**Post-Approval Problem Report**

*Cover Sheet*

|  |  |
| --- | --- |
| PI Name: | IRB#: |
| Protocol/Project Title: | |

Notice: *For items 1 & 2 below, the report to the IRB must be made without delay (no later than 7 days). Reports of problems involving items 3-7 should be made as promptly as possible after they occur or are discovered.* THIS REPORT AND THE SUPPORTING MATERIAL SHOULD BE SUBMITTED TO THE IRB USING VIRTRU SINCE IT MAY CONTAIN PARTICIPANT INFORMATION.

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
|  |  | **1. Is this a report of a “serious unexpected adverse event related to the study?”**  An “adverse event” is any undesirable effect upon a human participant occurring during or within a reasonable time after the conduct of research activities. An adverse event is “serious” when the undesirable effect is either:   1. a physical harm or injury characterized as death, life-threatening condition, in-patient hospitalization, persistent or significant disability/incapacity, congenital anomaly/birth defect, requires medical or surgical intervention to prevent any of the aforementioned physical harms; or 2. a psychological, social, or economic harm or injury of similar magnitude. |
|  |  | **2. Is this a report of an “unanticipated problem involving risk to human participants or others?”**  An “unanticipated problem involving risk to human participants or others” means any incident, experience, or outcome that meets all of the following criteria:   1. unexpected in terms of its nature, its severity, or its frequency (required considerations are what was disclosed during the recruitment process and what was described in the protocol-related documents); 2. related or having a reasonable possibility of being related to the participation in the research (required considerations include whether the sole cause can be identified and what is the natural progression of any pre-existing disease, disorder, or condition); and 3. suggests a greater risk of harm for human participants or others (in terms of its nature, severity, or frequency of either physical, psychological, economic, or social harm). |
|  |  | **3. Is this report about protocol noncompliance, violations, or deviations?**  Noncompliance may involve local IRB and/or federal requirements and has the potential to adversely affect the rights and welfare of human participants. (Examples include failure to obtain IRB approval for continuing review, enrolling subjects or conducting studies without IRB approval or outside of the approval period, failure to provide informed consent to one or more subject, and other.) |
|  |  | **4. Is this report about complaints about the study?** |
|  |  | **5. Is this report about sponsor clarifications that do not amend the study?** |
|  |  | **6. Is this report about updated safety information?** |
|  |  | **7. Is this a report about some other event or problem or issue?** |
|  |  | **8. Is this form accompanied by an application for Modifications to an Approved IRB Protocol that is designed to address the problem/s or issue/s noted in this report?** |

**This form must be accompanied by a formal letter, dated and signed by the PI\*, that includes:**

* A complete description of the event, problem, incident, or outcome;
* A description of, and rationale for, any actions already taken or those proposed to be taken due to the event, problem, incident or outcome *(or explain why no action is proposed).*

*\*A pdf of a signed letter is acceptable.*

**Submit using the Virtru email encryption extension to maintain participant privacy**