

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

**Effective Date:** July 15, 2008

**SOP Title:** Research and Development Committee <sup>Oversight</sup> Operations Procedure

**SOP Number:** RD-004<sup>2</sup>

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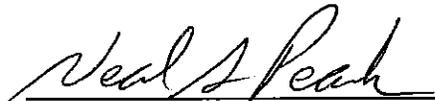
**SOP Version:** .04

  
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**Signature**

7/15/08  
**Date**

**Approved By:**

Associate Chief of Staff for Research

  
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**Signature**

7-16-2008  
**Date**

Chairperson of the Research and Development Committee

  
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**Signature**

7/21/08  
**Date**

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

**Effective Date:** 7/11/08

**SOP Title:** Research and Development Committee Oversight Procedure

**SOP Number:** RD-002

**SOP Version:** .04

1. **Purpose:** To establish procedures for how the Research and Development (R&D) Committee will provide oversight of the research program to ensure the effective operation of the research program and to make appropriate recommendations to the medical center Director based on the this oversight and the evaluation of the research program.
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, the security of VA data, and the security of VHA research laboratories.
3. **Definitions:**
  - a. 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).
4. **Responsibilities:**
  - a. The Associate Chief of Staff of Research and Development (ACOS/R), Administrative Officer/Research (AO/R), IRB Administrator, IACUC Coordinator, SRS Coordinator, Research Safety Officer, and Research Compliance Officer will provide necessary reports for R&D Committee review and approval.
  - b. The R&D Committee is responsible through the Chief of Staff to the facility Director for exercising oversight of the facility's research compliance program and committees.
5. **Procedures:**

To ensure effective oversight, the R&D Committee relies on information sources including activities of the R&D Committee, quality assurance activities, reports to the committee by the ACOS/R, AO/R, or other research staff members, subcommittee reports, facility reports or activities, and any other appropriate source. Specific issues to be considered include, but are not limited to:

  - a. Compliance with all policies related to personnel as defined in VHA research manuals, Handbooks, and Directives. **NOTE:** *All information related to compliance matters must be treated as confidential.*

- b. Information pertaining to all requests for Without Compensation (WOC) appointments for research.
- e. An annual review of the Subcommittee on Research Safety including planned training, compliance, and security issues. Upon review and approval by the R&D Committee this review will be forwarded to the Medical Center Director. This review will include the following:
  - 1) The budgetary and resource needs of the Subcommittee on Research Safety, including personnel, materials and supplies, space, capital equipment, training, education, security, and compliance.
- f. An annual review of the Animal Care and Use Program including inspection reports, Animal Research Facility (ARF) and IACUC composition, ARF and IACUC arrangements, ARF and IACUC budgets, ARF and IACUC space, ARF and IACUC support staff, ARF and IACUC training, ARF and IACUC quality improvement activities, ARF and IACUC compliance issues, and goals for next year. Upon review and approval by the R&D Committee this review will be forwarded to the Medical Center Director. This review will include the following:
  - 1) The budgetary and resource needs of the ARF and IACUC, including personnel, materials and supplies, space, capital equipment, training, and education
- g. An annual review of the Human Research Protection Program including IRB composition or IRB arrangements, credentialing and training status report, budget, space, support staff, quality improvement activities, compliance issues, and goals for next year. Upon review and approval by the R&D Committee this review will be forwarded to the Medical Center Director. This review will include the following:
  - 1) The budgetary and resource needs of the IRB, including personnel, materials and supplies, space, capital equipment, training, and education
- h. An annual review of the budgetary and resource needs of the Research & Development program, including personnel, materials and supplies, space, capital equipment, training, and education.
- i. An annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation.
- j. An annual quality assurance review of all Cooperative Research & Development Agreements (CRADAs).

All oversight evaluations will be conducted by the convened R&D Committee.

The evaluation and recommendation of the R&D Committee will be documented in the R&D Committee Minutes.

## **6. References**

## **7. Rescissions**