Expedited Submissions

January 2017

Background:

Federal regulations establish expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. Federal regulations define minimal risk as 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. The research must meet certain applicability criteria and fall in to one of the permissible categories of research (as defined by FDA and DHHS).

Q: How do I know if my research meets the Expedited criteria?

Research investigators who intend to involve human subjects in research will not make the final determination of Expedited from applicable Federal regulations; rather IRB Executive Reviewers (IRB Chair, Vice Chair) are responsible for reviewing the preliminary determinations of expedited made by investigators and their supervisors. Only the IRB may make the final determination that proposed research meets the regulatory criteria for Expedited. For VA research, the IRB will defer to the requirements for expedited research as outlined in the current VHA Handbook.

Q: How do I submit an Expedited Study?

All studies are submitted through our electronic myIRB system. The system allows an investigator to select the requested review type, in this case, Expedited. The investigator will continue to complete the remainder of the smartform application.

Q: What kind of IRB review is required for Expedited studies?

There are no deadlines for submitting paperwork for Expedited Review. Submissions that fit expedited criteria will be processed and assigned to a designated Executive Reviewer.

The Executive Reviewer can request additional information from the PI prior to approving an expedited submission. When official correspondence is generated, the response from the PI will be forwarded back to the requesting reviewer, when possible. If the Executive Reviewer is unable to approve the project under expedited review procedures, the Reviewer will refer it Full Board. The IRB Administrative Office will include the submission on the next applicable agenda and notify the investigator through the electronic system which full board meeting it is scheduled for review. Any expedited submission found to have issues of noncompliance (e.g. over-enrollment, failure to maintain consent forms, etc.) at the time of review by the Office Staff or the designated Executive Reviewer may be referred to the Full Board for review and action.

Q: Do I have to obtain consent from subjects on Expedited studies?

Yes, written informed consent is required prior to initiation of study procedures unless the IRB has approved the investigator’s request to waive consent or documentation of consent.
Q: Do I have to submit a Continuing Review or Revisions?

Yes, projects approved as expedited research are given an expiration date. A continuing review should be submitted to the IRB at minimum 6 weeks prior to the expiration date to avoid having the study expire. Changes in research activities must be submitted to the IRB as a Revision and approved prior to initiation. The IRB may, depending upon information submitted, change protocol status depending upon the proposed changes in the research activities. VA approved exempt protocols require continuing review by the VA R&DC as outlined in the VHA Handbook.

Q: Do I submit a closure for Expedited Studies?

Yes, as study closure will come in the form of a continuing review, and within this submission the investigator will indicate that they are closing the study.