Veterans Health Administration
Research & Development
Improving Veterans' Lives www.research.va.gov

Frequently Asked Questions: VHA Directive 1200.01, Research and Development Committee (January 24, 2019)

1. R&D Committee Review of Subcommittee Minutes

Question: Is the R&D Committee required to "approve" subcommittee minutes as part of the requirement for it to review subcommittees as described in VHA Directive 1200.01, Paragraph 6.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 . . ."*

Answer: No. The R&D Committee is not required to approve subcommittee minutes, but it must document in its minutes its review of the subcommittee minutes within 60 days of the subcommittee's finalization of the minutes (VHA Directive 1200.01, Paragraph 8.a.(3)).

An example of documentation of the R&D Committee's review of minutes when no issues required action is as follows: "The IRB's minutes were reviewed by the R&D Committee; there were no issues requiring discussion or action." An example of documentation of the R&D Committee's review of minutes when issues required action is as follows: "The IRB's minutes were reviewed by the R&D Committee; the IRB reviewed 101 protocol deviations for Dr. "121" in its last meeting, but there is no indication that any actions were taken by the IRB. Additional information will be requested from the IRB regarding its review of the protocol deviations for Dr. "121" and any required reporting."

The R&D Committee reviews the subcommittee minutes as a method to evaluate whether the subcommittee is functioning effectively and efficiently. This is one aspect of the R&D Committee's oversight of the VA Facility's R&D program. The R&D Committee's review of subcommittee minutes informs it of issues addressed or actions taken by the subcommittees that may require additional institutional action by the R&D Committee. The subcommittee minutes also provide the R&D Committee with documentation of the operations of the subcommittees. Reviewing these minutes is therefore a quality assurance activity permitting the R&D Committee to evaluate whether the subcommittee is serving the function for which it is constituted.

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2. R&D Committee Review of Subcommittee and Committees Through Quality Assurance and Quality Improvement Activities

Question: What are the quality assurance and quality improvement activities the Office of Research and Development (ORD) requires the R&D Committee to conduct as part of its review of research related committees and subcommittees as stated in VHA Directive 1200.01, Paragraph 6.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. . . ."*?

Answer: ORD does not prescribe the specific number or types of quality assurance and quality improvement activities that the R&D Committee uses for its periodic review (at least annually) of its research-related committees and subcommittees. The R&D Committee has discretion to select the quality indicators or quality measures it considers most meaningful to its review. Possibilities include, but are not limited to:

a. Comparison of VA studies approved by the research-related committee or subcommittee against the VA studies approved by the R&D Committee to ensure that all studies approved by a research-related committee or subcommittee to be conducted as VA research are approved by the R&D Committee;

b. Attendance of subcommittee or committee members;

c. Documentation in the minutes of information specified by regulatory requirements, such as attendance and voting;

d. Length of time required for the committee or subcommittee to review and approve modifications to previously approved research;

e. Number of actions taken by the committee or subcommittee during a convened meeting, and the duration of the meeting; and

f. Reviewing a subset of standard operating policies of its research-related committees and subcommittees to evaluate whether documentation reflects implementation of the reviewed standard operating policies.

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3. R&D Committee Approval of Inclusion of Non-Veterans in VA Research

Question: Why is the R&D Committee required to review and approve recruitment of non-Veterans in VA research instead of an Institutional Review Board (IRB)?

Answer: VA research focuses on health issues that affect Veterans. A Veteran as defined in 38 U.S. Code §101(2) *". . . means a person who served in the active military, naval, or air service, and who was discharged or released therefrom under conditions other than dishonorable."* The R&D Committee is responsible for ensuring that all research in which the facility is engaged is consistent with the VA mission. The evaluation of whether the inclusion of non-Veterans in a proposed VA research activity is consistent with meeting the VA mission cannot be delegated to an Institutional Review Board (IRB) because the evaluation is not a human subjects protections issue; it is an institutional evaluation. In addition, VA conducts many exempt human subjects research activities that could involve non-Veterans. Not all exempt human subjects research activities require IRB approval. Common examples of exempt human subjects research activities involving non-Veterans are survey research involving caregivers and employees.

For VA studies involving subjects receiving treatment as inpatients or outpatients, VA has strict regulations in 38 CFR §17.45 and 38 CFR §17.92 stating that non-Veterans may only be included in VA research involving VA outpatient or VA inpatient treatment when there are insufficient Veteran patients suitable for the study. The R&D Committee should evaluate who will be responsible for paying for any medical care or treatment for non-Veterans included in research activities involving VA hospital inpatient or outpatient treatment because VA's medical dollars appropriated for the care of Veterans cannot be used to provide care for non-Veterans.

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4. R&D Committee Approval of Inclusion of Non-Veterans in VA Research

Question: When can the R&D Committee approve the inclusion of non-Veterans through a designated review process?

Answer: VHA Directive 1200.01, Paragraph 13.a. describes the specific responsibilities of the VA Investigator and the R&D Committee when non-

Veterans are proposed to be included in VA research. ". . . 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." If the VA research activity can be approved by a R&D Committee through a designated review process, such as exempt human subject research protocols and protocols approved by expedited review by the IRB, the review and approval for inclusion of non-Veterans in a VA research protocol can be done by designated review.

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5. R&D Committee's Review of Subcommittee Review Procedures

Question: Is the R&D Committee required to review and approve all subcommittee standard operating policies and procedures (SOPs)?

Answer: No. The R&D Committee is not required to review and approve all subcommittee SOPs. For example, the R&D Committee is not required to review and approve the content of subcommittee SOPs that the Institutional Animal Care and Use Committee (IACUC) approves for its Veterinary Medical Unit (VMU) management. VHA Directive 1200.01, Paragraph 9.b.(1) states the following with the section related to R&D Committee review and approval of subcommittee SOPs underlined:

> *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.*

ORD's requirement of the policy statement in VHA Directive 1200.01, Paragraph 9.b.(1) related to review of subcommittee SOPs is that the R&D Committee must have a way to ensure that each of its subcommittees has effective standard operating procedures (SOPs) for protocol review. ORD does not prescribe the method used by each of the VA Facility's applicable subcommittees to establish these SOPs. The subcommittee's method for reviewing and approving its SOPs can be done by the subcommittee members or by other methods. For example, in many Institutional Review Boards (IRB) operated by VA Facilities, the VA IRB Administrator reviews and approves the IRB SOPs. To meet the ORD policy requirement, the R&D

Committee should document how it evaluates the adequacy of each subcommittee's review procedures.

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6. R&D Committee Quality Assurance Reviews

Question: Is the ACOS/R&D (or Coordinator for Research in a smaller VA medical facility) required to continue conducting the following quality assurance reviews described in the rescinded VHA Handbook 1200.01 (January 15, 2009) even though they are not included in VHA Directive 1200.01 (January 24, 2019)?

a. Conducting an annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation:

b. Providing an annual quality assurance review of research employees involved in human subject research to ensure the employees are working within their scopes of practice and their privileges allowed by the facility's by-laws and granted to them by the facility; and

c. Providing an annual quality assurance review of Cooperative Research and Development Agreements (CRADAs) and other agreements in support of the research program or specific research projects and an assessment of the impact of these agreements on the research program, when applicable.

Answer: No. The ACOS/R&D (or Coordinator for Research in a smaller VA medical facility) is not required by ORD policy in VHA Directive 1200.01 to be responsible for the referenced quality assurance activities described in VHA Handbook 1200.01. The R&D Committee is required at least annually to conduct quality assurance and quality improvement activities as part of its review of all research related committees and subcommittees as described in VHA Directive 1200.01, paragraph 6.

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7. R&D Committee: VA Central IRB

Question: Is the VA Central IRB a subcommittee of the R&D Committee?

Answer: The VA Central IRB is not a subcommittee of the R&D Committee. It is an external committee established by a Memorandum of Understanding (MOU) between it and a VA Facility for VA Central IRB services. As stated in

the Note in VHA Directive 1200.0, Paragraph 8.a., "*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)."* However, it is an internal VA IRB).

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8. R&D Committee: VA Central IRB

Question: VA Central IRB: Is the VA Central IRB an internal IRB or an external IRB?

Answer: The VA Central IRB is an internal IRB. As stated in the *Note* in VHA Directive 1200.01, Paragraph 5.h. (7): "*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)."* Internal IRBs include two types of IRBs: (a) a VA facility's IRB supported, and staffed within the VA Facility, including registration of the IRB; and (b) the VA Central IRB.

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9. R&D Committee approval: Single patient expanded access protocols

Question: When is the R&D Committee approval required for single patient expanded access protocols for investigational drugs or biologics or investigational medical devices?

Answer: The R&D Committee approval is required for single patient expanded access protocols for investigational drugs or investigational medical devices when IRB approval is required by FDA regulations for an expanded access protocol prior to the investigational medical product (drug, biologic, or medical device) being administered to the patient. The R&D Committee approval can be granted using a designated review procedure as permitted in VHA Directive 1200.01, Paragraph 9.e. (5) or the convened R&D Committee review procedure.

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10. R&D Committee approval: Continuing review

Question: Is the R&D Committee required to conduct continuing review for human subjects research activities approved by expedited review or transitioned to the 2018 Requirements of the Federal Policy for the Protection of Human Subjects (Common Rule) when the IRB does not conduct continuing review of the research activity?

Answer: No. The R&D Committee is not required to conduct continuing review of the non-exempt human subjects research activities because the research activities remain under the continuing oversight of the IRB.

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11. R&D Committee Chair and Members' Required Training

Question: Which two modules in the Collaborative Institutional Training Initiative (CITI) are required by ORD for the R&D Committee Chair and voting members to complete to meet the ORD training requirement in VHA Directive 1200.05 for training on ethical protections of human research protections?

Answer: VHA Directive 1200.01, Paragraph 14, states *"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."*

There are two stages (basic and refresher) in CITI for VA's Human Subjects Protections course. The required modules in the Human Subjects Protection course are:

For the basic stage:
History and Ethics of Human Subjects Research (ID: 498)
Informed Consent (ID: 3)

For the refresher stages:
History and Ethical Principles (ID: 511)
History and Ethical Principles – Research vs. Practice (ID 993)

ORD has set up the above modules as a separate course for R&D Committee members at each of the VA Facilities. Learners can get to it via the "add a course" link in their own accounts. Those who have already taken the VA Human Subjects Protection training in CITI, which includes the training required for R&D Committee members, will not have to take additional training; CITI will automatically grant those individuals credit for having already completed the training for R&D Committee members, when they enroll in the new course. Please contact Dr. Alice Huang at alice.huang@va.gov with any questions about this training.

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