



Monday Morning Practice Pearls #51

What research “events” need to be reported at the time of continuing review?

Effective October 12, 2020, the NIH has revised what research events need to be reported at the time of continuing review (CR) per [Policy 205 Requirements for IRB Submissions](#):

- Section E.1.c. Required materials for Continuing Review (CR) of non-exempt human subjects research:
 - V. A high-level summary (not a line item listing) of the following events that have occurred since the time of the last IRB review:
 - i. Major and minor protocol deviations;
 - Include whether the deviations combined have the *potential* to negatively impact the rights, safety or welfare of participants or others, or the scientific integrity or validity of the study
 - ii. Noncompliance reported to the IRB that is not related to a protocol deviation;
 - iii. Adverse Events and Serious Adverse Events that do not meet the definition of an Unanticipated problem (UP);
 - Include whether AEs and SAEs were as expected
 - iv. Unanticipated Problems (UPs) reported to the IRB; AND
 - v. Unresolved subject complaints

IMPORTANT: If the study did not have any major deviations, noncompliance, UPs or unresolved subject complaints during the reporting period, the CR summary **MUST** specifically indicate this.

- See M2P2 #50 for what events need to be reported in an expedited fashion to the IRB and OHSRP

How do I keep track of deviations that need to be reported at time of CR?

A CCR Deviation Tracking Tool has been developed to help teams keep track of and organize major and minor protocol deviations for reporting at CR – email [NCI CCR QA](#) for the current tool.

- All protocols must have a process to track protocol deviations, either the CCR tool or one supplied by the sponsor.
 - CCR-sponsored protocols that are monitored by the Office of Sponsor and Regulatory Oversight (OSRO) will be sent a nonadherence log that also contains information about protocol deviations.
- The CCR Deviation Tracking Tool (or the tool supplied by the sponsor) must be sent on a monthly basis to the CCR Office of the Clinical Director via the [NCI CCR QA](#) mailbox.

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

- Follow the continuing review reporting requirements of the external IRB
- See M2P2 #50 for what events need to be reported to OHSRP even if the protocol is reviewed by an external IRB

Definition:

- Minor Deviation:
 - Deviations from the IRB approved protocol that do not have the *potential* to negatively impact the rights, safety or welfare of participants or others, or the scientific integrity or validity of the study

NOTE: A series of minor deviations pointing toward a more global issue that could affect the rights, safety or welfare of the participant or affect the validity of the study should be reported as a major deviation.

REMEMBER: Both major and minor deviations need to be reported in summary at time of CR.