particular aspect/s on its study or related document that do not have impact on potential risk/harm to participants, and on the integrity of the research (e.g., incomplete documentation or informed consent elements, unsatisfactory informed consent format, etc.). This may include:
 - Administrative corrections like typographical errors or grammar
 - Minor changes on items not directly related to the procedure to be done
 - Revisions that will not impact risk-benefit ratio, e.g., additional related literature requested
- **Major Modification** – a recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives,

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recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that have impact on potential risk/harm to participants and on the integrity of the research. This may include:

- Major revisions on either the protocol or informed consent form; inclusion/exclusion criteria, safety issues, or methodology that may have impact on the scientific validity of the protocol
- Revisions that will have impact on the risk-benefit ratio

5.7.2.3. Disapproved

5.8. **Step 8 – Documentation of committee deliberation and action.** Refer to **SOP 26: Preparation of the Minutes of the Meeting**

5.9. **Step 9 – Communication of committee action to the researcher.** As soon as a committee decision is reached, it is communicated to the PI within five (5) working days from the adjournment of the full-board meeting. Refer to **SOP 27: Communicating DLSMHSI-IEC Decisions**

5.9.1. For approved protocol, the DLSMHSI-Staff prepares a Certificate of Approval for Reviewed Protocols (IEC Form 022/V4/2025) to be signed by the IEC Chair and sent to the PI. The Certificate of Approval for Reviewed Protocols (IEC Form 022/V4/2025) contains the identification of the document approved with version numbers and dates, the frequency of continuing review and the responsibilities of the PI throughout the course of the study. There should be a file/received copy with a specific date.

5.9.2. For protocols for **revision/modification**, a Notification Letter of Review Decision (IEC Form 019/V1/2025) is issued to the PI. The PI should revise the protocol or related document/s, and resubmit them to the IEC in accordance with the procedures stated in the notification letter. (Refer to **SOP 13: Management of Resubmissions**)

5.9.3. In the case of **disapproval**, the IEC staff notifies the PI using the Notification Letter of Review Decision (IEC Form 019/V1/2025). This shall include the reason for the disapproval of the study.

- If the PI wishes to appeal the decision, they may submit a written request to the IEC.
- The appeal will be included in the agenda for deliberation at the next scheduled full-board meeting.
- If the appeal is deemed valid and receives favorable consideration, the PI will be informed and instructed to submit a revised protocol addressing the IEC's recommendations to resolve the reasons for the initial disapproval.

5.10. **Step 10 – Filing of protocol-related documents and updating of the protocol database.**

The IEC Staff keeps copies of all protocol-related documents and compiles them in their respective protocol files. All meeting deliberations and decisions regarding a protocol are noted in the minutes of the meeting, with relevant sections filed in the specific protocol file. In updating

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the database all information regarding the IEC decision, such as the dates when the decision was written and signed by the IEC Chair and the date when it was delivered to the PI, are entered in the database. (Refer to [SOP 29: Management of Active Files](#))

6. GLOSSARY

- 6.1. **Consensus** – a collective agreement
- 6.2. **Decision** – the result of the deliberations of the IEC in the review of a protocol or other submissions
- 6.3. **Full-Board Review or 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.
- 6.4. **Independent Consultant** – resource person who is not a member of the Research Ethics Committee, 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.
- 6.5. **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.
- 6.6. **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.
- 6.7. **Minor 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.
- 6.8. **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.
- 6.9. **Primary Reviewers** – members of the Research Ethics Committee (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and 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 primary reviewers shall present their findings and recommendations during the meeting for discussion.
- 6.10. **Protocol Database** – a secure system used to record and track information on protocols submitted for review, including their classification, assigned reviewers, and review outcomes. This ensures efficient monitoring and documentation of all committee activities.

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- 6.11. **Protocol-Related Documents** – consist of all other documents aside from the proposal/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.
- 6.12. **Resubmissions** – revised study proposals that are submitted after the initial review.
- 6.13. **Voting** – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.
- 6.14. **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.

7. FORMS

IEC Form 013/V3/2025	Protocol Submission Checklist
IEC Form 017/V4/2025	Protocol Assessment Form
IEC Form 021/V3/2025	Informed Consent Form (ICF) Assessment Form
IEC Form 019/V1/2025	Notification Letter of Review Decision
IEC Form 022/V4/2025	Certificate of Approval for Reviewed Protocols

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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