INSTITUTIONAL REVIEW BOARD
UNANTICIPATED PROBLEM FORM

Project Title: Click or tap here to enter text.

Primary Investigator: Click or tap here to enter text.
Email: Click or tap here to enter text.

Faculty Advisor: Click or tap here to enter text.
Email: Click or tap here to enter text.

PART I: INFORMATION

1. Date of unanticipated problem: Click or tap here to enter text.
2. Date the research team discovered the problem: Click or tap here to enter text.
3. Did the problem occur at a local site ☐ or an outside site ☐ ?
4. Does the study include a clinical intervention or device? ☐ Yes ☐ No
   If yes, provide the name of the intervention or clinical devices(s): Click or tap here to enter text.
5. Date and description of latest study-related intervention or interaction (relevant to this event): Click or tap here to enter text.
6. Did the problem result in the harm, complaint, or death of the participant? ☐ Yes ☐ No

PART II: DESCRIPTION OF UNANTICIPATED PROBLEM (Adverse event, Incident, Experience or Outcome)

- List key words describing the problem (e.g., a breach of confidentiality): Click or tap here to enter text.

- Briefly describe the problem (identify/describe the medical nature of the unanticipated problem, including background, relevant history, major medical or physical problem, types of medication or treatments and dates. If it is a social/behavioral study, include information such as nature of the unanticipated problem, description of the situation that led to the problem, individuals present, referral for medical/ psychological care, etc.): Click or tap here to enter text.

PART III: <u>DETERMINATION OF UNANTICIPATED PROBLEM</u>

☐ Yes ☐ No The problem is **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied. **If yes, explain the basis for determining that the problem is unexpected:** Click or tap here to enter text.

☐ Yes ☐ No The problem is **related or possibly related** to participation in the research *(possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research). **If yes, explain the basis for determining that the problem is related or possibly related:** Click or tap here to enter text.

☐ Yes ☐ No The problem **places participants or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously recognized**. If yes, explain the basis for determining that the Problem placed participant or others at a greater risk of harm:** Click or tap here to enter text.

PART IV: <u>CORRECTIVE ACTIONS</u>

☐ Yes ☐ No **Should the protocol be revised?** If yes, provide a description of the proposed protocol changes: (Attach a protocol modification form with a revised protocol for any proposed change to the protocol.): Click or tap here to enter text.

☐ Yes ☐ No **Should the research be suspended?** If yes, describe the procedures you will follow for the suspension or termination of the research: Click or tap here to enter text.

☐ Yes ☐ No **Should enrolled participants be notified about the problem/event?** If yes, attach a protocol modification form with a revised consent form or draft letter of notification with this report: Click or tap here to enter text.

☐ Yes ☐ No **Should other corrective action be taken in response to the unanticipated problem?** If yes, provide a description of the proposed corrective action: Click or tap here to enter text.