|  |
| --- |
| INSTRUCTION:  This form is used to report any occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data. This form should be submitted together with the Progress Report Form and copy of approval letter. ***Incomplete submissions will NOT BE ACCEPTED.*** |

*------------------------------- Section A (for the primary investigator) ------------------------------------*

|  |  |  |  |
| --- | --- | --- | --- |
| SPUP REC Code: |  | | |
| Protocol Title: |  | | |
| Principal Investigator: |  | Contact Number: |  |
| Institution: |  | Email Address: |  |
| Adviser/s: |  | | |
| Date of Initial Submission: |  | 2nd Review 3rd Review | |
| Date of Approval |  | Last Review Date: |  |

|  |  |
| --- | --- |
| Number of participants at the start of study | Number of participants at the end of study |
|  |  |

|  |  |  |
| --- | --- | --- |
| Summary of the results of the research |  | |
| Brief description how the results was disseminated to the participant/community (if applicable) |  | |
| Summary of amendments to the  original protocol (include dates of approval) |  | |
| Summary of RNEs reported |  | |
| Summary of participants’ complaints, if applicable |  | |
| Summary of benefits documented |  | |
| If terminated early, state the reason |  | |
| Progress report dates with  corresponding SPUP REC actions |  | |
| Summary of study materials used |  | |
| Duration of the study |  | |
| Summary of Recruitment |  | No. of Participants on the approved protocol |
|  | No. of participants who are lost to follow up |
|  | No. of participants withdrawn from the study |
|  | No. of participants affected by RNEs |
|  | No. of participants who completed the study |
| List of informed consent form used (version/date) and attach most recent version |  | |
| Study Objectives |  | |
|  | |
|  | |
| 1. *(add rows when needed)* | |

*------------------------------- Section B (for the assigned primary reviewer) -----------------------------*

|  |  |  |
| --- | --- | --- |
| Assessment by the primary reviewer | | |
| Comments/Conclusion |  | |
| Recommendations |  | Acknowledged/Accepted |
|  | Request Additional Information |
|  | Further Action Required |

|  |  |  |  |
| --- | --- | --- | --- |
| Primary Reviewer  (Printed Name and Signature) |  | Date Submitted |  |