

## Tip Sheet: LU IRB Committee Action Options

**APPROVED:** Acceptable as is. *No changes are required.* Criteria for IRB approval have been met (i.e., 45 CFR 46.111 and 21 CFR 56.111).

**ACCEPTED PENDING MODIFICATION (APM):** *Minor, specific changes are required.* Criteria for IRB approval have been met (i.e., 45 CFR 46.111 and 21 CFR 56.111) except specific, non-substantial revisions are required. Member comments must be directive requesting simple concurrences or specific, non-substantive changes. Upon receipt of the required changes, the Committee Chair or another member designated by the Chair will verify that the appropriate additions/corrections were made and will either approve the study or return it to full committee.

**DEFERRED FOR RE-REVIEW:** *Substantial modifications and/or additional information* (e.g., details, clarifications, justifications) are required that are directly relevant to the Criteria for IRB approval (i.e., 45 CFR 46.111 and 21 CFR 56.111). Deferring a protocol requires that the study with the additional information or modifications be reviewed by the Full Board at a convened meeting.

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**DISAPPROVED:** *Criteria for IRB approval are not met* (i.e., 45 CFR 46.111 and 21 CFR 56.111). Only the full Board may disapprove a study. Disapprovals should be rare and may occur in one of two ways:

- After multiple attempts (i.e., typically at least two deferrals) have been made to resolve the issues, the full Board and the Investigator reach an impasse. At the discretion of the IRB, the investigator may be invited to a meeting, or the IRB may assign a subcommittee to meet with the investigator. The IRB may also honor a request from the Investigator to present his or her case to the board or a subcommittee.
- The study is disapproved outright because the Full Board determines that the science is clearly inadequate, the resources to conduct the study are not available, or that the research is inappropriate. In the first case, the IRB may ask the investigator to seek scientific review and redesign the project and submit an application for a new project.

**TABLED:** *Criteria for a convened full Board meeting are not met* (e.g., loss of quorum; non-scientific member not present) and/or appropriate expertise is not available at the meeting. Study will be reviewed at the next meeting of the duly constituted Full Board.