Research Service interaction with VA Central IRB (VA CIRB) when VA CIRB is the IRB of Record

1. PURPOSE:

This SOP establishes the procedures for local processes related to studies for which the VA Central IRB (VA CIRB) is the IRB of Record.

2. DEFINITIONS:

2018 Requirements: 45 CFR 46: *Protection of Human Subjects*, effective 2019 (replaced the Common Rule; also called the Revised Common Rule)
CIRB: Central IRB – an IRB external to MVAHCS
CR: IRB Continuing Review
CVRE: Center for Veterans Research & Education
Common Rule: 45 CFR 46: *Protection of Human Subjects*, effective 1991
EPMS: Electronic protocol management system
FDA: U.S. Food and Drug Administration
HRPP: Human Research Protection Program
IRB: Institutional Review Board
LSI: Local Site Investigator
LSL: Local Site Liaison
MCD: Medical Center Director
MVAHCS: Minneapolis VA Health Care System
NC: Non-compliance
NPC: Non-profit corporation
PI: Principal Investigator
RAB: Research Administration Board in IRBNet
RDC: Research & Development Committee
Revised Common Rule: Equivalent to the 2018 Requirements defined above.
RCO: Research Compliance Officer
SAE: Serious Adverse Event
SRS: Subcommittee on Research Safety
UP: Unanticipated Problem
UPIRTSO: Unanticipated Problem Involving Risks to Subjects or Others
UPR: Unanticipated Problem Report

3. OVERVIEW:

The VA Central IRB (CIRB) is one of the IRBs of record for research conducted at MVAHCS. Studies for which there are multiple sites within VA may have oversight by the VA CIRB rather than the MVAHCS IRB. A memorandum of understanding is in place between MVAHCS, the non-profit corporation (NPC) Center for Veterans Research and Education (CVRE), and the VA CIRB.

This SOP spells out the local responsibilities for studies under the oversight of the VA CIRB, as assured by the MVAHCS Local Site Liaison (LSL).

4. PROCEDURES:

a) MVAHCS investigators may be PI of the entire project, a Local Site Investigator (LSI), or both. The roles are approved separately by VA CIRB. The MVAHCS investigator role(s) are tracked by the MVAHCS LSL.

b) MVAHCS Investigator contacts the LSL to make aware of upcoming role as PI and/or LSI on a study under the oversight of the VA CIRB.

c) PI/LSI is referred to the application instructions in IRBNet in the Research Administration Board (RAB).

d) The LSL encourages dialogue/updates from the MVAHCS study team to facilitate smooth local review.

e) The LSL will utilize IRBNet reports to track initial and continuing approvals, and determinations regarding noncompliance/other issues reported in the conduct of the study.

NEW STUDIES

a) All MVAHCS Investigators on the project submit Research Financial Conflict of Interest Statements (COIs) through a separate package in IRBNet. This should be the first package submitted for the study. The VA - Project Cover Sheet must be submitted in this package.

b) The MVAHCS Investigator prepares the documents required by VA CIRB as noted on VA CIRB instructions, places these in an IRBNet package, and submits to MVAHCS.

c) The LSL assures the required elements are present in the package and verifies all training requirements for members of the study team have been met.

d) Once COIs are addressed by the COI Administrator, training has been verified, and all package elements have been found to be present, the LSL will download the unsigned VA CIRB Form 102 from the IRBNet package. LSL will ensure the Form 102 has been completed correctly (e.g., title, facility name). As the Form 102 is a Word document, the LSL will convert to an Adobe Form, then email it to the ACOS/Research for signature. After this signature is obtained, the LSL publishes the signed Form 102 as a Board Document.

e) Upon final approval by VA CIRB, the LSL directs the MVAHCS study team to submit a new package in IRBNet containing materials required for local review, including SRS(Research Personnel Safety Survey, Abstract) and Radiation Safety Committee, if indicated on the VA - Project Cover Sheet that radiation will be used. If non-Veterans are to be included, the request for their inclusion will be attached to this package.

f) LSL submits the VA CIRB-approved package to the R&D Committee (RDC) for review.

CONTINUING REVIEW

a) VA CIRB prompts the MVAHCS investigator to submit continuing review documents when continuing review is required.

b) The MVAHCS investigator submits a COI package to the MVAHCS Conflict of Interest board in IRBNet which includes COI disclosures for all MVAHCS investigators on the project.

c) At least 2 weeks prior to the VA CIRB due date, the MVAHCS investigator submits the continuing review package to the MVAHCS RAB. This package includes the unsigned VA CIRB Form 115c. LSL will ensure the Form 115c is completed correctly (e.g., title, facility name) and that COI review has been accomplished as applicable. As the Form 115c is a Word document, the LSL will convert to an Adobe Form, then email it to the

ACOS/Research for signature. After this signature is obtained, the LSL publishes the signed Form 115c as a Board Document.

d) The LSL will reconcile and verify training of all members of the study team as reported on the VA CIRB Continuing Review form and the VA - Project Cover Sheet.

e) The LSL will submit the package to VA CIRB in IRBNet.

AMENDMENTS & UPDATES, CLOSURES

a) The MVAHCS investigator submits packages containing amendments/updates/closures to the MVAHCS RAB.

b) The MVAHCS LSL reviews the content of amendments/updates to determine if the submissions involve personnel changes/issues which may require COI review.

c) For VA CIRB-approved amendments/updates which include changes to the informed consent document and/or HIPAA Authorization form, the MVAHCS LSL notifies the Research Compliance Officer (RCO).

d) SRS will request submission of a revised RPSS/Abstract when applicable.

e) When the MVAHCS LSL is notified by the VA CIRB of the transitioning of a study to the 2018 requirements, the LSL notifies the RCO of this determination. This will be noted in the LSL's tracking tool.

f) CLOSURES: Once the VA CIRB's memo documenting closure of the study is available in IRBNet, the LSL will place a board document in the final package indicating the required disposition of data.

(1) The LSL will change the study status in the RAB to CLOSED and add a CLOSED global tag in IRBNet.

SERIOUS/CONTINUING NON-COMPLIANCE
UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS
INFORMATION SECURITY AND PRIVACY INCIDENTS INVOLVING VA RESEARCH

a) The MVAHCS investigator submits the same package reporting these events *simultaneously* to MVAHCS and to VA CIRB in IRBNet.

b) The VA CIRB reviews and, when required, notifies the MVAHCS Medical Center Director (as Institutional Official) of any determinations of Serious or Continuing Noncompliance, or actual UPIRTSO.

c) As the LSL is not aware of VA CIRB's publication of board documents, the LSL will make a note in Outlook calendar to check for VA CIRB's determination.

d) MVAHCS LSL reads the VA CIRB's determination letter – for any determinations other than not serious and not continuing, or not UPIRTSO, the MVAHCS LSL notifies the RCO by forwarding the documents from VA CIRB.

5. REFERENCES:

VHA Directive 1200.05 (01/07/2019)

VA Central IRB Memorandum of Understanding

VA Central IRB *Investigators and Local Sites*:
https://www.research.va.gov/programs/orppe/vacentralirb/policies.cfm#5

6. **EXPIRATION DATE:** N/A

7. **FOLLOW-UP RESPONSIBILITY:** Human Research Protection Program