

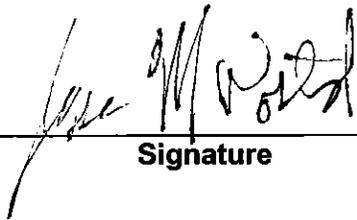
Louis Stokes Cleveland DVA Medical Center
Medical Research Service
SOP Cover Page

Effective Date: July 15, 2008

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

SOP Number: RD-005

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SOP Version: .01



Signature



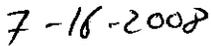
Date

Approved By:

Associate Chief of Staff for Research



Signature

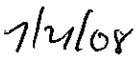


Date

Chairperson of the Research and Development Committee



Signature



Date

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

Effective Date: 07/11/08

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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 & Development (R&D) Committee for approval to conduct research. This Standard Operation Procedure (SOP) specifically addresses the review process for non-funded research projects.
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. Non-Funded Project Submission. A Non-Funded Project Submission is a project proposal that will receive no monetary support from a public or private institution.
 - c. Complete Non-funded Project Submission. A complete non-funded project submission is composed of the completed forms:
 - 1) Request to Review Research Proposal (RRRP)
 - 2) VA formatted abstract in electronic format whether these are covered under the Request to Review Research Proposal or as a stand alone document as determined by the current Research Services current documents

- 3) 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 document 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.
- 4) Complete Budget. This may be addressed under the RRRP or as a stand alone document as determined by current procedures.
- 5) Letters of Support for Services whether these are covered under the Request to Review Research Proposal or as a stand alone document as determined by the current Research Services current documents
- 6) Conflict of Interest Statements for each of the study staff who will be working on the proposed research project
- 7) Research Protocol Safety Survey.

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

- 1) IRB Initial Review Application.
- 2) Research Plan and all forms required by this document.
- 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 R&D Committee is responsible for reviewing all research under the auspices of the LSCDVAMC. Non-funded proposals are covered under this mandate. Non-funded research proposal 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 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 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-funded research proposals prior to initiating projects. They are also responsible for submitting complete R&D Subcommittee documents, defined

earlier in this SOP, at the time of initial submission to the to the R&D Committee.

- 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 non-funded project proposal as described earlier in this document. 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 non-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.

- c. Non-funded proposals 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) There is no conflict of interest for either the research staff or the LSCDVAMC.
- d. Determinations will be made for each non-funded project proposal according to the following procedure:
 - 1) The R&D Committee will review each non-funded research proposal 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.

- 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 R&D Coordinator to the appropriate subcommittees (IACUC, IRB, SRS) in a timely manner.
- f. The R&D Subcommittees will review, request modifications, 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 approval.

- 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).
 - 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.
 - 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