SOP 409: CATEGORIES OF ACTION

1. POLICY

The IRB may approve or disapprove research submissions. Except when the expedited review procedure is used, these actions shall be taken by a vote of the convened IRB. When the expedited review procedure is used, the IRB Chair or IRB designee may approve or contingently approve a submission.

Specific Policies

1.1 Determinations

The IRB will make one of the following determinations as a result of its review of research submitted for initial, modification/notification, or continuing review:

1.1.1 Approval: The IRB approves the research project and accompanying documents as submitted. Participants must not be recruited into the research project until final approval has been issued.

For research reviewed by the convened Board, final approval is effective on the day the research project 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 submission.

When the expedited review procedure is used, approval is effective on the day the submission is approved by the IRB Chair or IRB designee, and the approval period is based on the date the IRB Chair or IRB designee approved the submission.

For research determined by the IRB to be exempt from regulations, the effective date of the determination is the day the submission is approved by the IRB Chair or IRB designee. There is no expiration date associated with research exempt from regulations.

1.1.2 Contingent Approval: The IRB may stipulate revisions to a research project or accompanying documents, no matter the level of review (convened board or expedited).

1.1.2.1 Convened IRB Review

The stipulations and terms of the approval are voted upon during the IRB meeting.

Specific stipulations are clearly outlined by the IRB, and the IRB informs the investigator of the required revisions and/or requested information via the IRB’s electronic information system. The investigator must provide the IRB with the revised submission materials or information before the IRB will grant final approval. The revised submission can be reviewed by the IRB Chair or IRB designee on behalf of the IRB.

1.1.2.2 Expedited/Exempt Review

When the expedited review procedure is used or when research is determined to be exempt from regulations: The stipulations are from the IRB Chair or IRB designee on behalf of the Board.

An investigator has 60 University business days to respond to the IRB. If the requested information and/or revisions are not received within that time period, the submission may be administratively withdrawn by the IRB.
A. For research reviewed by the convened IRB: The IRB Chair or IRB designee has the authority to review the investigator’s response and revised documents submitted via expedited review unless the IRB requires, or the IRB Chair or IRB designee decides, that the investigator response, revised materials, or information must be reviewed by the convened IRB. Upon satisfactory review of the investigator’s response and revised documentation, the IRB Chair or IRB designee approves the research project on behalf of the IRB. The IRB approval date is the date that the submission was approved by the IRB Chair or IRB designee. 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.

1.1.3 Deferral (Convened IRB Action): The IRB defers a submission when there are significant questions regarding the submission or when the information provided is inadequate to assess risk/benefit ratio. The deferral and accompanying stipulations are voted upon during the IRB meeting.

The IRB informs the investigator through the IRB’s electronic information system of the IRB’s concerns and requests for additional information. The investigator has the opportunity to respond to the IRB with the revisions or information. The investigator’s response shall be reviewed by the convened IRB. The convened IRB shall reconsider the submission after additional substantive information is received from the investigator.

An investigator has 60 University business days to respond to the IRB. If the requested information is not received within this time period, the submission may be administratively withdrawn by the IRB.

1.1.4 Disapproval: The IRB disapproves submissions that fail to meet one or more criteria for approval of human participant research. Disapproval cannot be determined through the expedited review process and shall be determined only by a convened IRB.

The IRB informs the investigator through the IRB’s electronic submission system of the IRB’s determination. The investigator has the opportunity to respond to the IRB regarding the IRB’s disapproval. The investigator’s response shall be reviewed by the convened IRB. University administration shall not overturn the IRB’s disapproval of a submission.

2. SCOPE

This SOP applies to all research projects 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 or IRB designee 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

None
6. ATTACHMENTS
None

7. PROCESS OVERVIEW

7.1 As a result of its review of a research submission, the IRB will decide to approve, contingently approve, disapprove, or defer the submission. These actions are taken by a vote of the convened IRB.

7.2 When the submission is reviewed via expedited review, the IRB Chair or IRB designee may approve or contingently approve that submission. The IRB Chair or IRB designee shall not defer or disapprove a research project. To pursue a potential deferral or disapproval, the IRB Chair or IRB designee must refer the submission to the convened Board.

7.3 The IRB Administrator updates the IRB’s electronic information system with the actions and determinations made during the convened IRB meeting or during the expedited review. For items reviewed by the convened Board, the IRB Administrator records the voting results, including the number for, against, and abstentions; and records the names of members making the motions.

7.3.1 Approval:

A. For items previously contingently approved by the convened Board:

The IRB approves the revised submission and accompanying documents after the investigator addresses all stipulations. “Approved by Board” is the action designated by the IRB Administrator in the IRB’s electronic information system.

The IRB Chair or IRB designee approves the revised submission and accompanying documents under expedited review after the investigator addresses all stipulations. “Approved by Chair/Desigee” is the action recorded by the IRB Administrator in the IRB’s electronic information system.

Approval is effective on the day the new research project 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 research. The expiration date is calculated as the last day of the eleventh month from the date of IRB approval.

B. For items approved via expedited procedures:

When the expedited review procedure is used, approval is effective on the day the research project is approved by the IRB Chair or IRB designee, and the approval period is based on the date the IRB Chair or IRB designee approves the research project. The IRB Administrator records the approval date and expiration date in the IRB’s electronic information system and generates an approval letter. The investigator is notified of the IRB’s action through the IRB’s electronic information system.

7.3.2 Contingent Approval: When the IRB stipulates minor revisions to the research project and accompanying documents, the IRB must clearly define the minor revisions. The changes submitted by the investigator may be reviewed under the expedited review procedure by the IRB Chair or IRB designee.

A. For items contingently approved by the convened Board:

The IRB votes on the minor revisions and terms of approval during the convened IRB meeting. The IRB Administrator updates the IRB’s electronic information system with the actions and determinations made by the convened IRB as “Contingent Approval.”
The IRB Administrator is responsible for recording the contingent approval date and for generating a contingent approval letter. The investigator is notified of the IRB’s action through the IRB’s electronic information system.

The IRB Chair or IRB designee has the authority to review the information via expedited review unless the IRB requires or the IRB Chair or IRB designee decides that the investigator response, revised submission materials, or information must be reviewed by the convened IRB. 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 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 revisions. When the expedited review procedure is used, approval is effective on the day the research project is approved by the IRB Chair or IRB designee, and the approval period is based on the date the IRB Chair or IRB designee approves the research project. Participants must not be recruited into the research project until IRB approval has been issued.

B. For items contingently approved via expedited procedures:

For studies contingently approved by the IRB Chair or IRB designee under expedited review procedures, the IRB Chair or IRB designee communicates to the IRB Administrator their concerns, requests for additional information, and/or stipulations for minor revisions in the IRB’s electronic information system. The IRB Administrator forwards the requests for additional information, minor revisions, and/or stipulations to the investigator. An investigator has 60 University business days to respond to the IRB. If the requested information and/or revisions are not received within that time period, the project may be administratively withdrawn by the IRB. When revised submissions are approved, the IRB approval letter is issued as of the date that the submission is approved. “Approved by Chair/Designee” is the motion recorded by the IRB Administrator in the electronic information system.

7.3.3 Deferral: The IRB makes a motion of deferral at a convened Board meeting when significant questions are raised regarding the submission or when the information provided is inadequate to assess risk/benefit ratio. The deferral action is designated in the IRB’s electronic information system as “Deferred.” The IRB Administrator is responsible for recording the deferral date in the IRB’s electronic information system. The IRB Chair or IRB designee is responsible for promptly contacting the investigator and for preparing the deferral stipulations. An investigator has 60 University business days to respond to the IRB. The investigator’s response shall be reviewed by the convened IRB. If the requested information is not received within that time period, the submission may be administratively withdrawn by the IRB. The IRB Administrator is responsible for notifying the investigator of the IRB’s action through the IRB’s electronic information system.

7.3.4 Disapproval: The IRB makes a motion of disapproval at a convened Board meeting when the submission fails to meet one or more criteria used by the IRB for approval of human participant research. Disapproval cannot be decided through the expedited review process; it may be decided only by the convened IRB. A disapproval by the IRB is considered final and cannot be overturned by University administration.

The action of disapproval is designated in the IRB’s electronic information system as “Disapproved.” The IRB Administrator is responsible for recording the date of disapproval in the IRB’s electronic information system. The IRB Chair or IRB designee is responsible
for promptly contacting the investigator and for communicating the reasons for disapproval. The IRB Administrator is responsible for notifying the Investigator of the IRB’s action through the IRB’s electronic information system. Any response from the investigator shall be reviewed by the convened IRB.

APPROVED BY:________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020