

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

Effective Date: July 15, 2008

SOP Title: Research and Development Committee Operations Procedure

SOP Number: RD-001

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SOP Version: .01

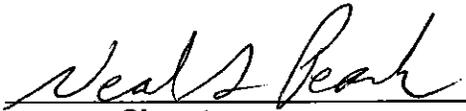


Signature

7/15/08
Date

Approved By:

Associate Chief of Staff for Research



Signature

7-16-2008
Date

Chairperson of the Research and Development Committee



Signature

7/21/08
Date

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

Effective Date: 7/11/08

SOP Title: Return of Studies to the Research and Development Committee Procedure

SOP Version: RD-006

1. Purpose: To establish a mechanism by which R&D Subcommittees may address scientific, resource, ethical, or data security deficiencies in research proposals or amendments to research proposals.

2. Policy: The R&D 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. In the course of performing research Investigators may make modifications to proposals that change or challenge their status with regard to the areas under the R&D Committee's purview.

3. Definitions:

- a. The 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).
- b. Research under the auspices of the LSCDVAMC. Research 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 VA duty time. It includes research conducted using non-public patient data from VA records, recruiting VA patients at VA facilities, utilizing VA resources, publishing or presenting results with the VA cited as supporting or conducting the research.

4. Responsibilities:

- a. The Research and Development Committee is responsible for evaluating research according to the following conditions:
 - 1) The Principal Investigator is qualified to conduct the research
 - 2) There is no Conflict of Interest for either the research staff or the LSCDVAMC
 - 3) Adequate resources are available to complete the proposed research
 - 4) The proposed research has scientific merit
 - 5) The proposed research is relevant to the VA mission

- 6) Data security concerns associated with the proposed research are appropriately addressed.
- b. The R&D Subcommittee's are responsible for reviewing research proposals as described in their respective SOPs and reporting any change or challenge to a research proposal's status with regard to the areas under the R&D Committee's purview to the R&D Committee.

5. Procedures:

If an R&D Subcommittee finds that the research proposed either in the initial application for approval or in an amendment changes or challenges the proposal's science, resources, ethics, or data security plan the subcommittee may choose to refer the proposal to the R&D Committee through the following procedure:

- a. The respective R&D Subcommittee Coordinator will communicate the subcommittee findings to the investigator with a copy of the targeted request for review by the R&D Subcommittee sent to the R&D Coordinator.
- b. The R&D Committee Coordinator, once notified by the Subcommittee Coordinator will send written correspondence inquiring as how to best to proceed with the issue.
- c. The Principal Investigator may choose to respond to the issue or let the decision of the subcommittee stand. If the Principal Investigator chooses to let the decision of the R&D Subcommittee stand the research proposed in the application or amendment must not be initiated without the appropriate approvals.
- d. If the Principal Investigator chooses to respond to the issue cited by the R&D Subcommittee, the R&D Committee Coordinator will communicate this issue to the R&D Committee Member who has the most expertise associated with the proposal at hand. The R&D Committee Member with the most expertise will be discerned with under the following guidelines:
 - 1) If the concern is associated with the qualifications of the research staff, relevance to the VA mission, science, or resources associated with a proposal and the R&D Committee Primary Reviewer for the proposal is available he or she will be the considered the member with the most expertise.
 - a) The R&D Committee Primary Reviewer may ask individually or through the R&D Coordinator, that the R&D Committee Chairperson or one of the R&D Vice-Chairpersons review the issue.
 - 2) If the concern is associated with a Conflict of Interest for the research staff or the LSCDVAMC, the Research Compliance Officer will be considered the member with the most expertise.
 - 3) If the concern is associated with the security of data or information associated with the proposed research the Information Security Officer, in conjunction with the ACOS/R, and R&D Coordinator will be considered the member with the most expertise.

- e. The designated R&D Committee Member will then make a decision, based on the concern of the subcommittee and the response by the Principal Investigator, as to whether the issue cited by the subcommittee is significant enough to warrant R&D Committee re-review of the proposal or is not significant enough to warrant full R&D Committee review.
- f. If the designated R&D Committee Member makes the decision that the subcommittee's concern is significant enough to warrant re-review of the proposal, the Principal Investigator must submit a revised proposal to the R&D Committee if he/she wishes to pursue the proposal further. The decision of the designated R&D Committee Member will be communicated by the R&D Committee Coordinator to the Principal Investigator and respective R&D Subcommittee Coordinator in writing. This proposal will be considered at its next meeting under the submission procedures associated with new studies. The Principal Investigator will submit revised documents pertaining to the revisions associated with the amendment or proposal. .
- g. If the designated R&D Committee Member makes the decision that the subcommittee's concern is not significant enough to warrant re-review the decision of the designated R&D Committee Member will be communicated by the R&D Committee Coordinator to the Principal Investigator and respective R&D Subcommittee Coordinator in writing. Upon receipt of this notification the proposal or proposal amendment will be considered by the respective subcommittee without further concern associated with the cited issue.
- h. In the event that the Subcommittee disagrees with the R&D Committee member decision, the respective Subcommittee Chairperson and/or Vice-Chairperson will communicate directly with the R&D Committee for resolution of this issue.

6. References: VHA Handbook 1200.1

7. Rescissions: None