Use of the VA Central IRB

SOP HSP-019

VA Northeast Ohio Healthcare System
Cleveland, Ohio 44106

Service Line(s):
Research Service

Signatory Authority:
Neal Peachey, Ph.D. ACOS/Research

Effective Date:
April 13, 2023

Responsible Owner:
VA CIRB Local Site Liaison

Recertification Date:
April 12, 2028

1. PURPOSE AND AUTHORITY

a. To establish the scope, policy, and processes for the use of the VA Central IRB (CIRB).

2. PROCEDURES

a. **Use of VAIRRS/IRBNet**. All new projects, amendments, continuing review applications and reportable events are submitted to the VA CIRB in IRBNet. All new applications are submitted to the local Research Office before coming to VA CIRB in order to allow for the local assessment of feasibility and alignment with local facility's research mission. This allows for the incorporation of any relevant state laws in order to ensure the legally effective informed consent of subjects and allows for the incorporation of the local context into the review process. After initial study approval, all subsequent submissions for CIRB review (e.g., amendments, continuing review applications, reportable events) should be submitted by the researcher directly to the VA CIRB in IRBNet.

b. **New Project Submissions**. For new projects, the Principal Investigator/Study Chair (PI/SC) submits the PISC New Project Application to their local Research Office for review. After local administrative review is complete, the local Research Office submits the project on behalf of the researcher to the VA CIRB. During the VA CIRB administrative review process, revisions, clarification, or other requests may be made prior to the submission receiving IRB review

c. Once VA CIRB approves the PI/SC project, the PI/SC follows VA and local R&D Committee policies to obtain final approvals at the local Research Office. After local R&D Committee approval is received, the PI/SC shares the project with the LSI(s) in IRBNet utilizing the "Multi-Site" function.

d. The Local Site Investigator (LSI) may then compile submission documents and submit the LSI New Project Application to their local Research Office for review. After local administrative review is complete, the local Research Office submits the project on behalf of the researcher to the VA CIRB. During the VA CIRB administrative review

process, revisions, clarification, or other requests may be made prior to the submission receiving IRB review.

e. Once VA CIRB approves the LSI project, the LSI follows VA and local R&D Committee policies to obtain final approvals at the local Research Office.

f. Once all local materials have been reviewed and approved, including applicable local Research and Development subcommittee materials, an R&D Committee approval memo will be generated and sent to the LSI.

g. The study cannot be initiated until the LSI has received an approval letter from both the CIRB and VANEOHS R&D Committee and the Associate Chief of Staff for Research & Development (ACOS/R&D) has notified the investigator in writing that all approvals are in place.

h. **Continuing Review**. Continuing review of the study will be conducted by the CIRB. The R&DC will review and acknowledge the Central IRB minutes at which the continuing review was discussed and approved.

i. **Local Audits**. Studies approved by the CIRB will be audited and monitored in accordance with all relevant local policies. All audit reports will be sent to the CIRB. The CIRB will be notified if a problem is discovered, or complaint received.

j. **Training**. Investigators and study staff are required to complete all applicable trainings and processes associated with human subjects' research. See policies on www.clevelandvaresearch.org

k. Documentation of study staff training, credentialing, and privileging will be maintained at the VANEOHS.

l. **CIRB Documents**. All official communications concerning determinations made by the VA CIRB are included in the published CIRB documents in IRBNet and available to the PISC, the LSIs, and to the local facility research office, which ensures they are also available to the R&D Committees and the facility in general (including RCO access).

3. ASSIGNMENT OF RESPONSIBILITIES

a. **Associate Chief of Staff for Research (ACOS/R) or his/her designee** is assigned the responsibility to:

(1) Maintain a current Federal Wide Assurance (FWA)

(2) Maintain a formal written agreement (MOU) with the CIRB

(3) Educate the members of the research community about the requirements of all aspects of the human research protection program

b. **Research Compliance Officer (RCO)** is assigned the responsibility to:

(1) Fulfill all auditing and reporting requirements related to the oversight and implementation of the continuous quality improvement program, including projects approved by the CIRB

(2) Promptly notify the CIRB of any complaints from subjects or others; unanticipated problems involving risks to subjects or others; serious adverse events that are unanticipated and related to the research; suspension or termination of research activities; or serious or continuing noncompliance encountered in VA human subjects research projects approved by CIRB; results or outcomes of all audits of protocols approved by the CIRB

(3) RCOs identifying instances of apparent serious and/or continuing noncompliance will submit a report directly to the VA Central IRB in accordance with VHA Directive 1058.01 and VA Central IRB SOPs

(4) RCOs who identify an issue that is not immediately reportable or apparent serious and/or continuing noncompliance, but in their opinion requires review by the VA Central IRB, will submit the report directly to the VA Central IRB with a request for review of the specific issue

c. **Research & Development Committee (R&DC)** is assigned the responsibility to:

(1) Approve all research conducted at VANEOHS, including studies approved by the VA CIRB

(2) Fulfill all responsibilities required in VHA Directive 1200.01, R&D Committee, for all research in which the local facility is engaged

(3) Notify the CIRB immediately of potential research impropriety, misconduct, suspension, debarment, or restriction of any local research team member associated with a CIRB-approved project

d. **Local Site Investigator (LSI)** is assigned the responsibility to:

(1) Adhere to VANEOHS policy, SOPs, and guidance regarding the conduct of human subject's research

(2) Promptly report any apparent serious noncompliance and apparent unanticipated problems involving risks to subjects or others (UPIRTSOs) for VA CIRB review per the requirements and timeframes in VHA Directive 1058.01

e. **Local Site Liaison (LSL)** is assigned the responsibility to:

(1) Facilitate communication with the VA Central IRB and ensure that all required VA CIRB documentation is made available for the site Research Office requirements

(2) Assist other designated site personnel in performing initial and final review functions as appointed per the MOU and relaying the results to the VA Central IRB

(3) Provide results of initial local site review and approval in accordance with local R&D policies on new project applications or other types of reviews, i.e., Biosafety and/or Radiation Subcommittees, performed on a VA Central IRB-approved projects

(4) Ensure results of audits by local facility staff or outside agencies are provided in a timely manner on projects overseen by the VA Central IRB

(5) Ensure the VA Central IRB is promptly informed of actions taken by VANEOHS involving restriction, suspension, or termination of research privileges involving the LSI or the research team members associated with a CIRB-approved project.

(6) Provide feedback to the VA Central IRB on its operations and ensure the VA Central IRB is included as part of the local site annual HRPP review

(7) Ensuring the VA Central IRB is informed when personnel designated to perform functions per the MOU change

4. DEFINITIONS

a. **Principal Investigator/Study Chair (PI/SC):** the investigator who is the lead on the main study reviewed by the CIRB. The PISC has responsibility over the entire study and oversees scientific, technical, and day-to-day management of the research conducted across engaged and non-engaged local sites.

b. **Local Site Investigator (LSI):** an investigator at a site participating in a multi-site research project under the review or oversight of CIRB. The LSI leads the local site project team and serves as the main point of contact for the PISC and the CIRB concerning the conduct of the project at that site. The LSI oversees scientific, technical, and day-to-day management of the research conducted at the local site.

c. **Local Site Liaison (LSL):** the VANEOHS designee who coordinates communication between Research Administration and the CIRB.

5. REFERENCES

a. Standard Operating Procedures for the VA Central IRB, Version 10.1, dated November 1, 2021, Standard Operating Procedures for the VA Central IRB

b. VA Central IRB Memorandum of Understanding Template

c. Information for VA Central IRB Local Site Liaisons, dated November 1, 2021, Local-Site-Liaison-Responsibilities.pdf (va.gov)

d. VA Central IRB Flowchart and Instructions for PI/SC and LSI New Project Submission, dated September 27, 2021, Central IRB Administration document library in VAIRRS at https://gov.irbnet.org/

6. REVIEW

At recertification or when there are changes to the governing documents.

7. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of April 12, 2028. In the event of contradiction with national policy, the national policy supersedes and controls.

8. SIGNATORY AUTHORITY

Neal Peachey 411157

Digitally signed by Neal Peachey 411157
Date: 2023.05.18 10:45:32 -04'00'

Neal Peachey, Ph.D.
Associate Chief of Staff/Research
Date Approved:

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

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