**Statement of Policy**

The REC 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 researcher.

**Objectives of the SOP**

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

**Scope/Applicability**

This SOP includes the steps in conducting visits to study sites for reasons set by the REC. 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

**Flowchart**

|  |  |  |
| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Selection of site to visit | REC Members | 1 day |
| Step 2: Notification of researcher | REC Staff | 1 day |
| Step 3: Creation of Site Visit Team | Chair | 1-3 days |
| Step 4: Conduct of site visit | Site Visit Team (members) | 3-7 days |
| Step 5: Draft of report and presentation of report during meeting and discussion for recommendations  | Site Visit Team (members) | 7 days |
| Step 6: Transmittal of Final Report and Recommendations to the Researcher/Investigator | Chair/ Staff | 1-2 days |
| Step 7: Filing of Site-Visit Reports in the protocol folder and update of Protocol database | Staff | 1 day |

**Description of Procedures**

Step 1 - Selection of site to visit: To determine the site to visit this criteria would serve as a guide. Criteria are as follows 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 decision on the site to visit would be done during a meeting.

Step 2 - Notification of researcher: The investigator or researcher will have a lead time of two weeks before the scheduled visit. The investigator would be informed through a letter and or an electronic mail. The following information would be included in the letter or email: visit details, documents to prepare.

Step 3 - Creation of Site Visit Team: A Site Visit Team is organized for each site visit. The members of the team is assigned by the Chair. The Site Visit Team should be composed of at least three (3) people: one (1) of the primary reviewers of the protocol, the member secretary and one (1) lay member. The Site Visit Team members are informed of their assignment through email or call or text message. A copy pf the approved study protocol and related documents would be provided to them as well.

The Site Visit Team prepares by reviewing the contents of the study file and the requirements of SOP 16 Form 21 Site Visit Report.

Step 4 - Conduct of Site Visit: Upon arrival in the study site, the Site Visit Team uses Form 21 Site Visit Report Form to do the following:

* Review the study protocol
* Review the informed consent documents and verify if the site is using the most recently approved version
* Ask the PI of staff to explain the informed consent process
* Review the post-approval documents and verify if the site is using the most recently approved version, or that these have been approved
* Verify security, privacy and confidentiality of the documents at the study site
* Observe facilities in the study site
* Make an overall determination of the protection of the rights, safety, and welfare of human participants in the study

At the end of the visit, the Site Visit Team will: (debriefing)

* Discuss the findings with the research team
* Solicit feedback

Step 5 - Draft of report and presentation of report during meeting and discussion for recommendations: The Site Visit Team completes Form 21 Site Visit Report form which should reflect the consensus opinion of the Site Visit Team members and submits it to the secretariat not later than seven (7) calendar days after the Site Visit. Secretariat logs the report and includes the site visit report in the agenda of the next meeting. The primary reviewer who did the site visit will present during the meeting. The REC deliberates on the implications of results of the Site Visit on the rights, safety and welfare of the study participants and makes an overall determination of protocol compliance in the study site.

Step 6: Transmittal of the Final Report and Recommendations to the Researcher/ Investigator: The staff prepares a summary of the findings and recommendations of the REC based on the deliberations during the meeting. The Chair finalizes the draft for transmittal to the Researcher/ investigator. (SOP # 21 Communicating REC Decisions). The PI is notified of the REC action or recommendations through an action letter. The PI may be requested to provide additional information, submit additional documents or implement corrective action.

Step 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 # 23 Management of Active Files)

**Forms:**

SOP 16 Form 021 Site Visit Report Form

 **History of SOP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 02/28/2017 | krva | Creation of SOP |
| 02 | 09/26/2022 | krva | Revision of SOP |