Reportable Events Guide

WHAT TO SUBMIT

An **Adverse Event** that meets the definition of an unanticipated problem involving risk to participants or others. An **Unanticipated Problem** is defined as:

- The reportable event was unexpected in terms of the nature, severity, or frequency; and
- The reportable event is related, or possibly related to the subject's participation in the research; and
- The reportable event suggests the research places the 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.

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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 that placed one or more **participants at increased harm**

Allegation or finding 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

Death of a research participant that is related or possibly related to the research

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 has mandated the research team to report to the IRB

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WHEN TO SUBMIT

Reports are due within seven (7) 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)
- Death of a research participant that is related or possibly related to the research (Submit as soon as possible, no later than 7 days)
- Audit, inspection, or inquiry by a federal agency (Submit when known so Castle IRB can best support documentation needs)

HOW 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**

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