

Review Outcome(s) for Full Review

An IRB member makes a motion, another member seconds the motion, and then the convened IRB votes for or against or abstains from one of the following five actions:

APPROVED (Vote for a #1): IRB approval - A vote for a #1 indicates that the IRB has concluded that the research and consent/assent forms meet the federal criteria for approval. IRB approval verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. ORI staff send the investigator an approval letter, according to the guidelines in the ORI Customer Service Standards, accompanied by an informed consent/assent document (if applicable) with the affixed "IRB Approval" validation stamp, which includes valid dates of IRB approval. If the IRB approves a HIPAA Waiver of Authorization Request, ORI staff send a separate approval letter as well. (See Federally Mandated Reporting to External Agencies SOP.)

REVISIONS and/or ADDITIONAL INFORMATION REQUIRED (Vote for a #2): A vote of #2 indicates that the IRB has given the individual chairing the meeting the authority to approve the minor revisions. The IRB withholds approval pending submission of minor revisions/additional information. ORI staff send the investigator a letter, according to the guidelines in the ORI Customer Service Standards, describing the revisions requested by the IRB.

The PI responds to the IRB's suggested revisions in writing and sends the response to the ORI, which gives the response to the IRB Chair or member who chaired the meeting for further review. The Chair or designee may forward the responses to the entire IRB for additional review, request additional information, or approve.

TABLED (Vote for a #3): A vote of #3 indicates that the IRB withholds approval pending submission of major revisions/additional information. ORI staff send the investigator a letter, according to the guidelines in the ORI Customer Service Standards. The letter lists the reasons for tabling and includes a description of the revisions or clarifications requested. For some studies, the IRB may appoint one or more members of the IRB to discuss the reasons with the investigator. If the vote is for a #3, ORI staff schedule the PI's response to the requested revisions for review by the full committee; the IRB does not require the PI to attend.

TABLED (Vote for a #4): If the vote is for a #4, the IRB follows the same procedure as for a vote of #3. In addition, ORI staff request that the PI attend the future IRB meeting at which the IRB reviews his/her response to requested revisions.

DISAPPROVED (Vote for a #5): If the vote is for a #5, ORI staff send the investigator a letter describing the reasons for disapproving the protocol. Disapproval of a protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the federal criteria for IRB approval.