Subject: Expedited Review Procedure

Section: 8-2

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Related Sections: 2-2-D, 5-4, 5-5, 6, 6-4-B, 6-4-C, 6-4-D, 6-8-A, 6-8-B, 6-8-C, 6-8-D, 6-9-F, 8-5, 8-6, 8-7, 8-8, 8-9

“An IRB may use the expedited review procedure to review either or both of the following:

1. some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,”

2. minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b) [§56.108].” 45 CFR 46.110 (b), 21 CFR 56.110(b) [FDA]

“Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” 45 CFR 46.102(i), 21 CFR 50.3(k)

The expedited review procedure may be used for initial applications, revisions and renewals when the appropriate conditions specified by 45 CFR 46.110 and/or 21 CFR 56.110(b) are met. While initial review for use of a Humanitarian Use Device must occur at a convened IRB meeting, the IRB may use the expedited review procedures (21 CFR 56.110) for continuing review.

The criteria for approval using the expedited review procedure are the same as those for review by the convened Institutional Review Board (IRB). See the Human Research Protection Program (HRPP) Manual 6 “IRB Evaluation Criteria.”

Criteria for Use – Initial Applications and Renewals

The expedited review procedure may be used for initial applications and renewals when:

1. Research involves no more than minimal risk to subjects;

2. Research involves only procedures listed in one or more of the expedited review categories provided by the Office for Human Research Protections (OHRP); and
3. Research is not subject to limitations on the use of the expedited review procedure (e.g., classified research, initial/renewal review of prisoner research).

Research that underwent full review during the initial review will typically not be eligible for expedited review at the time of continuing review unless it meets the criteria for expedited category 8 or 9.

The expedited review procedure cannot be used in any of the following circumstances:
1. Research study involves more than minimal risk
2. Research study involves minimal risk but does not appear in the categories of research eligible for expedited review
3. Where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal
4. When research is classified (in general, classified research at MSU requires explicit permission from the Board of Trustees for the specific research study)
5. Research involves prisoners unless the review involves a review for minor modifications only (see HRPP Manual 6-8-B “Prisoners”)
6. Initial review of research involving individuals with diminished capacity and use of a legally authorized representative to obtain consent (see HRPP Manual 6-8-D “Individuals with Diminished Capacity”)

If any of the above conditions exist, the research study may not undergo an expedited review procedure and must undergo a full review. IRB staff members evaluate the researcher's expedited review level and category selection when processing incoming applications. The IRB staff may consult with the IRB chair if they are unsure or believe that the application does not qualify for expedited review. The IRB staff may also forward such question to the IRB member assigned to review the application. IRB members should notify the IRB staff if they believe that the application does not qualify for expedited review.

**Expedited Review Categories**
A research study may undergo expedited review if it involves no more than minimal risk and only involves subjects in one or more of the following categories from the Federal Register: November 9, 1998 (Volume 63, Number 216):

**Category 1:** “Clinical studies of drugs and medical devices only when condition (a) or (b) is met. “

“(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)”

“(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.”
Category 2: “Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:"
   “(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or"
   “(b) from other adults and children 2 considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.”

Category 3: “Prospective collection of biological specimens for research purposes by noninvasive means.”
   “Examples:"
   “(a) Hair and nail clippings in a nondisfiguring manner;"
   “(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;”
   “(c) permanent teeth if routine patient care indicates a need for extraction;”
   “(d) excreta and external secretions (including sweat);”
   “(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;”
   “(f) placenta removed at delivery;”
   “(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;”
   “(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;”
   “(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;”
   “(j) sputum collected after saline mist nebulization.”

Category 4: “Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).”
   “Examples:"
   “(a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;”
   “(b) weighing or testing sensory acuity;”
   “(c) magnetic resonance imaging;”
   “(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;”
   “(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual”

Category 5: “Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for
the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)"

**Category 6:** “Collection of data from voice, video, digital, or image recordings made for research purposes.”

**Category 7:** “Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)"

**Category 8:** “Continuing review of research previously approved by the convened IRB as follows:”
  (a) “Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or”
  (b) “Where no subjects have been enrolled and no additional risks have been identified; or”
  (c) “Where the remaining research activities are limited to data analysis.”

**Category 9:** “Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.”

**Criteria for Use of Expedited Review – Minor Changes**

Expedited review may be used for minor changes in previously approved research during the period for which approval is authorized. Minor modifications cannot include addition of procedures that involve more than minimal risk or do not fall into categories (1) – (7) of research that could be reviewed using the expedited procedure. To determine if a change is minor, see HRPP Manual 8-6 “Revisions to an Approved Research Study.”

**Expedited Reviewer Assignment and Distribution of Materials**

For evaluation criteria and specific documents required for submission, see the following sections of the HRP Manual 8-5 “Initial Review,” 8-6 “Revisions to an Approved Research Study,” and 8-7 “Renewed Approval.”

The IRB chair or vice-chair will evaluate the research and determine who has the appropriate scientific or scholarly expertise to conduct an in-depth review of the research study. The chair or vice-chair will assign reviewer(s) and if needed a consultant to the research study. Reviewer(s) may be the IRB chairperson or one or more experienced reviewers designated by the chairperson from among members of the IRB.” 45 CFR 46.110(b), 21 CFR 56.110(b). See HRPP Manual 5-3 “IRB Membership” for the procedure for designation by the IRB chair of IRB members who may conduct review using the expedited procedure, including the definition of experienced reviewer.

**Expertise**
While all IRB members have the qualifications and training to review research studies submitted to the IRB, there are instances in which certain reviewers on the IRB have more expertise in the area under study than other members of the IRB, and those reviewers will be assigned the research study whenever possible. At least one IRB member with scientific or scholarly expertise must be assigned to conduct an in-depth review of each research study. For research studies that will involve subjects vulnerable to coercion or undue influence (e.g., children, students, disadvantaged populations), reviewers with appropriate expertise will be assigned. The roster may be used when making reviewer assignments. The IRB chair may determine that another individual on the IRB has appropriate expertise. If appropriate expertise is not available, additional expertise will be obtained as needed. See the HRPP Manual 5-4 “Additional Expertise” for policies and procedures. For Community Research Institutional Review Board (CRIRB) research studies, whenever possible, reviewers will be assigned from the institutions where the research study will be performed.

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

Initial Applications
The IRB chair reviews or assigns one (or more) experienced reviewer who is alerted of his/her assignment, typically by email. See HRPP Manual 8-5 “Initial Review” for materials provided to assigned reviewers.

Applications for Renewed Approval
The IRB chair or vice-chair reviews or assigns one experienced reviewer who is alerted of his/her assignment, typically by email. See HRPP Manual 8-7 “Renewed Approval” for materials provided to assigned reviewers.

Revisions – Minor Changes
The IRB chair reviews or assigns one experienced reviewer. See HRPP Manual 8-6 “Revisions to an Approved Research Study” for materials provided to assigned reviewers.

Minor Administrative Changes
One IRB staff member is assigned to review and process personnel forms for minor modifications.

Review Comments Procedure
Modifications or clarifications requested by the reviewers are communicated to researchers in writing via the MSU online system. If a reviewer has any questions or concerns or is requesting modifications to the research study, s/he should draft a reviewer comment and submit it to the IRB office via the MSU IRB online system. The IRB staff posts the reviewer comment(s) to the MSU IRB online system and notifies researchers via e-mail.
Once the researcher responds, the reviewer is notified. If the reviewer is satisfied with the response, the reviewer may issue his/her approval through the MSU online system. If the reviewer has additional questions or concerns, another reviewer comment is submitted to the IRB office and the same process as above is followed.

If the reviewer and the researcher are unable to come to resolution over the issue raised, the IRB chair will mediate such discussions. If a resolution cannot be reached, the IRB will discuss the research study at its next convened meeting.

**Recommend Disapproval**
If a reviewer indicates that he/she does not approve a research study, the IRB staff notifies the IRB administrator and the research study will be added to the IRB meeting agenda for review by the convened IRB.

“A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b).” (45 CFR 46.110(b))

See HRPP Manual 5-5 “Meetings” for the IRB process to report its findings and actions of disapprovals to researchers in writing.

**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

To request a waiver or alteration of the consent procedure, a waiver of documentation, and for research involving prisoners, the investigator typically 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 reviewer shall review the researcher’s explanation and the submitted application to determine if the appropriate criteria have been satisfied. Reviewer comments may be generated if clarification or explanations are needed.

If the applicable criteria have been satisfied, an IRB member shall document that each criteria have been met and provide research study specific information justifying why the research met each criteria. 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
Actions and Communication of Actions for Expedited Review
Expedited approvals are issued after all criteria necessary for approval have been met. Expedited approvals do not require convened IRB review. A standard approval letter shall be used to communicate such approval to researchers in writing. The approved version of the consent form and the approval letter will be available through the MSU online system. Research studies approved using an expedited review procedure will be listed on the agenda distributed at the convened IRB meeting. The research studies do not require any actions at the convened IRB meeting.

Initial Applications
All assigned reviewer(s) must issue an approval before the research study is given IRB approval. If there are multiple reviewers and they do not issue their approval on the same day, the date of approval will be the later of the dates of reviewer approval. The approval period is 364 days, unless otherwise noted. See HRPP Manual 8-8 “Demonstration Projects” for policies and procedures on issuing approval periods that are greater than 364 days.

Renewals
The renewal approval date is the date the assigned reviewer issues his/her approval. The approval period is 364 days, unless otherwise noted. This approval period replaces the research study’s last approval period. See HRPP Manual 8-8 “Demonstration Projects” for policies and procedures on issuing approval periods that are greater than 364 days.

Revisions – Minor Changes
The revision approval date is the date the assigned reviewer issues approval. The revision approval date does not change the approval period.

Approval Action Definitions
The following definitions apply to approval actions:

Approval date: Date the research study is initially approved.

Approval period: Period from which the research study is approved to the research study expiration date.

Expiration date: Last date the research study has approval or renewed approval. Approval expires at 11:59 P.M. of the expiration date. All research activities must stop and may not be conducted if a research study’s approval has expired. See HRPP Manual 8-9 “Closure” for requirements.
Calculation of the expiration date: Typically, date of approval to the same date in the following year less one day. However, if the IRB requires continuing review more or less often than annually, then expiration date is calculated from the date of approval to the period the IRB sets less one day. See HRPP Manual 8-8 “Demonstration Projects” for policies and procedures on issuing approvals greater than 364 days.

Revision approval date: Date the revision is approved. This is the date the revision may be implemented. Revision approval does not alter the research study’s expiration date.

Further Institutional Review
Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. University officials, however, may not approve the research if it has not been approved by an IRB. 45 CFR 46.112, 21 CFR 56.112.

Typical Review Time
Initial Applications: 2 – 4 weeks
Revisions to An Approved Research Study: 10 – 15 working days
Renewed Approval: 10 – 15 working days

Additional Requirements
See HRPP Manual 6-9-F, “Multiple Research Sites” for CRIRB specific requirements.

For research studies subject to the requirements of the U.S. Department of Education, see HRPP Manual 2-2-D “U.S. Department of Education.”