Baylor University
OFFICE OF THE VICE PROVOST FOR RESEARCH

Research Compliance Institutional Review Board Policies and Procedures	Effective Date: 1/21/2019 Revised: 11/15/2019

IRB-18: Expedited Review

PURPOSE

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

POLICY

The BU 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." 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 approval criteria without convening a full IRB meeting. The IRB Chair 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. Also, expedited reviewers ensure that the informed consent process and documentation meets the requirements as specified in 45 CFR 46.116, 45 CFR 46.117, unless the IRB waives the requirements in accordance with federal regulations (see Informed Consent SOP). For projects that have vulnerable populations, the reviewer will also 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 IRB minutes for convened meetings advises the IRB of projects approved using expedited review procedures. Any member can request to review the entire IRB file for an expedited project.

PROCEDURE

Submission and Screening

1. The PI submits a complete submission package to the ORC. Instructions for preparing the application are available on the IRB website. The researcher may call the ORC with questions.

2. Upon receipt of the submission, ORC staff conduct intake and pre-review activities as described in the Staff Processing of Submissions SOP. ORC staff make a preliminary determination that the project meets the federal criteria for expedited review, including minimal risk. If the application does not meet the criteria for expedited review, ORC staff schedule the project for full board review according to the Initial Full Review SOP.
3. If applicable, ORC staff note during the pre-review process that the proposal involves areas of research requiring federally mandated specific findings. ORC staff alert the expedited reviewer(s) of the areas requiring determinations.
4. ORC 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, ORC staff may consult with the ORC Director to ensure all legal requirements are addressed.
5. After completing pre-review activities, expedited reviewers are assigned the project to an expedited reviewer to conduct the review. Reviewers are selected based on expertise and availability.

IRB Expedited Review Process

1. Expedited reviewers are provided all documents submitted by the researcher. A reviewer can also request access to prior submissions by the researcher if needed to review the current submission.
2. The expedited 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. Expedited 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.

Review Outcomes

1. Expedited reviewers make the final determination as to whether research activities meet expedited review criteria.
2. The reviewers determine whether the research meets the federal criteria for approval as outlined in 45 CFR 46.111.
3. Expedited reviewers ensure that the researcher will conduct a informed consent process and obtain documentation of informed consent, as specified in 45 CFR 46.116 and 117 unless the IRB waives the requirements in accord with federal regulations (see Informed Consent SOP).
4. The expedited reviewers may document on the Reviewer Checklist their determinations regarding expedited eligibility, applicable expedited category, and whether the research meets the federal criteria for approval.
5. The expedited reviewer makes one of the following three determinations:
    a. APPROVED: IRB approval indicates that the 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. ORC staff send the researcher an approval letter.
    b. APPROVED WITH MODIFICATIONS REQUIRED: The reviewer(s) approve the research pending required modifications in order to secure final approval. ORC staff send the researcher a letter

describing the modifications requested by the IRB expedited reviewer(s). The PI responds to modifications requested by the IRB in writing and sends the response to the ORC. ORC staff forward the responses to the IRB Chair and/or the expedited reviewer(s) for confirmation that required modifications have been completed.

c. FULL BOARD REVIEW REQUIRED: The IRB expedited reviewer(s) may determine that the protocol requires full review by the IRB at a convened meeting. ORC staff schedule the submission for the next available IRB Meeting according to the Initial Full Review SOP.

6. The expedited 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 expedited reviewer, with assistance from ORC 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.
7. The ORC 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.
8. The reviewer(s) assigns the approval period at intervals appropriate to the degree of risk. In most cases, expedited research will not be subject to continuing review and will instead be subject to an annual status report. However, the IRB has the authority to determine that continuing review is required for the research study. Reasons why the IRB may determine that continuing review is required, include (but are not limited to):
    a. Required by other applicable regulations (e.g., FDA);
    b. The research involves topics, procedures, or data that may be considered sensitive or controversial;
    c. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
    d. An investigator has minimal experience in research or the research type, topic, or procedures; and/or
    e. An investigator has a history of noncompliance
9. When the IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement to the investigator in the IRB determination letter.
10. Approval and annual status report deadlines or expiration dates (i.e., the approval period) are set as follows:

Expedited Review Motion	Approval Date	Expiration Date
Approved	Date IRB Chair or designated IRB member determines approval.	No more than one year from date of expedited review approval.
Approved with Modifications Required	Date IRB Chair or designated IRB member determines that conditions are satisfied.	No more than one year from date of expedited review where approval with modifications was determined.

Informing the IRB

All members of the IRB will be apprised of all expedited review approvals by means of a list in the agenda at the next scheduled meeting. The agenda list will be translated over into the approved minutes of that meeting. Any IRB member can request to review the full protocol by contacting the ORC.

REFERENCES

45 CFR 46.110
Guidance on IRB Continuing Review of Research, OHRP, 2010
63 FR 60364-60367; 63 FR 60353 – 60356 DHHS-FDA list published in Federal Register November 9, 1998

REVISIONS FROM PREVIOUS VERSION

11/15/2019	Addition of annual status report information; changes to wording for clarity; update administrative information