

SUBJECT: ACOS/R&D Approval Prior to Initiation of Research

1. PURPOSE:

To ensure that all research conducted at the Minneapolis VA Medical Center has received all necessary review prior to initiation.

2. DEFINITIONS:

ACOS/R: Associate Chief of Staff for Research

ACR: Authorization to Conduct Research form

CIRB: a Central Institutional Review Board

IACUC: Institutional Animal Care and Use Committee

IRB: Institutional Review Board

PI: Principal Investigator

R&D: Research and Development

RDC: Research & Development Committee

SRS: Subcommittee on Research Safety

3. OVERVIEW:

No research may be initiated until the Associate Chief of Staff for Research and Development (ACOS/R) has signed the Authorization to Conduct Research (ACR) document, certifying that the project has undergone review and approval by the appropriate committee, subcommittee(s), or other entities.

4. PROCEDURES:

- a) **Initial Review:** Initial Review will be performed by the applicable committee or subcommittee(s) (i.e. IRB, a CIRB, IACUC, SRS, and/or RDC).
 - i) Approval from each relevant review subcommittee will be recorded in an electronic protocol management system by an authorized representative (e.g., IRB Coordinator, Research Safety Coordinator, etc.) following the review and the completion of any additional actions required to secure final approval. For CIRB projects, an authorized representative of the Research Service will record CIRB approval. If more than one subcommittee is reviewing the protocol, an authorized representative from each subcommittee will record approval as needed.
 - ii) When all subcommittees have approved a proposed research project, the application will be routed to the R&D Committee for review. Upon RDC review and approval, the RDC Coordinator will create an outcome letter showing RDC approval (Authorization to Conduct Research).
 - iii) The Authorization to Conduct Research document will be sent to the ACOS/R or the Acting ACOS/R&D for signature. The ACOS/R or delegate will verify any discrepancy with funding or administration of funding for the project prior to signing the ACR. For projects that indicate use of a CRADA or other research contract, the ACOS/R will verify that relevant agreements are fully executed prior to signing the ACR.
 - iv) Receipt of the ACR by the Principal Investigator indicates both RDC approval and that the research may be initiated. The ACR will also inform the study staff that any relevant approval memos from responsible subcommittees will be available under study

correspondence in the electronic protocol management system. The investigator must not initiate research prior to receipt of the ACR.

- b) **Continuing Review:** Continuing review requires approval by all research review committees and notification to the investigator that the approvals have been obtained. The same general procedure described in Section (a) above will be conducted for all continuing reviews:
 - i) Approval from relevant review subcommittee(s) will be recorded by authorized representative(s) as above. The RDC does not review or vote to approve Continuing Reviews for projects in which the RDC is not the committee of record.
 - ii) When each relevant subcommittee has approved continuing review of a research project, the subcommittee will create a notification memo to be sent to the investigator.
 - iii) Unlike initial approval, the ACOS/R&D is not required to notify investigators that the continuing review is complete.
- c) **Unapproved Research Activity:** Conduct of research before written confirmation of ACOS/R&D initial approval in the form of the ACR represents potential serious noncompliance and may result in disciplinary action.

5. **REFERENCES:**

VHA Directive 1200.01 “Research and Development Committee” (24 January 2019)

VHA Directive 1200.05 “Requirements for the Protection of Human Subjects in Research” (07 January 2019)

6. **R&D COMMITTEE APPROVAL:** 07 January 2025

7. **RECISSIONS:** Minneapolis Research Service SOP R&D-011 “ACOS/R&D Approval Prior to Initiation of Research” (05 April 2022).

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

9. **FOLLOW-UP RESPONSIBILITY:** Research and Development (R&D) Committee