



## Monday Morning Practice Pearls #80

### Single Patient Planned Modification (deviation): when and how do I request it from the NIH IRBO?

#### 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. Presently only NIH IRB has this specific request mechanism.

#### 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. Verify with study's PSO Manager if there is an ongoing protocol modification that will address the requested change.
2. Notify protocol Sponsor and get approval. The NIH IRBO Single Patient Modification Request form (see #3) can be completed and sent to the sponsor for approval. If the study does not have a sponsor listed on the first page of the protocol, this is not applicable.  
**Note:** CTEP as a Sponsor does not allow Single Patient Planned Modifications.
3. Once Sponsor has approved, if applicable, complete the NIH IRBO Single Patient Modification Request form from the PROTECT Library (under IRB tab > "Templates") and send to study's PSO Manager along with the Sponsor's Approval.  
**Note:** If this is an urgent request or an approval is needed by a certain date, please let the PSO Manager know so s/he 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 instead submit a full protocol amendment to the IRB. Please work with the PSO on the best strategy.
4. The PSO Manager will prepare the MOD for the PI to submit to the IRB for approval.  
**Note:** Once approved by the sponsor and IRB, a Single Patient Planned Modification is NOT a deviation – please do not submit in the Protocol Deviation Tracking System as a protocol deviation.