



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 device(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 participants? Yes No

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

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

Yes No The problem is unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol and related documents, such as the 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.](#)