## **Unanticipated Risk/Adverse Event**

This form is appropriate for use when research-related events may have negatively influenced the safety, well-being, or protection of human participants. It is the responsibility of the PI to communicate these events to the IRB as soon as possible. This form is not designed to document changes to the protocol, though unanticipated risks/adverse events may warrant a change in protocol (see the Amendment to Research Protocol form) or to request renewal (see the Continuing Research Renewal Request). Email this form to irb@calbaptist.edu with all necessary documentation.

**IRB Application Number (located on your approval letter):** Click here to enter text.

**Date of Original IRB Approval (located on your approval letter):** Click here to enter text.

**Principal Investigator (PI) Information**

**PI Name:** Click here to enter text.

**PI Preferred Salutation:** Choose an item.

**PI college/school at CBU:** Click here to choose a School

**PI Position (Asst. Prof, Undergraduate student, etc.):** Click here to enter text.

**PI email:** Click here to enter text.

**PI phone:** Click here to enter text.

**PI Date of most recent CITI HSR Certification**: Click here to enter a date.

**Date of Submission of Risk/Event Form:** Click here to enter a date.

**Original Research Project Title:** Click here to enter text.

**Co-PI Information** (delete this section if there is no Co-PI; copy if additional PIs need to be listed).

**Co-PI Name:** Click here to enter text.

**Co-PI Preferred Salutation:** Choose an item.

**Co-PI college/school at CBU:** Click here to choose a school

**Co-PI Position (Asst. Prof, Undergraduate student, etc.):** Click here to enter text.

**Co-PI email:** Click here to enter text.

**Co-PI phone:** Click here to enter text.

**Co-PI Date of most recent CITI HSR Certification:** Click here to enter a date.

**Faculty Advisor Information** (delete this section if there is no faculty advisor; *all student research requires a faculty advisor*.)

**Faculty Advisor Name:** Click here to enter text.

**Faculty Advisor Preferred Salutation:** Choose an item.

**Faculty Advisor college/school at CBU:** Click here to choose a school

**Faculty Advisor Position:** Click here to enter text.

**Faculty Advisor email:** Click here to enter text.

**Faculty Advisor phone:** Click here to enter text.

**Faculty Advisor Date of most recent CITI HSR Certification:** Click here to enter a date.

**Research Assistant (RA) Information** (delete this section if there are no RAs on this project; copy as needed if additional RAs need to be listed.)

*Note:* A research assistant includes any person who will assist in recruitment of human participants, data collection, data entry/cleaning, data analysis, etc. Engaging in a literature review or write up of results (already analyzed) does not constitute IRB-regulated research assistant activities.

**RA Name:** Click here to enter text.

**RA email:** Click here to enter text.

**RA Date of most recent CITI HSR Certification:** Click here to enter a date.

**Please describe fully and completely the unanticipated risk or adverse event. Be as specific as possible.** Click here to enter text.

**Describe the course of action taken, to date.** Click here to enter text. Click here to enter a date.

**Describe proposed course of action, to follow.** Click here to enter text.

**How many human participants have participated thus far, and of these, how many may have experienced a similar risk/event?** Click here to enter text.

**Signatures** (typed signatures are sufficient; severe penalties are enforced when false signatures are typed by someone other than the named individual. Delete any unnecessary fields; duplicate any signature fields as required.)

*As the PI, I/we certify this application and the attachments are an accurate and complete description of the events reported and we agree to protect the rights and welfare of all human participants involved in the research.*

**PI Signature and Date:** Click here to enter text.Click here to enter a date.

**Co-PI Signature and Date:** Click here to enter text.Click here to enter a date.

*As the faculty advisor, I understand the event that has occurred and will respond as outlined in this submission.*

**Faculty Advisor and Date:** Click here to enter text. Click here to enter a date.