“In order to fulfill the requirements of this policy each IRB shall:

(b) Except when an expedited review procedure is used (see §46.110) [(see § 56.110)], review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.” 45 CFR 46.108, 21 CFR 56.108 [FDA]

Full review by the convened Institutional Review Board (IRB) is required for:
1. Initial applications that are not eligible for exempt or expedited review procedures
2. Revisions that are non-minor changes
3. Renewals of research studies that initially required full review (with certain limited exceptions – see below)
4. Disapproval of a research study, regardless of review level
5. Issues in which resolution cannot be made between the IRB reviewer and the investigator

To determine if the research study may be reviewed using the expedited or exempt review procedure, see the Human Research Protection Program (HRPP) Manual 8-1 “Exemptions” or 8-2 “Expedited Review.”

To determine if a change is non-minor, see HRPP Manual 8-6 “Revisions to an Approved Research Study.”

Research that underwent full review during the initial review will typically not be eligible for expedited review at the time of continuing review unless the research meets the criteria under expedited review and the convened IRB determines that expedited review is appropriate. . See HRPP Manual 8-2 “Expedited Review Procedure” for requirements.

Prior to convened IRB review, a primary review procedure is used for full review research. It is important to note that while a primary review procedure is used, in order
for the research to be approved, a majority of members present at the convened IRB must vote for approval of the research study.

**Primary Review Procedure**
For specific documents required for submission and evaluation criteria, see HRPP Manual: 8-5 “Initial Review, 8-6 “Revisions to an Approved Research Study,” and 8-7 “Renewed Approval.”

**Assignment and Material Distribution**
An IRB staff member (initial applications) or the IRB chair or vice-chair (renewals, non-minor revisions) will assign the primary reviewer(s) to the research study. The process for the assignment of primary reviewer(s) based on expertise for full review utilizes the same mechanism described in HRPP Manual 8-2 “Expedited Review,” specifically the section titled “Expertise.” See HRPP Manual 8-2 “Expedited Review” for a description of the mechanism.

The primary reviewer(s) typically has seven days in which to review the research study. The review due date will be provided to the reviewer via email.

**Initial Applications**
Three primary reviewers are assigned the research study prior to the convened IRB review. For clinical investigations, one of the three primary reviewers must be a physician. The three primary reviewers are alerted via email of their assignment. See HRPP Manual 8-5 “Initial Review” for materials provided to assigned reviewers. The primary reviewers conduct an in-depth review of all submitted documents. One of the three primary reviewers will be assigned as the lead reviewer. The lead reviewer will also provide a written summary of the research study. The summary includes a synopsis of all reviewer comments, the investigators’ responses to comments, as well as issues that are outstanding at the time of the IRB meeting. The summary is presented to the convened IRB and is available for review prior to the meeting via the MSU IRB online system.

**Renewed Approval**
The IRB chair assigns one primary reviewer to the research study prior to convened IRB review. See HRPP Manual 8-7 “Renewed Approval” for materials provided to assigned reviewers.

**Non-Minor Changes**
The IRB chair assigns one or more primary reviewer(s). For clinical investigations, one or more of the reviewers assigned should be a physician. For non-clinical research studies, the reviewers will be assigned based on expertise. See HRPP Manual 8-6 “Revisions to an Approved Research Study” for materials provided to assigned reviewers.

**Review Comments Prior to Convened Meeting**

Recommending Disapproval
If a primary reviewer indicates that he/she would not recommend approval of the research study, the procedure for bringing disapprovals to the convened IRB occurs using the same procedure provided in HRPP Manual 8-2 “Expedited Review,” specifically the section titled “Recommending Disapproval.” See HRPP Manual 8-2 “Expedited Review” for a description of the procedure.

Convened IRB Review

Pre-Meeting Materials Distribution
All materials required for convened IRB review of a research study will typically be available online to all IRB members at least 10 days prior to the meeting date, including alternates. See HRPP Manual 5-5 “Meetings” for submission deadlines policy. Comments may be sent to the investigators from any member of the IRB via the primary review process described above prior to the meeting. Materials not available via the MSU IRB online system will be made available electronically.

Initial Applications
IRB members access the initial application, all supporting documents associated with the research study, primary reviewer(s) comment(s), and investigator(s) response(s) via the MSU IRB online system. For initial review of research by the convened IRB, all IRB members, including alternate members anticipated to attend the meeting, are expected to review the application for initial review, the proposed consent form, and recruitment materials in enough depth to discuss the information when present at the convened IRB meeting. Primary reviewers are expected to review all submitted documents.

Application for Renewed Approval
IRB members access the renewal application, all supporting documents associated with the application (e.g., current consent, any newly proposed consent form, status report), primary reviewer(s) comment(s), and investigator(s) response(s) via the MSU IRB online system. For continuing review by the convened IRB, all IRB members, including alternate members anticipated to attend the meeting, are expected to review the application history, the application for renewal, the current consent form, and any newly proposed consent form in enough depth to discuss the information when present at the convened meeting. Primary reviewers are expected to review the complete protocol including any protocol modifications previously approved by the IRB.

Non-Minor Changes
IRB members access the revision application, all supporting documents associated with the application (e.g., the revised and/or modified documents such as the consent, instrument), primary reviewer(s) comment(s), and investigator(s) response(s) via the
MSU IRB online system. For review of modifications to previously approved research by a convened IRB, all IRB members, including alternate members anticipated to attend the meeting, are expected to review all modified documents in enough depth to discuss the information when present at the convened meeting.

Meeting Material Distribution
See the HRPP Manual 5-5 “Meetings” for materials that will be available or distributed.

Review and Documentation of Waivers and Certain Vulnerable Populations
Additional criteria must be met and documentation must be maintained if the research involves the following:

- Children
- Pregnant women, fetuses, or neonates
- Prisoners
- Waiver or alteration of the consent procedure
- Waiver of documentation
- Alteration to, or waiver, in whole or in part, of the individual authorization required by 164.508 for use or disclosure of protected health information (PHI)

To request a waiver or alteration of the consent procedure, a waiver of documentation, alteration to, or waiver, in whole or in part, of the individual authorization required by 164.508 for use or disclosure of protected health information (PHI), and for research involving prisoners, the investigator must explain and provide rationale why each criterion are met. For research involving pregnant women, fetuses, neonates, or children, the criteria should be addressed throughout the IRB application.

The convened IRB shall review the researcher’s explanation and the submitted application and determine if the appropriate criteria have been satisfied.

If the applicable criteria have been satisfied, documentation that the criteria have been met and the research study specific information justifying why each criterion have been met shall be recorded in the minutes of the convened IRB meeting. A standard form shall be used for documentation and placed in the IRB file.

For applicable criteria, see the following sections of the HRPP Manual:
6-4-B Waiver or Alteration of Informed Consent
6-4-C Parental Permission and Child Assent
6-4-D Waiver of Documentation
6-8-A Pregnant Women, Human Fetuses, and Neonates
6-8-B Prisoners
6-8-C Children
7-6 Health Insurance Portability and Accountability Act Compliance in Human Research
7-6-B Alteration or Waiver of Individual Authorization
**Actions by the Convened IRB and Communication of Actions**

Approval will be granted when a majority of members present vote for approval. A majority of members present may also vote for conditional approval, tabling, or disapproval of research studies. The communication of actions taken by the IRB depend upon the action taken. Typically, the IRB administrator or IRB staff assists the IRB chair or vice-chair in drafting the communication.

**Tabling**

Tabling occurs when the IRB requests substantive clarifications or modifications regarding the research study or the informed consent form(s) that are directly relevant to the determinations required by the IRB according to 45 CFR 46.111 and 21 CFR 56.111 as appropriate. A letter from the IRB chair or vice chair will be sent to the researchers, with an explanation of the changes that need to be made and submitted to the IRB for further review prior to approval. The investigator needs to address the comments and submit his/her response to the IRB. The investigator’s response will be brought to a subsequent IRB meeting for review.

**Conditional Approval**

Conditional approval may be granted by the IRB when additional specific changes requiring simple concurrence by the investigator are needed. A letter from the IRB chair or vice chair will be sent to the researcher, if applicable, with an explanation of conditional approval and the specific revisions requested by the IRB. The investigator needs to address the comments and submit his/her response to the IRB office in writing. The IRB chair or designee will be given the discretion to accept those changes and determine that the conditions are met, or bring the research study back to the IRB for review. If the IRB chair or designee accepts the changes and determines the conditions are met, an approval letter with approved consent form(s) will be sent to the researchers. The approval date is the date the convened IRB approved the research study. However, research may not begin until the conditions are met and accepted by the IRB chair or designee and the approval letter is sent to and received by the investigator(s).

**Approval**

Approval may be granted if the IRB determines that appropriate approval criteria have been met. The approval date is the date the majority of the convened IRB voted to approve the research study. The approval letter(s) from the IRB chair or vice chair and IRB approved consent forms if applicable will be made available to the researchers through the MSU IRB online system. A notification will be sent to the researchers via email instructing them to print the approval letter(s) and consent forms if applicable from the MSU IRB online system.

**Disapproval**

The IRB may disapprove a research study. If a research study is disapproved, the investigator will be notified in writing. A letter from the IRB chair or vice-chair will be sent to the researchers and will include a statement of the reasons for the IRB’s decision.
The letter will inform the investigator of his/her opportunity to respond in person or in writing by providing an explanation of the appeal process.

The investigator may appeal the decision in person at the next IRB meeting or in writing. If the investigator responds in writing, the appeal will be discussed at the next IRB meeting. The IRB determines whether to change the disapproval determination after the appeal. The range of actions may include disapproval, approval, or request for modifications. The determination will be communicated in writing to the investigator.

Approval Action Definitions
The definitions for approval actions are the same as the definitions provided in HRPP Manual 8-2 “Expedited Review,” specifically the section titled “Approval Action Definitions.”

Further Institutional Review

Typical Review Time
Initial Applications: 4-6 weeks
Revisions: 2-4 weeks
Renewals: 3-6 weeks