OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #304.5 Revision 5	**TITLE: Expedited Review of Federally Funded Research**	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature	Date 3/1/2019
Approved By: IRB Chair	Signature	Date 3/1/2019

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

REVISIONS FROM PREVIOUS VERSION
Addition of requirement that IRB must provide justification for research that is included in the expedited categories but designated as greater than minimal risk

POLICY
The UNM 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, including the definition of "minimal risk" 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. The IRB Chairs and designated reviewers from among the IRB membership (regular 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 meets 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 accord with federal regulations (see Informed Consent SOP). For projects that have vulnerable populations, the reviewer will follow the procedures described in Protection of Vulnerable Populations SOP.

Expedited reviewers exercise all of the authority of the IRB except that the reviewers may not disapprove the research. The IRB only disapproves a research activity in accordance with non-expedited procedures set forth in the DHHS regulations.

The OIRB advises the IRB of projects approved using expedited review procedures via a monthly report. Any member can request to review the entire IRB file for an expedited project.

RESPONSIBILITIES
Execution of SOP: IRB Chairs, IRB Members, Researchers, OIRB Staff.

PROCEDURE

Submission and Screening

1. The PI submits a complete submission package to the OIRB through IRBNet. Instructions for preparing the application are available on the OIRB website. The researcher may call the OIRB with questions.
2. Upon receipt of the submission, OIRB staff conduct intake and pre-review activities as described in the Staff Processing of Submissions SOP. OIRB staff make a preliminary determination that the project is federally funded or may be submitted for federal funding, and meets the federal criteria for expedited review or limited IRB review, including minimal risk. If the application does not meet the criteria for expedited or exempt review, OIRB staff schedule the project for full board review according to the Initial Full Review SOP.
3. If applicable, OIRB staff note during the pre-review process that the proposal involves areas of research requiring federally mandated specific findings. OIRB staff provide the appropriate Reviewer Checklists to alert the expedited reviewer(s) of the areas requiring determinations.
4. OIRB staff screen for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family Educational Rights and Privacy Act (FERPA) concerns. If the PI includes a HIPAA form or otherwise indicates that Protected Health Information (PHI) is being collected or if there are any HIPAA or FERPA concerns, OIRB staff may consult with the OIRB Director to ensure all legal requirements are addressed.
5. After completing pre-review activities, OIRB staff assign the project to an expedited reviewer to conduct the expedited or limited IRB review.

Assigning Reviewers

1. Periodically, OIRB staff and IRB Chair query the board members to determine interest in serving as a minimal risk reviewer. Members are selected based on expertise and availability. All minimal risk reviewers undergo initial training with OIRB prior to conducting expedited reviews. Members who have served on the IRB for at least three months may qualify as a minimal risk reviewer. Once this additional training has been completed, the member receives a letter outlining associated responsibilities and officially designating them as a minimal risk reviewer.
2. OIRB staff make initial reviewer assignments based on the member's meeting availability, experience, and expertise. OIRB staff keep the approved list of minimal risk reviewers on file.
3. The expedited reviewer notifies OIRB staff if they are not available to conduct expedited review during the assigned time period or has a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOP. OIRB staff document who served as the minimal risk reviewer on the applicable reviewer form.

IRB Expedited Review Process

1. Minimal risk reviewers are provided all documents submitted by the researcher.
2. The reviewer documents federally mandated specific findings (e.g. Subpart B, C, D, or waiver of informed consent or documentation), if applicable, by completing the Reviewer Checklists.
3. Reviewers review all submission documents in enough depth to be familiar with the protocol, to determine whether the research is eligible for expedited review, and to determine whether the research meets the regulatory criteria for approval.
4. Research not involving interaction with prisoners (e.g. existing data, record review) may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

a. The prisoner representative must concur with the determination that the research involves no greater than minimal risk.
b. The prisoner representative must review the research as a reviewer. This may be as the sole reviewer or in addition to another reviewer, as appropriate.

Review Outcomes

1. Minimal risk reviewers make the final determination as to whether research activities meet expedited review or limited IRB review criteria.
2. Reviewers determine 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).
3. Reviewers 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, 21 CFR 50.25 and 27, and 45 CFR 46.104(d)(8) unless the IRB waives the requirements in accord with federal regulations (see Informed Consent SOP).
4. Reviewers only raise those controverted issues or request changes that they have determined do not meet the federal criteria for approval or UNM and OIRB policies.
5. Reviewers document on the Reviewer Checklist their determinations regarding expedited eligibility, applicable expedited category(ies), and whether the research meets the federal criteria for approval.
6. The reviewer makes 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. OIRB staff send the researcher an approval letter.
   - MODIFICATIONS and/or ADDITIONAL INFORMATION REQUIRED:
     The IRB reviewer(s) withhold approval pending submission of modifications/additional information. OIRB staff send the researcher a letter describing the modifications requested by the reviewer(s). The PI responds to modifications requested by the IRB in writing and sends the response to the OIRB. If the reviewer was unable to determine that all approval criteria were met, OIRB staff forward the responses to the reviewer for further review. If the modifications are minor, modifications can be verified administratively by OIRB 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.
7. The reviewer(s) can determine that the research is eligible for a less stringent mechanism of review (i.e. the project meets certain exemption criteria or the activities do not fall under the purview of the IRB). In these cases, the reviewer, with assistance from OIRB staff if necessary, documents the exempt categories or the rationale for determining that the activities do not meet the federal definitions of *research* or *human subject*.
8. The OIRB procedures for notifying the PI of the review outcome, obtaining follow up correspondence, and issuing approval letters outlined in the Initial Full Review SOP apply for expedited review as well. See Initial Full Review SOP for details.
9. The IRB reviewer(s) assigns the 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). Justification for requiring continuing review will be documented by the reviewer. The date the reviewer completes the review in IRBNet for final approval on the project is the date the approval period starts. If OIRB staff verify the modifications, the approval period starts from the date the IRB reviewer completed their review. OIRB staff 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 UNM Human Research Protections Program to ensure that conduct of projects are in accordance with the IRB approved protocol and to confirm that funding status has not changed (see SOP 409 Post Approval Monitoring Program).

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
63 FR 60364-60367; 63 FR 60353 – 60356 DHHS-FDA list published in Federal Register November 9, 1998