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DE LA SALLE MEDICAL AND HEALTH SCIENCES INSTITUTE
INDEPENDENT ETHICS COMMITTEE

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IDENTITY

De La Salle Medical and Health Sciences Institute is a world class, Catholic institution, founded on the charism of St. John Baptist de La Salle, committed to the global Lasallian mission.

VISION & MISSION

De La Salle Medical and Health Sciences Institute shall be the preferred institution and employer for medical and health education, patient care, and research.

CORE VALUES

SPIRIT OF FAITH

We shall produce God-loving, person-oriented, and patriotic nurturers of life.

ZEAL FOR SERVICE

We shall contribute to the transformation of our communities and country through excellent teaching, compassionate holistic and scientific inquiry.

COMMUNION IN MISSION

We shall promote the well-being and welfare of our employees through our policies and programs.

REVERENCE FOR LIFE

We shall be stewards of God-given life to the best of our ability and judgment.

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INTRODUCTION

The De La Salle Medical and Health Sciences Institute – Independent Ethics Committee (DLSMHSI-IEC) is an independent body established under the administrative oversight of the De La Salle Angelo King Medical Research Center (Research Services) at the De La Salle Medical and Health Sciences Institute (DLSMHSI). Its mandate is to uphold the highest ethical standards in all research activities conducted within the institution, and ensure the protection of the rights, dignity, and well-being of research participants.

In alignment with both international and national ethical guidelines for health research, the DLSMHSI-IEC conducts rigorous reviews of research protocols and related documents to maintain ethical compliance. It holds the authority to approve, require modifications to, or disapprove research protocols and ensures post-approval compliance with its policies and procedures.

While administratively supported by the institution—through the provision of adequate resources, infrastructure, and operational assistance—the DLSMHSI-IEC maintains full autonomy in its decision-making processes. This independence is critical to its function, allowing it to conduct impartial evaluations and ethical oversight without external influence, thereby reinforcing its credibility and integrity as a guardian of ethical research standards.

BRIEF HISTORY OF DLSMHSI-IEC

The Institutional Ethics Board was established in 1994 under the leadership of Dr. Charles Y. Yu, who was then the Research Director of the De La Salle University Angelo King Medical Research Center (DLSU-AKMRC), the research arm of the De La Salle University College of Medicine. This institution would later evolve into the De La Salle University Health Sciences Campus, now known as the De La Salle Medical and Health Sciences Institute (DLSMHSI). Dr. Yu also served as the inaugural Chair of the ethics board, laying a strong foundation for its operations and fostering a culture of ethical rigor in health research.

Over the years, the committee underwent several organizational transformations, including restructuring and renaming.

From 1996 to 2000, the committee was renamed the Ethics Review Board (ERB) and led by Rev. Fr. Danilo Tiong. In 2001, it underwent another rebranding as the Institutional Review Board/Ethics Review Board (IRB/ERB). Over the following eight years, it was successively chaired by Rev. Fr. Danilo Tiong, Dr. Melchor Victor G. Frias IV, and Dr. Angelica D. Francisco, who each contributed to strengthening the committee's role in ensuring the ethical integrity of research.

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In 2009, the committee was formally designated as the Independent Ethics Committee (IEC), with its primary mandate of ensuring the ethical integrity of research conducted within the institution. This transition reflected the growing emphasis on ethical compliance and research oversight.

Since its inception, five Chairs—Dr. Charles Y. Yu, Rev. Fr. Danilo Tiong, Dr. Angelica D. Francisco, Dr. Madeleine Matibag-Sosa, and Dr. Melchor Victor G. Frias IV—have guided the committee. Each chair significantly contributed to shaping its operations and reinforcing its commitment to safeguarding the rights, dignity, and welfare of research participants. The IEC and its predecessors have consistently adhered to a structured framework of protocols and procedures that have ensured clarity, consistency, and accountability in its review and decision-making processes.

In 2012, the IEC developed a provisional Standard Operating Procedure (SOP) to standardize its processes further. By 2015, as part of preparations for the initial Philippine Health Research Ethics Board (PHREB) accreditation, the SOP underwent substantial refinement, incorporating additional chapters and sections to meet evolving standards. The final SOP was approved by then Vice Chancellor for Research (VCR) and interim IEC Chair, Dr. Melchor Victor G. Frias IV, marking a pivotal milestone in the committee's operational development.

In January 2018, the institution reached a significant milestone by adopting its current name, the De La Salle Medical and Health Sciences Institute (DLSMHSI). With this change, the Independent Ethics Committee (IEC) was officially renamed the DLSMHSI-IEC. Initially, the committee operated under the direct supervision of the Vice Chancellor for Research. However, in 2023, as part of a comprehensive reorganization of Research Services through the current Vice Chancellor for Research Services, Dr. Susan A. Olavidez, the DLSMHSI-IEC was placed under the Research Integrity, Compliance, and Safety unit of the Research Administration and Compliance (RAC) department (**Figure 1**). This strategic reorganization was designed to strengthen institutional support and oversight while preserving the committee's independence in ethics reviews and decision-making. The pivotal role of the DLSMHSI-IEC was further emphasized through a memorandum issued on August 19, 2024 (Reference No. RAC-2425-002, **Appendix 1**), which reaffirmed its authority, autonomy, and the institutional commitment to providing operational and logistical support.

Today, the DLSMHSI-IEC, chaired by Dr. Nikki Eileen Valencia, continues to uphold the highest ethical standards in research. Its unwavering commitment to impartiality, transparency, and rigor has firmly established it as a cornerstone of ethical research at DLSMHSI, ensuring that the rights and welfare of research participants remain at the forefront of its mission.

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GUIDING PRINCIPLES AND FRAMEWORK

The DLSMHSI-IEC operates under the ethical principles and procedures outlined in internationally recognized guidelines, including:

- **Declaration of Helsinki (2024)**
- **Council for International Organizations of Medical Sciences (CIOMS) (2002, 2009, and 2016)**

It adheres to national laws, regulations, and guidelines, drawing on the following foundational documents for its operations:

- **WHO Tool for Benchmarking Ethics Oversight of Health-Related Research (2023, WHO)**
- **Operational Guidelines for Ethics Committees that Review Biomedical Research (2000, WHO)**
- **Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011, WHO)**
- **International Conference on Harmonization of Good Clinical Practice (ICH-GCP)**
- **National Ethical Guidelines for Research Involving Human Participants 2022 (PHREB)**
- Philippine Food and Drug Administration (FDA) regulations
- National laws, such as the **Data Privacy Act of 2012**, and other applicable laws.

The DLSMHSI-IEC is steadfast in its mission to uphold the highest ethical standards in health-related research. As a cornerstone of ethical research at DLSMHSI, it ensures that all research under its purview adheres to an ethical framework that balances scientific validity, social value, and participant welfare.

SCOPE OF RESPONSIBILITIES

The DLSMHSI-IEC recognizes its role in evaluating protocols within a diverse legal, cultural, and regulatory landscape. It takes steps to familiarize itself with the regulations and requirements of both sponsor countries and localities where DLSMHSI research is being conducted. Additionally, it collaborates with national and local ethics committees to ensure the ethical integrity and compliance of approved protocols.

In some cases, the DLSMHSI-IEC may review research referred by external organizations such as the Philippine National Health Research System (PNHRS), Philippine Health Research Ethics Board (PHREB), Department of Health (DOH), Single Joint Research Ethics Board (SJREB), industry organizations, or other academic institutions. Such reviews are conducted under the condition that the host institutions accept and

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adhere to DLSMHSI-IEC's rules and regulations, based on PHREB and FERCAP standards. Furthermore, these institutions must ensure an environment conducive to the safe and ethical conduct of research, providing oversight and stewardship as required. These agreements are formalized in signed documents outlining responsibilities and commitments.

OPERATIONS AND MEMBERSHIP

The DLSMHSI-IEC is composed of a multidisciplinary membership, including medical/scientific professionals and nonmedical/nonscientific members. To maintain high standards, all members undergo initial and continuing training in research ethics and Good Clinical Practice (GCP). The committee convenes at least once a month to review clinical trial protocols and research proposals submitted by fellows, residents, consultants, and other researchers affiliated with the De La Salle Angelo King Medical Research Center (DLSAKMRC).

The DLSMHSI-IEC also emphasizes transparency and rigor in its reviews, incorporating cultural sensitivity and community values. Its members are committed to upholding ethical principles and adhering to international and national guidelines in the review process.

INDEPENDENCE AND INSTITUTIONAL SUPPORT

The DLSMHSI-Independent Ethics Committee (DLSMHSI-IEC) operates as an autonomous body, ensuring impartiality in its ethics review and decision-making processes. This independence is critical to maintaining its integrity and credibility as a guardian of ethical standards in research involving human participants. To support its autonomy while enhancing its operational efficiency, the DLSMHSI-IEC requires substantial institutional backing, as outlined in the **2022 National Ethical Guidelines for Research Involving Human Participants (NEGRIHP)** and the **2023 WHO Tool for Benchmarking Ethics Oversight of Health-Related Research**.

The following institutional support mechanisms are essential to ensure the effective operations of the DLSMHSI-IEC:

1. Administrative and Logistical Support

- Provision of adequate office space, infrastructure, and resources, such as computing systems, secure storage for sensitive documents, and meeting facilities.
- Clerical and administrative assistance to manage documentation, scheduling, and communication.
- Financial resources to support operational expenses, including member compensation, training programs, and accreditation fees.

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2. Capacity-Building and Training

- Regular training sessions for IEC members on research ethics, Good Clinical Practice (GCP), and updates on national and international ethical guidelines.
- Access to workshops, seminars, and conferences on emerging ethical issues and advancements in research oversight.

3. Access to Expert Resources

- Technical experts and legal advisors to assist in complex cases requiring specialized knowledge.
- A multidisciplinary pool of reviewers to ensure diverse perspectives in protocol evaluation.

4. Policy and Procedural Support

- Development and regular updates of Standard Operating Procedures (SOPs) in alignment with guidelines such as the WHO Operational Guidelines for Ethics Committees and PHREB's accreditation requirements.
- Establishing mechanisms for monitoring approved research protocols and ensuring compliance with ethical standards.

5. Recognition and Authority:

- Institutional recognition formalized through documentation, such as the memorandum issued on August 19, 2024 (Reference No. RAC-2425-002), affirming the committee's independence and critical role.
- Clear delineation of the IEC's authority to review, approve, disapprove, or recommend revisions to research protocols, including those referred from external organizations.

6. Monitoring and Compliance Oversight:

- Support for the ongoing review and monitoring of approved studies to ensure continued adherence to ethical principles.
- Mechanisms for managing and investigating noncompliance or ethical breaches.

By providing these essential supports, the Institution ensures that the DLSMHSI-IEC operates independently and effectively while upholding its commitment to the highest ethical standards in research. This partnership between institutional support and DLSMHSI-IEC autonomy strengthens the integrity of health-related research and fosters trust among researchers, participants, and the community.



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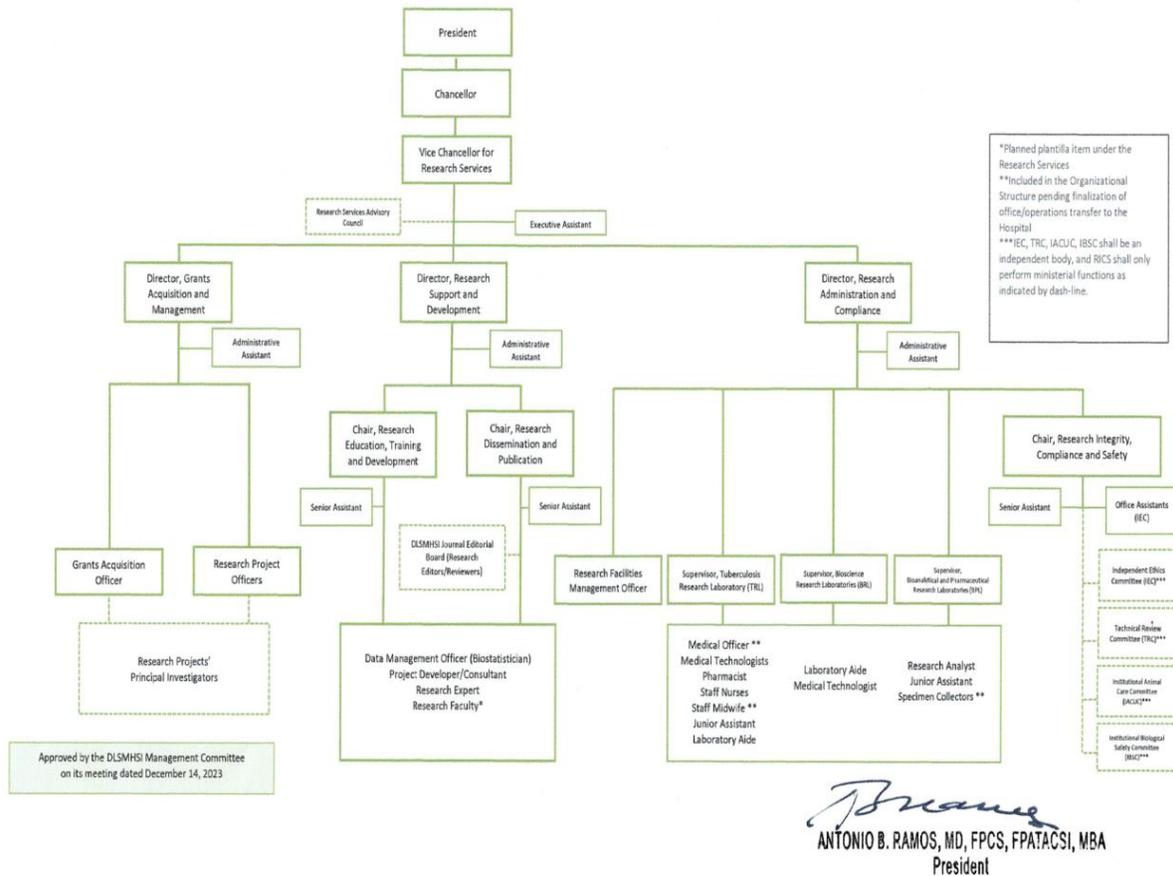


Figure 1. Research Services Organizational Structure

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1. POLICY STATEMENT

The selection process for DLSMHSI-IEC members is guided by international and national policies, including the **WHO Operational Guidelines for Ethics Committees that Review Biomedical Research (2000)** and the **National Ethical Guidelines for Research Involving Human Participants (2022)**. This process is designed to ensure a diverse and multidisciplinary committee capable of conducting thorough and impartial ethical reviews.

Members are selected through a nomination process that prioritizes representation across:

- **Disciplines:** Inclusion of both medical and non-medical professionals to provide balanced perspectives.
- **Sectors:** Representation of diverse demographics, such as gender (male and female) and age groups (older and younger).
- **Affiliations:** Inclusion of at least one member who is not affiliated with the institution to maintain independence and minimize conflicts of interest.

The Chair for Research Integrity Compliance and Safety (RICS) evaluates and recommends potential candidates for membership to the DLSMHSI President through channels. Once approved, the DLSMHSI President issues the letter of appointment to the members.

The IEC members are categorized as either regular members or alternate members. Regular members shall serve a term of three years, with eligibility for reappointment upon the expiration of their term. Staggered appointments are implemented to ensure continuity, promote institutional memory, and maintain the committee's expertise. Alternate members shall serve on a three-year renewable term. They are required to attend meetings as needed to ensure quorum requirements are met (at least five members) and support the regular members in fulfilling the committee's mandate.

2. OBJECTIVES

Selection and appointment of IEC members aims to ensure that the composition of the IEC complies with the international, national, and institutional guidelines and that appropriate expertise is taken into consideration.

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3. SCOPE

This SOP applies specifically to the selection of IEC members. This process starts with the call for nominations and ends with the filing of appointment documents and Curriculum Vitae (CV) of the appointed members in the membership file.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Nomination of potential new members</i>	IEC Chair/Co-chair and Members
Step 2: <i>Submission of names of potential members to the RICS Chair</i>	IEC Member-Secretary
Step 3 <i>Endorsement of potential members to the VCR through the RAC Director</i>	RICS
Step 4 <i>Endorsement of appointments to the DLSMHSI President through the Chancellor</i>	VCR
Step 5 <i>Approval of appointments of new members and issuance of Letter of Appointment</i>	DLSMHSI President
Step 6 <i>Receipt of Appointment Letters for new members</i>	IEC Member-Secretary
Step 7 <i>Forwarding Appointment Letters to new members with Confidentiality and Conflict of Interest Disclosure Agreement</i>	IEC Staff
Step 8 <i>Signing the conforme and submission of Appointment Letters, Confidentiality and Conflict of Interest Disclosure Agreement together with CV</i>	New IEC member/s
Step 9 <i>Filing of appointment documents and CVs in the membership file (SOP 29: Management of Active Files)</i>	IEC Staff

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5. DESCRIPTION OF PROCEDURES

5.1. Detailed Instructions

- 5.1.1. **Step 1 – Nomination of potential new members.** The IEC Chair/Co-chair informs the IEC members regarding the need for new member/s. The call for nominations shall be based on qualifications and requirements stated in the international, national and institutional policies. Members submit names, preferably with CV of possible new members to Member-Secretary for consolidation.
- 5.1.2. **Step 2 – Submission of names of potential members to the RICS Chair.** The Member-Secretary submits to the RICS Chair the final list of nominees with summary of credentials for reference. The RICS Chair evaluates and shortlists the nominees based on scientific and research ethics knowledge and expertise, as well as willingness to volunteer time and effort to perform the responsibilities and attend trainings as members of the IEC.
- 5.1.3. **Step 3 – Endorsement of potential members to the VCR through the RAC Director.** The RICS Chair submits recommendations for potential members to the RAC Director, who subsequently forwards these to the VCR for endorsement.
- 5.1.4. **Step 4 – Endorsement of appointments to the DLSMHSI President through the Chancellor.** The VCR endorses the appointments to the DLSMHSI President through the Chancellor.
- 5.1.5. **Step 5 – Approval of appointments of new members and issuance of Letter of Appointment.** The DLSMHSI President approves the appointments of new members. The RICS Chair oversees the preparation and consolidation of appointment letters signed by the DLSMHSI President, ensuring proper documentation and forwarding them to the newly appointed members.
- 5.1.6. **Step 6 – Receipt of Appointment Letters for new members.** The Member-Secretary receives the Appointment Letters from the RICS Chair and informs the IEC Chair accordingly. The Appointment Letters (IEC Form 001/V3/2025 or IEC Form 002/V1/2025) specify the conditions of the appointment including the roles and responsibilities.
- 5.1.7. **Step 7 – Forwarding Appointment Letters to new members with Confidentiality and Conflict of Interest Disclosure Agreement.** The IEC Chair instructs the IEC Staff to forward the Appointment Letters (IEC Form 001/V3/2025 or IEC Form 002/V1/2025) together with the Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025) to the concerned new member.
- 5.1.8. **Step 8 – Signing the conforme and submission of Appointment Letters, Confidentiality and Conflict of Interest Disclosure Agreement together with CV.** The new member/s sign the Appointment Letters and the Confidentiality and Conflict of Interest Disclosure Agreements.

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- 5.1.9. **Step 9 – Filing of appointment documents and CVs in the membership file.** The IEC staff files the appointment documents in the membership file. (Refer to **SOP 29: Management of Active Files**)

5.2. Requirements for Membership

- 5.2.1. The IEC shall be composed of nine regular members and at least three (3) alternate members.
- 5.2.2. Membership shall be multidisciplinary and multi-sectoral. Members shall have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted at DLSMHSI or its non-affiliated organizations.
- 5.2.3. Membership shall include persons whose primary concerns are in medical science, with at least one member who is a pediatrician, at least one member who is non-medical, non-scientist, or lay person, and at least one member who is non-affiliated.
- 5.2.4. Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science, and public health. It is recommended that the IEC should include a person who will represent the interest and concerns of the community.
- 5.2.5. The IEC shall aim for gender balance in its membership with equal representation of men and women members in order to promote gender sensitivity in its review procedures.
- 5.2.6. The IEC shall have representatives from both the older and younger generations.
- 5.2.7. Independent consultants shall be invited whenever necessary to provide expert opinion related to protocols under review.
- 5.2.8. The IEC shall adhere to quorum requirements as defined in international and national guidelines for research ethics committees that review health research.
- 5.2.8.1. Quorum is described as having at least five members present, following the fifty percent plus one (50% + 1) rule.
- 5.2.8.2. Quorum also requires the presence of at least one non-medical, non-scientist, or lay member, and one non-affiliated member to make decisions about the proposed research.
- 5.2.8.3. For interventional studies involving children, a quorum shall include the presence of a pediatrician or child development expert, as needed by the protocol.

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5.3. Terms of Reference

- 5.3.1. The Appointment Letter (IEC Form 001/V3/2025 or IEC Form 002/V1/2025) shall indicate the member's functions, terms of office, scope of work, and conditions of appointment.
- 5.3.2. The members shall be appointed and shall serve the committee for a period of three years, renewable upon the expiration of their term, up to a maximum of two consecutive terms. Request for reappointment shall come from the IEC Chair, recommended by the RICS Chair, and appointed by the DLSMHSI President,
- 5.3.3. The IEC shall adopt a mechanism for rotation of its membership roster to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity, development, and maintenance of expertise.

5.4. Qualifications of Members

- 5.4.1. Members are selected based on their good moral character and personal capacities, their ethical and/or scientific knowledge and expertise, as well as their willingness to dedicate their time and efforts to perform their functions in the IEC.
- 5.4.2. Members shall have prior training in Good Clinical Practice, research methodology and research ethics, or should be willing to undergo such training during their membership, which will be recorded in the Training Records Form (IEC Form 005/V2/2025). They shall ensure to renew their GCP training every three years.
- 5.4.3. Members shall disclose in writing any financial, professional, or personal interest or involvement in a project or proposal under consideration, which is in conflict with their function as a reviewer.
- 5.4.4. Members shall submit their Curriculum Vitae (IEC Form 004/V2/2025), properly signed and dated, and update them at least once every two years.
- 5.4.5. Members will be required to sign a Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025) at the start of their term. The agreement should cover all applications, meeting deliberations, information on research participants and related matters. The staff is likewise expected to sign a similar document. The Confidentiality/Conflict of Interest Agreement shall protect the privacy and confidentiality of all parties whose information may be disclosed to the IEC in the course of its work.
- 5.4.6. The IEC shall decide on how to manage specific conflicts of interest of members related to their participation in committee deliberations/actions regarding a particular protocol covered by the provisions of the Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025).

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5.5. Conditions of Appointment of Members

All prospective IEC members must be willing to:

- 5.5.1. Make public his/her full name, profession, and affiliation as a IEC member.
- 5.5.2. Disclose all financial accountability, reimbursement for work and expenses, related to their work in IEC that shall record and publicly disclose its financial records upon request.
- 5.5.3. All IEC members and independent consultants shall sign the Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025) regarding meeting deliberations, applications, information on research participants and related matters.

5.6. Roles and Responsibilities of Members

- 5.6.1. All IEC Members are expected to:
 - 5.6.1.1. Actively participate in the conduct of study protocol review and discussion during board meetings.
 - 5.6.1.2. Review, discuss, and consider research proposals submitted for evaluation.
 - 5.6.1.3. Be assigned as Primary Reviewer.
 - 5.6.1.4. Review progress reports and monitor ongoing studies as appropriate.
 - 5.6.1.5. Evaluate final reports.
 - 5.6.1.6. Maintain confidentiality of the documents and deliberations during board meetings.
 - 5.6.1.7. Declare any conflict of interest.
 - 5.6.1.8. Participate in continuing education activities in health research and ethics.
- 5.6.2. Scientific or medical members (affiliated or non-affiliated) assess Severe Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) and recommend appropriate action.
- 5.6.3. Non-medical, non-scientist, or lay members review the ethical considerations in the conduct of the research which includes: social value, vulnerability issues, risk vs benefit, measures to mitigate risks, privacy and confidentiality, and the informed consent process and forms. Non-medical, non-scientist, or lay members may review the informed consent forms (ICF) for clinical trials; however, they cannot review SAEs and SUSARs.

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5.7. Resignation, Disqualification and Replacement of Members

- 5.7.1. Members may resign their positions by submitting a letter of resignation to the IEC Chair and approved by the RICS Chair.
- 5.7.2. Members may be separated from the committee by disqualification for valid reasons as determined by majority vote of the committee members.
- 5.7.3. Members who have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.
- 5.7.4. The terms of replacements shall be limited to the remaining term of the members that they have replaced.

5.8. IEC Staff

- 5.8.1. The IEC staff is composed of the administrative support personnel who are DLSMHSI regular employees selected by the Director of Research Administration and Compliance.
- 5.8.2. The IEC Staff shall:
 - 5.8.2.1. Provide information required by research investigators regarding the IEC ethics review application process
 - 5.8.2.2. Ensure an efficient procedure to regularly monitor the review progress of research protocols submitted to IEC
 - 5.8.2.3. Conduct an initial screening of the documents submitted to IEC
 - 5.8.2.4. Assist the DLSMHSI Chair/Co-chair in logistical preparations of regular board meetings
 - 5.8.2.5. Prepare the meeting agenda and minutes of the meeting in coordination with the IEC Member-Secretary
 - 5.8.2.6. Ensure proper management of IEC databases, and physical and electronic protocol files
 - 5.8.2.7. Handle correspondences between IEC members and research investigators
 - 5.8.2.8. Provide clerical assistance in the preparation, review, revision, and distribution of SOPs
 - 5.8.2.9. Ensure the availability of relevant resource materials and references
 - 5.8.2.10. Provide any necessary administrative support for IEC-related activities of the IEC Chair

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5.9. Confidentiality/Conflict of Interest Disclosure Agreements

- 5.9.1. Each IEC member receives a copy of the Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025) along with their Appointment Letters (IEC Form 001/V3/2025 or IEC Form 002/V1/2025).
- 5.9.2. All members are required to read, understand, and sign the Confidentiality and Conflict of Interest Disclosure Agreements before commencing their ethical review responsibilities. Failure to sign the agreement may result in disqualification from serving on the committee.
- 5.9.3. Newly appointed members must carefully review the agreement, complete their details, and provide two signed and dated copies of the form.
- 5.9.4. Members may seek clarification or ask questions about the agreement from the IEC Chair or staff as needed.
- 5.9.5. Members retain one signed copy for their personal records, while the IEC staff securely files the other in the membership records.

6. GLOSSARY

- 6.1 **Alternate Members** – individuals who possess the qualifications of regular members. They are called to attend meetings and substitute for regular members to meet quorum requirements when the latter cannot attend.
- 6.2 **Confidentiality** – the duty to not disclose private or research information entrusted to an individual or organization.
- 6.3 **Conflict of Interest** – a situation where the aims or concerns of two different interests (primary and secondary) are incompatible, potentially affecting official or primary duties.
- 6.4 **Medical Members** – individuals with academic degrees in the medical profession or a master's degree in the nursing profession
- 6.5 **Non-affiliated Members** – regular members who are not part of the institution's roster of personnel or staff. They are not employees of the institution. They do not receive a regular salary or stipend from the institution.
- 6.6 **Non-medical Members** – individuals without academic degrees in the medical profession or a master's degree in the nursing profession
- 6.7 **Non-scientists** – Individuals whose primary interest is not in any of the natural, physical, or social sciences and whose highest formal education is a bachelor's degree
- 6.8 **Regular Members** – members of the research ethics committee who: receive official appointments from the institutional authority, and have specific terms and responsibilities, including the review of research proposals and attendance at meetings.
- 6.9 **Scientists** – individuals with a formal education of at least a master's degree in a scientific discipline (e.g., biology, physics, social science, etc.)

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7. FORMS

IEC Form 001/V3/2025	Appointment Letter of IEC Member (Template)
IEC Form 002/V3/2025	Appointment Letter of IEC Alternate Member (Template)
IEC Form 003/V2/2025	Confidentiality/Conflict of Interest Disclosure Agreement
IEC Form 004/V2/2024	Curriculum Vitae (Template)
IEC Form 005/V2/2024	Training Records Form

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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1. POLICY STATEMENT

The DLSMHSI-IEC shall be led by a Chair, Co-Chair, and Member-Secretary, selected from among the committee members. Eligibility for these positions requires the following:

- **Chair:** Must be a regular member with at least three years of service in the IEC. The term of chairmanship is limited to a maximum of two consecutive years. The Chair of Research Integrity, Compliance and Safety recommends potential candidate to the DLSMHSI President through channels.
- **Co-Chair and Member-Secretary:** Selected by the appointed Chair from among members who have served on the committee for at least one year, and recommended to the DLSMHSI President through channels.

2. OBJECTIVES

This activity aims to ensure that the IEC officers are qualified and are selected in a transparent manner in conformity with institutional policy and practice.

3. SCOPE

The scope of this SOP includes the selection of Chair, Co-chair, and Member-Secretary. It starts with the call for a nomination for appointment of the concerned officers and ends with the filing of appointment documents of the officers.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Call for nomination of potential IEC officers</i>	IEC Chair
Step 2: <i>Invitation of nominees</i>	IEC Chair
Step 3 <i>Acceptance of the invitation</i>	Candidate IEC Officers

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ACTIVITY	RESPONSIBILITY
Step 4 <i>Submission of names of potential IEC officers to the RICS Chair</i>	IEC Member-Secretary
Step 5 <i>Endorsement of potential officers to the VCR through the RAC Director</i>	RICS Chair
Step 6 <i>Endorsement of appointments to the DLSMHSI President through the Chancellor</i>	VCR
Step 7 <i>Approval of appointments of new officers and issuance of Appointment Letters</i>	DLSMHSI President
Step 8 <i>Forwarding Appointment Letters to new officers with Confidentiality and Conflict of Interest Disclosure Agreement</i>	IEC Staff
Step 9 <i>Receipt of Appointment Letters for new officers</i>	New IEC Officers
Step 10 <i>Signing of the conforme and submission of Appointment Letters, Confidentiality and Conflict of Interest Disclosure Agreement together with CV</i>	New IEC officer/s
Step 11 <i>Filing of appointment documents and CVs in the membership file (SOP 29: Management of Active Files)</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

5.1. Detailed Instructions

- 5.1.1. **Step 1 – Call for nomination of potential IEC officers.** The IEC Chair / Co-chair calls the IEC members for nomination of potential new officer/s. The IEC officers / members recommend or submit names of potential officers to the Chair using the Letter of Nomination (IEC Form 006/V2/2025).
- 5.1.2. **Step 2 – Invitation of nominees.** The IEC Chair evaluates the qualifications of the nominees and invites the candidates within five working days.
- 5.1.3. **Step 3 – Acceptance of the invitation.** The potential new officers accept the invitation.

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- 5.1.4. **Step 4 – Submission of names of potential IEC officers to the RICS Chair.** The IEC Chair submits the names of the potential officers to the RICS Chair for endorsement to the VCR.
- 5.1.5. **Step 5 – Endorsement of potential officers to the VCR through the RAC Director.** The RICS Chair submits recommendations for potential officers to the RAC Director, who subsequently forwards these to the VCR for endorsement.
- 5.1.6. **Step 6 – Endorsement of appointments to the DLSMHSI President through the Chancellor.** The VCR endorses the appointments to the DLSMHSI President through the Chancellor.
- 5.1.7. **Step 7 – Approval of appointments of new officers and issuance of Appointment Letters.** The DLSMHSI President approves the appointments of new officers. The RICS Chair oversees the preparation and consolidation of appointment letters, ensuring proper documentation and forwarding them to the newly appointed officers.
- 5.1.8. **Step 8 – Forwarding Appointment Letters to new officers with Confidentiality and Conflict of Interest Disclosure Agreement.** The RICS Chair instructs the IEC Staff to forward the Appointment Letters (IEC Form 007/V4/2025, IEC Form 008/V3/2025, or IEC Form 009/V3/2025) together with the Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025) to the concerned new officer.
- 5.1.9. **Step 9 – Receipt of Appointment Letters for new officers.** The new officers receive the Appointment Letters accordingly. The Appointment Letters (IEC Form 007/V4/2025 for Chair; IEC Form 008/V3/2025 for Co-chair; IEC Form 009/V3/2025 for Member-Secretary) specify the conditions of the appointment including the roles and responsibilities.
- 5.1.10. **Step 10 – Signing of the conforme and submission of Appointment Letters, Confidentiality and Conflict of Interest Disclosure Agreement together with CV.** The new officer/s sign the Appointment Letters and the Confidentiality and Conflict of Interest Disclosure Agreement.
- 5.1.11. **Step 11 – Filing of appointment documents and CVs in the membership file.** The IEC staff files the appointment documents in the membership file. (*Refer to [SOP 29: Management of Active Files](#)*).

5.2. Responsibilities of IEC Officers

5.2.1. Chair

- 5.2.1.1. Presides over IEC meetings and is accountable to the VCR
- 5.2.1.2. Prepares and submits an annual report summarizing IEC activities and decision outcomes to the VCR
- 5.2.1.3. Represents the IEC to the DLSMHSI



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- 5.2.1.4. Represents the DLSMHSI in national and international ethics fora
- 5.2.1.5. Principally responsible for the classification of study protocols
- 5.2.1.6. Assigns the primary reviewers of the initial protocols submitted for review
- 5.2.1.7. Nominates IEC members
- 5.2.1.8. As part of the composition of the IEC, adheres likewise to the roles and responsibilities of a member (*Refer to [SOP 1: Selection and Appointment of IEC Members](#)*)

5.2.2. Co-chair

- 5.2.2.1. Presides over meetings in the absence of the IEC Chair
- 5.2.2.2. Assists in the preparation and submission of annual report summarizing IEC activities and decision outcomes to the VCR
- 5.2.2.3. Represents the IEC to the DLSMHSI in the absence of the IEC Chair
- 5.2.2.4. Represents the DLSMHSI in national and international ethics fora in the absence of the IEC Chair
- 5.2.2.5. As part of the composition of the IEC, adheres likewise to the roles and responsibilities of a member (*Refer to [SOP 1: Selection and Appointment of IEC Members](#)*)
- 5.2.2.6. Performs other duties as designated by the IEC Chair

5.2.3. Member-Secretary

- 5.2.3.1. Assists the IEC Chair in evaluating protocols as to the type of review and implementing assignment of reviewers and invitation of Independent Consultants of the protocols
- 5.2.3.2. Oversees that the functions of the IEC Staff are done properly and in a timely manner
- 5.2.3.3. Assists in the assignment of the primary reviewers of the initial protocols submitted for review
- 5.2.3.4. Supports the IEC Chair in classifying study protocols
- 5.2.3.5. Supervises and supports the IEC Staff in resolving administrative issues and concerns
- 5.2.3.6. As part of the composition of the IEC, adheres likewise to the roles and responsibilities of a member (*Refer to [SOP 1: Selection and Appointment of IEC Members](#)*)

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5.3. Terms of Reference for Officers

- 5.3.1. The Appointment Letter (IEC Form 007/V4/2025, IEC Form 008/V3/2025, or IEC Form 009/V3/2025) shall indicate the officer's functions, terms of office, scope of work, and conditions of appointment.
- 5.3.2. The officers shall be appointed and serve for a period of three (3) years, renewable upon the expiration of their term up to a maximum of two (2) consecutive terms. Request for reappointment shall come from the IEC Chair, recommended by the RICS Chair, and appointed by the President.
- 5.3.3. The IEC shall adopt a mechanism for rotation of its officers' roster to enable participation of new members as officers with fresh outlook and approaches, but it shall also strive to ensure continuity, development, and maintenance of expertise.

5.4. Qualifications of Officers

- 5.4.1. Officers are selected based on their good moral character and personal capacities, their ethical and/or scientific knowledge and expertise, as well as their willingness to dedicate their time and efforts to perform their functions in the IEC.
- 5.4.2. Officers must have completed basic and advanced training in Good Clinical Practice, research ethics, Good Research Practice, and health research methodology. Their training will be recorded in the Training Records Form (IEC Form 005/V2/2024). They shall ensure to renew their GCP training every three (3) years.
- 5.4.3. Officers shall disclose in writing any financial, professional, or personal interest or involvement in a project or proposal under consideration, which is in conflict with their function as a reviewer.
- 5.4.4. Officers shall submit their Curriculum Vitae (IEC Form 004/V2/2024), properly signed and dated, and update them at least once every two (2) years.
- 5.4.5. Officers will be required to sign a Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025) at the start of their term. The agreement should cover all applications, meeting deliberations, information on research participants and related matters. The staff is likewise expected to sign a similar document. The Confidentiality and Conflict of Interest Agreement shall protect the privacy and confidentiality of all parties whose information may be disclosed to the IEC in the course of its work.
- 5.4.6. The IEC shall decide on how to manage specific conflicts of interest of members related to their participation in committee deliberations/actions regarding a particular protocol covered by the provisions of the Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025).

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5.5. Conditions of Appointment of Officers

All prospective IEC officers must be willing to:

- 5.5.1. Make public his/her full name, profession, and affiliation as a IEC member.
- 5.5.2. Disclose all financial accountability, reimbursement for work and expenses, related to their work in IEC that shall record and publicly disclose its financial records upon request.
- 5.5.3. All IEC officers and independent consultants shall sign the Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025) regarding meeting deliberations, applications, information on research participants and related matters.

5.6. Resignation, Disqualification and Replacement of Members

- 5.6.1. Officers may resign their positions by submitting a letter of resignation. The letter of resignation shall be submitted to the Chair or RICS. The Chair of the RICS shall approve/disapprove the resignation upon consultation with the officer and the Chair of IEC.
- 5.6.2. Officers who have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.
- 5.6.3. The terms of replacements shall be limited to the remaining term of the officers that they have replaced.

6. GLOSSARY

- 6.1 **Appointing authority** – the institutional official that has the power to designate or appoint individuals to specific offices or roles.
- 6.2 **Conforme** – acceptance of or agreement to an assignment or designation.
- 6.3 **Majority rule** – a policy based on the principle that the decision made by the greater number should be carried/accepted.
- 6.4 **Secret Ballot** – a system of casting votes (opinions or choices) such that the voters are not identified or are anonymous.
- 6.5 **Special meeting** – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action.
- 6.6 **Term of office** – the specified length of time that a person serves in a particular designation/role.

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7. FORMS

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IEC Form 007/V4/2025	Appointment Letter of IEC Chair (Template)
IEC Form 008/V3/2025	Appointment Letter of IEC Co-Chair (Template)
IEC Form 009/V3/2025	Appointment Letter of IEC Member-Secretary (Template)

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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	<p>III. APPOINTMENT OF INDEPENDENT CONSULTANTS AND ASSIGNMENT OF PROTOCOLS</p>	

1. POLICY STATEMENT

The DLSMHSI-IEC shall maintain a roster of independent consultants who can be engaged as needed to provide specialized expertise for the review of specific study protocols. These consultants are not required to be affiliated with the institution.

The IEC Chair identifies the need for expertise beyond the scope of the current IEC members and, with prior approval from the DLSMHSI President through appropriate channels, extends invitations to qualified professionals with specialized scientific knowledge. These individuals are selected to address gaps in expertise within the current IEC composition, ensuring comprehensive and informed reviews.

2. OBJECTIVES

This activity aims to ensure that the appointment of independent consultants conforms with the institutional practice and complements the pool of expertise in the IEC.

3. SCOPE

This SOP specifically pertains to the selection and designation of independent consultants in the review of research protocols of the IEC, and their assignment to review protocols. This SOP begins with the identification of the study that requires an independent consultant to the inclusion of the name of the independent consultant in the pool of consultants, and ends with submission of protocol assessment form.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1 <i>Identification of need for Independent Consultant</i>	IEC Chair
Step 2 <i>Selection and invitation for selected professionals</i>	IEC Chair

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ACTIVITY	RESPONSIBILITY
Step 3 <i>Acceptance of the invitation</i>	Independent Consultant
Step 4 <i>Communication and approval of the Independent Consultant</i>	IEC Chair
Step 5 <i>Appointment of the Independent Consultant</i>	DLSMHSI President
Step 6 <i>Inclusion in the roster of Independent Consultants</i>	IEC Staff
Step 7 <i>Filing of appointment documents and CVs in the roster of Independent Consultants file</i>	IEC Staff
Step 8 <i>Identification of study protocol that requires the expertise of Independent Consultants</i>	Primary Reviewer
Step 9 <i>Selection from the roster of Independent Consultants and assignment of protocol</i>	IEC Chair
Step 10 <i>Review and completion of Protocol Assessment Form</i>	Independent Consultant
Step 11 <i>Submission of Protocol Assessment Form</i>	Independent Consultant

5. DESCRIPTION OF PROCEDURES

DETAILED INSTRUCTIONS

5.1. Identification and Appointment of Independent Consultants

- 5.1.1. **Step 1 – Identification of need for Independent Consultant.** The IEC Chair identifies the need for independent consultants based on commonly reviewed protocols and the gap in expertise of the current IEC members.

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- 5.1.2. **Step 2 – Selection and invitation for selected professionals.** The IEC Chair, in consultation with the VCR, identifies various professionals with specific expertise to fill in the gap and invites them to be part of the IEC roster of independent consultants. (IEC Form 010/V1/2025)
- 5.1.3. **Step 3 – Appointment of Independent Consultant.** A Letter of Invitation (IEC Form 010/V1/2025) is sent to selected professionals and shall include the Terms of Reference, Roles and Responsibilities and Conditions of Appointments. A section for acceptance of the invitation is also included.
- 5.1.4. **Step 4 – Communication and approval of the Independent Consultant.** Upon the acceptance of the invitation, the IEC Chair informs the RICS Chair who compiles the proposed roster and submits it to the DLSMHSI President through appropriate channels for review and approval.
- 5.1.5. **Step 5 – Appointment of the Independent Consultant.** Once approved, the RICS Chair prepares an individual Letter of Appointment (IEC Form 0011/V3/2025) signed by the DLSMHSI President.
- 5.1.6. **Step 6 – Inclusion in the roster of Independent Consultants.** The Independent Consultants are required to sign the Letter of Appointments together with the Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2025).
- 5.1.7. **Step 7 – Filing of appointment documents and CVs in the roster of Independent Consultants file.** After signing the required documents, the Independent Consultant is included in the IEC Roster of Independent Consultants, and an Independent Consultant File shall be created.

5.2. Assignment of Protocol to Independent Consultants

- 5.2.1. **Step 8 – Identification of study protocol that requires the expertise of Independent Consultants.** The IEC Primary Reviewer identifies the study that requires an expertise necessary in the review of a research proposal and that may not be provided by the current members of IEC, and communicates the same to the IEC Chair.
- 5.2.2. **Step 9 – Selection from the roster of Independent Consultants and assignment of protocol.** The IEC Chair refers to the roster of Independent Consultants and selects consultants based on their expertise.
- 5.2.3. **Step 10 – Review and completion of Protocol Assessment Form.** A Letter of Assignment (IEC Form 012/V1/2025) is issued by the IEC Chair together with the Protocol Assessment Form (IEC Form 0017/V4/2025).
- 5.2.4. **Step 11 – Submission of Protocol Assessment Form.** The Independent Consultant shall review the protocol, completes the Protocol Assessment Form (IEC Form 0017/V4/2025) and submit it to the IEC Chair.

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5.3. Responsibilities of Independent Consultants

- 5.3.1. The independent consultants shall focus their review on:
- 5.3.1.1. Scientific procedures and methodology
 - 5.3.1.2. Any information about the disease or research topic, and the proposed interventions
 - 5.3.1.3. Benefits and risks of the intervention and how to mitigate the risk
- 5.3.2. They must complete the assessment form to be reviewed by the IEC at the time the study is reviewed.
- 5.3.3. They may attend the board meeting, present their assessment, and participate in the discussion, but they will not be allowed to vote. Their report becomes a permanent part of the study file.
- 5.3.4. The non-medical consultant reviews the ethical considerations in the conduct of the research, which includes: social value, vulnerability issues, risk vs benefit, measures to mitigate risks, privacy and confidentiality, and the informed consent process and forms. Non-medical, non-scientist, or lay members may review the ICF for clinical trials; however, they cannot review SAEs and SUSARs.

5.4. Termination of Services

- 5.4.1. The services of a consultant may be discontinued either at the consultant's request or at the discretion of the IEC.
- 5.4.2. Upon termination of the consultant's services, the IEC Staff shall ensure that all the necessary documentation related to the Independent Consultant is filed with the other administrative documents.

6. GLOSSARY

- 6.1. **Database** – a structured/organized collection of information so that the data can easily be accessed, managed, and updated
- 6.2. **Expertise** – a proficiency, skill or know-how possessed by experts in a certain academic or professional field
- 6.3. **Independent Consultants** – resource persons who are not members of the IEC, whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberations

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7. FORMS

IEC Form 010/V1/2025	Letter of Invitation for Independent Consultant (Template)
IEC Form 007/V3/2025	Appointment Letter of IEC Independent Consultant (Template)
IEC Form 012/V1/2025	Letter of Assignment for Independent Consultants (Template)
IEC Form 0017/V4/2025	Protocol Assessment Form

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

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1. POLICY STATEMENT

The ongoing education and training of DLSMHSI-IEC members and staff are essential to maintaining alignment with updated international, national, and institutional guidelines. This ensures that all members and staff remain knowledgeable and capable of fulfilling their roles with competence and consistency.

All IEC members and staff are required to participate in relevant training throughout their appointment. They are expected to continuously update their knowledge and skills to address emerging ethical, regulatory, and procedural developments. The IEC Chair is responsible for encouraging members and staff to attend necessary training programs, seminars, and workshops and for ensuring that appropriate resources are allocated for their professional development.

To support this commitment, DLSMHSI, through the Research Education, Training and Development (RETD) unit, is tasked with planning and allocating an annual budget for research training and educational activities, including training workshops for research ethics.

2. OBJECTIVES

This SOP describes IEC procedures to ensure initial and continuing training and professional education of members and staff.

3. SCOPE

This SOP applies specifically to the process of providing training to the IEC members and staff. It begins with the identification of training needs and ends with the filing of training records of IEC members in the membership file.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Identification of training needs of the IEC members</i>	RICS Chair IEC Members



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ACTIVITY	RESPONSIBILITY
Step 2: <i>Inclusion in the Research Services Training Plan and/or finding available training by external providers</i>	RETD Chair
Step 3: <i>Request for training by the IEC members and/or staff</i>	IEC members and staff
Step 4: <i>Evaluation and recommendation for training</i>	RICS Chair
Step 5: <i>Approval of the training and budget allocation</i>	RICS Chair, RETD Chair
Step 6: <i>Attendance in training and updating of training record</i>	IEC Members and Staff
Step 7: <i>File certificate of training in IEC membership file and update training records</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

5.1. Step 1 – Identification of training needs of the IEC members

5.1.1. The RICS Chair periodically reviews compliance with basic training requirements, training needs, expiry of training certifications (e.g., GCP has a 3-year validity period), and plan for continuing professional education of IEC members and staff. The following are required courses:

- 5.1.1.1. Good Clinical Practice (GCP)
- 5.1.1.2. Good Research Practice (GRP)
- 5.1.1.3. Basic Research Ethics Training (BRET)
- 5.1.1.4. IEC SOP Training

5.1.2. The IEC members and staff may also request training, workshops, and attendance to conferences based on identified needs of the committee and its members and new trends in health research ethics. Such requests shall be submitted to the RICS Chair who will review the training request.

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5.2. Step 2 – Inclusion in the Research Services Training Plan and/or finding available training by external providers

- 5.2.1. The RICS Chair coordinates the training requirement with the RETD unit. The RETD Chair includes the CPE in the Research Services Training Plan, allocates the necessary budget, and confirms its inclusion in the plan.
- 5.2.2. In cases where the training requirement cannot be included in the Training Plan, the RETD will look for the availability of other training providers, allocate the necessary budget, and coordinate with the RICS.

5.3. Step 3 – Request for training by the IEC members and/or staff

- 5.3.1. The IEC members or staff communicate their intention to attend available training, whether internal or external, using the Training Request Form (RICS Form 05/V1/2025) to the RICS Chair at least one month prior to the date of training.
- 5.3.2. For internally conducted training, the RICS Chair communicates the availability of training to the IEC members, and requests them to fill-out the Training Request Form (RICS Form 05/V1/2025). The Form shall be submitted to the RETD for approval and inclusion in the list of attendees.
- 5.3.3. For externally conducted training, the RICS Chair shall coordinate the training request to the RETD for review of training opportunities, budget certification and processing. Once approved, the member may register his/her attendance to the training program.

5.4. Step 4 – Evaluation and recommendation for training. The RICS Chair reviews and endorses the training request to the VCR through proper channels.

5.5. Step 5 – Approval of the training and budget allocation. If the training requested is in the Research Services Training Plan, the RICS Chair approves the request and coordinates with the RETD Chair on pertinent logistics.

5.6. Step 6 – Attendance in training and updating of training record.

- 5.6.1. The IEC members or staff attend the training and submit the Certificate of Participation/Attendance to the RICS Chair.
- 5.6.2. The certification shall be made available in the membership file.
- 5.6.3. The member shall also update his/her CV and training records.
- 5.6.4. Attendees are also encouraged to echo their experiences and learnings during the regular monthly board meeting.

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6. GLOSSARY

- 6.1. **Basic Research Ethics Training** – foundational training in research ethics that covers principles, guidelines, and practices to ensure the ethical conduct of research, particularly involving human participants.
- 6.2. **Echo training** – a practice where attendees share their learnings and experiences from a training program with other committee members during a regular meeting to disseminate knowledge and improve collective expertise.
- 6.3. **Good Clinical Practice** – an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials involving human participants. Compliance ensures the rights, safety, and well-being of trial participants and the credibility of trial data. GCP training is typically valid for three years.
- 6.4. **Good Research Practice** - A set of standards ensuring the quality, integrity, and reproducibility of research, promoting ethical and professional conduct throughout the research lifecycle.

7. FORMS

RICS Form 05/V1/2025
 IEC Form 005/V2/2024

Training Request Form
 Training Records Form

8. HISTORY

Version No.	Date	Authors	Main Revision
1	22 Oct. 2012	Dr. Melchor Victor G. Frias IV	
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1. POLICY STATEMENT

The IEC requires the submission of a complete set of pertinent documents for an application for ethical review. A **preliminary evaluation** determines whether a research proposal is exempted from review or requires ethical review, following the criteria outlined in the *2022 National Ethical Guidelines for Research Involving Human Participants (NEGRIHP 2022)* The Ethics Review Process. Protocols exempted from review must resubmit any amendments for reevaluation to confirm if the revised protocol still qualifies for exemption.

The **classification of protocol review** is based on the level of risk involved and adheres to the guidelines from the *2022 NEGRIHP*, *CIOMS (2016)*, and *Declaration of Helsinki (2013)*:

- **Exemption from Review:** Applies to protocols with minimal or no risk to participants. While exempted from standard review processes, these studies remain subject to ethical considerations.
- **Expedited Review:** Applies to protocols with minimal risk that do not include vulnerable groups or generate vulnerability.
- **Full-Board Review:** Required for protocols involving more than minimal risk, participation of vulnerable groups, or procedures that generate vulnerability.

This structured approach ensures that ethical review processes are proportionate to the level of risk posed by each research protocol.

2. OBJECTIVES

This SOP ensures that study documents are complete, properly recorded, and properly evaluated to determine appropriate action or type of review.

3. SCOPE

The IEC accepts the study protocols on health-related research dealing with human participants. Study protocols that may be accepted are as follows:

- Research conducted by members of DLSMHSI
- Research done in DLSMHSI by other institutions
- Research referred by the PNHRs, PHREB, DOH, industry organizations, or other academic institutions may be reviewed by the IEC, provided there is a formal agreement with the host hospital or institution where the research will be conducted. The host hospital or institution must explicitly accept the IEC's review and agree to adhere to its rules and regulations, which are based on PHREB and FERCAP standards. Additionally, other research sites involved must ensure a conducive environment for the safe and ethical conduct of the research. This includes

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providing oversight, stewardship, and monitoring procedures as deemed necessary by the IEC. These conditions must be documented in a formal agreement signed by the participating hospitals or institutions acknowledging and accepting the IEC review.

- Protocols referred by the Single Joint Review Ethics Board (SJREB) to be submitted by Sponsor/Principal Investigator (PI) or its representative where the IEC is one of the sites of a multicenter research (Appendix 2: DOH Administrative Order No. 2017-0021).

This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database and filing of the original study protocol package in the Active Study File cabinet.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1 <i>Receipt of study protocol package for initial screening</i>	IEC Staff
Step 2 <i>Assessment of the completeness and correctness of the protocol package and notifies the PI</i>	IEC Staff
Step 3 <i>Assignment of permanent code to the package</i>	IEC Staff and Member-Secretary
Step 4 <i>Logging the received protocol in the IEC database</i>	IEC Staff
Step 5 <i>Classifying the protocols into Exempt, Expedited, or Full-Board Review (SOP 7: Exempt from Review; SOP 8: Expedited Review; SOP 9: Full-Board Review)</i>	IEC Chair, Co-chair, or Member-Secretary
Step 6 <i>Assignment of the primary reviewers</i>	IEC Chair, Co-chair, or Member-Secretary
Step 7 <i>Distribution of copies of the protocol package to the reviewers</i>	IEC Staff
Step 8 <i>Filing the original protocol package in a properly coded Protocol File folder and place it in the Active Study File cabinet (SOP 29: Management of Active Files)</i>	IEC Staff

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5. DESCRIPTION OF PROCEDURES

5.1. Step 1 – Receipt of study package for initial screening.

- 5.1.1. The IEC staff receives one hard copy and one electronic copy (online) of the study protocol package for review.
- 5.1.2. All study protocols must obtain technical approval before proceeding to ethical review.
 - For **DLSMHSI-initiated protocols**, the protocol package submitted to the IEC must include a certification of technical approval. This certification should be signed by the Chair of the Technical Review Committee (institutional or departmental) and/or the Director of Research Administration and Compliance, indicating that the protocol has been reviewed and approved.
 - For **non-DLSMHSI-initiated protocols**, a document certifying that the research protocol has undergone and passed a technical review must be included with the submission for ethical review.
- 5.1.3. The PI submits protocol/proposal submission packages for review between the 1st and 15th day of each month, from 8:00 am to 5:00 pm.
- 5.1.4. Protocols must adhere to the standard protocol format and include a **Protocol Submission Checklist (IEC Form 013/V3/2025)**.
- 5.1.5. The **Protocol Review Application (IEC Form 014/V2/2025)** must be signed by the Principal Investigator (PI). A copy of the completed application form is retained by the IEC, and a duplicate is provided to the PI or their representative.
- 5.1.6. Study protocols qualified for SJREB review are given instructions to submit to SJREB and given endorsement letter to SJREB.
- 5.1.7. A **Protocol Package** has to include the following:

Basic Documents (must submit for initial review)

- Protocol Review Application (IEC Form 014/V2/2025)
- Protocol Submission Checklist (IEC Form 013/V3/2025)
- Study Protocol (complete with relevant documents)
- Data Collection Forms (including Case Report Forms or CRFs)
- Protocol Synopsis and Diagrammatic workflow (IEC Form 016/V1/2025)
- Curriculum Vitae for Principal Investigators, the study team members, and the Adviser if applicable (IEC Form 015/V3/2025)
- Technical Review Certificate

Study-Specific Documents (submit as needed)

- Institutional Endorsement from the Vice Chancellor, Dean, or Medical Director (for research by students, faculty, staff, or medical residents)
- Investigator's Brochure (for Clinical Trials Phase I , II, III) or Basic Product Information Document (for Clinical Trial Phase IV)



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- Informed Consent Form or ICF (for studies with human participants)
 - must include an English version and a Tagalog and/or other local language version/s
 - must have Version No., Date, Page No. in the footer
- Parent's Consent Form (for studies involving children/minor and relevant populations)
 - must include an English version and a Tagalog and/or other local language version/s
 - must have Version No., Date, Page No. in the footer Tagalog and/or other local version/s
- Assent Form (for studies involving minors and relevant populations deemed incompetent to sign an ICF)
 - must include an English version and a Tagalog and/or other local language version/s
 - must have Version No., Date, Page No. in the footer Tagalog and/or other local version/s
- Training Certificate in Health Research Ethics of PI, Co-investigator (Co-I), and the rest of the study team or Certificate of Good Clinical Practice (GCP) for clinical trials obtained within the last three years
- Recruitment advertisements (as needed by the study protocol)
- Other information or documents for participants (such as diaries, etc.)
- Certificate of Approval from the Institutional Biosafety Committee (for studies involving hazardous biological materials)
- Material Transfer Agreement (for any research involving transfer of biological specimens)
- Memorandum of Agreement or Terms of Reference (for collaborative studies)
- Grants Acquisition and Management (GAM)-endorsed Clinical Trial Agreement with approval from the Institutional Contract Review Committee (ICRC) (for sponsor-initiated clinical trials done in DLSMHSI)
- Site Resources Checklist (for clinical trials outside DLSMHSI done by DLSMHSI staff)
- Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
- National Commission for Indigenous People Clearance (for studies with indigenous populations) **can be processed while IEC review is ongoing*
- Insurance/Indemnity Policy
- Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)

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- 5.2. **Step 2 – Assessment of the completeness and correctness of the protocol.** The IEC staff verifies the completeness and correctness of all documents submitted using the **Protocol Submission Checklist (IEC Form 013/V3/2025)** including the completeness of all required information in the application form. Incomplete submission and incomplete information in the application form will be returned 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.
- 5.3. **Step 3 – Assignment of permanent code to the package.** If the documents are determined to be complete, the IEC staff with the supervision of the Member-Secretary assigns a permanent protocol code. This code is the ID number of the protocol and cannot be assigned to any other protocol. When referring to the protocol in communications or presentations, the code will always be indicated for easier referencing. All codes will follow the format: **Year submitted (e.g., 2025) – Assigned Protocol Number (e.g., 001) – Type of Research – Status of Research.**
- 5.3.1. Code for Type of Research
- 01 – Clinical Trial
 - 02 – Epidemiological (Cohort/Case-Control/Cross-Sectional)
 - 03 – Basic Science
 - 04 – Behavioral
 - 05 – Social Science
 - 06 – Community
 - 07 – Medical Devices
 - 08 – Bioavailability/Bioequivalence Studies
 - 09 – Health Economics
 - 10 – Others
- 5.3.2. Code for Status of Research
- A – **Active** (Ongoing study, no close-out or final report notification)
 - I – **Inactive** (Final study report approved, or no post-review response from PI more than 90 days, or no notification of termination)
 - C – **Completed** (Close-out notification submitted or final report not yet approved)
 - T – **Terminated** (Termination notification submitted before/during study implementation)
- 5.4. The protocol is logged in the DLSMHSI database and logbook. It is an official document that contains the receipt of a particular documents on a specific date and time. It includes information on (1) Title of the Study, (2) Name of Proponent, (3) Date of Submission, (4) Name of Receiver, and (5) Action. It is also good to include the name and signature of the individual who actually submitted the documents in case he/she is not the proponent.

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- 5.5. The IEC Chair, Co-chair, or Member-Secretary conducts a preliminary review of the protocol to determine level of ethical review: **Exempted from Review**, **Expedited Review**, or **Full-board Review**.
 - 5.5.1. If the preliminary reviewer decides that the protocol is exempted from review, he/she directs the IEC staff to follow the procedure to communicate the decision to the researcher. (Refer to **SOP 7: Exempt from Review**; **SOP 27: Communicating DLSMHSI-IEC Decisions**)
 - 5.5.2. If the preliminary reviewer determines that the protocol should undergo either Full or Expedited Review, then the IEC staff proceeds to follow either **SOP 8: Expedited Review** or **SOP 9: Full-Board Review**.
- 5.6. The IEC Chair, Co-chair, or Member Secretary assigns the primary reviewers. Primary reviewers are selected based on expertise related to the protocol.
- 5.7. The IEC Staff prepares the copies of protocol package for distribution to the reviewers. Alternatively, they may simply email the electronic copy of the protocol package. Only reviewers requesting for hard copies will be provided with such and sent physically.
- 5.8. The IEC Staff compiles the original package in a properly coded Protocol File folder (Refer to **SOP 29: Management of Active Files**). The complete Protocol File folder is filed for safekeeping in the Active Study File cabinet (Refer to **SOP 29: Management of Active Files**). Electronic database is likewise updated as to the type of review and assigned primary reviewers.

6. GLOSSARY

- 6.1. **Amendment** – a change in or revision of the protocol made after its approval
- 6.2. **Coding** – a unique number assigned to a protocol indicating the year and series it was received
- 6.3. **Database** – a collection of information 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. **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 NEGRH 2022 or 2022 National Ethical Guidelines for Research Involving Human Participants
- 6.5. **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
- 6.6. **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

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- 6.7. **Logbook** – a real-time, chronological record of incoming protocols that includes the Date/Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action Done
- 6.8. **Initial Review** – ethical and technical review conducted on the initially-submitted study documents. It may be expedited or full.
- 6.9. **Initial Submission** – a set of documents consisting of the full proposal and other study-related documents that need to be submitted so that review can be conducted
- 6.10. **Study Documents** – include all materials protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the IEC for review

7. FORMS

IEC Form 013/V3/2025	Protocol Submission Checklist
IEC Form 014/V2/2025	Protocol Review Application
IEC Form 015/V2/2025	Curriculum Vitae for Principal Investigators / Team Members (Template)
IEC Form 016/V2/2025	Protocol Synopsis and Diagrammatic Workflow

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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Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
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Approved by:	
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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:	<i>Submission of protocol package to IEC Chair, Co-chair, or Member-Secretary</i>	IEC Staff
Step 2:	<i>Conduct of Preliminary Review of the Protocol for Classification and Assignment of Primary Reviewers</i>	IEC Chair, Co-chair, or Member-Secretary
Step 3	<i>Preparation of copies of protocol package for distribution</i>	IEC Staff

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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 Assignment 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.

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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 NEGRHP 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 *NEGRHP (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
 IEC Form 017/V4/2025

Protocol Review Application
 Protocol Assessment Form

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8. HISTORY

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

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

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	ACTIVITY	RESPONSIBILITY
Step 7:	<i>Presentation of protocols exempted from review during full board review meeting.</i>	IEC Chair, Co-Chair, Member Secretary
Step 8:	<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	

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Version:	5
Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
Effective date:	January 2025
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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.

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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.

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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
Step 3: <i>Conduct of review and accomplishment of assessment forms</i>	Primary Reviewer and Independent Consultant/s
Step 4: <i>Consolidation and finalization of the review results or referral of protocol to full board review</i>	IEC Chair
Step 5: <i>Communication of review results to the researcher (SOP 27: Communicating of IEC Decisions)</i>	IEC Chair and Staff
Step 6: <i>Filing of documents in the protocol database (SOP 29: Management of Active Files)</i>	IEC Staff
Step 7: <i>Presentation of the result of the expedited review during full board meeting.</i>	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**)

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- 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.

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- 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 NEGRH 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.

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- 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
 IEC Form 017/V4/2025
 IEC Form 021/V3/2025
 IEC Form 019/V1/2025
 IEC Form 022/V4/2025

Protocol Submission Checklist
 Protocol Assessment Form
 Informed Consent Form (ICF) Assessment Form
 Notification Letter of Review Decision
 Certificate of Approval for Reviewed Protocols

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8. HISTORY

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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	
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INDEPENDENT ETHICS COMMITTEE

IX. FULL-BOARD REVIEW

DLSMHSI-IEC SOP Ver. 5

Approval Date:

Effective Date:
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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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Supersedes:	DLSMHSI-IEC SOP Chapter 2: 2.4. Review of Medical Device Protocol / V4 / 2024
Version:	5
Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
Effective date:	January 2025
Approved by:	
Approval date:	Pending

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1. POLICY STATEMENT

Experimental research often involves the use of medical devices, which, like drugs and other interventions, are investigated for their potential medical applications. As with other types of ethical reviews, the benefits and risks of medical devices to human participants are carefully assessed. However, the review process for medical devices has unique considerations due to the technical complexity of these devices, often necessitating the involvement of independent consultants with specialized expertise. These consultants provide insights into the technical and operational aspects of the device, which may be beyond the scope of the IEC members' expertise.

Depending on the level of risk posed by the medical device, the review process may follow either a full-board review or an expedited review pathway, ensuring that both the technical and ethical dimensions of the research are rigorously evaluated to safeguard participant welfare and uphold research integrity. Medical device protocols are reviewed using these procedures based on the risk classification of the investigational device. Devices are classified as Significant Risk (SR) or Non-Significant Risk (NSR) by regulators in the sponsor country, and this classification must be provided by the sponsor to the IEC. During the review process, the IEC evaluates the protocol and related documents to identify and implement measures to minimize risks to human participants.

2. OBJECTIVES

The activity aims to review research involving the use of medical devices on human participants, focusing on evaluating all relevant technical and safety data related to the device. It also assesses the level of risk posed to participants to ensure their safety and well-being. When necessary, the review process may include collaboration with an independent consultant possessing specialized knowledge and expertise on the medical device to provide a comprehensive and informed evaluation.

3. SCOPE

This policy governs the ethical review of research involving medical devices. It applies to studies using investigational medical devices and those utilizing previously approved devices that are being re-evaluated due to modifications or new applications.

According to the World Health Organization (WHO), a medical device is “any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings” for “specific medical purpose(s).” Unlike drugs, the effects of medical devices are not achieved through direct physiological interaction but rather through their intended use or application.

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Medical devices are utilized for a variety of specific purposes, including but not limited to:

- Diagnosis, treatment, and monitoring of diseases or injuries
- Augmentation, modification, or replacement of anatomic functions
- Life support
- Birth control
- Disinfection of other devices

The review of investigational medical devices shall include an evaluation of the benefits and risks to human participants within the context of the device's specific intended medical purpose. This policy also applies to the review of medical devices that:

- Have undergone modifications to their form, components, or design that may introduce new risks or benefits
- Are being repurposed for novel uses or “off-label” applications
- Are newly tested in the Philippines but previously approved in other countries

This SOP proceeds similarly as *SOP 5: Management of Initial Submissions*, as well as *SOP 8: Expedited Review* and *SOP 9: Full-Board Review*. It begins with the receipt of study documents for initial review and ends with the filing of protocol-related documents and updating of the protocol database.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt of submitted documents for review, verification of completeness and correctness, acknowledgment of receipt, coding, and logging (SOP 5: Management of Initial Submissions)</i>	IEC Staff
Step 2: <i>Determination of review type (Expedited or Full Board) based on SR or Non-SR classification and assignment of reviewers</i>	IEC Chair
Step 3: <i>Review of protocol documents using assessment forms and submission of decision/recommendation to the IEC staff</i>	Primary Reviewer
Step 4: <i>Communication of expedited review decision to reviewers for approval or revision and notification to the PI</i>	IEC Staff
Step 5: <i>Inclusion of protocol in the next meeting agenda for discussion and decision by the full board</i>	IEC Staff

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ACTIVITY	RESPONSIBILITY
Step 6: <i>Revision of protocol or related documents based on required modifications and resubmission to the IEC</i>	PI
Step 7: <i>Preparation of Certificate of Approval for Reviewed Protocols (IEC Form 022/V4/2025) by the staff, signature by the Chair, and communication to the PI</i>	IEC Staff
Step 8: <i>Compilation and storage of all related documents in respective protocol files</i>	IEC Staff
Step 9: <i>Updating of the IEC database</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Receipt of submitted documents for review, verification of completeness and correctness, acknowledgment of receipt, coding, and logging.** The IEC Staff receives submitted documents. The application documents received from investigator submission are checked for completeness and correctness using the Protocol Submission Checklist (IEC Form 013/V3/2025) as guide. After checking the documents are complete, the Staff signs a copy of the Protocol Review Application (IEC Form 014/V2/2025) to acknowledge receipt of the documents and return a copy to the principal investigator or a duly designated representative. For an all-electronic or online submission the staff shall likewise accordingly acknowledge the receipt online. Protocol is coded and recorded in the logbook and database.
- 5.2. **Step 2 – Determination of review type (Expedited or Full Board) based on SR or Non-SR classification and assignment of reviewers.** The Chair determines if the protocol is for expedited or full-board review depending on Significant Risk (SR) or Non-Significant Risk (NSR) determination and assigns reviewers to review the protocol and related documents within three days after the submission deadline. The information/communication from the principal investigator are checked as related to the SR or NSR determination by regulators (FDA) from the sponsor country. The protocol is assigned to expedited review or full board review depending on the risk assessment.
- 5.3. **Step 3 – Review of protocol documents using assessment forms and submission of decision/recommendation to the IEC staff.** The Primary Reviewers review the protocol documents using the Protocol Assessment Form (IEC Form 017/V4/2025) and the Informed Consent Form (ICF) Assessment Form (IEC Form 021/V3/2025) and submit the

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decision/recommendation to the IEC Staff at least five working days prior to the scheduled meeting.

- 5.3.1. Primary reviewers with appropriate expertise are assigned to review the protocol and related documents.
- 5.3.2. It is advisable that a bioengineer with appropriate experience related to the medical device together with a medical doctor with related clinical experience are assigned to review the protocol while a non-medical non-scientific lay member reviews the consent form.
- 5.3.3. When reviewing a medical device protocol, the reviewer should also consider the following:
 - Proposed investigational plan (use of the device in the study)
 - Informed Consent Form
 - Description of the device / product information
 - Description of study participant selection criteria
 - Reports of prior investigations conducted with the device
 - CV of the Principal Investigator
 - Risk assessment determination for new investigational device (significant risk or non-significant risk)
 - Safety monitoring procedure
 - Copies of all labeling for investigational use
 - Statistical plan and analysis
- 5.4. **Step 4 – Communication of expedited review decision to reviewers for approval or revision and notification to the PI.** The IEC Staff communicates the decision of the expedited reviewers (for approval, disapproval or revision) to the Primary Investigator within 1 week (7 days) after the decision is made.
- 5.5. **Step 5 – Inclusion of protocol in the next meeting agenda for discussion and decision by the full board.** The IEC Staff the protocol in the next meeting agenda for discussion and decision by full board. On full board review, a decision (for approval, disapproval or revision) is made after discussion and the PI is notified of the decision within 1 week (7 days) after the decision is made. If the protocols are for revision, they are sent back to the Principal Investigator for modification. Documents are resubmitted and reviewed at the level of the Chair/Co-Chair through expedited channels for minor revision or sent to primary reviewers for full board review if major modifications are required.
- 5.6. **Step 6 – Revision of protocol or related documents based on required modifications and resubmission to the IEC.** If modifications are required, the Principal Investigator is to revise the protocol or related documents and resubmit to the IEC.
- 5.7. **Step 7 – Preparation of Approval Letter (Form __) by the staff, signature by the Chair, and communication to the PI.** When a decision is reached after resubmission, as applicable, the Certificate of Approval for Reviewed Protocols (IEC Form 022/V4/2025) or a Notification Letter of Review Decision (IEC Form 019/V1/2025) is prepared by the Staff, signed by the Chair and

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communicated to the Principal Investigator. The frequency of continuing review is indicated in the approval letter.

- 5.8. **Step 8 – Compilation and storage of all related documents in respective protocol files.** The IEC Staff keeps copies of all related documents and compiles them in their respective protocol files.
- 5.9. **Step 9 – Updating of the IEC database.** The IEC Staff updates the IEC database.

6. GLOSSARY

- 6.1. **Expedited Review** – a streamlined review process for research protocols that pose minimal risk to participants. Only selected reviewers evaluate the protocol instead of the full board.
- 6.2. **Full-board Review or Full Review** – a comprehensive review conducted by the entire ethics committee for protocols that involve more than minimal risk or complex study designs.
- 6.3. **Informed Consent Form (ICF)** – a document that provides participants with clear and comprehensive information about the study, including its purpose, procedures, risks, benefits, and their rights, to ensure voluntary participation.
- 6.4. **Non-significant Risk (NSR) Device** – a medical device that does not pose a significant risk to participants and is typically subject to less stringent regulatory requirements. Examples include diagnostic devices and tools for routine clinical use.
- 6.5. **Protocol Database** – a secure system used to record, track, and update information on submitted protocols, including review outcomes, required modifications, and continuing review schedules.
- 6.6. **Protocol Package** – a comprehensive set of documents submitted by the Principal Investigator for ethical review, including the protocol, informed consent forms, investigator qualifications, and other supporting materials.
- 6.7. **Safety Monitoring Procedure** – a plan to monitor and address safety concerns during the study, including adverse events and unanticipated risks, to protect participants.
- 6.8. **Significant Risk (SR) Device** – a medical device that poses a potential for serious risk to the health, safety, or welfare of participants. This includes devices used for implants, life support, or sustaining human life.

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7. FORMS

EC Form 013/V3/2025	Protocol Submission Checklist
IEC Form 014/V2/2025	Protocol Review Application
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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Version:	5
Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
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Approved by:	
Approval date:	Pending

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1. POLICY STATEMENT

Assigned Primary Reviewers are required to submit completed assessment forms to provide a thorough evaluation of the study protocol. This includes reviewing the scientific design, identifying ethical issues, and assessing corresponding measures to minimize risks to human participants, laboratory animals, and the environment. Additionally, the evaluation covers the informed consent processes and forms to ensure clarity and compliance with ethical standards.

The names of the Primary Reviewers will be indicated on the assessment forms by the IEC Staff after the PI submits a complete protocol package.

2. OBJECTIVES

A comprehensive review of submitted study protocols is facilitated by the use of guided and detailed assessment forms. These forms ensure that all critical aspects of the study, including scientific design, ethical considerations, and the essential elements of informed consent from human participants, are thoroughly evaluated.

Primary reviewers must also ensure that the study protocol complies with applicable international and national guidelines and policies, including, but not limited to, the *2022 National Ethical Guidelines for Research Involving Human Participants* and the *Data Privacy Act of 2012*.

The assessment forms are specifically designed to standardize the review process, promote consistency, and facilitate the clear reporting of findings and recommendations related to the study protocol and its accompanying documents.

3. SCOPE

This SOP covers the use of the Protocol Assessment Form (IEC Form 017/V4/2025) and Informed Consent (ICF) Assessment Form (IEC Form 021/V3/2025) in the review and assessment of protocols and related documents submitted to IEC for initial review and approval. This SOP begins with the review exercise and accomplishment of the assessment forms including findings as well as recommendations and ends with the filing of the accomplished assessment forms in the respective protocol folders.

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4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Filling out of Part I of the Protocol Assessment Form (IEC Form 017/V4/2025) and Informed Consent (ICF) Assessment Form (IEC Form 021/V3/2025).</i>	IEC Staff
Step 2: <i>Filling out of the Part II and III of the assessment forms.</i>	Primary Reviewers
Step 3: <i>Forwarding of the accomplished assessment forms to the IEC Staff</i>	Primary Reviewers & IEC Staff
Step 4: <i>Filing of copies of duly accomplished forms in the Study File folder of the specific protocol</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

5.1. **Step 1 – Filling out of Part I of the Protocol Assessment Form (IEC Form 017/V4/2025) and Informed Consent (ICF) Assessment Form (IEC Form 021/V3/2025).** The DLSMHSI-IEC staff fills out the Part I of the assessment forms and make sure that all necessary information about the study is complete before sending it to the Primary Reviewers together with pertinent documents.

5.2. **Step 2 – Filling out of the Part II and III of the assessment forms.** The preliminary reviewers fill out the forms during the review of the study protocol and related documents. The Primary Reviewers shall make sure that all review points as indicated in the assessment forms are evaluated and the forms are completely filled-out. If assessment is handwritten, make sure that the handwritten notes are legible.

5.2.1. The Protocol Assessment Form (IEC Form 017/V4/2025) ensures evaluation of the scientific and ethical aspects of the protocol that may include:

- Scientific Validity
- Study Objectives
- Background information/data
- Inclusion/exclusion/withdrawal criteria
- Control arm/placebo
- sampling design



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- Recruitment plan
- specimen collection, processing and storage procedures
- statistical/data analysis plan
- data management plan
- research dissemination plan
- Benefit to local communities
- community engagement plan

5.2.2. The Informed Consent Form (ICF) Assessment Form (IEC Form 021/V3/2025) checks if the following are complied with:

- Full disclosure of information, including risks
- Benefits that may be derived from the study
- Use of understandable language
- Voluntary participation
- Confidentiality
- Appropriate persons to sign the consent form

5.2.3. During the assessment of the protocol, the primary reviewer should also:

- All protocols requiring ICF, has an acceptable recruitment procedure for obtaining informed consent. Appropriate comments and recommendations should be given.
- Ensure favorable risk-benefit ratio before approval of protocol.
- Review risk and provide recommendations to mitigate the risk
 - physical harm, inconvenience
 - risk of breach of confidentiality
 - risk of invasion of privacy
 - risk of social, emotional/psychological harm
- Identify benefits and recommend how to maximize benefit.
- Recognize all types of vulnerability & address specific vulnerability issues
 - Intrinsic
 - Medical
 - Deferential
 - Cognitive

5.2.4. In addition, the primary reviewers should ensure compliance of the study with the provisions of the Data Privacy Act of 2012 in terms of research adherence to the principles of transparency, legitimate purpose, and proportionality in the collection, storage/retention, processing and disposal of personal information and specimens. The review of medical records is treated with strict confidentiality which must comply

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with anonymizing and de-identification of participant information. Additionally, the use of human data from biobanks, registries, and databases shall comply with the Data Privacy Act of 2012 and its IRR of 2016.

- 5.2.5. At the institutional level, the IEC works alongside the Data Privacy Office in ensuring the proper implementation of security measures in dealing sensitive personal information. Part of its policy uses the following as basis in securing such information:
- Patient consent
 - Redacted document as defined by the Privacy Rule of HIPAA. A redacted document has simply had personal data deleted or blacked out; as a consequence, redacted is often used to describe documents from which sensitive information has been expunged. The Policy Adviser of the National Privacy Commission recommends the use of Safe Harbor Method in de-identification of the patients as described under the HIPAA Privacy Rule. Under this method, the 18-identifiers are “taken out” to anonymize the patient’s data.
 - Safe Harbor Method (18-identifiers)
 - Names
 - All geographic subdivisions smaller than a state usually except for the initial three digits of the ZIP code
 - All elements of dates except years (this includes the age)
 - Telephone numbers
 - Fax numbers
 - Email addresses
 - Social security numbers
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers
 - Vehicle identifiers and serial numbers including license plates
 - Device identifiers and serial numbers
 - Web URLs
 - Internet protocols addresses
 - Biometric identifiers (i.e., retinal scans, fingerprints)
 - Photos
 - Any unique identifying number, characteristic or code
 - Approval of the IEC

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- 5.3. **Step 3 – Forwarding of the accomplished assessment forms to the IEC Staff.** The primary reviewer signs and submits the forms together with the reviewed protocol back to the IEC Staff. The IEC Staff shall check the completeness of the assessment form before forwarding to the Chair who will consolidate and finalize the review results.
- 5.4. **Step 4 – Filing of copies of duly accomplished forms in the Study File folder of the specific protocol.** The DLSMHSI-Staff files the copies of duly accomplished forms in the Study File folder of the particular protocol after the PI has been notified of the IEC decision.

6. GLOSSARY

- 6.1. **Data Privacy** – the protection of individuals’ personal information collected during research. Data privacy involves ensuring that personal data is collected, stored, processed, and shared in compliance with ethical principles and applicable laws, such as the *Data Privacy Act of 2012*. It includes maintaining confidentiality, preventing unauthorized access, and ensuring that identifiable information is anonymized or de-identified whenever possible.
- 6.2. **Informed Consent** – a process through which a participant voluntarily confirms their willingness to participate in a particular study after being informed of all aspects of the research that are relevant to their decision. This includes the study's purpose, procedures, potential risks, benefits, and the participant’s rights, including the right to withdraw at any time. The process must ensure that participants fully understand the information provided and make their decision without coercion or undue influence.
- 6.3. **Informed Consent Assessment Form** – a standardized form used by reviewers to evaluate the informed consent documents and processes outlined in the study protocol. It focuses on assessing the clarity, accuracy, and comprehensiveness of the information provided to participants, as well as the process for obtaining voluntary consent. The form ensures that the informed consent complies with ethical standards and respects participants’ autonomy
- 6.4. **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.
- 6.5. **Protocol Assessment Form** – a structured tool used by ethics committee reviewers to systematically evaluate a research protocol. It includes sections for assessing the scientific validity, ethical considerations, risk-benefit analysis, safety measures, and compliance with relevant international and national guidelines. The form ensures that reviewers provide consistent, comprehensive, and documented feedback on the protocol.

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- 6.6. **Redacted Document** – a document in which sensitive or confidential information has been removed or obscured before sharing or publication to protect privacy, maintain confidentiality, or comply with ethical and legal requirements. Redaction ensures that identifiable or proprietary information is not disclosed while preserving the integrity of the remaining content.

7. FORMS

IEC Form 017/V4/2025

IEC Form 021/V3/2025

Protocol Assessment Form

Informed Consent Form (ICF) Assessment Form

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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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/>

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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

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1. POLICY STATEMENT

Review and approval of the Progress Report is necessary to renew the initial approval of the protocol and allow the PI to continue the conduct of the research.

The frequency of progress report submission to the IEC varies based on the level of risk associated with the study as decided by the Primary Reviewers and IEC Chair:

- **Low Risk:** Protocols posing no greater than minimal risk require progress reports to be submitted **at least annually**.
- **Medium Risk:** Protocols with risks greater, but not significantly greater than minimal, require progress reports to be submitted **at least every 6 months**, unless otherwise specified in the Certificate of Approval for Reviewed Protocols (IEC Form 022/V4/2025). These may also require monitoring by an Independent Safety Monitor or Data and Safety Monitoring Board (DSMB).
- **High Risk:** Protocols with significantly greater than minimal risk require progress reports to be submitted **at least every 3 months**, unless otherwise specified in the Certificate of Approval for Reviewed Protocols (IEC Form 022/V4/2025). Adequate protections, including monitoring by a DSMB, are mandatory.

Each risk category also mandates ongoing monitoring by the PI, with additional oversight by safety monitoring bodies as appropriate for medium and high-risk protocols. This requirement shall be explicitly stated in the Approval Letter.

2. OBJECTIVES

This SOP aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted.

3. SCOPE

This SOP applies to the management and review of progress submitted by the principal investigator, while the study is on-going or has ended. This begins with the receipt and entry to the logbook of incoming documents and the protocol database and ends with filing of progress report and committee decision in the protocol file.

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4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt and entry into logbook of the Progress Report (SOP 29: Management of Active Files)</i>	IEC Staff
Step 2: <i>Retrieval of pertinent protocol file</i>	IEC Staff
Step 3: <i>Notification of IEC Chair and Primary Reviewers</i>	IEC Staff
Step 4: <i>Review and Evaluation of Progress Report.</i>	Primary Reviewers
Step 5: <i>Discussion and/or reporting to a full-board meeting.</i>	Primary Reviewers
Step 6: <i>Communication of review result. (SOP 27: Communication of IEC Decisions)</i>	IEC Staff and Chair
Step 6: <i>Filing of Progress Report and Decision Letter, and update of the protocol database (SOP 29: Management of Active Files)</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Receipt and entry into logbook of the Progress Report.** The IEC Staff receives the Continuing Review Application Form (IEC Form 024/V4/2025) and enters the date and pertinent information in the logbook of incoming communications. This must be filed forty five (45 days) prior to expiry of the current IEC approval.
- 5.2. **Step 2 – Retrieval of pertinent protocol file.** The IEC Staff retrieves the corresponding protocol file to check the type of review and the assigned primary reviewers during the initial review.
 - 5.2.1. Progress reports or continuing review of protocols that underwent full-board review in its initial submission shall undergo full-board review. (Refer to **SOP 9: Full-Board Review**)
 - 5.2.2. Progress reports or continuing review of protocols that underwent expedited review shall undergo expedited review. (Refer to **SOP 8: Expedited Review**)

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- 5.3. Step 3 – Notification of IEC Chair and Primary Reviewers.** The IEC Staff notifies the IEC Chair within three (3) working days of the receipt of Progress Report and sends the pertinent protocol file to the previously assigned Primary Reviewers for review, with notation of the type of review.
- 5.4. Step 4 – Review and Evaluation of Progress Report.** The Primary Reviewers refer to the protocol file to check compliance with approval given by the IEC during initial review, and, if applicable, upon submission of amendments.
- 5.4.1. The Primary Reviewers recommend approval of the Progress Report if there is no deviation or violation of IEC approvals.
- 5.4.2. If there are any deviations of approvals given by the IEC or unanticipated problems such as unresolved adverse events (AEs) or protocol deviations that were not previously reported to the IEC, the Primary Reviewers recommend the appropriate action to be taken by the Principal Investigator, i.e., amendment of the protocol or consent form or explanation of deviation or violation.
- 5.4.3. If amendments are recommended, Primary Reviewers will recommend submission of amendment report. Amendments may either be minor or major. (*Refer to **SOP 15: Review of Amendments***)
- 5.5. Step 5 – Discussion and/or reporting to full-board meeting.** Protocols subject to full-board review are included for discussion and decision on the next full-board meeting. For protocols subject to expedited review, the result shall be reported during the full-board meeting by the Primary Reviewers.
- 5.6. Step 6 – Communication of review result.** The IEC communicates the review results and decision, which may be “Approved,” “Additional Information Required,” or “Specific Action/s Required from the Researcher.” The IEC Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting and have it signed and approved by the IEC Chair. The communication should be sent within five (5) calendar days after the decision was made by the primary reviewer (in an expedited review) or full board meeting (in a full board review).
- 5.7. Step 7 – Filing of Progress Report and Decision Letter, and update of the protocol database.** The IEC Staff files the Progress Report and a copy of the committee decision in the appropriate protocol folder and proceeds to update the pertinent protocol database.

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6. GLOSSARY

- 6.1. **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.
- 6.2. **Expedited Review** – the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only two to three members of the committee without involvement of the whole committee.
- 6.3. **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. **Logbook** – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.
- 6.5. **Primary Reviewer** – a member 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.
- 6.6. **Progress Report** – description of how the implementation of the study is moving forward. This is done by accomplishing the Continuing Review Application Form (IEC Form 024/V4/2025). The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the IEC based on the level of risk.

7. FORMS

IEC Form 024/V4/2025

Continuing Review Application Form

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	N/A	Dr. Melchor Victor G. Frias IV	

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Version No.	Date	Authors	Main Revision
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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Version:	4
Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
Effective date:	January 2025
Approved by:	
Approval date:	Pending

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1. POLICY STATEMENT

The DLSMHSI-IEC requires the submission of proposed amendments to study-related documents for review and approval prior to their implementation. This requirement will be explicitly stated in the Approval Letter issued to the Principal Investigator. No amendments to the study (i.e., changes in the composition of the study team, the study site, and the protocol) or its related documents may be implemented without prior review and formal approval from the IEC.

2. OBJECTIVES

This SOP aims to ensure that the study is conducted in strict compliance with the approved protocol, safeguarding the safety and welfare of study participants. It also ensures that any changes, such as amendments, are thoroughly reviewed to prevent adverse impacts on participant well-being and the integrity of the study.

3. SCOPE

This SOP applies to the management and review of protocol amendments submitted by the proponent while the study is on-going. This begins with the receipt and entry of the submission of amendment to logbook of incoming documents and the protocol database and ends with filing of the amendments and committee decision in the protocol file.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt and entry into logbook of the submission of amendments (SOP 29: Management of Active Files)</i>	IEC Staff
Step 2: <i>Retrieval of pertinent protocol file</i>	IEC Staff
Step 3: <i>Notification of IEC Chair and Primary Reviewers</i>	IEC Staff

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ACTIVITY	RESPONSIBILITY
Step 4: <i>Classification of amendment and determination of type of review, expedited (SOP 8: Expedited Review) or full-board review (SOP 9: Full-Board Review)</i>	IEC Chair and Primary Reviewers
Step 5: <i>Communication of committee action (SOP 27: Communicating DLSMHSI-IEC Decisions)</i>	IEC Chair
Step 6: <i>New protocol/ICF version assignment, and stamping of the approved version</i>	IEC Staff
Step 7: <i>Filing of Amendments and Decision Letter, and update of the protocol database (SOP 29: Management of Active Files)</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Receipt and entry into logbook of the submission of amendments.** The IEC Staff receives Protocol Amendment Form (IEC Form 025/V3/2025) and enters the date and pertinent information in the logbook of incoming communications.
- 5.2. **Step 2 – Retrieval of pertinent protocol file.** The IEC Staff retrieves the corresponding protocol file for reference and guidance of the of the IEC Chair and Primary Reviewers.
- 5.3. **Step 3 – Notification of IEC Chair and Primary Reviewers.** The IEC Staff notifies the IEC Chair and the previously assigned Primary Reviewers within three (3) working days of the receipt of Amendment Report and sends the pertinent protocol file.
- 5.4. **Step 4 – Classification of amendment and determination of type of review (expedited or full-board review).** The IEC Chair and Primary Reviewers decide together the type of review and proceed accordingly.
 - 5.4.1. The Primary Reviewers recommend the type of review to the IEC Chair, who subsequently determines the final type of review.
 - The Primary Reviewers check the amended documents and compare them with the previously approved documents in the protocol file.
 - The Primary Reviewers check if the amendments would alter the risk-benefit ratio of the study to make appropriate recommendations using Protocol Amendment Form (IEC Form 025/V3/2025).
 - 5.4.2. The IEC Chair shall determine the type of review based on the extent of amendment and its impact on risks/benefits to participants:



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- **Minor amendments** apply to amendments in protocols found to have particular aspect/s on the study or related document/s that do not impact on potential risks/benefits to participants and on the integrity of the research. There are no substantial changes in study population, methodology, and consent.
- **Major amendments** apply to amendments in protocols (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that increase risks/harms to participants and on the integrity of research. These may include, but are not limited to:
 - Change in study design
 - Additional treatments or the deletion of treatments
 - Any changes in inclusion/exclusion criteria
 - Change in dosage formulation or mode/route of drug intake (e.g., oral changed to intravenous)
 - Significant change in number of subjects (i.e., increase or decrease in sample size that alters the fundamental characteristics of the study)
 - Significant increase/decrease in dosage amounts

5.4.3. Review of amendments follows the policy that:

- **Minor amendments** that do not change the risk profile of study participants are classified for expedited review by the original Primary Reviewers. (*Refer to **SOP 8: Expedited Review***) Approved amendments are reported during the full-board meeting.
- **Major amendments** that increase risk to study participants are classified for full-board review. These are included in the Agenda of the full-board meeting for discussion and decision. (*Refer to **SOP 9: Full-Board Review***)

5.4.4. The major review points of amendment documents includes:

- Increase in vulnerability
- Change risk-benefit ratio
- Mitigation measures when research become more risky
- Change in feasibility of the study
- Need for revision of Informed Consent Form
- Need re-consent of participants

5.5. **Step 5 – Communication of committee action.** The IEC communicates the committee action. (*Refer to **SOP 27: Communicating DLSMHSI-IEC Decisions***) For amendments, the committee action may be any of the following: “Approved,” “Additional justification/information required,” “Reconsent required,” or “Disapproved.” The IEC Staff prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting. The IEC Chair signs the decision letter. (*Refer to **SOP 27: Communicating DLSMHSI-IEC Decisions***)

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- 5.6. **Step 6 – New protocol/ICF version assignment, and stamping of the approved version.**
The IEC staff assigns new version numbers to the protocol and ICF for approved amendments and stamps the approval date on the updated versions.
- 5.7. **Step 6 – Filing of Amendments and Decision Letter, and update of the protocol database.**
The IEC Staff files the Amendment and a copy of the committee decision in the appropriate protocol folder and proceeds to update the pertinent protocol database.

6. GLOSSARY

- 6.1. **Amendment** – any change or revision in the protocol made after its approval.
- 6.2. **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.
- 6.3. **Expedited Review** – the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only two to three 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. **Logbook** – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action Done
- 6.6. **Primary Reviewer** – a member of the IEC (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.

7. FORMS

IEC Form 025/V3/2025 Protocol Amendment Form

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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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Version:	4
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Approval date:	Pending

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1. POLICY STATEMENT

Protocol deviations and violations can significantly impact the safety and welfare of research participants as well as the integrity of the collected data. In sponsored clinical trials, the reporting of protocol deviations and violations must adhere to the **ICH-GCP guidelines**, typically facilitated by clinical monitors and auditors.

- **Protocol Deviations:** Instances of non-compliance with the approved protocol that do not have significant consequences for participant safety, rights, or data integrity.
- **Protocol Violations:** Breaches of the protocol that compromise data completeness or quality, or negatively affect the safety, rights, or welfare of participants.

To ensure an appropriate response, deviations and violations are classified at both scientific and ethical levels by the IEC. Based on this classification, the IEC may take actions such as no action, site visits, additional training, or withdrawal of affected participants from the study.

Researchers are required to report any protocol deviations or violations in the conduct of approved research to the IEC within **one week** of identifying them.

- **Major Protocol Deviations and Violations:** These will undergo a full board review to assess their implications and determine necessary corrective actions.
- **Minor Protocol Deviations and Violations:** These will be reviewed through an expedited process by the original Primary Reviewers.

2. OBJECTIVES

Review of protocol deviations and violations aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity of data are maintained.

3. SCOPE

This SOP applies to the review of reports concerning protocol deviations or violations in previously approved studies. The process begins with the receipt and documentation of the report in the logbook and concludes with the filing of all related documents and the updating of the protocol database.

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This SOP provides instructions for taking action and maintaining records of various types of protocol deviations or violations which include any of the following:

- Failure of the investigators to comply with the procedures in the approved protocol
- Failure of investigators to comply with national or international guidelines for the conduct of human research, including those who fail to respond to the IEC requests
- Any event at the site that is not in compliance with the previously approved protocol documents

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt and documentation of report of protocol violations and deviations in the logbook</i>	DLSMHSI-IEC Staff
Step 2: <i>Retrieval of pertinent protocol file</i>	DLSMHSI-IEC Staff
Step 3: <i>Notification of IEC Chair and Primary Reviewers</i>	DLSMHSI-IEC Staff
Step 4: <i>Determination of type of review, expedited (SOP 8: Expedited Review) or full-board review (SOP 9: Full-Board Review)</i>	DLSMHSI-IEC Chair and Primary Reviewers
Step 5: <i>Review and Evaluation of Progress Report.</i>	Primary Reviewers
Step 6: <i>Inclusion of report in the agenda of the next IEC board meeting</i>	IEC Chair and Staff
Step 7: <i>Communication of decision to the Principal Investigator (SOP 27: Communicating IEC Decisions)</i>	IEC Chair and Staff
Step 8: <i>Filing of all related documents, and update of the protocol database (SOP 29: Management of Active Files)</i>	IEC Staff

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5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Receipt and documentation of report of protocol violations and deviations in the logbook.** The IEC Staff receives the report on protocol deviation or violation using the Notification Letter for Review Decision (IEC Form 019/V1/2025) from investigators and other parties related to any event in the site that is not compliant with previously approved protocol and other related documents, including proof of corrective and preventive actions done by the site. The staff checks the completeness of the documents and ensures that full information about the event is secured and records this in the logbook of incoming communications.
- 5.2. **Step 2 – Retrieval of pertinent protocol file.** The IEC Staff retrieves the corresponding protocol file to check the assigned primary reviewers during the initial review. The original Primary Reviewers are required to conduct the review and evaluation of protocol violations and deviations.
- 5.3. **Step 3 – Notification of IEC Chair and Primary Reviewers.** The IEC Staff notifies the IEC Chair and the previously assigned Primary Reviewers within three (3) working days of the receipt of Protocol Deviation and Violation Report and sends the pertinent protocol file.
- 5.4. **Step 4 – Determination of type of review, expedited or full-board review.** The IEC Chair and Primary Reviewers determine the type of review.
 - 5.4.1. The protocol deviations/violations will be classified as Major or Minor with the following criteria:
 - **Minor Deviation/Violation** – non-systematic protocol non-compliance with minor consequence to the participant’s rights, safety or welfare, or integrity of study data; includes deviations that are administrative in nature.
 - **Major Deviation/Violation** – persistent protocol non-compliance with potentially serious consequences that could critically affect the data analysis or put the participant’s safety at risk
 - 5.4.2. Major protocol violations require a full-board review. On the other hand, minor protocol deviations require expedited review by Primary Reviewers.
- 5.5. **Step 5 – Review and Evaluation of Progress Report.** Primary Reviewers assess the extent and impact of deviation and/or violation from the approved protocol, as well as the root cause identified by the Principal Investigator and evaluate the proposed Corrective and Preventive Action (CAPA) plan for its adequacy and appropriateness.
- 5.6. **Step 6 – Inclusion of report in the agenda of the next IEC board meeting.** The IEC Chair includes the report on protocol deviation and violation in the agenda of the next full-board meeting if it is for full-board review; or the decision report if expedited review.
 - 5.6.1. Primary reviewers of minor protocol deviations/violations make a decision report to be discussed during the full-board meeting.

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5.6.2. Full-board review of study protocol non-compliance report entails:

- The Primary Reviewers present the documents to IEC members when study protocol non-compliance reports are deliberated on. The members deliberate on both the type and degree of non-compliance, and take the appropriate action.
- The IEC can recommend any of the following:
 - Submission of additional information
 - Submission of corrective action
 - Invitation to a clarificatory interview
 - Requirement for an amendment
 - Requirement for a site visit
 - Suspension of recruitment or study until the following are met:
 - Additional information is made available
 - IEC recommendations are implemented by the PI and considered satisfactory by the IEC
 - Withdrawal of ethical clearance due to repeated violation
 - Termination of the study on the basis of one or more of the following:
 - SAE reports indicate harm to participants
 - Breach of a previously approved conduct of research
 - Major changes, deviations, or amendments of the approved protocol without approval by the IEC
 - Revision in the Informed Consent Form without approval by the IEC
 - Repeated violations
 - Fraud

5.6.3. Whenever a protocol non-compliance (deviation or violation) has been observed:

- Ensure that the issues as well as the details of the non-compliance involving research investigators are included in the agenda of the IEC meeting.
- Maintain a file that identifies investigators who are found to be non-compliant with national or international regulations or who fail to follow protocol approval stipulations or fail to respond to the IEC's request for information or action.
- The IEC may elect to suspend or terminate approval of current or ongoing studies or refuse subsequent applications from the investigators cited. Such decisions are documented or recorded in the minutes.
- The IEC may require follow-up reports/updates and/or site visits to check if CAPA measures have been implemented.

5.7. Step 7 – Communication of decision to the Principal Investigator. The IEC Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full-board review.

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- 5.7.1. The IEC Staff informs the PI about the decision through a Notification Letter for Review Decision (IEC Form 019/V1/2025).
- 5.7.2. The PI is notified of the of the decision, which may be:
- Uphold original approval with no further action required
 - Request for further information specifying information that is required prior to upholding original approval
 - Recommend further action, specifying action required prior to upholding original approval. Actions may include:
 - Submission of corrective action
 - Invitation to a clarificatory interview
 - Requirement for an amendment
 - Site visit to check corrective and preventive actions done at the site
 - Suspension of recruitment

5.8. Step 8 – Filing of all related documents, and update of the protocol database. The IEC Staff collates and files the retrieved protocol documents, the report on protocol file and updates the protocol database with relevant information.

6. GLOSSARY

- 6.1 **Clarificatory Interview or Meeting** – is a meeting or consultation of the IEC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the IEC.
- 6.2 **Clinical Auditor** – an individual who systematically and independently examines trial related activities and documents at a particular period.
- 6.3 **Clinical Monitor** – an individual who oversees the progress of a clinical trial.
- 6.4 **Drug or Device** – health product used for diagnosis or treatment.
- 6.5 **Expedited Review** – the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only two to three members of the committee without involvement of the whole committee.
- 6.6 **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.
- 6.7 **Principal Investigator** – the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.
- 6.8 **Protocol Deviation** – non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

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- 6.9 **Protocol File** – an organized physical or electronic compilation of all documents related to a Protocol
- 6.10 **Protocol Violation** – non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.
- 6.11 **Regular Meeting** – a periodically scheduled assembly of the IEC.
- 6.12 **Researcher** – the individual primarily responsible for the conceptualization, planning and implementation of a study.
- 6.13 **Site Visit** – is an activity of the REC where an assigned team goes to the research site or office for specific monitoring purposes.
- 6.14 **Sponsored Clinical Trials** – are clinical studies on investigational drugs.

7. FORMS

IEC Form 026//V3/2025
 IEC Form 019/V1/2025

Noncompliance Report Form
 Notification Letter for Review Decision (Template)

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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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INDEPENDENT ETHICS COMMITTEE

XVII. REVIEW OF REPORTABLE NEGATIVE EVENTS

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Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
Effective date:	January 2025
Approved by:	
Approval date:	Pending

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1. POLICY STATEMENT

The DLSMHSI-IEC requires the submission of Reportable Negative Event (RNE) reports within three (3) days of the event coming to the researcher’s attention. A special meeting may be convened if the level of risk warrants immediate action.

A **Reportable Negative Event (RNE)** refers to an adverse event or incident likely to be classified by the IEC as an unanticipated problem posing risks to participants or others. These events are deemed reportable when they are:

1. Probably or definitely related to participation in the research, and
2. Occur during the implementation of the study, impacting the safety, dignity, and well-being of participants or the study team, as well as the integrity of the data.

When a Reportable Negative Event (RNE) is observed, the IEC ensures that the issues and details of the RNE are included in the agenda of its meeting for thorough discussion. A file is maintained to track investigators or sites found non-compliant with national or international regulations, those failing to adhere to protocol approval stipulations, or those who do not respond to the IEC’s requests for information or action. Depending on the severity of the RNE, the IEC may suspend or terminate approval of ongoing studies or refuse subsequent applications from the cited investigators or sites, with all decisions documented in the meeting minutes. Additionally, the IEC may require follow-up reports, updates, and/or conduct site visits to verify that appropriate mitigating measures have been implemented.

RNE reports are essential for maintaining a favorable balance of risks and benefits in the study. The Principal Investigator (PI) or designated safety personnel, such as a Data and Safety Monitoring Board (DSMB), must promptly report such events to the IEC to ensure appropriate oversight and action.

2. OBJECTIVES

The review of RNE reports aims to safeguard the safety and welfare of human participants and the research team while ensuring that RNEs are thoroughly documented and systematically evaluated.

3. SCOPE

This SOP applies to the review of RNE reports. This begins with the receipt and documentation of submission of RNE report in the physical logbook and electronic database and ends with the filing of all related documents and update of the protocol database.

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4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt and documentation of submission of RNE report in the physical logbook and electronic database</i>	IEC Staff
Step 2: <i>Retrieval of pertinent protocol file</i>	IEC Staff
Step 3: <i>Notification of IEC Chair</i>	IEC Staff
Step 4: <i>Call for a Special Meeting</i>	IEC Chair
Step 5: <i>Deliberation on the RNE</i>	IEC Members
Step 6: <i>Communication of IEC action to the researcher (SOP 27: Communicating IEC Decisions) and to the institutional authority</i>	IEC Chair
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 and documentation of submission of RNE report in the physical logbook and electronic database.** The IEC staff receives the completed Reportable Negative Event Report Form (IEC Form 029/V2/2025) from investigators or other relevant parties regarding any event at the site that deviates from the previously IEC-approved protocol and related documents. The staff verifies whether the submission meets the required timeline (within 24 hours up to 7 days of having been aware of the event), ensures that all necessary information about the event is provided, and records the submission in both the physical logbook and the electronic database.
- 5.2. **Step 2 – Retrieval of pertinent protocol file.** The IEC staff retrieves the approved protocol file and checks the identity of the primary reviewers.



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- 5.3. **Step 3 – Notification of Chair.** The IEC staff notifies and sends the report and the retrieved documents to the IEC Chair who may decide to call for a special meeting.
- 5.4. **Step 4 – Call for a Special Meeting.** The IEC staff prepares for a special meeting. (*Refer to SOP 25: Preparation and Conduct of Meetings*) The researchers and other members of the study team may be invited for a clarificatory meeting.
- 5.5. **Step 5 – Deliberation on the RNE.**
- 5.5.1. The IEC Chair leads the discussion of the special meeting, summarizes the RNE report and informs the IEC members regarding the presence of the research team for clarificatory meeting.
- 5.5.2. The safety issues are evaluated. Assessment points should include, but not limited to, the following:
- Identification of risks to the participants and/or research team,
 - Nature and effectiveness of preliminary interventions with or without the help of community constituents/authority
 - Impact on integrity of data and completion of the research.
- 5.5.3. The research team is excused, and the IEC members discuss possible decision and appropriate action for the reported or observed RNE.
- 5.6. **Step 6 – Communication of IEC action to the researcher and to the institutional authority.**
- 5.6.1. The IEC staff informs the PI about the IEC/s decision through a Notification Letter for Review Decision (IEC Form 019/V1/2025). (*Refer to SOP 27: Communicating IEC Decisions*)
- 5.6.2. The decision may include any of the following:
- Recommend suspension of the study until risk is resolved
 - Withdrawal of ethical clearance
 - Submission of a plan to mitigate risk/harm
 - Require an amendment to the protocol
 - Uphold original ethical clearance
- 5.7. **Step 7 – Filing of all related documents and update of the protocol database.** (*Refer to SOP 29: Management of Active Files*)

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6. GLOSSARY

- 6.1 **Clarificatory Meeting/Interview** – a face-to-face meeting or consultation of the IEC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the committee.
- 6.2 **Reportable Negative Events (RNE)** – occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.
- 6.3 **Special meeting** – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action
- 6.4 **Study Site** – physical location of where the study is being conducted, e.g., community, institutional facility.

7. FORMS

IEC Form 029/V2/2025
IEC Form 019/V1/2025

Reportable Negative Event Report Form
Notification Letter for Review Decision

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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	



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Approved by:	
Approval date:	Pending

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1. POLICY STATEMENT

The IEC requires the submission of Serious Adverse Event (SAE) and Suspected Unexpected Serious Adverse Reaction (SUSAR) reports by the Sponsor or PI within 24 hours up to seven working days of the PI becoming aware of the event. The Primary Reviewers evaluate the submitted reports and provide recommendations to the IEC for final action.

SAE and SUSAR reporting procedures comply with the ICH Harmonised Tripartite Guideline: Guideline For Good Clinical Practice, ICH GCP E6 (R1). It defines SAE as any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening
- Requires hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability or incapacity, or
- Results in a congenital anomaly or birth defect

On the other hand, a SUSAR is a serious event, the nature and severity of which, is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics.

The IEC follows the ICH E2A – Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, as adopted by the Philippine FDA, to ensure harmonization of data for both on-site and off-site cases. Additionally, the IEC refers to the WHO Uppsala Monitoring Centre System for Standardized Case Causality Assessment for consistent and standardized evaluation of causality.

All on-site SAE/SUSAR cases undergo Full Board Review, while all off-site SAE/SUSAR cases undergo Expedited Review by the initial Primary Reviewers.

2. OBJECTIVES

Review of SAE and SUSAR reports aims to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated.

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3. SCOPE

This SOP applies to the review of reports of SAEs in various studies and SUSARs in clinical trials. This begins with the receipt and documentation of submission of report of SAEs and SUSARs in the logbook and ends with the filing of all related documents and update of the protocol database.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt and documentation of submission of SAE or SUSAR reports in the logbook and electronic database</i>	IEC Staff
Step 2: <i>Retrieval of pertinent protocol file</i>	IEC Staff
Step 3: <i>Notification of IEC Chair and Primary Reviewers</i>	IEC Staff
Step 4: <i>Review and evaluation of SAE or SUSAR reports</i>	Primary Reviewers
Step 5: <i>Inclusion of report in the agenda of the next regular IEC board meeting</i>	IEC Chair and Staff
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

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5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Receipt and documentation of submission of SAE or SUSAR reports in the logbook and electronic database.**
- 5.1.1. PI accomplishes the **SAE/SUSAR Report Form (Form __)** and submits it to the IEC staff within 24 hours up to 7 days of having been aware of the event.
- 5.1.2. The IEC staff receives the completed **SAE/SUSAR Report Form (Form __)** and records the submission in the **physical logbook** and **electronic database**. The staff also verifies and notes whether the submission adheres to the required timeline.
- 5.1.3. Submissions of SAE/SUSAR report shall be classified according to their origin or site of occurrence: off-site (foreign site or local site) and on-site (DLSMHSI site).
- 5.1.4. Below are the required timelines for the submission of report:
- Any SAEs that result in death:
 - **On-site:** Within 24 hours after the PI is informed of the event
 - **Off-site:** Within 24 hours after the PI or site receives report from the Sponsor
 - Any SAEs that are related and expected:
 - **On-site:** Within 7 working days after the PI is informed of the event
 - **Off-site:** Within 7 working days after the PI or site receives report from the Sponsor
 - SUSARs:
 - **On-site:** Within 7 working days after the PI is informed of the event
 - **Off-site:** Within 7 working days after the PI or site receives report from the Sponsor
 - SAEs or SUSARs that are determined to change study risks and necessitate modification of the IEC-approved protocol or ICF:
 - **On-site and Off-site:** Within 7 working days after the PI or site receives report from the Sponsor
- 5.1.5. A digital copy of **SAE/SUSAR Report Form (Form __)** for adverse events occurring on weekdays/holidays may be reported to the IEC through email: iec@dlsmhsi.edu.ph. The duly accomplished form may be submitted on the nearest working day.
- 5.2. **Step 2 – Retrieval of pertinent protocol file.** The IEC staff retrieves the corresponding protocol file to check the assigned primary reviewers during the initial review.
- 5.3. **Step 3 – Notification of IEC Chair and Primary Reviewers.** The IEC Staff notifies the IEC Chair and the previously assigned Primary Reviewers within three (3) working days of the receipt of **SAE/SUSAR Report Form (Form __)** and sends the pertinent protocol file.
- 5.4. **Step 4 – Review and evaluation of SAE or SUSAR reports.**



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- 5.4.1. The original Primary Reviewers are required to conduct the review and evaluation of SAEs/SUSARs arising from the study protocol. The Primary Reviewers must be able to come up with a decision not later than three (3) working days prior to the next meeting.
- 5.4.2. To review SAE reports, the Primary Reviewer utilize the **SAE Reviewer Recommendation Form (Form __)** to assess the report and provide recommendations for appropriate actions to be taken by the IEC.
- 5.4.3. On-site SAE/SUSAR reports are reviewed regularly and recommended at the next IEC board meeting. Major review points for on-site SAE/SUSAR includes:
- relatedness or causality of event,
 - expectedness/ unexpectedness of the event,
 - description of how the PI managed the event, and
 - outcome of participant with SAE.
- Meanwhile, off-site SAE/SUSAR reports are analyzed as trends and reported to the IEC board meeting twice a year. For off-site SAE/SUSAR reporting, it is generally not necessary to report events that are considered unrelated to the study procedure or investigational medicinal product.
- 5.4.4. Based on the site of occurrence, the assigned Primary Reviewers will formulate an appropriate response:
- For off-site multicenter international studies, the IEC shall note the trend of occurrence of SAE/SUSAR in foreign and local study site.
 - For off-site multicenter national studies, the IEC shall note the nature of the SAE/SUSAR as either related or expected.
 - For SAEs that occur onsite, the IEC shall evaluate the investigator/sponsor assessment as to related or unexpected and may need to recommend some form of action to the investigator to ensure the safety of participants. The assigned Primary Reviewers should inform the IEC chair about their recommendations for appropriate IEC action.
- 5.4.5. The review and assessment process may result in the following recommendations:
- **No modification required** and the study is allowed to continue.
 - **More information needed.** The report is forwarded to the IEC Chair with request for information that is needed and for further review and evaluation if the report shall be reviewed at the convened meeting by the full board.
 - **Modifications needed.** The report is forwarded to the IEC Chair with the recommended modifications in specific areas of the protocol (i.e., inclusion-exclusion criteria, informed consent, etc.) and is added to the agenda for review at a convened meeting by full board.

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- **Implementation of additional procedures.** The report is forwarded to the IEC Chair with the recommended additional procedures (i.e., screening, additional labs, monitoring, etc.) and is added to the agenda for review at a convened meeting by full board.
 - **Suspension of enrollment, research procedure among current participants of entire study.** The report is forwarded to the IEC Chair with recommendations and is added to the agenda for review at a convened meeting by full board.
- 5.5. Step 5 – Inclusion of report in the agenda of the next regular IEC board meeting.**
- 5.5.1. The IEC staff includes SAE/SUSAR reports in the agenda for the next meeting, provided the reports are submitted by the cut-off deadline of 5 PM on the 15th day of the month preceding the scheduled full-board meeting. The meeting must include the attendance of a primary reviewer for the evaluation of these reports.
- 5.5.2. In the IEC board meeting, the IEC Chair and members appraise and discuss the recommendations of the Primary Reviewers for decision and appropriate action on reviewed on-site SAE/SUSAR reports.
- 5.5.3. The consolidated trend analyses of off-site SAE/SUSAR reports by the Primary Reviewers are presented to the IEC board meeting twice a year for discussion.
- 5.5.4. After the discussion, the IEC Chair may call for consensus to send notification to the PI and communicate the decision to:
- Uphold original approval with no further action and the study is allowed to continue
 - Recommend further action with recommendations and the response is processed by full-board review
 - Request for further information and the response is processed by full-board review
 - Have a pending decision with major clarifications and the response is processed by full-board review
- 5.6. Step 6 – Communication of IEC action to the Principal Investigator/Researcher.** The IEC Staff informs the PI about the IEC decision, whenever necessary. A Notification Letter for Review Decision (IEC Form 019/V1/2025) signed and dated by the IEC Chair is sent to notify the PI of the action points following the IEC decision. (Refer to **SOP 27: Communicating DLSMHSI-IEC Decisions**)
- 5.7. Step 7 – Filing of all related documents and update of the protocol database.** The IEC Staff files all the pertinent SAE/SUSAR documents in the SAE file folder. (Refer **SOP 29: Managing Active Files**)

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6. GLOSSARY

- 6.1 **Principal Investigator (PI)** – the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.
- 6.2 **Researcher-Initiated Studies** – research activities whose conceptualization, protocol development and implementation are done by a researcher or group of individuals who may request for external funding support
- 6.3 **Serious Adverse Event (SAE)** – an event, whether or not it is related to the study intervention, that are observed during the implementation of a study where the outcome is any of the following: (a) death, (b) life-threatening, (c) hospitalization (initial or prolonged), (d) disability or permanent damage, (e) congenital anomaly/birth defect, (f) required intervention to prevent permanent impairment or damage (devices), and (g) other serious (important medical) events
- 6.4 **Sponsor** – an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial
- 6.5 **Sponsored Clinical Trials** – systematic studies on pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization, protocol development and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities.
- 6.6 **Suspected Unexpected Serious Adverse Reaction (SUSAR)** – a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug inset

7. FORMS

IEC Form 000/V1/2025	SAE/SUSAR Report Form
IEC Form 000/V1/2025	SAE Reviewer Recommendation Form
IEC Form 019/V1/2025	Notification Letter (for Review of SAE/SUSAR Report)
IEC Form 000/V1/2025	SAE/SUSAR Log

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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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
Effective date:	January 2025
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Approval date:	Pending

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1. POLICY STATEMENT

The IEC requires the submission of a Continuing Review application prior to the expiration of the ethical clearance for a protocol. Ethical clearance is given for one year from the date of initial approval of the protocol. Renewal of the ethical clearance must be secured one (1) month before its expiry. The IEC Staff will send a Reminder Letter (for Post-Approval Requirement) (IEC Form 033/V2/2025) to the PI two (2) months before the expiry of ethical clearance. Protocols initially classified as requiring Full-Board Review will undergo the same type of review for their Continuing Review application. Similarly, protocols initially classified as Expedited Review will follow the same review process for Continuing Review.

2. OBJECTIVES

This activity aims to ensure that the study is conducted in strict compliance with the approved protocol, promoting the safety and welfare of study participants while safeguarding the integrity of data. It extends oversight beyond the initial ethical clearance period and continues through to the completion of the study.

3. SCOPE

This SOP applies to the management of an application for Continuing Review submitted by the proponent while the study is still on-going but whose ethical clearance is about to expire. This SOP begins with the receipt of an application for Continuing Review and ends with the entry to logbook and protocol database.

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4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Notification for the submission of continuing review	IEC Staff
Step 2: Receipt of the application for Continuing Review and entry to the physical logbook and electronic database (SOP 29: Management of Active Files)	IEC Staff
Step 3: Retrieval of pertinent protocol files	IEC Staff
Step 4: Notification of IEC Chair and Primary Reviewers	IEC Staff
Step 5: Determination of type of review: Expedited (SOP 8: Expedited Review) or Full-Board Review (SOP 9: Full-Board Review)	IEC Chair, Co-chair, or Member-Secretary
Step 6: Review and evaluation of the protocol submitted for continuing review	Primary Reviewers
Step 7: Inclusion of report in the agenda of the next regular IEC board meeting	IEC Chair and Staff
Step 8: Communication of IEC action to the Principal Investigator/Researcher (SOP 27: Communicating DLSMHSI-IEC Decisions)	IEC Chair and Staff
Step 9: Filing of all related documents (SOP 29: Management of Active Files) and update of the protocol database	IEC Staff

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5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Notification for the submission of continuing review.** The IEC staff sends a Reminder Letter (for Post-Approval Requirement) (IEC Form 033/V2/2025) to the PI, at least 8 weeks prior to the expiration, reminding of the expiration of their ethical clearance and the requirement for application for continuing review, 6 weeks prior to expiration, if needed.
- 5.2. **Step 2 – Receipt of the application for Continuing Review and entry to the physical logbook and electronic database.** The IEC Staff receives, logs, and enters in the protocol database the information included in the Continuing Review Application (IEC Form 024/V4/2025). Updated GCP certificate of the PI must also be submitted for monitoring of validity. (Refer to [SOP 29: Management of Active Files](#))
- 5.3. **Step 3 – Retrieval of pertinent protocol files.** The IEC Staff retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports, report of negative events (RNE), and corresponding decisions including the type of initial review during the period of effectivity of the initial ethical clearance.
- 5.4. **Step 4 – Notification of IEC Chair and Primary Reviewers.**
 - 5.4.1. The IEC Staff notifies the IEC Chair and the Primary Reviewers via SMS or email regarding the submission and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance.
 - 5.4.2. The IEC Chair and the Primary Reviewers shall be notified at least two weeks before the monthly full-board meeting, and no later than one month prior to the expiration of the initial ethical clearance of a protocol.
- 5.5. **Step 5 – Determination of type of review: Expedited or Full-Board Review.** The IEC Chair, Co-chair, or Member-Secretary shall determine the type of review for Continuing Review applications based on established policy. Protocols that initially underwent Full-Board Review during their initial submission shall undergo the same type of review for Continuing Review. Similarly, protocols that initially underwent Expedited Review shall follow the same review process, provided there is no increase in the level of risk.
- 5.6. **Step 6 – Review and evaluation of the protocol submitted for continuing review.**
 - 5.6.1. The Primary Reviewers will evaluate the protocols to ensure compliance with the protocols and related documents previously approved by the IEC.
 - 5.6.2. The Primary Reviewers recommend approval of the application for Continuing Review if there is no deviation or violation of IEC approvals.
 - If there is any deviation or violation of approvals given by the IEC, the Primary Reviewers will recommend that appropriate action to be taken by the PI, e.g., amendment of the protocol/consent form, or explanation of deviation/violation.
 - If amendments are recommended, the Primary Reviewers will recommend submission of Amendment Report. Amendments may either be Minor or Major. (Refer to [SOP 15: Review of Amendments](#))

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- 5.6.3. Approval or other recommendations by the Primary Reviewers for protocols subject to Expedited Review
- 5.7. Inclusion of report in the agenda of the next regular IEC board meeting.**
- 5.7.1. The IEC staff includes recommendations for Continuing Review applications in the agenda for the next meeting.
- Approval or other recommendations by the Primary Reviewers for protocols subject to Expedited Review of Continuing Review submissions shall be reported during the full-board meeting.
 - For protocols subject to Full-Board Review, recommendations are discussed during the full-board meeting.
- 5.7.2. In the IEC full-board meeting, the IEC Chair and members appraise and discuss the recommendations of the Primary Reviewers for decision and appropriate action.
- 5.8. Communication of IEC action to the Principal Investigator/Researcher.** The IEC Staff prepares the Notification Letter for Review Decision (IEC Form 019/V1/2025) to be signed by the Chair and sent to the PI at least 5 working days after the decision is made. (See [SOP 27: Communicating DLSMHSI-IEC Decisions](#))
- 5.9. Filing of all related documents and update of the protocol database.** The IEC Staff files the application for Continuing Review, the recommendations of the reviewers, and decision letter in the appropriate protocol folder. (See [SOP 29: Management of Active Files](#))

6. GLOSSARY

- 6.1 **Amendment** – a change in /revision of the protocol made after it has been approved.
- 6.2 **Continuing Review** – the decision of the REC to extend the ethical clearance of a study based on an assessment that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.
- 6.3 **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 **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.
- 6.5 **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.
- 6.6 **Logbook** – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.

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- 6.7 **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.
- 6.8 **Progress Report** – a description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form ##. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the REC based on the level of risk.
- 6.9 **Protocol Deviation** –non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.
- 6.10 **Protocol Violation** – non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.
- 6.11 **RNE** – an occurrence in the study site that indicates risks or actual harms to participants and to members of the research team. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,

7. FORMS

IEC Form 033/V2/2025	Reminder Letter (for Post-Approval Requirement)
IEC Form 024/V4/2025	Continuing Review Application
IEC Form 019/V1/2025	Notification Letter for Review Decision
IEC Form 000/V_/2025	Continuing Review Application (Log)

8. HISTORY

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1	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

	<p style="text-align: center;">De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114</p> <p style="text-align: center;">INDEPENDENT ETHICS COMMITTEE</p>	<p>DLSMHSI-IEC SOP Ver. 1 Approval Date:</p>
	<p style="text-align: center;">XIX. MANAGEMENT OF AN APPLICATION FOR CONTINUING REVIEW</p>	<p>Effective Date: January 2025</p> <p>Page 7 of 8</p>

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	<p align="center">De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114</p> <p align="center">INDEPENDENT ETHICS COMMITTEE</p>	<p>DLSMHSI-IEC SOP Ver. 1 Approval Date:</p> <p>Effective Date: January 2025</p> <p>Page 8 of 8</p>
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	XX. EARLY PROTOCOL TERMINATION	

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Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
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1. POLICY STATEMENT

Research protocols may be terminated early due to various reasons, including poor participant recruitment, frequent adverse reactions (e.g., SUSARs), lack of funding, or other factors that render the continuation of the study untenable. Early termination may be initiated by the Principal Investigator (PI), sponsor, Data Safety Monitoring Board (DSMB), scientific director, the RERC, or other authorized bodies.

In some cases, the RERC may recommend early termination if it determines that the study poses high risks to participants or the research team that cannot be adequately mitigated. Regardless of the reason, the safety, well-being, and privacy of participants already enrolled in the study must be the primary consideration. The termination plan must address these concerns and include a clear justification for ending the study.

Applications for early termination will undergo full-board review to ensure that the decision is justified and that participant welfare is prioritized throughout the termination process.

2. OBJECTIVES

The review of early protocol termination reports ensures that the decision prioritizes the safety and welfare of already-recruited study participants while adhering to the principle of fairness for all parties involved.

3. SCOPE

This SOP applies to the review of early termination reports. This begins with the receipt and entry to logbook of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating of the protocol database.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt of the application for early protocol termination and entry to the physical logbook and electronic database (SOP 29: Management of Active Files)</i>	IEC Staff

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ACTIVITY	RESPONSIBILITY
Step 2: <i>Submission of protocol termination package</i>	PI
Step 3: <i>Retrieval of pertinent protocol files</i>	IEC Staff
Step 4: <i>Notification of IEC Chair and Primary Reviewers</i>	IEC Staff
Step 5: <i>Preliminary review of the early protocol termination package</i>	Primary Reviewers
Step 6: <i>Inclusion of report in the agenda of the next regular IEC board meeting</i>	IEC Chair and Staff
Step 7: <i>Full-Board Review (SOP 9: Full-Board Review)</i>	IEC Chair, Co-chair, or Member-Secretary
Step 8: <i>Communication of IEC action to the Principal Investigator/Researcher (SOP 27: Communicating DLSMHSI-IEC Decisions)</i>	IEC Chair and Staff
Step 9: <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 the application for early protocol termination and entry to the physical logbook and electronic database.** The IEC Staff receives the application for early protocol termination from the PI or duly authorized representative, or recommendation for early termination from the DSMB, the scientific director, the sponsor, the IEC itself, and/or other authorized bodies utilizing the **Early Protocol Termination Application/Recommendation Form (Form __)**.
- 5.2. **Step 2 – Submission of protocol termination package.**
 - 5.2.1. If the early protocol termination is investigator-initiated, the **Early Protocol Termination Application/Recommendation Form (Form __)** is submitted together with the protocol termination package.

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- 5.2.2. If the early protocol termination is recommended by authorized external bodies, the IEC Staff shall inform the PI to submit the protocol termination package. This package should include the following:
- **Continuing Review Application (IEC Form 024/V4/2025)** up until application for early termination
 - A brief written summary of the protocol, its results, and accrual data (included in the request for termination memorandum)
- 5.3. **Step 3 – Retrieval pertinent protocol files.** The IEC Staff retrieves the protocol folder and summarizes the documents that have been submitted.
- 5.4. **Step 4 – Notification of IEC Chair and Primary Reviewers.** The IEC Staff informs the IEC Chair and the Primary Reviewers by SMS, email, etc. about the report and the summary of documents that have been submitted. The Primary Reviewers await for further instructions.
- 5.5. **Step 5 – Preliminary review of the early protocol termination package.**
- 5.5.1. The Primary Reviewers check the approval given by the IEC from the protocol files and collect relevant information.
- 5.5.2. The Primary Reviewers review the early protocol termination package or issues.
- The Primary Reviewers evaluate the safety data, emphasizing the need for the termination package to include a comprehensive follow-up plan for participants still active in the study. This plan should prioritize their ongoing safety and well-being.
- 5.5.3. The Primary Reviewers make recommendations.
- 5.6. **Step 6 – Inclusion of report in the agenda of the next regular IEC board meeting.** The IEC Staff includes the report in the agenda of the next meeting. The Primary Reviewers are given the necessary documents to be used in preparing the presentation during the next meeting.
- 5.7. **Step 7 – Full-Board Review.**
- 5.7.1. The full board of the IEC shall review and discuss the early termination application during an IEC meeting. (*Refer to **SOP 9: Full-Board Review***)
- 5.7.2. The review will ensure that the implications of the early termination on the rights, safety, and welfare of study participants are thoroughly evaluated. This includes examining the termination package, which should outline a set of procedures to address participant needs. These procedures may include specific provisions for continued access to protective mechanisms and relevant information to safeguard the well-being of participants.
- 5.7.3. Following the discussion and consideration of all comments and recommendations from members present at the meeting, the IEC may decide on one of the following actions:
- Acceptance of the decision for termination without further question or action
 - Request for additional information regarding the application for termination

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- 5.8. **Step 8 – Communication of IEC action to the Principal Investigator/Researcher.** The IEC Staff prepares the Notification Letter for Review Decision (IEC Form 019/V1/2025) to be signed by the Chair and sent to the PI at least 5 working days after the decision is made. (Refer to [SOP 27: Communicating DLSMHSI-IEC Decisions](#))
- 5.9. **Step 9 – Filing of all related documents and update of the protocol database.** The IEC Staff keeps copies of the finalized early termination report for documentation and updates the database accordingly. (Refer to [SOP 29: Management of Active Files](#))

6. GLOSSARY

- 6.1 **Database** – a collection of information (e.g. regarding a protocol/s) 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.
- 6.2 **Early Termination** – the decision of the researcher, principal investigator, the institution, or sponsor to end the implementation of a study before its completion.
- 6.3 **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 **Logbook** – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.
- 6.5 **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.
- 6.6 **Termination package** – the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned

7. FORMS

IEC Form 000/V_/2025	Early Protocol Termination Application/Recommendation Form
IEC Form 024/V4/2025	Continuing Review Application
IEC Form 019/V1/2025	Notification Letter for Review Decision
IEC Form 000/V_/2025	Early Protocol Termination Application/Recommendation Log

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8. HISTORY

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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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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

INDEPENDENT ETHICS COMMITTEE

XXI. REVIEW OF FINAL REPORT

DLSMHSI-IEC SOP Ver. 4

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Supersedes:	DLSMHSI-IEC SOP Chapter 3: 5. Review of Final Report / V3 / 2024
Version:	4
Authored by:	Susan A. Olavidez, RRT, EdD Sigfredo B. Mata, RPh
Effective date:	January 2025
Approved by:	
Approval date:	Pending

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1. POLICY STATEMENT

The submission and review of final reports mark the official completion of a study and its acceptance by the IEC. This step is critical in the study timeline as it informs subsequent decisions by researchers, institutions, or funding agencies, such as student or trainee eligibility for graduation, publication of results, or the release of final funding tranches. The Final Report Form serves as a tool to verify consistency between the study's implementation of the study and the approved protocol, as well as to summarize the knowledge gained from the research.

The Final Report includes updated information including completed data analysis, final results, and any relevant publications or conference presentations stemming from the study findings. The PI is required to submit the final report after completing participant enrollment and all follow-up procedures.

The IEC mandates the submission of the final report no later than 90 days after the study's conclusion. Final reports are reviewed through an Expedited Review unless deviations, violations of ethical approvals, or other concerns warrant a full review. This process ensures that the study is concluded in accordance with ethical and procedural standards, reinforcing the integrity of the research and its outcomes.

2. OBJECTIVES

This activity aims to ensure that the conduct of the study complied with the approved protocol and that the safety and welfare of study participants were promoted and the integrity of data protected until the end of the study.

3. SCOPE

This SOP applies to the management and review of final reports submitted by proponents at the end of the study. This begins with the receipt and entry of the final report into the logbook and ends with an update of the protocol database.

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4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt of the Final Report and entry to the physical logbook and electronic database (SOP 29: Management of Active Files)</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
Step 4: <i>Preliminary review of the pertinent protocol files</i>	Primary Reviewers
Step 5: <i>Inclusion of report in the agenda of the next regular IEC board meeting</i>	IEC Chair and Staff
Step 6: <i>Expedited Review (SOP 8: Expedited Review) or Full-Board Review (SOP 9: Full-Board Review)</i>	IEC Chair, Co-chair, or Member-Secretary
Step 7: <i>Communication of IEC action to the Principal Investigator/Researcher (SOP 27: Communicating DLSMHSI-IEC Decisions)</i>	IEC Chair and Staff
Step 8: <i>Filing of the Final Report and related documents (SOP 29: Management of Active Files) and update of the protocol files</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Receipt of the Final Report and entry to the physical logbook and electronic database.**
 - 5.1.1. The IEC Staff reviews the database to identify studies approaching their due date.
 - 5.1.2. The IEC Staff notifies the PI of the requirement to submit the Final Report (IEC Form 027/V4/2025) no more than 90 days after the study's completion.
 - 5.1.3. The PI then submits the completed Final Report (IEC Form 027/V4/2025) as required.
 - 5.1.4. The IEC Staff reviews the completeness of the submitted report.

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- 5.2. Step 2 – Retrieval of pertinent protocol files.** The IEC Staff retrieves the corresponding protocol files as reference in the review of the Final Report (IEC Form 027/V4/2025).
- 5.3. Step 3 – Notification of IEC Chair and Primary Reviewers.** The IEC Staff notifies the Chair and the previously assigned Primary Reviewers within three (3) working days of the receipt of Final Report and sends the pertinent protocol file.
- 5.4. Step 4 – Preliminary review of the pertinent protocol files.**
- 5.4.1. The Primary Reviewers review and evaluate the Final Report (IEC Form 027/V4/2025) to ensure it aligns with the IEC-approved protocol and related documents. (*Refer to [SOP 8: Expedited Review](#)*)
- 5.4.2. The Primary Reviewers refer to the protocol files to verify compliance with the approvals granted by the IEC during the initial review and, if applicable, upon submission of amendments.
- 5.4.3. The evaluation focuses on the following key points:
- Compliance with the approved protocol, particularly the explanation for the non-compliance.
 - Whether the findings and conclusions align with the study's objectives, methodology, and statistical analysis/plan
- 5.4.4. The Primary Reviewers recommend appropriate actions based on their evaluation:
- If there are no deviations or violations of IEC approvals, they determine whether any further action is necessary.
 - If deviations, violations, or unanticipated problems are identified—such as unresolved adverse events (AEs) or unreported protocol deviations—they recommend obtaining explanations or justifications for these issues from the Principal Investigator.
- 5.5. Step 5 – Inclusion of report in the agenda of the next regular IEC board meeting.** The IEC Staff includes the report in the agenda for the next meeting and ensures that the necessary documents are provided to the Primary Reviewers, enabling them to prepare for their presentation at the meeting.
- 5.6. Step 6 – Expedited Review or Full-Board Review.**
- 5.6.1. The IEC Staff submits the recommendations of the Primary Reviewers to the IEC Chair, who determines whether the Final Report should undergo Expedited Review or Full-Board Review. (*Refer to [SOP 8: Expedited Review](#) and [SOP 9: Full-Board Review](#)*) Regardless of the review type, Final Reports are presented to the full board during the next scheduled meeting.
- **In Expedited Review**, the Primary Reviewers present their recommended actions for the Final Report to the board.
 - **In Full-Board Review**, the IEC members, under the guidance of the Chair, Co-Chair, or Member-Secretary, discuss the Final Report to reach a collective decision and determine the appropriate course of action.

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5.7. Step 7 – Communication of IEC action to the Principal Investigator/Researcher.

5.7.1. Decisions and appropriate actions will be communicated to the PI via a Notification Letter for Review Decision (IEC Form 019/V1/2025).

5.7.2. The IEC Staff receives the decision from the IEC and communicates to the PI the possible decisions as follows:

- Uphold original approval with no further action with the renewal of approval of the protocol and related documents to enable the PI to continue the conduct of the research
- Request for further information, specifying information that is required prior to renewal of approval
- Recommend further action, specifying action required prior to renewal of approval

5.8. Step 8 – Filing of the Final Report and related documents and update of the protocol files.

The IEC Staff files the Final Report and related documents in the appropriate folder and updates the protocol database.

6. GLOSSARY

6.1 **Agenda** – the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a “Call to Order”.

6.2 **Benefits** – summary of probable positive or favorable outcomes ranging from benefit to the community (or society), indirect gains such as education, or direct therapeutic value

6.3 **Database** – a collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

6.4 **Expedited Review** – the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only two to three members of the committee without involvement of the whole committee.

6.5 **Final Report** – a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The DLSMHSI-IEC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

6.6 **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.

6.7 **Logbook** – a real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.

6.8 **Primary Reviewers** – members of the DLSMHSI-IEC (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.

- 6.9 **Risks** – summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol
- 6.10 **Status of participants** – summary of what happened to (condition of) participants recruited to the study, including those that completed the study, those that dropped out, or those withdrawn for specific reasons in accordance with the protocol

7. FORMS

IEC Form 027/V4/2025
 IEC Form 019/V1/2025

Final Report
 Notification Letter for Review Decision

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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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De La Salle Medical and Health Sciences Institute
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INDEPENDENT ETHICS COMMITTEE

XXII. MANAGEMENT OF APPEALS

DLSMHSI-IEC SOP Ver. 1

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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

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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 (Form __)** 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 (Form __)** 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 000/V_/2025

Letter of Appeal

IEC Form 019/V1/2025

Notification Letter for Review Decision



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

INDEPENDENT ETHICS COMMITTEE

XXIII. SITE VISITS

DLSMHSI-IEC SOP Ver. 4

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1. POLICY STATEMENT

The DLSMHSI-IEC shall conduct visits of selected sites of approved protocols that fall within the following established criteria for such visits: (a) high risk studies, (b) receipt of significant number of protocol violations, (c) receipt of complaints from participants and families, (d) non-receipt of required after-approval reports from the and (e) multiple studies conducted by a Principal Investigator.

2. OBJECTIVES

Site visits are mechanisms with which the IEC monitors compliance with approved protocols, ICF process and continuing protection and promotion of participant’s dignity, rights and well-being.

3. SCOPE

This SOP includes the steps in conducting visits to study sites for reasons set by the IEC. It begins with the selection of the site to be visited and ends with filing of Site-Visit Reports in the protocol folder and updating of the protocol database

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Selection of site to visit</i>	IEC Chair and Members
Step 2: <i>Notification of the PI</i>	IEC Staff
Step 3: <i>Creation of the Site Visit Team</i>	IEC Chair
Step 4: <i>Conduct of site visit</i>	Site Visit Team (Members)
Step 5: <i>Draft of Site Visit Report, presentation of the report during meeting, and discussion for recommendations</i>	Site Visit Team (Members)

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ACTIVITY	RESPONSIBILITY
Step 6: <i>Transmittal of Final Report and Recommendations to the PI</i>	IEC Chair and Staff
Step 7: <i>Filing of Site-Visit Reports in the protocol folder and update of protocol database</i>	IEC Staff

5. DETAILED DESCRIPTION

5.1. Step 1 – Selection of site to visit.

5.1.1. The IEC Chair and designated members regularly review the database files of submitted and approved study protocols to identify study sites requiring monitoring.

5.1.2. Study sites are selected for monitoring based on the following criteria:

- Sites with **new Principal Investigators** or newly initiated studies, to ensure proper implementation of ethical standards.
- Sites reporting **significant serious adverse events (SAEs)**, which may indicate risks to participant safety.
- Sites conducting a **large number of studies**, which may require additional oversight to ensure quality and compliance.
- Sites with a **high frequency of protocol submissions** for IEC review, indicating potential overextension or administrative challenges.
- Sites identified for **non-compliance** or showing **suspicious conduct**, such as failure to adhere to ethical standards or protocol requirements.
- Sites that **frequently fail to submit final reports**, highlighting potential lapses in study completion and documentation.
- Sites with **frequent protocol violations**, which could indicate systemic issues in study conduct or oversight.

5.1.3. The IEC Chair records the reasons for selecting specific study sites and secures consensus or approval from designated IEC members before initiating site visits.

5.2. Step 2 – Notification of the PI.

5.2.1. The PI or researcher must be informed of the scheduled site visit at least two weeks in advance to allow adequate preparation.

5.2.2. The IEC staff sends a formal notification to the PI or researcher via an official letter, **Notification Letter for Site Visit (Form __)**, sent traditionally or in email. This communication ensures clarity and provides a documented record of the notification.

5.2.3. The **Notification Letter for Site Visit (Form __)** includes the following information:



- **Purpose of the Site Visit:** A clear explanation of the reason for the visit, such as routine monitoring, compliance verification, or follow-up on reported issues.
- **Date and Time of the Visit:** The specific schedule for the site visit.
- **IEC Representatives:** Names and roles of the IEC members or representatives who will conduct the visit.
- **Documents to Prepare:** A detailed list of required documents, such as:
- **Expected Duration:** An estimated timeframe for the visit.
- **Contact Information:** Contact details of the IEC Staff or Chair for any clarifications or concerns regarding the visit.

5.2.4. The PI or researcher is requested to acknowledge receipt of the notification and confirm their availability on the scheduled date.

5.3. Step 3 – Creation of the Site Visit Team.

5.3.1. The IEC Chair is responsible for creating the Site Visit Team. The team is selected based on the expertise required for the specific study and site visit objectives.

5.3.2. The team typically includes:

- **Primary Reviewers** familiar with the protocol under review.
- **IEC Members** with relevant expertise in the study area or ethical standards.
- **A non-affiliated member** (e.g., a lay representative) to provide an independent perspective, if applicable.
- **IEC Staff** to assist with documentation and logistical support during the visit.

5.3.3. The Site Visit Team convenes for a preparatory meeting to:

- Review the objectives of the site visit.
- Assign specific responsibilities to each team member, such as reviewing informed consent practices, participant safety measures, or compliance with approved protocols.

5.3.4. Each team member must be familiar with:

- The **Site Visit Report Checklist (Form __)** and other templates to be used during the visit for recording observations and findings.
- IEC Guidelines and applicable national/international regulations, such as ICH-GCP and 2022 National Ethical Guidelines for Health Research Involving Human Participants (NEGRIHP).

5.3.5. Prior to the visit, the Site Visit Team reviews the following:

- The **approved study protocol** and any amendments.
- Participant enrollment logs.
- Reports of adverse events or serious adverse events.
- Informed consent forms and processes.
- Communication records between the IEC and the Principal Investigator.
- Monitoring or audit reports, if available.



5.4. Step 4 – Conduct of Site Visit.

5.4.1. The Site Visit Team uses the **Site Visit Checklist (Form __)** as the primary tool for recording observations, findings, and recommendations during the site visit. It ensures that all relevant aspects of the visit, such as compliance, documentation, and interviews, are systematically reviewed and documented.

5.4.2. The Site Visit Team compares onsite documents with those in the approved protocol files to ensure consistency. Key points of observation include:

- **Study Protocol Version:** Verify that the site is using the most recently approved version.
- **Informed Consent Documents:** Verify that the site is using the most recent IEC-approved version.
- **Post-Approval Documents:** Verify that required post-approval documents, such as amendments or reports, have been submitted to and approved by the IEC.
- **Subject Files:** Randomly review participant files to confirm that participants have signed the correct ICF.
- **Participant Rights, Safety, and Welfare:** Ensure measures are in place to protect the rights, safety, and well-being of human participants in the study.
- **Facilities at the Study Site:** Assess whether the site has the necessary infrastructure and resources to conduct the study effectively and ethically.
- **Document Security and Confidentiality:** Check that participant data and study documents are stored securely, maintaining privacy and confidentiality.
- **Document Organization:** Check that files are orderly, properly maintained, and confidentiality of participant data is upheld.

5.4.3. The Site Visit Team conducts interviews with the Principal Investigator and/or research staff to:

- Address discrepancies in documentation.
- Gain insights into the implementation of the study protocol.
- Evaluate adherence to ethical standards and regulatory requirements.

5.4.4. At the conclusion of the site visit, Site Visit Team debriefs the PI to:

- Share preliminary findings and observations, including any compliance concerns or areas for improvement.
- Provide comments on the overall conduct of the study.
- Obtain immediate feedback or clarification on any issues raised during the visit.

5.4.5. The Site Visit Team fills out the **Site Visit Checklist (Form __)** during the visit to guide observations and ensure thorough assessment.

5.5. Step 5 – Draft of Site Visit Report, presentation of the report during meeting, and discussion for recommendations.

5.5.1. The designated IEC members write a comprehensive report utilizing the **Site Visit Checklist (Form __)** to document the findings and provide recommendations. The report includes details on protocol compliance, informed consent processes, participant safety, document security, and any observed deviations or violations.



- 5.5.2. The Noncompliance Report Form (IEC Form 026/V3/2025) is then accomplished within one week of the Site Visit.
- 5.5.3. A copy of the completed report is forwarded to the IEC Staff for inclusion in the agenda of the next board meeting, provided it meets the cut-off date (i.e., 5 PM on the 15th of the month preceding the meeting).
- 5.5.4. The Noncompliance Report Form (IEC Form 026/V3/2025) is documented as follows:
- The report is sent to the study site for their records.
 - A copy of the report is placed in the respective site file within the IEC records.
 - All actions and communications related to the report are logged in the IEC's physical and electronic databases for tracking and reference. (Refer to **SOP 29: Management of Active Files**)
- 5.5.5. The designated IEC member(s) who conducted the site visit presents the findings and recommendations from the **Site Visit Checklist (Form __)** and Noncompliance Report Form (IEC Form 026/V3/2025) to the Full Board during the meeting.
- 5.5.6. The Full Board discusses the findings presented and evaluates compliance and any identified issues.
- 5.5.7. Based on the discussion, the board makes a decision on appropriate action, which may include:
- Issuing recommendations for corrective measures
 - Requiring follow-up visits or reports
 - Implementing sanctions, such as suspending or terminating the study
- 5.5.8. The decision is documented in the meeting minutes and communicated to the study site and Principal Investigator.
- 5.6. **Step 6 – Transmittal of Final Report and Recommendations to the PI.** The IEC Staff prepares a summary of the findings and recommendations of the IEC based on the deliberations during the meeting. The IEC Chair finalizes the draft for transmittal to the PI or researcher. The staff forwards the committee's decision to the PI through a **Notification Letter for Post-Approval Requirements (Form __)**. (Refer to **SOP 27: Communicating DLSMHSI-IEC Decisions**)
- 5.7. **Step 7 – Filing of Site-Visit Reports in the protocol folder and update of protocol database.** The IEC Staff files the Site Visit documents in the appropriate folder and updates the protocol database accordingly.

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6. GLOSSARY

- 6.1 **After-approval reports** – reports, e.g. progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the IEC for submission by the researcher/investigator after the study has been approved for implementation.
- 6.2 **Decision** – the result of the deliberations of the IEC in the review of a protocol or other submissions.
- 6.3 **Full Review** – the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the IEC *en banc*, in the presence of a quorum, using established technical and ethical criteria.
- 6.4 **High Risk Studies** – research where harm or danger resulting from the study intervention is very likely for participants.
- 6.5 **Primary Reviewer** – a member of the IEC assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.
- 6.6 **Protocol Database** – a collection of information regarding protocols that is structured and organized
- 6.7 **Protocol File/Folder** – an organized compilation of all documents (physical or electronic form) related to a study.
- 6.8 **Protocol Violation** – non-compliance with the approved protocol that may result in an increased risk or decreased benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.
- 6.9 **Site Visit** – an action of the IEC (based on established criteria) in which an assigned team goes to the research site or office for specific monitoring purposes.

7. FORMS

IEC Form 000/V_/2025	Notification Letter for Site Visit
IEC Form 000/V_/2025	Site Visit Checklist
IEC Form 026/V3/2025	Noncompliance Report Form
IEC Form 000/V_/2025	Notification Letter for Post-Approval Requirements

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8. HISTORY

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1	22 Oct. 2012	Dr. Melchor Victor G. Frias IV	
2	20 Jun 2016	Dr. Melchor Victor G. Frias IV Ms. Genevieve V. Bayas	
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4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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De La Salle Medical and Health Sciences Institute
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INDEPENDENT ETHICS COMMITTEE
**XXIV. PREPARATION AND
DISTRIBUTION OF MEETING
AGENDA**

DLSMHSI-IEC SOP Ver. 4

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1. POLICY STATEMENT

Meetings are a critical activity for the research ethics committee, serving as venues for the deliberation and decision-making process in the ethical evaluation of study protocols. They also provide opportunities for the committee to stay informed and updated on its operations and relevant matters. To ensure efficient and timely reviews, the DLSMHSI-IEC conducts at least one regular (full-board) meeting each month, held on weekdays between the 16th and 30th, for the expedited review and full-board review of protocols classified as such, as well as the reporting of approved protocols and post-approval submissions.

The meeting agenda plays a vital role in guiding the conduct of meetings. A standard template is used to ensure consistency, and the agenda includes protocols submitted at least ten (10) working days before the scheduled meeting. The provisional agenda is attached to the Notice of Meeting, ensuring members are well-prepared for discussions and deliberations. Regular meetings are essential to maintaining the efficiency and integrity of the ethics review process.

2. OBJECTIVES

The objective of this SOP is to ensure the smooth, orderly, inclusive, and efficient conduct of meetings through the proper preparation and distribution of the meeting agenda.

3. SCOPE

This SOP covers all activities related to the preparation and distribution of the meeting agenda for regular and special IEC meetings, beginning with the drafting of the agenda and ending with the filing of the final meeting agenda approved during the meeting.

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4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Preparation of the draft meeting agenda</i>	IEC Member-Secretary and Staff
Step 2: <i>Preparation of the provisional meeting agenda</i>	IEC Chair
Step 3: <i>Distribution of the provisional meeting agenda and confirmation of attendance</i>	IEC Staff
Step 4: <i>Approval of the provisional meeting agenda</i>	IEC Members
Step 5: <i>Filing of the final meeting agenda (SOP 29: Management of Active Files)</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

5.1. Step 1 – Preparation of the draft meeting agenda.

- 5.1.1. The IEC Staff under the supervision of the Member-Secretary prepares the draft agenda two weeks before the scheduled meeting, using the Notice of Regular Meeting (IEC Form 028/V3/2025).
- 5.1.2. The date of issuance, along with the date, time, and venue of the meeting, shall be clearly indicated on the draft meeting agenda.
- 5.1.3. The agenda items include the following:
 - Opening Prayer
 - Checking of Quorum
 - Declaration of Quorum and Call to Order
 - Approval of the Provisional Agenda
 - Disclosure of Conflict of Interest
 - Review and Approval of the Minutes of the Previous Meeting
 - Business Arising from the Minutes of the Previous Meeting



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- New Business:
 - Full-board Review
 - Initial Review
 - Resubmission
 - Requirement for Clarificatory Interview
 - Protocol Amendment Applications (Major)
 - Continuing Review Applications
 - Final Reports
 - SAE Reports
 - Site Visit Reports
 - Non-compliance Reports (Minor and Major)
 - Early Protocol Termination
 - Queries and Complaints
 - Expedited Review Report / Report of Approved Protocols by Expedited Review
 - Initial Review
 - Resubmission
 - Protocol Amendment Applications (Minor)
 - Continuing Review Applications
 - Protocol Withdrawal
 - Final Reports
 - Non-compliance Reports
 - Early Protocol Termination
 - Queries and Complaints
 - Exemption Report (Report of Exempted Protocols)
- Other Matters
- Adjournment

5.2. Step 2 – Preparation of the provisional meeting agenda. The IEC Chair reviews the draft agenda (within one week) as the basis of preparing the provisional agenda for inclusion in the Notice of Regular Meeting (IEC Form 028/V3/2025).

5.3. Step 3 – Distribution of the provisional meeting agenda and confirmation of attendance. The IEC Staff distributes the provisional meeting agenda through email one week before the scheduled meeting. A follow-up communication shall be conducted at least three (3) working days before the meeting to confirm members' attendance and ensure that quorum requirements are met. If a quorum cannot be met, the IEC Staff promptly informs the IEC Chair and Member-Secretary to allow for the invitation of alternate members.

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- 5.4. **Step 5 – Approval of the provisional meeting agenda.** The IEC members approve the provisional agenda during the meeting. (Refer to [SOP 25: Preparation and Conduct of Meetings](#))
- 5.5. **Step 6 – Filing of the final meeting agenda.** The IEC Staff files the approved meeting agenda in a special order that contains all meeting agenda in chronological order. (Refer to [SOP 29: Management of Active Files](#))

6. GLOSSARY

- 6.1 **Conflict of Interest** – a situation in which aims or concerns of two (primary and secondary) different roles or duties are not compatible such that decisions may adversely affect the official/primary duty.
- 6.2 **Draft Meeting Agenda** – the order of business that includes the list of topics or items recommended for discussion in a meeting. This is endorsed to the IEC Chair for his/her approval.
- 6.3 **Exemption Report** – a list of protocols submitted for review that were deemed not to require the conduct of either expedited or full review. This report is presented during a regular committee meeting or as required by the institutional authority.
- 6.4 **Expedited Review Reports** – an enumeration of protocols (including titles, code number, proponent, submission date, names of reviewers and decisions) that underwent expedited review for information of the IEC members and for record viewers.
- 6.5 **Final Meeting Agenda** – the order of business that includes the list of topics or items approved for discussion in a meeting by the IEC Members in a regular or special meeting.
- 6.6 **Post-approval Reports** – accounts of the ongoing implementation of an approved study (e.g., progress report, amendment, safety report, protocol deviation/violation, early termination, final report, or application for continuing review) that are required be submitted by the researcher to the IEC for monitoring purposes.
- 6.7 **Protocols for Full Review** – study proposals that require an *en banc* ethical assessment because they entail more than minimal risks to the participants and/or that participation generates vulnerability issues.
- 6.8 **Provisional Meeting Agenda** – the order of business that includes the list of topics or items approved for discussion in a meeting by the IEC Chair.
- 6.9 **Quorum** – the minimum number (i.e., majority of the members) and type of members of the IEC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least five (5) regular members including the non-affiliated and the no-medical, non-scientist, lay members.

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7. FORMS

IEC Form 028/V3/2025

Notice of Regular Meeting Template

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1	22 Oct. 2012	Dr. Melchor Victor G. Frias IV	
2	20 Jun 2016	Dr. Melchor Victor G. Frias IV Ms. Genevieve V. Bayas	
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DE LA SALLE MEDICAL AND HEALTH SCIENCES INSTITUTE
INDEPENDENT ETHICS COMMITTEE

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	De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114	DLSMHSI-IEC SOP Ver. 1 Approval Date:
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1. POLICY STATEMENT

The DLSMHSI-IEC shall hold regular monthly meetings every 3rd Wednesday of the month within the premises of the institution, with special meetings convened as needed to address urgent issues such as participant safety or protocol violations impacting research integrity. Meetings shall be presided over by the Chair or a designated substitute, proceed only when a quorum is declared, and follow the approved agenda. Any conflicts of interest among members must be disclosed prior to the discussion of protocols under review.

2. OBJECTIVES

The objective of this SOP is to ensure the smooth, orderly, and efficient preparation and conduct of meetings, providing a venue for the IEC to make collegial decisions on study protocols and operations, and to address pertinent administrative matters.

3. SCOPE

This SOP outlines the preparation and conduct of IEC meetings, covering all activities from logistical preparations, notification and confirmation of attendance by IEC members, and dissemination of pertinent meeting materials, to the conduct of the meeting, and the proper collection, storage, and disposal of meeting materials. The process begins with the dissemination of the Notice of Meeting and ends with the secure handling of meeting materials after the meeting is adjourned.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Notification of IEC members and confirmation of attendance (SOP 24: Preparation and Distribution of Meeting Agenda)</i>	IEC Staff
Step 2: <i>Preparation of meeting venue and logistics</i>	IEC Staff
Step 3: <i>Assembly of materials and documents needed for the meeting</i>	IEC Staff



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ACTIVITY	RESPONSIBILITY
Step 4: <i>Arranging the appearance of Principal Investigators/Researchers for protocol clarifications and Independent Consultants</i>	IEC Staff
Step 5: <i>Preparation and distribution of meeting materials</i>	IEC Staff
Step 6: <ul style="list-style-type: none"> <i>Opening of the meeting</i> 1. <i>Opening Prayer</i> 2. <i>Declaration of Quorum</i> 3. <i>Confirmation of Quorum and Call to Order</i> 4. <i>Approval of the provisional agenda</i> 5. <i>Disclosure of Conflict of Interest</i> 6. <i>Review and approval of the Minutes of the Previous Meeting</i> 	IEC Chair, Co-chair and Member-Secretary
Step 7: <i>Discussion of business arising from the Minutes of the Previous Meeting</i>	IEC Members
Step 8: <ul style="list-style-type: none"> <i>Discussion of new business:</i> 1. <i>Full-board review</i> 2. <i>Expedited review report</i> 3. <i>Exemption report</i> 	IEC Members
Step 9: <i>Discussion of operations-related matters</i>	IEC Members
Step 10: <i>Adjournment</i>	IEC Chair
Step 11: <i>Collection, storage, and disposal of meeting materials (SOP 29: Management of Active Files)</i>	IEC Staff

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5. DESCRIPTION OF PROCEDURES

- 5.1. Step 1 - Notification of IEC members and confirmation of attendance.** The IEC Staff distributes the Notice of Regular Meeting (IEC Form 028/V3/2025) containing the provisional agenda through email one week before the scheduled meeting. Attendance of IEC members is confirmed at least three (3) working days before the meeting. If a quorum cannot be met, the IEC Staff promptly informs the IEC Chair and Member-Secretary to allow for the invitation of alternate members. *(Refer to [SOP 24: Preparation and Distribution of Meeting Agenda](#))*
- 5.2. Step 2 – Preparation of meeting venue and logistics.**
- 5.2.1. The IEC Staff coordinates with the RAC Administrative Assistant to reserve a conference room at least one week prior to the scheduled meeting.
- 5.2.2. For hybrid or online meetings, the IEC Staff coordinates with the ICT team to set up the online conference link.
- 5.2.3. The IEC Staff ensures the preparation and availability of all necessary equipment and arrangements for the on-site meeting, including:
- Laptops (at least two: one for writing the minutes and another for presentations)
 - Projector and screen
 - Microphones (as needed, depending on the size of the conference room)
 - Adequate tables, chairs, and proper ventilation (ACU)
 - Sufficient food and drinks/water, depending on the expected meeting duration
- 5.3. Step 3 – Assembly of materials and documents needed for the meeting.** The staff gathers the documents and materials for the meeting based on the provisional agenda, e.g. copies of the provisional agenda, provisional minutes of the previous meeting, protocols and related documents submitted, at least 2 weeks before the meeting, post-approval reports, expedited review reports, administrative memos, etc.
- 5.4. Step 4 – Arranging the appearance of Principal Investigators/Researchers for protocol clarifications and Independent Consultants.**
- 5.4.1. If recommendations on protocols require clarifications, the IEC Staff notifies the Principal Investigator (PI) of the meeting schedule and communicates their assigned time slot for appearing at the IEC meeting.
- 5.4.2. If specialized inputs are needed for specific protocols, the IEC staff communicates this to the PI upon the advice of the IEC Chair.
- 5.5. Step 5 – Preparation and distribution of meeting materials.**
- 5.5.1. The IEC Staff prepares sufficient hard copies of meeting materials for all members who will be attending onsite and who requested a hard copy of the material. For all



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other members, electronic copies are sufficient. Meeting materials shall be sent to the IEC members at least one week prior to the scheduled meeting.

- Agenda for the meeting
- Study protocols and related documents (e.g., informed consent forms, amendments, progress reports, etc.)
- Minutes of the previous meeting
- Reviewer assessment forms
- Relevant correspondence or communication

5.5.2. The Member-Secretary oversees the preparation and ensures that all required materials are complete and distributed to IEC members before the meeting.

5.6. Step 6 – Opening of the meeting.

5.6.1. The meeting begins with an opening prayer led by the Chair, Member-Secretary, or an assigned member.

5.6.2. The Member-Secretary notifies members that the meeting will be recorded.

5.6.3. Attendance is called, and members are identified by their role (e.g., medical/non-medical, institutional/non-institutional) and any guest or independent consultants are acknowledged.

5.6.4. The Member-Secretary ensures quorum is met (50% + 1 of members present, including at least one non-medical, non-scientist, lay member and one non-affiliated member). For interventional studies involving children, a quorum shall include the presence of a pediatrician or child development expert, as needed by the protocol.

5.6.5. Once quorum is confirmed, the meeting is called to order, and the Chair or Co-chair is declared the presiding officer.

5.6.6. The presiding officer invites members to review the provisional agenda and propose any additions, deletions, or revisions.

5.6.7. The revised or original agenda is then approved by the members present. This is now referred to as the approved agenda.

5.6.8. The presiding officer asks members to disclose any conflicts of interest (COI) for the protocols under review.

5.6.8.1. Members declaring a COI complete and sign the Confidentiality and Conflict of Interest Disclosure Form (IEC Form 003/V2/2025).

5.6.8.2. For on-site meetings, members with COI are asked to step out of the room before the discussion begins and return after the decision is made. For online meetings, members with COI are asked to log out of the platform during the discussion and return after the decision.

5.6.8.3. The IEC Staff records the time members with COI step out/log out and the time they rejoin the meeting. This time record must be included in the Minutes of the Meeting.



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- 5.6.9. The presiding officer reminds members that the minutes of the previous meeting were distributed via email.
- 5.6.10. A page-by-page review of the minutes is conducted, and members may suggest corrections, additions, or deletions.
- 5.6.11. The presiding officer seeks approval of the revised or original minutes from the members present.
- 5.7. Step 7 – Discussion of business arising from the Minutes of the Previous Meeting.** The presiding officer discusses any business arising from minutes and a consensus shall be met after the discussion.
- 5.8. Step 8 – Discussion of new business.**
- 5.8.1. The primary reviewer presents the protocol, covering key aspects such as objectives, clinical significance, methods, outcomes, and ethical considerations. The presentation is guided by the assessment form. (*Refer to **SOP 9: Full-Board Review***)
- 5.8.2. Following the presentation, other members are invited to provide their comments, leading to an open discussion. The discussion follows a structured sequence considering the key points below:
- **Technical Issues:** Feasibility, design, and scientific soundness of the protocol
 - **Ethical Issues:** Risk-benefit analysis, participant protections, and privacy
 - **Informed Consent Process/Form:** Clarity, completeness, and adherence to ethical guidelines
- 5.8.3. If additional clarification is required, the PI may be invited for an interview during the current meeting or at a later date using the Notification Letter for Review Decision (IEC Form 019/V1/2025). During the meeting, the PI will be invited to appear only at the scheduled time for the discussion of their protocol. They will have the opportunity to address specific concerns raised by the IEC and will leave once the necessary clarifications have been provided.
- 5.8.4. Independent consultants, if involved, provide specialized input during the discussion of specific protocols but do not participate in decision-making or voting.
- 5.8.5. The presiding officer summarizes the recommendations and checks quorum before requesting a motion regarding the action for the protocol (approval, minor or major modification, or disapproval).
- 5.8.6. Voting is conducted via a show of hands. If consensus is not achieved, members with differing opinions voice their concerns, and unresolved issues are summarized.
- 5.8.7. Recommendations or decisions are documented, and a summary is sent to the PI.
- 5.8.8. For the expedited review report, the primary reviewers present their findings and decisions (approved, minor modification, or major modification). Members review the expedited review results for informational purposes. These results are documented but do not require further action unless a full-board review is recommended.



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- 5.8.9. Reports of protocols exempted from review are presented to the IEC for documentation and noted without requiring discussion.
- 5.8.10. Approved final reports are presented during the full-board meeting on the 3rd Wednesday of the month for documentation and noting by members.

5.9. Step 9 – Discussion of operations-related matters.

- 5.9.1. Operations-related matters typically include administrative issuances, schedules, and assignments for members participating in IEC-related workshops, lectures, and conferences, as well as updates to policies and guidelines from accrediting bodies such as PHREB, FERCAP, and other relevant organizations.
- 5.9.2. Items requiring deliberation and approval by members include:
- Schedules and assignments for workshops, lectures, and conferences, especially if they involve funding, institutional representation, or workload considerations.
 - Adoption or implementation of updates to policies and guidelines from accrediting bodies that may affect the IEC's operations or review processes.
- 5.9.3. Items for information only include:
- General administrative announcements or reminders
 - Informational updates from accrediting bodies that do not necessitate immediate action or changes to IEC procedures

- 5.10. **Step 10 – Adjournment.** Meeting must be adjourned after all items in the agenda have been discussed and/or resolved. A member must move for the adjournment of the meeting, and seconded, for it to be declared.

5.11. Step 11 – Collection, storage, and disposal of meeting materials.

- 5.11.1. For on-site meetings, all hard copies of the minutes distributed to members must be returned to the Secretariat immediately after the meeting. For online meetings, IEC members are responsible for storing the soft copy of the minutes securely in a password-protected folder within their email.
- 5.11.2. The IEC Staff sorts returned meeting materials into protocol-related and administrative documents.
- 5.11.3. The original hard copy of the minutes is retained and placed in a separate folder designated for meeting documentation.
- 5.11.4. Hard copies of retained documents are filed in clearly labeled folders and stored in a locked cabinet within the IEC office to ensure confidentiality and secure access.
- 5.11.5. The IEC Staff updates an electronic database to log the meeting date, agenda items, and corresponding documents for easy tracking and retrieval.

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- 5.11.6. Extra hard copies of meeting materials that are no longer needed are shredded to maintain confidentiality and comply with data protection regulations. For electronic copies, outdated or unnecessary files are deleted securely using software that ensures permanent removal.
- 5.11.7. The IEC staff maintains a logbook or electronic tracker to record the collection, storage, and disposal of meeting documents, ensuring accountability and proper management of all materials.

6. GLOSSARY

- 6.1 **Adjournment** – formal closure of the meeting. Motion for adjournment and record of the time are noted.
- 6.2 **Administrative Documents** – documents that pertain to the operations of the REC and are not directly related to a study or protocol.
- 6.3 **Agenda** – the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a “Call to Order”.
- 6.4 **Alternate Members** – individuals who possess qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting.
- 6.5 **Ballot** – voting (indicating the choice) by writing the choice on a form for the purpose. Ballots are subsequently counted to determine how the majority of members voted for decision-making.
- 6.6 **Business Arising from the Minutes** – matters generated from the discussions in the previous meeting that need continuing attention and require reporting.
- 6.7 **Clarificatory Interview/meeting** – a face-to-face consultation between the IEC and the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the IEC to make these issues less confusing or more comprehensible.
- 6.8 **Collegial Decision** – a course of action arrived at after a group deliberation where members were considered of equal authority such that the course of action is considered a group action and is not ascribed to any one member.
- 6.9 **Conflict of Interest** – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.
- 6.10 **Consensus** – the process of arriving at a decision without voting but by generating the overall sentiment of a group such that deliberations continue until no more strong objection is registered.
- 6.11 **IEC Operations** – the overall activities of the IEC that reflect performance of its functions and responsibilities.
- 6.12 **Meeting Minutes** – the official narration and record of the proceedings of the assembly of REC Members, based on the agenda.

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- 6.13 **Operations-related Matters** –items included in the agenda that are not directly related to any protocol under review.
- 6.14 **Protocol** – documentation of the study proposal that includes a presentation of the rationale and significance of the study, background and review of literature, study objectives, study design and methodology, data collection, dummy tables, plan for analysis of data, ethical consideration, and dissemination plan.
- 6.15 **Protocol-related submissions** – other documents that are included (required) in the submission of the protocol, e.g., Informed Consent Forms, study tools (Interview guide, survey questionnaire, FGD guide) and CVs of the proponents and certificates of training.
- 6.16 **Quorum** – the minimum number (i.e., majority of the members) and type of members of the IEC that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 5 regular members including the non-affiliated and the non-scientist members.
- 6.17 **Regular Meeting** – a periodically scheduled assembly of the IEC
- 6.18 **Special Meeting** – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action
- 6.19 **Voting** – act of formally manifesting a choice in a meeting.

7. FORMS

IEC Form 028/V3/2025	Notice of Regular Meeting
IEC Form 003/V2/2025	Confidentiality and Conflict of Interest Disclosure Form
IEC Form 019/V1/2025	Notification Letter for Review Decision
IEC Form 000/V_/2025	Meeting Database

8. HISTORY

Version No.	Date	Authors	Main Revision
1	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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1. POLICY STATEMENT

The Minutes of the Meeting shall be based on the approved agenda and shall be the basis of the decision letter on protocols.

2. OBJECTIVES

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in a DLSMHSI-IEC meeting.

3. SCOPE

This SOP includes DLSMHSI-IEC actions related to the documentation of the proceedings of a meeting, the final output of which is the minutes of the meeting. This begins with the entry of preliminary information on the minutes template and ends with the filing of the approved minutes.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Entry of preliminary information on the minutes template</i>	IEC Staff
Step 2: <i>Preparation of the draft minutes</i>	IEC Member-Secretary and Staff
Step 3: <i>Notation of the draft minutes</i>	IEC Chair
Step 4: <i>Approval of the minutes in the next IEC meeting</i>	IEC Chair and Members
Step 5: <i>Filing of the approved minutes (SOP 29: Management of Active Files)</i>	IEC Staff

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5. DESCRIPTION OF PROCEDURES

5.1. Step 1 – Entry of preliminary information on the minutes template.

- 5.1.1. The IEC Staff, under the supervision of the Member-Secretary, organizes the documents in the Minute's template at least 2 days before the scheduled meeting.
- 5.1.2. The Minute's template shall be based on the provisional meeting agenda that is included in the Notice of Meeting. (For the typical items included, refer to **SOP 24: Preparation and Distribution of Meeting Agenda**)
- 5.1.3. The Member-Secretary reviews the Minute's template and verifies the completeness of its content.

5.2. Step 2 – Preparation of the draft minutes.

- 5.2.1. During the meeting, the IEC Staff is tasked with the documentation of proceedings in accordance with the agenda.
- 5.2.2. For on-site meetings, the IEC Staff performs real-time notetaking using the agenda template projected on the screen to guide the recording process. For online meetings, the IEC Staff takes notes in real-time using the screen-shared agenda template on the online platform. The agenda template may be simultaneously projected on the screen and screen-shared during hybrid meetings (with on-site and online attendees).
- 5.2.3. Comments and recommendations are documented for all relevant sections of the agenda, including scientific issues, ethical issues, and informed consent form issues.
- 5.2.4. The opinions and actions documented are understood to be collective and are not attributed to specific members unless they pertain to administrative or operational queries requiring follow-up.
- 5.2.5. The IEC Staff ensures that all discussions and board opinions are recorded systematically, with respective reasons provided for protocol-related actions. The Member-Secretary oversees the task to ensure that all key points from the discussions are captured accurately.
- 5.2.6. Mandatory information to be included are as follows:
 - 5.2.6.1. Comments and recommendations on:
 - **Scientific issues:** Feasibility, design, and soundness of the protocol
 - **Ethical Issues:** Risk-benefit analysis, participant protections, and privacy considerations.
 - **Informed Consent Issues:** Clarity, completeness, and adherence to ethical standards
 - 5.2.6.2. Collective board opinions and decisions on protocol actions, such as approval, modification, or disapproval, with corresponding justifications
- 5.2.7. The IEC Staff uses the documented information to compile the draft minutes of the meeting, ensuring that all sections of the agenda are addressed comprehensively.

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5.2.8. The minutes should also include administrative or operational follow-ups, if applicable, without attributing opinions to individual members.

5.3. Step 3 – Notation of the draft minutes.

5.3.1. The IEC Staff prepares a complete draft of the minutes and submits the document to the Member-Secretary within one (1) week after the meeting for verification, review, corrections, and to the Chair for approval as provisional minutes.

5.3.2. In general, the following items are included in the Minutes of the Meeting:

- Date and venue of meeting
- Members attendance (members present and absent)
- Presence of Independent Consultants, Primary Investigators, guests, and observers (if any)
- Time when the meeting was called to order
- Declaration of quorum
- Name of presiding officer
- Conflict of Interest disclosure
- Items discussed, issues raised, and resolutions
- IEC decisions and recommendations
- Name and signature of person who prepared the minutes
- Name and signature of the Chair and date of notation

5.3.3. The Member-Secretary ensures the IEC Staff fulfills this task accurately and comprehensively, verifying that all critical discussions and decisions are reflected in the draft minutes.

5.4. Step 4 – Approval of the minutes in the next DLSMHSI-IEC meeting.

5.4.1. The IEC Chair approves the draft minutes, which becomes the provisional minutes.

5.4.2. The provisional minutes is then send to the IEC members through email. The provisional minutes are formally approved during the next full-board meeting.

5.5. Step 5 – Filing of the approved minutes. The IEC staff files the signed approved Minutes of Regular Meeting (IEC Form 031/V3/2025) to the Notice and Minutes of the Meeting folder. (Refer to [SOP 29: Management of Active Files](#))

6. GLOSSARY

- 6.1 **Conflict of Interest** – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.
- 6.2 **Draft Minutes of the Meeting** – proceedings of the meeting prepared by the IEC Staff under the supervision of the Member-Secretary.
- 6.3 **Final Meeting Minutes (Approved Minutes of the Meeting)** – proceedings of the meeting that have been approved by the IEC members.
- 6.4 **Meeting Agenda** – the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a “Call to Order”.
- 6.5 **Provisional Minutes of the Meeting** – proceedings of the meeting that have been noted or approved by the IEC Chair.
- 6.6 **Real-time Recording** – the process of documenting the minutes of the meeting as the meeting proceeds simultaneously.

7. FORMS

IEC Form 031/V3/2025

Minutes of Regular Meeting

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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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City of Dasmariñas, Cavite, Philippines 4114

INDEPENDENT ETHICS COMMITTEE

XXVII. COMMUNICATING DLSMHSI- IEC DECISIONS

DLSMHSI-IEC SOP Ver. 1

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	<p>De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114</p>	<p>DLSMHSI-IEC SOP Ver. 1 Approval Date:</p>
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1. POLICY STATEMENT

The DLSMHSI-IEC shall communicate its decision to the researcher within five (5) working days after the expedited or full board meeting or deliberation as the case may be. The communication document shall include clear instructions/recommendations for guidance of the researcher, and it must be written on an official stationery of the IEC and signed by the IEC Chair.

2. OBJECTIVES

The management of communicating DLSMHSI-IEC decisions ensures that all stakeholders are appropriately, accurately and promptly informed of the results of deliberations of the DLSMHSI-IEC.

3. SCOPE

This SOP covers the communication of DLSMHSI-IEC decisions, including actions on applications submitted to the IEC. It begins with the finalization of committee or reviewer recommendations and encompasses the preparation, transmittal (in both soft and hard copies), and filing of decision documents, concluding with their proper storage in the protocol file.

4. WORKFLOW

	ACTIVITY	RESPONSIBILITY
Step 1:	<ol style="list-style-type: none"> For Full-Board Review: Finalization of recommendations of the committee (SOP 9: Full-Board Review) For Expedited Review: Finalization of recommendations of reviewers (SOP 8: Expedited Review) For Exempt from Review: Classification of protocol and issuance of certification of exemption (SOP 7: Exempt from Review) 	IEC Chair, Co-chair, and Member Secretary
Step 2:	Transfer of information from Minutes of the Meeting or reports to IEC decision forms or templates	IEC Member-Secretary and Staff
Step 3:	Approval of the IEC decision document	IEC Chair

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ACTIVITY	RESPONSIBILITY
Step 4: <i>Transmittal of the IEC decision to researcher</i>	IEC Staff
Step 5: <i>Filing of the decision document in the protocol file (SOP 29: Management of Active Files) and update of protocol database</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

5.1. Step 1

For Full-Board Review: Finalization of recommendations of the committee (*SOP 9: Full-Board Review*)

For Expedited Review: Finalization of recommendations of reviewers (*SOP 8: Expedited Review*)

For Exempt from Review: Classification of protocol and issuance of certification of exemption (*SOP 7: Exempt from Review*)

5.2. Step 2 – Transfer of information from Minutes of the Meeting or reports to IEC decision forms or templates.

Following the finalization of the reviewers' recommendations and the approval of the minutes, the IEC Staff, under the supervision of the Member-Secretary, prepares the necessary communication documents, which may include:

- Notification Letter for Review Decision (IEC Form 019/V1/2025)
- Certificate of Exemption from Ethical Review (IEC Form 020/V1/2025)
- Certificate of Approval for Reviewed Protocols (IEC Form 022/V4/2025)
- Review of Resubmitted Protocol (IEC Form 023/V4/2025)
- Noncompliance Report Form (IEC Form 026/V3/2025)
- Final Report Form (IEC Form 027/V4/2025)
- RNE Report Form (IEC Form 029/V2/2025)
- Reminder Letter for Post-Approval Requirements (IEC Form 033/V2/2025)
- Close-Out Form (IEC Form 030/V4/2025)

5.3. Step 3 - Approval of the IEC decision document.

The IEC Chair reviews, approves, and signs the decision documents within five (5) working days from the decision of the committee for full-review or the decision of the reviewers for expedited review.

5.4. Step 4 - Transmittal of the DLSMHSI-IEC decision to researcher.

5.4.1. After approval, the IEC Staff sends the signed review results to the PI or researcher via email or makes the hard copy available for pickup at the IEC office within two

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working days of the committee's decision or its presentation in the previous full-board meeting.

- 5.4.2. Recipients may receive the communication either in person or electronically. For in-person receipt, the recipient signs a duplicate copy of the communication, which serves as the IEC Secretariat's receiving copy. For electronic communication, the recipient acknowledges receipt via email.
- 5.4.3. The duplicate receiving copy or acknowledged electronic communication is logged in real-time and appropriately filed in the corresponding protocol folder. Electronic communications are also saved in the designated IEC electronic folder.
- 5.4.4. The IEC Staff maintains a log of communications, which also serves as a record of submissions when the communication includes accompanying documents. This ensures proper documentation, organization, and traceability of all correspondence. (Refer to [SOP 28: Management of Incoming and Outgoing Communications](#))

5.5. Step 5 - Filing of the decision document in the protocol file and update of protocol database.

- 5.5.1. All meeting deliberations and decisions related to a protocol, along with copies of the assessment forms, are filed in the specific protocol folder.
- 5.5.2. Filing follows a protocol index or chronological order for consistency and ease of access.
- 5.5.3. The physical folder is securely stored in a locked filing cabinet within the IEC office.
- 5.5.4. Digital records of active protocol documents are maintained in a designated Protocol Box. Once a protocol is completed or terminated, its digital files are transferred to Google Drive and a secure hard drive for long-term storage.
- 5.5.5. The IEC database is subsequently updated to reflect the protocol's status, ensuring accurate and up-to-date records.

6. GLOSSARY

- 6.1 **Active Files** – documents pertaining to protocols which are currently being assessed, managed or monitored by the REC.
- 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 two to three members of the committee without involvement of the whole committee.
- 6.3 **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 **Protocol Database** – a collection of information about protocols that is structured and organized for easy access, management, interpretation, analysis and updating. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

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6.5 **Protocol Index** – a chronological record of the documents in the protocol file. The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking.

7. FORMS

IEC Form 019/V1/2025	Notification Letter for Review Decision
IEC Form 020/V1/2025	Certificate of Exemption from Ethical Review
IEC Form 022/V4/2025	Certificate of Approval for Reviewed Protocols
IEC Form 023/V4/2025	Review of Resubmitted Protocol
IEC Form 026/V3/2025	Noncompliance Report Form
IEC Form 027/V4/2025	Final Report Form
IEC Form 029/V2/2025	RNE Report Form
IEC Form 033/V2/2025	Reminder Letter for Post-Approval Requirements
IEC Form 030/V4/2025	Close-Out Form

8. HISTORY

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1	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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1. POLICY STATEMENT

DLSMHSI-IEC communications encompass all documented correspondences, which may take the form of hard copy letters, emails, official memoranda, reports, applications, and forms. The IEC maintains both physical and digital storage systems (offline and online) for incoming and outgoing communications. To ensure proper documentation of actions, instructions, and responses to queries, it is strongly encouraged that all IEC communications, both received and issued, adhere to this format.

All incoming and outgoing communications must be accurately and appropriately recorded in both a physical logbook and an electronic database. Protocol-related communications are maintained separately from administrative communications to ensure clarity and organization. Communication documents are filed by year, with all records considered permanent and strictly confidential.

Incoming communications shall be reviewed and acted upon promptly to maintain efficiency and responsiveness in the IEC's operations.

2. OBJECTIVES

The management of IEC incoming and outgoing communications aims to establish accountability and ensure an efficient and effective tracking system. It also enhances the operational efficiency of the IEC and contributes to improving the quality of service provided..

3. SCOPE

This SOP encompasses IEC actions related to the organization and management of incoming and outgoing communications. It covers the process from receiving of communications to ensuring appropriate IEC responses and concludes with the secure storage or filing of communication documents.

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4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receiving of communications</i>	IEC Staff
Step 2: <i>Sorting of incoming/outgoing communications</i>	IEC Staff
Step 3: <i>Recording of incoming/outgoing communications</i>	IEC Member-Secretary and Staff
Step 4: <i>Acting on incoming communications</i>	IEC Chair or Member-Secretary
Step 5: <i>Filing of incoming/outgoing communications and updating of respective databases</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1: Receiving of communications.** The IEC staff receives the communications either in person or electronically.
 - 5.1.1. For in-person communications, the IEC staff signs a duplicate copy of the document, which serves as the receiving copy. The signed receiving copy is logged in real-time and filed in the corresponding protocol folder.
 - 5.1.2. For electronic communications, the IEC staff responds with an acknowledgment of having received the communications. Acknowledged electronic communications are saved in the designated IEC digital folder (offline, i.e., hard drive, and online, i.e., Google Drive) to ensure proper documentation and organization.

- 5.2. **Step 2: Sorting of incoming/outgoing communications.**
 - 5.2.1. The IEC staff is responsible for sorting all incoming and outgoing communications, categorizing them as **protocol-related** or **administrative**.
 - 5.2.1.1. **Protocol-related communications**, such as submissions, reports, and amendments, are documented in both a physical logbook and an electronic database before being routed to the appropriate reviewers or the IEC Chair.



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- 5.2.1.2. **Administrative communications**, including internal memoranda and general inquiries, are directed to the IEC Member-Secretary, or designated IEC member for action. They are kept in a file folder separate from the protocol-related communications.
- 5.2.2. Urgent incoming communications, such as regulatory queries or participant complaints, are flagged for priority handling.
- 5.2.3. Outgoing communications are similarly documented and organized to ensure proper tracking and timely responses.
- 5.2.4. Ensuring all communications are addressed efficiently and appropriately, the IEC Chair and Member-Secretary oversees this step in the management of IEC communications.
- 5.3. Step 3: Recording of incoming/outgoing communications.** The IEC staff, supervised by the IEC Member-Secretary, then records in a log which also functions as a log of submissions if the communication is protocol-related, and another log for administrative communications.
- 5.3.1. Record of administrative communications shall include the following:
- Date of Receipt or Dispatch of Communication
 - Name of IEC Representative Contacted
 - Details or Content of Communication
 - Record of Required Follow-up Actions
 - Sender's Contact Information (Address, Telephone Number, and Email)
 - Name and Signature of Recipient Recording the Communication
- 5.3.2. Record of protocol-related communications shall include the following:
- Date of Communication Submission
 - Name of IEC Representative Contacted
 - Study Details (e.g., Sponsor, Protocol Number, Principal Investigator, etc.)
 - Summary of Communication or Submission Content
 - Record of Follow-up Actions, if applicable
 - Submission Type (if the communication relates to a submission)
 - Sender's Contact Information (Address, Telephone Number, and Email)
 - Name and Signature of the Recipient Recording the Communication
- 5.4. Step 4: Acting on incoming communications.**
- 5.4.1. The IEC Chair or Member-Secretary, upon being informed by the IEC staff, reviews and finalizes responses to all incoming communications, whether protocol-related or administrative.
- 5.4.2. Outgoing protocol-related communications are typically signed by the IEC Chair or Co-Chair.

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5.4.3. Outgoing administrative communications are signed by the RICS Chair, subject to approval by the RAC Director and the Vice Chancellor for Research Services.

5.5. Step 5: Filing of incoming/outgoing communications and updating of respective databases.

5.5.1. Protocol-related communications are filed in the study protocol file folder. Likewise, administrative communications are filed in the appropriate IEC administrative folders.

5.5.2. The IEC staff stores both physical and digital copies of the communications.

5.5.2.1. For physical filing, the IEC staff files hard copies of communications in their respective folders, with protocol-related documents stored in the relevant protocol file and administrative communications in designated administrative files.

5.5.2.2. For digital filing, a scanned or electronic version of each communication is stored in the IEC hard drive and backed up in a secured Google Drive. Digital folders are organized by category and protocol ID, and communications are filed with the most recent documents placed on top for easy reference.

5.5.3. The IEC staff shall use a unique indexing system that incorporates protocol numbers for protocol-related communications and subject headings for administrative communications. This system ensures efficient retrieval and tracking of documents.

5.5.4. All filed communications are logged in both the physical logbook and the IEC electronic database in real-time. Each entry includes the communication date, sender/recipient, and type of communication.

5.5.5. The IEC staff is responsible for filing all communications in their respective folders, both physical and digital. The IEC Member-Secretary supervises the process to ensure accuracy, compliance, and proper organization. Overall oversight of the filing and database update process is provided by the IEC Chair, who ensures adherence to filing protocols and maintains the integrity of the communication records.

6. GLOSSARY

6.1 **Administrative Communications** – documents that pertain to the operations of the IEC and are not directly related to a study or protocol. Examples include the SOPs, membership files, meeting agenda and minutes, and administrative issuances.

6.2 **Digital Filing** – the process of organizing and storing electronic versions of documents in designated digital folders on a computer or storage device

6.3 **Electronic Database** – a structured collection of digital data used to log, track, and retrieve information related to communications and other records efficiently.

6.4 **Incoming Communications** – documents which are directed to and received at the IEC office.

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- 6.5 **Indexing System** – a method of assigning unique identifiers or categories to documents to facilitate easy organization, retrieval, and tracking.
- 6.6 **Offline Digital Storage** – the storage of digital files on physical devices such as hard drives, USB drives, or local servers, without requiring an internet connection.
- 6.7 **Online Digital Storage** – the storage of digital files on cloud-based platforms that require an internet connection, providing remote access and backup capabilities.
- 6.8 **Outgoing Communications** – documents generated within the IEC office intended for individuals or offices related to the operations of the IEC.
- 6.9 **Physical Filing** – the process of organizing and storing hard copies of documents in labeled folders or cabinets for easy retrieval and safekeeping.
- 6.10 **Protocol-related Communications** – consist of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., informed consent form, survey questionnaire, CV of proponent, advertisements, in-depth interview guide questions indexing system.

7. FORMS

Form IEC-00_V1/2025
 Form IEC-00_V1/2025

Administrative Communications Log
 Protocol-related Communications Log

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9. REFERENCES

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INDEPENDENT ETHICS COMMITTEE

XXIX. MANAGEMENT OF ACTIVE FILES (ADMINISTRATIVE AND STUDY FILES)

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	De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114	DLSMHSI-IEC SOP Ver. 4 Approval Date:
	INDEPENDENT ETHICS COMMITTEE XXIX. MANAGEMENT OF ACTIVE FILES (ADMINISTRATIVE AND STUDY FILES)	Effective Date: January 2025 Page 2 of 6

1. POLICY STATEMENT

DLSMHSI-IEC-approved initial protocol submissions are considered active from the time they are received for review until they are archived, whether as completed, withdrawn, or terminated protocols. These files shall be systematically sorted, coded, and securely stored in a locked cabinet. They will be organized in a well-ordered manner to ensure easy identification and prompt retrieval when needed. Access to the active files shall be governed by [SOP 31: Management of Access to Confidential Files](#).

2. OBJECTIVES

The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality.

3. SCOPE

This SOP covers procedures done related to protocols accepted for review, undergoing review, or has been approved by the IEC. This begins with the classification and coding of active files and ends with the periodic updating of the file.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Classification and coding of Active Files</i>	IEC Staff
Step 2: <i>Preparation of the Protocol Folder</i>	IEC Staff
Step 3: <i>Periodic updating of the Protocol File</i>	IEC Member-Secretary and Staff

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5. DESCRIPTION OF PROCEDURES

5.1. Step 1 – Classification and coding of active files.

5.1.1. The IEC Staff under the supervision of the Member-Secretary classifies active files as follows:

- Initial Submission
- Resubmission
- Progress Report
- Amendment
- Protocol Deviation
- Protocol Violation
- Serious Adverse Event (SAE)
- Suspected Unexpected Serious Adverse Reaction (SUSAR)
- Early Termination
- Continuing Review
- Final Report / Close-Out Report

5.1.2. The DLSMHSI-IEC Staff assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the Initial Submission. The code consists of the year and the serial number that indicate the sequence order of receipt.

5.2. **Step 2 – Preparation of the protocol folder.** The IEC Staff files all documents pertaining to a study in a vertical folder that is labeled on the front cover and along the spine with: Protocol Code – Study Title – Proponent’s Family Name – Sponsor or Funding Agency. The staff attaches a protocol index on the inside front cover that indicates the contents of the folder.

5.3. Step 3 – Periodic updating of the protocol file.

5.3.1. The DLSMHSI-IEC Staff ensures that the documents are filed in chronological order such that the most recent documents are topmost. These documents include the following:

- Protocol (Original and Revised) versions
- Informed consent (Original and Revised) versions
- Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final Amendment, Early Termination, Site Visit Reports
- Assessment Forms for each of the submitted and reviewed reports which should be signed and dated
- Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda
- Decision and Approval Letters
- Communications

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- 5.3.2. The staff updates the protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness.

6. GLOSSARY

- 6.1 **Amendments** – a change in or revision of the protocol made after it has been approved.
- 6.2 **Assessment Form** – evaluation tool accomplished by the reviewers when appraising the protocol or the informed consent form.
- 6.3 **Continuing Review** – the decision of the IEC to extend ethical clearance of a study beyond the initial period of effectivity based on an appreciation that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion.
- 6.4 **Early Termination** – ending the implementation of a study before its completion. This is a decision made by the sponsor or a regulatory authority and/or recommended by the Data Safety Monitoring Board, researcher/investigator in consideration of participant safety, funding issues, protocol violations, and data integrity issues.
- 6.5 **Final Reports/ Close Out Reports** – a summary of the outputs and outcomes of the study upon its completion. The IEC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.
- 6.6 **Initial Submission** – a set of documents consisting of the full proposal and other study-related documents that is received by the IEC so that ethical review can be done.
- 6.7 **Progress Reports** – a systematized description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form ##. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the REC based on the level of risk.
- 6.8 **Protocol Deviation** – non-compliance with the approved protocol that does not increase risk nor decrease benefit to participants and does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.
- 6.9 **Protocol Index** – a chronological record of the documents in the protocol file. The protocol index is in table form indicating the date of filing, the nature of the document filed, the name and signature of the person who filed and an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file/folder for easy reference and checking.
- 6.10 **Protocol Violation** – non-compliance with the approved protocol that may result in an increased risk or decreased benefit to participants or significantly affect their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.
- 6.11 **Resubmission** – the revised study proposal that is forwarded to the REC in response to the recommendations given during the initial review.

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- 6.12 **Serious Adverse Event (SAE)** – an event observed during the implementation of a study where the outcome is any of the following:
- 6.13 **Suspected Unexpected Serious Adverse Reaction (SUSAR)** - a noxious response to a drug that is not described in the Investigator’s Brochure nor in the drug insert.

7. FORMS

Form IEC-00_V1/2025 Protocol Index

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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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	XXX. ARCHIVING OF TERMINATED, INACTIVE, OR COMPLETED STUDIES	

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Supersedes:	DLSMHSI-IEC SOP Chapter 4: 5. Archiving of Study Files, Documents, and Records / V3 / 2024
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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
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1. POLICY STATEMENT

Archived study files refer to the records of studies that meet any of the following criteria:

- Completed studies with approved or accepted Final Reports.
- Terminated studies with approved Early Termination Reports.
- Declared inactive studies due to the failure of the proponent/researcher/investigator to respond to the DLSMHSI-IEC recommendations within 90 days of receiving the Notification Letter and properly marked as inactive.

Archived study files must be securely stored and maintained for a specified retention period, typically 5 years for both researcher-initiated studies and clinical trials. These files should include all essential study-related documents such as protocols, informed consent forms, progress reports, final reports, correspondence, and ethics committee decisions, ensuring accessibility for audits, inspections, or future reference. The archiving process must align with international and national ethical guidelines, including the WHO Operational Guidelines, CIOMS, ICH GCP, and NEGRIHP.

Access to archived files is strictly limited to authorized personnel, such as DLSMHSI-IEC members, regulatory authorities, or auditors, to ensure confidentiality and data security. All files must be stored in secure locations, such as locked cabinets or password-protected databases, with access logs maintained to document retrievals and usage. Each file must be labeled and cataloged with unique identifiers to facilitate easy tracking and retrieval.

Retrieval of archived files requires proper authorization, and the process must be documented to ensure accountability. Files must remain secure during retrieval and handling, with unauthorized copying or removal strictly prohibited. Retrieved files must be returned promptly and logged to maintain the integrity of the archival system. These measures safeguard the confidentiality, security, and availability of research files in compliance with ethical and regulatory standards.

2. OBJECTIVES

Archiving inactive, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines.

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3. SCOPE

This SOP includes procedures related to storage and retrieval of protocols that are classified as inactive, terminated, or completed. This begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Acceptance of Final or Early Termination Reports (SOP 21: Review of Final Report; SOP 20: Early Protocol Termination), and Identification of a Protocol as Inactive</i>	IEC Member-Secretary, and Staff
Step 2: <i>Updating of corresponding protocol folder</i>	IEC Staff
Step 3: <i>Transfer of the protocol folder in the Archive Room and update of the protocol database</i>	IEC Staff
Step 4: <i>Retrieval of documents from Archive Room</i>	IEC Staff
Step 5: <i>Disposal of archived protocol files (SOP 31: Management of Access to Confidential Files)</i>	IEC Staff and Member
Step 6: <i>Disposal of administrative records</i>	IEC Staff

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5. DESCRIPTION OF PROCEDURES

- 5.1. **Step 1 – Acceptance of Final or Early Termination Reports, and Identification of a Protocol as Inactive.**
 - 5.1.1. The IEC members shall approve or accept the Final Report or Early Termination Report of the protocol during a meeting. (*SOP 21: Review of Final Report; SOP 20: Early Protocol Termination*)
 - 5.1.2. In the identification of an Inactive File, the IEC Staff informs the Member-Secretary of the failure of a concerned researcher/proponent/investigator to respond to the recommendations of the IEC in the last 90 days during which time the researcher/proponent/investigator has been appropriately reminded of the requirement. This is included in the agenda of the next meeting where the protocol is declared inactive.
 - **For Protocols with Minor/Major Modifications Undergoing Review:** If no response is received within 90 days of the issuance of the Notification Letter for Review Decision (IEC Form 019/V1/2025).
 - **For Approved Protocols:** If the Continuous Review Application (IEC Form 024/V4/2025), Final Report Form (IEC Form 027/V4/2025), or **Early Protocol Termination Application (Form __)** is not submitted upon the expiration of the one-year IEC approval period.
 - 5.1.3. Archiving notifications will be communicated to the PI within seven calendar days after the board meeting.
 - 5.1.4. The IEC Member-Secretary supervises the management of inactive files for archiving.
- 5.2. **Step 2 – Updating of corresponding protocol folder.** The IEC staff files the Final or Early Termination Report of the protocol in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.
- 5.3. **Step 3 – Transfer of the protocol folder in the Archive Room and update of the protocol database.**
 - 5.3.1. The IEC Staff checks whether the documents listed in the protocol file index are complete and removes extraneous documents. The staff then transfers the folder to the Archive Room and updates the protocol database.
 - 5.3.1.1. The archive code is assigned to the protocol by changing the suffix of the original protocol code from A (Active) or C (Completed) to I (Inactive) and adding an extension of the month and year where the Close-Out, Final Report, or Early Protocol Termination is approved. For example, the Final Report for protocol 2012-01-03-A is approved dated May 2014, the archiving code is 2012-01-03-I/05-2014.

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- 5.3.1.2. The archiving data should be entered accordingly in the protocol database.
- 5.3.2. Archived study files are stored in proper cabinets labelled as **Inactive Files** with lock and key, and kept closed at all times.
- 5.3.3. Online archived study files are secured by regularly saving in the external hard drive.
- 5.4. Step 4 – Retrieval of documents from Archive Room.** Only the IEC Staff can retrieve the documents either from the active study files or from the archives. Archived study files can be retrieved within the five-year archiving period in accordance with **SOP 31: Management of Access to Confidential Files**.
- 5.5. Step 5 – Disposal of archived protocol files.** Archived files must be reviewed at the end of the year.
- 5.5.1. At the end of the year, the IEC Staff generates:
- List of inactive protocols that are beyond five years past its date of inactivation from the protocol database;
 - List of completed and terminated protocols that are beyond five years past its date of archiving from the protocol database;
 - List of clinical trial protocols that are beyond five years past its date of archiving from the protocol database or the retention period indicated in the Clinical Trial Agreement or the retention period as indicated in the Clinical Trial Agreement, whichever is later
- 5.5.2. The IEC Staff submits the list to the IEC Chair for review, verification and approval of disposal in accordance with government rules.
- 5.5.3. The IEC Staff retrieves the archived study files and disposes them accordingly using a paper shredder. The shredding of files must be witnessed by a IEC member.
- 5.5.4. The IEC Staff shall update the **Register of Archived Protocols (Form __)**, and the **Register of Disposed Protocols (Form __)** as to date of actual disposal.
- 5.6. Step 6 – Disposal of administrative records.** Guidelines and references that have been superseded or outdated for five years must be removed from the files and disposed of properly. Removed document files are shredded and permanently deleted from electronic storage.

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6. GLOSSARY

- 6.1 **Active Study** –an ongoing study, implementation of which is within the period covered by ethics clearance.
- 6.2 **Archiving** – the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, terminated, or declared inactive.
- 6.3 **Confidentiality of Documents** – the recognition and awareness that certain documents that have been entrusted or submitted to the IEC must not be freely shared or disclosed.
- 6.4 **Controlled Document** –the document that have been entrusted or submitted to the REC that must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored and appropriately recorded.
- 6.5 **Early Termination** – ending the implementation of a study before its completion.
- 6.6 **Final Report** –a summary of the outputs and outcomes of the study upon its completion. The IEC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.
- 6.7 **Inactive Study** –a study whose proponent has not communicated with the IEC with regard to issues pertaining to the approval or implementation of the study—within a period of time required by the IEC.

7. FORMS

Form IEC-00_V_/2024	Register of Archived Protocols (Log)
Form IEC-00_V_/2024	Register of Disposed Protocols (Log)

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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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

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De La Salle Medical and Health Sciences Institute
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INDEPENDENT ETHICS COMMITTEE

XXXI. MANAGEMENT OF ACCESS TO CONFIDENTIAL FILES

DLSMHSI-IEC SOP Ver. 4

Approval Date:

Effective Date:

January 2025

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Supersedes:	DLSMHSI-IEC SOP Chapter 4: 6. Maintenance of Confidentiality of Study Files and DLSMHSI-IEC Documents / V3 / 2024
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1. POLICY STATEMENT

Access to the DLSMHSI-IEC confidential files shall be regulated and limited to the IEC members and staff. Other persons with legitimate interest in these files (e.g., institutional authorities, regulatory agencies, sponsors) shall be allowed to access specific files with proper justification. Researchers/Investigators shall be allowed access only to their own protocol files upon request.

2. OBJECTIVES

Management of access to confidential files helps protect the intellectual property rights of researchers, compliance with the mandate of the **Data Privacy Act of 2012** and enhances the credibility and integrity of the IEC.

3. SCOPE

This SOP consists of procedures for accessing confidential files including document handling and distribution. This begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

The DLSMHSI-IEC considers the following as confidential:

- Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions, or reviews)
- DLSMHSI-IEC documents (minutes of the meeting, notifications, decisions, and certificates of approval, etc.)
- Study protocol-related communications

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt and logging of request for access to confidential files</i>	IEC Staff
Step 2: <i>Approval of requests for access and retrieval of documents</i>	IEC Chair or Member-Secretary

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ACTIVITY	RESPONSIBILITY
Step 3: <i>Supervision of use of retrieved document</i>	IEC Staff
Step 4: <i>Return of document to the files</i>	DLSMHSI-IEC Staff

5. DESCRIPTION OF PROCEDURES

5.1. **Step 1 – Receipt and logging of request for access to confidential files.** The IEC Staff receives the **Request for Access to Confidential Files (Form __)** to access specific files and forwards this to the IEC Chair or Member-Secretary.

5.2. **Step 2 – Approval of requests for access and retrieval of documents.** The IEC Chair or Member-Secretary reviews the stated reason for the request and, if deemed satisfactory, grants its approval. The IEC staff requires individuals requesting the document to sign the Confidentiality and Conflict of Interest Disclosure Agreement (IEC Form 003/V2/2024) for IEC members/staff. For individuals not affiliated with the IEC, the staff requests them to sign the **Confidentiality and Conflict of Interest Disclosure Agreement for Non-members (Form __)** before retrieving the pertinent document.

Note: Regulatory authorities (e.g., DOH, FDA, etc.) are granted full access to IEC documents, provided the request aligns with their mandate and is accompanied by reasonable notice. Such requests must be signed by a recognized official of the regulatory authority, such as the DOH Secretary or FDA Director.

5.3. **Step 3 – Supervision of use of retrieved document.**

5.3.1. The IEC staff requires users to sign the logbook and ensures that access is recorded in the electronic database **(Access to Confidential Files)**.

5.3.2. Access to IEC documents is strictly limited to room-use only; however, requests for photocopies may be accommodated on a case-by-case basis.

5.3.3. Only the DLSMHSI-IEC staff is authorized to photocopy documents, and all photocopying must be conducted within the DLSMHSI-IEC office. Documents cannot be photocopied outside the office under any circumstances.

5.3.4. The DLSMHSI-IEC staff maintains a record of every instance when a confidential document is photocopied and ensures that only the exact number of copies requested is made. Recipients are required to sign upon receipt of the copies in the logbook/database: **Request for Copies of Documents**.

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- 5.3.5. The record of Access to Confidential Files contains the following information:
- Study file code
 - Date retrieved
 - Name of borrower
 - Signature of borrower upon retrieval
 - Signature of DLSMHSI-IEC staff upon return of document to protocol folder.
 - Document copied, if any, including the:
 - Number of copies made
 - Number of copies received by borrower

5.4. Step 4 – Return of document to the files. The DLSMHSI-IEC Staff returns the retrieved files to the protocol folder.

6. GLOSSARY

- 6.1 **Anonymization** – process of removing the link between the research participant and the personally identifiable data, in such a way that the research participant cannot be determined nor traced.
- 6.2 **Confidentiality** – the duty to refrain from freely disclosing private/ research information entrusted to an individual or organization.
- 6.3 **Conflict of interest** – a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.
- 6.4 **Intellectual property** – intangible creations of the human mind (such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce, that are considered as owned by the one who thought of it. Intellectual property includes information and intellectual goods.
- 6.5 **Intellectual property right** – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.
- 6.6 **Meeting Minutes or Minutes of the Meeting** – narration of the proceedings of the assembly of IEC members.
- 6.7 **Regulatory Authorities** – government agencies or institutions that have oversight or control over the conduct of research, e.g., Department of Health, Food and Drug Administration, as well as national or international research institutions.
- 6.8 **Room-use Only Restriction** – the rule that limits the use of a document within the designated premises.
- 6.9 **Sponsor** – an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.
- 6.10 **Study-related Communications** – documents that refer to an exchange of information or opinions regarding a study, usually between the IEC and the researcher.

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7. FORMS

IEC Form 000/V_/2025	Request for Access to Confidential Files
IEC Form 003/V2/2025	Confidentiality and Conflict of Interest Disclosure Agreement
IEC Form 000/V_/2025	Confidentiality and Conflict of Interest Disclosure Agreement for Non-Members
IEC Form 000/V_/2025	Access to Confidential Files Log
IEC Form 000/V_/2025	Request for Copies of Documents Log

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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

9. REFERENCES

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	<p>INDEPENDENT ETHICS COMMITTEE</p> <p>XXXI. MANAGEMENT OF ACCESS TO CONFIDENTIAL FILES</p>	<p>Effective Date: January 2025</p> <p>Page 6 of 6</p>

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	XXXII. MANAGEMENT OF PARTICIPANTS' QUERIES AND COMPLAINTS	

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Supersedes:	DLSMHSI-IEC SOP Chapter 3: 7. Participant's Requests/Queries / V3 / 2024
Version:	4
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

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1. POLICY STATEMENT

Queries and complaints from clients, patients, or research participants shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the DLSMHSI-IEC staff or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee *en banc* with the primary reviewers leading the discussion. The primary reviewers present all protocol-related queries that have been resolved and their resolution during the nearest full-board review meeting.

2. OBJECTIVES

Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the IEC and to ensure that the rights and well-being of participants are attended to. Communication of queries and complaints, particularly from research participants, supports in maintaining transparency in the IEC's decision-making processes while empowering study participants.

3. SCOPE

This SOP is limited to queries and complaints of research participants, or their families, in studies that have been issued an ethical approval by the IEC. The IEC will also accept queries, notifications, and complaints from other parties, provided they are relevant to the scope of the committee's oversight. This SOP begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the IEC meeting.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Receipt, logging, and acknowledgement of queries and complaints (SOP 28: Management of Incoming and Outgoing Communications)</i>	IEC Member and Staff

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ACTIVITY	RESPONSIBILITY
Step 2: <i>Referral of query or complaint to competent authority</i> 2.1. <i>Referral of protocol-related query to primary reviewers</i> 2.2. <i>Referral of all complaints (non-protocol-related) to the IEC Chair</i>	IEC Staff
Step 3: <i>Formulation of response</i> 3.1 <i>Protocol-related queries</i> 3.2 <i>Minimal-risk complaints</i> 3.3 <i>More than minimal risk complaints</i>	Primary Reviewers Primary Reviewers IEC Chair and Members
Step 4: <i>Communication of response (SOP 27: Communicating DLSMHSI-IEC Decisions for protocol-related queries, if applicable)</i>	IEC Staff
Step 5: <i>Logging of the response (SOP 28: Management of Incoming and Outgoing Communications) and inclusion in the agenda of DLSMHSI-IEC meeting (SOP 24: Preparation and Distribution of Meeting Agenda)</i>	IEC Staff
Step 6: <i>Filing copies of Queries and Complaints Report (Form __) on relevant protocol folder</i>	IEC Staff

5. DESCRIPTION OF PROCEDURES

5.1. Step 1 – Receipt, logging, and acknowledgement of queries and complaints.

5.1.1. The DLSMHSI-IEC will maintain a logbook and/or electronic database dedicated to queries and complaints. This will indicate the following:

- Date
- Time
- Name of Concerned Party
- Specific Study Protocol Number and Title
- Name of Principal Investigator
- Nature of Query or Complaint

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- 5.1.2. Study participants, their families, or any related parties may submit queries or complaints through various channels, including direct face-to-face reporting (walk-in), traditional mail, email, telephone, or written correspondence.
- 5.1.3. The attending DLSMHSI-IEC member or staff shall document the account using the **Queries and Complaints Report Form (Form ___)**. The DLSMHSI-IEC staff will then record the report in the logbook and/or update the electronic database.
- 5.2. Step 2 – Referral of query or complaint to competent authority.**
- 5.2.1. The DLSMHSI-IEC Staff forwards queries related to specific protocols approved by the DLSMHSI-IEC to the assigned Primary Reviewers for evaluation and response.
- 5.2.2. The DLSMHSI-IEC Staff escalates complaints to the DLSMHSI-IEC Chair, who assesses the level of risk posed by the issue and determines the appropriate action.
- 5.2.2.1. Minimal risk complaints are referred to the Primary Reviewers of the concerned protocol.
- 5.2.2.2. Complaints that involve more than minimal risk are referred to the DLSMHSI-IEC through a special meeting that shall be called within 48 hours. The DLSMHSI-IEC Staff notifies the concerned primary reviewers that they will lead the discussion, such that pertinent materials are provided to them as reference.
- 5.3. Step 3 – Formulation of response.**
- 5.3.1. For queries and minimal risk complaints, the Primary Reviewers accomplish the “Action Taken” in the **Queries and Complaints Report (Form ___)**.
- 5.3.2. For complaints with more than minimal risk, the DLSMHSI-IEC may do the following:
- 5.3.2.1. Constitute a site visiting team to gather more information, verify and clarify the source and cause/s of the complaint for early resolution.
- 5.3.2.2. Designate the Primary Reviewers to meet the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.
- 5.3.2.3. Formulate recommendation if satisfied with the adequacy of information:
- Request for explanation/justification from researcher
 - Accept request/demand of participant
 - Suspension of further recruitment
 - Amendment of protocol and reconsent of participants
 - Others (to be specified)
- 5.4. Step 4 – Communication of response.** The DLSMHSI-IEC Staff prepares the official communication of response to queries and complaints by filling out the **Queries and Complaints**

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Report (Form) duly signed by the DLSMHSI-IEC Chair. (Refer to **SOP 27: Communicating DLSMHSI-IEC Decisions** for protocol-related inquiries, if applicable)

- 5.5. **Step 5 – Logging of response.** Refer to **SOP 28: Management of Incoming and Outgoing Communications** and **SOP 24: Preparation and Distribution of Meeting Agenda**.
- 5.6. **Step 6 – Filing copies of Queries or Complaints Report on relevant protocol folder.** The IEC Staff stores the signed forms in the study protocol folder.

6. GLOSSARY

- 6.1 **Competent Authority** – designated officer or member of the DLSMHSI-IEC with the authority to respond to queries and complaints regarding studies approved by the committee.
- 6.2 **Complaint** – the act of expressing discontent or unease about certain events or arrangements in connection with a study.
- 6.3 **Primary Reviewers** – are members of the DLSMHSI-IEC (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.
- 6.4 **Query** – the act of asking for information or clarification about a study.
- 6.5 **Regular Meeting** – a periodically scheduled assembly of the REC.
- 6.6 **Site Visiting Team** – members/staff of the DLSMHSI-IEC (two to four members) assigned by the DLSMHSI-IEC Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data.
- 6.7 **Special Meeting** – an assembly of the DLSMHSI-IEC outside of the regular schedule of board review meetings and conducted for a specific purpose.

7. FORMS

IEC Form 000/V_/2025 Queries and Complaints Report

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	<p align="center">XXXII. MANAGEMENT OF PARTICIPANTS' QUERIES AND COMPLAINTS</p>	<p align="right">Effective Date: January 2025</p> <p align="right">Page 6 of 7</p>

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	N/A	Dr. Melchor Victor G. Frias IV	
4	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

9. REFERENCES

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	XXXII. MANAGEMENT OF PARTICIPANTS' QUERIES AND COMPLAINTS	

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

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	De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114	DLSMHSI-IEC SOP Ver. 5 Approval Date:
	INDEPENDENT ETHICS COMMITTEE SOP XXXIII: WRITING AND REVISING STANDARD OPERATING PROCEDURES	Effective Date: January 2025 Page 1 of 7

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

Supersedes:	DLSMHSI-IEC SOP Chapter 5: 1. Writing and Revising Standard Operating Procedures / V3 / 2024
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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
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	INDEPENDENT ETHICS COMMITTEE SOP XXXIII: WRITING AND REVISING STANDARD OPERATING PROCEDURES	Effective Date: January 2025 Page 2 of 7

1. POLICY STATEMENT

This SOP outlines the process for preparing, approving, and distributing the DLSMHSI-IEC SOP Manual, which serves to ensure the efficiency, transparency, and consistency of IEC operations. The manual is subject to periodic review to assess the need for revisions or the development of new SOPs in response to emerging operational challenges and requirements.

The IEC shall appoint a dedicated team to conduct an annual review of its SOPs, ensuring their continued relevance and effectiveness in supporting IEC operations.

2. OBJECTIVES

The objective of this SOP is to ensure the continuous quality assurance and improvement of IEC functions through the systematic writing and revision of SOPs.

3. SCOPE

This SOP outlines the procedures established by the IEC for developing new, relevant SOPs and revising or updating existing ones. It applies to all IEC activities related to the creation, revision, approval, publication, and distribution of its SOPs as authorized by the institution. The process begins with the proposal and approval for the revision of an existing SOP or the development of a new SOP and concludes with the integration of the new or revised SOP into the SOP Manual and its dissemination to relevant stakeholders.

4. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: <i>Proposal and approval for revision or writing of a new SOP</i>	IEC Member / Staff
Step 2: <i>Designation of the SOP Team</i>	IEC Chair
Step 3: <i>Drafting of the revision or new SOP</i>	SOP Team

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ACTIVITY	RESPONSIBILITY
Step 4: <i>Review and finalization of SOP</i>	IEC Members, RICS Chair, VCR
Step 5: <i>Submission of finalized SOP to the DLSMHSI President through channels</i>	VCR
Step 6: <i>Inclusion of the new or revised SOP in the SOP Manual and its dissemination</i>	IEC Staff

5. DETAILED INSTRUCTIONS

- 5.1. **Step 1 – Proposal and approval for revision or writing of a new SOP.** Any IEC member or staff may propose a revision to an existing SOP or the development of a new SOP. Such proposals can be included as part of the agenda during a full-board meeting for discussion and approval.
- 5.2. **Step 2 – Designation of the SOP team.**
 - 5.2.1. The Chair designates an SOP Team, assigning members and, if necessary, non-members to participate. Non-members may include the administrative officers of RAC, such as the Director and the RICS Chair.
 - 5.2.2. The Chair conducts an orientation for the SOP team to identify their duties and responsibilities.
 - 5.2.3. To streamline the drafting and revision process, the Chair may also organize workshops for the SOP Team to facilitate the development and refinement of SOPs.
- 5.3. **Step 3 – Drafting of the revision or new SOP.**
 - 5.3.1. The SOP Team will prepare a draft of the new SOP or the revision of existing SOP.
 - 5.3.2. The layout of the SOP follows the guidelines in The SOP Workbook (PHREB, 2020).
 - 5.3.3. The contents include the following:
 - Title, which is descriptive of contents
 - Policy statement
 - Objective/s of the activity, which defines the purpose and intended outcome
 - Scope, which defines the coverage of the SOP and its limitations
 - Workflow, which provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step
 - Detailed instructions, which elaborate the steps listed in the Workflow



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

INDEPENDENT ETHICS COMMITTEE

SOP XXXIII: WRITING AND REVISING STANDARD OPERATING PROCEDURES

DLSMHSI-IEC SOP Ver. 5

Approval Date:

Effective Date:
January 2025

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- Glossary, which contains the acronyms and terms which need to be defined
- Forms, which include documents to be accomplished by different parties as required by the SOP
- Document history, which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
- References, which list the instruments used to draft the SOP

5.3.4. Each SOP shall be given a number and a title that is self-explanatory and easily understood.

5.3.5. The header of each page shall contain the following information:

- Name of institution
- Address
- Independent Ethics Committee
- SOP # (Roman Numeral): Title
- Version Number
- Approval date of the version
- Effectivity date of the version

5.4. Step 4 – Review and finalization of SOP. The IEC Chair, in consultation with IEC members, oversees the review and approval process for both new and revised SOP drafts during a full-board meeting.

5.4.1. Revisions in existing SOPs are classified as **minor** or **major**:

- **Minor revisions** include editorial, grammatical, or administrative changes that do not substantially affect procedures.
- **Major revisions** include significant changes to procedures, definitions, requirements, or other essential considerations.

5.4.2. The Chair presents the draft of SOP revisions or new SOP to the IEC full board for discussion and deliberation.

5.4.3. Once approved by the full board, the Chair endorses the SOP to the RICS Chair, who seeks recommending approval from the VCR through proper channels.

5.5. Step 5 – Submission of finalized SOP to the President through channels. The VCR presents the SOP to the ManCom for review and approval. The final authority for SOP approval rests with the President. Once approved, the SOP is officially registered with the IQMO for documentation and compliance purposes.

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- 5.6. **Step 6 – Inclusion of the new or revised SOP in the SOP Manual and its dissemination.**
 Upon approval by the DLSMHSI President, the IEC Staff distributes the SOP within thirty (30) days for hard copies and immediately for digital copies.

6. GLOSSARY

- 6.1 **Coding** – unique number assigned to a particular SOP that reflects its serial position among the SOPs and version number to indicate the number of times it has been revised.
- 6.2 **Date of Effectivity** – date when the guidelines shall be enforced.
- 6.3 **Format** – general style or layout of the document
- 6.4 **Standard Operating Procedures (SOP)** – the step-by-step description of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for ethical review to ensure quality and consistency.

7. FORMS

Form IEC-034/V2/2025 SOP Template

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	NA	Dr. Melchor Victor G. Frias IV Prof. Nenita B. Panaligan	
5	10 Jan 2025	Dr. Susan A. Olavidez Mr. Sigfredo B. Mata	

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9. REFERENCES

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	De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114	DLSMHSI-IEC SOP Ver. 5 Approval Date:
	INDEPENDENT ETHICS COMMITTEE SOP XXXIII: WRITING AND REVISING STANDARD OPERATING PROCEDURES	Effective Date: January 2025 Page 7 of 7

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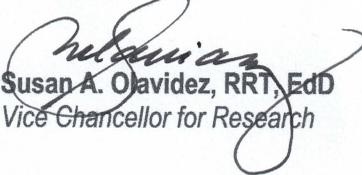
Reference No. RAC-2425-002

August 19, 2024

For: **DLSMHSI Community**

From: 
Jennilyn Nicole G. Mendoza, RMT, AHI (AMT), LSSGB-T
Chair, Research Integrity, Compliance, and Safety


Sigfredo B. Mata, RPh
Director, Research Administration and Compliance

Approved: 
Susan A. Ojavez, RRT, EdD
Vice Chancellor for Research

Subject: **Updated Institutional Recognition of the Independent Ethics Committee (IEC)**

Greetings of peace in the name of St. La Salle!

This is to formally inform you that the Independent Ethics Committee (IEC) is hereby recognized by the De La Salle Angelo King Medical Research Center (Research Services) at the De La Salle Medical and Health Sciences Institute (DLSMHSI). The IEC is officially acknowledged for its critical role in conducting ethics reviews of research proposals submitted to our institution.

In support of the IEC's vital function, the De La Salle Angelo King Medical Research Center (Research Services) shall provide administrative assistance through the Research Integrity, Compliance, and Safety to facilitate the smooth operation of the committee. This includes logistical, clerical, and other necessary support to ensure that the IEC can effectively carry out its mandate.

This recognition affirms the authority of the IEC to conduct comprehensive and impartial ethics reviews of research proposals submitted to the DLSMHSI. The IEC's mandate is to ensure that all research conducted within the Institution adheres to the highest ethical principles, safeguarding the rights, dignity, and well-being of research participants. We entrust this mandate to the IEC members, which shall be constituted by a duly recognized authority and shall adhere to national and international research ethics guidelines.

We greatly value the IEC's commitment to ethical principles and its dedication to transparency and rigor in the review process. We trust the IEC to provide comprehensive evaluations of research protocols, thereby contributing to the advancement of ethical research practices within our academic community.



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

OCT 30 2017

ADMINISTRATIVE ORDER
NO. 2017-0021

SUBJECT: Guidelines for the Operationalization of the Single Joint Ethics Review Process for Multi-site Researches in the Department of Health

I. BACKGROUND

As one of the pillars of the Philippine National Health Research System (PNHRS), the Department of Health commits to support the National Ethical Guidelines set forth by the Philippine Health Research Ethics Board (PHREB) stipulating mandatory ethics review for all researches involving human participants.

The Department as one of the primary consumers of research acknowledges the importance of ethics review in conducting various types of studies. However, the influx of health policy and systems research sponsored by the Department has magnified bottlenecks in the conduct of ethics review process. One critical cause of delay is the individual review conducted for multi-site studies.

In 2015, a study to streamline the ethics review structure and process was undertaken and a recommendation to adopt a single joint ethics review mechanism has been proposed. In view of this, the guidelines for the institutionalization of the single joint ethics review is being issued through this Administrative Order.

II. OBJECTIVES

General Objective:

This Order aims to institutionalize the single joint ethics review process in the Department of Health

Specific Objectives:

1. To provide general framework and guidelines on the single joint ethics review mechanism for multi-site researches
2. To identify the roles and responsibilities of key actors and stakeholders in the single joint ethics review process

III. SCOPE AND COVERAGE

This Order shall cover all DOH units including regional offices, hospitals, and attached agencies with research ethics committees. Further, this Order shall apply to private research ethics committees who opted to participate in the single joint ethics review process.

IV. DEFINITION OF TERMS

- A. **Multi-site Research** - refers to researches that will be conducted in three or more sites that utilize the same study protocol.
- B. **Single Joint Ethics Review** - refers to reviews for the purpose of approving multi-site research that will be conducted in sites within the purview of the Department of Health. For non-DOH hospitals, participation in this review is voluntary.

V. GENERAL GUIDELINES

1. Applicability of Single Joint Review Process in RECs

- a. All DOH hospital research ethics committees (RECs) shall adhere to the guidelines set forth by this Order in the implementation of single joint review.
- b. All other non-DOH RECs may voluntarily participate in the single joint review.

2. Standardized Process for Single Joint Review

- a. All DOH RECs shall adopt and incorporate a chapter of the single joint review mechanism on their Standard Operating Procedures on or before the 4th quarter of 2017.
- b. All non-DOH RECs with the intent to participate in the single joint review shall adopt the same in their SOPs prior to joining any deliberation.
- c. All externally funded research protocols shall require technical review clearance from the funding institution. Institutional RECs may only require technical review for studies funded by the home institution. Ethical review shall apply both for internally and externally funded research studies.

3. Operationalizing the Single Joint Review

- a. The single joint review shall be facilitated by a Single Joint Research Ethics Board, participating RECs and supported by a secretariat.
- b. All participants shall be monitored for compliance to standards.

4. Appropriation of Funds

- a. The DOH-Health Policy Development and Planning Bureau (HPDPB) shall allocate funds and provide support to operationalize the Single Joint Ethics Review Process.

- b. All participating RECs shall allocate funds for the participation of the site representatives specifically with regards to honorarium, transportation, accommodation, and other relevant expenses.

VI. SPECIFIC GUIDELINES

A. Single Joint Review Participants' Functions, Qualifications, and Engagement

1. **Single Joint Research Ethics Board (SJREB)** is a group of experts who shall facilitate and provide oversight to the overall operations of the review process. This board shall be convened during full board ethics review and joint ethics review with the participating sites.
 - a. **Composition.** The SJREB shall consist of five (5) permanent members which include the chair, independent consultants, lay person, and representative from participating sites. The role of the SJREB members, qualifications and other details of their engagement are outlined in **Annex A**.
 - b. **Selection.** The SJREB members shall be appointed by the Office for Policy and Health Systems Cluster Head for a term of 3 years. In order to ensure continuity of functions, at least half of the SJREB shall be retained/re-appointed for at least one (1) year before a new set shall be appointed.
2. **SJREB Secretariat** consists of technical and administrative staff from the DOH who provide support on the day-to-day operations of the single joint ethics review. See **Annex A** for the qualifications and specific roles and responsibilities.
3. **Participating Site RECs** are DOH units (i.e., hospital RECs) that were identified by the sponsors and/or principal investigators to be a study site. See qualifications in **Annex A**.

B. Single Joint Ethics Review Process

- a. **Standard Operating Procedures.** The SOP for the single joint review shall be made available through an issuance of a Department Circular. This shall serve as the reference document for the single joint ethics review and will be periodically revised and updated as per the latest PHREB guidelines. A Department Circular will also be issued should there be any updates and revisions in the SOP. The following are the key provisions:
 - i. **Frequency of Meeting.** The SJREB shall convene at least once a month, or more frequently depending on the volume of protocol submissions. The secretariat shall assess and recommend the need to conduct meeting.
 - ii. **Quorum.** The meeting shall only proceed if the SJREB voting members and at least three (3) participating REC representatives are present.

- iii. **Voting Conditions.** Only PHREB-accredited RECs are allowed to cast a vote while independent consultants are not allowed to vote. Decisions are arrived through majority vote of members present.
- iv. **Timelines of reviews.** All research protocols subjected for ethics review shall receive the results/decisions of the joint ethics review 30-60 days after the REC submission of complete protocol documents. See **Annex B** for the timelines of the review, the single joint ethics review process flow diagram and description of each of the process.

C. Appropriation of Funds.

1. All the permanent SJREB members shall receive honorarium for facilitating the joint ethics review. The honorarium for the members shall be Php 3,000 and Php 5,000 for the Chair, for every meeting attended/facilitated.
2. The DOH-HPDPB shall make available dedicated office space, archiving system, office equipment and supplies and designate full-time administrative support staff.

D. Roles and Responsibilities of Other Clusters/Offices

1. Health Policy Development and Planning Bureau
 - i. Provide oversight of the single joint ethics review process in the DOH;
 - ii. Provide the overall technical and administrative support to SJREB;
 - iii. Provide training and other capacity building activities for the single joint review mechanism;
 - iv. Monitor the day-to-day operations of the SJREB;
 - v. Ensure credibility, acceptability, and validity of reviews coursed through the single joint ethics review process; and
 - vi. Ensure compliance and adherence to the national ethics guidelines set forth by PHREB.
2. DOH Hospitals Research Ethics Committees
 - i. Adopt the standard operating procedures for single joint ethics review set forth by this Order;
 - ii. Develop/update hospital policies in compliance with the provisions recommended by this policy issuance; and
 - iii. All DOH research ethics committees shall accept the decision of the single joint ethics review for implementation at the site.
3. Partners from the private sectors and/or other research institutions
 - i. Ensure compliance with the standard operating procedures for multi-site research implementation set forth by the Department of Health;

- ii. Provide support to the SJREB and its review process mechanism through recognition of its decisions and recommendations; and
- iii. All participating private research ethics committees who shall accept the decision of the single joint ethics review for implementation at the site

VII. EFFECTIVITY

This Order shall be effective immediately.


PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II
Secretary of Health

Annex A. Single Joint Ethics Review Operational Structure

Single Joint Research Ethics Board (SJREB)

1. Membership

- a. The **Chair** is a dedicated individual from an REC with experience to review different types of researches with a fixed term as stipulated in the joint review SOPs.
- b. The **Independent consultants** are to be identified based on the following criteria:
 - i. Health Systems Consultant for Research Ethics
 - ii. Public Health Consultant
- c. Designated **Philippine Health Research Ethics Network (PHREN) Representative** with a fixed term as stipulated in the joint review SOPs
- d. **Subject matter expert from the specialty hospitals** who is a designated representative from DOH specialty hospitals to review a multi-site research within its area of specialization i.e., Philippine Heart Center, National Kidney and Transplant Institute, Lung Center of the Philippines, etc.
- e. The **lay person/non-affiliated** is a non-medical/non-scientific member who shall review the informed consent forms (ICF) and provide inputs from the community/people's perspective.
- f. The **participating site REC representatives** are identified point persons from the sites who are knowledgeable on the study protocols being reviewed.

2. Qualifications

- a. Knowledgeable about international and national guidelines and regulations: ICH-GCP 2016 update, Declaration of Helsinki 2013, CIOMS 2016, FDA regulations and procedures, sponsor country regulations, local laws, National guidelines on health research ethics, etc.
- b. Knowledgeable about scientific design and issues in various types of researches including investigational medicinal products (Phase 1, 2, 3, 4) difference between clinical research vs. clinical trials, treatment vs. non-treatment studies, observational vs. interventional methods, biomedical vs. socio-behavioral research, scientific/ statistical analysis tools, etc.
- c. Knowledgeable about analysis of ethical issues such as conflict of interest, vulnerability, risks, benefits, privacy and confidentiality, informed consent issues, etc.
- d. Knowledgeable about good clinical practice (GCP) compliant procedures in research including SOP for joint review.
- e. Subject matter experts on their own fields of practice e.g., health research ethics, epidemiology, social science, medicine, etc.

3. Roles and Responsibilities

- a. Prepare Standard Operating Procedures (SOPs) for the joint ethics review panel;
- b. Facilitate initial full board review of multi-site protocols with representatives from participating sites;
- c. Provide decisions and/or actions for the scheduled protocols for review through casting of votes
 - i. Voting:
 - Chair
 - PHREN Representative
 - Lay Person/Non-affiliated
 - Participating Site Representative
 - Specialty hospitals consultant
 - ii. Non-voting:
 - Public health consultant
 - Health research ethics consultant;
- d. Review amendments of approved protocols.

Single Joint Review Secretariat

1. Qualifications

- a. Technical Staff
 - i. Well versed on the ethics review system in the country
 - ii. With health-related educational background such as Doctor of Medicine, Nursing, Public Health, Epidemiology, Health Research Ethics
 - iii. Has basic knowledge and training on health research ethics which includes:
 1. Good Clinical Practice (GCP) training
 2. Advanced courses on research ethics
 3. CIOMS Guidelines
 4. Other relevant skills and trainings
 - iv. Knowledgeable about international and national guidelines and regulations: ICH-GCP 2016 update, Declaration of Helsinki 2013, CIOMS 2016, FDA regulations and procedures, sponsor country regulations, local laws, National guidelines on health research ethics, etc.
- b. Secretary and Administrative Staff
 - i. Graduate of any management related course
 - ii. Knowledgeable of effective archiving mechanism of protocol submission

2. Roles and Responsibilities

- a. Coordinates with SJRB members the submissions of multi-site study protocols

- b. Conducts initial screening of submitted protocol documents both new and with amendment
- c. Facilitates communication with participating site RECs
- d. Monitors implementation of ongoing multi-site studies
- e. Prepares administrative support and logistics during meetings e.g., record keeping and documentation of proceedings.
- f. Manages protocol submissions, amendments, and archiving of active and inactive researches

Representatives from Participating Sites

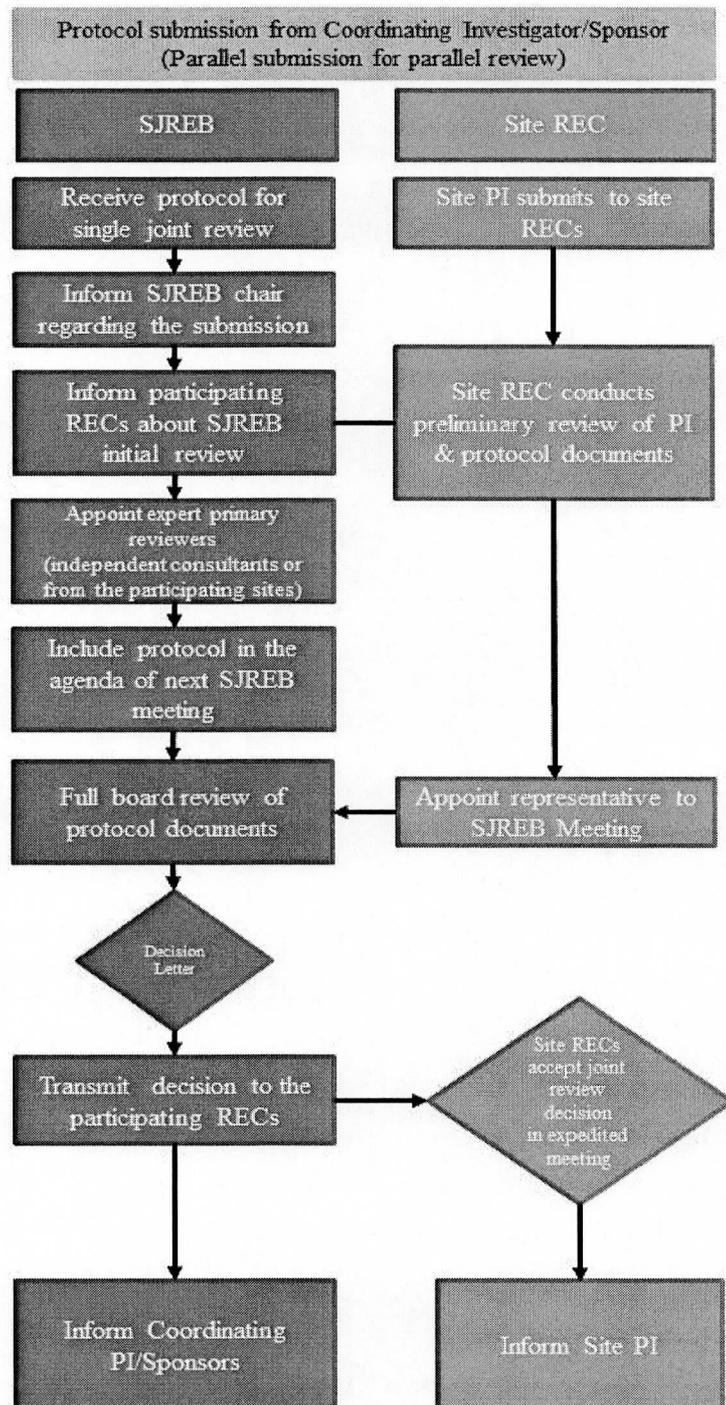
1. Qualifications

- a. PHREB accredited RECs
- b. Should have Level 3 accreditation for interventional new drugs (IND) studies
- c. Should have at least Level 2 accreditation for public health researches
- d. For sites with REC but is not PHREB accredited, attendance and participation in the discussion is allowed. The only limitation is that these RECs are not allowed to vote.
- e. For sites with no REC, affiliation to hospitals with PHREB accredited REC is allowed.

2. Roles and Responsibilities

- a. The participating sites shall designate permanent and alternate representatives to attend during joint ethics review meeting.
- b. The representative shall communicate the results of the ethics review from their respective sites during the joint ethics review.
- c. The representative shall actively participate in the joint ethics review and meeting as well as in the votation for acceptance/non-acceptance of the protocol.

Annex B. Single Joint Ethics Review Process and Timelines for Review



Initial and Annual Renewal of Approval Review Procedures

Note: The target turnaround time for the entire review process is 30-60 days

Legend:
 Orange – PI/Sponsors
 Blue – SJREB Secretariat
 Red – Joint Review
 Green – Site RECs

Description of each of the process in the joint ethics review:

1. **Protocol submission from PI/Sponsors.** The PI and/or sponsors shall submit study protocol package to both the SJREB Secretariat and all the identified participating sites.
2. **Receive protocol for single joint review.** SJREB Secretariat shall acknowledge the receipt of the study protocol from the principal investigators and/or the sponsors.
3. **Inform SJRB chair regarding submission.** The secretariat ensures completeness of the documents submitted by the proponents (i.e., investigator brochure, protocol package, curriculum vitae, advertisements and recruitment materials, and complete versions of informed consent forms) and shall notify the chair for the new protocol submission and protocol amendments. The chair is responsible for the conduct of the entire review process.
4. **Inform participating RECs about SJREB initial review.** The SJREB shall conduct a full board review of the submitted multi-site study protocol. The participating site RECs shall conduct a parallel preliminary review of the protocol submission.
5. **Appoint expert primary reviewers (independent consultants or from the participating sites).** The SJREB secretariat shall identify appropriate primary reviewers for the submitted research protocol. The reviewers shall reassess the package for completeness of documents and conduct review based on the timeline set forth in the SOPs. The expert primary reviewers may be the identified independent consultants of the SJREB and/or subject matter experts from the participating sites.
6. **Include protocol in the agenda of next SJREB meeting.** The SJREB secretariat shall be responsible in convening the SJREB members and the participating REC representatives for a meeting. The secretariat shall ensure quorum prior to the scheduled date of the meeting.
7. **Full board review of protocol documents.** SJREB shall facilitate initial full board review of all protocol submissions. Decisions on this review shall be communicated to participating RECs during the meeting.
8. **Decision.** The SJREB secretariat shall communicate the results of the review to the PI and/or sponsors after the scheduled meeting. The decision will either be:
 - a. Acceptance of the protocol submission
 - b. With minor or major revisions. The PI and/or sponsors shall be requested to address revisions as deemed necessary by the board and participating RECs. Resubmission of revised protocol shall follow the timeline set by the SJRB SOPs.

c. Non-acceptance/disapproval

Timelines for Review

ACTIVITY		TIMELINE
FROM	TO	
Submission of research protocol from Sponsors/Principal Investigators	Assessment of the research protocol and endorsement to the Single Joint Review Board	7 – 15 calendar days
Single Joint Research Ethics Board	Review of the Single Joint Research Ethics Board and primary reviewers	7 – 15 calendar days
Single Joint Research Ethics Board Decision	Sponsor/Principal Investigator (if there are any revisions)	7 – 15 calendar days
Revised research protocol from the Sponsors/Primary Investigators	Single Joint Research Ethics Board (for final decision)	7 – 15 calendar days