Expedited Submissions

December 2018

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).

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

   When a protocol is submitted, the research investigator who intends to involve human subjects in research will choose “Expedited” as the submission category. Ultimately, only the IRB may make the final determination that proposed research meets the regulatory criteria for Expedited review. For VA research, the IRB will defer to the requirements for expedited research as outlined in the current VHA Handbook.

2. **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 smart form application.

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

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

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

   It depends on how the IRB approved the protocol. 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.
5. Q: Do I have to submit a Continuing Review or Revisions?

It depends, for minimal risk protocols approved under and “Expedited” category, in most instances the IRB will not require continuing review, but instead will require an every 3 year Status Report (see Investigator Guideline on Status Report.”

Projects approved as expedited research will require continuing review if under FDA guidance, or if otherwise determined by the IRB to require continuing review. When such is the case, the protocol will be 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.

6. Q: Do I submit a closure for Expedited Studies?

Yes. If the Expedited study was approved with a continuing review requirement, then the study closure will come in the form of a continuing review/closure report, and within this submission the investigator will indicate that they are closing the study. If the Expedited study was approved with a Status Report, then closure of the protocol is submitted by that activity on your myIRB history page for your study (see Investigator Guideline on Status Reports).