**SITE VISIT REPORT FORM**

**INSTRUCTIONS TO THE PSURERC SITE VISIT TEAM (SVT) MEMBER/ REPRESENTATIVES:**

The site visit is conducted as a result of committee action to monitor compliance with the study protocol at the study site. Site visits are necessary for high-risk studies, frequent non-submission or failure to submit continuing review requirements, reports of major protocol noncompliance, significant serious adverse events, reports of complaints from study participants that have been issued ethical clearance by RERC, and limited to document review. As a member of the visiting team, you are expected to maintain and protect the privacy and confidentiality of research-related information of study participants/subjects. To ensure readiness during the visit, kindly review the study protocol folder before the visit. The content of this form reflects the findings of the Site Visit Team; the same will be reported in the next RERC meeting.

|  |  |
| --- | --- |
| **PSURERC Code** |  |
| **Protocol Title** |  |
| **Principal Investigator/Lead Researcher** |  |
| **Protocol Approval Date/s** *(indicate dates of continuing review and/or protocol amendment dates, if applicable***)** |  |
| **Start Date** *(stated in the approved protocol; start of study includes the start of all data collection-related activities post-approval, e.g., communication with recruitment party, invitation, etc.; if not started, indicate target date; if started, indicate actual start date )* |  |
| **Target Completion Date** *(as stated in the approved protocol)* |  |
| **Study Site** |  |
| **Current Status** (*specify the current stage of the study)* |  |

**ON STUDY PARTICIPANTS**

|  |  |
| --- | --- |
| Target Number of Participants (*approved by RERC)* |  |
| Number of Participants Invited |  |
| Number of Participants Enrolled |  |
| Number of Participants Withdrawn *(include reasons for withdrawal)* |  |
| Number of Participants Who Completed |  |

**SITE VISIT DETAILS: Provide a description and details. Indicate NA if not applicable.**

| **ITEMS** | **YES OR NO AND COMMENTS** |
| --- | --- |
| 1. Are site facilities appropriate? |  |
| 1. Are informed consent documents updated to the version approved by the PSURERC? |  |
| 1. Are there any RNE/SAE/SUSAR reports not previously reported to the PSURERC? |  |
| 1. Are there any events of protocol noncompliance not previously reported to the PSURERC? |  |
| 1. Are investigation products and study documents secured adequately? |  |
| 1. Are all other PSURERC-approved documents (e.g., advertisements) used following the approved study protocol? |  |
| 1. Are there any significant findings in this visit that could affect the participant’s rights, safety, or welfare? |  |
| 1. Overall, does the study site provide adequate protection for the rights, safety, or welfare of study participants? |  |
| 1. How well are study participants protected? |  |
| 1. Are there further actions or queries resulting from this site visit? |  |
| 1. Additional remarks | |

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| --- | --- | --- |
| **Duration of visit:** <hours >**/** From <hh:mm> to <hh:mm> | | |
| **COMPLETED BY THE FOLLOWING PSURERC SITE VISIT TEAM MEMBER/ REPRESENTATIVES:** | | |
| **NAME** | **SIGNATURE** | **DATE** |
| SVT Member 1 |  | <dd/mm/yyyy> |
| SVT Member 2 |  | <dd/mm/yyyy> |
| SVT Member 3 |  | <dd/mm/yyyy> |

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| **RECOMMENDATIONS:** | [ ] No further action  [ ] Request additional information: <specify>  [ ] Request further action  [ ] Amendment in the protocol  [ ] Amendment in the ICF/assent  [ ] Others  [ ] Suspend the study  [ ] Terminate the study  [ ] Withdraw approval |