

Louis Stokes Cleveland DVA Medical Center
Medical Research Service
SOP Cover Page

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SOP Title: Research and Development Committee Submission Procedure for Non-VA Funded Projects

SOP Number: RD-003

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Signature



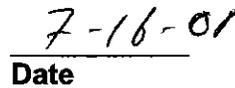
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Approved By:

Associate Chief of Staff for Research



Signature

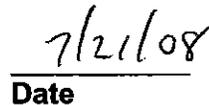


Date

Chairperson of the Research and Development Committee



Signature



Date

Louis Stokes Cleveland DVA Medical Center
Medical Research Service
Standard Operating Procedure

Effective Date: 7/11/08

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1. **Purpose:** To establish review procedures to allow research projects conducted under the auspices of the LSCDVAMC to be submitted to the Research and Development (R&D) Committee for approval to conduct research. This Standard Operating Procedure (SOP) specifically addresses the review process for research projects to be submitted for funding to within the VA system. Specifically this SOP defines the submission process for Merit, Career Development Award, VISN Research Initiative Program grants, Research Enhancement Award Programs, and other applications to the VA.
2. **Policy:** The Committee is responsible for maintaining high standards throughout the R&D Program, which include ensuring the scientific and ethical quality of VA research projects, the protection of human subjects in research, the safety of personnel engaged in research, the welfare of laboratory animals, security of VA data, and the security of VA research laboratories.
3. **Definitions:**
 - a. Research under the auspices of the LSCDVAMC. Research considered under the auspices of the LSCDVAMC includes all research that is conducted completely or partially in LSCDVAMC facilities, conducted in approved off-site locations, facilities, and/or conducted by LSCDVAMC researchers, employees, or agents, while on official LSCDVAMC duty time. It includes research conducted using non-public patient data from LSCDVAMC records, recruiting LSCDVAMC patients at LSCDVAMC facilities, utilizing LSCDVAMC resources, publishing or presenting results with the VA cited as supporting or conducting the research. The research may be VA funded, funded from non-VA entities, or conducted without direct funding.
 - b. Complete VA Funded Project Submission. A complete VA funded project submission is composed of the following completed forms:
 - 1) Request to Review Research Proposal (RRRP)
 - 2) All VA specific application forms (10-1313-1 through 8).
 - 3) Application narrative.
 - 4) Data Security Checklist. This may be addressed under the RRRP or as a stand alone document as determined by current procedures. If the Principal Investigator intends to take data offsite, other documents in addition to the Data Security

Checklist should be included (these may include a Memo to Remove Sensitive Research Information, Data Transfer Agreement, or Data Use Agreement). The Principal Investigator should consult the Information Security or Privacy Officer when developing his or her research plan.

- 5) Conflict of Interest Statements for each of the study staff who will be working on the proposed research project.
 - 6) Letters of Support for Services. This may be addressed under the RRRP or as a stand alone document as determined by current procedures.
 - 7) Response to reviewers (If the proposal is a resubmission of a Merit Award or Career Development Application this is limited to 3 pages).
 - 8) Off Site Research Request (if applicable).
- c. Just in Time (JIT) submission process. JIT procedures allow research projects to be submitted for funding consideration prior to receiving final R&D Committee approval to conduct the research. Research protocols that are to be submitted to VA, other Federal agencies, or other entities for funding consideration must undergo a preliminary review and receive concurrence from the R&D Committee prior to submission of the protocol to VA under a JIT procedure.
 - d. R&D Subcommittees. Subcommittees of the R&D Committee include the LSCDVAMC Institutional Animal Care and Use Committee (IACUC), the LSCDVAMC Institutional Review Board (IRB), and the LSCDVAMC Subcommittee on Research Safety (SRS).
 - e. Final R&D Committee Approval. Final R&D Committee Approval is defined as approval from all relevant R&D Subcommittees and hospital committees (these include, but are not limited to, the Environment of Care, Laser, Pharmacy and Therapeutics, and Radiation Safety Committees). Final approval is required before the Principal Investigator may begin research.

4. Responsibilities:

- a. The R&D Committee is responsible for reviewing VA funded submissions under a JIT process. Proposals funded by Merit or Career Development Award Applications will be evaluated by the R&D Committee to ensure the following:
 - 1) The Principal Investigator is qualified to conduct the research.
 - 2) Adequate and appropriate resources are available to complete the proposed research. This includes the presence of an adequate and appropriate budget.
 - 3) The proposed research has scientific merit and is feasible (in some cases this may require preliminary data).
 - 4) The proposed research is relevant to the VA mission.
 - 5) Data security concerns associated with the proposed research are appropriately addressed.

- 6) That human protection standards are in place.
 - 7) That standards of animal welfare are met.
 - 8) There is no conflict of interest for either the research staff or the LSCDVAMC.
- b. Principal Investigators are responsible for initiating R&D Committee review of VA funded project submissions prior to submitting the projects for funding. They are also responsible for submitting documents to the R&D Subcommittees and ensuring that they have final R&D Committee approval prior to initiating the project.
 - c. The R&D Subcommittees are responsible for reviewing, requesting modification of, and rendering a determination of approval or disapproval on each submitted proposal as outlined under their respective SOPs.

5. Procedures:

- a. The Principal Investigator will submit a complete Merit and/or Career Development Award Application as described earlier in this SOP. The R&D Committee Coordinator will place this proposal on the agenda for the next available R&D Committee Meeting. The LSCDVAMC will be responsible for making the R&D Committee Meeting schedule publicly available.
- b. Administrative Pre-review: All VA funded project proposals submitted to the R&D Committee will undergo an administrative pre-review. During this pre-review the R&D Coordinator will ensure that the submission is complete and has no outstanding concerns. Outstanding concerns are defined as incomplete or inconsistent documentation of proposed research procedures as this relates to
 - 1) Completeness.
 - 2) The presence of conflict of interests both at the level of Research Staff and the Institution.
 - 3) Security of VA data.

The Principal Investigator will be notified by the R&D Coordinator of the outstanding issues and have an opportunity to redress them. If a research proposal is incomplete the proposal may be returned at the discretion of both the R&D Chairperson and R&D Coordinator.

- c. Proposals funded by VA funds will be evaluated by the R&D Committee to ensure the following:
 - 1) The Principal Investigator is qualified to conduct the research
 - 2) Adequate and appropriate resources are available to conduct the proposed research. This includes the presence of a complete budget.

- 3) The proposed research has scientific merit and is feasible (in some cases this may require preliminary data).
 - 4) The proposed research is relevant to the VA mission
 - 5) Data security concerns are appropriately addressed.
 - 6) That human protection standards are in place.
 - 7) That standards of animal welfare are met.
 - 8) Safety
 - 9) There is no conflict of interest for either the research staff or the LSCDVAMC.
- d. Determinations will be made for each funding proposal according to the following procedure:
- 1) The R&D Committee will review each VA funding proposal received and make one of the following determinations:
 - a) Approvable as submitted. Indicating that the proposal as reviewed by the R&D Committee requires no further revision and may be forwarded to the VA with no further changes necessary.
 - b) Approvable with suggestions for improvement. Indicating that minor changes are suggested that may improve the likelihood of the proposal being funded by the VA. These suggestions may be followed at the discretion of the Principal Investigator.
 - c) Approvable with minor changes or conditions. Indicating that minor changes must be made to the proposal with subsequent review and approval by the assigned R&D Committee Primary Reviewer(s), Chairperson, or Vice-Chairpersons if the Chairperson is not available prior to the proposal being forwarded to the VA.
 - d) Approvable with major changes or conditions. Indicating that major changes must be made along with subsequent review and approval by a fully convened R&D Committee meeting prior to the proposal being forwarded to the VA.
 - e) Deferral. Indicating the submission as submitted contains insufficient information to review the proposed research project. The proposal may be resubmitted to the R&D Committee with sufficient information for further consideration.
 - f) Disapproval. The proposal as submitted will not undergo further consideration.

The determination for a given proposal will be communicated to the associated Principal Investigator, in writing, usually within three business days of the R&D Committee meeting during which the proposal was reviewed.
- e. Once the R&D Committee has given the proposal initial approval, research protocol

specific documents (such as, ACORPs, Research Plans, IRB Initial Review Applications) will be submitted by the Principal Investigator to the appropriate subcommittees (IACUC, IRB, SRS) in a timely manner to ensure funding or the collection of supporting data for the VA application.

- f The R&D Subcommittees will review, modify, or render a determination regarding each submitted proposal as outlined through their respective SOPs. The R&D Subcommittee Coordinators will notify the R&D Coordinator in writing of the respective subcommittee's approval in a timely manner.
- g Once all R&D Subcommittee approvals are obtained the R&D Committee Coordinator and Chairperson or Vice-Chairperson will review the approved research proposal and associated protocol documents to ensure that all appropriate subcommittee and extra-research approvals have been obtained. The proposal will be listed on the agenda for the next R&D Committee Meeting. Objections by the R&D Committee, in the form of a quorum based majority vote based on scientific quality, ethical quality, and security of VA data, may rescind the approval of the proposal.
 - 1) If a proposal is found to be lacking in scientific quality, ethical quality, and security of VA data by the Committee the Principal Investigator will be notified in writing of this finding. The Principal Investigator will have the opportunity to redress these issues as described in the Return of Studies to the Research and Development Committee SOP (RD-006).
- h If the proposal is given Final R&D Committee Approval, the Principal Investigator will be notified of final approval in writing by the R&D Committee Coordinator. The approval and all copies of relevant research materials will be returned as described in IRB and IACUC SOPs. The Principal Investigator may begin the proposed research project when and only when the proposal has received Final R&D Committee Approval.
 - 1) If a proposal has both animal and human research components the proposal may be given partial Final R&D Committee approval for the animal or human component of the research alone. To achieve partial approval the proposal will need to have gained approval from the SRS and approval from the IACUC or IRB as appropriate. Final R&D Committee approval, for a project with both animal and human research components is contingent upon approval from both the IACUC and IRB.

6. References: VHA Handbook 1200.1
Return of Studies to the Research and Development Committee SOP (RD-006)

7. Rescissions: None

8. Follow-Up Responsibilities: R&D Committee Coordinator