



Stratton VA Medical Center
Research & Development
Standard Operating Procedure:
R&D Committee

I. Mission

The research mission of the Department of Veterans Affairs (VA) is conducted within individual VA medical centers according to the highest ethical standards with accountability to all involved stakeholders. Responsibility for oversight and maintaining high standards is assigned to the R&D Committee.

II. Purpose

This SOP establishes the responsibilities and operations of the Research and Development (R&D) Committee, which functions at the facility level. The Research and Development (R&D) Committee will focus on oversight of the local research program rather than individual protocols. This is accomplished by permitting the R&D Committee to assign scientific review and some administrative responsibilities, including compliance issues, to more appropriate subcommittees and individuals. The R&D Committee will prioritize their deliberations around broad areas of program development, risk management, and quality and performance activities.

III. Scope

The R&D Committee is responsible, through the Chief of Staff (COS) to the medical center Director for:

- (1) Advising and assisting the medical center Director in providing oversight, planning, and execution of the local research Program; and
- (2) Assisting the medical center Director in maintaining high standards of protocol review and relevance to the mission of the VA throughout the R&D Program.

Those standards include ensuring the:

- (a) Scientific and ethical quality of VA research projects;
- (b) Protection of human subjects in research (including privacy and confidentiality, and the implementation of adequate safety measures for research subjects and personnel;
- (c) Safety of personnel engaged in research;
- (d) Welfare and appropriate use of animals in research;
- (e) Security of VA data, VAPI and VA sensitive information; and
- (f) Security of VHA research laboratories where hazardous agents are stored or utilized. *There are no Level-3 (BSL-3) laboratories at the Stratton VA.

The R&D Committee is assisted by the Associate Chief of Staff (ACOS) for R&D and the Administrative Officer (AO) for R&D in carrying out its duties.

Research in which the facility is to be engaged may not be undertaken without review and written approval of all appropriate subcommittees of the R&D Committee. The investigator must not initiate a research project until after being notified in writing by the ACOS for R&D that the project has been approved by all relevant committees, subcommittees, or other entities. The Institutional Review Board (IRB), Subcommittee on Research Safety (SRS), Animal Care and Use Committee (IACUC) and other such entities must notify the R&D Committee of project

approvals via a written communication signed by a voting committee member for the committee. The R&D Committee must notify the Associate Chief of Staff (ACOS) for R&D of project approvals via a written communication signed by a voting R&D Committee member for the committee. A single memorandum that lists by title, project number, or similar unique identifier all of the protocols receiving final approval at a given meeting is sufficient. **The R&DC committee will verify receipt of Privacy Officer (PO) and Information Security Officer (ISO) reviews prior to giving final approval of protocols; letters/emails stating concerns, if any by the ISO and PO will be included as attachments on R&DC agendas.** Once R&D Committee approval has been given, the research becomes VA approved research.

The R&D Committee may serve as the R&D Committee of record for another VA facility. In doing so, it must fulfill all R&D Committee responsibilities for that VA facility including oversight of its subcommittees if applicable. The R&D Committee may not serve as the R&D Committee of a non-VA institution.

IV. R&D Responsibilities

RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR

The medical center Director, acting in the capacity of the Institutional Official, is responsible for:

1. The facility's research program, and is assisted by an R&D Committee. The medical center Director serves as the Institutional Official responsible for all aspects of the research program including but not limited to: human subjects protection, animal welfare care and use, privacy and security of VA data, and biosafety.
2. Retaining institutional responsibility for the research program at the facility if the facility's R&D Committee of record is that of another VA facility.
3. Ensuring that research in which the facility is engaged is approved by the appropriate R&D Committee subcommittees.
4. Ensuring there are adequate resources and administrative support, including personnel, space, equipment, and training, for the R&D Committee and its subcommittees to fulfill their responsibilities.
5. Ensuring appropriate education and training for members of the R&D Committee, the research administration staff, and other staff involved in research.
6. Ensuring that investigators meet the requirements outlined in this SOP.
7. Appointing the members of the R&D Committee following the specifications outlined in this SOP.

RESPONSIBILITIES OF THE ACOS FOR R&D

The ACOS for R&D is responsible for:

- Notifying the investigator when a research project can be initiated. This notification occurs only after the research project has been approved by all relevant committees, subcommittees, or other entities.
- Notifies the PI of approval after continuing review by the R&DC subcommittees.
- Functioning as Executive Secretary of the R&D Committee.
- Conducting an annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation.

- Ensuring that information pertaining to all requests for WOC appointments for research have been appropriately justified and the appointments are in compliance with all applicable research, Human Resource Management, and other VA policies. (Also refer to Stratton VA Policy on credentialing of research staff.)
- Providing a quality assurance review of research employees involved in human subject research to ensure the employees are working within their scopes of practice and their privileges allowed by the facility's by-laws and granted to them by the facility. The ACOS/R&D reviews all scopes and signs off on them as they are submitted.
- Providing a quality assurance review of Cooperative Research and Development Agreements (CRADAs) and other agreements in support of the research program or specific research projects and an assessment of the impact of these agreements on the research program, when applicable. The ACOS/R&D reviews all scopes and signs off on them as they are submitted.
- Ensuring that all minutes of the R&D Committee and its subcommittees, including those from subcommittees at VA facilities or at the affiliate, are sent to the medical center Director and COS for review and appropriate action.

Review of research manuscripts, abstracts, letters-to-the-editor, and presentations:

The ACOS R&D will review all research manuscripts, abstracts, letters to the editor, and presentations (referred to collectively below as manuscript). The review will specifically focus on the appropriate acknowledgement of VA support and on rights of human subjects or animal component of the research. Specifically, the ACOS-R&D will verify that the appropriate research committee approvals for the research described in the manuscript was obtained. If approved, research office staff will draft a letter of approval for signature by the ACOS-R&D. This information will be on the agenda and recorded in the minutes (for-the-minute records) of the next R&D committee meeting.

RESPONSIBILITIES OF THE INVESTIGATOR

The investigator is responsible for:

1. Confirming with the applicable service chief that they have been awarded the appropriate credentials and privileges to conduct research at VA prior to initiating any research.
2. Complying with all applicable personnel and other VA requirements whether the investigator is compensated, WOC, or IPA.
3. Obtaining the complete approval of all appropriate non-research entities and R&D Committee subcommittees, and written notification from the ACOS for R&D prior to initiating a research project.
4. Developing a research plan that is scientifically valid; minimizes risk to human subjects, animals used in research, and personnel; and contains a sufficient description of the research including all procedures and the plan for statistical analysis, to allow the R&D Committee subcommittees to fully review the research project.
5. Developing and implementing plans for data use, storage, and security that are consistent with VA Directive 6500, Information Security Program, and its implementing Handbooks and other legal requirements.

6. Preparing and submitting information, at least annually or as required, on their research program(s) and on each project to the appropriate R&D Committee subcommittee for continuing review as required by the respective R&D Committee subcommittees.
7. Ensuring that all research proposals submitted for funding, from any source, support the mission of VHA and enhance the quality of health care delivery to Veterans.

RESPONSIBILITIES OF THE R&D COMMITTEE

The R&D Committee assists the medical center Director in fulfilling responsibilities for the facility's research program. The R&D Committee is responsible for ensuring the effective operation of the research program through oversight of the R&D Committee's subcommittees and making appropriate recommendations, including space and resource needs, to the medical center Director based on the Committee's oversight and evaluation of the research program.

The R&D Committee must accomplish its responsibilities through the following activities or procedures:

- (1) Planning and developing broad objectives for the research program so that it supports VA's mission;
- (2) Determining the extent to which the research program has met its objectives;
- (3) Overseeing all research activities for each VA facility for which it serves as the R&D Committee of record; and
- (4) Reviewing all written agreements that establish:
 - A committee from another VA or non-VA entity in lieu of a required committee or subcommittee for the R&D Committee; and
 - The R&D Committee or one of its subcommittees, as a committee or subcommittee of another VA facility.
- (5) Reviewing and evaluating all R&D subcommittees both within the VA facility and at external entities that function in lieu of R&D subcommittees, such as affiliate Institutional Review Boards (IRBs), Institutional Animal Care and Use Committee (IACUC), or biosafety committees. A summary of these reviews and evaluations must be sent to the medical center Director annually.
- (6) In fulfilling its responsibilities of ensuring the effective oversight of the research program and making appropriate recommendations to the medical center Director, including the suspension of a research study or remedial or restrictive action regarding a principal investigator, the R&D Committee needs to rely on a variety of information sources including:
 - Quality assurance activities, reports to the committee by the ACOS for R&D, AO for R&D, or other research staff members, subcommittee reports, facility reports or activities, and other appropriate sources.
 - Review of subcommittee activities including:
 - Annual reviews of the Research Safety and Security Program (including planned training, compliance, security issues, etc.);
 - The Animal Care and Use Program (including inspection reports, IACUC composition, IACUC arrangements, budgets, space, support staff, training, quality improvement activities, compliance issues, and goals for the next year); and
 - 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 the next year).
- The R&D Committee is responsible for fulfilling such other functions as may be specified by the medical center Director and VHA procedures. These functions may include review and approval of individual research projects.

These activities are reviewed via the review and approval of sub-committee meeting minutes, which contain as attachments all applicable reports.

PERFORMANCE MEASUREMENT & IMPROVEMENT

Quality Assurance and Quality Improvement: The R&D Committee will assess its performance and that of its subcommittees with regard to compliance to established policies and procedures. Performance measures will include:

- Review of facility RCO audits and reports, such as, QA review of research personnel folders (scopes of practice, CVs, training certificates, appointment letters, etc.)
- Review of R&D and subcommittee work load, volume, and assessment of whether sufficient resources are available to the R&D and each subcommittee to function effectively.
- Assessment and review of whether current R&D and subcommittee functioning is in compliance with required regulations, and effective in promoting each committees mission and improving quality of such functions.
- Timeliness intervals. Several intervals will be calculated and tracked with regard to receipt and processing of proposals and communications to researchers. The principle focus of tracking these intervals will be to assess effectiveness of administrative workflow and assure that reviews are accomplished in a thorough and timely manner. This information will also be used to assess if there are a sufficient number of IRB's.
- Annual survey of investigators. This survey will poll a variety of items including satisfaction with the R&D processes and suggestions for improvement.
- Review of reported unanticipated problems regarding the research program, or R&D or subcommittee function.
- Review of any comments or complaints received or reported to the R&D or any of its subcommittees.

Productivity: The R&D Committee will evaluate investigator productivity. This will be assessed by reviewing grant submissions, funding awards, presentation of abstracts, publications in peer-reviewed journals, invited presentations, and awards and honors.

Planning and Recommendations for Facility Research & Development: In addition to its oversight role for individual research projects, the R&D Committee is tasked with continuous quality assurance and improvement in the Research and Development Program. A review of these activities will be included in a report at least annually. The report will give an overview of the current status of the Research Service and will include elements from the prior fiscal year.

- Summary of all VA and Non-VA (Albany Research Institute) funding
- A list of funded Research Investigators

- A list of the number of research grants submitted for funding and the number funded.
 - Summary of review of committee make-up with attention to whether each committee's membership is in compliance with regulations.
 - Summary of current administrative staffing
 - Summary of off-site research activities
 - Summary of current overall resources and whether they are sufficient for current and projected workloads.
1. The R&D will review and approve the Standard Operating Procedures for the R&D committee and all of the subcommittees (IRB, IACUC and SRS&B) at least annually.
 2. The HRPP Resource Plan is reviewed annually.
 3. The WOC appointment status list (which is maintained by the Research Office) is reviewed at least annually.

R&D COMMITTEE REVIEW OF RESEARCH

Initial Reviews: Immediately following the subcommittee approval, the R&D Committee will receive initial review summaries at the R&D meeting. The R&D Committee will vote on the acceptance of the subcommittee reviews of the protocol. The ACOS/R&D will communicate the R&D Committee findings to the Principle Investigator(s) within three (3) days after the meeting.

V. R&D Committee Operations

The R&D Committee must meet at least monthly, except for 1 month during the year, if it appears that a quorum (i.e. a majority of voting members) cannot be obtained. VHA recommends, but does not require, that R&D Committee members be physically present at the meeting. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. 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.

The R&D Committee may develop procedures that allow the Committee to hold unscheduled meetings in response to emergent issues.

- (1) There must be a quorum present in person or by teleconference or video conference for any unscheduled meetings.
- (2) A quorum must be present to conduct business and must be present for each vote.

Administrative Support and Resources: Administrative support and resources for the operations of the R&D Committee and its subcommittees (IRB, IACUC SRS&B) are provided by the Director (IO) through the ACOS/R&D and the Research Administration offices. A program assistant shall be assigned by the Research Administration to serve as coordinator and recorder for the Committee, with other support staff assigned to assist as necessary. Resources may include but are not limited to; conference room areas for meetings, all necessary office equipment (computers, printers, photocopiers, etc.) for preparation of meeting agendas,

research protocol files and maintenance of all other essential documents for the R&D Committee activities.

Standard operating procedures or other written procedures must be maintained for all recurring processes. These processes include, but are not limited to, communication with the medical center Director, the COS, investigators, and committees or subcommittees.

Review of R&D Committee subcommittee operations must be conducted as an ongoing function of the R&D Committee. The review must be conducted at least annually and must be accomplished in part by: reviewing the minutes of each subcommittee that reviews VA research protocols (whether those of the VA or non-VA institutions when allowed); by close communication with the subcommittees; and through Quality Assurance and Quality Improvement activities.

VII. R&D Committee Records

The adequate documentation of all of the activities of the R&D Committee must be maintained (in accordance with the record control schedule), including, but not limited to, the following:

1. Minutes of the R&D Committee and R&D Committee subcommittees
2. Copies of all written correspondence
3. Written standard operating procedures

Research records may be electronic and if required paper. When original signatures are required on documents, either a paper copy of the signature sheet must be maintained or an electronic signature may be used. If an electronic signature is used, it must meet all of the requirements of VA, the Office of Human Research Protection, the Food and Drug Administration (FDA), and any other Federal requirements.

All research records are kept confidential in the Research Administration Offices. Normal access is limited to the ACOS/R&D, the Administrative Officer for Research, research administrative staff, Chairs of the R&D Committee or its subcommittees, authorized VA representatives, officials of federal or state regulatory agencies and appropriate accreditation organizations. All other access to R&D records is tracked in a log and is limited to those who have legitimate need, as determined by the R&D committee, ACOS-R&D, Medical Center Director, or VA National Headquarters.

Research records relating to a study are retained in accordance with the record control schedule. The PI may arrange with the research office to turn over responsibility for continued storage of terminated protocols to the research office.

Records that pertain to clinical investigations regulated by the Food & Drug Administration (FDA) will be accessible for inspection and copying by authorized representatives of the FDA at reasonable times and in a reasonable manner.

Research Databases: The Research Administration maintains computer databases on all research protocols and investigators.

1. Project Management & Information System (PROMISE): This database is linked to VA National Headquarters R&D Computer Center responsible for maintaining the VA Research and Development Information System (RDIS).

2. MIRB: The electronic database system (MIRB) tracks all events related to the research, such as initial review, continuation review, AE's, as well as the documents submitted that are related to the events.

IRB records and Investigator records are the property and the responsibility of the Stratton VA Medical Center.

Agendas for R&D Committee Meetings:

The HRPP Coordinator prepares agendas for the R&D Committee meeting to include:

1. Time, date, and location of meeting
2. Declaration of conflicts of interest
3. Minutes- R&D and R&D subcommittee meeting minutes that were approved since the last R&D meeting
4. Old business items
5. Education items
6. Reports and Announcements- Reports to the Committee shall be made by the chair, ACOS/R&D, AO/R&D and/or any other responsible individual on matters of concern to the Research Program that need to be called to the Committee's attention. These will include local and central office R&D policy updates.
7. Report on items approved. These will include: manuscripts, abstracts, and presentations. The reviewer, date reviewed, and action taken will be noted.

Minutes for R&D Committee Meetings:

Minutes for each meeting must be recorded. The minutes need to include the following information:

1. Time, date, and location of meeting
2. Declaration of quorum
3. Members present, excused, or absent, and guests present (if any) will be recorded. Members may be noted as being excused if the Chair or the Recorder is notified in advance of the meeting that the member will not attend.
4. Declaration of conflicts of interest
5. R&D and R&D subcommittee meeting minutes that were approved since the last R&D meeting.
6. Old business items
7. New business items
8. Education items
9. Reports and Announcements - Reports to the Committee shall be made by the chair,
10. ACOS/R&D, AO/R&D and/or any other responsible individual on matters of concern to the Research Program that need to be called to the Committee's attention. These will include local and central office R&D policy updates.
11. Report on items approved under expedited review. These will include; manuscripts, abstracts, and presentations. The reviewer, date reviewed, and action taken will be noted.
12. The minutes shall be signed by the Chair, and the Executive Secretary (ACOS/R&D).
13. Votes on motions for actions taken shall be reported to include the names of the voting members who make the motion and second the motion, number of members voting for the motion, voting against the motion, abstaining, recusing or excusing themselves from the vote and quorum. The minutes are reviewed, edited, approved and signed by the Chair and ACOS/R&D; and submitted to the full committee for review, corrections (if necessary), and approval at the following meeting. Copies of the minutes are

maintained by the Research Administration office and will be made available to VHA Headquarters or to any investigator upon request.

14. Communication of R&D Committee findings, stipulations and actions: All formal communications of the R&D Committee are in writing from the Chair. Correspondence to the research investigators following review of research proposals from investigators will indicate findings, stipulations, requests for additional information, and/or final actions as noted above.

All minutes of the R&D Committee and its subcommittees, including those from “in lieu of” subcommittees at VA facilities or at the affiliate, must be sent to the medical center Director through the ACOS for R&D and COS for review and appropriate action. They may also be sent through other committees such as Executive Committee of the Medical Staff or the Executive Leadership Committee.

VIII. R&D Committee Membership

The members of the R&D Committee are appointed by the medical center Director and must reflect the types and amount of research being conducted at the facility. Nominations for membership may be from current R&D Committee members, subcommittee members, and the facility’s staff.

The R&D Committee must consist of at least five voting members.

Whenever possible, one member of the Committee needs to have expertise in biostatistics and research design.

If the facility has any Centers, such as Centers of Excellence, (e.g., Health Services Research and Development (HSR&D), Rehabilitation Research and Development (RR&D), or Cooperative Studies Program (CSP) Centers), it is recommended, but not required, that at least one voting member of the R&D Committee be chosen from the Center.

The members need to have diverse backgrounds with consideration as to race, gender, ethnicity, and expertise.

Attendance Requirements, Quorum and Voting at meetings: A quorum, consisting of a majority of all the voting R&D Committee members, must be present to conduct official business of the committee. If a quorum is lost during the meeting, further R&D business must be suspended. Whenever a committee member recuses him or herself or leaves the meeting, there must be enough individuals remaining to constitute a quorum (recused members and members who temporarily excuse themselves from the meeting are not counted towards a quorum). Each voting member has one vote with no proxy voting allowed. A motion is approved if accepted by more than half of the votes cast by voting members present at a meeting.

VOTING MEMBERS

Voting members of the R&D Committee must include:

- (1) At least two members from the VA facility’s staff who have major patient care or management responsibilities.
- (2) At least two members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise.

- (3) In facilities affiliated with academic institutions, at least one member who holds an academic appointment, and is either a full-time Federal employee or a part-time permanent Federal employee.

All voting members must be compensated full-time or permanent part-time Federal employees.

A voting member may fill more than one criterion for required membership, for example, the member may have both major patient care or management responsibilities and be actively engaged in major R&D programs.

If the facility conducts research involving the use of investigational drugs, consideration needs to be given to including a representative from the investigational pharmacy or Pharmacy Service as either an ex officio nonvoting member or a voting member.

If the R&D Committee serves as the R&D Committee of another VA facility, it is recommended, but not required, that at least one representative from that other facility be included. The representative must be appointed by the other facility's medical center Director and the medical center Director of the facility having responsibility for the R&D Committee must concur on the appointment. If the R&D Committee is the R&D Committee for a second VA facility, the medical center Director of the second facility must appoint its representative(s), when applicable.

If a facility has alternate members, they must be appointed by the facility 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. The alternate member can only vote in the absence of the primary member.

All R&D Committee members will be provided with orientation by the ACOS/R&D or R&D Chair about the VA Research and Development Program, the values that guide all R&D efforts, and access to the standard operating procedures of the R&D Committee. On-going training and education regarding new information on VA research guidelines, research protection (good clinical practice, human and animal subjects, safety) issues, etc., will be reviewed and discussed at Committee meetings.

All members of the R&D Committee must fulfill the educational requirements specified by; *R&D SOP: Procedural Protocol: Initial and Continuing Education Requirements and Tracking for the Office of Research & Development (WOC's, committee members, Investigators and staff)*.

The R&D Committee may require attendance by R&D subcommittee members, but subcommittee members who are not also members of the R&D committee must recuse themselves (i.e., leave the room or hang up from a conference call) before an R&D Committee vote is taken.

TERMS OF MEMBERS

Voting members are appointed by the medical center Director in writing and serve terms of 3 years with a possibility for extension. Members may be reappointed without any lapse in time if it is deemed in the Committee's best interest.

The terms of members must be staggered to provide partial change in membership annually.

CHAIRPERSON

Committee members, exclusive of ex officio members, must elect a Chairperson every 1 or 2 years.

- (1) The Chairperson must be approved and officially appointed, in writing, by the medical center Director for a term of 1 to 2 years.
- (2) The Chairperson may be reappointed without any lapse in time.
- (3) The Chairperson must not simultaneously chair a subcommittee of the R&D

Committee.

Role and Responsibilities of the R&D Chair:

- (1) Providing leadership for the committee and ensuring that it meets all areas of designated responsibility.
- (2) Conducting the monthly-convened meetings of the committee after verifying a quorum has been established.
- (3) Reviewing, editing, and adding to the meeting agenda prepared by the R&D office staff to verify it is complete and contains all items necessary to conduct the business meeting of the committee.
- (4) Reviewing the formal minutes of the meeting and signing to verify that they accurately reflect the business conducted at the meeting.
- (5) Signing VA form 10-9012 for approved studies involving investigational drugs.
- (6) Serve as the contact and resource for the chairs of the subcommittees.

EX OFFICIO MEMBERS

Ex officio (non-voting) members include the medical center Director, the COS, the ACOS for R&D, the AO for R&D, and research compliance officers (or those who are responsible for compliance) of the facility. The ACOS for R&D functions as Executive Secretary of the R&D Committee.

Other ex officio members, such as the information security officer, may be appointed to the Committee if their appointments assist the R&D Committee in fulfilling its responsibilities.

Others may be invited to assist the R&D Committee because of their competence in special areas in the review of issues requiring expertise beyond, or in addition to, that available on the Committee. These individuals may not contribute to a quorum or deliberate or vote with the Committee.

IX. Subcommittees of the R&D Committee

The R&D Committee may establish any subcommittee(s) deemed necessary for the efficient and effective management and oversight of the R&D Program.

The R&D subcommittees are responsible for the review and reporting of new protocols for scientific and scholarly validity.

At a minimum, subcommittees must be appointed to oversee R&D activities related to human studies, animal studies, and biosafety including biosecurity.

Findings and recommendations of the subcommittees are recorded and reported to the R&D Committee.

The R&D Committee must approve final subcommittee minutes.

Continuing review requires approval by relevant non-research committees and R&D Committee subcommittees, and ACOS for R&D notification of the investigator that the approvals have been obtained.

The R&D Committee does not perform a continuing review.

The required subcommittees of the R&D Committee are:

- (1) Institutional Review Board: Every VA facility conducting research involving human subjects must have, or must establish an IRB, or the facility must secure the services of an IRB as described in VHA Handbook 1200.05.
- (2) Institutional Animal Care and Use Committee (IACUC): Every VA facility conducting research involving the use of live vertebrate animals must establish an IACUC, or secure the services of an IACUC as described in VHA Handbook 1200.7.
- (3) Subcommittee on Research Safety (SRS), or an Institutional Biosafety Committee (IBC): Every VA facility conducting research must establish either a Subcommittee on Research Safety (SRS), an Institutional Biosafety Committee (IBC), or secure the services of an analogous committee at another VA or university affiliate. These alternative committees must deal with different aspects of research safety and security of all VHA research laboratories, as required in VHA Handbook 1200.8, and other applicable regulations and policies.

Each subcommittee must maintain adequate records, and retain such records according to VHA Directive 6300. These records must include the following:

- (1) Copies of all research proposals and their amendments reviewed by the R&D Committee subcommittees and any accompanying materials;
- (2) All continuing or final reports;
- (3) Minutes of its meetings;
- (4) Copies of all written correspondence;
- (5) A membership list of all voting, non-voting, and ex-officio members including their appointed roles;
- (6) Written records documenting actions taken to carry out the subcommittee's responsibilities;
- (7) Standard Operating Procedures (SOPs); and
- (8) All communications to and from investigators, other committees, subcommittees, and other entities or individuals.

Each subcommittee must make available to the R&D Committee a complete, unredacted, final set of minutes.

Reporting between the R&D Committee and its Subcommittees

In order to fulfill the responsibility of protecting research participants and research data, it is necessary to ensure the flow of critical information between the R&D committee and its subcommittees in an expeditious manner. The following procedure is established to ensure that this occurs and delineate circumstances when this might be necessary. This limited e-mail string

will ensure that only those individuals responsible for responding to reported issues will be apprised of them and reduce the risk of the issues becoming general knowledge at the facility before being fully explored. It will also provide a forum for a continuing dialog among those responsible for acting on these issues.

The following is a list of circumstances where expeditious communication between the R&D and its subcommittees is necessary. Such communications may include but are not limited to:

1. Reportable issues involving research
2. Suspension of studies
3. Conflicts of interest
4. Research non-compliance
5. Termination of studies for cause
6. Delays of protocol approval due to "approval with modifications"

Circumstances requiring expeditious communication may be reported to the Research Office from any source, including the results of discussions at the IRB meetings. This information will be communicated to the applicable subcommittee chair, or designee, to determine whether immediate action needs to be taken to protect research subjects or data. The subcommittee Chair, or designee, will compose an e-mail message to be sent to:

1. R&D Chair
2. ACOS-R/R&D
3. Research Office
4. Research Compliance Officer, when appropriate

This email will apprise them of the situation and any immediate action taken. Any immediate actions taken will be reported to the applicable subcommittee for review at the next convened meeting and entered into the minutes. Non-emergent issues will be discussed at the next convened meeting of the IRB and entered into the minutes.

X. Conflict of Interest

The mission of ORD is to discover knowledge, develop VA researchers and health care leaders, and create innovations that advance health care for the Nation and its Veterans. In order to fulfill this mission, VHA must preserve public trust in the integrity and quality of research carried out by its investigators and in its facilities. One way to maintain public trust and safeguard the integrity and quality of VA research is to ensure that VA investigators and members of R&D Committees avoid actual or perceived financial conflicts of interest in the research they conduct or review.

VA investigators and R&D Committee members must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal criminal code. The obligation to follow applicable ethics laws and regulations also applies to WOC employees and IPAs conducting VA research or participating on a R&D Committee. R&D Committee members and VA investigators must comply with VA requirements on financial conflicts of interest in research. Failure to follow these ethics laws and regulations can have serious consequences. If criminal ethics statutes are violated, civil fines and imprisonment can result. Severe administrative disciplinary action can result from violating ethics regulations, including suspension from employment, termination of employment, and other administrative punishment.

R&D Committee members with outside consulting, employment, or royalty payment opportunities must ensure that these activities do not present any actual or perceived financial conflict of interest, and must recuse themselves from the review of proposals for which any conflict of interest may exist. Such members may not be present during the deliberations or the vote on such research proposals.

The R&D Committee is subject to regulation and/or inspection by the Department of Veterans Affairs and other authorized federal and accreditation agencies (e.g., FDA, OHRP, OIG, ORO and AAHRPP).

XI. Non-Compliance and Research Misconduct:

Serious deviations from accepted practice in carrying out research, in reporting of research results, or material failure to comply with Federal regulations affecting specific aspects of the conduct of research (e.g. the protection of human subjects and the welfare of laboratory animals) will also be reviewed. Current ORD policies and procedures dealing with misconduct can be found in VHA Handbook 1058.2, "Research Misconduct".

XII. References

VHA Handbook 1200.01 (The Research and Development (R&D) Committee Handbook)
Title 38, U.S.C. Chapter 73, Section 7303 (Authorization for R&D Program)
7361–7368 of Title 38, United States Code (U.S.C.) (Authorization for NPC's)
Station Memorandum No. SL-00-45 (Research & Development Committee)
38 CFR 16 (VA IRB Regulations)
VHA Handbook 1200.05 (Human Research Protection Program)
VHA Handbook 1200.07 (IACUC)
VHA Handbook 1200.06 and 1200.08 (SRS&B)
Animal Welfare Act (CFR. 1985. Title 9, Subchapter A)
21 CFR 56 (FDA Regulations for Research Involving Humans)
VHA Handbook 1058.2 Research Misconduct
Memo, "What to Report to the Office of Research Oversight"
Memo SL-151-06, "Credentialing Process and Scope of Practice for Individuals Involved in Human Subjects Research"