EVENT REPORTING FOR UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS, ADVERSE EVENTS, AND OTHER PROBLEMS

Principal Investigator:

Protocol Short Title:

Protocol HU Number:

1. Type of Report

- ☐ Adverse device effect (Report only if unanticipated.)
- ☐ Adverse event or injury (Report only if serious, unexpected, and related.)
- ☐ Breach of confidentiality (Report only if involving risk.)
- ☐ Data and Safety Monitoring Board (DSMB) report, interim analysis, or other oversight committee/monitoring report (Report information altering the risk/benefit profile.)
- ☐ Event requiring prompt reporting (Report only when required by the protocol, sponsor, or funding agency.)
- ☐ New information (Report information indicating an unexpected change in risks or potential benefits, e.g., literature/scientific report or other published finding.)
- ☐ Protocol deviation, violation, or unintentional change to protocol or procedures (Report only those involving risk or with the potential to recur.)
- ☐ Subject complaint (Report complaints indicating unanticipated risks or those that cannot be resolved by the research staff.)
- ☐ Unapproved change made to the research to eliminate an apparent immediate hazard
- ☐ Other problem or finding (e.g., loss of study data, a subject becomes a prisoner **(upload Appendix L to IRBNet)** while participating in research) - specify:

2. Assessing the Event

Does the event or information represent an unanticipated problem involving risks to subjects or others?

◯ Yes
◯ No

Unanticipated problems involving risks 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.

Explain why or why not:

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3. Research Interventions or Interactions

a. The event involves (check all that apply):

- ☐ Drug(s)
- ☐ Device(s)
- ☐ Research-related procedure(s) or activity
- ☐ None of the above

b. Provide the names or description of any drugs, devices, or study procedures/activities involved.

4. Source of the Report

- ☐ Internal (occurring in URI research, at a site under an URI IRB's jurisdiction)
- ☐ External (occurring in research at a site other than URI, over which a non-URI IRB has jurisdiction)

If External, list the location where the research was performed and/or the event occurred.

5. Date(s) of the Event

6. Description of the Event

Describe in detail the event or problem being reported. Please include laboratory information. ***Use complete sentences. Attach additional documents as necessary. Do not include (and remove as necessary) participants' personally identifiable information.***

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7. Research Status

a. The research participant(s) involved is/are:

- ◯ Still on study
- ◯ No longer on study
- ◯ N/A or unknown

b. Research recruitment (in University of Rhode Island research at a site under an URI IRB's jurisdiction) is:

- ◯ Ongoing
- ◯ Completed (or stopped)

c. Research interventions/interactions involving other participants are:

- ◯ Ongoing
- ◯ Completed (or stopped) for all participants

8. Other Reporting

a. The adverse event or problem will also be reported to (check all that apply):

- ☐ Sponsor
- ☐ Collaborating investigators
- ☐ No other reporting or unknown
- ☐ Other - specify:

9. Actions to be Taken

a. As a result of the event (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. ***(This requires immediate reporting.)***
- ☐ The URI research is being stopped. ***(This requires immediate reporting.)***
- ☐ No action is planned. ***Provide explanation below:***
- ☐ Other - specify:

*Upload the **Amendment Form / Changes to Research** form for all proposed changes. Include new/revised document(s), e.g., protocol, consent forms, letters or other communications for participants, etc.*