

Guidance on whether convened IRB request should be designated as minor (vote #2) or major (vote # 3 or 4)

The DHHS Office of Human Research Protection policy states that contingent approval of revisions without subsequent review by the convened IRB (i.e. expedited review) is permitted only when the requested revisions are non-substantive (minor).

A vote of #2 at a convened meeting indicates that the IRB has given the individual chairing the meeting (and/or other IRB member with appropriate expertise or qualifications) the authority to approve minor revisions which do not involve substantive issues. The types of revisions that can be approved by expedited review must be **directive** (specific changes or revisions requested of the investigator to secure approval) or **non-substantive** (a change in which the judgment of the IRB reviewer, makes no substantial alteration in risks to subjects, selection of subjects, informed consent process, informed consent documentation, safety and monitoring or subjects' privacy or data confidentiality. Examples of these are as follows:

- Changes in study research personnel;
- Adding a blood draw to a research study;
- Decreasing the amount of a blood drawn or the frequency of blood drawn;
- Adding research site(s) to a research study;
- Adding a standardized test instrument to a research study;
- Changes to improve the clarity of statements or to correct typographical errors without altering the content or intent of the statement (e.g. minor changes in the consent form).

When the convened IRB requests **substantive** (major) clarifications or revisions (i.e. vote # 3 or 4) directly relevant to the regulatory determinations required by the IRB, or does not have the information needed to determine whether the regulatory criteria are met, the protocol revisions must be deferred to the convened IRB for review and approval and can not be reviewed and approved by expedited review procedure.

For example, review of requested revisions by the convened IRB should occur when there are changes that are substantive and non-directive or there are questions, clarifications or requests for information such as:

- Clarify whether participants will be offered counseling services at the end of the study;
- Explain why participants less than 18 years of age will be allowed to participate;
- Provide additional information regarding study endpoints;
- Provide corrected informed consent documents (when incorrect consent documents have been submitted).

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