Reportable Events

A reportable event is an adverse event or incident that has the potential to be classified by the IRB as an unanticipated problem posing risks to participants or others. An incident is determined to be reportable to the IRB when it is both probably or definitely **related** to participation in the research, AND **unexpected** in terms of nature, severity, or frequency. **This Includes serious and non-serious events.**

To request IRB review of a Reportable Event please provide the following to your study point of contact:

- **Reportable Event Form** (see https://irb.upenn.edu/reportable-event)
- Supporting documentation from sponsors, medical monitor, local research review committees, etc...

The table below clarifies reporting requirements:

Relation to the research	Expectedness	Reportable to IRB?	When to Report
Unrelated or Unlikely related	Expected and Unexpected	NO	Record only. Do not report
Possibly, Probably, or Definitely related	Expected	NO	Record only. Do not report.
Possibly related AND event suggests research presents greater risk than previously known	Unexpected	YES*	WITHIN 10 bus. days
Probably or Definitely related	Unexpected	YES*	WITHIN 10 bus. days
Probably or Definitely related **death**	Unexpected	YES*	WITHIN 3 calendar days

*Any events that are reported to the IRB individually will also be summarized at continuing review by the lead site submitting through HSERA.

Reliance Agreement Guidance:
Quick Reference for Relying Sites

Penn
University of Pennsylvania
Institutional Review Board
Phone 215-573-2540
www.irb.upenn.edu

This quick reference guide is an abridged version of the "Post Approval Submission Guidance" posted on the Penn IRB website. This guidance is meant to assist sites outside of Penn who have a fully executed reliance agreement in place for Penn to serve as their IRB of record.

Multi-Site Research and Ongoing Engagement:

The Penn IRB requires multi-site management plans for all research where Penn is asked to serve as the IRB of record. This guidance should be used in context of the approved management plan for the specific study. Submissions to the Penn IRB must be received through the HSERA system by a Penn affiliate or non-affiliate granted special access generally referred to in our guidance as the point of contact.

Collaboration Tips

The following info should be readily available to all sites to support communication among relying sites, lead sites, local IRBs and the IRB of record (Penn):

Penn IRB Assigned Protocol Number:

Study Title:

Lead Site Name:

Point of Contact Name

Email

Phone

Continuing Review (CR)

If the research requires continuing review, all relying sites should provide their study point of contact with a completed copy of the **Continuing Review Relying Site Supplement form**

(see https://irb.upenn.edu/forms)

CR Submission requirements are based on the IRB established risk level of the research.

- **Greater Than Minimal Risk** research requires responses to **all sections of the form**.
    - Additional documentation for site deviations may also be required based on the study design and management plan.
- **Minimal Risk research** is only required to provide responses to sections I-IV and VII.
- The Point of Contact submitting to the IRB through HSERA will also need to provide clean copies of your site's consent forms (when applicable).

Amendments (Site Specific)

If your site needs to make a change during the course of the study that does not affect other sites , please provide the following to your point of contact for submission through HSERA:

- **Modification Form (required)**
- **Updated Participating Site Addition Form (if applicable)**

(see https://irb.upenn.edu/forms)

- Summary of Changes describing each change and providing rationale for each change (may be inserted into form or separate document)
- Tracked changes (marked) version of each document being updated
- Changes accepted (clean) version of each document being updated

Exception (Site Specific)

IRB approval is required prior to implementing any exception request (also referred to as a planned deviation). Exception requests are a prospective, intentional, one time departure from the approved protocol parameters.

To request IRB approval of an exception request please provide the following to your study point of contact:

- **Exception request form**

(see https://irb.upenn.edu/Exception)

Approval of a site specific exception request may also require:

- foreign language short form consent form
- Documented approval from the study sponsor, medical monitor and other oversight entities as applicable

Deviation (Site Specific)

A major deviation is a deviation from the IRB approved protocol, human research regulations, or human research university policies that adversely affects:

-The rights and welfare of participants, including actual or potential substantive harm

OR

-The scientific integrity of the study

These deviations must be reported to the IRB within 10 business days of discover as they require an assessment of noncompliance by the IRB.

To request IRB review of a Major deviation please provide the following to your study point of contact:

- **Deviation Form**

(see https://irb.upenn.edu/Deviation)