RESEARCH AND DEVELOPMENT COMMITTEE
PROJECT STATUS UPDATE AND CONTINUING REVIEW PROCEDURES

SOP RD-003

VA Northeast Ohio Healthcare System
Cleveland, OH 44106

Service Line(s):
Research

Signatory Authority:
VANEOHS Associate Chief of Staff/R&D

Effective Date:
April 1, 2021

Responsible Owner:
VANEOHS RDC Coordinator

Recertification Date:
April 30, 2026

1. PURPOSE AND AUTHORITY

a. The purpose of this SOP is to establish procedures for continuing review and project status updates of research studies by the Research & Development Committee (RDC). This SOP must be followed for any study under sole oversight of the RDC.
b. With the exception of exempt human subjects research studies, the RDC must conduct continuing reviews for studies under the sole oversight of the RDC according to VHA Directive 1200.01. For exempt research under sole RDC oversight, a project status update is required annually.

2. PROCEDURES

a. Project Status Update

i. Exempt human research studies that are under the sole oversight of the RDC do not require continuing review by the RDC. For these studies, investigators must submit an RDC Project Status Update form annually.
ii. All personnel serving in an investigator role are required at the time of the project status update to submit a VA OGE Form 450 (Research FCOI) to the research office for review.

b. Continuing Review

i. For studies requiring RDC continuing review, the RDC will conduct the review at intervals that are appropriate to the level of risk for each research protocol, but not less than once per year. Continuing review must occur as long as the project remains active with the RDC.

ii. The investigator must complete the RDC Continuing Review form and submit in VAIRRS/IRBNet. Information that must be received by the committee from the PI for continuing review includes:
   (a) Scientific progress of the research.
   (b) Budget requirements changes.

(c) Changes in requirements for space, personnel, equipment, and supplies.
(d) Summary and impact of any unanticipated problems.
(e) Any issues of serious non-compliance with applicable policies, including privacy and security that have occurred since last approval.

iii. All personnel serving in an investigator role are required at the time of continuing review to submit a VA OGE Form 450 (Research FCOI) to the research office for review.

iv. If the VA research activity can be approved by a R&D Committee through a designated review process, such as exempt human subject research protocols and protocols approved by expedited review by the IRB, the continuing review can be approved by designated review.

v. Once the R&D Committee approves the protocol's continuation, written notification is sent to the PI.

vi. For each initial or continuing approval, the RDC will indicate an approval period with an approval expiration date specified when the study is under sole RDC oversight. RDC approval is considered to have lapsed at midnight on the expiration date of the approval. For a study approved by the convened RDC, the approval period starts on the date that the RDC conducts its final review of the study. For a study approved under designated review, the approval period begins on the date the RDC Chairperson or RDC member(s) designated by the Chairperson gives final approval to the protocol. The approval date and approval expiration date are clearly noted on the initial RDC approval letter and RDC continuing review approval letter. Investigators should allow sufficient time for development and review of renewal submissions.

vii. The PI will receive automatic alerts from VAIRRS/IRBNet at 90, 60, and 30 days prior to expiration, and on the day of study expiration, should the study expire.

viii. If the study expires, the RDC Coordinator, ACOS/R&D and RDC Chairperson are copied on the expiration alert sent to the PI. The regulations permit no grace period or approval extension after approval expiration. Research that continues after the approval period has expired is research conducted without RDC approval. If the continuing review does not occur within the timeframe set by the RDC, all research activities must stop, including interventions, interactions, data collection, and data analysis. An IRBNet alert will notify the investigator of the expiration of approval and that all research activities must stop. The study expiration will be placed on the next RDC agenda for review action by the RDC.

3. DEFINITIONS

a. **Research and Development Committee.** The RDC is a committee formally established by a VA medical facility to review, approve, require modification, disapprove, and oversee research in accordance with VHA Directive 1200.01. An R&D Committee at each facility oversees the maintenance of high standards within VA's research program and ensures that VA research is scientifically valid and complies with regulatory and ethical standards

b. **Principal Investigator.** The Principal Investigator (PI) is a qualified person who directs a research study or program. The PI oversees scientific, technical, and day-to-day management of the research. If a study is conducted by a team of individuals, the PI is the responsible leader of that team.

c. **Exempt Human Subjects Research.** Research activities in which the only involvement of human subjects will be in one or more of the categories outlined in 38 CFR 16.104(d) and which have been determined to meet criteria for exemption by the VA facility's exempt determination officials. A complete list of the exempt categories for VA Research can be found in VHA Directive 1200.05.

4. REFERENCES

VHA Directive 1200.01, Research and Development Committee, dated January 24, 2019 (amended January 8, 2021).

5. REVIEW

Review is required at minimum at recertification. This review is documented on the VAIRRS/IRBNet site (see https://gov.irbnet.org/release/index.html)

6. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of April 2026. In the event of contradiction with national policy, the national policy supersedes and controls.

7. SIGNATORY AUTHORITY

Neal Peachey 411157

Digitally signed by Neal Peachey 411157
Date: 2021.04.07 11:49:27 -04'00'

Neal Peachey
VANEOHS Associate Chief of Staff/R&D
Date Approved: April 1, 2021

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

DISTRIBUTION: SOPs are available at: https://www.clevelandvaresearch.org/research-sops