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| IRB-417- Serious Adverse Event (SAE) Report Form | |
| Study Title: |  |
| IRB Number: |  |
| SDR Number: |  |
| Principal Investigator: |  |
| Subject ID: |  |
| Date Participant Reported/Date of Site Awareness: | (dd/mmm/yyyy) |
| Date of Report: | (dd/mmm/yyyy) |
| Type of Report: | Initial Follow-up Final |
|  | |
| Please report **within one (1) week** of initial receipt or when you become aware of any SERIOUS ADVERSE EVENTS by completing all the details below and submitting the form on IRBNet.org  If the report cannot be completed in its entirety within the required time period, a preliminary report should be submitted. The report should be amended once the event is resolved and/or more information becomes available and submitted again to Sidra IRB  For questions regarding the POL - O - Institutional Review Board (IRB) Reporting of Unanticipated Problems and Serious Adverse Event, please contact IRB office at 4003 7747 or email at [irb@sidra.org](mailto:irb@sidra.org) | |
| **“Serious Adverse Event” (SAE)** is any adverse event temporally associated with the subject’s participation in research (whether or not considered related to the subject’s participation in the research) that meets any of the following criteria:   * results in death; * is life-threatening (places the subject at immediate risk of death from the event as it occurred); * requires inpatient hospitalization or prolongation of existing hospitalization; * results in a persistent or significant disability/incapacity; * results in a congenital anomaly/birth defect; or * any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject’s health, and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition | |
| 1. **BACKGROUND INFORMATION:** | |
| 1. **Is this a multi-site study where Sidra Medicine IRB is serving as the reviewing IRB for external sites?**   YES  NO  If Yes, please identify the site where the SAE occurred in the text box below and provide the names, email addresses & phone numbers for the site Investigator and Study Contact that the IRB can contact with questions related to the SAE.     1. **Please note the study Enrollment Status:**   Open to subject enrollment  Closed to subject enrollment   1. **Please note the current enrollment at the site where the incident occurred:**   Total number of subjects consented:  Number of active subjects:  Number of subjects in follow up:   1. **Is the SAE reported to the IRB with within one (1) week of initial receipt or when you become aware of it?** Yes  No   If No, please provide justification below:     1. **Is there a possibility this event will occur again?** Yes  No | |
| 1. **SUMMARY:** Please provide the following details for the SAE being reported. If there was a significant delay in reporting from the time of identification, please describe the reason for this delay. | |
| 1. **SAE Event Term** (Diagnosis, ex: Stroke, Myocardial Infarction): 2. **SAE onset date:**                 (dd/mmm/yyyy) 3. **SAE Ongoing:**  Yes  No 4. **SAE stop date:**                 (dd/mmm/yyyy) 5. **Location of SAE:** 6. **Was this an unexpected serious adverse event?**  Yes  No 7. **Brief description of participant with no personal identifiers:**   Sex:   F  M Age:  Diagnosis for study participation:   1. **Brief description of the nature of the SAE** (attach description if more space is needed):      1. **Category of the SAE:**  |  |  | | --- | --- | | Date of death               (dd/mmm/yyyy)  Life threatening  Hospitalization – initial or prolonged  Disability/incapacity | Congenital anomaly/birth defect  Required intervention to prevent permanent impairment  Other: |  1. **Intervention type:**   Medication or nutritional supplement (specify):  Device (specify):  Surgery (specify):  Behavioral/lifestyle (specify): | |
| 1. **Assessment:** To determine the level of review required please address the following: | |
| 1. **Has a Data Safety and Monitoring Board (DSMB) or Data Monitoring Committee (DMC) reviewed the reported SAE?** (Choose one):   N/A; Project does not have a DSMB or DMC.  No, a review has not yet been conducted by the DSMB or DMC.  Yes, a review has been conducted by the DSMB or DMC.  Please check this box if the DSMB or DMC report is attached   1. **Relationship of event to intervention:**   Unrelated (clearly not related to the intervention)  Possibly Related (may be related to the intervention)  Related (clearly related to the intervention)   1. **Was study intervention discontinued due to event?**  Yes  No 2. **Has the event/s been reported in DATIX?** Yes No NA    1. If you answered Yes, please add Date of Reporting:                 (dd/mmm/yyyy) and Datix Reference Number:    2. If you answered No or NA, please provide the reason below:      1. **What medication(s) or other steps were taken to treat the SAE?**   **Steps Taken:**  **Medication List:**   |  |  |  | | --- | --- | --- | | Medication Name | Medication Start Date  (dd/mmm/yyyy) | Medication End Date  (dd/mmm/yyyy) | |  |  |  | |  |  |  | |  |  |  |  1. **List any relevant tests, laboratory data, and history, including preexisting medical conditions**.      1. **Was this event a study related endpoint?**      1. **Did this SAE adversely affect the scientific integrity of the study? Address the prompts below in your response:**    1. Why or Why not?    2. If yes, what is the plan to account for this in the analysis?      1. **Did this SAE adversely affect the rights\* of participant(s)? Why or Why not?**   \* These rights include:   * 1. To have enough time to decide whether or not to be in the research study and to make that decision without any pressure.   2. To refuse to be in the study at all, and to stop participating at any time.   3. To be informed of all the applicable required elements of consent.   4. To receive a copy of the consent form   5. To ask questions      1. **Did this SAE affect the subject’s willingness to participate in the research? Why or Why not?**      1. **Is this SAE a recurrence of a SAE(s) previously reported to the IRB on this protocol?**   YES  NO  If “Yes,” please identify the IRBNet package number under which the incident was submitted:  If “Yes,” how will the revised corrective and preventative action plan prevent this event from being repeated in the future? | |
| 1. **Completion of Report:** | |
| By signing this form, the principal investigator certify that he/she has disclosed to the IRB all relevant information that might affect the risk to benefit analysis of this study.  **Signature of principal investigator:**                 Date:                 (dd/mmm/yyyy) | |