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

Description of Amendment #1 (January 8, 2021) to VHA Directive 1200.01: Research and Development Committee

Description of Amendment: Eleven revisions are present in the January 8, 2021 technical amendment to VHA Directive 1200.01. The amendments described in detail in the following tables are summarized as follows with revisions highlighted in red.

- Paragraph 2: Revised summary of changes.
- Paragraph 3.f: Added a "Note" to the definition of VA research to state that emergency use of a test article is VA research even though it does not require R&D Committee approval.
- Paragraph 4: Clarified the "Scope" to state that R&D Committee approval is not required for emergency use of a test article.
- Paragraph 5.h.(6): Removed the requirement that all research requires Privacy Officer review and clarified the scope of the ISSO review.
- Paragraph 5.j: Clarified the ISSO review.
- Paragraphs 5.h.(9); 5.i., and 5.l.(3): Deleted
- Paragraph 5.l.(4): Clarified the instruments used to conduct the ISSO reviews.
- VHA Directive 1200.01, Paragraph 9.d.(2): Eliminated the requirement for continuing review of exempt research to align with elimination of continuing review for expedited research.
- VHA Directive 1200.01, Paragraph 9.e.(5): Clarified the use of designated review processes in expanded access.

Non-Amended VHA Directive 1200.01	Amended (January 8, 2021) VHA Directive 1200.01
Paragraph 2: SUMMARY OF MAJOR CHANGES: 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.	**Paragraph 2: SUMMARY OF MAJOR CHANGES:** Amendment date 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.

Non-Amended VHA Directive 1200.01	Amended (January 8, 2021) VHA Directive 1200.01
Paragraph 3. DEFINITIONS: 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.	**Paragraph 3. DEFINITIONS:** 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.
Paragraph 4. SCOPE: 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 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.	**Paragraph 4. SCOPE:** 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.

Non-Amended VHA Directive 1200.01	Amended (January 8, 2021) VHA Directive 1200.01
Paragraph 5. RESPONSIBILITIES: h.(6) Ensuring Information System Security Officer (ISSO) and Privacy Officer (PO) review is complete before a study is given final approval. NOTE: The R&D Committee can approve contingent on ISSO and PO review.	**Paragraph 5. RESPONSIBILITIES:** h.(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 ~~and Privacy Officer (PO) review is~~ complete before a study is given final approval. NOTE: The R&D Committee can approve contingent on ISSO and PO review.
Paragraph 5. RESPONSIBILITIES: h.(9) Establishing a local R&D Conflict of Interest Committee to ensure that potential financial conflicts of interest are reported, reviewed, and managed in accordance with government ethics rules and regulations and VA ethics policies. See VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry, dated November 24, 2014. NOTE: Any concerns that involve criminal conflict of interest law or Standards of Conduct are matters for the Designated Agency Ethics Official (DAEO). The DAEO, the Principal Deputy General Counsel, the Alternate DAEO, and the OGC Ethics Specialty Team address issues involving the application of criminal conflict of interest laws (18 U.S.C. Chapter 11) and the Standards of Conduct for Executive Branch Employees (5 CFR Part 2635). The DAEO, the Alternate DAEO and the Ethics Specialty Team are the only sources of authoritative advice on criminal conflicts of interest and the legal questions relating to Standards of Conduct. These Deputy Ethics Officials can be contacted at governmentethics@va.gov. Full disclosure of all the relevant facts to the designated agency ethics officials and good faith reliance on that advice provides the employee with meaningful protection from criminal or administrative sanctions. The imposition of criminal sanctions ultimately rests with the Department of Justice after receiving the matter from the Inspector General.	**Paragraph 5. RESPONSIBILITIES:** **Paragraph 5.h.(9) deleted.** **Please note: VA Facilities should continue following their procedures developed prior to the release of the revised VHA Directive 1200.01 for identifying and managing financial conflicts of interest for VA Investigators, including filing of the Alt 450s by VA Investigators conducting VA research.**

Non-Amended VHA Directive 1200.01	Amended (January 8, 2021) VHA Directive 1200.01
Paragraph 5. RESPONSIBILITIES: i. Research and Development Conflict of Interest Committee. The local R&D Conflict of Interest Committee is responsible for reviewing completed, signed and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement submitted by VA investigators.	**Paragraph 5. RESPONSIBILITIES:** **Paragraph 5.i. deleted.**
Paragraph 5. RESPONSIBILITIES: j. The ISSO is responsible for ensuring that the proposed research complies with information security requirements for VA sensitive information (see VA Handbook 6500, Managing Information Security Risk: VA Information Security Program, dated September 20, 2012).	**Paragraph 5. RESPONSIBILITIES:** j. 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) ~~ensuring that the proposed research complies with information security requirements for VA sensitive information (see VA Handbook 6500, Managing Information Security Risk: VA Information Security Program, dated September 20, 2012)~~.
Paragraph 5. RESPONSIBILITIES: l.(3) Submitting a completed, signed and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement (https://www.research.va.gov/programs/tech_transfer/model_agreements/conflict_of_interest.pdf), for review by the R&D Conflict of Interest Committee prior to: (a) Initial review of a study protocol in which the employee is listed as Investigator; (b) Continuing review of a study protocol in which the employee is listed as Investigator; (c) The employee being added as an Investigator to a study protocol; and (d) When a change in relevant information requires that the investigator change an answer in Section I of an earlier-filed OGE Form 450 Alternative – VA to "yes" or that changes the reason for a "yes" answer.	**Paragraph 5. RESPONSIBILITIES:** **Paragraph 5.l.(3) deleted.** **Please note: VA Facilities should continue following their procedures developed prior to the release of the revised VHA Directive 1200.01 for identifying and managing financial conflicts of interest for VA Investigators, including filing of the Alt 450s by VA Investigators conducting VA research.**

Non-Amended VHA Directive 1200.01	Amended (January 8, 2021) VHA Directive 1200.01
Paragraph 5. RESPONSIBILITIES: (4) Submitting and implementing plans for data use, storage, and security to the PO and ISSO that are consistent with VHA Directive 1605.01, VA Directive 6500, implementing handbooks, and other legal requirements.	**Paragraph 5. RESPONSIBILITIES:** (3) Submitting and implementing the VHA Research Protocol Privacy Review Checklist and OIS Enterprise Research Data Security Plan for data use, storage, and security ~~plans for data use, storage, and security to the PO and ISSO~~ that are consistent with VHA Directive 1605.01, VA Directive 6500, implementing handbooks, and other legal requirements.
Paragraph 9. RESEARCH AND DEVELOPMENT COMMITTEE REVIEW OF RESEARCH: No current language.	**Paragraph 9. RESEARCH AND DEVELOPMENT COMMITTEE REVIEW OF RESEARCH:** Added new policy: 9.d.(2)(c) Continuing review approval for exempt research is not required by the R&D Committee for continuing review following initial approval.
Paragraph 9. RESEARCH AND DEVELOPMENT COMMITTEE REVIEW OF RESEARCH: (5) Single patient expanded access protocols approved by the IRB Chair or another appropriate IRB voting member.	**Paragraph 9. RESEARCH AND DEVELOPMENT COMMITTEE REVIEW OF RESEARCH:** (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. ~~Single patient expanded access protocols approved by the IRB Chair or another appropriate IRB voting member.~~

This is the first amendment to VHA Directive 1200.01 since it was signed on January 24, 2019. The amended VHA Directive 1200.01 is published on the VHA Publications page at: https://www.va.gov/vhapublications/publications.cfm?pub=1.

Please send any questions regarding this amendment to the ORD Regulatory Mailbox at VHACOORDRegulatory@va.gov.