Monday Morning Practice Pearls #80

What is a Single Patient Planned Modification (deviation)?

Definition

Single Patient Planned Modification refers to any planned change, divergence, or departure from the IRB-approved research protocol for a single patient in a research study. These deviations can occur due to various reasons, such as unexpected events, modifications in treatment plans, or unforeseen circumstances. To proceed with implementing a single patient planned modification, you need to have IRB approval. If the protocol is an IND/IDE, sponsor approval is required first and submitted with the Single Patient Planned Modification to the NIH IRB.

IMPORTANT: The Single Patient Planned Modification is an NIH IRB-specific action and can only be used for protocols when the NIH IRB is the IRB of record.

When to Request

You are planning to deviate from the protocol and there is no pending protocol modification in progress that would address this change.

How to Request

1. PI or designee first verifies with study's PSO Manager if there is an ongoing protocol modification that will address the requested change.
2. For IND/IDE sponsored protocols, the PI or designee contacts the sponsor to seek approval. This can be done via email, a sponsor form, or by completing and sending the sponsor a completed NIH IRBO Single Patient Medication Request form (see #4). If the sponsor doesn't approve the deviation, then the process stops here.

   Note: For CCR-held IND/IDE protocols, please use the OSRO *Clinical Protocol Planned Deviation Request* form.

   Note: CTEP as a Sponsor does not allow Single Patient Planned Modifications. Click here for their policy.
3. For non-IND/IDE sponsored protocols, proceed to #4.
4. PI or designee completes the NIH IRBO *Single Patient Modification Request* form from the PROTECT Library (under IRB tab > "Templates") and sends to study's PSO Manager along with the sponsor's approval, if applicable.

   Note: If this is an urgent request or an approval is needed by a certain date, please let the PSO Manager know so they can notify the IRB. If the modification being requested is significant, the IRB may need to take the request to a full board meeting – i.e., not all Single Patient Planned Modifications can be approved in an expedited manner. If expedited review is not possible, it may be worthwhile to submit a full protocol amendment to the IRB. Please work with the PSO on the best strategy.
5. The PSO Manager will prepare the MOD for the PI to submit to the IRB for approval.
6. Once approved by the IRB, the deviation doesn't need to be entered into the Protocol Deviation Tracking System.