EXPEDITED IRB REVIEW

1. PURPOSE

This SOP establishes the procedures to be followed when a new research study, amendment, continuing review is submitted which qualifies for the IRB expedited review process. IRB Exempt submissions which require limited IRB review receive this review by IRB expedited processes.

2. POLICY

a. An IRB may use the expedited review process to review the following:

1) Any of the categories of research appearing on the list found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html unless the reviewer(s) determines and documents that the study involves more than minimal risk;
2) Minor changes in previously approved research during the period for which approval is authorized; or
3) Research for which limited IRB review is a condition of exemption.

b. The reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure.

3. DEFINITION

a. **IRB expedited review:** In lieu of full committee review, the IRB Chair may carry out the review or delegate the review to one or more experienced voting IRB members.

4. RESPONSIBILITIES

a. **IRB Chair, IRB member:** Conduct review of submitted materials and document stipulations/comments and, upon resolution of identified issues.

b. **Privacy Officer/Information Systems Security Officer:** Conduct review of submitted materials and document stipulations/comments.

5. PROCEDURES

a. IRB staff ensures all required elements for review are present, training is current for study personnel, and ensure the PI has appropriate status (i.e., PI cannot be a trainee).

b. and assigns the review to the IRB member(s) with experience pertinent to the type of study (e.g., assigns psychology studies to an IRB member who is a psychologist). If a Community Based Outpatient Clinic (CBOC) is noted as a site at which research will occur, IRB staff ensures that the MVAHCS Federalwide Assurance (FWA) includes the CBOC.

c. IRB Chair or experienced IRB member reviews the materials provided by the investigator. One or more members may be designated as a reviewer.

d. The expedited reviewer will utilize a review checklist as a guide in their review.

e. The IRB member(s) conducting the expedited review may determine that the submission may be approved by the IRB without modification or stipulate required revisions/actions. Alternatively, the reviewer(s) may determine convened IRB review is required. These decisions are conveyed to the IRB staff for follow up.

f. Upon approval of a submission by IRB expedited procedures, the IRB staff notes this approval in the electronic protocol management system for reporting to the upcoming convened IRB meeting. The approval document sent to the investigator includes documentation of the review process used.

g. The approved IRB minutes are placed in a designated folder for reporting to the upcoming RDC meeting.

REFERENCES

VHA Directive 1200.05 (01/07/2019)