

Research & Development Committee

STANDARD OPERATING PROCEDURES

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Revisions

REVISIONS

Major revisions from the October 23, 2013 to the November 27, 2013 version include:

Section	Title	Revision Description and Revision Rationale
Appendix 4	R&DC Reviewer Checklist	<ul style="list-style-type: none">• Added question 13: Will non-Veterans be recruited and/or enrolled in the research? *If yes, greater than minimal risk studies will come to R&D after IRB approval (which addresses human safety) and not necessarily institutional obligations.

1. PURPOSE AND AUTHORITY

The Research & Development Committee (R&DC) is responsible, through the Chief of Staff (COS) to the Medical Center Director (MCD), for oversight of the research program and for maintaining high standards throughout the R&D Program. The standards concern assuring the scientific and ethical quality of research and development projects, the protection of human subjects in research, the use and welfare of laboratory animals, the safety of personnel engaged in research, the safety and security of VHA research laboratories, the security of research data, and resources.

The MCD is the institutional official responsible for Federal Wide Assurance (OHRP) and the Animal Welfare Assurance (OLAW). The MCD delegates the authority to administer the R&D program to the Associate Chief of Staff for Research & Development (ACOS/R&D), who reports to the MCD through the COS. The R&DC is assisted by the ACOS/R&D and the Administrative Officer for (AO) for R&D in carrying out its duties. The Research Compliance Officer(s) (RCO) advises the R&DC on regulatory affairs and federal, VHA, and accreditation standards and has delegated authority for evaluation and monitoring of research activities at the level of individual investigator and research personnel. The R&DC advises the MCD on professional and administrative procedures involving the R&D Program.

Research in which the Durham VAMC is to be engaged may not be undertaken without review and written approval of all appropriate subcommittees of the R&DC. The investigator must not initiate a research project until after being notified in writing by the ACOS/R&D that the project has been approved by all relevant committees, subcommittees, or other entities.

2. DEFINITIONS

Data Repository: A database or collection of databases that have been created or organized to facilitate the conduct of multiple research protocols, including future protocols not yet envisioned. It may also have been created for other purposes such as administrative and clinical purposes. The terms “data repository” and “data warehouse” have the same meaning.

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research Data Repository: A data repository created from data obtained either to conduct a research protocol(s) or gathered in the course of conducting a research protocol and is maintained after the completion of the research protocol. The protocol may be a primary research project designed to prove or disprove a specific hypothesis or it may be a protocol specifically designed to collect data (either a one-time-only collection of data or an ongoing collection) that will be placed in a research data repository for future use.

VA Research: Research that is conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreements (IPA) appointments) while on VA time, utilizing VA resources (e.g., equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.

VA Data / VA Information: VA data or VA information owned or in possession of VA or any entity acting for, or on behalf of VA.

VA Sensitive Information: All VA data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and information that can be withheld under FOIA. Examples of VA sensitive information include:

- 1) Individually-identifiable medical, benefits, and personnel information;
- 2) Financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, investigations, and law enforcement information;
- 3) Information that is confidential and privileged in litigation, such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege;

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- 4) Other information which, if released, could result in violation of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of federal programs.

VA Protected Information: VA sensitive information, Privacy Act Information (PAI), Protected Health Information (PHI), or other VA information that has not been deliberately classified as public information for public distribution. VA information that VA would have to release under the Freedom of Information Act (FOIA) is not VA protected information. All VA protected information needs to be classified as one of the following: VA Proprietary, VA Restricted, or VA Highly Restricted.

3. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR

The MCD is responsible for the R&D program and is assisted by the R&DC. The MCD:

- 1) Serves as the Institutional Official (IO) responsible for all aspects of the research program and signs all assurances;
- 2) Ensures that research in which Durham VAMC is engaged is approved by the R&DC or appropriate subcommittee, as applicable. In this capacity, the MCD serves as an *ex-officio* member of the R&DC and reviews and approves R&DC minutes;
- 3) Ensures there are adequate resources and administrative support, including personnel, space, and equipment, for the R&DC and its subcommittees to fulfill their responsibilities;
- 4) Ensures appropriate educational and training opportunities for members of the R&DC, the research administration staff, and other staff involved in research;
- 5) Appoints R&DC and subcommittee members;
- 6) Complies with all Facility Director responsibilities of VHA Handbook 1200.05 and the current Facility Director's Certification of Research Oversight.

4. RESPONSIBILITIES OF THE ACOS/R&D

The ACOS/R&D is responsible for:

- 1) Notifying the investigator when a research project can be initiated. This notification occurs only after the research project has been approved by all applicable R&DC subcommittees and after the R&D subcommittees' notifications of approvals have been approved by the R&DC. The ACOS/R&D is responsible for notifying the investigator of approval after continuing review by the R&DC and subcommittees.
- 2) Functioning as Executive Secretary of the R&DC.
- 3) Conducting an annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation.
- 4) 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.
- 5) Providing an annual 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.
- 6) Providing an annual 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.
- 7) Ensuring that all minutes of the R&DC and its subcommittees, including those from subcommittees at VA facilities or at the affiliate (if applicable), are sent to the MCD and COS for review and appropriate action.
- 8) Monitoring changes in VA and other federal regulations and policies that relate to human research protection and accreditation of the human research protection program.

5. RESPONSIBILITIES OF THE R&D COMMITTEE

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

The R&DC is responsible for maintaining high standards throughout the medical center's R&D program, to promote protection of human subjects and the implementation of adequate safety measures for research subjects and personnel engaged in research, to promote the welfare and appropriate use of animals in research, to promote the security of research labs, to promote the security of VA data, VA protected information and VA sensitive information, to promote availability of adequate resources to conduct research and to assure that the R&D program is concordant with the patient care mission of the medical center.

The R&DC and/or its Subcommittees is/are responsible for considering the impact of proposed research on hospital resources. If the proposed research could potentially impact limited hospital resources (e.g. use of telemetry beds, colonoscopy waitlists, clinical laboratory staffing, etc.) or could negatively impact access to care for VA patients the R&DC and/or its Subcommittee may require special research justification in order to secure approval.

Other functions of the R&DC include:

- 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. A committee from another VA or non-VA entity in lieu of a required committee or subcommittee for the R&DC; and
 - b. The R&DC 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

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(IACUC), or biosafety committees. A summary of these reviews and evaluations must be sent to the MCD annually.

In fulfilling its responsibilities of ensuring the effective oversight of the research program and making appropriate recommendations to the MCD, including the suspension of a research study or remedial or restrictive action regarding a principal investigator, the R&DC needs to rely on a variety of information sources including:

- 1) Quality assurance activities, reports to the committee by the ACOS/R&D, AO/R&D, or other research staff members, subcommittee reports, facility reports or activities, and other appropriate sources.
- 2) Review of R&DC subcommittee operations must be conducted as an ongoing function of the R&DC. 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. Review of subcommittee activities including:
 - a. Annual reviews of the Research Safety and Security Program (including planned training, compliance, security issues, etc.);
 - b. 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
 - c. 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&DC is responsible for fulfilling such other functions as may be specified by the MCD and VHA procedures. These functions may include review and approval of individual research projects. **NOTE:** *The R&DC may not approve human subjects' research if it has not been approved by an IRB (see Title 38 Code of Federal Regulations section 16.112).*

5.1 Review of Research

The R&DC is responsible for establishing policy to ensure that all research in which the facility is to be engaged has been reviewed and approved for the ethical use of human subjects, animals, and biohazards. This review must promote:

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- 1) Maintenance of high standards of protocol review, and relevance to the mission of VA;
- 2) Protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel;
- 3) Welfare and appropriate use of animals in research;
- 4) Safety of personnel engaged in research;
- 5) Security of research laboratories where hazardous agents are stored or utilized and of all Biosafety Level 3 (BSL-3) research laboratories; and
- 6) Security of VA data and VA sensitive information.

If a research protocol requires review by a facility's non-research entities, such as the Radiation Safety Committee, this review may be conducted at any time, but the research may not be initiated until the non-research entity has approved the project, and the project has been approved by all applicable R&DC subcommittees, and the investigator has been notified in writing by the research office.

The IRB, SRS, IACUC and other such entities must notify the R&DC of final project approvals via a written communication signed by a voting committee member for the committee. For Durham VAMC subcommittees, a single memorandum that lists the study title and unique study number for all studies receiving final approval before or during the last convened subcommittee meeting will be provided to R&DC. For Central IRB (CIRB) studies, the R&DC must have the signed final CIRB approval letter. The R&DC must notify the ACOS/R&D of project approvals via a written communication signed by a voting R&DC member for the committee. Once R&DC approval has been given, the research becomes VA approved research.

5.2 Review of Subcommittee Research/Items

Effective October 1, 2009, the DVAMC R&DC will not routinely provide protocol review for projects that have been reviewed by the Durham's IRB (including expedited review) and/or IACUC. Research projects that are deemed by the IRB to not be human subjects research, projects deemed by the IRB to be exempt from IRB review, projects that are science-only, projects that are otherwise only reviewed by the Subcommittee on Research Safety (SRS), and Central IRB studies will be fully reviewed by the R&DC. In addition, the R&DC will review the creation and operation of research data repositories, and will review individual protocols that will use data from a research or non-research data repository in accordance with VHA Handbook 1200.12. A research data repository can be created only after a research repository protocol and corresponding standard operating procedures are developed and approved by the IRB (if human research is

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involved) and the R&D Committee. If the research data repository or use of data from a data repository involves human subjects, the repository and/or protocol will first be reviewed by the IRB, then the R&DC.

The R&DC will review all greater than minimal risk human subjects studies in which the initial submission, continuing review, or amendment indicates that non-Veterans will be enrolled.

The R&DC will also review all requests to transfer/change Principal Investigator responsibilities to another Principal Investigator.

In general, R&D review involves review of the description and justification of the scientific merit and design, and whether the design is adequate to answer the research questions(s). Reviewers evaluate whether the aims/objectives are likely to be achievable within the given time period and whether the statistical analysis plan is appropriate. Reviewers also evaluate whether there was a thorough evaluation of relevant literature and previous studies as well as the investigator's qualifications by education/training to conduct the study. In addition, the R&DC evaluates whether the investigator has adequate resources (i.e., staff, space) to conduct the project and in the case of continuing review, was the VA appropriately acknowledged in the submitted publication/manuscript(s). The R&DC determines if a conflict of interest has been identified and if responses to the SRS's recommendations have been satisfied. The reviewers' determination of applicable criteria are recorded on a review checklist (Appendix 4) in addition to any other comments and kept in the protocol file.

The R&DC will conduct continuing review of research projects that are not otherwise reviewed by the IRB or IACUC. The R&DC will also conduct continuing review assessments for research data repositories and individual protocols that use data from a data repository. A specific approval period not to exceed 1 year must be set and is based on risk assessment. The R&DC may approve, approve with conditions, table, or disapprove a research project, program or center. This review includes assessment of research activities that have occurred, the research progress made in the last year, any issues that might impact progress such as compliance issues, whether the basis for IRB exemption still exists (if applicable), and if the project's scientific quality, ethical appropriateness and safety of the research continues to meet the criteria for approval.

5.2.1 Review of SRS Studies

The SRS reviews research that involves biological, chemical, physical, or radiation hazards to research staff but does not routinely conduct a scientific review. (Note: The SRS is designated as the Institutional Biosafety Committee (IBC) for the purpose of reviewing research involving recombinant DNA). The R&DC reviews studies that are otherwise only reviewed by the SRS-IBC to assess issues such as, but not limited to: scientific merit, investigator qualification, adequate resources, conflict of interest, and data use and/or storage.

If the R&DC has any recommendations above or beyond those of the SRS/IBC, the R&DC will provide such recommendations to the SRS/IBC and/or the Investigator, as appropriate.

5.2.2 Review of IACUC Studies

The R&DC does not routinely review research that is monitored and approved by the IACUC. However, the IACUC initiated a post-approval monitoring (PAM) program to provide assurance to regulatory and accrediting agencies that laboratories using animals are operating in compliance with approved protocols. Any practices/techniques performed outside of the approved parameters of the protocol are immediately brought to the attention of the research team and the IACUC, and the IACUC recommends an action plan for the research team/PI as necessary. PAM reports are reviewed by the R&DC to ensure that the R&DC is aware of current practices and/or issues in animal research.

The R&DC may acknowledge the PAM and/or the IACUC's corrective action plan and/or make additional suggestions, and/or request additional information. Deliberations and/or suggestions will be documented in the R&DC minutes and the Investigator will be notified, if appropriate.

5.2.3. Review of CIRB Studies

Per the CIRB and Durham VAMC Memorandum of Understanding, the R&DC provides a local review of CIRB-approved studies. This review of the research assesses local impact of the research and ensures that the research has adequate resources. The R&DC must approve a CIRB study before the research may be initiated or continued.

5.2.3.1 Initial Review

The R&DC must conduct an initial review of studies approved by the CIRB. This review submission must include the CIRB-approved Principal Investigator/Study Chair (PI/SC) documents as well as the CIRB-approved Local Site Investigator (LSI) documents. The R&DC must approve the research before any research procedures or activities can be initiated at the Durham VAMC.

5.2.3.2 Continuing Review

The R&DC must conduct a continuing review of studies approved by the CIRB at intervals appropriate to the research's degree of risk, but not less than once per year. The local review interval will be determined during the R&DC's initial review of the research, but the R&DC may change the review interval any time such a change is warranted.

The CIRB continuing review cycle and the local R&DC continuing review cycle may be asynchronous. If this occurs (e.g., the CIRB continuing review is scheduled after the Durham R&DC continuing review), the LSI should submit the CIRB's continuing review

approval documents to the R&DC as a notification.

5.2.3.3 Amendments and Other Submissions

Local Site Investigators must submit notifications of CIRB-approved amendments, study closure, and reviews of serious adverse events, unanticipated problems, protocol deviations, continuing reviews, etc., to the R&DC as notifications. In the case of amendments or changes approved during a CIRB continuing review, LSIs may immediately act and change local procedures once the LSI receives written approval from the CIRB. Notice of CIRB's amendment approval must be submitted for review at the next available regularly-scheduled R&DC meeting. In the event that the R&DC has questions or concerns about CIRB-approved changes, the R&DC will notify the LSI.

LSIs may amend study procedures without CIRB or R&DC approval only when necessary to eliminate apparent immediate hazards to human subjects.

5.2.4 Review of Serious or Continuing Noncompliance, Unanticipated Problems, or other Reportable Issues from any Subcommittee

Any subcommittee of the R&DC can send issues to the R&DC for review, including but not limited to compliance issues, unanticipated problems, or any event mentioned in VHA Handbook 1058.01, Research Compliance Report Requirements. The R&DC expects that the committee of record will have reviewed the event and devised a corrective action plan, if necessary. The R&DC will review the subcommittee's recommendations for corrective action and may acknowledge the event and/or the subcommittee's determination, and may also make additional suggestions to the committee of record or request additional information. Deliberations and/or suggestions will be documented in the R&DC's minutes and the Investigator will be notified as appropriate.

5.3 Suspensions and Terminations

The R&DC shall notify the Principal Investigator in writing of suspensions or terminations and shall include a statement of the reasons for the R&DC's actions. The terms and conditions of the suspension must be explicit. The investigator shall be provided with an opportunity to respond in person or in writing.

Where the R&DC Chairperson determines that such action is necessary to ensure the rights and welfare of animal or human subjects, the Chairperson may require an immediate, temporary suspension of enrollment of new subjects or of continued participation of previously enrolled subjects, pending review of the situation by the convened R&DC.

NOTE: *If protocol modifications are required by the R&DC, applicable subcommittees must review and approve the amendment prior to the amendment being initiated.*

6. R&D COMMITTEE MEMBERSHIP

The members of the R&DC and its subcommittees are nominated by the R&DC and appointed by the MCD. The R&DC may serve as the R&DC of record for another VA facility, however, the Durham R&DC does not currently serve nor has it ever served as the R&DC for another VA facility. The R&DC may not serve as the R&DC of a non-VA institution.

Members and alternate members of the R&DC may be nominated by current R&DC members, subcommittee members, or members of the Durham VAMC staff. Members and alternate members are formally appointed by the MCD. The Durham R&DC has voting members that reflect the types of research conducted at the Durham VAMC. Alternate members must have comparable qualifications to those of the primary member. Members and alternates are listed on the R&D roster and listed in R&D minutes. The Research Program Administrator will maintain a suspense listing of member appointment and expiration dates and MCD appointment letters and will notify the ACOS/R&D of member term expirations.

The R&DC 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&DC be chosen from the Center. The members need to have diverse backgrounds with consideration as to race, gender, ethnicity, and expertise.

Membership will meet the following requirements of VHA Handbook 1200.01:

- 1) At least two members from Durham VAMC's staff who have major patient care or management responsibility;
- 2) At least two members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise;
- 3) At least one member who holds an academic appointment, and is either a full-time Federal employee or a part-time permanent Federal employee;
- 4) All voting members must be compensated full-time or permanent part-time Federal government employees;
- 5) A voting member may fill more than one criterion for required membership, for example, the member may have both major care or management responsibilities and be actively engaged in major R&D programs;

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- 6) If the facility conducts research involving the use of investigational drugs, consideration needs to be given to include a representative from the investigational pharmacy or Pharmacy as either an ex officio nonvoting member or a voting member;
- 7) Ex-officio members without a vote include the MCD, the COS, the ACOS/R&D, the AO/R&D, the Veterinary Medical Officer (VMO), and the Research Pharmacist. The ACOS/R&D functions as Executive Secretary of the Committee. Other ex-officio members may be appointed to the Committee if their appointments assist the R&DC in fulfilling its responsibilities. Other individuals may be invited to assist the R&DC because of their competence in special areas in the review of issues requiring expertise beyond, or in addition to, that available to the Committee. These individuals may not contribute to a quorum or deliberate or vote with the Committee (see "Use of ad hoc Expert Review section).
- 8) Voting members are appointed by the MCD in writing and serve terms of 3 years. 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.
- 9) Alternate members, like primary members, are formally appointed by the MCD and serve terms of 3 years. Each alternate member may substitute for one or more primary members, and each primary member may have one or more alternate. 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. If the alternate member and the primary member both attend an R&DC meeting, only the primary member may vote and only the primary member counts towards the quorum.
- 10) Committee members must elect a Chairperson every 1 or 2 years. The Chairperson must be approved and officially appointed, in writing, by the MCD for a term of 1 or 2 years. The Chairperson may be reappointed without any lapse in time. The Chairperson must not simultaneously chair a subcommittee of the R&DC. The Committee members may choose to elect a vice-Chairperson (equivalently designated as Co-Chairperson). The Co-Chairperson must also be approved and officially appointed, in writing, by the MCD for a term of 1 year. The Co-Chairperson may be reappointed without any lapse in time and must assume the responsibilities of the Chairperson when the Chairperson is not available.
- 11) All members of the R&DC must fulfill the educational requirements specified by VHA's Office of Research & Development (ORD) and other applicable

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requirements found on ORD's web site at
<http://www.research.va.gov/programs/PRIDE/>.

- 12)Note: Names of potential new IRB voting members for the VA Central IRB must be submitted to the VHA Central Office IO, or designee, and that IO, or designee, must appoint VA Central IRB voting members in writing.

There may be cross membership between the R&DC and its subcommittees. If a subcommittee does not have a member serving on the R&DC, it has established a liaison in order to facilitate continuous communication between committees. This responsibility will be fulfilled by the Subcommittee Chair, unless otherwise designated. The liaison is responsible for submission of monthly executive summaries to the R&DC.

6.1 Use of ad hoc Expert Review

An expert ad hoc review member(s) may be requested to assist the R&DC if his/her subject matter expertise is required to provide adequate and appropriate review of the proposed research. Such expertise may be beyond, or in addition to, that available on the Committee. Ad hoc reviewers may not be counted towards quorum and cannot vote. Ad hoc reviewers are required to disclose any conflict of interests prior to giving expert advice.

6.2 Training

It is the responsibility of the ACOS/R&D to provide committee members with an initial orientation to their committee activities and appropriate annual continuing education required by ORD and other applicable regulations. The R&DC provides training guidelines for R&DC Membership (Appendix 3) for new members. In addition, the R&D Chairperson offers and recommends a face-to-face meeting with new members.

Training is tracked and documented by the Research Office. Updated versions of the R&DC SOP and subcommittee SOPs are readily available to all members on the shared ("S:\") drive and/or hard copy.

R&DC members must also maintain current training as required by the IRB, IACUC, and/or SRS, depending on the type(s) of research the R&DC member conducts. Such training will be tracked by the appropriate subcommittee (see Section 9, Subcommittees of the R&DC, for more information).

6.3 Conflict of Interest

Conflicts of interest (COI) may include circumstances where financial, professional, or other personal issues are involved.

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Like all VA employees, VA investigators and R&DC members must comply with the current 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. 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/or other administrative punishment.

6.3.1 R&DC Member COI

An R&DC member has a COI with a research study if s/he (or spouse or dependent child) has any significant financial interests in the study as defined by current VHA COI standards, or if s/he (or spouse or dependent child) is involved in the design, conduct, or reporting of the research.

An R&DC member must disclose the COI to the R&DC Chairperson and/or R&DC Administrator if the member has a perceived or actual conflict of interest with a research study to be reviewed. The R&DC member may not be the reviewer for a research project with which s/he has a COI. The research project will be reassigned and reviewed by an R&DC member that does not have a COI with the research to be reviewed.

The conflicted committee member may answer members' questions during the review process but must leave the room during discussion and vote on the study. The minutes for the meeting will show the member was recused from the vote and the member will not be counted in the quorum for the vote.

6.3.2 Investigator COI

An Investigator has a COI with a research study if s/he (or spouse or dependent child) has any significant financial interests in the study as defined by current VHA COI standards, or if s/he (or spouse or dependent child) is involved in the design, conduct, or reporting of the research.

Should the R&DC review research where it appears one or more of the Investigators may have a COI, the convened R&DC must review and discuss the potential COI when a quorum is present. The R&DC will deliberate and vote on actions to minimize, monitor, and/or eliminate all potentially significant COIs.

6.3.3 Institutional COI

An institutional financial COI may exist when:

- 1) A Durham VAMC employee has disclosed an invention to the Department of Veterans Affairs (DVA), and/or

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- 2) The DVA has formally retained rights (issued a Determination of Rights letter) to the invention, and/or
- 3) The Durham VAMC has rights to royalties from a licensing arrangement for the invention, and/or
- 4) The invention will be used in or will be the subject of research conducted at the Durham VAMC.

Should any of those conditions exist, the R&DC will develop a plan to manage or eliminate the conflict. Such plans may include but are not limited to public disclosures of the institutional COI in publications, presentations, or other public announcements.

7. R&D COMMITTEE MEETINGS

The R&DC meets monthly on the fourth Wednesday at 12pm.

7.1 Agenda preparation and distribution

Investigators submit items for review to the Research Office; Research Office staff log items into the research tracking database (MIRB) and assign the submission to the R&DC or relevant subcommittee. Meeting agendas for each committee are created based on this assignment. Research Office staff distribute agendas and materials for review to each committee one week prior to the scheduled committee meeting.

7.2 Conduct of meetings

The R&DC conducts in-person meetings. 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. Scheduled meetings may be cancelled and re-scheduled under special circumstance (e.g. lack of quorum, holiday, inclement weather, emergent issues, etc.). Unscheduled meetings will have the same quorum requirements as scheduled meetings.

R&D Committee actions on research proposals can be to:

- 1) Approve with no changes (or no additional changes). The research may proceed.
- 2) Approve with small number and/or narrow focus of substantive scripted or non-scripted changes (contingent approval). The revised application must be reviewed by full Committee at a convened meeting. The research may proceed after the required changes are verified, the protocol approved by the full committee and all approval letters have been provided to the investigator. Any significant changes to the protocol require tabling rather than contingent approval.
- 3) Table – significant changes to the protocol are required. Additional information or substantive changes are required. The R&D Committee determines that it lacks sufficient information about the research to proceed with its review and that the changes are significant and/or so numerous as to require Full Committee re-review. The research may not proceed until the convened R&D Committee has approved a revised application incorporating all stipulations.
- 4) Disapprove – the research cannot be approved and initiated at Durham VAMC due to serious scientific or ethical concerns.

Section 7: R&D Committee Meetings

- 5) Defer – if the R&D Committee finds that it has received insufficient information to review the research, it may defer the review until all required information has been obtained.

7.3 Quorum

Initial and continuing review of research requires review by a convened meeting in which there is a quorum consisting of a majority of voting members of the Durham VAMC R&DC. Quorum can be lost if a member or members have to leave a meeting early or recuse themselves due to conflicts of interest. In such circumstances affected item(s) for review would be deferred until a quorum was re-established, reviewed at a specially-convened meeting, or postponed until the next regularly-scheduled meeting. The Research Program Assistant is responsible for monitoring the quorum during R&D meetings. Should the Research Program Assistant not be present at a convened meeting the Chairperson or designee will assume this role.

7.4 Voting

All R&DC actions (approvals, contingent approvals, tabling, disapprovals, and deferrals) must be by a majority vote of the convened quorum. Each voting member has one vote. No proxy votes (written or telephone) are allowed. Types of votes include:

- For: Present at the convened meeting, participates in final deliberations and votes for approval.
- Against: Present at the convened meeting, participates in final deliberations and votes for disapproval.
- Abstained: Present at the convened meeting, participates in final deliberations and chooses not to vote. Members who abstain are counted toward the quorum.
- Recused: Present at the convened meeting, declares a Conflict of Interest, leaves the room, does not participate in final deliberations and does not vote. Recused members are not counted towards the quorum.
- Excused: Present at the convened meeting however has left the room for personal reasons during final deliberations and does not vote. Excused members are not counted towards the quorum.

In instances where the R&DC is being informed of an item or event, the R&DC may acknowledge the item or event without taking a vote. Such instances include, but are not limited to: old business items, new business items, notifications, compliance reviews, and subcommittee reports of serious adverse events, noncompliance (serious or continuing), and (serious) unanticipated problems, etc.

8. R&D COMMITTEE RECORDS

Required R&DC records include, but not limited to: minutes of the R&DC and R&DC subcommittees, copies of all written correspondence, and membership lists for the R&DC and all R&DC subcommittees.

8.1 Minutes

In general, minutes shall include items discussed, any modifications required, all actions taken by the convened R&DC and the votes underlying those actions. Minutes must document the approval of prior R&DC or subcommittee minutes, and discussions regarding all items of business or information brought before the R&DC.

Minutes are recorded and include names of all voting members and non-voting members (including ex-officio members), indicating the category of their membership and whether the member was present or absent. If an alternate member is present in place of a voting member, the minute must indicate this fact and name who the alternate member is replacing.

Minutes document the presence of a quorum and types of actions taken by the Committee (i.e. Approved, Contingent Approved, Tabled, Disapproved, Deferred), the vote on the action, including the number voting for, against, and abstaining. Excused members must be listed by name. Recused members from the vote must be named and it must be documented whether or not the member was present during the discussion.

Minutes document summaries of discussions (including controverted issues) and any decisions made as a result of the discussion. Minutes document the basis for requiring changes to a research project, program, or center in order to obtain approval; any required follow-up and which committee, subcommittee, or person is responsible for the follow-up; and the basis for disapproving a research project, program, or center when this occurs. Minutes will also include the stipulations required for research projects that have been contingently approved, tabled or disapproved. For contingent approvals, minute will document that stipulations were met and that final approval has been granted.

Draft minutes from the most recent subcommittee meetings are distributed to all R&DC members prior to the next R&DC meeting so that draft minutes may be used to aide reviewers in their deliberations, if applicable.

Final subcommittee minutes (e.g., minutes that have been approved by the subcommittee) are also distributed to the R&DC with the agenda packet. During the convened R&DC meeting, members review and vote to approve or disapprove the final subcommittee minutes. If the R&DC has questions or concerns about a subcommittee's final minutes, comments will be relayed back to the subcommittee for possible revision.

Draft minutes from the previous R&DC meeting are provided to R&DC members with the next meeting agenda packet. The convened R&DC will review the minutes from their previous meeting and vote to approve or disapprove. If any R&DC member has questions or concerns with the draft R&DC minutes, revisions will be made and presented for review and approval at the next R&DC meeting. R&DC minutes are filed with the Research Service. All minutes of the R&DC are sent to the MCD through the ACOS/R&D and COS for review and appropriate action.

8.2 Research Proposal Records

Each research proposal is given a separate file. Protocols are assigned a unique number from Management of Institutional Review Board software (MIRB) and a unique grant number from the electronic Project Management and Information System (ePROMISE) for tracking and administrative purposes. MIRB stores information regarding each document received, when it was reviewed, and the results of that review. Additionally, MIRB tracks changes that are needed, when those changes were received and approved, and the date of Continuing Review. MIRB also tracks R&DC membership and generates meeting minutes and correspondence regarding Committee actions to principal investigators. Research Service also enters data into the ePROMISE Database system that is provided by VA Central Office to track research projects.

Copies of all research proposals, amendments reviewed, and all other submitted and reviewed material, compliance reports, all continuing and final reports, R&DC and Subcommittee minutes, copies of all written correspondence, membership rosters for the R&DC and all Subcommittees, are stored in secure locations. The records of VA-approved research studies conducted at Durham VAMC are stored in a locked secure room in the Research Office of the Durham VAMC and archived accordance with National Archives and Records Administration (NARA) regulations at the NARA facility in Neosho, Missouri. Research Service maintains all records collected over the course of a study. Currently, there is no approved destruction disposition schedule for research records. All records are accessible for inspection and copying by representatives of VA, sponsors, other Federal regulatory agencies or others with written authorization at reasonable times and in a reasonable manner. Information on the HIPAA authorization form will record who is authorized to review protected health information.

Records are maintained in locked Research Office space. Access to records is limited to the ACOS/R&D, AO, Committee and Sub-committee members, RCO(s), Research Administrative Office staff, authorized VA representatives, officials of Federal and State regulatory agencies, including but not limited to the Office of Research Oversight (ORO), the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). Research investigators shall be provided reasonable access to files related to their research in the presence of a Research Office staff person. Appropriate accreditation bodies, such as Association for Assessment and Accreditation

of Laboratory Animal Care (AAALAC), etc., shall be provided access to research records.

Research records may be electronic or 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, OHRP, FDA, and any other Federal requirements.

8.3 Correspondence with Investigators

The Principal Investigator is notified in writing of the R&DC's decision to approve, approve with conditions, disapprove a proposed research activity, or if modifications are required to secure R&D approval. The PI is notified in writing of the results of the R&DC's continuing review of the project. If the R&DC disapproves or requires modifications of proposed research to obtain approval, and the disapproval or modification affects a subcommittee review, the appropriate committees or subcommittees (e.g., IACUC, IRB, and SRS), must be notified in writing and reconsider the proposal.

Signed hard copies of the correspondence will be provided to investigators for their files. Responses to the R&D Committee should come from the Principal Investigator or a designated study coordinator and must be signed by the PI.

9. SUBCOMMITTEES OF THE R&D COMMITTEE

The R&DC may establish any subcommittees deemed necessary for the efficient and effective management and oversight of the R&D Program. The Durham VAMC R&DC established the following sub-committees and is responsible for reviewing and approving their final minutes:

- Institutional Review Board (IRB): Durham
- Institutional Review Board (IRB): VHA Central Office (Central IRB)
- Institutional Animal Use and Care Committee (IACUC)
- Subcommittee on Research Safety (SRS)
- Research Space Subcommittee (RSS)

Each subcommittee must maintain adequate records and retain such records according to current VHA standards. These records include research proposals, amendments, continuing or final reports, minutes of meetings, all written correspondence, membership roster listing all voting, non-voting, and ex-officio members including their appointed roles, written records documenting actions taken to carry out the Committee's responsibilities, standard operating procedures, and all correspondence to and from investigators, other committees, subcommittees, and other entities or individuals.

Each subcommittee records minutes of its meetings and reports to the R&DC, which approves, disapproves its findings or requires modifications in order to secure approval, **except that the R&DC cannot approve a study that is disapproved by a Subcommittee but the R&DC may disapprove a study approved by the Subcommittee.** The Durham R&DC may request that a Subcommittee re-review an action if R&DC feels that new information needs to be considered. Changes resulting from R&DC review affecting human, animal, safety, or space issues are referred to the appropriate subcommittee for further review and/or consideration. Minutes of the R&DC and its subcommittees are maintained in the Research Office.

The R&DC and each subcommittee must maintain standard operating procedures that govern the conduct of the research that the subcommittee reviews. Standard Operating Procedures are written by designated individual(s) with knowledge of the committee's practices and may be reviewed annually or as needed, depending on the procedures of the subcommittee. The R&DC will review and approve all updates to a subcommittee's standard operating procedures either as they occur in real time or at annual review, in accordance with the subcommittees standard operating procedures.

Each subcommittee must track completion of training required to conduct the research that the subcommittee reviews. The IRB tracks required training in MIRB, using reports from the Collaborative Institutional Training Initiative (CITI) website. The IACUC tracks required training via the CITI website. The SRS tracks required training via the CITI website, the VA's Talent Management System (TMS) and locally-created spreadsheets. Each committee is responsible for and has procedures for ensuring that investigators

and/or research staff do not conduct research if their required training is missing or lapsed.

Annual quality assurance reviews are conducted on the human, animal, safety and space programs including the respective subcommittees. These reviews are completed and submitted to and reviewed by the R&D Committee.

9.1 Institutional Review Board (IRB)

The R&DC has charged the Durham VAMC Institutional Review Board (IRB) with the scientific and ethical review and oversight of all research activities involving the use of human subjects. This includes the responsibility of maintaining the assurances of compliance set forth in the Federal Wide Assurance and according to the standards set by the accrediting organization under contract with the VHA. The R&D Committee oversees the IRB in this responsibility. The IRB meets monthly.

The Policies and Standard Operating Procedures for Human Research Protection detail the procedures, ethical principles, and regulations by which the IRB abides in the review and oversight of research involving human research subjects.

An annual quality assurance review of the IRB is conducted. This review consists of IRB composition, report of credentialing and training, budget, space, support staff, quality improvement activities, compliance issues, and goals for the next year.

9.2 Institutional Animal Care and Use Committee (IACUC)

The R&DC has charged the Durham VAMC Institutional Animal Care and Use Committee (IACUC) with the scientific and ethical review and oversight of all research activities involving the use of animals in research. This includes the responsibility of maintaining an Animal Welfare Assurance set forth in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. The R&D oversees the IACUC in this responsibility. The IACUC meets monthly.

An annual review of the Animal Care and Use Program, including the IACUC, is conducted and includes inspection reports, IACUC composition, IACUC arrangements, budgets, space, support staff, training, quality improvement activities, compliance issues, and goals for the next year.

9.3 Subcommittee on Research Safety (SRS)

The R&D Committee has charged the Durham VAMC Subcommittee on Research Safety (SRS) with the review and oversight of research proposals involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to submission for R&D funding. This includes a review of

Section 9: Subcommittees of the R&D Committee

all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding located off-site. The SRS assesses the impact of each agent on the safety of personnel working in research laboratories. All research projects involving biological, chemical, physical, and radiation hazards must be approved by SRS and then by the R&D Committee prior to commencement. The SRS meets monthly.

An annual review of the Research Safety and Security Program is conducted and includes planned training, compliance, and security issues.

9.4 Research Space Subcommittee (RSS)

The R&DC has charged the Durham VAMC Research Space Subcommittee with implementing research space policies regarding the utilization and assignment of space. Specifically, the Subcommittee will review space requests, carry out annual reviews (of current utilization of space) as directed by the ACOS/R&D or the R&DC, and recommend assignment of new space to individual investigators. The RSS meets as necessary.

An annual review of the Research Space Subcommittee is conducted and includes the RDIS Part I report, RSS minutes, and Research Service space policies and procedures.

9.5 Central Institutional Board (Central IRB)

The VA Central IRB maintains its own FWA and accreditation and functions as an IRB of record for the Durham VAMC. The VA Central IRB currently only reviews ORD-funded multisite research projects. As a fully constituted and independent review board, the Central IRB maintains their own Standard Operating Procedures and conducts an annual assessment of their performance.

An annual review of the Central IRB is conducted. This review consists of IRB composition, report of credentialing and training, budget, space, support staff, quality improvement activities, compliance issues, and goals for the next year.

10. INVESTIGATOR RESPONSIBILITIES

The Principal Investigator (PI) assumes ultimate responsibility for the conduct of research according to federal, sponsor and organizational guidelines and attests that adequate resources are available to conduct the study. The investigator may delegate responsibility but is ultimately responsible for the conduct of research. Investigators are required to complete annual research training and to provide adequate documentation of training to the Research Office. The PI is ultimately responsible for training and oversight of his/her research staff. Numerous training courses are required, and depend on the type of research conducted. Core training for human subjects research and animal research is located on the Collaborative Institutional Training Initiative (CITI) website at <http://www.citiprogram.org/>. The Research Office can be contacted for other current training requirements. The investigator assumes responsibility for his/her research subjects and employees and is available to answer questions. Investigators are authorized to have access to the VA shared drive where research policies, submission forms and SOPs are posted and available.

The Durham R&DC recognizes one PI for each project. Physician PIs (and others as required by VA regulations) must be credentialed and privileged at Durham VAMC. All PIs and research staff must have VA employee status (with or without [WOC] compensation status) or be appointed or detailed to VA under the Inter-governmental Personnel Act (IPA) of 1970 and have provisions for appropriate space at the VA prior to initiating research activities. Co-investigators communicate with the R&DC through the PI. Non-licensed physicians cannot practice medicine; authorized research duties are described in a Research Scope of Practice. Physicians in training need to be supervised and supported by a clinical faculty member who will serve as a Co-Investigator. The PI has ultimate responsibility for his/her research project and all official R&DC and Subcommittee correspondence is addressed to the PI. Trainees cannot serve as PIs unless they have completed their clinical training. New investigators are strongly encouraged to attend a Good Clinical Practice or analogous course(s) offered by such organizations as ACRP, DIA, SOCRA, FDA, VHA, OHRP, OLAW, ORO and ORD. Durham VAMC research personnel may only perform duties according to their licensure, education, training, experience, job description, Research Scope of Practice, VHA credentialing, and Human Resources policies as applicable. The IRB generally communicates with external sponsors through the investigator however the R&DC is authorized to contact sponsors directly if appropriate to human subject protections.

Investigators are responsible for:

- 1) Holding specific credentials and privileges awarded by the VA facility and VHA (where applicable) to conduct research in VA. Investigators must be qualified through education and experience.
- 2) Complying with all applicable personnel and other VHA policies, whether the investigator is compensated, WOC, or IPA.

Section 10: Investigator Responsibilities

- 3) Obtaining the complete approval of all appropriate non-research entities and R&D Committee subcommittees, and written notification from the ACOS/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 Subcommittee to fully review the research project. Information on such issues as budgetary issues and/or needs, source of funding, space, and required personnel needs must also be submitted for review.
- 5) Developing and implementing plans for data use, storage, and security that are consistent with VA, VHA, and other Federal statutes, regulations, and policies.
- 6) Preparing and submitting information at least annually on their research program(s) and on each project to the appropriate R&DC or subcommittee for continuing review as required by the respective R&DC or subcommittee.
- 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. NOTE: Examples of research that may not support the mission of VHA includes research involving children or prisoners.
- 8) Acknowledging VA research support and/or VA employment in all publications, presentations, media interviews, or professional activity where research results are being publicized, presented, recognized, or discussed as required by VHA Handbook 1200.19, Publication of Research Results.
- 9) Following ORD's current guidelines for submitting publications or presentations of original research, commentaries, review articles, letters to the editor, and other journal publications to ORD's PubTracker prior to publication or presentation.

Appendix 1: Protect VA Sensitive Information

PROTECT VA SENSITIVE INFORMATION

DEFINITION OF VA SENSITIVE INFORMATION:

“VA sensitive information” is data that requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction. The term includes (1) information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, (2) proprietary information, (3) records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the HIPAA Privacy Rule, and (4) information that can be withheld under the Freedom of Information Act (FOIA). Health information de-identified in accordance with VHA Handbook 1605.1 Appendix B would not be considered sensitive information.” -- VACO Office of R&D Key Points Related to Privacy & IT Security, June 04, 2007

ACTION REQUIRED:

Don't leave hard copies/charts with VA sensitive information in open areas for others to see or take.

Don't store VA sensitive information on unencrypted computers or unencrypted storage devices (e.g., thumb drives).

Don't store VA sensitive information off-site unless you obtain written permission (contact the ISO or PO).

Don't transmit VA sensitive information in unencrypted e-mails (contact ISO if you need PKI encryption software installed on your machine).

Report privacy or information security incidents within 1 hour to:

Information Security Officer (ISO) – Scott Gardiner or LaToya Butler-Cleveland
Jeffrey.Gardiner@va.gov / LaToya.Butler-Cleveland@va.gov
(919) 286-0411 x 5793 / (919) 286-0411 x 6973

Privacy Officer (PO) – Emily Fuemmeler
Emily.Fuemmeler@va.gov
(919) 286-0411 x 5981

Note: You may notify the ISO, PO, ACOS/R&D, and other research personnel by sending an e-mail describing the incident to VHADURResearchEventReport@va.gov.

Appendix 2: Procedures for Loss or Theft of Computer Devices

Appendix 2: Procedures for Loss or Theft of Computer Devices

DEPARTMENT OF VETERANS AFFAIRS

VA Medical Center
508 Fulton Street
Durham, NC 27705

Procedures for Loss or Theft of Computer Devices

What to Report: Loss or theft of any VA-owned computer device (such as PC, laptop, external hard drive, personal data assistant (PDA), flash drive, zip drive, thumb drive, CD, DVD), and loss or theft of any non-VA owned device that stores VA sensitive information. *When in doubt, report it.*

When to Report: Immediately – as soon as you realize the item is gone and you have quickly ruled out other explanations.

Step 1: Report the loss to the Police.

Loss Discovered at the VA

Call VA Police
Extension 6230

Loss Discovered Elsewhere

Call security at location (hotel, airport, etc.) and also local Police. Get phone #, badge #, case #, copy of report, if possible.

Step 2: Send email with brief details and also call:

Notify your supervisor

Bradley Olson
(919) 286-0411 x 7632
bradley.olson@va.gov

Notify Information Security Officer

Scott Gardiner
(919) 286-0411 x 5793
jeffrey.gadiner@va.gov
or IRM help desk x5812

Notify Privacy Officer

Emily Fuemmeler
(919) 286-0411 x 5981
emily.fuemmeler@va.gov

Step 3: Supervisor will notify the Service Chief. ISO will notify the Medical Center Director. The Medical Center Director will notify VA Central Office.

Key Contacts and Phone Numbers:

VA Medical Center Main Switchboard: (919)286-0411 or (888)878-6890

VA Police		Extension 6230
Information Security Officer	Scott Gardiner	Extension 5793
Privacy Officer	Emily Fuemmeler	Extension 5981
IRM Help Desk		Extension 5812
Administrative Officer of the Day (after hours)		Extension 6250

Appendix 3: Training Guidelines for R&DC Membership

1. Primary responsibility: The R&D Committee is responsible for oversight of the research program and for maintaining high standards throughout the R&D Program. The R&D Committee reports through the Chief of Staff to the Medical Center Director. The R&D Committee is assisted by the Associate Chief of Staff and Administrative Officer of R&D to collectively ensure the:

- a) scientific and ethical quality of VA research projects,
- b) protection of human subjects in research,
- c) safety of personnel engaged in research,
- d) welfare of laboratory animals,
- e) security of VA data, and
- f) security of VHA research laboratories.

Research at the facility may not be undertaken without R&D and appropriate subcommittee approval.

2. Review R&D Committee Handbook (1200.01 dated June 16, 2009)

3. Administrative Duties

- a) Planning and developing broad objectives for R&D program.
- b) Determining the extent to which R&D has met its objectives.
- c) Reviewing budgetary and other resource needs, at least annually and making appropriate recommendations regarding these needs (e.g., personnel, materials, supplies, space, capital equipment, training, and education).
- d) Assuring compliance with all personnel policies.
- e) Annual quality assurance review of all subcommittees and other key components of R&D functions.

4. Review of Research: The R&D Committee is responsible for reviewing research that is otherwise not reviewed by the IRB or IACUC for scientific quality and appropriateness to promote the maintenance of high scientific standards, the protection of human subjects including privacy and confidentiality, the welfare and appropriate use of animals for research, the safety of personnel involved in research, the security of research laboratories, the security of VA data protected and sensitive information, the availability of adequate resources to conduct and complete the research, and the relevance of research to support the VA mission. Each research project otherwise not reviewed by the IRB or IACUC must be reviewed and approved initially and at least annually thereafter.

Initial Reviews: In conducting an initial review of otherwise projects not reviewed by the Durham IRB or IACUC, the R&D Committee must evaluate the scientific quality, relevance, and ability of the investigator to perform and complete the research. The review must include information on the use, storage, and security of VA data and sensitive information, budget, requirements for space, personnel, equipment, and supplies, the role of the investigator at the facility, the investigator's qualifications, and any subcommittee findings. The R&DC also reviews studies approved by the CIRB, the creation and operation of research data repositories, and individual protocols that will use data from a research or non-research data repository

Appendix 3: Training Guidelines for R&DC Membership

Continuing Reviews: The continuing review of CIRB studies, research data repositories, protocols that use data from a data repository, and projects otherwise not reviewed by the Durham IRB or IACUC must assess the research activities that have occurred, the progress of the research, and any issue that may impact the progress of the research including compliance issues. The review must include an assessment of data security, confidentiality of data, release of data, and control of the data so that reuse of the data is within an approved research protocol and in compliance with VHA procedures. The review must include a quality assurance review of publications assessing the acknowledgement of VA support and affiliation.

5. R&D Committee Meetings: The R&D Committee meets monthly (4th Wednesday of every month at noon). Review agenda carefully for study assignments.
 - a. Scientific Reviews
 - i. Minutes from previous meetings are reviewed and voted on.
 - ii. Continuing reviews are divided between two committee members for review.
 - iii. Contingent reviews are reassigned if possible to the persons who requested a contingency for review to determine if contingencies have been met.
 - iv. Initial reviews are divided by expertise among the committee members not involved in the continuing reviews. This must be the most thorough and comprehensive review of all reviews (see above for guidelines).
 - b. Business Items
 - i. Monthly combined executive subcommittee reports reviewed
 - ii. Monthly business report from the AO
 - iii. Old Business items discussed as needed
 - iv. New business items discussed as needed

If you are not able to attend a specified meeting, please let the research office know in advance so that scientific reviews can be appropriately assigned. Once assigned, if you are unable to attend a meeting, you should send your written review of assigned projects to the research office, R&D chair, and the second reviewer of your assigned protocols.

Appendix 4: R&DC Reviewer Checklist

Appendix 4: R&DC Reviewer Checklist

PI:

Date:

Project Title: _____

	YES	NO	N/A	COMMENTS
1) Is the scientific design described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2) Is the scientific design adequately justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3) Is the scientific design adequate to answer the questions(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4) Are the aims/objectives likely to be achievable within the given time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5) Is the statistical analysis plan appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6) Is the safety monitoring plan appropriate for human studies? (e.g., Is there a need for a DSMB/Data Monitoring Committee if one does not exist?)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7) Was there a thorough evaluation of relevant literature and previous studies?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8) Is the investigator qualified by education/training to conduct the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9) Does the investigator have adequate resources (i.e., staff, space) to conduct the project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10) Has a Conflict of Interest been identified? a) If yes, has the COI been adequately managed?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	
11) Does the protocol involving the collection, use and/or storage of research information including subject identifiers and PHI contain specific information on all sites where the data will be used or stored, how the data will be transmitted or transported, who will have access to the data, and how the data will be secured?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12) Is the research relevant to Veterans or active duty military personnel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Appendix 4: R&DC Reviewer Checklist

PI:

Date:

Project Title:

13) Will non-Veterans be recruited and/or enrolled in the research? *If yes, greater than minimal risk studies will come to R&D after IRB approval (which addresses human safety) and not necessarily institutional obligations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Additional Recommendation(s):				
Signature of Reviewer/Date of Review:				

- Version 4, November 2013