

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

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SOP Title: Research and Development Committee Operations Procedure

SOP Number: RD-001

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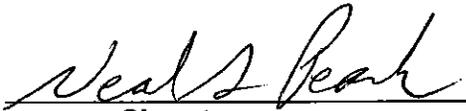


Signature

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: Research and Development Committee Operations Procedure

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1. **Purpose:** To establish procedures for how the Research and Development Committee will function.
2. **Policy:** The Research and Development (R&D) Committee is responsible for ensuring the effective operation of the research program and making appropriate recommendations to the Medical Center Director based on the Committee's oversight and evaluation of the research program.
3. **Definitions:** None
4. **Responsibilities:**
 - a. The Medical Center Director is the Institutional Official and has ultimate responsibility for all research conducted under the auspices of the LSCDVAMC. As such, the Director ultimately supervises the Associate Chief of Staff of Research and Development (ACOS/R), and appoints all members of the R&D Committee and its subcommittees. The Director will also ensure that members of the R&D Committee and all the subcommittees have adequate resources to successfully meet their responsibilities (VHA Handbook 1200.1).
 - b. The ACOS/R, Administrative Officer/Research (AO/R) and Chairperson of the R&D Committee share equally in assuring the effective operation of the research program.
5. **Procedures:**
 - a. The R&D Committee meets at least monthly; a quorum must be present. On rare occasions there may be a cancellation of a monthly meeting due to lack of quorum.
 - 1) Materials for an R&D Committee Meeting will be distributed to the R&D Committee by the R&D Committee Coordinator at least four business days prior to the respective meetings. For normally scheduled meetings these materials will include:
 - a) An R&D Committee Meeting Agenda. To include:
 - i. A listing of all R&D Minutes and Subcommittee Minutes to be reviewed by the R&D Committee.
 - ii. A listing of all policy changes to be reviewed by the R&D Committee.

- iii. A listing of R &D Committee Members and Subcommittee Members who have been re-nominated from their prior term
 - iv. A listing of all research proposals that have attained final R&D approval with accompanying dates of final R&D Committee approval and the approval of each respective subcommittee.
 - v. A listing of all VA funded, non-VA funded, and unfunded proposals to be reviewed by the R&D Committee.
 - vi. A listing of all continuing reviews to be reviewed by the R&D Committee
 - vii. Any other items that merit discussion by the R&D Committee.
- b) Minutes from the prior R&D Committee Meeting.
 - c) Resumes for all newly nominated R&D Committee or R&D Subcommittee members
 - d) Minutes from the subcommittees for the preceding time span following the last R&D Committee Meeting
 - e) CRADAs for quality assurance review when appropriate
 - f) Reviews of subcommittees when appropriate
 - g) Review of Centers of Excellence when appropriate
 - h) Any new research proposals. To include:
 - i. If a VA funded project:
 - VA formatted abstract
 - VA Application specific forms (10-1313-1 through 8)
 - Response to reviewers (If the proposal is a resubmission for a Merit Review or Career Development Application – This is limited to 3 pages)
 - Funding narrative
 - Data Security Checklist, whether this is covered under the Request to Review Research Proposal or as a stand alone document as determined by the current Research Services current documents.
 - ii. If a Non-VA Funded Application:
 - Complete non-VA funding application

- Budget either as a part of a Request to Review Research Proposal or as a stand alone document as determined by the current Research Services documents. This budget must include the names, job titles, and percent efforts of each member of the research staff. NIH funded material proposals may use their NIH budgets in place of LSCDVAMC forms.
- IRB Initial Review Application (if a human subjects research study)
- IRB Research Plan (if a human subjects research study)
- Informed Consent Documents (if a human subjects research study)
- Research Plan
- ACORP (if an animal subjects research study)
- ACORP Appendices (if an animal subjects research study)
- Data Security Checklist, either as a part of the Request to Review Research Proposal or as a stand alone document as determined by the current Research Services documents.

iii. If a Non-Funded Research Proposal:

- Budget either as a part of the Request to Review Research Proposal or as a stand alone document as determined by the current Research Services current documents. Note that the budget must include the names, job titles, and percent efforts of each members of the research staff.
- IRB Initial Review Application (if a human subjects research study)
- IRB Research Plan (if a human subjects research study)
- Informed Consent Documents (if a human subjects research study)
- ACORP (if an animal subjects research study)
- ACORP Appendices, if applicable (if an animal subjects research study)
- Research Plan
- Data Security Checklist, either as a part of the Request to Review Research Proposal or as a stand alone document as determined by the current Research Services current documents.

- i) R&D Committee Continuing Review Reports for each active research project, as completed by the research project's Principle Investigator. To include:

- i. An updated project data sheet
 - ii. A list of all publications in professional journals and conferences
 - iii. A data security checklist reflecting the current status or any changes in the data security.
 - j) A list of publications from VA affiliated investigators for quality assurance review reference to VA support.
 - k) A listing of all without compensation appointment requests as appropriate.
- b. R&D Committee members should be physically present at the meeting. If this is not possible, a member may be considered present if he/she participates through tele- or video-conferencing. In that case, the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions.
- c. The R&D Committee may hold additional meetings, as initiated by the R&D Committee Chairperson or Vice-Chairperson, in response to emergent issues. There must be a quorum of voting members present in person or by tele- or video-conference to conduct business.
- d. Minutes for each meeting will be recorded. The minutes must include the following information:
- 1) A list of all voting and non-voting members, including ex officio members, indicating the category of their membership and whether they are present or absent. If an alternate is present in place of a voting member, the minutes must indicate this fact and name who the alternate member is replacing.
 - 2) The presence of a quorum of voting members.
 - 3) Actions taken by the R&D Committee, to include:
 - a) The type of action.
 - b) The vote on the action, including the number voting for, against, and abstaining.
 - c) Any member with a conflict of interest for a topic under consideration must be named, and his or hers absence from the discussion or vote documented.
 - d) Any required follow-up and which committee, subcommittee, or person is responsible for the follow-up.
 - e) The basis for requiring changes to an application to obtain approval.
 - f) The basis for disapproving an application when this occurs.
 - g) Action taken on minutes from Research Subcommittees submitted to the

Committee for review.

e. R&D Committee Records

- 1) The R&D Committee and its subcommittees will maintain adequate documentation of all the activities:
 - a) Copies of all research proposals, all amendments reviewed, and any accompanying materials.
 - b) All continuing and final reports.
 - c) Minutes of the R&D Committee and subcommittees.
 - d) Copies of all written correspondence.
 - e) Membership lists for the R&D Committee and all subcommittees.
 - f) Written records documenting actions taken to carry out the committees' responsibilities for review of research, and for oversight of the research program, if not recorded adequately in the R&D Committee Minutes.
- 2) Records are the property of VA and must be maintained for a minimum of 6 years. *NOTE: Record retention may be longer depending upon other policies and regulations such as Food and Drug Administration (FDA) regulations or medical record retention policies.*

f. Assignment of Reviewers. Each topic listed on the R&D Committee Meeting Agenda will be assigned one or more reviewers. The R&D Committee Chairperson, and R&D Committee Vice-Chairperson(s) in conjunction with the R&D Committee Coordinator are responsible for the assignment of reviewers for each agenda item. Agenda items may be designated for the all members to review if it is determined that the items are sufficiently broad in scope.

g Membership. The R&D Committee will vote to recommend each of its officio members to the Medical Center Director. The R&D Committee is composed of the following classes of members:

- 1) Officio Voting Members. Their will be at least five Officio Voting Members, who must be compensated full-time or permanent part-time federal employees. Officio Voting Members will fulfill the following roles:
 - a) At least two members from the VA facility's staff who have major patient care or management responsibilities.
 - b) At least two members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise.
 - c) At least one member will hold an academic appointment at Case Western Reserve University and will be either a full-time Federal employee or a part-time permanent Federal employee.

- d) If research involving investigation drugs is performed at the LSCDVAMC at least one member will be employed by the Pharmacy Service.

Officio Voting Members must possess sufficient expertise to be valuable to the R&D Committee in the evaluation of research proposals and the oversight of the R&D Program. A recommendation by the R &D Committee, operationalized by a quorum based R&D Committee vote and appointment by the Medical Center Director will be required for each officio voting member member.

Terms for Officio Voting Members will be three-years.

- 2) Officio non-Voting Members. Officio non-Voting Members are those members with sufficient research or scientific expertise to be considered valuable to the R&D Committee and therefore warrant appointment, but who may not meet the other requirements for membership. A recommendation by the R &D Committee, operationalized by a quorum based R&D Committee vote and appointment by the Medical Center Director will be required for each officio non-voting member.
- 3) Ex-Officio Voting Members. Ex-Officio Voting Members are those whose membership are the virtue of a position external to the R&D Committee and must be compensated full-time or permanent part-time federal employees. In order ensure adequate representation of the R&D Subcommittees, R&D Subcommittee Chairpersons are considered Ex-Officio Voting Members. The appointments of Subcommittee Chairpersons to the R&D Committee are concurrent to their Subcommittee Chairpersonships. Ex-Officio Voting Members may contribute to quorum provided that they have no conflict of interest for the topic under consideration.
 - a) R&D Subcommittee Vice Chairpersons may serve as alternates to their R&D Subcommittee Chairpersons. Their appointments to the R&D Committee are concurrent to their Subcommittee Vice-Chairpersonships.
 - b) Additional Ex-Officio Voting Members may be added by the R&D Committee by a quorum based vote of R&D Committee Members based on representative needs of the Medical Center.
- 4) Ex-Officio Non-Voting Members. Ex-Officio Non-Voting Members are members whose membership is the virtue of a paid position. Examples include the Medical Center Director, COS, ACOS/R, AO/R, R&D Committee Coordinator, Institutional Review Board (IRB) Administrator, Institutional Animal Care and Use Committee (IACUC) Coordinator, Subcommittee on Research Safety (SRS) Coordinator, Information Security Officer(s), and the Research Compliance Officer of the facility. The ACOS/R functions as Executive Secretary of the Committee while the R&D Committee Coordinator functions as the secretary.
- 5) The R&D Committee Chairperson. Voting Committee Members must elect a Chairperson on an annual basis. The Chairperson must be approved and officially appointed, in writing, by the Medical Center Director for a term of 1 year. The Chairperson may be reappointed without any lapse in time. The Chairperson must not simultaneously chair a subcommittee of the R&D Committee.

- 6) R&D Committee Vice-Chairpersons. Voting Committee Members may elect Vice-Chairpersons on an annual basis. R&D Committee Vice-Chairpersons must also be approved and officially appointed, in writing, by the Medical Center Director for a term of 1 year. The Vice-Chairperson may be reappointed without any lapse in time and may assume the responsibilities of the Chairperson when the Chairperson is not available.
- 7) R&D Committee Officio Alternate Members. Voting Committee Members may elect R&D Committee Officio Alternate members. Alternate members, if any, serve if they are formally appointed as alternate members by the Medical Center Director. The roster must identify the primary member(s) for whom each alternate member may substitute. The alternate member's qualifications must be comparable to those of the primary member to be replaced. If the alternate member and the primary member both attend an R&D Committee meeting, only the primary member may vote and only the primary member counts towards the quorum.
- 8) Principle investigators or consultants may attend R&D Committee Meetings at the discretion of the AO/R, ACOS/R, and/or R&D Committee Chairperson. These guests may present materials and / or contribute to discussion – provided they have no conflict of interest regarding the topic at hand, but may not contribute to quorum or vote.

All members regardless of status will have completed their ORD training requirements.

6. **References:** VHA Handbook 1200.1
38 CFR 16.112
45 CFR 46.112
21 CFR 56.112

7. **Rescissions:** None