The IRBs are required to render motions and determinations for research applications received. It is essential that IRB members and investigators share a common understanding of what those motions and determinations mean. This document only defines the meaning of IRB motions and determinations. Details of the basis for those motions and determinations are described in many other policies. Investigators will receive letters from IRB reporting the board’s decision about their applications and describing needed revisions or rationales for decisions.

I. These terms are those listed on the IRB Voting Sheet.

**Approved**: Approved protocols are those which meet the criteria for approval as defined in 45 CFR 46.111 and no changes are required.

**Approved With Revision**: Protocols approved with revision(s) meet the criteria in 45 CFR 46.111 but require modifications specified by the IRB. Modifications in this category essentially require simple concurrence by the investigator and include correction of typographical errors, misspellings or grammar; revisions of readability or clarity; and additions of specific statements dictated by the IRB, e.g., “Please add the remark “You will be informed if any new information becomes available that might affect your willingness to continue in the study’ to the consent form.”

- The IRB shall specify who will review the revisions. Options include review and decision by a Research Compliance Specialist, the Director of Research Compliance (for revisions of exempt protocols), or a sub-committee chosen by the Director of Research Compliance or the IRB itself. The Board may direct that the judgment of assigned reviewers about revisions will be final or may ask that the revisions be returned for review by the full board. This will be recorded in the minutes.

- The designated reviewer(s) granted decision-making authority have the options to decide that the revisions comply with the requests made by the IRB or to refer the revised proposal back to the IRB in the event that new elements have been introduced or new issues created by the revisions. For example, instructions to improve the readability of a consent form may raise then questions about the adequacy of the information provided.

**Resubmit With Revision**: Proposals for resubmission and revision have major deficiencies that must be addressed before it can be determined that they meet criteria for approval in 45 CFR 46.111. Such protocols may be missing essential information
or appendices, fail to address all elements of informed consent, pose threats to participant privacy or confidentiality, or may state a risk-benefit ratio with which the IRB does not concur. The weaknesses are of such magnitude or frequency that rethinking by the investigator rather than mere concurrence is needed and rewriting will often be substantive and extensive. Proposals recommended for Resubmit with Revisions will be reviewed by the full Board upon resubmission.

**Not Approved:** Protocols that are not approved do not meet the criteria for approval defined in 45 CFR 46.111, lack enough evidence or sufficient clarity for the IRB to establish a risk-benefit ratio, or pose unacceptable risks to participants. The problems are so significant that the board doubts the proposal can be conducted ethically or within regulatory requirements without major changes. When the IRB does not approve or approves with modifications, a statement of the reasons for its decision and an opportunity to respond in person or in writing is given to the investigator. The investigator’s written response will be reviewed by the full IRB at the next scheduled meeting after it is received. The investigator may also request to attend the meeting in order to discuss the issue with the board.

**Tabled:** Protocols may be tabled for two reasons. The first and more usual case is that the application lacks sufficient information or sufficient clarity for the Board to be able to conduct an adequate review. (The missing information is not as severe as in applications that are not approved, nor is there evidence that the protocol poses unacceptable risks to participants or does not meet federal regulations.) The Board will review the application at its next convened meeting upon receipt of the requested information. The second and much rarer case is when a proposal cannot be reviewed at a given meeting for lack of time. The Board will make every effort to minimize this occurrence, including scheduling a supplemental meeting. If this is not possible, the study will be reviewed first at the next scheduled meeting. The reason for tabling will be given to the investigator.

**Abstain:** An individual decision by a board member not to vote on a protocol and recorded on the voting sheet. Board members may choose to abstain from voting on any protocol. The rationale for this choice may be that the member feels unable to reach a decision or that a circumstance short of an actual conflict of interest exists for which the member feels that an abstention would avoid any appearance of conflict of interest (COI).

**Conflict:** An individual decision by a board member recorded on the voting sheet. IRB chairs and members are expected to identify COI with proposals according to university and IRB policies and any unique personal circumstances related to an investigator or study in advance of the meeting or at the meeting prior to any discussion of the proposal. If the Chair is in conflict, the Vice Chair or the Research Compliance Officer will lead the proposal review. If a member has a conflict, s/he will either leave the room for discussion of the proposal and the vote or, with concurrence of the board, may be present for the discussion (usually to provide additional information) but will not vote. The Board may also have two discussions, one with the conflicted member present and one without.
\textbf{Expired/Expiration}: A currently approved study is expired when continuing review has not been conducted and approved prior to the study's expiration date. Principal investigators must stop all participant recruitment, enrollment and data collection on applications not submitted in time for continuing review.

\textbf{II. The following set of motions and determinations deal with suspensions and terminations and are not listed on the voting sheet. If these motions are made, the Board will vote on them, the results will be described in the minutes, and an appropriate letter will be prepared and sent to the investigator.}

\textbf{IRB-Imposed Suspension}: The chair, board, or designated IRB member requests the investigator to place some or all research activities of one or more approved protocols on hold for more information, post-approval monitoring, or investigation of an allegation of noncompliance. Principal investigators must stop all participant recruitment, enrollment and data collection on applications on which the IRB imposes a suspension.

\textbf{Sponsor-Imposed Suspension}: A sponsor-imposed suspension is when the IRB receives written notification from the Office For Sponsored Programs or the principal investigator that the sponsor has suspended the research study. This will be acknowledged by the IRB chair, board, or their designees when the appropriate level of review determines the suspension is appropriate. The IRB may impose additional criteria for suspension if needed to protect participants from potential harm.

\textbf{Suspension for Cause}: Suspension of an approved study when the IRB has determined that there is evidence of a possible increase in risk to participants or non-compliance by the Investigator. Suspensions for cause are made under full board review procedures.

\textbf{Termination for Cause}: An approved study is shut down because it is not being conducted in accordance with IRB policies, in not in compliance with federal regulations, and/or has been associated with unexpected serious harm to participants. Terminations for cause are made under full board review procedures.