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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12. R&D Committee Review of Subcommittee Minutes

Question: Does the R&D Committee use the date subcommittee minutes are signed or the date subcommittee minutes are received to determine when a subcommittee finalizes minutes for purposes of the R&D Committee conducting its review of those minutes within 60 days?

Answer: ORD policy does not define what date must be used. ORD requires that the R&D Committee review subcommittee minutes within 60 days of the subcommittee's finalization of the minutes (VHA Directive 1200.01, Paragraph 8.a.(3)). Some subcommittee minutes require approval and signature, such as the Institutional Animal Care and Use Committee (IACUC) as described in VHA Handbook 1200.07, Paragraph 8.h.(2). Other subcommittee minutes, such as the IRB, do not unless there is a local applicable policy. Subcommittee policies and procedures should define how minutes are finalized.

The R&D Committee as part of its operations must maintain standard operating procedures or other written procedures for all recurring processes (VHA Directive 1200.01, Paragraph 6.e.). ORD recommends that the R&D Committee's written procedures include a statement(s) defining how the R&D Committee determines when subcommittee minutes are finalized for purposes of conducting the ORD required review of subcommittee minutes within 60 days. The following, which does not represent an all-inclusive list, are two examples of sample language defining how the R&D Committee determines the date of subcommittee finalization of minutes:

(1) *If date of subcommittee signature is used to define finalization of the minutes*:

The convened R&D Committee must review subcommittee minutes within 60 days after the subcommittee minutes are signed. Subcommittee minutes are considered final as of the date of signature.

(2) If date of receipt by the R&D Committee is used to define finalization of the minutes.

The convened R&D Committee must review subcommittee minutes within 60 days after they are received physically or electronically, or notification is received that the subcommittee minutes are available for review. Subcommittee minutes are considered final as of that date.

Release Date: 09-20-2019

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

Question: If the R&D Committee approves the inclusion of non-Veterans in an ORD-funded study, does it replace any required approvals or waivers for inclusion of non-Veterans by the ORD funding service?

Answer: No. R&D committee approval of inclusion of non-Veterans in an ORD-funded study does not replace any requirements of the applicable funding service.

Release Date: 09-20-2019

14. R&D Committee Approval: Research Under the Oversight of a Subcommittee or Committee

Question: Is the R&D Committee required to approve research under the oversight of a research-related subcommittee or committee?

Answer: Yes. The R&D Committee must provide final approval of VA research before the research can be initiated regardless of the committee or subcommittee that will oversee it. Final R&D Committee approval can only be granted once the R&D Committee has received documentation from all applicable subcommittees/committees of their review and non-contingent approval (VHA Directive 1200.01, Paragraph 9.b.(1)). However, because emergency use of a test article under FDA regulations does not require prospective IRB approval, prospective R&D Committee approval is also not required.

Release Date: 06-03-2020

15. R&D Committee Approval: Lifecycle Study Actions

Question: After initial approval, is the R&D Committee required to approve lifecycle actions of studies such as continuing reviews, amendments, reportable events, etc.…?

Answer: Yes, however, only if the R&D Committee is the only committee overseeing the study. If another committee or subcommittee is responsible for overseeing the lifecycle actions of the study, then the R&D Committee is not required to approve those actions (VHA Directive 1200.01, Paragraph (1200.01 Paragraph 9.b.(4) and 9.c.(3)). Committees and subcommittees may request that the R&D Committee review an action (e.g. an amendment is submitted that has the potential to significantly impact the facility) or ORD policy may require that the R&D Committee approve an action (e.g. approval of an amendment to add non-Veteran enrollment in VA research (VHA Directive 1200.01, Paragraph 13.a.)).

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16. ACOS/R&D Notification

Question: When is ACOS/R&D notification required for R&D Committee actions?

Answer: After the research project has been granted final approval by the R&D Committee, the ACOS/R&D is responsible for notifying investigators, in writing that the research project can be initiated, and the period for which the project is approved (VHA Directive 1200.01, Paragraph 5.g.(2)). Local policy will dictate timeframes and format for that notification.

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17. ACOS/R&D Notification

Question: Does the ACOS/R&D have to notify investigators of approvals of amendments and continuing reviews by the reviewing subcommittees or committees?

Answer: No. There is no ORD policy requirement for notification by the ACOS/R&D of subsequent subcommittee or committee actions, such as approval of amendments or continuing reviews, in addition to the notifications sent by the reviewing subcommittees or committees.

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18. ACOS/R&D Notification

Question: If a study is not approved by the R&D Committee is the ACOS/R&D required to send a letter to the investigator?

Answer: No. There is no ORD policy requirement for the ACOS/R&D to notify the investigator in addition to the R&D Committee's notification of the study disapproval (VHA Directive 1200.01, Paragraph 9.b.(3).

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19. Communicating with the R&D Committee

Question: What is the best way to make sure that actions on research under the oversight of a subcommittee or committee are communicated to the R&D Committee?

Answer: There is no single best way to ensure that actions on research under the oversight of a subcommittee or committee are communicated to the R&D Committee. Different factors impact when and how actions are communicated and will vary among committees, including use of electronic vs. paper-based systems.

R&D Committee subcommittees are required to provide the R&D Committee with copies of subcommittee minutes within 60 calendar days of the finalization of the minutes. A well-constructed quality assurance program at your site will also help to ensure that the reporting of minutes is happening within the required 60 calendar days of finalization. The minutes must include information on actions approved by the convened committee as well as a list of actions that were approved outside of committee, via an expedited (IRB) or designated member review (IACUC and SRS) process.

The Memorandum of Understanding (MOU) or reliance agreement between the VA facility and the external committee must stipulate how actions approved by the committee will be communicated to the R&D Committee. The MOU or reliance agreement should be reviewed on at least an annual basis to ensure the obligations detailed in the MOU are being met.

Elements of the MOU should include:

a. How the R&D Committee will be made aware of actions approved by the committee, to include a mutually agreed upon time frame for such notification. Notification can take the form of submission of meeting minutes, a list of actions approved, copies of approval notices, or some other means by which the R&D Committee is made aware of actions that have been approved by the committee.
b. A provision to allow the VA facility access to unredacted copies of meeting minutes within 2 business days of a written request to allow the R&D Committee to review deliberations on VA protocols.
c. Information on how the R&D Committee will either receive copies of actions and the supporting documents approved by the committee or be able to access those records remotely.

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20. R&D Committee Records

Question: For studies overseen by an external committee, does the R&D Committee need to retain copies of the complete protocol file on all actions approved by the external committee?

Answer: No. The R&D Committee is not required to physically maintain a copy of the complete protocol file on all actions approved by the external committee. However, the R&D Committee must have the ability to access the protocol file if it does not physically maintain a paper or electronic copy of the complete protocol file. VHA Directive 1200.02, Paragraph 12.a.(4)(c) requires VA research to maintain and control a copy (paper or electronic) of all approved Research Protocols, amendments, consent document templates, and other documents submitted to a research review committee/subcommittee, and documents related to the actions of the research review committees.

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21. R&D Committee Designated Review

Question: Is the R&D Committee required to convene a R&D Committee meeting to review all new (initial) studies for approval?

Answer: No. ORD policy in VHA Directive 1200.01 allows the following new (initial) studies to be approved by the R&D Committee using a designated review process with no convened R&D Committee requirement:

a. Exempt human subject research protocols
b. Protocols approved by expedited review by the IRB.
c. Patient expanded access protocols regulated under FDA's expanded access regulations (please note that single patient emergency use of a test article does not require prospective IRB approval or R&D committee approval).
d. 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.

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22. R&D Committee Designated Review

Question: Can an R&D Committee chair or designated member of the R&D Committee approve research through the designated review process?

Answer: Yes. VHA Directive 1200.01, Paragraph 9.e. allows the R&D Committee to review the activities defined in the applicable ORD policy using a designated review process. However, only the R&D Committee Chair or a voting member designated by the Chair can review and approve the activity on behalf of the R&D committee. If the research study is eligible for designated review at initial approval, subsequent actions that are required to be approved by the R&D Committee on the study, to include approval of amendments and continuing reviews, for studies overseen solely by the R&D Committee can also be approved by designated review.

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23. R&D Committee Designated Review

Question: When does the designated R&D Committee reviewer have to report the review approval to the R&D Committee?

Answer: Final initial R&D Committee approval of research by designated review must be reported to the full R&D Committee at its next convened meeting and noted in the minutes (VHA Directive 1200.01, Paragraph 9.b.(1)). The R&D Committee's standard operating procedures (SOPs) should specify how approvals by designated review are communicated to the rest of the committee and the timeframe for communication. While ORD policy does not currently require reporting of other designated review approvals, such as exempt research, to the convened R&D Committee, ORD recommends that all designated review approvals be reported to the R&D Committee and noted in the minutes. ORD does not prescribe a specific method for VA facilities to report designated review approvals to the R&D Committee. However, ORD recommends that a minimum of the name of the research study, name of Principal Investigator, the type of designated review action (e.g., exempt research approval; final approval after ISSO and PO reviews), and date of designated review approval be included in the information reported to the R&D Committee.

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24. R&D Committee Approval of Study Team Members

Question: For research under the sole oversight of the R&D Committee, is the R&D Committee required to approve changes to investigators?

Answer: Yes. It is the responsibility of the overseeing committee to ensure the availability of qualified research team members, including investigators, who can conduct the approved research. Changes to investigators, to include Principal Investigators/co-investigators/sub-investigators, constitute amendments to approved research. Amendments to approved research under the sole oversight of the R&D Committee must be submitted to the R&D Committee for approval prior to implementation.

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25. R&D Committee Approval of Study Team Members

Question: For research under the sole oversight of the R&D Committee, is the R&D Committee required to approve changes to study team members who are not investigators?

Answer: Yes, if the names of the study team members are named in the protocol, information sheet received by VA subjects or advertisement materials. Changes in study team members who are not investigators on committee applications are not required by ORD policy to be approved by the R&D Committee prior to that individual being permitted to work on the study. Changes in personnel are required to be reported to the R&D Committee annually as part of the R&D Committee's continuing review requirements (VHA Directive 1200.01, Paragraph 9.d.(2)(a)(3)). R&D Committee SOPs must specify when such changes in study team members are to be submitted and how they are reviewed.

However, any study team member cannot be a VA study member unless they have the required appointment, qualifications, and training. For example, a VA Investigator cannot add a study team member as a member of the VA research team who does not have a VA appointment. VHA Directive 1200.02, Paragraph 14.a.(7) requires the VA Principal Investigator to ensure that all research staff are qualified (including but not limited to appropriate training, education, expertise, and credentials) to perform procedures assigned to them during the course of the research. Written procedures must be in place to ensure that all research personnel hold an official VA appointment from HRMS (as a compensated, full-time or part time employee, a WOC, or under an IPA) prior to conducting or being involved in any way in VA research activities, and that the individuals maintain their appointment while conducting or being involved in any way in any VA research activities.

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26. R&D Committee Approval Expiration

Question: What is required of the R&D Committee and the PI if there is a lapse in approval for studies that are under the sole oversight of the R&D Committee?

Answer: A lapse of R&D Committee approval is an expiration of study approval. For studies requiring R&D Committee continuing review, the time frame for R&D Committee approval cannot exceed 365 days (VHA Directive 1200.01, Paragraph 9.d.(1)(d)). When a study has lapsed R&D Committee approval, the study no longer has any institutional approval to be conducted by the VA Investigators. A study cannot be conducted without approval.

The R&D committee must have written policies and procedures for recurring processes (VHA Directive 1200.01, Paragraph 6.3.). For continuing review, the R&D Committee must have written policies and procedures for conducting continuing review, including processes for investigator submission and R&D Committee review procedures. If approval expires for a study under sole oversight of the R&D Committee, the R&D Committee must notify the investigator that R&D Committee approval has expired and all study activities must stop, including any data analyses. Any requirements for continuing review submission or review of received materials must be completed before approval can be obtained following expiration of the study's approval. Once approval is obtained, the study continuation written notification is sent to the PI. If the requirements for continuing review submission or review are not completed, the study must be closed. The R&D Committee should include in its written policies and procedures time frames by which additional actions such as study closure will occur following expiration of study approval.

ORD wishes to emphasize that R&D Committee written policies and procedures should be put in place to prevent lapses in study approval when the R&D Committee is the sole oversight committee. When a study lapse occurs, the R&D Committee should evaluate the root cause of the lapse in study approval, and if appropriate, initiate correction actions and/or revise policies and procedures to remediate or prevent lapse of R&D Committee continuing review approvals.

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