|  |  |
| --- | --- |
| **PI NAME** |  |
| **STUDY TITLE** |  |

**TYPE OF REPORT**

|  |  |
| --- | --- |
|  | Adverse action from another BU review committee (e.g., IACUC, IBC, Radiation Safety, etc.) |
|  | Allegation or finding of non-compliance |
|  | Allegation or finding of scientific misconduct |
|  | Audit, inspection, or inquiry by a federal agency |
|  | Written report from a federal agency (e.g., FDA Form 483) |
|  | Suspension or termination by a sponsor, funding agency, or institution other than BU |
|  | Breach of confidentiality |
|  | Oversight committee/monitoring report (e.g., DSMB, DMC, etc.) |
|  | Incarceration of a subject in a research study not approved to involve prisoners |
|  | Adverse event or injury that is (1) serious, (2) unexpected, and (3) related or possibly related. |
|  | New or increased risk or benefit |
|  | Protocol deviation that harmed a subject or placed subject at risk of harm |
|  | Protocol deviation made without prior IRB approval to eliminate an apparent immediate hazard |
|  | Protocol deviation that affected the integrity of the study data |
|  | Unresolved subject complaint |
|  | Unanticipated adverse device effect |
|  | Adverse action by a licensing entity (e.g., state medical board, state nursing board, etc.) |
|  | Other– specify: |

**ASSESSMENT**

|  |  |
| --- | --- |
| Does the event or information represent an unanticipated problem involving risk to subjects or others?  Explain why or why not: | Yes  No |
| **Unanticipated problems involving risk to subjects or others** are defined as unforeseen events (given the nature of the research procedures and subject population) that suggest subjects, research staff, or others are placed at greater risk by the research than previously expected. (Includes physical, psychological, social, legal, or economic risks.) | |

**RESEARCH INTERVENTIONS OR INTERACTIONS**

|  |  |
| --- | --- |
| The event/information involves (check all that apply): | |
|  | Drug/Biologic/Supplement/Botanical. Identify: |
|  | Device. Identify: |
|  | Research-related procedure or activity. Identify: |
|  | Collected research data |
|  | None of the above. Explain: |

**SOURCE OF THE REPORT**

|  |  |
| --- | --- |
|  | Internal (occurring in Baylor University research, and/or at a site under the BU IRB’s jurisdiction.) |
|  | External (occurring in research at a site other than Baylor University, over which a non-BU IRB has jurisdiction).  List the location where the research was performed and/or the event occurred: |

**DATE(S) OF THE EVENT**

|  |  |
| --- | --- |
| Date(s) of the Event: | |
| Has the event/problem been resolved?  **If no**, explain: | Yes  No |

**DESCRIPTION**

|  |
| --- |
| Describe in detail the event or problem being reported. For medical events, include relevant dose, treatment, and laboratory information. *Use complete sentences. Attach additional documents as needed. Do not include (and remove as necessary) subjects’ personally identifiable information.* |

**RESEARCH STATUS**

|  |  |  |
| --- | --- | --- |
| **A.** | The research participant(s) involved is/are: | |
|  | Still on study |
|  | No longer on study |
|  | N/A or unknown |
|  | | |
| **B.** | Research recruitment (at Baylor University research at a site under the BU IRB’s jurisdiction) is: | |
|  | Ongoing |
|  | Completed (or stopped) |
|  | | |
| **C.** | Research interventions/interactions involving other participants are: | |
|  | Ongoing |
|  | Completed (or stopped) for all participants |

**OTHER REPORTING**

|  |  |
| --- | --- |
| The adverse event or problem will also be reported to (check all that apply): | |
|  | Sponsor / Funding Agency |
|  | Collaborating investigators |
|  | Privacy Officer (if involving protected health information) |
|  | Campus Safety / Information Technology (if security incident involving restricted data) |
|  | No other reporting required |
|  | Other – specify: |

**ACTIONS TO BE TAKEN**

|  |  |
| --- | --- |
| As a result of the event/information (check all that apply): | |
|  | The protocol or study procedures will be modified |
|  | The consent form or process will be modified |
|  | Additional information and/or follow-up will be provided to current and/or past participants |
|  | Current participants will be asked to re-consent to participation. |
|  | The research will be voluntarily placed on hold, pending more information or resolution of problem. |
|  | The research is being stopped. |
|  | No action is planned. Explain: |
|  | Other – specify: |

**Any new or revised documents, e.g., protocol, consent forms, letters or other communications for participants, must be submitted for review and approval with the “Change to Research Protocol” (F-11) form.**