



Initial Expedited Review

I. Purpose

To define policies and procedures for conducting expedited review of human research.

II. Revisions from Previous Version

None.

III. Definitions

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.

IV. Policy

The Institutional Review Board (IRB) uses an expedited review process to review projects covered under its Federalwide Assurance (FWA) that meet the categories adopted by the Department of Health and Human Services (DHHS) that involve no greater than “minimal risk” as well as projects that require limited IRB review as specified in 45 CFR 46.104(d). The expedited applicability criteria and federally mandated categories are available online. Expedited review procedures allow the IRB to review and approve projects that meet the criteria for approval without the fully convened IRB. IRB staff, IRB Chairs, and designated reviewers from among the IRB membership (prime and alternate members) conduct expedited reviews.

The expedited reviewers only approve research that meets the federal criteria for approval as specified in 45 CFR 46.111 and 21 CFR 56.111. Also, expedited reviewers ensure that the project's informed consent process and documentation meet the requirements as specified in 45 CFR 46.116, 45 CFR 46.117, 21 CFR 50.25 and 21 CFR 50.27, unless the IRB waives the requirements in accordance with federal regulations. For projects that include vulnerable populations, the reviewer(s) will follow consider the appropriate protections necessary.

Expedited reviewers exercise all of the authority of the IRB except for the disapproval of research. The IRB may only disapprove a research activity in accordance with non-expedited procedures set forth in the DHHS regulations.

The IRB staff advise the IRB of research approved using expedited review procedures via a quarterly report. Any IRB member can request to review the entire IRB file for an expedited project.

V. Procedure

Submission and Screening

1. After having completed the Intake in WRG, the Principal Investigator (PI) will submit a complete submission (initial application and other project documents) to the IRB via WRG-HS. Instructions for preparing the application are available on the IRB website. The researcher may contact the IRB office with questions.
2. The IRB staff will make an initial assessment to determine whether the project is minimal risk and direct the submission to the appropriate review process.
3. Upon receipt of the submission, IRB staff will conduct pre-review activities as described in the Staff Processing of Submissions SOP. The IRB staff will make a preliminary determination that the project meets

the federal criteria for expedited review, exempt or limited IRB review, including minimal risk. If the application does not meet the criteria for expedited, exempt, or limited IRB review, the IRB staff will assign the project for full board review according to the Initial Full Review SOP.

4. If applicable, the IRB staff will note during the pre-review process that the proposal involves areas of research requiring federally mandated protocol specific findings. The IRB staff will then alert the expedited reviewer(s) of the areas requiring determinations.
5. After completing pre-review activities, the IRB staff will assign the project to an agenda, resulting in an assignment to an expedited reviewer to conduct the review.

Assigning Reviewers

1. All expedited reviewers undergo training prior to conducting reviews.
2. The IRB staff make reviewer assignments, as designated by the IRB Chair, from the general expedited board based on the member's availability, experience, and expertise. Experienced IRB staff are listed on the roster and can conduct expedited reviews.
3. The assigned reviewer will notify the IRB staff if they are not available to conduct the review during the assigned time period or has a conflict of interest. The IRB staff will document who served as the expedited reviewer in WRG-HS. Reviewer assignments will not be made known to the PI or research team.

IRB Expedited Review Process

1. Expedited reviewers have access to all documents submitted by the researcher.
2. The reviewer will document federally mandated protocol specific findings (e.g. Subpart B, C, D, or waiver of informed consent or documentation), if applicable, by completing the Reviewer Checklists.
3. Reviewers will review all submission documents in enough depth to be familiar with the protocol, to determine whether the research is eligible for expedited review, confirm the activity is minimal risk, and to determine whether the research meets the regulatory criteria for approval and determinations with protocol specific justifications. The reviewer will ensure that the research meets ethical principles and standards for protecting research participants.
4. If a non-staff reviewer is unable to respond within a week, the IRB staff may forward the protocol to another reviewer.

Review Outcomes

1. The expedited reviewers will make the final determination as to whether research activities meet expedited review or limited IRB review criteria and whether the research meets the federal criteria for approval as outlined in 45 CFR 46.111, 21 CFR 56.111 or 45 CFR 46.104(d).
2. The expedited reviewers will ensure that the researcher will conduct the informed consent process and obtain documentation of informed consent, as specified in 45 CFR 46.116 and 117 and 21 CFR 50.25 and 27 unless the IRB waives the requirements in accordance with federal regulations and documents the protocol specific findings.
3. Reviewers only request changes that they have determined do not meet the federal criteria for approval or IRB policies.
4. The reviewers will document on the Reviewer Checklist their determinations regarding expedited eligibility, applicable expedited category(ies), whether the research meets the federal criteria for approval, and appropriate determinations with protocol specific findings.
5. The reviewer will make one of the following three determinations:
 - **APPROVED:** IRB approval indicates that the IRB reviewer(s) has concluded that the research and informed consent process meet the federal criteria for approval. An 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. IRB staff will send the researcher an approval letter, stamped consent form(s), and other stamped documents as appropriate through WRG-HS.
 - **MODIFICATIONS REQUIRED:**
The IRB reviewer(s) withhold approval pending submission of modifications. The IRB staff will send the researcher a letter describing the modifications requested by the reviewer(s). The PI will respond to modifications requested by the IRB in writing and send the response through WRG-HS. If the reviewer was unable to determine that all approval criteria were met, the IRB staff will forward the responses to the reviewer for further review. If the modifications are directive, the modifications can

be verified administratively by IRB staff.

- **FULL REVIEW REQUIRED:** The reviewer(s) may determine that the protocol requires full review by the IRB at a convened meeting. If a reviewer finds that research appearing in the expedited categories is greater than minimal risk, the reviewer will document their rationale.
6. The reviewer(s) may determine that the research is eligible for a less stringent mechanism of review (i.e. the project meets certain exemption criteria or the activity(ies) does not fall under the purview of the IRB). In these cases, the reviewer, with assistance from IRB staff if necessary, will document the exempt categories or the rationale for determining that the activities do not meet the federal definitions of *research* and/or *human subject*.
 7. Once the IRB approves a protocol, the IRB staff will send an approval letter to the PI, which includes the approval period, when applicable, a reminder to use only the approved (stamped) consent/assent form(s), and a reminder that the IRB must approve any changes to the protocol prior to the initiation of the changes.
 8. The IRB reviewer(s) will assign an approval period at intervals appropriate to the degree of risk. In most cases, minimal risk research will not be subject to continuing review by the IRB (excluding FDA regulated research). However, at its discretion, the IRB may require continuing review of projects that meet certain criteria, including, but not limited to: inclusion of vulnerable populations, research on criminal behavior, use of substance abuse or mental health data, or research conducted at external sites (e.g. secondary schools). A justification for requiring continuing review will be documented by the reviewer. The date the reviewer completes the review in WRG-HS for final approval on the project is the date the approval period starts. If the IRB staff verify the modifications and the reviewer determined and justified the need for continuing review, the expiration date is set from the date the IRB reviewer completed their review. The IRB staff will document the approval period dates in the approval letter to the PI.

Post Approval Monitoring

Projects reviewed under this policy will be subject to post-approval monitoring by the WCM Human Research Protections Program to ensure that conduct of projects are in accordance with the IRB approved protocol.

VI. References

45 CFR 46.102(i)

45 CFR 46.110

45 CFR 46.104

21 CFR 56.102(i)

21 CFR 56.110

21 CFR 50.25

21 CFR 50.27

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