IRB Tip Sheet: Practical Review of Modifications

All changes to currently approved research must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the human subjects. 45 CFR 46.108(a)(3)(iii)

- **Substantive changes to studies previously determined to require Full Board review will require review by the fully convened IRB.**
- **Minor changes to studies previously determined to require Full Board review are required to be reviewed by at least one member of the IRB and may not require consideration by the fully convened IRB.**

Completing your review before the IRB Meeting:

1. *Review the Modification PROTECT Smart Form*
   - **What is the purpose of this submission:**
     - This section indicates the type of submission (only one of the following options will be selected):
       - **Modification / Update:** The submission only contains a Modification (MOD).
       - **Modification and Continuing Review:** The submission contains a MOD and a continuing review (CR).
       - **Continuing Review:** The submission does not contain a MOD (See the CR Tip Sheet).
   - **Modification scope:**
     - The type of MOD in the submission: Other parts of the study and/or study team member information.
   - **Active Continuing Review or Modification for this Study:**
     - This section will list any other MODs or CRs that are also in the process of IRB approval.
   - **Is Scientific Review required for this Modification:**
     - This section will indicate if Scientific Review was required before the submission was submitted to the IRB.
     - If required, approval by the Scientific Review Committee will have been granted beforehand.
   - **Does this action require review by your IC DEC office:**
     - DEC approval is required when adding AIs to the protocol or if a protocol is newly considered covered.
     - If DEC is not approved before the IRB meeting, the submission can only be approved with stipulations until DEC review is complete.
   - **Study enrollment status:**
     - This section lets you knows the status of subjects in the study.
     - This information is needed particularly to determine if the proposed plan for notification of subjects of any changes is appropriate. If required, a more detailed breakdown of subjects can be requested from the PI.
   - **Notification of subjects:**
     - The study team will check a box if they plan to inform current or former subjects. If no box is checked, then they are proposing that no subjects need to be informed of the changes from the MOD.
     - When applicable, the research team should have provided the details of their proposal as a part of the MOD. If the plan is unclear or there are any concerns, the PI should be notified before the IRB meeting to allow them enough time to respond.
     - *Those subjects who are presently enrolled and actively participating in the study should be informed of any change if it might relate to the subjects' willingness to continue their participation in the study (21 CFR 50.25(b)(5)). Subjects that have completed their active participation in the study, or subjects who are still actively participating but the changes will not affect their participation, do not need to be informed.*
   - **Summarize the Modifications and provide rationale for each change:**
     - The PI should have provided a summary of the proposed changes along with a justification.
     - If the justifications are not adequate or the information is unclear, the research team should be contacted **before the meeting** to allow them to provide further explanation or an alternate solution that would allow the submission to be approved at the IRB meeting. This helps to prevent delays for the study team and saves time for the IRB since a deferred submission will have to return to the Full Board IRB.
     - If the changes are extensive, the summary of changes are more likely to be included as an attachment to the submission in the section titled *Local Site Documents* that also contains certain study documents.

- **Basic Study Information:**
  - This section includes the study information and documents previously approved by the IRB along with any changes (Study summary, protocol, consents, recruitment material, questionaries, appendices, etc.)
  - Components that were previously approved by the IRB should not be changed unless the change is needed for the protocol to meet the criteria for IRB approval of research.
- **Comparing documents that have been updated:**
  - Click on the "Documents" tab to review the documents that have been updated in the MOD.
  - The modified version of the document will be listed under "Draft." Note the date of the document under the "Final" column to the right of the draft; This is the current previously approved version. Click on the "History" link to the right under "Document History." A list of all versions of the document will pop up in a new window. Select the most recent version of the draft document (at the top) and the currently approved final version. Click compare and a tracked change version of the document will be generated.

2. *Review the History Tab of the Modification*
   - Pre-Review analyst note in the History tab.
   - Pre-Review Clarification Responses and Added Comments from the Study Team.
   - "Review Comments" entered by the other IRB member(s).
   - "Private Comments" entered by the IRB staff or members.

3. *Enter your reviewer's note into the system using the "Add Review Comments" activity*
   - If you are an assigned reviewer, please enter a note even if it only states that you have no concerns.
   - Any IRB members that are not the assigned reviewer for a submission should also enter a review comment if they have a concern. If not, they are welcome to add a note stating they have no concerns but are not required to do so.
   - Any proposed edits to the consent can be attached to your review. The changes should be made to the document using the "tracked changes" function.
   - Check in the "Reviews" tab to see if other members have already tracked changes to the consent. If yes, use their version to make your additional changes.
   - Providing your edits in a timely manner allows the IRB Chair and IRB analyst time to review and compile any concerns. This also allows them time to contact the PI if additional information is needed.
   - The goal is to approve the submission at the meeting whenever possible.

Presenting a Modification during the IRB Meeting:

1. *Presentation of the MOD by the Primary Reviewer*
   - The introductory explanation of the protocol can be a few summary sentences.
   - Presentation and discussion of a MOD should focus on the changes proposed by the study team.
   - The discussion will first focus on any changes in the protocol itself and any new determinations that must be made. This includes any changes involving special populations, waivers, and devices. Once that is complete, the discussion will move on to the consent or any other relevant research documents.
   - Remember that the other members were also required to review all the material relevant for the MOD.

2. *IRB Determination and voting*
   - Focus on if the study meets the criteria for IRB approval of research when discussing the determination.
   - If the study does not meet the criteria, see if the IRB can provide the team with specific prescriptive changes that allow the study to be approved with stipulations. The stipulations should be specific enough that they can be reviewed by the IRB analyst for completion. If the IRB cannot provide specific requirements, then the submission must be deferred and will have to come back to the Full Board IRB for future consideration.
   - **Remember:** If the PROTECT submission is both a CR and a MOD, you cannot give separate determinations for each item.