PCMC IR-EC SOP 21.0: Site Visits

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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21.0 SITE VISITS

21.1 Policy Statement

The IR-EC shall conduct study site monitoring for cause or routine audit to check compliance with GCP and PCMC IR-EC approved protocol and related documents.

21.2 Purpose of the Activity

The study site visit aims to ensure the safety of participants and adherence to protocol by the research team.

21.3 Scope

This SOP includes the procedures in conducting a study site visit that begins from the selection of the study site to visit and ends with the filing of pertinent documents.

21.4 Process Flow/Steps for Site Visit

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Selection of the study site to visit	IR-EC Member
2	Creation of the Study Site Visit Team	IR-EC Chair
3	Preparing the Study Site Visit Plan	Study Site Visit Team
4	Notifying the PI of the date of site visit	Secretariat
5	Conducting the site visit and debriefing the study team	Study Site Visit Team
6	Presentation of the findings during full board meeting	Study Site Visit Team
7	Communicating the results of site visit and recommended actions	Secretariat
8	Filing of pertinent documents	Secretariat

21.5 Detailed Instructions

21.5.1 Selection of the study site to visit

21.5.1.1 Any IR-EC Member may recommend to visit study sites for any of the following reasons:

a. Frequent occurrence of SAE or protocol violations / deviations
b. Failure to submit safety reports and progress reports
c. Complaints about PI performance
d. Monitor implementation of risky protocols

e. PI with > 2 ongoing clinical trials
f. Protocols involving terminally ill patients
g. Clinical trials in Phase 1
h. Routine

21.5.1.2 Study site visit may be conducted upon recommendation of Primary Reviewers.

21.5.2 Creation of the Study Site Visit Team

21.5.2.1 The Chair shall assign a Site Visit Team and the Team Leader who shall conduct the onsite evaluation for the PCMC IR-EC with the approval of the full board. Members should include the Primary Reviewers whenever possible.

21.5.2.2 The Site Visit Team members shall be formally informed of their assignment.

21.5.2.3 The IR-EC Secretariat shall prepare the Study Site Visit package consisting of the latest version of the approved protocol and informed consent documents, and other relevant documents (like protocol deviation reports, on-site SAEs/SUSARs – initial and follow-up reports) and a copy of the Study Site Visit Report Form 21.1

21.5.3 Preparing the Study Site Visit Plan

21.5.3.1 The Study Site Visit Team prepares the Study Site Plan that includes the following:

a. Date and Time of the planned visit
b. Members of the Study Site Visit Team
c. Objectives of the Visit
d. Documents to be reviewed
e. Persons to be interviewed

21.5.3.2 The Study Site Team shall also discuss the logistics (transportation, accommodation, meals, etc.) of a planned site visit that is outside of PCMC.

21.5.3.3 The Study Site Visit Team, in consultation with the IR-EC Chair, shall be given access to documents in the protocol file folder of a study for monitoring. The Team may also photocopy some parts of the files (e.g. Informed Consent Form, advertisement materials, Case Report Form) for comparison with the documents used in the study site.

21.5.4 Notifying the PI of date of site visit

21.5.4.1 The IR-EC Secretariat shall prepare the letter informing the PI of the

planned study site for signature by the IR-EC Chair. Attached to the letter shall be the Study Site Visit Plan and the Study Site Visit Report Form (Form 21.1).

21.5.5 Conducting the site visit and debriefing the study team

21.5.5.1 The Study Site Visit Team shall conduct the site visit as per the Study Visit Plan. Additional guide in the conduct of the visit shall be the Study Site Visit Report Form. The following are things that can be done:

a. Review the informed consent document to make sure that the site is using the most recent version.
b. Review randomly the subject files to ensure that subjects are signing the correct informed consent.
c. Check if the files are orderly and confidentiality is maintained.

21.5.5.2 At the end of the visit, the Study Site Visit Team shall present the findings to the Study Team and solicit feedback.

21.5.5.3 The Study Site Visit Team shall complete the Study Site Visit Report Form. It shall include comments on protocol violation / deviation noted during the site visit.

21.5.5.4 Conflicting findings shall be resolved by consensus.

21.5.5.5 The report shall be submitted to the IR-EC Secretariat within 7 calendar days from the date of the visit.

21.5.5.6 The IR-EC Secretariat shall include the presentation of the study site visit report in the meeting agenda.

21.5.6 Presentation of the findings during full board meeting

21.5.6.1 The Study Site Visit Team shall present the report during the full board meeting.

21.5.6.2 The IR-EC shall make a determination whether the rights, safety and welfare of research participants are compromised and shall make appropriate recommendations to the PI, if any.

21.5.7 Communicating the results of Site Visit and recommended actions

21.5.7.1 Based on the minutes of the meeting, the IR-EC Secretariat shall prepare a Notification Letter – Study Site Visit for signature of the IR-EC Chair.

21.5.7.2 The PI may be requested to provide additional information or documents or implement corrective actions.

21.5.8 Filing of pertinent documents

21.5.8.1 The IR-EC Secretariat shall file the Study Site Visit Report, excerpt of the minutes of the meeting when report was discussed and the Notification

Letter (including the response from the PI, if any) in the protocol file folder and shall update the protocol file index.

21.4 Forms

Form 21.1 V.2.0 Site Visit Form

21.5 Glossary