

## What to Submit

**Unanticipated Problem.** An event, accident, experience, or outcome that meets all 3 of the following criteria of an Unanticipated Problem:

- A. Unexpected in terms of the nature, severity, or frequency; and
- B. Related, or possibly related to the subject's participation in the research; and
- C. Places participant or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized

New information that indicates there is increased risk and unanticipated device effects may be unanticipated problems and should be submitted for IRB review.

**Important Protocol Deviation.** An event may be considered an important protocol deviation if it may significantly affect the completeness, accuracy, and/or reliability of the study data or may significantly affect a participant's rights, safety, or well-being. Important protocol deviations may include, but are not limited to:

- Failure to conduct study procedures designed to assess participant safety or failure to adequately monitor participants; for example, failure to collect important laboratory assessments for monitoring safety issues or failure to administer the study product according to specifications in the protocol
- Administration of concomitant treatment prohibited by the study protocol that may increase risks to participants (e.g., drug-drug interactions) and/or impact interpretation of a device's safety and efficacy
- Failure to obtain informed consent or meet other applicable requirements under FDA regulations for the protection of human subjects under 21 CFR part 50
- Failure to protect a participant's identifiable private protected health information, including data security breaches that were unexpected and placed participants or others at greater risk of harm
- Failure to withdraw investigational product administration from participants who meet withdrawal criteria
- Administration of the wrong treatment or incorrect dose to participants or implantation of an incorrect device
- Failure to adhere to the protocol-specified randomization scheme
- Enrollment of a participant in violation of key eligibility criteria designed to ensure a specific participant population
- Failure to collect data to evaluate important study endpoints (e.g., primary or secondary endpoints)
- Premature unblinding of a participant's treatment allocation for reasons other than those specified in the study protocol

*Reference "Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices Guidance for Industry", FDA Draft Guidance (December 2024), for more information on Important Protocol Deviations.*



**Continuing Noncompliance.** An event may be considered continuing noncompliance if it represents a pattern of repeated noncompliance.

**Suspension or premature termination by the sponsor, investigator, or institution.**

**State medical board or federal agency action** (e.g., Form FDA 483 related to active study under Sabai IRB review, FDA Warning Letter, medical license action).

**Incarceration of an active study participant or a participant has become a ward of the state.**

**Protocol Exception Request.** This is an intentional change/alteration to the protocol for one participant, including enrollment exceptions (**Submit for IRB review and approval prior to implementation**).

## When to Submit

**Reports are due within (10) calendar days** once known to the research team, even if only preliminary information is available. **Exceptions to this timing include Protocol Exception Requests** (intentional change/alteration to the protocol for one participant, including enrollment exceptions) **which need to be submitted for approval prior to implementation.**

## How to Submit

Login at: <https://review.sabaiglobal.com>

1. Select the specific protocol number on your Home page, under the heading My Protocols
2. This will re-direct you to the specific Protocol page
3. Under 'Actions' on left side, click on Start xForm
4. This will re-direct you to all the protocol driven forms, select Reportable Events Form
5. Complete the form and attach documentation and Submit.

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