**Event Reporting Form**

Note to Investigators: If you are uncertain but believe that the event might qualify as an unanticipated problem, this report should be completed and uploaded to your eProtocol file.

PI Name:       IRB Protocol Number:

**DEFINITIONS (Types of reportable events)**

**Unanticipated problems involving risk to participants or others (UAPs)*.*** *Unanticipated problems involving risks to participants or others refer to any problem, event, or new information that:*

1. *Is unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent documents; and the characteristics of the subject population being studied; and*
2. *Is related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and*
3. *Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.*

**Protocol Deviation.** *A protocol deviation is defined as a deviation from the approved research activity without prior approval of the IRB that is unanticipated and happens without any prior agreement.*

**Non-compliance.** *Failure to comply with or adhere to rules, regulations, policies and standards of conduct that govern human subject research, failure to follow the determinations of the IRB or failure to follow institutional policies relating to human participant research.*

**TYPE OF EVENT**

Investigators must report the following events or issues to the IRB as soon as possible, but in no event later than 10 business days after the investigator first learns of the event.

Check all that are applicable.

Changes made to the research without prior IRB approval to eliminate apparent immediate hazards to the subject(s).

An unanticipated event related to the research that exposes participants to potential risk but that does not involve direct harm to subjects (e.g. lost laptop).

An unanticipated event related to the research that resulted in actual harm or exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk.

New information that may impact the willingness of participants to continue in the research.

A breach of confidentiality.

Incarceration of a participant in a protocol not approved to enroll prisoners.

Complaint from a subject when the complaint indicates unexpected risks.

Protocol/research plan deviation(s) or non-compliance.

Other

**DESCRIPTION OF EVENT**

* 1. Date of Occurrence:
  2. Date you became aware of occurrence:
  3. Describe the event or unanticipated problem (e.g. loss of confidentiality, increased risk and/or harm).

* 1. Did the event or problem involve a participant(s) in the study?  Yes  No

If No, describe other individual(s) involved and how they were involved?

* 1. Was the event **Unexpected** (in frequency of occurrence and/or magnitude)?  Yes  No

Explain:

* 1. Was the event **Related** or possibly related to participation in the research?  Yes  No

Explain the relationship:

* 1. Does the event suggest that the research places participants or others at a **Greater Risk of Harm** (including physical, psychological, economic, or social harm) than was previously known or recognized?

Yes  No

Explain:

* 1. Did the event or problem cause **actual harm** to participants or others?   Yes  No

If yes, describe.

* 1. Did the event or problem present the possibility that there may be delayed harm/negative affect to participants or others?  Yes  No

If yes, describe.

* 1. Describe any corrective actions taken to mitigate risk or harm related to the event and any actions that have been or will be taken to prevent recurrence of similar or the same event. If the protocol and/or consent are to be modified submit an amendment request in eProtocol.

* 1. Do currently enrolled subjects or others require notification?  Yes  No

If yes, identify your planned method of communication and submit any materials to be used for this purpose.

Re-Consent will occur at the participant’s next scheduled visit

Participant will be called at home

Participant will be sent a text message (SMS)

Participant will be contacted via social media (i.e. twitter, Facebook, 2nd Life, or other virtual means)

Participant will be sent an email

A letter will be mailed to the participant’s home (a copy of the letter must be included with this submission.)

Other:

* 1. Please provide any other information that could be of importance to the IRB in its review: