Castle IRB - Reportable Events Guide

WHAT TO SUBMIT

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

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

An **Unanticipated Adverse Device Effect** if that effect, problem or death was not previously identified in nature, severity, or degree of incidence in the protocol, or any unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

- An Unanticipated Adverse Device Effect is any serious adverse effect on health, safety or any life-threatening problem or death caused by or associated with a device.

New information that indicates there are **new or increased risks** to participants or others, or decreased benefits of the research.

- For studies subject to ICH-GCP Guidelines this includes new information or changes that significantly impact or adversely affect the conduct of the clinical trial.

Castle IRB – Reportable Events Guide

WHAT TO SUBMIT

- **Data security breach** that was unexpected and places participants or others at greater risk of harm
- Change made to **remove apparent, immediate hazards** to participants **without prior approval of the IRB**
- Protocol deviation or noncompliance event that may reasonably be regarded as having **increased the risk of harm to the participants, adversely affected the safety, rights, or welfare of research participants, or adversely affected the integrity of the data and research**
- **Allegation (unproven assertion) of noncompliance**
- **Participant complaint** that **could not be addressed** by the research team or indicates an increase in risk
- **Protocol exception request** - Intentional change/alteration to the protocol for one participant, including enrollment exceptions
- **Incarceration** of an active study participant or a participant has become a ward of the state
- **Audit, inspection, or inquiry by a federal agency**
- **Suspension or premature termination** by the sponsor, investigator, or institution
- **State medical board or federal agency action** (e.g., Form FDA 483, FDA Warning Letter, medical license action)
- **Other information the sponsor/CRO/site/IRB has mandated** the research team to report to the IRB

Castle IRB - Reportable Events Guide

When to Submit

Reports are due within ten (10) calendar days once known to the research team, even if only preliminary information is available. **Exceptions to this timing include:**

- Protocol exception request - Intentional change/alteration to the protocol for one participant, including enrollment exceptions (Submit for approval prior to implementation)
- Audit, inspection, or inquiry by a federal agency (Submit when known so Castle IRB can best support documentation needs)

When to Submit

Login at: https://castleirb.my.irbmanager.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**

Contact us

WWW.SABAIGLOBAL.COM
888-442-2472
irbteam@castleirb.com