**1. Policy Statement**

The ISU-IREB shall conduct site visits to ensure that the IREB recommendations are well implemented and protocols are properly followed. The site visit is a mechanism that will be used by the IREB to monitor adherence to authorized protocols, the process of obtaining Informed Consent Form (ICF), and the overall security of participant against any form of exploitation. Site visits shall be conducted to selected sites of approved protocols that fall within the following criteria:

(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; and

(e) multiple studies conducted by a researcher.

**2. Objective of the Activity**

The site visits primarily aim to protect the participants’ dignity and rights, as well as to promote the participant’s well-being. Specifically, it aims to meet the following objectives:

1. monitor the adherence of researchers to authorized protocols
2. check the process of obtaining Informed Consent Form (ICF), and
3. ensure that participants are secured against any form of exploitation.

**3. Scope**

The conduct of site visits shall cover all approved researches forwarded to the ISU-IREB that fall within the following criteria as reflected in the policy statement above.  It starts with deciding which site to visit and concludes with submitting Site-Visit Reports in the protocol folder and updating of the protocol database.

**4. Workflow**

The following steps shall be observed in the site visits with corresponding persons responsible in each step.

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| **ACTIVITY** | **RESPONSIBILITY** |
| 1. Selection of site to visit | IREB Members |
| 2. Notification of researcher | IREB Member Secretary & Secretariat |
| 3. Creation of Site Visit Team | IREB Chairperson, IREB Member secretary, IREB secretariat |
| 4. Conduct of site visit | Site Visit Team (members) |
| 5. Draft of report and presentation of report during meeting and discussion for recommendations | Site Visit Team (members) |
| 6. Transmittal of Final Report and Recommendations to the Researcher/Investigator | IREB Chairperson, IREB Member secretary IREB secretariat |
| 7. Filing of Site-Visit Reports in the protocol folder and update of Protocol database | IREB secretariat |

**5. Description of Procedures**

**5.1. Selection of site to visit**: The IREB shall identify researches that are covered by the criteria provided in the policy statement such as high risk studies, consistent non-submission or failure to submit after-approval submission requirements, reports of major protocol noncompliance, significant number of serious adverse events, reports of complaints from study participants. The IREB members during the monthly IREB meeting shall decide the researches to be visited and monitored based on the consensus of the IREB chairperson and committee members.

**5.2. Notification of researcher**: A notification of the visit shall be given to the researcher through a letter sent through regular mail and/or email for atleast 1 week or five (5) working days before the site visit. The letter provides the details of the visit such date, time, visiting team composition, people involved in the site visit, as well as the necessary documents to prepare.

**5.3. Creation of Site Visit Team**: The composition of the Site Visit team shall be determined by the IREB chairperson as agreed upon by the committee members. The selection of the visiting team is based on the expertise and area of specialization of the IREB members. The visiting team shall be composed of atleast two(2) IREB members which must include the primary reviewer. To ensure a systematic conduct of the site visit, the visiting team are expected to have conducted a thorough review on the full documents of the research most specially the research protocols. It is expected that the team members are familiar with the Site Visit Report Form and the specific areas to monitor.

**5.4. Conduct of Site Visit**: The site visit shall be scheduled every every 2nd and 3rd week of the month. During the site visit, the visiting team shall conduct a courtesy call followed by a prelimary meeting with the researchers to discuss the sequence of activities to be done. The researches shall be oriented on the data and information to be obtained in the Site Visit Report Form to be used.

Typically, important points to cover during the site visit include:

* Study protocol version
* Informed consent documents: verify if the site is using the most recently approved version
* Post-approval documents:  verify if these have been submitted to and approved by the IREB.
* Security, privacy, and confidentiality of the documents at the study site
* Facilities in the study site
* Determination of the protection of the rights, safety, and welfare of human participants in the study

An exit conference shall be made as a concluding activity of the visit. The researchers are informed on the points of observation based on the documents that are validated and the interview with the research subjects/ participants, the researchers themselves and other people involved during the visit. The accomplished Site Visit Report Form shall be conformed by the researches and a copy shall be provided to the researchers.

**5.5. Draft of report and presentation of report during meeting and discussion for recommendations**: The Site Visit Report Form must be accomplished by the visiting team at the end of every scheduled visit. A summary of the report including the accomplished site visit form shall be submitted to the IREB secretariat within three (3) working days following the scheduled date of site visit. The cut-off date of for inclusion in the next IREB agenda is five (5) working days before the scheduled meeting. The primary reviewer is responsible to make the necessary presentation during the IREB meeting. The course of action shall be determined based on the consensus of the committee.

**5.6. Transmittal of the Final Report and Recommendations to the Researcher/ Investigator:** The staff prepares a summary of the findings and recommendations of the IREB based on the deliberations during the meeting. The member secretary finalizes the draft for transmittal to the Researcher/ investigator an reviewed by the Committee chairperson. (SOP 21 Communicating IREB Decisions)

**5.7. Filing of the Site Visit documents and update of the Protocol database**: The staff files the Site Visit Report and the recommendations in the appropriate folder and updates the protocol database accordingly. (SOP\_\_\_ Management of Active Files)

1. **8. Glossary**

**Site Visit** -is an action of the IREB (based on established criteria) in which an assigned team goes to the research site or office for specific monitoring purposes.

**After-approval reports** – are reports, e.g. progress report, protocol deviation/violation report, amendment, early termination report, final report, application for continuing review, required by the IREB for submission by the researcher/investigator after the study has been approved for implementation.

**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. This may include but not limited to the following :  incorrect treatment, non-compliance with inclusion/exclusion criteria.

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

**Primary Reviewer**– a member of the Research Ethics assigned to do an in-depth evaluation

of the research-related documents using technical and ethical criteria established by the committee.

**Full Review** – is 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.

**Decision** - the result of the deliberations of the IREB in the review of a protocol or other submissions.

**Protocol File/Folder** – is an organized compilation of all documents (physical or electronic form) related to a study.

**Protocol Database** - a collection of information regarding protocols that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated.

**9. Forms**

Forms/templates/tools are used in the implementation of this SOP:

Form XVIA - Site Visit Report Form

1. **10. History of SOP**

Is this the first time that this SOP is being prepared? If yes, then indicate the date of the first draft and the authors, date of approval of the final draft, and the approving authority. If this is not the first time, then it should include information on the previous versions (see SOP on Writing and Revising SOPs (SOP#\_\_)).

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| **Version No.** | **Date** | **Authors** | **Main Change** |
| 0 | October 24, 2023 | REC member | First draft |
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1. **11. References**

The following references are used in crafting this protocol.

1. WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
2. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
3. Philippine Health Research Ethics Board Standard Operating Procedures 2020
4. National Ethical Guidelines for Research Involving Human Participants 2022

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| Prepared by: |  |
| Recommending Approval: |  |
| Approved by: |  |
| Approval Date: |  |