

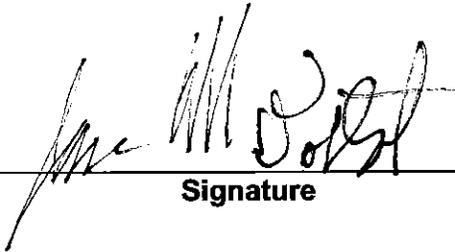
Louis Stokes Cleveland DVA Medical Center
Medical Research Service
SOP Cover Page

Effective Date: July 15, 2008

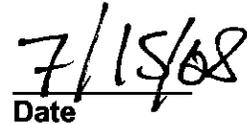
SOP Title: Research and Development Committee Submission Procedure for Non-VA
Funded Projects

SOP Number: RD-004

Author: Jesse M. Dostal
Title: Health Science Information Officer
SOP Version: .01



Signature



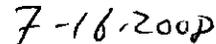
Date

Approved By:

Associate Chief of Staff for Research



Signature

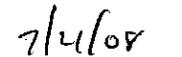


Date

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

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

SOP Number: RD-004

SOP Version: .01

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 non-VA funded research proposals.
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 VHA 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. Non-VA Funded Research Proposals. Non-VA Funded Research Proposals are proposals, which are not receiving VA monetary support and for which Principal Investigator does not intend to submit for VA funding.
 - c. Complete non-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) A copy of the complete non-VA funding proposal.

- 3) VA formatted abstract in electronic format. This may be addressed under the RRRP or as a stand alone document as determined by current procedures.
- 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) Complete Budget. This may be addressed under the RRRP or as a stand alone document as determined by current procedures.
- 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) Conflict of Interest Statements for each of the study staff who will be working on the proposed research project.
- 8) Research Protocol Safety Survey.

If a proposal has a human subjects' research component complete proposals will also include the following completely filled out documents:

- 1) IRB Initial Review Application.
- 2) IRB Research Plan.
- 3) Consent or Request for Waiver of Consent Documents.
- 4) Authorization for Release of Protected Health Information for Research Purposes or Waiver Documents (if applicable).
- 5) Request for Expedited Review (if applicable).

If a proposal has an animal research component complete proposals will also include the following completed documents:

- 1) Animal Component of Research Protocol (ACORP).
- 2) ACORP Appendices.

If a proposal is deemed exempt from IRB review but still involves human subjects' research components complete proposals will also include the following completed documents:

- 1) IRB Initial Review Application
- 2) IRB Research Plan

- 3) Authorization for Release of Protected Health Information for Research Purposes or Waiver Documents (if applicable)

If a proposal involves only basic science research complete proposals will also include:

- 1) Research Plan

Basic science research involves no animals, animal tissue (including human) or human data.

- d. R&D Subcommittees. Subcommittees of the LSCDVAMC R&D Committee (also referred to as 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 Associate Chief of Staff of Research and Development (ACOS/R) is responsible through the R&D Committee for reviewing non-VA funded submissions. Proposals funded by Merit or Career Development Award Applications will be evaluated by the R&D Committee to ensure the following:
 - 1) The scientific methodology is appropriate;
 - 2) The project is relevant to the VA's mission;
 - 3) The investigator is qualified to conduct the research;
 - 4) Adequate resources are available to conduct the research.
- b. The R&D Committee is responsible for reviewing all research under the auspices of the LSCDVAMC:
 - 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. Investigators are responsible for initiating R&D Committee review of non-VA funded Applications prior to actually submitting the projects for funding under the R&D Committee expedited review of research projects to be submitted for other than VA funding SOP. They are also responsible for submitting complete R&D Subcommittee documents described earlier in this SOP.
 - 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 investigator will submit to the ACOS/R and the R&D Committee Coordinator via e-mail or hardcopy the entire proposal including the narrative and the budget as well as a statement of the relevance to the VA's mission.
- b. The ACOS/R will review the submission and complete the Expedited Review Checklist. This review will determine whether:
 - 1) The scientific methodology is appropriate.
 - 2) The project is relevant to the VA's mission.
 - 3) The investigator is qualified to conduct the research.
 - 4) Adequate resources are available to conduct the research.

If the ACOS/R is not available the R&D Committee Chairperson, or one of the Chairpersons will conduct the review.

- c. The ACOS/R will send a communication via e-mail to the Investigator, the R&D Coordinator and the R&D Chairperson indicating whether the project is approved for external submission or if there are concerns that must be addressed prior to submission. This action will be reported at the next meeting of the R&D Committee.
- d. Before the research can be initiated, the investigator must submit a complete package to the R&D Committee for review and approval before it is forwarded to the appropriate subcommittees. This will include, but is not limited to the RRRP,

Conflict of Interest Statements, the Principal Investigator's Checklist and Data Security Certification, the budget as well as applicable subcommittee forms.

- e. The Principal Investigator will submit a complete non-funded project proposal 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.
- f. 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 Committee Coordinator of any outstanding issues and have an opportunity to address them. Incomplete research proposals may be returned to the Principal Investigator at the discretion of either the R&D Committee Chairperson or R&D Committee Coordinator.

- g. Proposals funded by non-VA entities will be evaluated by the Research and Development 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) There is no conflict of interest for either the research staff or the LSCDVAMC.
- h. Determinations will be made for each funding proposal according to the following procedure:

- 1) The R&D Committee will review each non-VA funded 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 respective R&D Subcommittees 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 approved outright by the respective R&D Subcommittees. 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 it to the respective R&D Subcommittees.
 - 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 it to the respective R&D Subcommittees.
 - 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.

- i. Provided 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.
- j. The R&D Subcommittees will review, modify, or render a determination regarding each submitted proposal as outlined through their SOPs. The R&D Subcommittee Coordinators will notify the R&D Coordinator in writing of the respective subcommittee's determination.
- k. 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).
- I. 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 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 Final R&D Committee approval for the animal component of the research or the human subjects' component of the proposal. If the IACUC has approved the animal component of the research, the SRS has approved the animal components of the proposal, and all other conditions listed above are met outside of IRB Approval. Human Subjects Research R&D Committee Approval may given if the IRB has approved the human subjects research component of the research, the SRS has approved the human research components of the proposal, and all other conditions listed above are met outside of IACUC Approval.
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