



De La Salle Medical and Health Sciences Institute
City of Dasmariñas, Cavite, Philippines 4114

INDEPENDENT ETHICS COMMITTEE

XXII. MANAGEMENT OF APPEALS

DLSMHSI-IEC SOP Ver. 1

Approval Date:

Effective Date:

January 2025

Page 1 of 6

TABLE OF CONTENTS

1. Policy Statement	2
2. Objectives	2
3. Scope	2
4. Workflow	2
5. Description of Procedures	3
6. Glossary	4
7. Forms	4
8. History	5
9. References	5

Supersedes:	None
Version:	1
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

Appeals are requests submitted by researchers, sponsors, or funding agencies for the reconsideration of a decision or action taken by the research ethics committee regarding a protocol or its related documents. Addressing appeals demonstrates the openness of DLSMHSI-IEC members and their commitment to transparency and fairness.

The IEC will consider the PI's perspective on the feasibility and acceptability of IEC recommendations, including cases of disapproval. All appeals will undergo Full-Board Review and will be resolved within thirty (30) calendar days of receiving a fully documented appeal.

2. OBJECTIVES

This activity aims to outline the IEC's management of appeals to ensure fairness, transparency, and a comprehensive ethics review process that considers the perspective of the PI. It also seeks to detail the procedures for reconsideration and appeals of unfavorable decisions rendered by the IEC.

3. SCOPE

This SOP outlines the procedures for handling appeals to IEC decisions, beginning with the receipt of the appeal and concluding with the communication of the committee's decision to the researcher and the updating of the protocol records.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt of an appeal</i>	IEC Staff
Step 2: <i>Retrieval of pertinent protocol files</i>	IEC Staff
Step 3: <i>Notification of IEC Chair and Primary Reviewers</i>	IEC Staff



ACTIVITY	RESPONSIBILITY
Step 4: <i>Inclusion of the appeal in the agenda of the next regular IEC board meeting</i>	IEC Chair and Staff
Step 5: <i>Discussion and deliberation on the appeal</i>	IEC Chair and Members
Step 6: <i>Communication of IEC action to the Principal Investigator/Researcher (SOP 27: Communicating DLSMHSI-IEC Decisions)</i>	IEC Chair and Staff
Step 7: <i>Filing of all related documents (SOP 29: Management of Active Files) and update of the protocol database</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Receipt of an appeal.** The IEC Staff receives the Letter of Appeal (IEC Form 036/V1/2025) of the PI/researcher and enters the pertinent information into the logbook. Appeal requests must be submitted to the IEC Chair in writing no later than thirty (30) calendar days after the IEC has rendered the written decision letter.
- 5.2. **Step 2 – Retrieval of pertinent protocol files.** The IEC Staff retrieves the pertinent files for reference in the review. These files include the initially submitted protocol, ICF, research tools, and other related documents.
- 5.3. **Step 3 – Notification IEC Chair and Primary Reviewers.** The IEC Staff informs the IEC Chair and Primary Reviewers about the receipt of the Letter of Appeal (IEC Form 036/V1/2025) and awaits further instructions. The IEC Chair acknowledges the appeal request in writing within five (5) working days of its receipt, providing details of the appeal process and outlining the required documentation.
- 5.4. **Step 4 – Inclusion of the appeal in the agenda of the next regular IEC board meeting.** The IEC Staff includes the appeal in the agenda for the next full-board meeting. They shall also ensure the availability of the retrieved protocol and related documents during the meeting and notify the PI/researcher to be available on the scheduled date in case further clarification is required.
- 5.5. **Step 5 – Discussion and deliberation of the appeal.**
 - 5.5.1. The Primary Reviewer provides a summary of the protocol and the previous discussions related to the issues as context for the appeal.
 - 5.5.2. The IEC Chair presents the content of the appeal and facilitates the discussion.
 - 5.5.3. If needed, the PI/researcher may be invited to provide further clarification on specific issues.



- 5.5.4. After addressing the points for clarification, the PI/researcher is asked to leave the meeting to allow the committee to deliberate.
- 5.5.5. The IEC convenes to reach a decision, by consensus, on whether to accept any or all of the points raised in the appeal.
- 5.6. **Step 6 – Communication of IEC action to the Principal Investigator/Researcher.**
 - 5.6.1. Based on the deliberations, the IEC Chair summarizes the decision points.
 - 5.6.2. The IEC Staff then prepares the draft Notification Letter for Review Decision (IEC Form 019/V1/2025) for approval by the IEC Chair. (Refer to **SOP 27: Communicating DLSMHSI-IEC Decisions**)
 - 5.6.3. The PI will receive the final Notification Letter for Review Decision (IEC Form 019/V1/2025) shall satisfactorily address all the conditions and concerns raised by the IEC to receive ethical approval.
 - 5.6.4. The decision of the IEC shall be final and no further appeals will be granted.
- 5.7. **Step 7 – Filing of all related documents and update of the protocol database.** The IEC Staff files all the documents into the appropriate folder and updates the protocol database accordingly.

6. GLOSSARY

- 6.1 **Appeal** – a request of a researcher/ investigator for a reconsideration of the IEC recommendation.
- 6.2 **Primary reviewer** – a member of the IEC who is assigned to do an in-depth evaluation of research-related documents using technical and ethical criteria established by the committee.
- 6.3 **Protocol database** – a collection of information (e.g., regarding protocols) 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 **Protocol File/Folder** – an organized compilation of all documents (in physical or electronic form) related to a study.

7. FORMS

IEC Form 036/V1/2025
IEC Form 019/V1/2025

Letter of Appeal
Notification Letter for Review Decision



De La Salle Medical and Health Sciences Institute
City of Dasmariñas, Cavite, Philippines 4114

INDEPENDENT ETHICS COMMITTEE

XXII. MANAGEMENT OF APPEALS

DLSMHSI-IEC SOP Ver. 1
Approval Date:

Effective Date:
January 2025

Page 5 of 6

8. HISTORY

Version No.	Date	Authors	Main Revision
1	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>

	De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114	DLSMHSI-IEC SOP Ver. 1 Approval Date:
	INDEPENDENT ETHICS COMMITTEE	Effective Date: January 2025
XXII. MANAGEMENT OF APPEALS		Page 6 of 6

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/>