Procedure


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This procedure provides guidance for the review of human subjects research activities that qualify for expedited review under the federal regulations.

I. Investigator Responsibilities.
   A. The Request for “Application for Human Research” is completed in its entirety and submitted to the HRPP for processing. The application and instructions for completion are located on the HRPP Website at http://www.mc.vanderbilt.edu/irb/.
   B. A separate protocol is required for all studies submitted for IRB review regardless of the type of review. The sponsor’s protocol may be used if it is in sufficient detail to include all of the required elements (See Health Sciences Sample Protocol and the Behavioral/Social Sciences Sample Protocol under the IRB Forms Section of the HRPP Website at http://www.mc.vanderbilt.edu/irb/).
   C. The Consent form(s) is written using the template consent document. Instructions for writing informed consent documents are located on the HRPP Website.
   D. Studies that include vulnerable populations are submitted with supplemental information demonstrating added protections and a rationale as to why these populations are to be included in the proposed research. Supplemental information is required for:
      1. Pregnant women, human fetuses, neonate and fetal material;
      2. Children;
      3. Prisoners;
      4. Cognitively impaired.
   E. Studies involving the use of an investigational drug, agent, biologic or device must be reviewed by the full Committee.
   F. The Investigator replies to all requests for revisions and/or clarifications requested by the pre-reviewers or reviewers, when applicable, and provide an explanation if the requested revisions are not made.
   G. Any proposed changes to IRB approved documents are submitted to the IRB using the “Amendment Request”. The Investigator must receive written IRB approval before implementing any changes to the research study (See HRPP Policy III.J).
   H. All serious adverse events and unanticipated problems to participants or others are submitted to the IRB using the “Report of Unanticipated Problems Involving Risk to Participants or Others”.

II. IRB Committee Responsibilities.
   A. Expedited studies are assigned to one experienced Reviewer from the designated IRB Committee for review and approval. The Reviewer assigned will have expertise in the area of the research adequate to the scope and complexity of the research. If the Reviewer has a conflict of interest, the Reviewer will contact the Regulatory Compliance Analyst and recuse themselves from the review. The Reviewer may request a second reviewer, request review by an expert consultant to the IRB, or refer the study to full IRB Committee for determination. However, the determination of disapproval can only be made at full Committee.
      1. The Reviewer reviews the “Application for Human Research” and validates or declines the researcher’s claim for review under the expedited category. When declined, the Reviewer refers the study to full Committee.
      2. The Reviewer assesses the protocol for both scientific and scholarly merit in relationship to the level of risk.
3. The Reviewer reviews the proposed research, consents, and applicable documents to determine whether the study meets criteria 45 CFR 46.111 and if applicable, FDA 21 CFR 56.111 for approval. In order to provide written documentation of these criteria, the Reviewer completes the "Reviewer's Comment" form detailing how each of these criteria is met.

4. The Reviewer determines the review interval appropriate to the degree of risk, but not less than once per year.

5. The Reviewer may request that the study be approved, approved pending modifications, deferred (with referral to full Committee), or placed on administrative hold.

6. When revisions are requested, the modified documents are re-reviewed and, if acceptable, final approval granted. If they are not acceptable, the reviewer contacts the Investigator for a resolution. If a resolution cannot be reached, the modification is referred to full Committee.

7. The Chairperson or his/her Designee verifies and signs the Committee Action Letter (CAL) or Final Approval Letter (FAL).

8. The full Committee reviews the FYI section of the weekly IRB agenda for notifications of research proposals/activities that have been approved under an expedited review procedure.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA conducts a pre-review for studies submitted requesting expedited review. The RCA determines whether the application includes all information required and requests additional information, if needed, from the Investigator, to assist the Reviewer in making a determination.

B. When the study is found by the RCA not to qualify under the criteria for expedited review, the RCA contacts the Investigator and assists with determining the appropriate level of review for which the study may qualify.

C. E-mails requesting pre-review changes are to be sent by the RCA to the Investigator.

D. The RCA assigns a Reviewer with expertise in the area of the research adequate to the scope and complexity of the research and prepares the review materials for the assigned Reviewer.

E. When consultants to the IRB are utilized, the RCA assists in obtaining a completed confidentiality agreement and the assembling and distribution of review materials.

F. Letters requesting revisions from the Reviewer and final approval letters are drafted using the appropriate template which includes a citation to the specific permissible category or categories justifying the expedited review. The letters are then forwarded to the Chairperson or his/her Designee for signature.

G. Amendments, adverse events, and continuing reviews are processed according to corresponding HRPP policies and procedures.

H. Appropriate database entries are completed, including Committee notification of all research proposals/activities that received approval under expedited review procedures on the next available agenda.