VA NEBRASKA-WESTERN IOWA HEALTH CARE SYSTEM (VA NWIHCs) Omaha, NE (636)

RESEARCH AND DEVELOPMENT COMMITTEE STANDARD OPERATING PROCEDURES

A MANUAL

for

R&D Committee Members, Principal Investigators, & Staff

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I. DEFINITIONS

VA Investigator. A VA investigator is an individual who conducts research approved by the R&D Committee while acting under a VA appointment on VA time, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970 (5 U.S.C. 3371 et seq.). As a VA investigator, that individual represents the interests of the VA in conducting the study. NOTE: Individuals working under a contract with VA cannot be given a WOC appointment to conduct research on their contract time. Contractors can provide clinical services or other activities in support of VA research in accordance with their contract.

VA Research. VA research is research conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the R&D Committee before it is considered VA research and before it can be initiated. The R&D Committee only reviews research that is considered VA research as defined above.

VA Data or VA Information: VA data or VA information is data or information owned, in the possession of, under the control of, or collected by VA or any entity acting for or on behalf of VA. The data may be identifiable, de-identified, sensitive, or non-sensitive.

VA Protected Information (VAPI): VAPI is 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.

VA Sensitive Information and Data: VA sensitive data means 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 and includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, and records about individuals requiring protection under applicable confidentiality provisions (see 38 U.S.C. 5727).

Institutional Review Board (IRB): An IRB is a board, committee, or other group formally designated by an institution to review, approve, require modification, disapprove, and conduct continuing oversight of human subject research in accordance with the Common Rule (38 CFR Part 16) and other applicable regulations.

Institutional Animal Care and Use Committee (IACUC): The IACUC is the local committee charged with ensuring compliance with animal research regulations and guidelines. In the VA system, the IACUC is organized administratively as a subcommittee of the Research and Development Committee.

Subcommittee on Research Safety (SRS): The purpose of the Subcommittee on Research Safety (SRS) is to review all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines.
II. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR

A. The Medical Center Director (MCD) serves as the Institutional Official responsible for all aspects of the research program including but not limited to protection of human subjects, the care and use of animals in research, privacy and security of VA data, biosecurity, and biosafety. The MCD is responsible for suspending or terminating research when concerns about research conduct are raised and/or substantiated. The MCD delegates the authority to administer the R&D program to the Associate Chief of Staff for Research (ACOS/R), who reports to the COS. The RDC advises the MCD through the COS on professional and administrative aspects of the R&D program.

The Research and Development (R&D) Committee at the VA Nebraska-Western Iowa Health Care System serves in an advisory capacity and is responsible through the Chief of Staff to the MCD for oversight of the research program and for maintaining high standards throughout the R&D program. The Associate Chief of Staff (ACOS) for R&D and the Administrative Officer (AO) is assisted by the R&D Committee for carrying out its duties. These standards include ensuring the scientific and ethical quality of VA research projects, protection of human subjects in research, the safety of personnel engaged in research, the welfare of laboratory animals, privacy and security of VA data and the security of VHA research laboratories.

B. The MCD ensures:
   1. Research in which the facility is engaged is approved by R&D and the appropriate subcommittees.
   2. Members of the R&D Committee are appointed following the specifications in the VHA R&D Committee Directive.
   3. 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.
   4. Research that is approved by R&D is suspended or terminated when concerns are raised and substantiated about the conduct of research. For additional information see VHA Handbook 1058.02, Research Misconduct, dated February 7, 2014, and VHA Handbook 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research, dated April 15, 2013.
III. RESPONSIBILITIES OF THE ACOS/R&D

A. The ACOS/R&D is responsible for:

(1) Serving as the Executive Secretary of the R&D Committee and providing administrative support, including correspondence, scheduling meetings, and responding to questions about the Committee.

(2) Notifying investigators, in writing, when a research project can be initiated, and the period for which the project is approved. This notification occurs only after the research project has been approved by all applicable R&D Committee subcommittees and the R&D Committee. **NOTE:** The ACOS/R&D notification may be combined with the R&D Committee approval notice. If combined, the R&D Committee approval notice may be signed by the ACOS/R&D alone, or together with the R&D Committee Chair, per local policy. ACOS/R&D notification is not required for continuing review.

IV. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

A. Developing a research plan that is scientifically valid; minimizes risk to human and animal subjects used in research and to research personnel; and contains a sufficient description of the research, including all procedures and the plan for statistical analysis, to allow the R&D Committee and its subcommittees and other research-related committees to fully review the research project.

B. Obtaining approval by all appropriate non-research entities and R&D Committee subcommittees, and written notification from the ACOS/R&D prior to initiating a research project.

C. Submitting a completed, signed and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement (https://www.research.va.gov/programs/tech_transfer/model_agreements/conflict_of_interest.pdf), for review by the R&D Conflict of Interest Committee prior to:

1. Initial review of a study protocol in which the employee is listed as Investigator;
2. Continuing review of a study protocol in which the employee is listed as Investigator;
3. The employee being added as an Investigator to a study protocol; and
4. When a change in relevant information requires that the investigator change an answer in Section I of an earlier-filed OGE Form 450 Alternative – VA to “yes” or that changes the reason for a “yes” answer.

D. Submitting and implementing plans for data use, storage, and security to the PO and ISSO that are consistent with VHA Directive 1605.01, VA Directive 6500, implementing handbooks, and other legal requirements.

E. Preparing and submitting information, at least annually or as otherwise required, on all research projects to the appropriate R&D Committee subcommittee or the R&D Committee for continuing review.
F. Ensuring that research proposals support the mission of VHA and enhance the quality of health care for Veterans.

**NOTE:** See VHA Directive 1200.02(1), Research Business Operations for general requirements for all VA investigators.
V. Responsibilities of Research and Development Committee. The R&D Committee is responsible for:

A. Assisting the medical facility Director in fulfilling responsibilities for the facility’s research program by making recommendations regarding personnel, space, and other resource needs of the research program.

B. Reviewing research proposals and approving the research, requiring modifications to obtain approval, or disapproving the research.

C. Ensuring the effective operation of the facility research program through oversight of all R&D Committee subcommittees and the facility’s research portfolio.

D. Ensuring that all research in which the facility is engaged is consistent with the VA mission and complies with all applicable statutory and regulatory requirements.

E. Establishing appropriate subcommittees (IRB, IACUC, SRS) to review and oversee human subjects research, animal research, and safety and security reviews. For protocols not meeting criteria for assignment to any subcommittee according to local SOPs, the R&D Committee is the review and approving committee of record. NOTE: While the R&D Committee can disapprove research approved by one of its subcommittees, it is not permitted to approve research that has been disapproved by an appropriate subcommittee.

F. Ensuring Information System Security Officer (ISSO) and Privacy Officer (PO) review is complete by subcommittee before a study team is given the ACOS signed approval letter. NOTE: The R&D Committee can approve contingent on ISSO and PO review.

G. Determining whether the facility should participate in a study and ensuring that the appropriate Institutional Review Board (IRB) agreements are in place as required by VHA Directive 1200.05(2), Requirements for the Protection of Human Subjects in Research, and VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research, prior to using the external IRB when a study is reviewed by an IRB of another Federal agency (for example, the National Cancer Institute Central IRB) or a non-VA IRB serving as the multi-site IRB for a study. NOTE: An external IRB is an IRB of another Federal agency or another non-VA institution’s IRB. For purposes of this directive, use of the VACO IRB or another VA facility’s internal IRB is not considered to be an external IRB. See VHA Handbook 1200.05(2).

H. Establishing procedures to ensure that all research in which the facility is to be engaged has been reviewed and approved for high scientific quality, the protection of human subjects and research staff, the welfare of animal subjects, the safety of all involved in research, the security of research laboratories, and the security of VA Data and sensitive information.

Establishing a local R&D Conflict of Interest Process- (ACOS, AO, and or R&D Chair/ Designee) to ensure that potential financial conflicts of interest are reported, reviewed, and managed in accordance with government ethics rules and regulations and VA ethics policies. See VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry. NOTE: Any concerns that involve criminal conflict of interest law or Standards of Conduct are matters for the Designated Agency Ethics Official (DAEO). The DAEO, the Principal Deputy General Counsel, the Alternate DAEO, and the OGC Ethics Specialty Team address issues involving the application of criminal conflict of interest laws (18 U.S.C. Chapter 11) and the Standards of Conduct for Executive Branch Employees (5 CFR Part 2635). The DAEO, the Alternate DAEO and the Ethics Specialty Team are the only
J. Ensuring that Classified Research is not conducted as VA research.

K. Reviewing the operations of all research-related committees and subcommittees as an ongoing function.

L. Fulfilling such other functions as may be specified by the medical facility Director, ORD, and VHA leadership.

VI. MEMBERSHIP OF THE R&D COMMITTEE

Annually, members of the R&D Committee are nominated from current R&D Committee members, Subcommittee members and the facility’s staff. The Research Executive Committee (composed of the ACOS, Deputy ACOS, AO, R&D Committee Chair and R&D Committee Coordinator) evaluates the nominations. A review of the membership roster and election of a committee chair and vice-chair are conducted at the R&D Committee meeting prior to being forwarded by the ACOS/Research to the Medical Center Director for appointment in writing. Voting members may serve a term of 3 years and may be reappointed without a lapse in time if deemed in the committee’s best interest. The terms are staggered to provide a partial change in membership at one time. The Chair and Vice-Chair may serve a term of 1-2 years and may be reappointed without any lapse in time. The Vice-Chair will assume the responsibilities of the Chairperson when the Chair is not available or when there is a conflict of interest. Alternate members are appointed by the Medical Center Director in the same manner as voting members with qualifications comparable to the primary member being replaced.

A. R&D Membership Roster: The composition of the committee strives to have diverse backgrounds with consideration to race, gender, ethnicity and expertise available within the NWIHCS. All members of the R&D Committee must hold a VA appointment (permanent, term, IPA, or WOC). The current roster of the R&D Committee in terms of members and alternate members by name, degrees held, and representative capacity is published annually in January of each year. In addition, the membership is summarized in the R&D Committee meeting minutes including any ad hoc review conducted. The voting membership includes representatives from the following categories:

1. Two members from the NWIHCS staff with major patient care or management responsibilities.
2. Two members who are NWIHCS investigators actively engaged in major R&D programs or can provide R&D expertise.
3. 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.
Ex-Officio non-voting members include the:
1. Medical Center Director
2. Chief of Staff
3. Associate Chief of Staff, Research & Development who functions as Executive Secretary
4. Administrative Officer, Research & Development
5. Research & Development Committee Coordinator

Non-voting Consultant who routinely attends the meeting:
Research Compliance Officer

The VHA Directive 1200.01 suggests that consideration be given to include a representative from the Pharmacy Service. The Pharmacy Service representative serves as a voting member of the NWIHCS IRB. If questions arise during R&D Committee review, the Pharmacy Service representative will be contacted.

B. Alternate R&D Committee Members: Alternates are evaluated by the Research Executive Committee and appointed by the Medical Center Director. The alternate member has a similar or related work specialty, background, or responsibility as the member he/she represents in the member’s absence. The alternate member may be re-appointed to serve on the R&D Committee as an alternate for a new member appointed to serve on the committee. The alternate member is allowed to vote in the absence of the member he/she represents. When the alternate member and the primary member both attend a R&D Committee meeting, only the primary member may vote and count toward the quorum.

C. Ad Hoc Reviewers: The R&D Committee may, at its discretion, obtain services of ad hoc reviewers when additional expertise is required. Ad hoc reviewers do not vote with the committee. Such consultants may be asked to submit written evaluations of the project or, when necessary, to present their recommendations to the committee in person. The R&D Coordinator will consult with the R&D Committee Chair to obtain an ad hoc reviewer. In addition, the ACOS/R&D may be consulted as needed. The ad hoc reviewer will be asked to comply with the conflict of interest rules as required for R&D Committee members.

D. Training of R&D Committee Members: Committee members should be up to date with CITI human subjects training. OVAMC may also require other training. Members will receive updated versions of the RDC SOP as they are issued. The ACOS/R may provide further guidance and training as needed.

E. Conflict of Interest of Committee Members: R&D Committee members, like all VA employees, must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal criminal code. The R&D Committee members, or their immediate family 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 with proposals being reviewed and must recuse themselves from the discussion and vote. At the beginning of the meeting when a quorum is present, the Chair asks members to declare any conflicts they may have with research studies being reviewed on the agenda. When conducting the initial review and subsequent continuing review of a study, the R&D Committee member must be aware of any financial conflicts, others working on the research project, or others that may influence the conduct of and reporting on the research. The recusal is documented in the minutes.
VII. RESPONSIBILITIES OF THE R&D COMMITTEE RELATED TO THE RESEARCH PROGRAM

A. The R&D Committee through ongoing review and annual evaluations is responsible for ensuring the effective operation of the research program and making appropriate recommendations to the Medical Center Director through the Chief of Staff on the oversight and evaluation of the research program. A timeline was developed which outlines the approximate annual and/or semi-annual reporting to the R&D Committee.

B. The R&D Committee is assisted by the ACOS, and AO of Research in planning and developing broad objectives for the R&D Program so that it supports the VA’s mission. The R&D Committee evaluates whether objectives of the R&D Program are being met through the ongoing review and approval process of research, annual and semi-annual inspections, subcommittee, quality assurance, ACOS and AO reports. The R&D Committee oversees all research activities for the NWIHCS and reviews the agreement/memorandum of understanding that establishes a committee from another VA or non-VA entity in lieu of a required subcommittee for the R&D Committee.

C. The R&D Committee oversees the following program duties:

1. The R&D Committee reviews all research related committees and subcommittees at least annually in part by: reviewing the minutes of each subcommittee that reviews VA research protocols; by close communication with the subcommittees; and through

2. Quality Assurance and Quality Improvement activities. When a VA facility uses an IRB other than its own internal IRB, such as, but not limited to, the VACO IRB, the IRB of another Federal agency, or a non-VA academic institution’s IRB, the role of the R&D Committee is to review and evaluate facility-specific aspects of these relationships, rather than the subcommittee itself, to ensure the obligations as detailed in the MOU are being met. For example, review of an external committee would include evaluation of the number of projects handled by the committee, communication between entities, changes in MOUs or other agreements, change in processes, and challenges. A summary of these reviews and evaluations must be sent to the medical facility Director annually.

VIII. OPERATION OF THE R&D COMMITTEE

A. Meeting Date: The R&D Committee meets on a regular schedule or as needed to meet the demands of the research program. The deadline for new submissions, continuing reviews and full committee amendments is the 20th of the month prior to the next month’s meetings. This allows for proposals to go to the applicable subcommittees and R&D Committee. This deadline is adjusted for VA-funded merit submissions requiring R&D Committee review only, as appropriate. The meeting is convened by the Chair or Vice-Chair when a quorum is present, consisting of a majority, of the voting membership. A quorum must be maintained to approve research and other issues presented to the committee. If physical presence is not possible, a member may participate through teleconference or videoconferencing and will have received all pertinent material being discussed prior to the meeting.

B. Committee Tracking Software: Research proposals are entered in the research database program which tracks the volume and status of studies, generates the agenda,
minutes, correspondence to the principal investigator and tracks continuing review, amendments and other events in monitoring the research. The Office of Research and Development also requires all projects be entered and annually updated in the national database called ePromise. The ePromise abstract serves as the summary of findings required at continued review for all committees.

C. Agenda: The agenda is distributed to voting and non-voting committee members and alternates, when applicable, one week in advance of the meeting.

The agenda includes the following:

1. R&D Committee minutes of previous meeting.
2. Action Summary List of most recent Subcommittees meeting
3. Final approved subcommittee minutes from previous meetings.
4. Old business
5. New Business (This will include topics from Section IV related to the Research program)
6. Quality Assurance/Quality Improvement
7. Education
8. Merit Review Submissions for funding with primary reviewers identified
9. Initial Review of research projects with primary reviewers identified
10. Continuing review of research projects with primary reviewers identified
11. Amendments to ongoing research projects
12. Open Items
13. Closed items

D. R&D Committee Responsibilities for the Review of Research:

1. All research in which the NWIHCS is engaged must be reviewed and approved for the ethical use of human subjects, animals and biohazards. The R&D Committee provides oversight of its subcommittees for the maintenance of high standards of protocol review and relevance to the mission of the VA and the NWIHCS; scientific and ethical quality of VA research projects; protection of human subjects; animal welfare; safety of personnel engaged in research; security of research laboratories where hazardous agents are stored or utilized and security of VA data, VA protected information, and VA sensitive information.

2. The R&D Committee may approve a protocol contingent on the protocol being approved by one or more subcommittees. The R&D Committee must ensure the adequacy of each subcommittee’s review procedures, including reviewing and approving all subcommittee SOPs maintained by respective program Coordinators. Final approval may only be given after the R&D Committee receives documentation from all applicable subcommittees of their review and non-contingent approval. Final approval can be provided by a designated reviewer if there were no major changes made by the subcommittee(s). The designated reviewer must have sufficient documentation from the subcommittee(s) to make a determination about any changes requested. This final approval will be reported to the full R&D Committee at the next convened meeting and noted in the minutes.

When the R&D Committee relies on the initial review of the subcommittee, the R&D Committee must receive notice from the subcommittee that the research protocol has been approved and a brief written summary of the research to be conducted. The R&D Committee may require specified changes or modifications that would require subcommittee re-review.
The R&D Committee may disapprove a study even if approved by all subcommittees. The disapproval may be based on such issues as inadequate qualifications of the investigator(s); insufficient relevance to the VA’s mission; the presence of inadequate resources to conduct the study; the poor design of the study; concerns related to the protection of human subjects, the welfare of animals used in the research, safety to personnel, the environment, or others; unresolved conflicts of interest that may be detrimental to the research or the facility; or other serious concerns as defined by the R&D Committee.

3. The R&D committee delegates the scientific review responsibilities to the IRB for human studies and to the IACUC for animal studies, respectively. Safety of personnel engaged in research is reviewed by the Subcommittee for Research Safety. R&D reviews to ensure that all research in which the NWIHCS is to be engaged has been reviewed and approved according to program requirements before final approval is granted.

4. 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 this review has been conducted.

5. For protocols not meeting criteria for assignment to any subcommittee, the R&D Committee is the review and approving committee of record.

6. Initial Review: For each new research proposal reviewed and followed by the R&D Committee, the R&D Committee will review the relevance to research to VA’s mission and care of Veterans at a convened meeting where there is a quorum consisting of a voting members by evaluating the following:
   (a) Scientific merit of the research proposal;
   
   **NOTE:** If the protocol has been peer reviewed by a VA merit review committee, a National Institutes of Health (NIH) study section, or other Federal peer review committee, the R&D Committee or subcommittee may rely on that peer review if the findings of the peer review committee are submitted with the protocol. If the protocol has not been reviewed by a peer review committee, the R&D Committee must ensure that the protocol is reviewed by the appropriate subcommittee or R&D Committee itself to ensure scientific merit.
   (b) Protection of Human subjects
   (c) Welfare of and appropriate use and care of animals in research
   (d) Investigator’s qualifications and his/her role at the facility;
   (e) Budget and resources: requirements for space, personnel, equipment and supplies;
   (f) Security of VA data, VA Protected Information and VA sensitive information
   (g) Security of Laboratories;
   (h) Actions taken by the appropriate subcommittees (i.e., Subcommittee for Research Safety, VA Central IRB, and other facility entities when applicable.)

Members are provided the full protocol and applicable attachments via the secure Research server. Primary reviewers are assigned to review the study and present their findings at the meeting. The Principal Investigator/designee may be invited to present a brief summary of the protocol prior to the deliberations and vote by the committee. The Scientific Initial Review Checklist (Appendix A) is completed by the primary reviewers to document the initial review of each proposal. The initial approval period for a research study must be
specified not to exceed one year. The Designated Member Review (DMR) process can be utilized for initial review when DMR criteria is met (see #9).

7. Continuing Review: Continuing review of research studies followed by the R&D Committee only are conducted by the full R&D Committee at least annually at a convened meeting where there is a quorum consisting of a majority of voting members. Studies exempted from further review by the NWIHCS IRB/VA Central IRB according to 38 CFR16.101 are included in the annual review of projects. Ongoing studies, where animal use has been deleted, will be included in the annual review of projects as well.

For studies followed by the R&D Committee only, the continuing review submission form, current project data sheet, abstract and updated findings are made available to all members. In addition, the primary reviewer reviews a copy of the approved protocol and completes the R&D Committee Continuing Review/Status Report Update Form. The approval period must be specified not to exceed one year.

For studies followed by the primary subcommittee(s) for continued review the actions taken are included in the subcommittee’s minutes reviewed by the R&D Committee. The approval period is set by the subcommittee (IRB or IACUC) for applicable human and animal research. The DMR process can be utilized for continued reviews when DMR criteria is met (see #9).

8. R&D Committee Review of Research Overseen by an External IRB. (1) The R&D Committee must determine, and specifically document its determination, that the research:
   (a) Supports the VA mission and is relevant to the care of Veterans.
   (b) Is scientifically meritorious.
   (c) Ensures the security of VA Data, and storage of data and specimens in accordance with all applicable requirements (see VHA Directive 1605.01 and VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, dated March 10, 2015).

   (2) During a convened meeting, the R&D Committee must then vote to approve, approve with contingencies, or not approve the research to be conducted at the facility unless the research can be approved by a designated review process. **NOTE: The full protocol must be available for review by the R&D Committee.**

   (3) The R&D Committee does not need to approve continuing reviews and amendments but should be provided sufficient documentation in the committee minutes that are provided to the R&D Committee.

9. Designated Member Review (DMR): A designated member review process may be assigned for projects that fall into one of the following categories:

   (1) Minor changes to a protocol required by the R&D Committee, following full board review; personnel changes, or SOPs.
(2) Initial approval of protocols approved contingent on the full approval of a subcommittee, provided the RDC verifies that final approval of the subcommittee did not require substantive change to the proposal reviewed by the RDC;

(3) Initial approval for protocols approved contingent upon completion of the PO and ISSO review;

(4) Initial approval of exempt human subject research protocols and protocols approved by expedited review by the IRBs;

(5) Initial approval of protocols that do not involve human subjects, biosafety level (BSL-3) or higher containment, use of select agents or non-exempt quantities of select toxins, United States Department of Agriculture (USDA)-regulated animal species, or any animal research involving more than momentary pain or distress to animals.

For studies in the above categories, the RDC Chair or a voting member designated by the Chair may conduct an initial review outside of a convened meeting. All other proposals will be reviewed in a convened meeting at which a full quorum is present.

Final approvals made by designated reviewers of protocols initially reviewed by the convened R&D meeting must be reported to the full R&D Committee and the next convened meeting.

10. Information System Security Officer: The ISSO is responsible for ensuring that the proposed research complies with information security requirements for VA sensitive information (see VA Handbook 6500, Managing Information Security Risk: VA Information Security Program)

11. Privacy Officer: The PO is responsible for ensuring that the proposed research complies with VA Privacy requirements and the HIPAA Authorization contains all required elements (see VHA Directive 1605.01, Privacy and Release of Information).

E. Merit Review Submission and Just-in-Time (JIT) Procedures:

VA-Funded research projects: Proposals submitted for VA funding consideration (i.e., BLR&D, CSR&D, Rehab R&D, HSR&D, or Career Development Awards) are reviewed by the R&D Committee and must be granted approval prior to submission to the funding agency. The VHA Directives/Handbooks outlining the various VA funding opportunities are found at the ORD website. Whereas VA funding is the most important component of the VA Research enterprise, these proposals warrant special attention. The review to submit the project must assess the appropriateness of the scientific methodology, the relevance of the research to the VA’s mission, the investigator’s qualifications to perform the work and the adequacy of resources. The abstract, budget, investigator(s) biosketch, and research plan will be reviewed by one member of the R&D Committee and an expert in the scientific field of the proposal. This expert can be a R&D member or an ad hoc reviewer chosen from investigators at the NWIHCs, our affiliates, (UNMC or Creighton University), or an outside institution. Effort will be made to find the most appropriate content expert. The principal investigator may submit names of suitable reviewers. To assure the highest quality review, the Research Service (usually through NEBRA, our non-profit corporation) will provide monetary compensation to reviewers from outside institutions. This scientific review is expected to be as thorough as those done by the VA’s Merit Review panels. The Scientific
Review Checklist *(Appendix A)* will be used to evaluate the applicable components. In addition, a scientific review template will include those categories covered by the panel: Significance, Approach, Innovation, Investigator Qualifications, Multiple PI Leadership Plan (if applicable), Environment, Feasibility, Ethics, Safety, Clinical Relevance and the Budget. These reviews will be shared with the PI, with the expectation they will incorporate the comments in any revision of the grant.

When the project receives a fundable score, the grant and compliance documentation will receive initial review by the appropriate subcommittees (IRB or VA Central IRB/NCI, IACUC, and Safety) and other committees such as the Radiation Safety Committee prior to final approval by the R&D Committee. The ACOS/R&D will issue the approval to initiate the study. The appropriate subcommittee or the R&D Committee will then be responsible for continuing reviews. **NOTE:** The DMR process *may* be used for JIT approved studies.

**F. Non-VA funded research projects:** All non-VA funded grants where the work will be performed at the VA and will be submitted to a funding source that allows just-in-time approval must have a review and a letter of concurrence from the R&D Committee at the time the grant is submitted. This includes grants submitted through the academic affiliates for funding that will be performed at the VA. This also applies to grants to non-VA funding sources where the local VA will administer the funds. The process for R&D review follows:

1. PIs must submit the abstract or the typical first page of the text of the grant with the specific aims outlined electronically to the ACOS/R for review prior to submitting the grant.

2. During this preliminary review, the appropriateness of the scientific methodology, the relevance of the research to VA’s mission, the investigator qualifications to conduct the research and adequacy of the resources must be assessed. The ACOS/R will review and provide feedback or ask questions of clarification as needed. The PI will provide all information requested in order for this review to be completed.

3. Once reviewed in this expedited fashion, a letter of concurrence will be generated to the PI. Depending on the specific instructions of a funding agency, this letter of concurrence may or may not be required with the actual grant submission.

4. The expedited review by the ACOS/R will be reviewed by the full committee at next R&D committee meeting that occurs. A notification will be placed on the R&D Committee agenda for acknowledgement.

5. At the time of funding of a proposal, a full application to the relevant subcommittees and the R&D Committee is required in order to obtain approval to begin the work. A copy of the letter of concurrence for submitting the grant is required with the protocol submission.

**G. Amendments to Ongoing Research:**

Designated member review can be used for amendments submitted to the R&D Committee with minor changes (e.g., personnel changes). Basic science studies which do not involve humans or animals and studies exempt from further IRB review are monitored by the R&D Committee. Amendments for these types of studies are reported on the R&D Committee Amendment/Revised Protocol Reporting Form. Other amendments are under the purview of the applicable subcommittee charged with continued review. There may be amendments...
reviewed by the subcommittee(s) that require R&D Committee review as well as subcommittee review. Requests for enrollment of non-Veterans to an ongoing study are reviewed by the IRB and R&D Committee. A designated reviewer is assigned to review a copy of the amendment form and applicable attachments. If the amendment requires a change to the protocol, the reviewer will review a copy of the protocol. A copy of the amendment is made available to all members. Amendments will be reported in the sequential meetings minutes.

H. R&D Committee Documentation:

The minutes are completed by the R&D Coordinator and include:
1. Date and time of meeting
2. Attendance and absence of members (voting, alternates, non-voting including ex-officio)
3. Review of all minutes presented to the committee and actions taken
4. All business and information items
5. Education
6. Quality Assurance/Quality Improvement
7. Actions taken by the R&D Committee (i.e., initial, continuing review, amendments, notifications) including a summary of controversial issues and their resolution. Stipulations and follow-up requirements are stated. Actions can be approved, contingently approved, tabled or disapproved. The basis for disapproving a study must be stated.
8. Votes on these actions are categorized as: for, against, abstained, recused, or excused.
9. Persons who recused or were excused
10. Open items and closed items where prior contingencies have been met
11. Date and time of next meeting
12. Signatures of Chair, R&D Committee, ACOS/R&D as Executive Secretary, Chief of Staff and Medical Center Director.

The minutes are filed with a copy of the agenda and materials submitted for each meeting. The Scientific Review Checklist is completed by the primary reviewer(s) and filed with the research protocol.

I. Communication of R&D Committee Actions

1. Approved. Approved means there are no stipulations requested by the R&D Committee. When the subcommittee requests minor contingencies or stipulates specific revisions requiring simple concurrence by the investigator and approval by the subcommittee Chair/designee, the R&D Committee reviews the original submission, revisions requested and approves the study "with the required modification(s) being met as requested by the subcommittee" when appropriate.

2. Require modifications to obtain approval. Minor changes (minor typos, personnel changes, or changes that do not impact research design) or specific revisions which require simple concurrence by the investigator and approval by the R&D Chair/Designee. The applicable subcommittees are alerted of the modification requested for review and approval before the change is initiated.
3. Disapproved. The R&D Committee lacks sufficient information about the research to grant approval. The applicable subcommittees are alerted of this action.

2. Communication to the Subcommittee(s): The minutes of the R&D Committee are forwarded to the Chairs and Coordinators of the subcommittees via e-mail following the R&D Committee meeting. The subcommittees are made aware of any R&D Committee modifications for the subcommittee’s review and approval in addition to any modifications that were requested by the subcommittee during its review. When R&D modifications or disapproval are requested, these are also reported in the Business section of the following month’s subcommittee minutes. A memorandum will also be sent by the R&D Committee Chair to the appropriate Subcommittee Chair when warranted.

The R&D Committee Chair meets periodically with the Subcommittee Chairs to discuss new issues and processes affecting the research program.

3. Communication with the VA Central IRB: The Point of Contact will communicate actions taken by the R&D Committee for all research approved or determined exempt by the VA Central IRB. The R&D Committee review will be conducted at its next regularly scheduled meeting following notification of approval by the VA Central IRB.

4. Communication to Executive Committee of the Medical Staff (which includes the Medical Center Director and Chief of Staff): The approved R&D Committee minutes signed by the R&D Chair, ACOS/R&D, Chief of Staff and Medical Center Director are also sent to the Executive Committee of the Medical Staff. Following their review, a memorandum of acceptance or recommendation is received from the Chair, Executive Committee of the Medical Staff.
IX. R&D COMMITTEE RECORDS

Records must be maintained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA Records Control Schedule (RCS 10-1). The R&D Committee records are kept with the IACUC, IRB and Safety records and managed according to VHA Directive 6300. These records include:

1. Copies of all research proposals
2. Copies of all written correspondence including communication to and from investigator, other committees, subcommittees, VA Central IRB, and other entities or individuals
3. Continuing review and final reports
4. Amendments
5. Minutes of the R&D Committee meeting and its subcommittees
6. R&D Committee and its subcommittees' membership rosters
7. R&D Standard Operating Procedures
8. Activity reports related to the NWIHCS research program
9. Resume/curriculum vitae of each R&D Committee member

X. REPORTING REQUIREMENTS FOR PROBLEMATIC EVENTS

A. The R&D Committee reviews problems brought forward to the committee and forwarded by its subcommittees, ACOS/R&D, and Research Compliance Officer. The problematic research event may be related to the animal research program, the human research program, research safety, laboratory security, research information security, as well as failure to satisfy requirements of the committee(s) responsible for oversight of the research, or research misconduct.

B. The VHA Handbooks 1058.01 and 1058.02 outline the reporting requirements to the Office of Research Oversight (ORO). The VHA Directives/Handbooks and local Standard Operating Procedures, applicable to the types of events (i.e., unanticipated problems involving risks to participants or others, serious or continuing non-compliance, deviations/violations, suspension or terminations, safety, security breaches) being reviewed, should be referenced for reporting requirements to other individuals and agencies.

C. The R&D Committee has oversight to see that action is taken when appropriate or concur with the actions forwarded to them by an oversight subcommittee or individual. The VA Central IRB is notified and participates in the reporting for studies approved by them. The report should be provided to the Facility Director as soon as possible but no later than 5 working days after the event has come before a responsible facility official (ACOS/R&D, RCO, R&D Committee and/or its subcommittee Chairs). The Facility Director signs the report being submitted to ORO within 5 working days after being notified.
XI. Collaborative (Involves VA Data and Affiliate Data) Research Studies
Separating VA Research from Non-VA Research

a. Approval of Research. Each institution is responsible for safeguarding the rights and welfare of human subjects, ensuring the welfare of animals, complying with all applicable biosafety and biosecurity requirements and for providing oversight of the research activities conducted at that institution. VA R&D Committee must ensure it only approves VA research activities in a collaborative study. (1) Each collaborating institution engaged in the research must obtain approval from the applicable research review committees such as the IRB or IACUC. Each institution must hold a Federalwide Assurance (FWA) if the research is non-exempt human subjects research or a Public Health Service Assurance when conducting research involving animals (see VHA Handbook 1058.03).

(2) For each individual research study, VA investigators must submit a protocol and other relevant or required documentation to their VA research review committees and subcommittees such as the IRB, the IACUC, the SRSS, and the R&D Committee.

b. Research Data. The protocol, protocol addendum, and/or subcommittee application must describe the data (identifiable or de-identified if from human subjects or sensitive or non-sensitive if animal or other research) to be disclosed to collaborators, the entity(ies) to which the data are to be disclosed, the method of how the data are to be transmitted, and the person who will own or have responsibility for the disclosed copies of the data. This includes data developed directly from the research including the analytic data and the aggregate data. (1) Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Record Control Schedule 10-1.

(2) All disclosures and data transmission must meet privacy and security requirements per VHA Directive 1605.01 and VA Handbook 6500.

c. Biospecimens. The protocol, addendum, and/or subcommittee application must describe the applicable collection, use, transfer, and disposition of biospecimens obtained or collected. A Material Transfer Agreement (MTA) must be used to transfer biospecimens from VA unless the biospecimens’ transfer is addressed in another agreement executed between VA and the receiving institution or party, such as a CRADA, subaward, or MOU. **NOTE:** If a CRADA is executed for a research study where the scope of work specifically describes analysis, retention, and disposal of biospecimens by a central laboratory, then an MTA is not required.
XII: USE OF THE VHA CENTRAL OFFICE INSTITUTIONAL REVIEW BOARD (IRB) OR NATIONAL CANCER INSTITUTE (NCI) AS IRB OF RECORD

A. PURPOSE: The use of the VHA Central Office Institutional Review board (IRB) or National Cancer Institute (NCI) to review select VA funded multi-site studies involving human subjects including initial, continuing review, amendments, monitoring, reporting and other relevant requirements are outlined in a Memorandum of Understanding (MOU) between VHA Central Office and the Nebraska-Western Iowa Health Care System (NWIHCS) or National Cancer Institute (NCI). The FWA Assurance includes the VA Central IRB/NCI as an IRB of record. The appropriate Office of Research and Development (ORD) funding Service (CSP, RR&D, HSR&D, QUERI, etc.) will determine if a study should be reviewed by the VA Central IRB.

B. RESPONSIBILITIES: Responsibilities of the VHA Central Office Human Research Protections Program and VA Central IRB/NCI and the NWIHCS are outlined in the Memorandum of Understanding signed by both parties, the non-profit (NEBRA) signatory official, and the VISN 23 Network Director. The VA Central IRB/NCI IRB will maintain current FWA registration, human protections accreditation, ensure appropriate training for its members and staff. They will meet at least monthly and maintain Standard Operating Procedures available on their website. Responsibilities at the NWIHCS are met by maintaining current FWA registration, accreditation through the VA designated organization and providing local accountability. All review of the research by the VA Central IRB/NCI to be conducted at the NWIHCS must be approved by the R&D Committee.

C. VA CENTRAL IRB/NCI IRB APPLICATION PROCESS:

1. The Principal Investigator (PI)/Study Chair (SC), or designee, submits all required documentation regarding the project to the VA Central IRB/NCI IRB, to include all requirements as specified in VHA Directive 1200.05. The application includes the Principal Investigator/Study Chair New Project Application found at the cIRB/NCI IRB websites and all associated attachments to include the protocol and the informed consent document and HIPAA authorization if applicable.

2. The PI/SC recruits the Local Site Investigator (LSI) for each of the other participating sites as applicable. The PI/SC is responsible for reviewing all the LSI applications to ensure consistency with the PI/SC application and/or any modifications that are requested by the VA Central IRB. The PI/SC then submits the LSI applications to the VA Central IRB. The PI/SC is responsible for ensuring that no research begins at any of the engaged sites in the study until all required approvals have been received.

3. The LSI must provide a rationale for any differences between the PI/SC and LSI application. The LSI is responsible for all aspects of the research project conducted at the local site in accordance with paragraph VHA Directive 1200.05 and for ensuring compliance at that site with all VA and other requirements for the conduct of human research. The LSI recruits the local site project team and prepares the LSI application for the specific participating local site. The research project may not begin at this site until all required approvals have been received.
D. REVIEW OF PI/SC AND LSI APPLICATIONS:

**Principal Investigator (PI)/Study Chair (SC)**

1. The PI/SC of the entire project is notified that his/her project has received a fundable score. The PI completes the PI/SC New Project Application.

2. The PI/SC submits the new project application to the Research Administrative Office (RAO) to obtain the signature of the ACOS on the application. The RAO retains a copy for the protocol file. The application is returned to the PI/study staff to be submitted to the VA Central IRB.

3. The PI/SC contacts the VA Central IRB/NCI IRB administrative staff to coordinate the management of study documents. Access to the VA Central IRB/NCI IRB SharePoint folder for the study is given to the PI/SC, study staff, and the local site liaisons (ACOS, AO, RDC Coordinator, ISO and RCO).

4. The PI/SC application is reviewed by the convened VA Central IRB/NCI IRB or via expedited review. The PI and site liaisons will receive correspondence detailing any contingencies that must be addressed if the study is contingently approved.

5. When the PI/SC New Project Application has been fully or contingently approved, the main study site and the multiple local sites identified in the application are sent a copy of the application package. The PI/SC, and local site investigators and liaisons are required to review the documents and provide comments to VA Central IRB/NCI IRB voicing any concerns regarding the study. The PI/SC and the local site investigators and liaisons have 15 calendar days to provide comments on the initial VA Central IRB review of the application. This is an opportunity for the PI/SC or local site investigator and liaisons to provide input to the VA Central IRB/NCI IRB regarding the study design. The local site liaison can request review of the documents by an individual with a particular area of expertise, if necessary.

6. The VA Central IRB/NCI IRB will review local site comments and require PI/SC to make changes as applicable. A final determination of the study will be sent to the PI/SC and site liaisons. Whatever revisions are made by the VA Central IRB/NCI IRB must be accepted in full by the NWIHCS, or, if the final approval documents are not acceptable to the NWIHCS PI/SC or local site liaison, participation in the study must be declined.

7. When the PI/SC has full approval by the VA Central IRB/NCI IRB, the review of local site investigator applications will begin. If the study will include the enrolling of subjects at the NWIHCS, a local site investigator application must be submitted to the VA Central IRB.

**Local Site Investigator (LSI) Application:**

1. Once the main PI/SC application is approved, the local site investigators are instructed to prepare the local site investigator application. The local site investigators are contacted by the main PI/SC regarding participation as an investigator at the NWIHCS.

2. The local site investigator submits the New Project Application to the Research Administrative Office (RAO) to obtain the signature of the ACOS on the application and
retains a copy for the RAO protocol file. The application is returned to the PI/study staff to be submitted to the VA Central IRB.

3. The LSI coordinates with the main PI/SC to facilitate uploading the documents to the VA Central IRB/NCI IRB SharePoint study folder. Study documents are uploaded to the SharePoint study folder by the PI/SC or local site investigator, or study staff. The local site liaisons do not submit study documents or applications.

4. The local site investigator application is reviewed by the convened VA Central IRB/NCI IRB or via expedited review. The local site investigator and liaisons will receive correspondence detailing any contingencies that must be addressed if the study is contingently approved. The primary liaison and/or designee (i.e., IRB Chair) will provide comments within 15 calendar days of the receipt of the initial review determinations.

5. When the approval documents are ready, a link to the folder on the SharePoint site will be sent to PI/SC, local site investigators/staff, and local site liaisons. When the signed minutes from the VA Central IRB meeting are complete, a link to a folder on the SharePoint site will be sent to the PI/SC, LSI and local site primary liaison. The minutes from the VA Central IRB/NCI IRB meeting at which the project was reviewed will be included for review at the next R&D Committee meeting.

E. NWIHCS /LOCAL R&D PROCEDURES:

Submission to R&D Committee:
1. The complete and approved PI/SC or LSI application is submitted to the R&D Committee along with the Request to Review found at the NWIHCS website: http://www.nebraska.va.gov/services/Research/rd/rd_forms.asp Other subcommittee reviews and approvals (i.e., Subcommittee for Research Safety, Radiation Safety) must have occurred prior to R&D Committee review and approval. Any local service support should be identified (i.e. Pharmacy, Pathology).

2. The study is entered on the R&D Committee agenda in electronic database and assigned a reviewer. The ePromise database is updated with the local study information. Credentialing and education requirements must be met by the local site investigator and study staff. A Scope of Practice is required for each team member.

3. Following R&D Committee approval and ACOS/Research signature to initiate the study, the approval is sent to the local PI and a copy to the VA Central IRB/NCI IRB Coordinator for that study.

Continuing Reviews:
The VA Central IRB/NCI IRB will conduct continuing review of approved projects at least once per year, or more often if determined appropriate. The R&D committee will review and approve the VA Central IRB/NCI IRB minutes at which the continuing reviews were discussed and approved. The PI/SC or LSI is required to provide a copy of the VA Central IRB continuing review application and approval for the RAO protocol file.

Reporting to VA Central IRB/NCI IRB:
1. The PI/SC or LSI must promptly inform the VA Central IRB/NCI IRB of modifications, complaints from subjects or others, unanticipated problems involving risks to
subjects or others, unanticipated serious adverse events, suspensions or terminations of research. No changes to the protocol should be implemented until the proposed modifications are approved by the VA Central IRB/NCI IRB. Modifications may only be implemented locally to eliminate apparent immediate hazards to the human subjects and appropriate reporting are made.

2. If any local action is mandated by the R&D Committee, the local site liaison should notify the VA Central IRB. Research compliance reporting requirements must be met according to VHA Handbook 1058.01. Refer to the VA Central IRB/NCI IRB website for information on specific reporting requirements and procedures. A link to notification, amendment, and serious adverse event approval documents on the SharePoint site will be sent to the PI/SC, local site investigators and staff, and local site liaisons by the VA Central IRB/NCI IRB. Copies of the documents will be stored in the PI’s study files and the protocol file located in the RAO. Notifications, amendments, and serious adverse events do not need to be reviewed by the R&D Committee per requirements of VHA Directive 1200.01. When the RCO or ACOS/Research requests R&D Committee review, the item will be placed on the R&D Committee agenda.

3. If the modification includes study personnel being added to a study that is reviewed by the VA Central IRB/NCI IRB, a personnel initiation sheet is submitted to the RAO. Credentialing and education requirements must be met and a scope of work form must be received for that individual.

**Privacy Officer (PO) and Information Security Officer (ISO) Review:**

1. The VA Central Office PO and ISOs perform the required privacy and information security reviews as part of the study reviews. The NWIHCS PO does not conduct a separate privacy review of studies overseen by the VA Central IRB/NCI IRB. The NWIHCS ISO may need to review some studies overseen by the VA Central IRB/NCI IRB due to local project-specific information security issues. In these cases, the VA Central Office ISO will work with the NWIHCS ISO to resolve these issues.

2. Any unauthorized use or disclosure of protected health information (PHI) or any violations of VA information security requirements in projects overseen by the VA Central Office must be reported to the VA Central IRB/NCI IRB, and the local PO and ISO.

**Review of VA Central Office Human Research Protection Plan (HRPP) Annual Report**
The VA Central IRB/NCI IRB HRPP annual report is reviewed by the NWIHCS R&D Committee annually. The review will be scheduled according to the R&D Committee Timeline.

**Review of Audits:**

1. Routine and other compliance audits of VA Central IRB/NCI IRB-approved projects conducted by the Research Compliance Officer (RCO) will be reported to the R&D Committee.

2. Results of special audit requests made by the VA Central IRB/NCI IRB as part of its oversight responsibilities for projects for which it serves as the IRB of record will be reported to the VA Central IRB and the R&D Committee.
XIII: REFERENCES

The following list of references is not all-inclusive, but is provided to assist in locating some frequently requested resources related to the R&D program.

VHA Directive 1200.01 Research & Development Committee Directive
VHA Handbook 1200.04 Research Career Development Program
VHA Directive 1200.05 Requirements for the Protection of Human Subjects in Research
VHA Handbook 1200.06 Control of Hazardous Agents in VA Research Laboratories
VHA Handbook 1200.07 Use of Animals in Research
VHA Handbook 1200.08 Safety of Personnel Engaged in Research
VHA Handbook 1058.01 Research Compliance Reporting Requirements
VHA Handbook 1058.02 Research Misconduct
VHA Handbook 1058.05 VHA Operations Activities That May Constitute Research
VHA Handbook 1200.19 Presentation of Research Results
VHA Handbook 1202.01 BLR&D &CSR&D Merit Review Award Program Process
VHA Handbook 1203.01 Rehab R&D Merit Review Program
VHA Handbook 1204 VHA Health Services Research & Development
VHA Directive 2007-040 Appointment of Facility Information Security Officer (ISO) and Privacy Officer (PO) to the Institutional Review Board (IRB) or the Research and Development (R&D) Committee
VHA Directive 6300 Records Management

IACUC Standard Operating Procedures
IRB Standard Operating Procedures
Research Safety Operating Procedures
VA Central IRB Memorandum of Understanding between VHACO and NWIHCS