



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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Page 1 of 9

TABLE OF CONTENTS

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

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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. 4 Approval Date:
	INDEPENDENT ETHICS COMMITTEE	Effective Date: January 2025
XXIII. SITE VISITS		Page 2 of 9

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)

	De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114	DLSMHSI-IEC SOP Ver. 4 Approval Date:
	INDEPENDENT ETHICS COMMITTEE	Effective Date: January 2025
XXIII. SITE VISITS		Page 3 of 9

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 (IEC Form 037/V3/2025), 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 (IEC Form 037/V3/2025) 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 Checklist (IEC Form 038/V3/2025) 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 (IEC Form 038/V3/2025) 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 (IEC Form 038/V3/2025) 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 (IEC Form 038/V3/2025) 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 (IEC Form 038/V3/2025) 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 (IEC Form 033/V2/2025). (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.

	De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114	DLSMHSI-IEC SOP Ver. 4 Approval Date:
	INDEPENDENT ETHICS COMMITTEE	Effective Date: January 2025
XXIII. SITE VISITS		Page 7 of 9

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 037/V3/2025	Notification Letter for Site Visit
IEC Form 038/V3/2025	Site Visit Checklist
IEC Form 026/V3/2025	Noncompliance Report Form
IEC Form 033/V2/2025	Notification Letter for Post-Approval Requirements

	De La Salle Medical and Health Sciences Institute City of Dasmariñas, Cavite, Philippines 4114	DLSMHSI-IEC SOP Ver. 4 Approval Date:
	INDEPENDENT ETHICS COMMITTEE	Effective Date: January 2025
XXIII. SITE VISITS		Page 8 of 9

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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	<p>XXIII. SITE VISITS</p>	

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