

IRB Procedures 8a: Expedited review procedures
Revision date: October 6, 2008, revision November 11, 2009, revision July 17, 2010, revision January 27, 2011, revised February 9, 2015, revised October 15, 2015

I. Summary

The IRB policy is to make guidelines and procedures for investigators, IRB staff, and IRB members understandable and available to all involved in the process, including this information about procedures for submitting research for an expedited review.

II. Responsibilities

A. IRB Administration Responsibilities

1. The IRB Coordinator will review the new protocol submission xform and attachments for completeness and inform the PI of any needed documents (IRB Pre-Review Stage for non-VA submissions). Once the IRB Pre-Review stage is complete, the IRB Coordinator forwards the new protocol submission xform for required signatures. IRB coordinator then completes the IRB Initial Review and IRB Coordinator Stage, which includes a submission checklist. IRB coordinator checks the question regarding external sites to identify whether the PI has provided complete information for each external site. IRB Coordinator contacts PI and/or site if additional information is needed. If documents are not received at time of review, the approval letter will indicate approval pending receipt of necessary documents. For studies that have an associated contract, the IRB coordinator forwards a copy of the contract or, at minimum, a copy of any contract pages referencing provisions for medical care or other care and services for research-related injury and any information regarding the consent process to Sponsored Programs. The IRB Coordinator provides the contract consistency checklist to the expedited reviewer(s) when complete. For VA studies, the IRB Coordinator verifies that the VA new protocol submission xform was submitted and that the VA signatories have indicated that the submission meets VA requirements.
2. The IRB Coordinator makes the initial determination of whether the proposal is routed to the ETSU IRB or the ETSU/VA IRB by evaluating the protocol by the criteria outlined in IRB Policy II. The IRB Coordinator documents this determination on the IRB Initial Review

Stage. The IRB Coordinator forwards the proposal to the relevant IRB Chair who makes the final determination of board assignment.

3. The study will be reviewed by the IRB Chair (or Vice Chair, in his/her absence or when conflict of interest is identified), who will determine if the proposal meets criteria for expedited review. (See Policy VIII). The IRB Chair will document the specific review categories justifying the expedited review as well as other determinations as outlined in Policy VIII.
4. If the Chair or Vice Chair determines that the proposal meets the criteria for expedited review, the IRB Coordinator forwards the proposal within 7 days of receipt, to reviewers as indicated by the Initial Expedited xForm for IRB Chairs. The Chair or Vice Chair may choose to conduct the expedited review. If the IRB Chair determines that an external consultant is necessary, the Chair or Director is responsible for contacting the designated consultant to determine his/her availability and lack of conflict of interest, and to ensure consultant agrees to confidentiality per policies. The IRB Coordinator forwards a Conflict of Interest Form for Consultants in addition to a copy of the IRB Conflict of Interest Policy to the consultant. Upon receipt of the signed Conflict of Interest Form for Consultants indicating no conflict, the IRB coordinator immediately forwards the proposal to the consultant. If the conflict of interest form indicates any conflict, the IRB Coordinator must immediately notify the Director, and the consultant is disqualified and the proposal is not forwarded to him/her for review. Another consultant will then be identified by the Chair. The consultant's written report is then included in the proposal forwarded to reviewers.
5. The following materials are provided to the Chair and any other reviewer for expedited review applications:
 - a. Completed new protocol submission xform (VA or non-VA), which includes narrative section, with required signatory attestations
 - b. Full protocol, if applicable
 - c. Proposed informed consent document(s)*
 - d. Copies of scripts, surveys, questionnaires, or video recordings, if applicable
 - e. Relevant grant applications
 - f. Investigator's brochure (if one exists);
 - g. Advertising intended to be seen or heard by potential subjects, including email solicitations.
 - h. Investigator CV
 - i. Consultant's written report (if applicable)
 - j. for HHS supported multicenter clinical trials, a copy of

- the HHS approved sample informed consent document*
- k. for HHS supported multicenter clinical trials, a copy of the complete HHS approved protocol
- l. for studies that have an associated contract, verification from Sponsored Programs of the consistency for provisions of medical care or other care and services for research-related injury between the consent document and the contract

*Standard requirements for informed consent or its waiver or alteration apply to all studies meeting criteria for approval under the expedited criteria. (See informed consent policy)

6. If the Chair or the expedited reviewers deny expedited status, the IRB Coordinator will notify the Principal Investigator and schedule the proposal for review by the convened IRB at the next meeting.
7. The IRB Coordinator will ensure that the full Committee is advised of research proposals/activities that have been approved through the expedited review procedure. The IRB Coordinator enters the appropriate agenda date in IRBManager and creates an expedited agenda approximately two weeks prior to the convened meeting date.
8. If the expedited reviewer(s) determines an approval of the proposal, the IRB coordinator prepares the appropriate approval letters (see below). All assigned reviewer forms must be received, and an approval consensus reached before approval can be issued.
9. If an expedited reviewer requests changes, the IRB coordinator will inform the PI in writing of those requested changes requiring his concurrence. (All assigned reviewer forms must be received and all requested changes compiled.)
10. Upon receipt of those changes, the IRB Coordinator will review those changes for completeness and obtain the Chair's or his/her Designee's expedited approval of those changes. A final approval letter will not be issued until any requested changes are received and approved.

For non-VA studies, the IRB Coordinator will post the expedited approval letter on the "New Protocol Submission" event. For VA studies, the IRB Coordinator will post the approval letter as an INTERNAL ONLY attachment on the "New Protocol Submission" event in IRBManager. When the VA R&D approval letter is verified by the IRB, the IRB Coordinator will remove the "Internal only" status so that the letter is visible to study staff. For both VA and non-VA, the IRB Coordinator changes the status in IRBManager to "approved" and enters the date of the initial expedited approval as a new approval

period, enters the length of approval, and selects “calculate”. The IRB Coordinator enters “expedited” in the fields “last review” and “next review”.

11. Upon study approval (except in cases of waiver), the IRB Coordinator is responsible for posting an approved copy of the Informed Consent document in IRBManager for non-VA studies. Each page of the Consent will bear an IRB stamp of approval and expiration date over the initials of either the IRB Chair, Vice Chair, Director or IRB Coordinator. For non-VA studies, the IRB Coordinator will post the stamped approved consent document as an attachment on the “New Protocol Submission” event and on the protocol page (Attachment Section). For VA studies, the IRB Coordinator will post the informed consent document as an INTERNAL ONLY attachment on the “New Protocol Submission” event and on the protocol page (Attachment Section) in IRBManager. When VA R&D approval is verified by the IRB, the IRB Coordinator will remove the “Internal only” status so that the informed consent document is visible to study staff. In addition, for both VA and non-VA, the IRB Coordinator enters the version date and the date of approval of the informed consent document in the appropriate protocol field in IRBManager.
12. The IRB Coordinator is responsible for filing any paper documentation, and appropriate data entry in the IRBManager.

B. Principal Investigator Responsibilities

1. The PI is responsible for submitting a complete new protocol submission xform for initial review. The PI may request review through an expedited mechanism based on his/her assessment, but the IRB makes the final determination of protocol qualification. Each project is initially reviewed by the IRB Chair to determine if the project fits the criteria for expedited review. Expedited projects may be submitted to the IRB office anytime during the month. Investigators do not have to meet a submission deadline.
2. PI is responsible for submitting:
 - a. new protocol submission xform (VA or non-VA) which includes narrative portion
 - b. Full protocol, if applicable
 - c. proposed informed consent document
 - d. Copies of scripts, surveys, questionnaires, or video recordings, if applicable
 - e. Relevant grant applications
 - f. Investigator’s brochure (if one exists);

- g. Advertising intended to be seen or heard by potential subjects, including email solicitations.
 - h. Investigator CV
 - i. For studies that have an associated contract, a copy of the contract, or at minimum, a copy of any contract pages referencing provisions for medical care or other care and services for research-related injury
 - j. for HHS supported multicenter clinical trials, a copy of the HHS approved sample informed consent document*
 - k. for HHS supported multicenter clinical trials, a copy of the complete HHS approved protocol
3. If an approval pending modifications is received by the PI, the investigator is required to concur and provide written revisions of the documents in order to receive expedited approval. If the PI does not concur with the requested changes, the study will be referred to the convened board. The PI does not initiate the study until final written approval is received.
 4. If the study is deferred to the full IRB for review, the investigator is informed of the action and may choose to present the study to the board for full review or withdraw the proposal.

C. Chair Responsibilities

1. The IRB Chair evaluates the proposal and determines whether the IRB Coordinator's choice of board assignment is appropriate. The IRB Chair ensures that the proposal is assigned to the appropriate board with relevant expertise and documents this determination on the Initial Expedited Form for IRB Chairs.
2. The Chair (or Vice Chair) will determine if the research meets the regulatory applicability criteria for expedited review. Refer to Policy VIII for the listing of all applicable determinations.
3. The Chair (or Vice Chair) reviews each expedited initial submission to determine which IRB members have the relevant expertise to conduct an in-depth evaluation of the protocol. The Chair is responsible for evaluation of the proposal for recommendation of any special representation needed among the reviewers, i.e., pediatric expertise for a study involving children. The Chair determines that at least one reviewer has the appropriate scientific and disciplinary expertise and determines which IRB members will serve as expedited reviewers. In studies that involve

vulnerable populations, the IRB Chair will assign a primary reviewer that serves as an advocate for that population.

D. IRB Expedited Reviewer Responsibilities

1. IRB Expedited Reviewers may not review studies in which they have a conflict of interest. Reviewers are required to identify their conflict and return the study to the IRB coordinator for re-assignment.
2. IRB Expedited reviewers may exercise all of the authorities of the IRB except that they may not disapprove the research. The reviewers will communicate a determination of deferral to full board to the IRB administrative staff promptly so the proposal may be scheduled for full review.
3. The Expedited Reviewers have the authority to contact the PI for clarification. The contact must be documented in writing for the study file.
4. The IRB Expedited Reviewers will conduct their review in accordance with applicable IRB Policies and Procedures. Refer to IRB Policy VIII- Expedited Review Policy and Informed Consent Policy.
5. All initial expedited review determinations are completed using the criteria found in 45 CFR 46.111 for approval of research. In addition, the review interval is determined after consideration of the criteria identified in IRB Policy 8, Section VII. The reviewer documents the review of approval criteria and appropriate interval determination criteria using the Initial Expedited Reviewer xform. In addition, the reviewer documents the review of the informed consent process using Form 128 section of the xform. The reviewer who serves as an advocate for a vulnerable population documents the review of required determinations using the appropriate form(s) (Forms 130-138 sections of the xform). Reviewers will return their review within a timely manner (within 2 weeks of receipt).

References:
IRB Expedited Review Policy