How to Draft a Modification Summary of Changes

All modification submissions require a summary of changes document that outlines all changes and provides rationale for each revision. Please review the guidance below for developing an appropriate summary

Separate out logistical/administrative revisions from substantial ones:

- The rationale for this is that logistical/administrative revisions do not require rationale or detailed explanation and substantial revisions do
- Logistical/administrative revisions can be summarized and simply noted to be tracked in the updated protocol/consent form/HS-ERA application/etc.

Provide revision listings per document:

- Provide an overall list of all documents being revised with the modification
- If there are new documents being added along with revisions to approved documents, please differentiate in the cover letter or summary document to avoid confusion
  *For new documents, provide an explanation for why they are being added to the study with the modification
- For each document being revised, provide the list of revisions and corresponding rationale/justification for substantial revisions
  *Before submitting the modification to the IRB, review your list of revisions against your tracked copies/other updates to be sure that the submission is complete

Explain the "why" behind the revisions:

- The Principal Investigator (PI) and Study Team are the most familiar with the protocol and the corresponding revisions; IRB Administrative Staff will not be able to provide justification or explanation for your proposed revisions to the convened board or reviewer, this MUST BE provided by the PI and Study Team
- Things to think about when writing the summary of revisions: 1) why is the change being made at this time?, 2) what are the implications of the change?, 3) will current participants be affected by the change?, and 4) do the revisions propose any changes that might overall affect the risk/benefit ratio as currently assessed for the study?
- If the revisions are being proposed to qualify for expedited review (not requiring review by the convened board), provide sufficient rationale as to why the revisions (especially if substantial/comprehensive) do not warrant convened review (i.e. the revisions don't impact the Penn participants, revisions align with previous determinations made by the convened board, etc.)

DO NOT RELY on Sponsor summaries:

- The summary of revisions from the Sponsor is often a good tracking mechanism or table of contents for the revisions, but is often lacking specific rationale and explanation of the impact of the revisions (this will be requested from the PI/Study Team to process the modification if not provided)

Consider needs for re-consent:

- If there are any subjects on study when the modification is submitted, and there are revisions to the consent form or other substantial revisions, a plan for whether the revised/updated information will be shared with the current subjects must be provided and justified (the modification form provides a good framework for thinking through those who are active versus in follow-up)

Logistical considerations:

- If the study is greater than minimal risk, a documents list will be required for the IRB correspondence letter
- Please provide both tracked and clean copies of all documents (note: if a tracked document is not available from the Sponsor, further summary/explanation of revisions may be required in order to process the modification)
- Consider source of revisions from the IRB perspective; if you are adding information to the protocol and/or consent form and don't have documentation to support where the new information is coming from, please explain the source/rationale for the revisions in order to assist the IRB in the review/approval process