Use of the National Cancer Institute's Central Institutional Review Board

SOP HSP- 001

VA Northeast Ohio Healthcare System
Cleveland, Ohio 44106

Service Line(s):
Research Service

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

Effective Date:
January 5, 2023

Responsible Owner:
ACOS/R&D

Recertification Date:
January 5, 2028

1. PURPOSE AND AUTHORITY

i. To describe the standard operating procedures (SOPs) for the use of the National Cancer Institute's (NCI) Central Institutional Review Board (CIRB) for cancer studies conducted at the VANEOHS. This SOP is supplemental to the VANEOHS IRB Policies and Procedures found at: https://www.clevelandvaresearch.com, and the NCI CIRB IRB SOPs found at: https://www.ncicirb.org/about-cirb/sops.

ii. A national Memorandum of Understanding (MOU) is in place between the Veterans Health Administration (VHA) Office of Research and Development (ORD), Office of Research Oversight (ORO), and NCI, Cancer Therapy Evaluation Program (CTEP), CIRB Initiative for human research involving NCI-sponsored cancer research conducted by VA Medical Facilities.

iii. VANEOHS may rely on the services of the NCI CIRB for review of certain cancer research human studies. Under its Federal wide Assurance (FWA00004231), VANEOHS is the Signatory Institution. The VANEOHS IRB will assist the VA R&D Committee in addressing issues related to the local conduct of research, as outlined below, that are not overseen by the NCI CIRB. The investigators must follow the NCI CIRB guidelines and must also obtain VANEOHS R&D Committee (R&DC) and applicable local research subcommittee approval to conduct these studies. Oncology studies under the purview of the NCI CIRB at VANEOHS may not enroll nonveterans, prisoners, or children.

iv. Neither the local VANEOHS IRB nor any other IRBs used by VANEOHS have regulatory jurisdiction over research conducted under the jurisdiction of the NCI CIRB.

2. PROCEDURES

a. Prior to initiating any study, the PI must complete the Annual Investigator Worksheet About Local Context and submit it to the Signatory Institution Primary Contact (SIPC) for review. Once the SIPC has completed the review and responded to the PI, the PI will then submit the form for review by the NCI CIRB. Following

approval of the NCI CIRB, the PI may begin submitting consideration for specific research studies to the appropriate local oversight committees following VANEOHS standard new study submission process.

b. Initiating a request for VANEOHS site consideration for studies overseen by the NCI CIRB:

i. The PI will submit the Study-specific Worksheet about Local Context and any other relevant documents, to the SIPC for review and consideration.

ii. The ACOS/R&D or designee will review the submission on behalf of the R&DC and determine if the study should be conducted at the VANEOHS. The ACOS/R&D or designee will communicate the determination to the VANEOHS Liaison, who will then coordinate the submission of the package to the NCI CIRB with the PI.

iii. The PI submits the Study-Specific Worksheet About Local Context to the NCI CIRB using the local CTEP site number.

iv. If needed, the PI will contact the SIPC to request access to NCI CIRB Participant Area. PI will contact the SIPC to request guidance for modified initial submission to the NCI CIRB

v. The PI submits required documents to the NCI CIRB for review.

vi. The PI receives the NCI IRB approval letter as well as the approved informed consent document.

vii. The PI submits appropriate study documents, including the approved informed consent and HIPAA authorization documents, to the SIPC, who forwards the documents to the VANEOHS IRB for review and determination on issues under their purview (to include waivers of HIPAA authorization for recruitment.)

viii. The SIPC ensures studies are reviewed, as necessary, by the Privacy Officer (PO) and Information Security Officer (ISSO) and documents the results of the reviews conducted by the PO and ISSO.

ix. The SIPC confirms completed VA credentialing and training for listed study personnel.

x. Once all requirements have been met by applicable subcommittees, The SIPC will submit NCI CIRB initial review approvals to the R&DC.

xi. The R&DC reviews the study documents, including the Study-Specific Worksheet About Local Context.

xii. The SIPC will note in the Research protocol tracking system that the NCI CIRB is the IRB of record.

xiii. The PI will be notified once final approval is received from the RD&C.

xiv. The SIPC submits NCI CIRB minutes to R&DC for review.

c. **Continuing Review/Amendments**

i. Studies that require a modification/amendment must be submitted as outlined by the NCI CIRB SOP. After NCI CIRB approval, the amendment/modification will be communicated to the R&DC by the SIPC via IRBNet.

ii. The PI will submit all required documents to the NCI CIRB for review once prompted by the NCI CIRB.

iii. The SIPC processes study personnel change and confirms completed VA credentialing prior to submitting the change to the NCI CIRB.

iv. The SIPC will receive NCI CIRB continuing review approvals, as well as amendment and other event approvals.

d. **Reporting**

i. Local unanticipated problems must be reported to the NCI CIRB Operations Office within five business days of awareness.

ii. Local apparent serious or continuing noncompliance must be reported to the NCI CIRB within five business days of awareness. This may include complaints from subjects or others, protocol deviations (as defined in the NCI “SOP for Reporting Research Events and Problems”) and audit findings.

iii. Local deaths are reported verbally immediately and written within two business days to both the ACOSR and NCI CIRB.

iv. Other serious adverse events, termination or suspension of research, and privacy or information security incidents related to VA research must be reported to the R&DC within five business days of awareness.

v. The VANEOHS R&DC will provide a plan to manage the incident, experience, or outcome, including measures to prevent similar occurrences when notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing noncompliance.

vi. The SIPC will receive copies of any NCI CIRB determinations (local or remote) that must be reported by the NCI CIRB to federal regulatory agencies.

vii. The SIPC will ensure the NCI CIRB is notified when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review.

e. **Study Closure**

i. The PI or NCI CIRB will notify the SIPC regarding study closure.

ii. The SIPC notifies the R&DC Coordinator for addition to agenda.

iii. Studies will be closed with the NCI CIRB using the procedures outlined in the NCI CIRB SOP https://www.ncicirb.org/about-cirb/sops.. In addition, the study will be closed at VANEOHS by the PI notifying the R&DC according to the VANEOHS study closeout procedures.

3. ASSIGNMENT OF RESPONSIBILITIES

a. The **Medical Center Director/ Signatory Official** is responsible for:

i. appointing in writing the SIPC to the NCI CIRB;

ii. reporting unanticipated problems, serious and/or continuing noncompliance, local deaths and other serious adverse events, termination or suspension of research, and privacy or information security incidents related to VA research, and other events originating at VANEOHS as required by VHA Directive 1058.01 to the Office of Research Oversight (ORO) and external federal agencies or oversight bodies;

iii. updating and signing the FWA; and

iv. signing the Authorization Agreement/Division of Responsibilities between the VAMC and the NCI CIRB. Copies of the initial signed agreement will be sent to the VHA Office of Research Oversight (ORO).

b. The **ACOS/R&D** is responsible for:

i. In addition to the responsibilities outlined in the VHA Directive 1200.01, the ACOS/R reviews the proposed application, and determines on behalf of the R&DC whether a study under purview of NCI CIRB should be conducted at VANEOHS prior to submission of the application to the NCI CIRB.

c. The **R&D Administration Office** is responsible for:

i. ensuring NCI CIRB requirements for enrollment of the Institution and submission of local context forms are met. Completing and submitting the Annual Signatory Institution Worksheet About Local Context, and any other

worksheets/forms required by the NCI CIRB for participation;

ii. providing boilerplate language agreed upon by the NCI CIRB and VHA that will be common to all VA research, and, with the PI, resolving concerns related to local study-specific language with the NCI CIRB;

iii. managing evaluation of financial conflict of interest;

iv. receiving correspondence on project approvals, renewals, and determinations from NCI CIRB;

v. notifying the R&DC when a VANEOHS Principal Investigator (PI) replacement is necessary;

vi. tracking and maintaining all required study related documents in the R&D protocol tracking system;

vii. If the study involves pregnant women, advising the R&DC that the proposed research meets the requirements of 45 CFR 46.204, VHA Directive 1200.05 par 19, and the ORD guidance on the conduct of such research. The R&D Administrative Office will ensure the facility Director Certification for inclusion of this vulnerable population has been completed Should a subject become pregnant while undergoing treatment in a research study, R&D Administration Office will notify the NCI CIRB for IRB review.

viii. releasing the renewed stamped study documents (informed consent and HIPAA authorization) once the continuing review approval is received from NCI CIRB;

ix. notifying the ACOS/R&D, R&DC, and Institutional Official (IO) of any determinations regarding event reports received from NCI CIRB involving VANEOHS.

d. The **R&D Committee** is responsible for:

i. overseeing the conduct of the research, monitoring protocol compliance, ensuring that reporting occurs to the NCI CIRB, and ensuring that reporting occurs by the responsible officials to ORO, the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA) and sponsors as required;

ii. providing a mechanism to receive and address concerns from local study subjects and others about the conduct of the research;

iii. ensuring the NCI CIRB is notified when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for

study review;

iv. conducting annual review of the NCI CIRB as part of an annual quality assurance review of the Human Research Protection Program (HRPP), which may include any annual self-assessment completed by the NCI CIRB;

v. reviewing the Study-Specific Worksheet About Local Context to open a study as part of the PO/ISO/Research Office review process;

vi. investigating, managing, reporting, and providing any necessary or remedial action to the NCI CIRB per their requirements of any study-specific incidents, experiences, or outcomes regarding any reportable incidents in the timeframes defined by VHA Directive 1058.01; via the methods specified by the NCI CIRB.

vii. ensuring nonveterans, prisoners, and children are excluded from enrollment in NCI CIRB approved studies;

viii. determining if flags are needed within CPRS for study participants.

ix. ensuring the Information System Security Officer (ISSO) and Privacy Officer (PO) review is complete prior to study approval;

x. providing final approval to the ACOS/R&D for all initial reviews; and

xi. acknowledging notification of NCI CIRB study closures, reviews of serious adverse events, unanticipated problems and any other items requiring R&DC oversight of the remediation or resolution of the item.

xii. identifying a designee to acknowledge PI and staff changes before they are sent to NCI CIRB to ensure the individuals are qualified.

e. The **VANEOHS IRB** is responsible for:

i. Assisting the R&DC with oversight of institutional requirements that are not overseen by the NCI CIRB;

ii. reviewing and approving requests for waivers of Health Insurance Portability and Accountability Act (HIPAA) authorization needed for subject recruitment and ensure that the investigator has made the correct determination about whether a HIPAA Authorization or a Waiver of Authorization is required.

f. The **PI** is responsible for:

i. completing and submitting the Annual Investigator Worksheet about Local Context, the Study-specific Worksheet about Local Context, the Proposed Project Questionnaire (PPQ), and any other relevant documents, to the

VANEOHS R&D Administration Office;

ii. incorporating VA-approved specific language into the NCI CIRB-approved model consent form to create the consent form to use for a specific study; Where VA-required language may conflict with IRB approved language, the PI and/or study team member providing the informed consent process must explain any conflicts.

iii. developing a recruitment plan, which includes, when applicable, a waiver of HIPAA authorization for screening/recruitment approved by the VANEOHS IRB;

iv. maintaining regulatory documents for each study under NCI CIRB purview;

v. providing timely notification of NCI CIRB approval of staff changes to the SIPC whenever a VANEOHS Principal Investigator is replaced, or study personnel are added or removed

vi. maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;

vii. notifying the SIPC if a subject becomes incarcerated or pregnant during participation in a study;

viii. developing a study-appropriate plan for determining (and, as applicable, monitoring) decisional capacity;

ix. forwarding all applicable continuing review and any other event review materials to the SIPC once uploaded by NCI CIRB;

x. reporting to the NCI CIRB all reportable events and/or incidents as defined and required by VHA Directive 1058.01;

xi. reporting to the VANEOHS R&DC or SIPC any reportable incidents as defined by VHA Directive 1058.01; and

xii. assuring studies are reviewed as necessary by the PO and ISSO and documenting the results of those reviews;

g. The **VANEOHS** Signatory Institution Primary Contact (SIPC) is responsible for:

i. acting as the institutional designee to receive all NCI CIRB notifications that are communicated to VANEOHS researchers;

ii. maintaining VANEOHS NCI CIRB study files;

iii. administrative review of initial and ongoing qualifications of investigators and research staff;

iv. as needed forwarding appropriate study documents to VANEOHS IRB for review and approval;

v. assuring studies are reviewed as necessary by the PO and ISO and documenting the results of those reviews;

vi. processing study personnel changes;

vii. submitting initial and continuing review approvals to the VANEOHS R&DC;

viii. sending lapse notices to the PI following notification from the NCI CIRB of the lapse;

ix. processing requests for study closure;

x. responding to requests for consultation, (i.e., questions regarding IRB policies and procedures, etc.) from investigators, research staff, clinicians, etc., IRB members and/or Chairs.

xi. submitting NCI CIRB minutes to R&DC for review and approval.

xii. receiving copies of any NCI CIRB determinations (local or remote) that must be reported by the NCI CIRB to federal regulatory agencies.

h. The **Research Compliance Officer (RCO)** is:

i. Conducts audits to ensure compliance with applicable federal, VA and local policy.

ii. Reports any study-specific incident, experience, or outcome that may rise to the level of an apparent unanticipated problem and/or apparent serious or continuing noncompliance per the requirements of VHA Directive 1058.01.

iii. Reports to the NCI CIRB are sent by the Signatory Institution Principal Investigator (PI) per VHA Directive 1058.01 via the pathway described by the NCI CIRB SOPs.

iv. Submits all audit reports to the R&D Committee. Note: According to the Authorizing Agreement, the NCI CIRB does not oversee the conduct of the study. Therefore, the audit reports with no immediate findings do not need to be sent to the NCI CIRB. Only apparent unanticipated problems and/or apparent serious or continuing noncompliance should be submitted to NCI CIRB by the PI.

4. DEFINITIONS

a. "None."

5. REFERENCES

a. VHA Directive 1205.05, Requirements for the Protection of Human Subjects in Research http://vaww.va.gov/vhapublications/publications.cfm?Mode=CURRENT&pub=2&order=asc&orderby=pub_Number)

b. VHA Directive 1058.01, Research Reporting Requirements http://vaww.va.gov/vhapublications/publications.cfm?Mode=CURRENT&pub=2&order=asc&orderby=pub_Number)

c. Checklist for VAs establishing an Authorization Agreement with the NCI Central IRB https://www.swog.org/sites/default/files/docs/2018-09/CIRBChecklist.pdf

d. NCI CIRB website https://www.ncicirb.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 January 5, 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: 2023.01.11 15:12:44 -05'00'

Neal Peachey
Associate Chief of Staff/Research
Date Approved: January 5, 2023

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

DISTRIBUTION: This will be posted on the Research Service website: https://www.clevelandvaresearch.org/