VA Northeast Ohio Healthcare System (VANEOHS)
Medical Research Service
Standard Operating Policy/Procedure (SOP)

Effective Date: April 2, 2020

SOP Title: Use of the VA Central IRB

SOP Number: HSP-019

Version: .03

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

2. POLICY: In 2008, the Office of Research and Development (ORD) established the VA Central IRB (CIRB) to be the official IRB of record for VA Cooperative Studies (CSPs). The VANEOHS Federal wide Assurance (FWA) was amended to add the VA Central IRB as a second IRB for the facility. In 2020 the VANEOHS Federal wide Assurance (FWA) was again amended to add the VA Central IRB Board 2 as an additional IRB for the facility All VANEOHS research is the ultimate responsibility of the VANEOHS. Research reviewed and approved by the CIRB must be approved by the R&D Committee.

3. DEFINITIONS

a. **Principal Investigator/Study Chair (PI/SC):** The Principal Investigator who is the lead on the main study reviewed by the CIRB.

b. **Local Site Investigator (LSI)** – the investigator at a local participating site who leads the local site project team and serves as the main point of contact for the PI or SC and the CIRB concerning the conduct of the project at that site.

c. **Local Site Liaison** – the VANEOHS designee who coordinates communication between research administration and the CIRB.

4. RESPONSIBILITIES

a. **Associate Chief of Staff for Research (ACOS/R) or his/her designee**

(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)

(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.

c. **Research & Development Committee (R&DC)**:

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

(2) 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)**

(1) Will adhere to VANEOHS policy, SOPs, and guidance regarding the conduct of human studies research.

a. **Local Site Liaison**

(1) Facilitate communication with the VA Central IRB as needed and ensure copies of all approved study documents that are loaded onto the VA Central IRB SharePoint site are downloaded for the Research Office files as applicable; this also includes VA Central IRB reviews of serious adverse events, unanticipated problems involving risks to subjects or others, complaints, protocol deviations or other reports of non-compliance, such as VA Central IRB responses to RCO regulatory or informed consent audit reports.

(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 immediately 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 VA Central IRB-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.

5. PROCEDURE

a. The Principal Investigator/Study Chair (PI/SC) submits the New Project Application to the CIRB. When the PI/SC application is reviewed and initially approved, it is approved contingent upon receipt of local site comments. VANEOHS local site liaison will be notified by the CIRB if the facility is included in the list of potential local sites.

b. During the 30-day open review period, the local site liaison will coordinate local review by the ACOS/R and others as applicable. S/he will collect and communicate local site comments and /or concerns to the CIRB.

c. Once the 30-day open review period has ended and all local site comments have been received and the PI/SC application has been revised as needed due to comments received, the study will receive final approval and the approval date will be set by the CIRB.

d. The LSI may then submit the LSI Application package to the CIRB for review. After review and signature by VANEOHS ACOS/R, the local site application will be submitted to the CIRB through the PI/SC study team for consistency with the PI/SC application.

e. The LSI Application package will then be reviewed by CIRB. The CIRB will send the local investigator notification and may require that s/he address stipulations raised during the review. This process includes making sure the local site consent form, as well as other submission documents meet site criteria.

f. The local site investigator has 30 calendar days to address initial review considerations such as minor modifications requested by the convened CIRB. The LSI response will be sent to the CIRB for further review.

g. Once the LSI receives official approval from the CIRB, VANEOHS has 15 calendar days to determine whether it wishes to be a local site for the study. This determination is made by a review of the approved PI/SC application and approved LSI application by the local ACOS/R. This review is coordinated by the local site liaison. A copy of the approved application will be kept electronically.

h. If it is determined that the VANEOHS will not be a local site, the local site investigator and the CIRB are notified accordingly.

i. If it is determined that VANEOHS will be a local site, the local site PI will submit a complete VANEOHS new study packet and send it to the R&D Committee Coordinator for review.

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

k. Once all local materials have been reviewed and approved, including applicable local Research and Development Sub-Committee materials, an R&D Committee approval memo will be generated. The approval will be sent to the LSI, who will forward it to the CIRB study-specific Coordinator.

l. The study cannot start until the LSI has received the approval letter from both the CIRB and VANEOHS R&D Committee.

m. Electronic copies of the LSI approval letter, approved amendments, reviewed reports of serious adverse events, etc. will be kept by the local site liaison in a secured file on the Research Service shared drive.

n. 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.

o. 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.

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

6. REFERENCE: VA Central IRB Standard Operating Procedures, VA Central IRB Memorandum of Understanding Template, CIRB document Information for VA Central IRB Local Site Liaisons

7. RESCISSION: The rescission date for this SOP is April 1, 2023

8. FOLLOW UP RESPONSIBILITY: VA CIRB Local Site Liaison