REQUIRING MODIFICATIONS OR VOTE TO DEFER

When the IRB requires modifications to research to secure approval, verification of those modifications by an IRB chair or experienced IRB reviewer without review by the convened IRB represents review by the expedited procedure, and should comply with regulations and guidance governing such review. This process is sometimes referred to as "contingent approval." When the IRB grants contingent approval, the IRB should have in mind a clearly defined protocol that it is willing to approve. This protocol does not exist in final form, but represents the submitted protocol with specific required modifications. The IRB should document the required modifications so that an IRB chair or experienced IRB member can judge whether the revised protocol matches the one the IRB was willing to approve.

Examples of how NOT to document changes required under a "Req. Mod":

- "Explain why participants less than 18 years of age will be allowed to participate"
- "Provide additional justification for the use of placebo"
- "Clarify whether participants will be offered counseling services at the end of the study"
- "Indicate how often the data and safety monitoring board will meet," or "Provide animal data for the study drug."

Instead the IRB should provide the investigator specific modifications required to secure approval. Examples of **how to** document changes required under a "Req Mod":

- "Participants must be 18 years or older."
- "Drop the placebo controlled arm of this study."
- "Offer psychological counseling all participants at the study's conclusion."
- "Require CAT scans every three months."
- "Require the data and safety monitoring board to meet every three months."
- "Include in the consent all side effects listed in the investigator's brochure."

The IRB may be less specific the required modifications may be reviewed using the expedited procedure. For example, "Rewrite the content of the

consent into lay language," "Modify advertisements according to IRB policy," or "Submit quality of life surveys for review."

When the committee votes to defer further action on the study, the investigator's responses should be reviewed at a convened IRB meeting. For example, the convened IRB should review responses to provide an acceptable data monitoring plan, rewrite major portions of the consent document to include specific information about the study, its risks, procedures, etc., or include a rationale for the number of study participants.

AAHRPP warns that IRBs should exercise caution before delegating to an IRB member or committee the authority to negotiate changes without review of those changes by a convened IRB. In these instances, the IRB should take care that the changes required are very specific and only require that the individual member(s) confirm that the changes were made.

Reference:

AAHRPP Evaluation Tool