

SOP: 409
CATEGORIES OF ACTION

1. POLICY

The IRB may approve or disapprove proposed research activity or specify modifications required to secure IRB approval of the research activity. Except when the expedited review procedure is used, these actions shall be taken by a vote of a majority of the IRB members present. When the expedited review procedure is used, the IRB Chair or designee may approve or contingently approve a study.

Specific Policies

1.1 Determinations

The IRB may make one of the following determinations as a result of its review of research submitted for initial or continuing review:

- A. Approval: The IRB approves the protocol and accompanying documents as submitted. Final approval is effective on the day the study is approved by the convened IRB and the approval period is based on the date of the convened meeting at which the IRB approved the protocol. When the expedited review procedure is used, approval is effective on the day the study is approved by the IRB Chair or designee and the approval period is based on the date the IRB Chair or designee approves the protocol.

The conditions for continued approval and the time frame (if any) within which they must be returned to the IRB are clearly stated in the approval letter. If the conditions of the approval are not met, the IRB may withdraw the approval.

- B. Contingent Approval: The IRB requires specific modification of a protocol or accompanying document(s). Changes and terms of the approval are voted upon during the IRB meeting. Specific changes are clearly outlined by the IRB, and the IRB informs the investigator in writing of the required changes and/or requested information. The Investigator must provide the IRB with the changes or information before the IRB will grant final approval.

The IRB Chair or designee has the authority to review the changes the submitted via expedited review unless the IRB requires or the IRB Chair decides that the material or information must be reviewed by the convened IRB, the primary reviewer, or another individual delegated by the IRB to review the response. Board requested changes may be taken to the convened IRB if all changes are not met. Upon satisfactory review, the IRB issues approval as of the date that the requested information or materials are approved. However, the expiration date of IRB approval is based on the date of the convened meeting at which the IRB approved the research with modifications. When the expedited review procedure is used, final approval is effective on the day the study is approved by the IRB Chair or designee and the approval period is based on the date the IRB Chair or designee approves the protocol. Participants must not be recruited into the study until final approval has been issued.

- C. Deferral: The IRB raises significant questions regarding the proposal or determines the information provided is inadequate to assess risk/benefit ratio.

The IRB shall reconsider the research proposal after additional substantive information is received from the investigator and/or sponsor. The IRB informs the investigator in writing of the IRB's concerns and requests for additional information. The investigator has the opportunity to respond to the IRB with the changes or information. The investigator's response shall be reviewed by the convened IRB.

- D. Disapproval: The IRB determines the proposal fails to meet one or more criteria for approval of research. Disapproval cannot be granted through the expedited review mechanism and shall be given only by majority vote at a convened meeting of the IRB. The IRB informs the investigator in writing of the IRB's concerns and requests for additional information. The investigator has the opportunity to respond to the IRB. University administration shall not overturn the IRB's disapproval of a study. The investigator's response shall be reviewed by the convened IRB.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

The IRB Chair and HRPP Director are responsible for complying with all University and regulatory requirements.

The IRB Chair is responsible for the appropriateness of all IRB decisions and actions.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111, 56.113

45 CFR 46.109

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1.1 As a result of its review of research submitted for initial or continuing review, the IRB may decide to approve, contingently approve, disapprove, or defer the proposed research activity. These actions are taken by a vote of the majority of the members present (except for those members who have recused themselves in accordance with the IRB conflict of interest policy, per SOP 104B, Conflict of Interest – IRB Members).

7.1.2 When the proposal is reviewed via expedited review, the IRB Chair or designee may approve or contingently approve that research. The IRB Chair cannot disapprove a study.

7.1.3 The IRB Administrator records the actions and determinations made during the meeting utilizing the IRB database. The IRB Administrator records the voting results, including number for and against, names of members making the motions, and the name of any members abstaining.

7.1.4 Approval: The IRB approves the protocol and accompanying documents as submitted. "Approved by Board" is the action designated by the IRB Administrator in the IRB database for Approval.

The protocol and accompanying documents are approved under expedited review by the IRB Chair as submitted with no changes. "Approved by the Chair" is the action recorded by the IRB Administrator in the IRB database for approval.

Approval is effective on the day the study is approved by the convened IRB and the approval period is based on the date of the convened meeting at which the IRB approved the protocol. The expiration date is calculated as the last day of the eleventh month from the date of IRB approval. For examples of this calculation process, refer to SOP 404A, Determination of Approval & Expiration Date Examples. When the expedited review procedure is used, approval is effective on the day the study is approved by the IRB Chair or designee and the approval period is based on the date the IRB Chair or designee approves the protocol. The research may proceed as soon as the Investigator receives the IRB approval letter for the study. The IRB Administrator records the approval date and expiration date in the IRB database and generates an approval letter. The IRB approval letter is sent to the principal investigator.

7.1.5 Contingent Approval: The IRB requires minor changes to the protocol and accompanying document(s). The changes may be reviewed under expedited review by a designated reviewer.

The IRB must clearly define the minor changes. The IRB votes on the minor changes and terms of approval during the convened IRB meeting. The action of contingent approval is recorded by the IRB Administrator in the IRB database as "Contingently Approved by Board." The IRB Administrator is responsible for recording the contingent approval date and for generating a contingent approval letter. The IRB contingent approval letter is sent to the principal investigator.

The IRB Chair or designee has the authority to review the information via expedited review unless the IRB requires that the material or information be reviewed by the convened IRB, the primary reviewer, or another individual delegated by the IRB to review the response.

The information requested by the IRB and received from the Investigator must provide the IRB with all of the required changes or information in order for final approval to be granted. However, the expiration date of IRB approval is based on the date of the convened meeting at which the IRB approved the research with modifications. When the expedited review procedure is used, final approval is effective on the day the study is approved by the IRB Chair or designee and the approval period is based on the date the IRB Chair or designee approves the protocol. For examples of this calculation process, refer to SOP 404A, Determination of Approval & Expiration Date Examples.

Participants must not be recruited into the study until final approval has been issued.

For studies reviewed and given contingent approval by the IRB Chair or designee under expedited review criteria, the IRB Chair notes the requested changes in the file. The IRB Administrator delineates in writing the minor changes requested by the IRB Chair. These changes are sent to the Principal Investigator. Upon satisfactory review of the proposed research, final approval is issued as of the date that the requested information or materials are approved. "Approved by the Chair" is the motion recorded by the IRB Administrator in the IRB database for approval.

An investigator has 60 days to respond to the IRB. If the requested information is not received, the project may be administratively withdrawn by the IRB.

7.1.6 Deferral: The IRB makes a motion of deferral when significant questions are raised by the IRB concerning the protocol or pending receipt of substantive information from the Investigator and/or Sponsor. The motion of deferral is designated in the IRB database as "Deferred by Board." The IRB Administrator is responsible for recording the Deferral Date in the database. The IRB Chair is responsible for promptly contacting the investigator and for drafting the deferral letter for the IRB Administrator. The deferral letter is sent to the principal investigator.

An investigator has 60 days to respond to the IRB. The investigator's response shall be reviewed by the convened IRB. If the requested information is not received, the protocol may be administratively withdrawn by the IRB.

7.1.7 Disapproval: The IRB makes a motion of disapproval when the protocol fails to meet one or more criteria used by the IRB for approval of research. Disapproval cannot be decided through the expedited review mechanism, only by majority vote at a convened meeting of the IRB.

The action of disapproval is designated in the IRB database as "Disapproved by Board." The IRB Administrator is responsible for recording the Date of Disapproval in the database. The IRB Chair is responsible for promptly contacting the investigator and for drafting the disapproval letter for the IRB Administrator. The IRB sends the disapproval letter to the principal investigator. Any response from the investigator shall be reviewed by the convened IRB.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012