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

FREQUENTLY ASKED QUESTIONS

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The National Cancer Institute's Central IRB (NCI CIRB)

Question 1: Can a VA facility obtain a waiver from the CRADO to designate the National Cancer Institute's Central IRB (NCI CIRB) as an IRB of record?

Response 1: No. VHA Handbook 1200.05 Subparagraph 5e(1) states "Under exceptional circumstances, a VA facility may request a waiver from the CRADO to utilize the services of an IRB operated by another Federal department or agency that is signatory to the Common Rule." At present, however, such waivers will not be approved for designation of the NCI CIRB as an IRB of Record for a VA Facility. [I didn't want to say ORD won't approve since it is a CRADO decision, not ORD] (Updated March 26, 2012)

Question 2: Can a research study be conducted at a VA facility if the VA facility's affiliate IRB delegated review of the study to the NCI CIRB?

Response 2: No. All IRBs that review studies for a VA facility must be listed on the VA Facility's Federal Wide Assurance (FWA) and, at present, waiver requests will not be approved to designate the National Cancer Institute's Central IRB (NCI CIRB) on a VA Facility's FWA (see Question 1). However, the research study can be conducted at a VA Facility if an IRB listed on its FWA (e.g., its local IRB, the IRB of another VA facility, or its affiliate IRB) reviews and approves the study (i.e., without delegating the review to the NCI CIRB). (Updated March 26, 2012)

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Standalone HIPAA Authorizations

Question 1: Must all VA research approved by an IRB after March 31, 2011, and involving the use and disclosure of protected health information (PHI) have a HIPAA authorization that is separate from the informed consent form (unless the authorization is formally waived by the IRB)?

Response 1: HIPAA authorizations and informed consent forms must now be separate documents for all VA research **initially** approved by an IRB after March 31, 2011. (Updated March 12, 2012)

Question 2: When a VA study approved before March 31, 2011, is amended or comes up for continuing review, must the HIPAA authorization be separated from the informed consent form if the forms were previously combined?

Response 2: No. The VHA Handbook 1200.05 requirement that the informed consent form and the HIPAA authorization be two separate documents is only applicable to protocols undergoing **initial review** (whether by full board review or by expedited procedures) **after** March 31, 2011. This requirement does **not** apply to amendments or continuing reviews of projects that were **initially** approved by the IRB **on or before** March 31, 2011. (Updated March 12, 2012)

Reference:
VHA Handbook 1200.05 §37.a(2)

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Retroactive CRADO Waivers

Question 1*:* If it is discovered that a study involves international research, children, or prisoners, but the required waiver from the Chief Research and Development Officer (CRADO) has **not** been obtained, can a retroactive CRADO waiver be obtained?

Response 1*:* No. As a matter of policy, the CRADO and the Office of Research and Development (ORD) do **not** issue "retroactive" waivers for international research, research involving children, or research involving prisoners that **has already been conducted**. (Updated March 12, 2012)

Question 2: Suppose the results of the study have **already been published** when the lack of the required CRADO waiver is discovered?

Response 2: The noncompliance should be reported to the responsible IRB, and to ORD if the research was funded by ORD. The IRB must determine (a) whether the failure to obtain the required waiver constitutes serious or continuing noncompliance reportable to ORO, and (b) whether any remedial or corrective action is warranted. (Updated March 12, 2012)

Question 3: Suppose data analysis has been **completed** when the lack of the required CRADO waiver is discovered, can the results be published?

Response 3: There are no VHA policies that specifically address whether these results can be published. The IRB must determine (a) whether the failure to obtain the required waiver constitutes serious or continuing noncompliance reportable to ORO, and (b) whether any remedial or corrective action is warranted. ORD must also be consulted if the research was funded by ORD. (Updated March 12, 2012)

Question 4: Suppose data collection or data analysis is **in progress** when the lack of the required CRADO waiver is discovered, can the already-collected data be used and published?

Response 4: See Response 3. In addition, any **continued use** of such data would need a CRADO waiver prior to the continued use. Likewise, any **collection of new data** for continuation of the research would require a CRADO waiver. (Updated March 12, 2012)

Question 5: Can data obtained without a required CRADO waiver be used in a subsequent study?

Response 5: Any secondary use of data collected without a required CRADO waiver, including use in a subsequent study, requires a CRADO waiver prior to the secondary use. (Updated March 12, 2012)

References
VHA Handbook 1200.05 §47.b, §48.a, and §56.c
VHA Handbook 1058.01 §7.f(11) and §7.i

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Implementation of IRB-Approved Revisions to Protocols and Consent Forms

Question 1: How soon after IRB approval must a protocol or informed consent revision be carried out by the research team?

Response 1: Although changes in approved research require IRB approval, neither the Common Rule (38 CFR Part 16) nor VHA Handbook 1200.05 specifically stipulates how quickly an IRB must communicate its approval of changes to the investigator or how quickly the investigator must carry out the approved changes. The safety of the research subjects should be of primary concern in this regard. Safety concerns related to the timely implementation of IRB-approved changes should be brought to the attention of the IRB. Where warranted to ensure subject safety, IRBs may stipulate that the approved changes must be implemented prior to the enrollment of new subjects and/or that previously enrolled subjects must be informed of the changes. In such circumstances, the IRB has an obligation to provide the investigator with timely notification sufficient to address the safety issues involved.

Implementation delays that appear to pose an increased risk of harm to subjects should be brought to the attention of the IRB. It is the IRB's responsibility to determine whether or not such delays constitute serious or continuing noncompliance or serious unanticipated problems involving risks to subjects or others. (Updated March 12, 2012)

Question 2: Must the revised informed consent form be employed at the same time by all sites involved in a multi-site research project?

Response 2: No. If multiple IRBs are involved, it is unlikely that they will all approve the document at the same time. Even if a single IRB (e.g., the VA Central IRB) is involved, release of approval letters for dozens of sites at the same time may not be practical because the forms may need to be individualized for the specific sites. (Updated March 12, 2012)

References
38 CFR 16.109(a) and 16.116(b)(5)
VHA Handbook 1200.05 §14.e
VHA Handbook 1058.01 §7.d and §7.i

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Expiration Dates on Informed Consent Forms

Question: Must expiration dates appear on informed consent forms for VA research?

Response: No. Neither the Common Rule (38 CFR Part 16) nor VHA Handbook 1200.05 requires that expiration dates appear on informed consent forms. Each IRB has the authority to determine whether or not expiration dates are to appear on the consent forms that it approves. (Updated March 12, 2012)

References:
VHA Handbook 1200.05 §33

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Administrative Staff Membership on the IRB

Question 1: Can VA Associate Chiefs of Staff (ACOSs) for Research and Development (R&D), VA Administrative Officers (AOs) for R&D, VA research office staff, VA IRB administrators, or VA IRB administrative staff serve as voting members or alternate voting members of a VA facility's local IRB of record?

Response 1: No. VA ACOSs for R&D, VA AOs for R&D, VA research office staff, VA IRB administrators, and VA IRB administrative staff cannot serve as voting members or alternate voting members of a VA facility's local IRB of record, whether that IRB is an internal VA IRB, the IRB of another VA facility, or an affiliate IRB. (Updated March 12, 2012)

Question 2: Can affiliate administrative staff, including affiliate IRB administrative staff, serve as voting members or alternate voting members of an affiliate IRB serving as a VA facility's IRB of record?

Response 2: Yes. VHA policy cannot address this issue. The affiliate IRB has the authority to decide whether or not to allow affiliate administrative staff to serve as voting members or alternate voting members of the affiliate IRB, even when it serves as the IRB of record for a VA facility. (Updated March 12, 2012)

Reference:
VHA Handbook 1200.05 §12.j

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"Recruitment Only" Studies

Question: Does VA permit its Research and Development (R&D) Committees to approve studies in which VA's **sole** involvement is to solicit the participation of Veterans in research that is conducted entirely by a non-VA entity?

Response: VA R&D Committees may only approve research that supports VA's mission to advance the health care of the Nation's Veterans. VA R&D Committees may not approve research that does not support this mission. In addition, approval by a VA R&D Committee makes a study VA research and obligates the VA to provide care for research-related injuries to subjects. VA R&D Committees cannot approve studies that are conducted **entirely** by non-VA investigators. (Updated March 12, 2012)

NOTE: This guidance does not preclude VA clinicians, in the normal course of their clinical duties, from discussing specific research studies with their patients where appropriate, and referring them to a non-VA investigator for more information about a non-VA study. However, VA personnel should not provide the non-VA investigator with the names or contact information of Veterans who might be eligible for the study. Instead, the VA clinician should provide the Veteran with the contact information for the non-VA investigator so the Veteran may initiate contact if he/she is interested in participating in the non-VA study. VA personnel should not provide the non-VA investigator with protected health information (PHI) about Veterans who choose to participate in non-VA studies without a signed release form, ***and*** *a signed HIPAA authorization,* ***and*** *adherence to local requirements for the release of medical information.*

References:
VHA Directive 1200 §2.b and §5.tt
VHA Handbook 1200.01 §8.g and §10.a(1)
VHA Handbook 1200.05 §3.xxx(note)

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Ads, Fliers, and Other Recruitment Materials for Non-VA Studies

Question: Does VA permit fliers, advertisements, or other recruitment materials for non-VA research to be posted on VA premises?

Response: No. VA does not permit recruitment fliers or advertisements for non-VA research to be posted within or on the premises of a VA facility. The word "posting" includes announcing, distributing, publishing, or advertising the study either electronically or by hard copy to anyone, including Veterans, clinicians, or other staff. Therefore, ads, fliers, or other recruitment materials for non-VA research cannot be distributed, posted, or laid out in clinic waiting rooms; posters for non-VA research cannot be placed on VA bulletin boards; and recruitment materials for non-VA research cannot be provided on VA websites or included in VA e-mails. (Updated March 12, 2012)

References:
VHA Handbook 1200.05 §5.n

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Recruitment of Non-Veterans for VA Research

Question 1: The VA investigator for an industry-sponsored, multi-site investigational drug study relevant to the Veteran population has been unable to find enough Veterans who meet the study's inclusion criteria. The investigator wants to recruit non-Veterans by posting fliers in the community informing potential subjects about the trial and instructing them to contact the VA investigator for additional information. Is this form of recruitment permissible?

Response 1: A VA facility's IRB of record may permit the recruitment of non-Veterans into VA research only if a there is a compelling argument for their inclusion (e.g., a study-wide shortage of eligible Veterans) **and** the research is relevant to the care of Veterans or active duty military personnel. Non-Veterans **cannot** be recruited into VA research if the research is not relevant to the care of Veterans or active duty military personnel The IRB must specifically document in the IRB meeting minutes or IRB protocol file its determinations regarding participation of non-Veterans in the study. The IRB should also review and approve any proposed recruitment materials to be used for the study. (Updated March 12, 2012)

Question 2: A VA facility is considering participating in a multi-center, industry-sponsored clinical trial. The industry sponsor wants to post national ads soliciting prospective subjects to call a national 1-800 number staffed by the sponsor. The prospective subject would provide health information to the sponsor for initial screening, and if eligible, would be instructed to contact the nearest study site, which could be the VA. Can the VA facility participate in a study with this recruitment procedure?

Response 2. A recruitment strategy using a sponsor's 1-800 call center to refer potential subjects to a VA study site could be acceptable to VA under certain conditions. However, additional information is needed before a determination can be made about the acceptability of this study for VA. In order to determine whether all requirements for VA research have been satisfied, the VA facility's IRB of record would need to review not only the complete protocol and clinical investigators' brochure, but also (a) a detailed justification for the VA investigator to enroll non-Veterans, (b) the proposed sponsor protections at the call center and elsewhere to ensure the privacy of subjects and the confidentiality of subjects' health information, and (c) the proposed recruitment procedures, including the text of the proposed ads. (Updated March 12, 2012)

Reference:
VHA Handbook 1200.05 §27.c and §58

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Delegation of ACOS/R&D Responsibilities

Question 1: Can the ACOS/R&D delegate to others the Scope of Practice approvals required by VHA Directive 1200 §5.pp and VHA Handbook 1200.05 §62.c?

Response 1: The ACOS/R&D **cannot** delegate Scope of Practice approvals to others. However, the ACOS/R&D **can** rely on information and recommendations from others in granting such approvals. (Updated March 12, 2012)

Question 2: Can the ACOS/R&D delegate to others the notifications to investigators, required by VHA Handbook 1200.01 §7.a, that research can be initiated or continued?

Response 2: The written notification informing the investigator that research can be initiated or continued must come from and be **signed by** the ACOS/R&D. (Updated March 12, 2012)

References:
VHA Directive 1200 §5.pp
VHA Handbook 1200.01 §7.a
VHA Handbook 1200.05 §62.c

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