Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

AMENDED
April 1, 2025

VHA DIRECTIVE 1200.01(2)
Transmittal Sheet
January 24, 2019

RESEARCH AND DEVELOPMENT COMMITTEE

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive outlines the requirement that every VA facility engaged in research establish a Research and Development (R&D) Committee.

2. SUMMARY OF MAJOR CHANGES:

Amendment dated April 1, 2025, changes language from “gender” to “sex” to comply with EO 14168.

Amendment dated January 8, 2021, updates the definition of VA Research (see ***NOTE:****), clarifies one sentence in the policy paragraph adding an exception for emergence use of a test article, clarifies responsibilities paragraph 5.h.(6), removes paragraphs 5.h.(9) and 5.i. updates two paragraphs under the responsibilities of the Information System Security Office (ISSO) (see paragraph 5.i.(1)-(2)), clarifies paragraph 5.l.(3), adds clarification paragraph 9.d.(2)(c) and clarifies paragraph 9.e.(5).*

This directive clarifies the role of the R&D Committee relative to other research-related committees, the role of the R&D Committee relative to quality assurance activities, and the requirements for membership on the R&D Committee.

3. RELATED ISSUES: VHA Directive 1200, Research and Development Program, dated May 13, 2016; VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017; VHA Handbook 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated November 12, 2014.

4. RESPONSIBLE OFFICE: The Office of Research and Development (10X2) is responsible for the contents of this VHA directive. Questions may be addressed to 202-443-5600.

5. RESCISSIONS: VHA Handbook 1200.01, Research and Development (R&D) Committee, dated June 16, 2009, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on, or before, the last working date of January 2024. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Discovery, Education, and Affiliate Networks

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter*.

DISTRIBUTION: Emailed to the VHA Publication Distribution List on January 24, 2019.

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RESEARCH AND DEVELOPMENT COMMITTEE

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes the responsibilities and operations of the Research and Development (R&D) Committee. It also establishes the responsibilities of other research and facility staff relating to the operation of the R&D Committee. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7303.

2. BACKGROUND

a. The research mission of the Department of Veterans Affairs (VA) is conducted primarily within individual VA medical facilities according to the highest ethical standards, with accountability to all involved stakeholders. An R&D Committee at each facility oversees the maintenance of high standards within VA's research program and ensures that VA research is scientifically valid and complies with regulatory and ethical standards.

b. VA medical facilities must provide necessary medical treatment to research subjects injured as a result of participation in a research study approved by an R&D Committee and conducted under the supervision of one or more VA employees. VA research subjects are provided necessary medical treatment in VA medical facilities, including joint VA-Department of Defense (VA-DoD) Federal health care facilities (see 38 CFR 17.85).

3. DEFINITIONS

a. **Classified Research.** Classified research is research that is considered restricted or secret by the Federal government, sponsor, or any third party. For example, research for the Federal government that is considered sensitive or would affect national security.

b. **Collaborative Research.** Collaborative Research is a research collaboration involving investigators from VA and other institutions, with VA investigators having a substantive role in the design, conduct, and/or analysis of the research.

c. **Cooperative Research and Development Agreement.** A Cooperative Research and Development Agreement (CRADA) is an agreement established pursuant to 15 U.S.C. 3710a between VA and one or more non-Federal parties under which VA may accept, retain, and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the other party, as well as provide personnel, services, facilities, intellectual property, equipment or other resources, excluding funding, toward the conduct of specified research and development that is consistent with VA's mission. (See VHA Directive 1206, Use of a Cooperative Research and Development Agreement (CRADA), dated June 19, 2018.)

d. **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.

e. **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.*

f. **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. All research activities approved by the R&D Committee are considered VA Research. ***NOTE:*** Any emergency use of a test article does not require R&D Committee approval but is VA research under this policy.

g. **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).

4. POLICY

It is VHA policy that each VA medical facility conducting research must establish an R&D Committee or enter into a written agreement with another VA medical facility to use that institution's R&D Committee. All VA research except for any emergency use of a test article must be approved by the R&D Committee and cannot be initiated until the Associate Chief of Staff for Research & Development (ACOS/R&D) has notified the Principal Investigator (PI) in writing that all approvals are in place. Once approved, VA is responsible for all aspects of the research, including oversight by the R&D Committee, appropriate subcommittees, and when applicable, VHA Office of Research and Development and VHA Office of Research Oversight. ***NOTE:*** The R&D Committee is not responsible for overseeing emergency use of a test article.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The

Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all of the VA medical facilities that conduct research within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

c. **Chief Research and Development Officer, Office of Research and Development**. The Chief Research and Development Officer (CRADO), ORD, is responsible for establishing the overall VA policy regarding review and oversight of VA research by VA medical facility R&D Committees.

d. **Executive Director, Office of Research Oversight, VA Central Office.** The Executive Director, Office of Research Oversight, is responsible for reviewing VA facility standard operating procedures (SOPs) to ensure they are compliant with this directive.

e. **Veterans Integrated Service Network Director.** Each Veterans Integrated Service Network (VISN) Director is responsible for ensuring that all research programs at VA medical facilities within the VISN comply with this directive.

f. **VA Medical Facility Director.** Each VA medical facility Director is responsible for:

(1) Serving as the Institutional Official (IO) 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.

(2) Establishing the facility's R&D Committee, or retaining institutional responsibility for the research program if the facility's R&D Committee of Record is that of another VA facility.

(3) Appointing members of the R&D Committee and its subcommittees in writing.

(4) Ensuring that research in which the facility is engaged is approved by the appropriate R&D Committee and subcommittees.

(5) Suspending or terminating research that has been approved by the R&D Committee when concerns are raised and substantiated about the conduct of the 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.

(6) Ensuring there are adequate resources and administrative support, including personnel, space, equipment, and training for the R&D Committee and its subcommittees to fulfill their responsibilities.

(7) Approving a memorandum of understanding (MOU) that establishes an R&D Committee from another VA facility.

g. **Associate Chief of Staff for Research and Development.** The Associate Chief of Staff for Research and Development (ACOS/R&D) (or Coordinator for R&D in a smaller facility) 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.*

h. **Research and Development Committee.** The R&D Committee is responsible for:

(1) 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.

(2) Reviewing research proposals and approving the research, requiring modifications to obtain approval, or disapproving the research.

(3) Ensuring the effective operation of the facility research program through oversight of all R&D Committee subcommittees and the facility's research portfolio.

(4) 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.

(5) Establishing appropriate subcommittees to review and oversee human subjects research, animal research, and safety and security reviews (see paragraph 8). 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.*

(6) Ensuring Information System Security Officer (ISSO) review of studies that involve the collection, processing, storage, and transmission of research data and Privacy Officer (PO) review of studies using human data are complete before a study is given final approval. ***NOTE:*** *The R&D Committee can approve contingent on ISSO and PO review.*

(7) 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 Handbook 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated November 12, 2014, and VHA Handbook1058.03, Assurance of Protection for Human Subjects in Research, dated November 21, 2014, 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).*

(8) 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.

(9) Ensuring that Classified Research is not conducted as VA research.

(10) Reviewing the operations of all research-related committees and subcommittees as an ongoing function. See paragraph 6.f. for details of the review process.

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

i. **Information System Security Officer.** The ISSO is responsible for:

(1) Ensuring that the proposed research complies with information security requirements for VA research data; and

(2) Participating in the Institutional Review Board (IRB) protocol review and approval process, evaluating the study's data usage, and making recommendations to ensure implementation of reasonable safeguards for the data as determined within the Office of Information Security (OIS) Research Support Division (RSD) developed Enterprise Research Data Security Plan (ERDSP).

k. **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, dated August 31, 2016).

l. **VA Investigators.** Each VA investigator is responsible for:

(1) 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.

(2) 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.

(3) Submitting and implementing the VHA Research Protocol Privacy Review Checklist and OIS Enterprise Research Data Security Plan 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.

(4) 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.

(5) 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, dated March 10, 2017, for general requirements for all VA investigators.*

6. RESEARCH AND DEVELOPMENT COMMITTEE OPERATIONS

a. The R&D Committee meets on a regular schedule as needed to meet the demands of the research program. Members' physical presence at meetings is recommended but not required; 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.

b. The R&D Committee may develop procedures that allow unscheduled meetings in response to emergent issues. There must be a quorum present in person or by teleconference or videoconference for any unscheduled meetings.

c. All official business must be conducted at a convened meeting with a quorum present except for when this policy allows a designated review procedure.

d. Minutes for each meeting must be documented and disseminated to the facility leadership council. The minutes must include the following information:

(1) A list of all voting members indicating the category of their membership and whether they are present or absent, and any other attendees. If an alternate is present in place of a voting member, the minutes must indicate this fact and name the voting member being replaced.

(2) The presence of a quorum (a majority of members).

(3) Actions taken by the R&D Committee, to include:

(a) The type of action.

(b) The vote on the action, including the number voting for, against, and abstaining. In addition, any recused member from the vote must be named, and whether the person was present during the discussion. ***NOTE:*** *If the member is recused, the member must not be present for the vote, and may not be counted toward the quorum.*

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

f. 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 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.

7. RESEARCH AND DEVELOPMENT COMMITTEE MEMBERSHIP

a. **Appointment of Members.** The members of the R&D Committee are appointed by the VA medical facility Director and must reflect the types of research being conducted at the facility. Nominations for membership may be submitted by current R&D Committee members, subcommittee members, and the facility's staff. All members of the R&D Committee must hold VA appointments (permanent, term, IPA, or WOC).

b. **Number of Members.** The R&D Committee must consist of at least five voting members.

(1) Whenever practicable, one member of the R&D Committee should have expertise in biostatistics and research design.

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

(3) To the extent possible, members should be diverse with respect to race, sex, ethnicity, and expertise.

c. **Voting Members.** Voting members of the R&D Committee must include:

(1) At least two members from the VA medical facility's staff who have major patient care or management responsibilities.

(2) At least two members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise.

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

(4) 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.

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

(6) A VA facility's Veterinary Medical Officer/Veterinary Medical Consultant may be appointed to the R&D Committee as a voting member or designated an ex officio, non-voting member.

d. **Alternate Members.** Alternate voting members must be appointed by the facility Director. The roster must identify the primary voting member(s) for whom each alternate voting member may substitute. The alternate member's qualifications must be comparable to those of the primary member(s) to be replaced. The alternate member can only vote in the absence of the primary member.

e. **Ex Officio, Non-voting Members.** Individuals may be designated by local SOPs to attend R&D Committee meetings as ex officio, non-voting members if designating their attendance assists the R&D Committee in fulfilling its responsibilities.

(1) The medical facility Director, Chief of Staff, and Administrative Officer for R&D (AO/R&D) may be designated as ex officio, non-voting members.

(2) The Associate Chief of Staff for Research and Development (ACOS/R&D) serves as the Executive Secretary of the R&D Committee and is an ex officio, non-voting member.

(3) The facility Privacy Officer and Information Security Officer may be designated as ex officio, non-voting members.

(4) If local SOPs call for titles of positions (for example, ACOS/R&D, AO/R&D), instead of named individuals, to serve as ex officio, non-voting members, the individuals themselves do not have to be designated by the medical facility Director. They are considered to be ex officio, non-voting members of the R&D Committee by virtue of their position and local SOPs if appointed to their positions by the facility Director.

f. **Consultants.** Others may be invited to assist the R&D Committee in its review of issues that go beyond the R&D Committee's expertise but are in the purview of the invited individuals. These individuals may not contribute to a quorum or deliberate or vote with the R&D Committee.

g. **Research Compliance Officer.** The Research Compliance Officer (RCO) may serve as a non-voting consultant, as needed, to the facility's R&D Committee. The RCO may attend meetings when requested by the R&D Committee or specified by local SOPs.

h. **Terms of Members.**

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

(2) The terms of members must be staggered to provide continuity in membership.

i. **Election of Chairperson.** Committee members, exclusive of ex officio, non-voting members, must elect a Chairperson every 1 or 2 years.

(1) The Chairperson must be approved and officially appointed, in writing, by the medical facility Director for a term of 1 or 2 years according to local SOPs.

(2) The Chairperson may be reappointed without any lapse in time.

(3) The Chairperson must not simultaneously chair a subcommittee of the R&D Committee.

(4) The committee also may appoint a Chair Pro Tempore or Vice Chair to serve when the Chairperson is absent or has a conflict of interest that requires recusal.

8. RESEARCH AND DEVELOPMENT COMMITTEE SUBCOMMITTEES

a. The R&D Committee may establish any subcommittee(s) deemed necessary for the efficient and effective management and oversight of the R&D Program. ***NOTE:*** *External committees established by MOUs or other agreements in lieu of required subcommittee(s) are not considered subcommittees and are governed by the agreement (e.g. the VA Central IRB).*

(1) At a minimum, subcommittees must be appointed to oversee R&D activities related to human studies, animal studies, and research safety and security.

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

(3) The R&D Committee must review subcommittee minutes within 60 days of the subcommittee's finalization of the minutes.

b. The required subcommittees of the R&D Committee are:

(1) **Institutional Review Board.** Every VA facility conducting research involving human subjects must have, or must establish an IRB, or the facility must secure the services of an IRB as described in VHA Handbook 1200.05(2).

(2) **Institutional Animal Care and Use Committee.** Every VA facility conducting research involving the use of live vertebrate animals must establish an IACUC, or secure the services of an IACUC as described in VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011.

(3) **Subcommittee on Research Safety and Security.** Every VA facility with research laboratories or conducting research involving chemical, biological, physical, or radiation hazards must establish an SRSS as described in VHA Handbook 1200.08, Safety of Personnel Engaged in Research, dated March 6, 2009.

c. Additional subcommittees may be established as determined by the needs of the local research program.

9. RESEARCH AND DEVELOPMENT COMMITTEE REVIEW OF RESEARCH

a. **Authority of the R&D Committee.** The R&D Committee has the authority to review research and approve the research, require modifications to obtain approval, or disapprove the research. It also has the authority to suspend or terminate a research protocol; suspend an investigator's or a research staff member's privilege to conduct research pending appropriate investigation and decision by the medical facility Director; and require the implementation of additional safeguards related to the safety of human subjects, the welfare of research animals, the protections of employees or the environment, or the security of VA Data and VA Sensitive Information.

b. **R&D Committee Review of Research Overseen by a Subcommittee.**

(1) 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. 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 must be reported to the full R&D Committee at its next convened meeting and noted in the minutes.

(2) 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.

(3) 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.

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

c. **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.

d. **R&D Committee Review of Research as the Only Oversight Committee.**

(1) **Initial Review.**

(a) The R&D Committee may use a primary reviewer system, or may have one or more members of the R&D Committee review the protocol. The protocol and all applicable documents must be available for all members to review.

(b) A quorum must be present during the review and approval of the study unless a designated review is used. If the required number of voting members is not present at any point during a meeting, a quorum must be restored before any discussion of, or action on, issues requiring a vote.

(c) For protocols that require modification to obtain approval, the R&D Committee must communicate their action to the VA investigator. Minor changes (as defined in local SOPs) may be reviewed and approved by the Chair or a designated voting member of the R&D Committee and given final designated approval of the protocol. This final approval must be noted in the minutes of the next R&D Committee when reported to the full R&D Committee at its next convened meeting.

(d) At approval, the R&D Committee must set the time frame for continuing review. The time frame may not exceed 365 days. For designated approval, the date of approval is the date of final approval by the designated reviewer once all changes have been made.

(e) For protocols approved or disapproved by the R&D Committee, a written notification is sent to the ACOS/R&D. The ACOS/R&D notifies investigators, in writing, when a research project can be initiated, and the approval period for the project.

(2) **Continuing Review.**

(a) Information that must be received by the committee from the PI for continuing review includes:

1. Scientific progress of the research.

2. Budget requirements changes.

3. Changes in requirements for space, personnel, equipment, and supplies.

4. Summary and impact of any unanticipated problems.

5. Any issues of serious non-compliance with applicable policies, including privacy and security that have occurred since last approval.

(b) Once the R&D Committee approves the protocol’s continuation written notification is sent to the PI.

(c) Continuing review approval for exempt research is not required by the R&D Committee for continuing review following initial approval.

(3) **Review of amendments.** Amendments to approved research must be submitted to the R&D Committee for approval.

e. **Designated Review.** The following activities may be approved by the Chair, R&D Committee or a voting member designated by the Chair:

(1) Minor changes to a protocol required by the R&D Committee, following full board review.

(2) Final approval for protocols approved contingent on the full approval of a subcommittee if the subcommittee had not required major changes (as defined in local SOPs) to the protocol since the R&D Committee conducted its review.

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

(4) Exempt human subject research protocols and protocols approved by expedited review by the IRB.

(5) Non-emergency expanded access protocols or activities approved by the IRB. ***NOTE:*** Emergency expanded access protocols or activities do not require prospective R&D Committee approval or notification.

(6) 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.

10. COLLABORATIVE 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.*

11. RESEARCH AND DEVELOPMENT COMMITTEE RECORDS

a. The adequate documentation of all the activities of the R&D Committee must be maintained, including, but not limited to, the following:

(1) Copies of all research proposals and their amendments reviewed by the R&D Committee and subcommittees and any accompanying materials.

(2) Copies of all continuing and final reports.

(3) Minutes of the R&D Committee and R&D Committee subcommittees.

(4) Copies of all written correspondence.

(5) Membership lists for the R&D Committee and all R&D Committee subcommittees.

(6) SOPs.

b. Written records documenting actions taken to carry out the committees' responsibilities for review of research, and for oversight of the research program.

c. Records are the property of VA and the policy for record retention is outlined in VHA Records Control Schedule (RCS) 10-1. ***NOTE:*** *Record retention may be longer depending upon other policies and regulations such as Food and Drug Administration (FDA) regulations or medical record retention policies.*

12. RESEARCH REVIEW COMPONENTS

a. Reviews by the R&D Committee and its subcommittees must ensure:

(1) Relevance of the research to VA's mission and the care of Veterans.

(a) Protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel.

(b) Welfare of and appropriate use and care of animals in research.

(c) Security of research laboratories. This includes laboratories utilizing or storing hazardous agents, for example, select agents and toxins, or other hazardous agents, and the security of all BSL-3 research laboratories. See VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories, dated October 21, 2005.

(d) Security of VA Data and VA sensitive information and storage of data and specimens in accordance with all applicable requirements.

(e) 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.*

(f) Availability of required resources, investigator's time, and appropriate location where the research will be conducted.

(g) Availability of qualified research team members, including investigators, who can conduct the approved research, and prove successful completion all relevant research-related training requirements.

13. PARTICIPATION OF NON-VETERANS AS RESEARCH SUBJECTS

a. Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment, but only when there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45, 17.92). The investigator must justify including non-Veterans, and the R&D Committee must review the justification and provide specific approval for recruitment of non-Veterans.

(1) **Outpatient Care for Research Purposes.** Any person who is a bona fide volunteer may be furnished outpatient treatment when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (see 38 CFR 17.92).

(2) **Hospital Care for Research Purposes.** Any person who is a bona fide volunteer may be admitted to a VA hospital when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45).

b. Non-Veterans may be recruited for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans' family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they should be included in VA studies whenever appropriate.

c. In addition to the non-Veterans referenced above, active duty military personnel may be entered into VA research conducted jointly by VA and DoD or within DoD facilities.

d. All VA regulations and policies related to Veterans as research subjects apply to non-Veterans entered into VA research.

e. Non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the investigator.

f. Investigators must follow VHA Handbook 1605.04, Notice of Privacy Practices, to provide notice of privacy practices and acknowledgement for any non-Veteran enrolled in the approved protocol.

14. TRAINING REQUIREMENTS

Every 3 years the Chair and voting members of the R&D Committee are required to complete two modules from ORD and Collaborative Institutional Training Initiative (CITI) on ethical principles of human research protection. See https://www.research.va.gov/pride/training/options.cfm for approved courses and VHA Handbook 1200.05(2) for additional information.

15. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If you have any questions regarding any aspect of records management you should contact your facility Records Manager or your Records Liaison.

16. REFERENCES

a. Pub. L. 104-191, Health Insurance Portability and Accountability Act of 1996.

b. 5 U.S.C. 3371, Definitions.

c. 15 U.S.C. 3710a, Cooperative Research and Development Agreements.

d. 18 U.S.C. 11, Bribery, Graft, and Conflicts of Interest.

e. 38 U.S.C. 5727, Information Security, Definitions.

f. 38 U.S.C. 7303, Functions of Veterans Health Administration: Research Programs.

g. 5 CFR 2635, Standards of Ethical Conduct for Employees of the Executive Branch.

h. 38 CFR 16, Protection of Human Subjects.

i. 38 CFR 17, Medical.

j. VA Directive 6500, Managing Information Security Risk: VA Information Security Program, dated September 20, 2012.

k. VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, dated March 10, 2015.

l. VHA Directive 1200, Research and Development Program, dated May 13, 2016.

m. VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017.

n. VHA Directive 1206, Use of a Cooperative Research and Development Agreement (CRADA), dated June 19, 2018.

o. VHA Directive 1400, Office of Academic Affiliations, dated September 14, 2009.

p. VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

q. VHA Directive 6300, Records Management, dated July 10, 2012.

r. VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry, dated November 24, 2014.

s. VHA Handbook 1058.02, Research Misconduct, dated February 7, 2014.

t. VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research, dated November 21, 2014.

u. VHA Handbook 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research, dated April 15, 2013.

v. VHA Handbook 1106.1, Pathology and Laboratory Medicine Services (PALMS) Procedures, dated January 29, 2016.

w. VHA Handbook 1200.05(2), Requirements for the Protection of Human Subjects

in Research, dated November 12, 2014.

x. VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories, October 21, 2005.

y. VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011.

z. VHA Handbook 1200.08, Safety of Personnel Engaged in Research, dated March 6, 2009.