**Report of Unanticipated Problems**

**Involving Risk to Participants or Others**

**An unanticipated problem involving risk to participants or others is any event that was:**

1. **unexpected-not in the consent form, investigator brochure, or protocol; AND**
2. **harmful-caused harm to participants or others, or placed them at increased risk of harm**

**The following are types of events that require reporting to the Institutional Review Board. Check the type of event that prompted this report:**

**Any event that in the Investigator’s opinion was unanticipated, involved risk to participants or others and was possibly related to the research procedures;**

**Any event that requires prompt reporting to the sponsor in accordance with the protocol;**

**Any accidental or unintentional change to the IRB-approved protocol that increases risk or decreases benefit, affects the participant’s rights, safety, welfare, or affects the integrity of the resultant data;**

**Any accidental or unintentional change to the IRB-approved protocol that has the potential to recur;**

**Any deviation from the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant;**

**Any publication in the literature, including a Data and Safety Monitoring Report, interim result, or other finding that increases risk or decreases benefit, affects the participant’s rights, safety, welfare, or affects the integrity of the resultant data;**

**Any event that is both a serious event and an unexpected event, which in the Investigator’s opinion is more likely than not to be related to the research procedures;**

**A breech in confidentiality that may involve risk to that individual or others;**

**Any complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff; and**

**Any other event that, in the opinion of the Investigator, constitutes an unanticipated risk.**

**IRB#:**

**Project Title:**

**Principal Investigator:**

**This event was:**

**Unanticipated or unforeseeable at the time it occurred?**  **Yes**  **No**

**Harmful or adversely alters the risk/benefit relationship of the research?**  **Yes**  **No**

**Related or likely to have been caused by the research procedures?**  **Yes**  **No**

**Date of unanticipated problem:**

**Location of the unanticipated problem:**

**Provide a summary of the problem:**

**Is the problem already described in the consent forms?**  **Yes**  **No**

**If no, should the consent form be updated?**  **Yes**  **No**

**Should the research study be changed to address this problem?**  **Yes**  **No**

**Has there been a change to the risk/benefit ratio?**  **Yes**  **No**

**Have any corrective actions or measures been take to address this**

**unanticipated problem and to prevent future problems?**  **Yes**  **No**

**Provide a brief summary of corrective measures:**

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**Principal Investigator’s Signature**

**Date**