**Research Ethics Board**

**Unanticipated Problems Report Form**

All information must be typewritten in the space provided. Do not leave any boxes blank. Indicate “not applicable” by typing “N/A.”

Unanticipated problems must be submitted to the REB within 15 calendar days of occurrence (local) or of receipt of notification from the sponsor (external). Local events that are fatal or life-threatening must be reported within seven (7) calendar days.

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| --- | --- | --- |
| 1.PRINCIPAL INVESTIGATOR’S SURNAME, GIVEN NAME(S):       | 2. SHA DEPARTMENT      | 3. PHONE NUMBER:      |
| 4. FACILITY IN WHICH THE RESEARCH IS BEING CONDUCTED: [ ]  RGH [ ]  PH [ ]  WRC [ ]  Other:       |
| 5. TITLE OF PROJECT:      |
| 6. NAME OF DRUG/DEVICE:       | 7. SHA REB FILE NUMBER:       |
| **8. REPORT DATES:** | **9. EVENT:** |  | **10. REPORT NUMBER(S) AND A BRIEF CLINICAL DESCRIPTION** |
| Click here to enter a date. | [ ]  LOCAL [ ]  EXTERNAL | [ ]  INITIAL [ ]  FOLLOW-UP #    |       |
| Click here to enter a date. | [ ]  LOCAL [ ]  EXTERNAL | [ ]  INITIAL [ ]  FOLLOW-UP #    |       |
| Click here to enter a date. | [ ]  LOCAL [ ]  EXTERNAL | [ ]  INITIAL [ ]  FOLLOW-UP #    |       |
| 11. SHA PRINCIPAL INVESTIGATOR’S ASSESSMENT OF UNANTICIPATED PROBLEMS If a change to the consent form is required, please attach a copy with the changes highlighted or marked using track changes.1. INDIVIDUAL ADVERSE EVENTS

IS THE EVENT SERIOUS? [ ]  YES [ ]  NO  IS THE EVENT UNEXPECTED? [ ]  YES [ ]  NO IS THE EVENT (POTENTIALLY) A DIRECT RESULT OF PARTICIPATION IN THE RESEARCH? [ ]  YES [ ]  NO DOES THE EVENT PLACE THE PARTICIPANT OR OTHERS AT GREATER RISK OF HARM?\* [ ]  YES [ ]  NO \*Including physical, psychological, economic, or social harm 1. OTHER UNANTICIPATED PROBLEMS

 ARE SERIOUS ADVERSE EVENTS OCCURING GLOBALLY AT A RATE HIGHER THAN EXPECTED?\*\* [ ]  YES [ ]  NO\*\*As described in a memo from the sponsor, periodic safety report, or Data Safety Monitoring Board reportDID A PROTOCOL VIOLATION OCCUR THAT HAS THE POTENTIAL TO HARM THE PARTICIPANT?\*\*\* [ ]  YES [ ]  NO\*\*\*e.g., enrollment of an illegible patient, incorrect dosage of study drugHAS A BREACH OF PRIVACY OR CONFIDENTIALITY OCCURRED LOCALLY? [ ]  YES [ ]  NO  HAS DATA INTEGRITY BEEN COMPROMISED? (E.G., LOSS OF ORIGINAL DATA OR CONSENT FORMS) [ ]  YES [ ]  NO **IF YOU ANSWERED “NO” TO ALL OF THE ABOVE, DO NOT SUBMIT THIS REPORT OR RELATED DOCUMENTATION TO THE REB.****IF SUBMITTING A REVISED CONSENT FORM, HIGHLIGHT OR USE TRACK CHANGES TO MARK ALL REVISIONS. UPDATE THE VERSION NUMBER/DATE.** |
| 12. INVESTIGATOR’S COMMENTS: (Please append additional comments as required)      |
| 13. CONTACT PERSON FOR CORRESPONDENCE:NAME:        | PHONE:       | EMAIL:       |
| 14. SIGNATURE:  PRINCIPAL INVESTIGATOR DATE | 15. REVIEW COMPLETED BY: ON BEHALF OF THE SHA REB DATE |
| 16. ATTACHMENTS: [ ]  SAE REPORTS [ ]  DSMB/PERIODIC SAFETY REPORT [ ]  REVISED ICF [ ]  OTHER: |