IRB EXEMPT STUDIES

1. PURPOSE

This SOP establishes the procedures to be followed when a research study is submitted which appears to qualify for IRB Exempt status.

2. POLICY

Exempt activities must follow the requirements of this section and as specified in the applicable exempt category. There are eight categories of exempt research activities for research that must be compliant with the 2018 Requirements. Minneapolis VA Health Care System (MVAHCS) does not approve studies under IRB Exempt categories 7 or 8 as they entail use of broad consent.

3. DEFINITION

a. **IRB Exempt under the 2018 Requirements of the Common Rule:** Proposed work meets the criteria for exemption from IRB oversight according to 45CFR46.104.

b. **Limited IRB review:** The IRB is required to conduct a limited review to determine that when appropriate there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

4. RESPONSIBILITIES

a. **Investigators:** The investigator submits a proposed research study protocol, application, and associated components as requested.

b. **IRB Chair, IRB member and/or IRB Staff:** Exempt determinations may be made by the IRB Chair, an experienced IRB member, or qualified administrative staff with expertise in applying human research exempt regulations.

c. **Privacy Officer/Information Systems Security Officer:** Review submissions to ensure that all privacy, confidentiality, and information security elements are in compliance with federal requirements and VA policy.

d. **R&D Committee (RDC):** RDC reviews the determination made by the IRB Chair/member/staff to determine if the project may appropriately be approved as IRB Exempt research, and documents its approval.

5. PROCEDURES

a. Submissions which appear to meet IRB Exempt criteria based on the documents submitted are routed to the IRB office. IRB staff ensure all required elements for review are present, verify training is current for study personnel, and ensure the PI has appropriate status (i.e., PI cannot be a trainee).

b. IRB staff assign the review to the Information Systems Security Officer (ISSO) and Privacy Officer (PO), and to one of the following: IRB Chair, an experienced IRB member, or qualified administrative staff with expertise in applying human research exempt regulations to determine exemption status.

c. In addition to IRB exemption determination, projects which are in IRB Exempt Category 2.iii or 3.i.C. require limited IRB review.

   1) If the exempt activity involves PHI (at MVAHCS: IRB Exempt categories 2.iii., 3.i.C., 4.iii.), a waiver of HIPAA authorization must be approved by the appropriate authority (IRB or Privacy Board, or designated member of the IRB or Privacy Board), a written HIPAA authorization must be obtained from the subject or subject's LAR or a DUA for use or disclosure of a limited data set must be obtained.

d. For exempt research activities involving the investigator interacting with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human subject as applicable in writing or orally:

   1) The activity is research;

   2) Participation is voluntary;

   3) Permission to participate can be withdrawn;

   4) Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and

   5) Contact information for the VA Investigator.

e. Once IRB exemption status has been determined, the IRB will provide documentation of this status determination to the investigator.

   1) The IRB memo will note the approval to conduct the research will be made by the RDC.

   2) If limited IRB review was conducted, the memo will state this.

   3) If a HIPAA Authorization form and/or Waiver of HIPAA Authorization was reviewed by the IRB in its role as Privacy Board, this will be noted in the document to the investigator.

f. The IRB will provide the determination and the project documents to the RDC for review and approval.

REFERENCES

VHA Directive 1200.05 (01/07/2019)

45 CFR Part 46 (07/19/2018)