

	<b>De La Salle Medical and Health Sciences Institute</b> City of Dasmariñas, Cavite, Philippines 4114 <b>INDEPENDENT ETHICS COMMITTEE</b>	<b>DLSMHSI-IEC SOP Ver. 5</b> Approval Date:  Effective Date: January 2025  Page 1 of 8
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## 1. POLICY STATEMENT

The DLSMHSI-IEC recognizes that certain types of research may pose minimal or no risk to participants and therefore qualify for exemption from full ethical review. These protocols are exempted 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). These exemptions do not imply that the research is free from ethical considerations but acknowledge that standard review processes may not be necessary.

A protocol may qualify for exemption if it satisfies the following conditions:

- The research neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols).
- The research involves the use of publicly available data or data that cannot be linked to identifiable individuals.
- The research is educational in nature and conducted in standard educational settings (e.g., surveys, classroom observations).
- The study involves public behavior observations without interaction, recording, or identifiable data collection.
- The research exclusively uses existing, anonymized data, documents, or specimens.
- The research is a program evaluation, quality assurance/improvement initiative, or public health surveillance activity not intended to contribute to generalizable knowledge.

Protocols will not qualify for exemption if they:

- Involve vulnerable populations, such as children, pregnant women, or persons with disabilities
- Include sensitive topics or activities that could pose psychological, legal, or social risks to participants
- Intend to collect identifiable private information or biospecimens

The decision to grant exemption must be documented and reported during the next full board meeting. Protocols that qualify for exemption are archived and reclassified as inactive. Protocol records will be retained and made available for a period of three years from the date of exemption. Exempt protocols are not subject to further reviews, including progress or continuing reviews. However, any modifications to the protocol that may significantly alter the previous risk-benefit assessment or its qualification for exemption must be promptly reported to the IEC. If such modifications are deemed substantial, the protocol must be resubmitted as a new protocol for initial review.

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## 2. OBJECTIVES

This SOP defines the criteria and procedures for determining research protocols that qualify as exempt from full ethical review by the IEC, in accordance with international and national ethical guidelines. The aim is to ensure that exempt protocols meet ethical standards while streamlining the review process for studies involving minimal or no risk to participants..

## 3. SCOPE

This SOP outlines the process for the initial evaluation of study protocols submitted for exemption from ethical review. It applies to protocols that meet the criteria for exemption and begins with the submission of a complete protocol package to the IEC Chair, or in their absence, the Co-Chair or Member-Secretary. The process includes classifying the level of ethical review required and concludes with the proper filing and documentation of protocols deemed exempt from ethical review.

## 4. WORKFLOW

ACTIVITY	RESPONSIBILITY
<b>Step 1:</b> <i>Self-assessment of protocol.</i>	PI
<b>Step 2:</b> <i>Application for exemption from ethical review.</i>	PI
<b>Step 3:</b> <i>Verification of completeness and correctness of documents.</i>	IEC Staff
<b>Step 4:</b> <i>Assignment of protocol code.</i>	IEC Staff
<b>Step 5:</b> <i>Review and verification of exemption.</i>	IEC Chair, Co-Chair, Member Secretary
<b>Step 6:</b> <i>Communication of decision to the PI.</i>	IEC Staff

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	ACTIVITY	RESPONSIBILITY
<b>Step 7:</b>	<i>Presentation of protocols exempted from review during full board review meeting.</i>	IEC Chair, Co-Chair, Member Secretary
<b>Step 8:</b>	<i>Filing of documents in the protocol database.</i>	IEC Staff

## 5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Self-assessment of Protocol.** A principal investigator who thinks that his/her study protocol is exempted from ethical review shall conduct a self-assessment using the Checklist for Exemption from Ethical Review (IEC Form 018/V2/2025).

The checklist includes requirements for exemption as follows:

- Protocol does not involve more than minimal risks or harms
- Protocol neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols)
- Protocol for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests
- Protocol that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:
  - There will be no disclosure of the human participants' 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.
  - 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.
- Protocol that only involve the use of publicly available data or information
- Protocol should follow the Institutional Data Privacy Policy in Research. (<https://www.dlshsi.edu.ph/data-privacy-policy-research>)

- 5.2. **Step 2 – Application for Exemption from Ethical Review.** Once the PI determined that his/her study qualifies for exemption, he/she submits application for exemption from ethical review. The application should include study protocol package (Refer to **SOP 5: Management of Initial Review**) together with the Checklist for Exemption from Ethical Review (IEC Form 018/V2/2025)

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- 5.3. **Step 3 – Verification of Completeness and Correctness of Documents.** The IEC staff verifies the completeness and correctness of all documents submitted using the Protocol Submission Checklist (IEC Form 013/V3/2025), returns incomplete submissions 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.
- 5.4. **Step 4 – Assignment of Protocol Code.** If the documents are determined to be complete, the IEC staff with the supervision of the Member-Secretary assigns a permanent protocol code. (Refer to [SOP 5: Management of Initial Review](#))
- 5.5. **Step 5 – Review and Verification of Exemption.** The protocol is forwarded to the IEC Chair, Co-Chair and/or Member Secretary for review and verification if the protocol qualifies for exemption. If the protocol is deemed not exempted from ethical review, the reviewer shall also decide the level of ethical review required whether expedited or full board and shall proceed as such. (Refer to [SOP 8: Expedited Review](#) and [SOP 9: Full Board Review](#))
- 5.6. **Step 6 – Communication of decision to PI.** The IEC staff communicates the decision to the researcher. (Refer to [SOP 27: Communicating IEC Decisions](#)). If the decision affirms the exemption, the IEC Staff prepares the Notification Letter of Review Decision (IEC Form 019/V1/2025) and the Certificate of Exemption from Ethical Review (IEC Form 020/V1/2025). If deemed not exempted, the communications should include the reasons for rejection and the recommendation for either expedited or full-board review.
- 5.7. **Step 7 – Presentation of protocols exempted from review during full board review meeting.** Protocols that have been classified as exempt from ethical review must be formally presented during the nearest scheduled full board review meeting. This presentation serves to inform all committee members of the exemption decisions, ensuring transparency and proper documentation. The presentation should include a summary of the protocol, the rationale for exemption based on the applicable criteria, and any specific conditions or considerations related to the exemption. This step ensures that all decisions are recorded in the meeting minutes and fosters accountability within the IEC.
- 5.8. **Step 8 – Filing of documents in the protocol database.** The complete protocol folder, including all protocol-related documents, is filed for safekeeping in the Archived Study File cabinet. (Refer to [SOP 30: Archiving of Terminated, Inactive and Completed Studies](#)) Electronic database is likewise updated as to the type of review and assigned primary reviewers.

## 6. GLOSSARY

- 6.1. **Archived Study File** – a repository for securely storing terminated, inactive, or completed study documents, ensuring accessibility for future reference and compliance with record-keeping policies.
- 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 NEGRHIP 2022 or 2022 National Ethical Guidelines for Research Involving Human Participants

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- 6.3. **Minimal Risk** – the probability and magnitude of harm or discomfort anticipated in the research are not greater than those encountered in daily life or during routine physical or psychological examinations.
- 6.4. **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.
- 6.5. **Primary Reviewers** – members of the ethics committee assigned to evaluate specific aspects of a research protocol in detail, including scientific validity, ethical soundness, and regulatory compliance. Primary reviewers are selected based on their expertise and experience.
- 6.6. **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.
- 6.7. **Protocol Package** – a comprehensive set of documents submitted for ethical review, including the study protocol, informed consent forms, investigator qualifications, and other relevant materials. The package ensures that the ethical, scientific, and procedural aspects of the study are adequately addressed.
- 6.8. **Publicly Available Data** – data that is accessible to the general public without restrictions and does not contain identifiable information that could pose a risk to privacy or confidentiality.

## 7. FORMS

IEC Form 018/V2/2025  
 IEC Form 019/V1/2025  
 IEC Form 020/V1/2025

Checklist for Exemption from Ethical Review  
 Notification Letter of Review Decision  
 Certificate of Exemption from Ethical Review

## 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	

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Version No.	Date	Authors	Main Revision
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

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