

Continuing Review Form Monitoring Guidance for Greater than Minimal Risk Research

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Safety Monitoring and Adverse Event Reporting

Safety Monitoring

It is the expectation of the IRB that all Greater Than Minimal Risk research protocols will include a plan for safety monitoring and submission of unanticipated problems posing risk to subjects or others. The IRB does not require a summary of the safety monitoring plan in your progress report. Please answer the questions in the continuing review form and provide clarifying information in your progress report as directed. It is also the IRB's expectation that the study team will be aware of who is conducting safety monitoring for each study in order to answer these questions appropriately. Please refer to your protocol as you answer the questions in the form.

Reporting of Adverse Events

All study teams should record and assess all internal adverse events in their research records when they occur. The assessment should include seriousness, expectedness, and relatedness. Per IRB SOP RI 801, an investigator is responsible for the accurate documentation, investigation and follow up of all adverse events that are possibly study related. Please see the table below for IRB reporting criteria of adverse events. Definitions of Expectedness and Relatedness are fully explained in the [How to Submit: Reportable Events page](#).

Relatedness	Expectedness	Reportable to IRB?	When to Report
Unrelated or Unlikely related	Expected and Unexpected	NO	N/A
Possibly, Probably, or Definitely related	Expected	NO	N/A
Possibly related	Unexpected	YES* ONLY IF: The event suggests that the research places subjects at greater risk than was previously known or recognized (i.e., changes to the study conduct are required to mitigate risk and/or participants' willingness to participate may be adversely impacted)	EXPEDITED REPORTING WITHIN 10 bus. days Summarize at continuing review
Probably or Definitely related	Unexpected	YES*	EXPEDITED REPORTING WITHIN 10 bus. days Summarize at continuing review
Probably or Definitely related death	Unexpected	YES*	EXPEDITED REPORTING WITHIN 3 calendar days Summarize at continuing review

*Includes serious and non-serious events.

Please answer the questions in the Continuing Review form and provide clarifying information on **adverse events that meet reporting criteria** as directed. Additionally, please provide a summary of applicable events as described in the table above within your progress report. The summary of these events is required so that the convened board may review **aggregated** information to confirm that:

- Risks to subjects remain minimized;
- Risks remain outweighed by, or appropriately balanced by, potential benefits; and
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

There is no required structure for the adverse event summary. It will vary depending on the complexity of the study. Please ensure your summary mentions relatedness and seriousness / grading of the events. Please provide any new information related to these events, if available. Summarize the impact of these unexpected events on the risk - benefit ratio of the study. Summarize any actions taken in response.

Study Monitoring, Quality Control, & Deviation Reporting

It is the expectation of the IRB that all Greater Than Minimal Risk research protocols will include a plan for site monitoring, quality control and deviation reporting for noncompliance assessments. Some clinical trials require an independent study monitor to review the quality of the study activities. The study monitor conducts *quality control* by inspecting study records. Some clinical trials may also be audited by one or more entities for quality assurance. See the [Penn Manual](#) for more detail about study monitoring.

The study team should know who is conducting study monitoring in order to answer the questions correctly in the continuing review form. Please refer to your protocol to assist you in answering the following questions within the Risks and Benefits panel within eIRB during your initial submission:

Please indicate your protocol's quality control monitoring plan:

- The Regulatory Sponsor's designated study monitor is conducting quality control activities by reviewing the study records
- There is no Sponsor appointed monitor, the PI and study team is conducting all quality control activities

Does the protocol identify a group, entity, or individual that will periodically assess safety data [e.g., independent Data Safety Monitoring Board (DSMB) or Data Safety Monitoring Committee (DSMC), or other safety monitoring entity, independent medical monitor, etc.]?

Yes

No

These questions impact visibility within the continuing review form.

Reporting of Deviations

All study teams should record, assess, and develop corrective actions for all deviations that occur during the conduct of the research study. Deviations should be assessed in the context of the protocol, and it should be determined whether expedited IRB reporting is required. Events that require expedited IRB reporting are those that **may have an adverse impact on:**

- subjects' rights, OR
- subjects' welfare / safety (including any **potential or actual *substantive*** harm), OR
- the scientific integrity of the study

More information about deviations is available on the [How to Submit: Deviations](#) page

If there is no sponsor appointed monitor conducting quality control monitoring, at the time of continuing review the study team should review deviation logs to ensure all recorded deviations have been assessed appropriately and reported in an expedited fashion when necessary.

Please provide a summary of deviations within your progress report **as directed in the continuing review form.**

If the study has a regulatory sponsor that is responsible for the oversight and conduct of the protocol and the **sponsor has appointed an individual to conduct quality control monitoring**, summarize **reportable deviations** from the last year.

If the study is investigator-initiated (i.e., the protocol was designed and/or authored by the principal investigator, a sub-investigator, or a faculty member at Penn or another academic institution) and does not have a sponsor appointed monitor to conduct quality control, summarize or provide a report of **all deviations** from the last year.

The summary of these events is required so that the convened board may review **aggregated** information to confirm that:

- There are adequate resources to conduct the study;
- Risks to subjects remain minimized; and
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

There is no required structure to deviation summaries. It will vary depending on the complexity of the study and the number of deviations. Note that the summary requirements are different depending on whether Pathway A or B is required within the continuing review form. Please follow the requirements as directed in the form. Regardless of structure or format the summary must include:

1. when each deviation occurred;
2. a description of the deviation;
3. if and when the deviations were previously reported to the IRB;
4. assessments of each deviation to determine whether it adversely affected: subjects' rights, OR subjects' welfare /safety (including any potential or actual substantive harm), OR the scientific integrity of study; and
5. any corrective actions put in place in response to each deviation.