



Monday Morning Practice Pearls #50

What are the new expedited IRB reporting requirements for “events” that happen during research?

Effective July 1, 2019, the NIH has new requirements for what needs to be reported to the IRB and when per [Policy 801 Reporting Research Events](#):

- The following must be reported to the NIH IRB within seven (7) calendar days of a research team member becoming aware of event:
 - Unanticipated Problems (actual or suspected)
 - Non-compliance (actual or suspected) not related to a protocol deviation
 - Major protocol deviations (actual or suspected)
 - New information that might affect a participant’s willingness to enroll or remain in the study
 - Suspension or termination of research activities
- Deaths that are possibility, probably or definitely related to the research must be reported within 24 hours of research team member awareness
- The above events are reported via iRIS – see below
- See M2P2 #51 for what events need to be reported at time of continuing review

IMPORTANT: For multi-site studies when NIH IRB is NOT the IRB of record, but the event occurred with a participant enrolled at an NIH site, the above expedited reporting requirements still apply. The event must be reported in iRIS for OHSRP review.

NOTE: Expedited event reporting to the sponsor is unchanged. Refer to protocol for details.

And is the Problem Form going away??

No – the form has been re-named “Reportable Event Form” (REF); some questions have been removed and new questions have been added including:

- Questions about IRB of Record/Reviewing IRB
- Name of event – there are now 5 options only, including “Other”
- Form will now “branch” to different questions depending on type of event being reported
- Will need to include enrollment numbers, including number of participants still receiving study intervention and number of participants in follow-up
- Form no longer includes a question about the seriousness of the event

My study has external IRB review – what do I do?

- Follow the reporting requirements of the external IRB
- If the event happened with a participant enrolled at an NIH site, a REF still needs to be submitted in iRIS for OHSRP review
- If the external IRB makes a determination of serious and/or continuing noncompliance, this must be reported within seven (7) calendar days of notification via iRIS for OHSRP review

Definitions:

- Unanticipated Problem:
 - Any incident, experience or outcome that is unexpected, related or possibly related to participation in research and suggests that the research places participants or others at a greater risk of harm than was previously known.
 - Definition is largely unchanged from previous SOP - see Policy 801 for complete description.
- Non-compliance:
 - Failure of investigator(s) to follow the applicable laws, regulations, or institutional policies governing the protection of human subjects in research, or the requirements or determinations of the IRB, whether intentional or not.
 - Serious non-compliance: non-compliance, whether intentional or not, that results in harm or otherwise materially compromises the rights, welfare and/or safety of the subject and/or materially effects the scientific integrity or validity of the research
 - Continuing non-compliance: pattern of recurring non-compliance that either has resulted, or, if continued, may result in harm to subjects or otherwise materially compromise the rights, welfare and/or safety of subjects, affect the scientific integrity of the study or validity of the results
- Major Deviation (subset of non-compliance):
 - Deviations from the IRB approved protocol that have, or may have the *potential* to, negatively impact the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study