IRB Adverse Event Form

Instructions: Federal regulation requires that any Adverse Events associated with participation in a research study be reported to the IRB. The U.S. Department of Health & Human Services defines an Adverse Event as follows:

> *Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).*

Section I Study Information

Study Title:

IRB Protocol #:

Name of Primary Investigator (PI):

PI Email: **PI Phone Number:**

Section II Adverse Event Description

Date of event:

Location of event:

Please describe the nature of the adverse event in detail:

How many participants have participated in this study to date?

How many more participants are needed?

Have any similar adverse events occurred in this study? ☐ **Yes** ☐ **No**

If yes, describe:

How likely was the adverse event caused by the procedures of this study?

- ☐ **Not Related**
- ☐ **Unlikely**
- ☐ **Possibly**
- ☐ **Probably**
- ☐ **Definitely**

How was the adverse event handled and the situation resolved?

Describe how you intend to protect future participants from experiencing the same harm:

As a result of the event, indicate the modifications you will make to resolve the current issue and/or prevent similar events from occurring in the future (select all that apply):

- ☐ Modification to protocol/study procedures
- ☐ Modification to level of risk
- ☐ Modification to informed consent form
- ☐ Provide additional information to participants
- ☐ Re-consent current participants
- ☐ Research will voluntarily be placed on hold
- ☐ Re-training of research staff to prevent future events
- ☐ No action is planned
- ☐ Other action planned (describe):

Additional comments:

Section III Certification

I certify that the adverse event information is accurate to the best of my knowledge.

PI name:

PI signature: **Date:**

Completed IRB Adverse Event Forms should be submitted electronically to IRB@broward.edu.