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| **Principal Investigator:** |  | | |
| **Study Title:** |  | **IRB Protocol #:** |  |

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| **Date event became known to study staff** | **Description of Event** | **RNI Category \****(from chart below)* | **Risk or Harm Classification\*** *(from chart below)* | **Date IRB Notified**  *(if applicable)* | **Date Sponsor Notified**  *(if applicable)* | **PI’s signature** | **Date signed** |
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***\*RNI Category*** *– Use appropriate RNI Category letter code in log.* ***Include all that apply****.*

***\*\*RNI Classification*** *– Use appropriate Risk or Harm Classification number code in log.*  ***Include all that apply***.

\* **RNI Category**

1. **Non-compliance**: Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
2. **Audit:** Audit, inspection, or inquiry by a federal agency.
3. **Report:** Written reports of study monitors.
4. **Researcher Error:** Failure to follow the protocol due to the action or inaction of the investigator or research staff.
5. **Confidentiality:** Breach of confidentiality.
6. **Unreviewed Change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
7. **Incarceration:** Incarceration of a subject in a study not approved by the IRB to involve prisoners.
8. **Complaint:** Complaint of a subject that cannot be resolved by the research team.
9. **Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.
10. **Unanticipated Adverse Device Effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
11. **VA-SAE:** For Department of Veterans Affairs (VA) research, all local or internal serious adverse events (SAEs)

**\*\* Risk or Harm Category**

1. **Risk:** Information that indicates a new or increased risk or safety issue such as:
   1. New Information(e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) that indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
   2. Investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk.
   3. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
   4. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
   5. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
   6. Any changes significantly affecting the conduct of the research.
2. **Harm**: Any harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and at least possibly related to the research procedures.
   1. A harm is “unexpected” when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
   2. A harm is “possibly related” to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.