Wichita State University Institutional Review Board (IRB)

EVENT REPORTING
For Unanticipated Problems Involving Risks To Subjects or Others, Adverse Events, and Other Problems

IRB Number: Date of Report:

Study Title:

Name of Principal Investigator(s):

E-Mail Address: Phone:

Department/Program Affiliation:

Type of Report

- ☐ Adverse device effect ***(Report only if unanticipated.)***
- ☐ Adverse event or injury ***(Report only if serious, unexpected, and related.)***
- ☐ Breach of confidentiality
- ☐ Data and Safety Monitoring Board (DSMB) report, interim analysis, or other oversight committee/monitoring report
- ☐ Investigator's brochure update
- ☐ 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
- ☐ Subject complaint ***(Report complaints indicating unanticipated risks.)***
- ☐ 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 while participating in research) – specify:

Research Status

a. The research participant(s) involved is/are:
   - ☐ Still in the study
   - ☐ No longer in the study
   - ☐ N/A or unknown

b. Research recruitment is:
   - ☐ Ongoing
   - ☐ Completed (or stopped)

c. Research interventions/interactions involving other participants are:
   - ☐ Ongoing
   - ☐ Completed (or stopped) for all participants

Describe in detail the event or problem being reported. Include all details such as the date(s) of event, number of events, number of participants involved, known or potential impact on participants, and any other relevant information. ***Attach additional documents as necessary. Do not include (and remove as necessary) participants' personally identifiable information.***

Actions to be taken:

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.
- ☐ The research is being stopped.
- ☐ No action is planned. ***Provide explanation below****:*

- ☐ Other – specify:

Provide the IRB Amendment form for all proposed changes.

PI Signature: Date: