SAMFORD UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Incident / Adverse Event Form

Instructions: Complete this form when an approved human subject research project has resulted in adverse events or reactions. Submit this form to the Faculty Sponsor (if applicable). It is the responsibility of the faculty sponsor to submit the adverse event from to the IRB chair as soon as possible after the event. If there is no faculty sponsor, the principal investigator is responsible for submitting directly to the current IRB Chair as soon as possible after the event.

An adverse event is defined as any unfavorable and unintended accident, diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or, if present at baseline, appears to worsen. (NIH, OHRP)

PROJECT TITLE:

IRB protocol number: Number of Subjects Enrolled to Date:

PRINCIPAL INVESTIGATOR(S):

Phone: Samford email:

FACULTY SPONSOR (if applicable):

Department:

Phone: Samford email:

INCIDENT REPORT:

Date & Time of Incident:

Place of Incident:

Affected Subject ID#/Initials: Age: Gender:

Witness(es) to the event:

Date & Time Sponsor was notified (if applicable):

Date & Time IRB Chair was notified:

*****Attach a detailed description of the adverse event.*****

A Serious adverse event is defined as any untoward medical occurrences that: result in death, are life threatening, require (or prolong) hospitalization, cause persistent or significant disability/incapacity, result in congenital anomalies or birth defects, or are other conditions which in the judgment of the investigators represent significant hazards. (NIH, OHRP) **Is this a Serious adverse event?** ◯ Yes ◯ No

An unanticipated adverse event is defined as those adverse events not described in the Package Insert, Investigator's Brochure, in published medical literature, in the protocol, or in the informed consent document. (NIH, OHRP)
Is this an unanticipated adverse event? ◯ Yes ◯ No

An Unrelated adverse event is clearly due to extraneous causes (e.g., underlying disease, environment). **In your opinion was this adverse event related to the intervention?** ◯ Yes ◯ No

Did the participant receive medical/professional treatment related to this event? ◯ Yes ◯ No
If Yes, please describe in detail:

Does the participant require additional medical/professional treatment? ◯ Yes ◯ No
If Yes, please describe in detail:

Will the participant remain in the study? ◯ Yes ◯ No

Is the event likely to occur again? ◯ Yes ◯ No
Provide a detailed description of the course of action/safeguards that will be implemented to ensure this does not happen again (if applicable):

Has this same type of event occurred previously in this study? ◯ Yes ◯ No
If yes, please indicate the number of times:

Is the event adequately described in the protocol and consent form? ◯ Yes ◯ No
If no, does the protocol/consent form need to be modified? ◯ Yes ◯ No
Please explain your answer in detail:

_____ _____
Date Principal Investigator

_____ _____
Date Faculty Sponsor (if applicable)