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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.

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.

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.

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 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.

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.

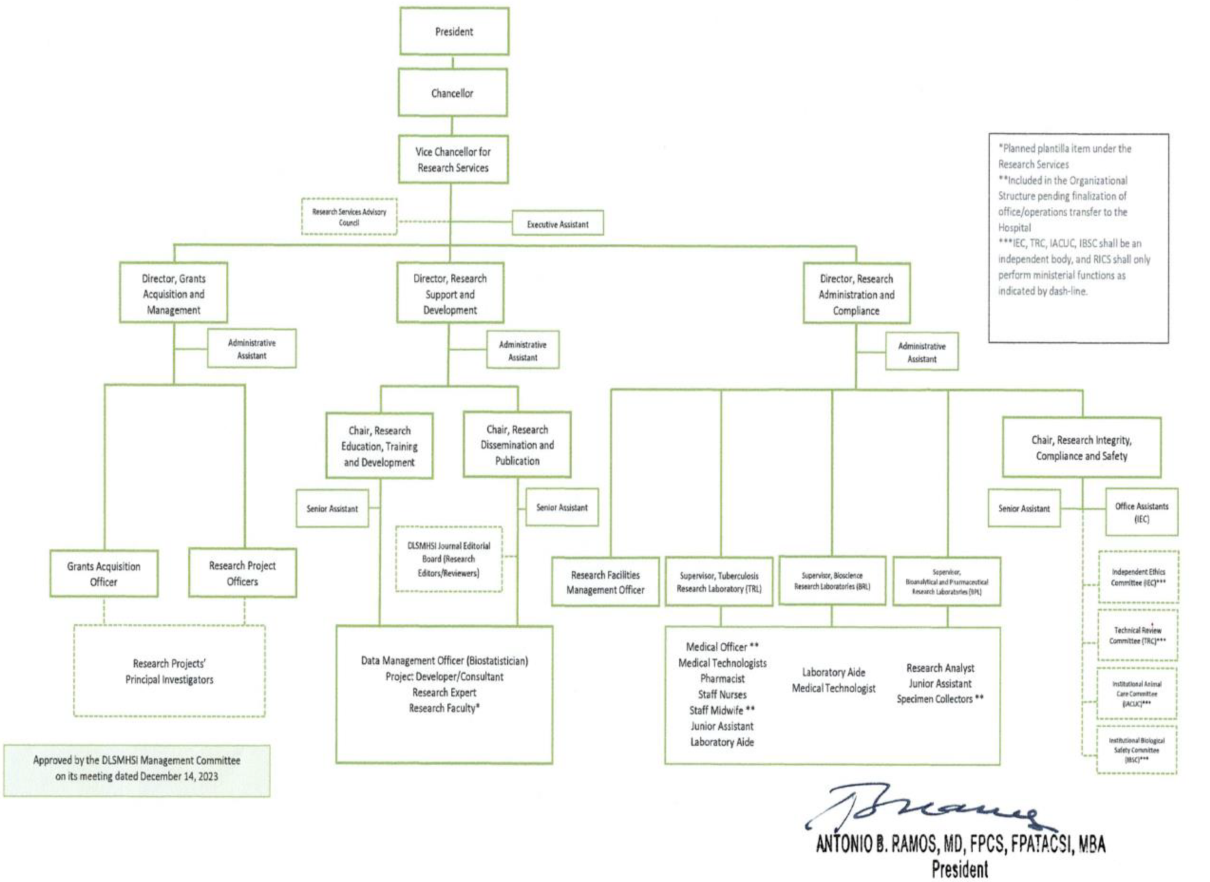

Figure 1. Research Services Organizational Structure

LIST OF ABBREVIATIONS AND ACRONYMS

ACRONYM	MEANING
1. **AEs**	Adverse Events
2. **BRET**	Basic Research Ethics Traininng
3. **CIOMS**	Council for International Organizations of Medical Sciences
4. **COI**	Conflict of Interest
5. **CV**	Curriculum Vitae
6. **CPE**	Continuing Professional Education
7. **DLSMHSI**	De La Salle Medical and Health Sciences Institute
8. **DLSMHSI-IEC**	De La Salle Medical and Health Sciences Institute - Independent Ethics Committee
9. **DOH**	Department of Health
10. **ERB**	Ethics Review Board
11. **FDA**	Food and Drug Administration (Philippines)
12. **FERCAP**	Forum for Ethical Review Committees in the Asian and Western Pacific Region
13. **GCP**	Good Clinical Practice
14. **ICH**	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
15. **ICF**	Informed Consent Form
16. **IEC**	Independent Ethics Committee
17. **IQMO**	Institutional Quality Management Office
18. **IRB**	Institutional Review Board
19. **NEGRIHP**	National Ethical Guidelines for Research Involving Human Participants
20. **PHREB**	Philippine Health Research Ethics Board
21. **PI**	Principal Investigator
22. **PNHRS**	Philippine National Health Research System
23. **RAC**	Research Administration and Compliance
24. **RETD**	Research Education, Training, and Development
25. **RICS**	Research Integrity, Compliance, and Safety
26. **RNE**	Reportable Negative Events
27. **RSD**	Research Support and Development
28. **SAEs**	Serious Adverse Events
29. **SJREB**	Single Joint Research Ethics Board
30. **SOP**	Standard Operating Procedure
31. **SUSARs**	Suspected Unexpected Serious Adverse Reactions
32. **VCR**	Vice Chancellor for Research
33. **WHO**	World Health Organization

GLOSSARY

1. **Active Files** – documents for protocols currently under review or management by the IEC.
2. **Active Study** – an ongoing study, implementation of which is within the period covered by ethics clearance.
3. **Adjournment** – formal closure of the meeting. Motion for adjournment and record of the time are noted.
4. **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.
5. **Administrative Documents** – records supporting IEC operations, not tied to specific research protocols.
6. **Adverse Events (AEs)** – unfavorable incidents linked to the use of medical products or procedures.
7. **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.
8. **Agenda (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”.
9. **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.
10. **Amendment** – a change in or revision of the protocol made after its approval.
11. **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.
12. **Archiving** – the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, terminated, or declared inactive.
13. **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.
14. **Appeal** – a request of a researcher/ investigator for a reconsideration of the IEC recommendation..
15. **Appointing Authority** – the institutional official that has the power to designate or appoint individuals to specific offices or roles.
16. **Assessment Form** – evaluation tool accomplished by the reviewers when appraising the protocol or the informed consent form.

17. **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..
18. **Basic Research Ethics Training (BRET)** – foundational training in research ethics that covers principles, guidelines, and practices to ensure the ethical conduct of research, particularly involving human participants.
19. **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
20. **Business Arising from the Minutes** – matters generated from the discussions in the previous meeting that need continuing attention and require reporting.
21. **Clarificatory Meeting/Interview** – consultation between the IEC and a researcher to resolve identified research issues.
22. **Clinical Auditor** – an individual who systematically and independently examines trial related activities and documents at a particular period.
23. **Clinical Monitor** – an individual who oversees the progress of a clinical trial.
24. **Coding** – a unique number assigned to a protocol indicating the year and series it was received.
25. **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.
26. **Competent Authority** – designated officer or member of the IEC with the authority to respond to queries and complaints regarding studies approved by the committee.
27. **Complaint** – the act of expressing discontent or unease about certain events or arrangements in connection with a study.
28. **Conflict of Interest (COI)** – a situation where the aims or concerns of two different interests (primary and secondary) are incompatible, potentially affecting official or primary duties.
29. **Confidentiality** – the duty to not disclose private or research information entrusted to an individual or organization.
30. **Conforme** – acceptance of or agreement to an assignment or designation.
31. **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.
32. **Continuing Review** – the IEC's decision to extend ethical clearance based on ongoing compliance and progress.
33. **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.

34. **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.
35. **Database** – a structured/organized collection of information so that the data can easily be accessed, managed, and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study
36. **Date of Effectivity** – date when the guidelines shall be enforced
37. **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.
38. **Draft Minutes of the Meeting** – proceedings of the meeting prepared by the IEC Staff under the supervision of the Member-Secretary
39. **Decision** – the result of the deliberations of the IEC in the review of a protocol or other submissions.
40. **Digital Filing** – the process of organizing and storing electronic versions of documents in designated digital folders on a computer or storage device.
41. **Drug or Device** – health product used for diagnosis or treatment
42. **Early Termination** – the decision of the researcher, principal investigator, the institution, or sponsor to end the implementation of a study before its completion.
43. **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.
44. **Electronic Database** – a structured collection of digital data used to log, track, and retrieve information related to communications and other records efficiently.
45. **Exempted from Review** – a decision made by the IEC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGRIHP 2022 or 2022 National Ethical Guidelines for Research Involving Human Participants
46. **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
47. **Expertise** – a proficiency, skill or know-how possessed by experts in a certain academic or professional field
48. **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.

49. **Final Meeting Minutes (Approved Minutes of the Meeting)** – proceedings of the meeting that have been approved by the IEC members

50. **Final Report (Close-Out 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 IEC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

51. **Format** – general style or layout of the document

52. **Full Review (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

53. **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.

54. **Good Research Practice** – a set of standards ensuring the quality, integrity, and reproducibility of research, promoting ethical and professional conduct throughout the research lifecycle.

55. **High-Risk Studies** – research where harm or danger resulting from the study intervention is very likely for participants.

56. **IEC Operations** – the overall activities of the IEC that reflect performance of its functions and responsibilities

57. **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.

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

59. **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

60. **Indexing System** – a method of assigning unique identifiers or categories to documents to facilitate easy organization, retrieval, and tracking.

61. **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.

62. **Informed Consent Form (ICF)** – 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

63. **Initial Review** – ethical and technical review conducted on the initially-submitted study documents. It may be expedited or full.

64. **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

65. **Intellectual Property (IP)** – 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.

66. **Intellectual Property Right (IPR)** – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.

67. **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.

68. **Major Modification** – significant changes to a study that impact participant safety or study integrity.

69. **Majority Rule** – a policy based on the principle that the decision made by the greater number should be carried/accepted.

70. **Medical Members** – individuals with academic degrees in the medical profession or a master's degree in the nursing profession.

71. **Meeting Minutes (Minutes of the Meeting)** – the official narration and record of the proceedings of the assembly of IEC members, based on agenda.

72. **Minimal Risk** – the term used when 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.

73. **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.

74. **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.

75. **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.

76. **Non-medical Members** – individuals without academic degrees in the medical profession or a master's degree in the nursing profession.

77. **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.

78. **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.

79. **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.

80. **Online Digital Storage** – the storage of digital files on cloud-based platforms that require an internet connection, providing remote access and backup capabilities.

81. **Operations-Related Matters** – items included in the agenda that are not directly related to any protocol under review

82. **Outgoing Communications** – documents generated within the IEC office intended for individuals or offices related to the operations of the IEC.

83. **Physical Filing** – the process of organizing and storing hard copies of documents in labeled folders or cabinets for easy retrieval and safekeeping.

84. **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.

85. **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.

86. **Primary Reviewer** – an IEC member assigned to conduct in-depth evaluations of specific research submissions. 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.

87. **Principal Investigator (PI)** – the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.

88. **Progress Reports** – updates provided by researchers on the implementation of a study.

89. **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

90. **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 NEGRIHP (2022) standards.

91. **Protocol Deviation** – minor non-compliance with a protocol that does not increase risk or impact data integrity.

92. **Protocol File/Folder** – organized compilation of all documents related to a study.

93. **Protocol Index** – chronological record of protocol file documents for easy reference.

94. **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.

95. **Protocol-Related Documents (Protocol-Related Communications/Submissions)** – 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.

96. **Protocol Violation** – major non-compliance affecting participant safety, data integrity, or the study's outcome.

97. **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.

98. **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.

99. **Provisional Minutes of the Meeting** – proceedings of the meeting that have been noted or approved by the IEC Chair.

100. **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.

101. **Query** – the act of asking for information or clarification about a study.

102. **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.

103. **Real-time Recording** – the process of documenting the minutes of the meeting as the meeting proceeds simultaneously

104. **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.

105. **Regular Meeting** – a periodically scheduled assembly of the IEC

106. **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.

107. **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.

108. **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.

109. **Researcher** – individual primarily responsible for the conceptualization, planning and implementation of a study.

110. **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

111. **Resubmission** – revised study proposals that are submitted after the initial review.

112. **Reviewer** – a regular member of the IEC 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.

113. **Risks** – summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol

114. **Room-use Only Restriction** – the rule that limits the use of a document within the designated premises.

115. **Safety Monitoring Procedure** – plan to monitor and address safety concerns during the study, including adverse events and unanticipated risks, to protect participants.

116. **Secret Ballot** – a system of casting votes (opinions or choices) such that the voters are not identified or are anonymous.

117. **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

118. **Scientists** – individuals with a formal education of at least a master's degree in a scientific discipline (e.g., biology, physics, social science, etc.).

119. **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.

120. **Site Visit** – an activity of the IEC where an assigned team goes to the research site or office for specific monitoring purposes.

121. **Site Visiting Team** – members/staff of the IEC (two to four members) assigned by the 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.

122. **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.

123. **Sponsor** – an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.

124. **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.

125. **Standard Operating Procedures (SOPs)** – 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.

126. **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

127. **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

128. **Study Site** – physical location where research activities are conducted.

129. **Study-Related Communications** – documents that refer to an exchange of information or opinions regarding a study, usually between the IEC and the researcher.

130. **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.

131. **Term of Office** – the specified length of time that a person serves in a particular designation/role.

132. **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

133. **Voting** – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.

134. **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.

LIST OF STANDARD OPERATING PROCEDURES

SOP NO.	TITLE
I	Selection and Appointment of DLSMHSI-IEC Members
II	Designation of DLSMHSI-IEC Officers
III	Appointment of Independent Consultants and Assignment of Procotols
IV	Training of DLSMHSI-IEC Members and Staff
V	Management of Initial Review
VI	Selection of Primary Reviewers
VII	Exempt from Review
VIII	Expedited Review
IX	Full-Board Review
X	SJREB Protocol Review
XI	Review of Medical Device
XII	Use of Protocol and Informed Consent Assessment Forms
XIII	Management of Revisions
XIV	Review of Progress Reports
XV	Review of Amendments
XVI	Management of Protocol Deviation and Violation Report
XVII	Review of Reportable Negative Events
XVII	Review of SAEs and SUSARs
XIX	Management of an Application for Continuing Review
XX	Early Protocol Termination
XXI	Review of Final Report
XXII	Management of Appeals
XXIII	Site Visits
XXIV	Preparation and Distribution of Meeting Agenda
XXV	Preparation and Conduct of Meetings
XXVI	Preparation of the Minutes of the Meetings
XXVII	Communicating DLSMHSI-IEC Decisions
XXVIII	Management of Incoming and Outgoing Communications
XXIX	Management of Active Files (Administrative and Study Files)
XXX	Archiving of Terminated, Inactive, or Completed Studies
XXXI	Management of Access to Confidential Files
XXXII	Management of Participants' Queries and Complaints
XXXIII	Writing and Revising SOPs