TABLE OF CONTENTS

Supersedes:	DLSMHSI-IEC SOP Chapter 2: 2.2. Expedited Review / V4 / 2024
Version:	5
Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
Effective date:	January 2025
Approved by:	
Approval date:	Pending

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

An expedited review shall be conducted for study protocols that (1) do not entail more than minimal risk to the study participants, (2) do not have study participants belonging to a vulnerable group, and (3) the study procedures do not generate vulnerability. These protocols are given expedited review based on the criteria listed in the 2022 National Ethical Guidelines for Health Research Involving Human Participants (NEGRIHP 2022) and international frameworks such as Council for International Organizations of Medical Sciences (CIOMS, 2016) and the Declaration of Helsinki (2024).

Criteria for protocols to be initially classified as subject to Expedited Review are as follows:

1. **The study protocols do not entail more than minimal risk to the study participants:**

    - Protocols that will not likely harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.
    - Protocols that involve collection of anonymized personal data, anonymized biological specimens for research purposes by non-invasive means (e.g., collection of small amounts of blood, body fluids, or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
    - Protocols that deal with data or documents involving anonymized human data, biological specimens that have been already collected or will be collected for ongoing medical treatments or diagnosis.

2. **The study protocols do not have participants belonging to a vulnerable group:**

    - Protocols that will not deal with patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent

3. **The study procedures do not generate vulnerability:**

    - Protocols that are non-confidential in nature (not of a private character, e.g., relate to sexual preference, etc., or not about a sensitive issue that may cause social stigma).

Protocols referred by the Single Joint Research Ethics Board (SJREB) may also be classified for Expedited Review by the IEC Chair. *(Refer to **SOP 10: SJREB Protocol Review**)*

Criteria for study protocols to be subject to Expedited Review, after initial approval:

1. Protocols initially classified for Expedited Review, even if with major modifications recommended, will still undergo expedited review upon resubmission as long as minimal risk is not elevated.

2. All post-approval amendments, deviations, violations, off-site SAEs/SUSARs shall be subject to Expedited Review, regardless of initial review classification if the study protocols satisfy any of the following criteria: *(Refer to **SOP 13: Management of Resubmission**)*
   - Administrative revisions, such as correction of typing error
   - Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
   - Minor protocol amendments, deviations, violations on the study and related documents that do not impact on the potential risks/benefits to the participant and no substantial change in the study population, methodology, and consent that will impact on the integrity of the research

3. Progress Reports and Continuing Review Applications will be subject to Expedited Review if initial classification of study protocol was likewise expedited.

4. All Final Reports, regardless of type of initial classification of review, will be subject to Expedited Review. However, in the event that a PI decides not to continue the application for ethical review, the PI must write a letter requesting for withdrawal of study protocol from the IEC. All requests for withdrawal will be discussed during the full-board review meeting regardless of review classification.

The results of the initial review shall be released to the principal investigator within four weeks after the submission of all the required documents. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular committee meeting.

2. OBJECTIVES

Expedited review aims to demonstrate due diligence and high standards in the system of protection of human participants. This SOP defines the criteria and procedures for determining research protocols that qualify for expedited review by the IEC, in accordance with international and national ethical guidelines.

3. SCOPE

This SOP applies to the initial review of protocols and resubmissions involving studies that present no more than minimal risk to participants. It is applicable only when the study population does not include vulnerable groups, and no issues of vulnerability arise. The SOP outlines the process beginning with the assignment of reviewers or independent consultants and concludes with the inclusion of the review on the agenda of the next IEC meeting.

4. WORKFLOW

	ACTIVITY	RESPONSIBILITY
Step 1:	*Assignment of Reviewers and Independent Consultant/s (SOP 6: Selection of Primary Reviewers and SOP 3: Appointment of Independent Consultants and Assignment of Protocols)*	IEC Chair, Co-chair, or Member-Secretary
Step 2:	*Notification of Primary Reviewers and Independent Consultant/s*	IEC Staff
Step 3:	*Conduct of review and accomplishment of assessment forms*	Primary Reviewer and Independent Consultant/s
Step 4:	*Consolidation and finalization of the review results or referral of protocol to full board review*	IEC Chair
Step 5:	*Communication of review results to the researcher* ***(SOP 27: Communicating of IEC Decisions)***	IEC Chair and Staff
Step 6:	*Filing of documents in the protocol database* ***(SOP 29: Management of Active Files)***	IEC Staff
Step 7:	*Presentation of the result of the expedited review during full board meeting.*	Primary Reviewer

5. DESCRIPTION OF PROCEDURES

5.1. **Step 1 – Assignment of Reviewers and Independent Consultant/s.** Once the protocol was determined for expedited 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. *(See* ***SOP 3: Appointment of Independent Consultants and Assignment of Protocols****)*

5.2. **Step 2 – Notification of Primary Reviewers and Independent Consultant/s.** The IEC Chair, Co-chair, or Member-Secretary instructs the DLSMHSI Staff to notify the primary reviewers and consultants and forward the pertinent documents with the instruction to conduct expedited review. Such notification should be done immediately and at least ten working days prior to the next IEC full board meeting.

5.3. **Step 3 – Conduct of review and accomplishment of assessment forms.** The assigned Primary Reviewers shall carry out the expedited review on the protocol and related documents (patient information sheet, consent form, advertisements, etc.).

5.3.1. The review shall be carried out within 10 working days after the receipt of the documents.

5.3.2. 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.

5.3.3. The Primary Reviewers shall complete the Protocol Assessment Form (IEC Form 017/V4/2025) and Informed Consent Form (ICF) Assessment Form (IEC Form 021/V3/2025) and make the recommendations to the IEC Chair. The Primary Reviewers may recommend for approval, revision, or elevation to full-board review of the study protocol.

5.3.4. 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. **Step 4 – Consolidation and finalization of the review results.** The IEC Staff shall check the completeness of the assessment form before forwarding to the Chair who will consolidate and finalize the review results. In cases of differing opinions among reviewers, the Chair may mediate to facilitate consensus and, if necessary, make the final decision. If significant disagreements persist and consensus cannot be reached, the Chair may escalate the protocol for full-board review by the IEC.

5.4.1. The protocol is approved if there are no ethical issues identified by the Primary Reviewers.

5.4.2. If there are findings, the protocol shall be recommended for revision. 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**)*

5.4.3. Expedited review cannot issue a disapproval as a final decision. A protocol with significant recommendations shall be referred to full board review for a final decision. Similarly, if consensus among reviewers cannot be reached or if a member raises significant concerns, the protocol will be elevated to the full board for comprehensive review. The IEC Chair shall request for the inclusion of the protocol in the next meeting agenda for deliberation and final decision.

5.5. **Step 5 – Communication of review results to the researcher.** The IEC Staff communicates the review result to the PI through a notification letter no more than 5 working days after the decision was made.

5.5.1. For approved protocol, a Certificate of Approval for Reviewed Protocols (IEC Form 022/V4/2025) is issued to the PI.

5.5.2. If for revision a Notification Letter of Review Decision (IEC Form 019/V1/2025) is issued to the PI

5.6. **Step 6 – Filing of documents in the protocol database.** The IEC Staff keeps copies of all related documents, including the excerpts of the decision from the minutes of meeting, and compiles them in their respective protocol files. *(Refer to **SOP 29: Management of Active Files**)*

5.7. **Step 7 – Presentation of the result of the expedited review during full board meeting.** Results of the expedited review must be formally presented during the nearest scheduled full board review meeting. This presentation serves to inform all committee members of the result of the expedited review, ensuring transparency and proper documentation. The presentation should include a summary of the protocol, the result of the review and its rationale, and any specific conditions or considerations related to the protocol. This step ensures that all decisions are recorded in the meeting minutes and fosters accountability within the IEC.

6. GLOSSARY

6.1. **Decision** – the result of the deliberations of the IEC in the review of a protocol or other submissions.

6.2. **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. This means that the protocol will not undergo an expedited nor a full review.

6.3. **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.

6.4. **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.

6.5. **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.

6.6. **Minimal Risk** – term used when the probability and magnitude of harm or discomfort anticipated in 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. **More than Minimal Risk** – term used when the probability and magnitude of harm or discomfort anticipated in 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.

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

6.9. **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	

9. REFERENCES

Council for International Organizations of Medical Sciences (CIOMS). (2016). *International ethical guidelines for health-related research involving humans.* CIOMS. https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/

Department of Health. (2017). *Administrative Order No. 2017-0021: Guidelines for the operationalization of the single joint ethics review process for multi-site researches in the Department of Health.* Department of Health. Published October 30, 2017. https://doh.gov.ph/

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (1996). *ICH harmonised tripartite guideline: Guideline for good clinical practice E6(R1).* https://www.ich.org/page/good-clinical-practice

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2016). *Integrated addendum to ICH E6(R1): Guideline for good clinical practice E6(R2).* https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2023). *ICH E6(R3): Guideline for good clinical practice (draft guideline)*. https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf

Philippine Health Research Ethics Board. (2017). *National ethical guidelines for health and health-related research.* Department of Science and Technology - Philippine Council for Health Research and Development.

Philippine Health Research Ethics Board. (2020). *A workbook for developing standard operating procedures: The SOP workbook.* Philippine Health Research Ethics Board.

Philippine Health Research Ethics Board. (2022). *National ethical guidelines for research involving human participants.* Department of Science and Technology - Philippine Council for Health Research and Development.

World Health Organization. (2011). *Standards and operational guidance for ethics review of health-related research with human participants.* World Health Organization. https://www.who.int/publications

World Health Organization. (2000). *Operational guidelines for ethics committees that review biomedical research.* World Health Organization. https://www.who.int/publications

World Health Organization. (2023). *WHO tool for benchmarking ethics oversight of health-related research involving human participants.* World Health Organization. https://www.who.int/publications

World Medical Association. (2024). *Declaration of Helsinki: Ethical principles for medical research involving human participants.* https://www.wma.net/policies-post/wma-declaration-of-helsinki/