



Department of Veterans Affairs Revisions to 1200.05, 1058.01, and 1058.03

General Overview

This document lists the Standards and Elements where the US Department of Veterans Affairs (VA) requires additional protections.

VA follows the Belmont Report and the Common Rule, including Subparts B, C, D, and E, except where noted below. Organizations following the Common Rule must meet all Essential Requirements in the *Evaluation Instrument*, and Common Rule requirements described under DHHS regulations in the *Evaluation Instrument* (except where noted below).

VA also follows FDA requirements, which are described under FDA requirements in the Evaluation Instrument.

This document summarizes VA requirements based on:

- 38 CFR 16
- VHA Directive 1200.05, Requirements for Protection of Human Subjects in Research
- 1058.01 Research Compliance Reporting Requirements,
- 1058.03 VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research

The additional protections described below are focused on those most applicable to non-VA organizations, such as universities serving as academic affiliates and independent IRBs that review VA studies. (Note: For VA hospitals seeking accreditation, there are additional requirements not described here.)

Underlined text indicates new requirements or revisions to requirements in the *Evaluation Instrument*.

~~Strikethrough~~ text indicates previously included information in the *Evaluation Instrument* that are no longer required.

Domain I: Organization

Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program with appropriate leadership.

Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program.

(4) When following VA requirements (VHA Directive 1200.05, section 2):

(a) VA research is research that is conducted by researchers (serving on VA 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. VA research must have Research and Development (R&D) Committee approval 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.

- (b) VA-affiliated nonprofit research and education corporations (NPC) are authorized by Congress under 38 U.S.C. 7361-7366 to provide flexible funding mechanisms for the conduct of research and education at one or more VA facilities. Research approved by a facility R&D Committee are considered to be a VA research project or a VA education activity respectively, regardless of the source of funding, the entity administering the funds, or the research or education site (see VHA Handbook 1200.17, Department of Veterans Affairs Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C. Sections 7361 Through 7366, dated April 27, 2016 and revised May 9, 2017).
- (c) VA research includes VA-approved research conducted at international sites not within the United States, its territories, or Commonwealths; and includes research where human tissues are sent outside the United States.
- (c) The VA does not conduct Written materials indicate classified research involving human participants. cannot be approved by a VA facility, IRB, or Research and Development Committee or performed at VA facilities.

Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.

(2) When following VA requirements:

- (a) Policies and procedures describe the responsibilities of the facility director:
- (i) Serves as the organizational Official responsible for the facility's research program, and the development and implementation of a human research protection program. This responsibility cannot be delegated.
 - (ii) Oversees the research and development committee, the IRB, other subcommittees of the research and development committee, and all VA researchers and research staff.
 - (iii) Delegates authority in writing for respective roles and responsibilities for the HRPP. This delegation of authority must provide the organizational structure and ensure leadership for oversight activities for all human participants research conducted at or by the facility.
 - (iv) Obtains permission from the central research and development officer if the facility wants to establish a new IRB or change the IRB of record, and ensuring any IRB is established according to VA requirements, and has approval from the Office of Research Oversight (ORO).
 - (v) When the facility engages another entity's IRB, ensures responsibilities are detailed in a memorandum of understanding or authorizing agreement.
 - (vi) Obtains accreditation of the facility's HRPP by the accrediting organization specified by the VA Office of

- ~~Research and Development (ORD), in accordance with a schedule determined by ORD.~~
- ~~(vii) Ensures that IRB members, researchers and research staff are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations.~~
- ~~(viii) Develops and implements an educational plan for IRB members, staff, researchers, and research staff including initial and continuing education.~~
- ~~(ix) Fulfils all educational requirements mandated by ORD and OHRP.~~
- ~~(x) Appoints one or more research compliance officers to conduct annual research consent document audits and triennial regulatory audits, and to assist in the VA facility's assessments of regulatory compliance.~~
- ~~(xi) Unless a waiver for a part-time research compliance officer is approved by the under secretary for health, each VA facility conducting research must designate at least one full-time research compliance officer.~~
- ~~(xii) Reports any appointment, resignation, or change in status of the research compliance officer to Office of Research Oversight VHA Central Office, with a copy to the relevant ORO research officer, within 10 business days after the appointment, resignation, or change takes effect.~~
- ~~(xiii) Reports to ORO in writing within two business days after being notified of any research-related citation or determination of non-compliance by any state or federal agency; or any situation that has generated media attention or Congressional interest.~~
- ~~(xiv) The facility director's written report is required regardless of whether disposition of the event has been resolved at the time of the report.~~
- ~~(xv) Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO office at intervals and in a manner specified by that office.~~
- ~~(xvi) Provides a copy of any ORO compliance reports regarding the research program to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.~~
- ~~(xvii) Reports the following research events to ORO Central Office, with a simultaneous copy to the appropriate ORO research officer:~~
- (A) ~~IRB changes in number of IRBs and changes in membership rosters.~~
- (B) ~~Substantive Memorandum of Understanding (MOU) changes must be reported to ORO Central Office within five business days.~~

(xviii) Ensures that individuals working under a contract with VA cannot serve as VA researchers, but may participate in research in other ways, such as collaborators or consultants.

Element I.1.C. The Organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics Committee to function independently of other organizational entities in protecting research participants.

(2) When following VA requirements:

(a) Policies and procedures indicate:

- (i) The facility director is responsible for ensuring that the IRB functions independently.
- (ii) In addition to the IRB, the privacy officer, information security officer, and research and development committee must provide their final approval before research can be initiated.
- (iii) The facility director, research and development committee, and ORD can disapprove research.
- (iv) If research is disapproved by the IRB, or the IRB requires modifications, the disapproval or need for modifications cannot be overruled by any other authority.

Element I.1.E. The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

(2) When following VA requirements:

(a) Policies and procedures indicate that all individuals who are subject to VA regulations are required to complete training in the ethical principles on which human research is to be conducted before they may participate in human participants research in accordance with requirements specified by ORD; the local site can require additional training.

Standard I-2: The Organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants for the research activities that the Organization conducts or oversees.

When following VA requirements:

(a) The VA facility has an established or designated IRB by:

- (i) Establishing its own IRB.
- (ii) Securing the services of an OHRP registered IRB established by another VA facility, VA central IRB, or affiliated medical or dental school, or an IRB of another federal agency.
 - (A) The provision of services by the IRB, including the VA Central IRB, is established through a memorandum of understanding or other written agreement that outlines the responsibilities of the VA and the academic affiliate.

- (B) When relying on another IRB, the memorandum of understanding requires the other IRB to comply with VA requirements when reviewing VA research.
- (C) A VA facility's own internal IRB cannot serve as an IRB of record for any non-VA entity except a DoD facility, DOE Laboratory, or a VA Nonprofit Research and Education Corporation (VA NPC).
- (iii) If using the VA Central IRB, the facility director delegates authority to one or more individuals from the local VA facility to:
- (A) Provide comments or suggestions to VA Central IRB, in response to VA Central IRB's initial review considerations.
- (B) Respond to VA Central IRB's approval of the study on behalf of the VA facility as to whether the VA facility chooses to participate or declines to participate in the study.
- (C) Serve as liaison between the VA facility and both the local site researcher and VA Central IRB.

Standard I-3: The Organization's transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the Organization's principal location while complying with local laws and taking into account cultural context.

- (2) When following VA requirements:
- (a) The facility director must ensure all international research is approved explicitly in a document signed by the facility director, except for Cooperative Studies Program activities which must be approved by the CRADO.
- (b) All international sites must hold an international federalwide assurance, and the research must be approved by the IRB or Ethics Committee of the participating sites listed on the international Federalwide assurance.
- (c) International research includes VA approved research conducted at international sites not within the United States, its territories, or Commonwealths; and includes research where human tissues are sent outside the United States.
- (d) The researcher must conduct the research in accordance with VA requirements and all other applicable federal requirements for protecting human participants, tissue banking, use of databases, federal criminal laws, and the standards of ethical conduct for employees of the executive branch.

Standard I-5: The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.

Element I.5.A. The Organization conducts audits or surveys or uses other methods to assess compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization makes improvements to increase compliance, when necessary.

(2) When following VA requirements:

- (a) Policies and procedures indicate the facility director is responsible for ensuring appropriate auditing of local human participants research studies to assess compliance with all applicable local, VA, and other federal requirements including, but not limited to, Office of Research Oversight requirements.
- (b) A research compliance officer is an individual whose primary responsibility is auditing and reviewing research projects relative to requirements for the protection of human participants, and who:
 - (i) Conducts annual consent document audits.
 - (ii) Conducts triennial regulatory audits on all research protocols.
- (c) The VA facility's lead research compliance officer must report directly to the facility director. The activities of the research compliance officer may not be determined or managed by the Research Service, researchers, or any other research personnel.
- (d) The IRB may observe, or have a third party observe research activities, including the informed consent process. Procedures must include, but are not limited to:
 - (i) Criteria that might prompt increasing the frequency of audits beyond the minimal required frequency.
 - (ii) The timeframe for reporting audit findings to the IRB.
 - (iii) Types of corrective actions the IRB can require based on the audit findings.
 - (iv) Who should implement and review the corrective actions.
 - (v) How to evaluate the results of any corrective actions.
- (e) The IRB can accept audits conducted by the research compliance officer to fulfill auditing requirements.
- (f) The IRB may require more frequent audits by the research compliance officer or by other means. The IRB also may require the research compliance officer to conduct more focused audits of one or more aspects of the study. The requirement to increase the frequency of audits or to audit specific aspects of the study might be based on considerations including, but not limited to:
 - (i) Involvement of vulnerable populations.
 - (ii) Level of risk.
 - (iii) Phase I or Phase II studies.
 - (iv) Involvement of FDA approved drugs for which there has been a new safety warning issued, or change in the labeling that indicates increased risks.
 - (v) Issues of noncompliance.
 - (vi) Data confidentiality or security concerns.

Element I.5.D. The Organization has and follows written policies and procedures for addressing allegations and findings of non-compliance

with Human Research Protection Program requirements. The Organization works with the Institutional Review Board or Ethics Committee, when appropriate, to ensure that participants are protected when non-compliance occurs. Such policies and procedures include reporting these actions, when appropriate.

(5) When following VA requirements (VHA Directive 1058.01 Section

(3):

(a) Policies and procedures include the following definitions, procedures, and timeframes:

(i) Serious noncompliance is any failure to adhere to requirements for conducting human research that may reasonably be regarded as:

(A) Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research participants, research staff, or others, including the rights to privacy and confidentiality of identifiable private information.

(B) Presenting a genuine risk of substantive harm to the safety, rights, or welfare of research personnel who conduct research.

(C) Presenting a genuine risk of substantive reputational harm to VA.

(B) Substantively compromising a VA facility's HRPP.

(ii) Continuing noncompliance is a persistent failure to adhere to the laws, regulations, or policies governing human research means repeated instances of noncompliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of noncompliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance.

(A) The determination that noncompliance is "serious" or "continuing" rests with the IRB.

(b) Apparent serious or continuing noncompliance:

(i) VA personnel must ensure that the appropriate IRB of Record is notified, in writing, within five (5) business days after becoming aware of any apparent serious and/or continuing noncompliance with applicable laws, regulations, policies, and agreements pertaining to non-exempt human participants research. This includes, but is not limited to, serious or continuing noncompliance with the Common Rule, local VA medical facility policies and SOPs related to human participants research, if developed, IRB-approved protocols, and the requirements or determinations of the IRB. (VHA Directive 1058.01 Sections 5, 7) Within five business days of becoming aware of any apparent or possible serious or continuing non-compliance are responsible for providing written notification members of the VA research community are required to ensure that the apparent non-compliance has been reported in writing to the IRB.

(c) Research compliance officer reports of apparent serious or continuing non-compliance.

- (i) Within five business days of identifying apparent serious or continuing non-compliance based on a consent document audit, regulatory audit, or other Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP systematic audit of VA research, the research compliance officer must provide a written report of the apparent non-compliance directly (without intermediaries) to:
- (A) Facility director.
 - (B) Associate chief of staff for research.
 - (C) The Research and Development Committee.
 - (D) The IRB.
 - (E) Other relevant research review committees.
- (ii) Within five business days of receiving such notification, the facility director must report the apparent serious or continuing non-compliance to:
- (A) The appropriate Office of Research Oversight research officer.
 - (B) Veterans Integrated Service Network (VISN) director.
 - (C) Office of Research Development.
- (iii) An initial report of apparent serious or continuing non-compliance based on a research compliance officer consent document audit, research compliance officer regulatory audit, or other systematic research compliance officer audit is required regardless of whether disposition of the matter has been resolved at the time of the report.
- (d) IRB review of apparent serious or continuing non-compliance when following VA regulations.
- (ii) In response to the written notification, the IRB must:
- (A) Review the written notification at its next convened meeting, not to exceed 30 calendar days after the date of written notification. NOTE: Incidents covered by this paragraph may call for immediate attention and require the IRB to convene an emergency session prior to its next scheduled meeting.
 - (B) Determine and document within 60 calendar days of the convened IRB's initial review:
 - (I) Whether or not serious or continuing noncompliance actually occurred; and if so,
 - (II) What, if any, remedial actions are needed to resolve present noncompliance or prevent future noncompliance.
 - (C) If the IRB determines that serious or continuing noncompliance actually occurred, it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations within five (5) business days after making those determinations.
- (ii) The IRB must review a report of apparent serious or continuing non-compliance at the earliest practicable opportunity, not to exceed 30 days after notification. The IRB chair may take interim action to eliminate apparent immediate hazards to participants.

- (ii) The IRB must reach a determination that serious or continuing non-compliance did (or did not) occur within 30-45 days after receiving a report of apparent non-compliance.
- (iii) Remedial actions involving a specific study or research team must be completed within 90-120 days after the IRB's determination.
- (iv) Remedial actions involving programmatic non-compliance must be completed within 120-180 days after the IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.
- (e) Should the IRB determine that the reported incident constitutes serious non-compliance or continuing non-compliance, within five business days after the determination the IRB chair, or designee must provide a written report of the determination directly to:
 - (i) Facility director.
 - (ii) Associate chief of staff for research.
 - (iii) Research and Development Committee.
 - (iv) The RCO, if the apparent serious or continuing non-compliance was identified by an RCO audit, regardless of outcome.
 - (v) Other relevant research review committee.
- (f) Unless the non-compliance has already been reported, within five business days after receiving such notification, the facility director must report the determination to:
 - (i) The appropriate Office of Research Oversight research officer.
 - (ii) The VISN director.
 - (iii) Office of Research Development.
 - (iv) An initial report of an IRB determination that serious non-compliance or continuing non-compliance occurred is required, even where the determination is preliminary or disposition of the matter has not been resolved at the time of the report.
- (g) Members of the VA research community must report possible serious or continuing non-compliance with VA or other federal requirements related to human research or with IRB requirements or determinations to the associate chief of staff for research and development and the IRB within five business days after becoming aware of it.
- (h) Policies and procedures describe the reporting of serious or continuing non-compliance to:
 - (i) The Office of Research and Development, if VA funded.
 - (ii) The Regional Office of Research Oversight.
 - (iii) The VA Privacy Office, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.
 - (iv) The VHA Information Security Officer when the report involves violations of VA information security requirements.
 - (i) A research compliance officer identifying serious or continuing noncompliance, during an informed consent or regulatory audit, must report the noncompliance to the facility director, the associate chief of staff for research and development, the Research and

~~Development Committee, and the IRB as soon as possible but no later than five business days after becoming aware of the noncompliance.~~

~~(j) IRBs of academic affiliates that are the IRB of record for VA facilities must follow the VA requirements.~~

Standard I-6: The Organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.

Element I.6.B. The Organization has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of researchers and research staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The Organization works with the Institutional Review Board or Ethics Committee in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate.

(3) When following VA requirements:

- (a) VA facilities are not required to follow PHS requirements, even when research is funded by a PHS agency (e.g., NIH).
- (b) Affiliates that serve as IRBs of record for VA facilities must use the VA financial conflict of interest form, and may not create, re-draft, or change this form.

Standard I-7: The Organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.

Element I.7.A. When research involves investigational or unlicensed test articles, the Organization confirms that the test articles have appropriate regulatory approval or meet exemptions for such approval.

(3) When following VA requirements:

- (a) Policies and procedures have the researcher ensure the local Pharmacy Service or Research Service Investigational Pharmacy receives:
 - (i) Documentation of IRB and any other relevant approvals.
 - (ii) A copy of VA Form 10-9012 (if applicable).
 - (iii) A copy of the current approval protocol.
 - (iv) A copy of the consent document for each participating participant with all appropriate signatures.
 - (v) Documentation of IRB continuing review approval.
 - (vi) Copies of sponsor related correspondence specific to the drugs as appropriate.
 - (vii) Copies of all correspondence addressed to the researcher from the FDA specific to the investigational drugs as appropriate.

(b) Policies and procedures have the researcher inform the chief, pharmacy service, the research pharmacy when applicable, and the IRB in writing with a study involving investigational drugs has been suspended, terminated, or closed.

- (i) Comply with all dispensing requirements.
- (ii) Comply with all documentation requirements and make relevant records accessible to the investigational drug pharmacist when requested.

Element I.7.C. The Organization has and follows written policies and procedures for compliance with legal and regulatory requirements governing emergency use of an investigational or unlicensed test article.

(4) When following VA requirements (VA: VHA Directive 1200.05 Section 3):

- (a) Policies and procedures state that a patient receiving a test article in an emergency use that is regulated by FDA is not considered to be involved in research and is not a research participant.
- (a) Any emergency use of a test article does not require R&D Committee approval but is VA research under this policy.

Standard I-9: The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization the rights and welfare of research participants are protected.

When following VA requirements (VHA Directive 1200.05, Sections 5, 8):

(4) When serving as a reviewing IRB for VA research:

- (a) All IRBs overseeing VA human participants research must meet all the IRB requirements described in 38 CFR Part 16.
- (b) When the IRB of Record is directly operated and supported by a non-VA entity, the policies and procedures related to the review of VA research by the non-VA entity must be consistent with VHA Directive 1200.05, 1005.01, and all requirements applicable to VA research.
- (c) VAs may rely upon the VHA Central Office IRB (VA Central IRB), an IRB of another VA facility, the IRB(s) of a medical or dental school, or the IRB of another federal agency. A VA facility may also use an IRB for multi-site protocols that has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facilities.
- (d) VA will permit the use of a commercial IRB as an IRB of Record if it has been specifically designated by ORD as a commercial IRB that may serve as an IRB for cooperative research.
- (d) When a VA facility engages the services of another entity's IRB as its IRB of Record, a Memorandum of Understanding (MOU) or Authorizing Agreement must be established and signed with the external organization(s) providing IRB services.

(e) IRBs of Record used by a VA facility must hold current IRB registrations with FDA/OHRP and provide updates to membership as required by VHA Handbook 1058.03.

Domain II: Institutional Review Board or Ethics Committee

Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.

Element II.1.A. The IRB or EC membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. The IRB or EC has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB or EC regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.

(2) When following VA requirements (VHA Directive 1200.05 Section 7):

(a) VA representation on external IRBs, such as academic IRBs, is optional and at the discretion of the organizational official and the external IRB.

(i) IRBs serving VA should consider including a veteran or veteran's representative.

(a) For a VA using an academic affiliate's IRB or other local VA facility's IRB, policies and procedures indicate:

(i) The IRB includes at least two VA employees who hold a minimum of 1/8ths VA compensated appointments to serve as voting members to each IRB of record, except the VA Central IRB or the central IRB of another federal agency (e.g., National Cancer Institute Central IRB). VA facilities with fewer than ten active protocols are only required to appoint one voting member and one alternate member. Members appointed to affiliate IRBs may be scientific or non-scientific members.

(ii) Alternate members must have qualifications similar to the member they replace. Alternate members may not serve for a class of members (for example a physician may not serve for all physician regular members, but must be designated to serve for a specific physician member). The individual the alternate is serving for must be referenced specifically by name.

(iii) At least one VA voting member of the IRB must be in attendance when VA research is discussed at a convened meeting.

(iv) IRBs serving VA should consider including a veteran or veteran's representative.

- (v) ~~Physicians, dentists, nurses, pharmacists, social workers, other clinicians, statisticians, and allied health professionals are considered scientists.~~
- (vi) ~~Veterans whose only relationship with the VA facility is receiving care at a VA facility or receiving benefits from the Veterans Benefits Administration are not considered to be affiliated for the purpose of being an IRB member. Individuals who perform occasional volunteer activities without compensation (WOC) are not considered affiliated. However, those who hold a WOC appointment for volunteer activities other than IRB service are considered to be affiliated. Individuals who have retired from the VA and who are receiving VA retirement benefits are considered affiliated.~~
- (d) ~~The facility director, administrative staff, chief of staff, other senior administrators such as associate or assistant directors, or chief nurse, may observe meetings but not serve as voting or non voting members of the facility's IRB. Research office staff including, but not limited to, the associate chief of staff for research and development, the administrative officer for research and development, and IRB administrative staff, may not serve as voting members of the IRB.~~
- (viii) ~~The facility director appoints the privacy officer and information security officer as non voting members or consultants of the IRB or research and development committee.~~
- (b) VA facility research office staff including, but not limited to, the ACOS/R&D, the AO for R&D, and IRB administrative staff may not serve as members of the IRB. They may serve as ex officio attendees.
- (c) Research Compliance Officers (RCOs) may act as consultants to the IRB, but may not serve as members of the IRB. RCOs may attend IRB meetings when requested by the IRB or as specified by the IRB's SOPs. RCOs must be aware of and manage any potential, actual, apparent, or perceived conflicts of interest that arise because of their role.
- ~~The research compliance officer may serve as a non voting consultant, as needed, to the VA facility's IRB. The research compliance officer may not serve as a voting or non voting member of the IRB. The research compliance officer may attend meetings of the IRB when requested by the IRB or as specified by local procedure. These requirements are also relevant for an affiliate IRB.~~
- (d) Facility Directors, their administrative staff, COS, other facility senior administrators such as Associate or Assistant Directors or Chief Nurse, and NPC Administrative Staff may observe IRB meetings, but may not serve as members of the IRB.

Element II.1.B. The IRB or EC has qualified leadership (e.g., chair and vice chair) and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed and adjusted as appropriate.

(2) ~~When following VA requirements (VHA Directive 1200.05 Section 7):~~

~~(a) Policies and procedures indicate the facility director is responsible for appointing the IRB chair (or co-chairs, or chair and vice chair), and IRB voting members in writing.~~

- (b) IRB members are appointed for a period of up to three years. They may be re-appointed to a new terms of up to three years without a break in service at the end of each term. There is not a maximum number of terms for IRB members as long as the composition of the IRB meets all requirements.
- (c) The IRB chair (or co-chairs, or chair and vice chair) are appointed for a term of up to three years, and may be re-appointed indefinitely.
- (d) There may be one IRB chair, co-chairs, or a chair and a vice chair.
- (e) The IRB chair, co-chairs, and vice chairs are voting members of the IRB.
- (f) The IRB chair at the VA facility must be a paid VA employee.

Standard II-2: The IRB or EC systematically evaluates each research protocol or plan to ensure the protection of participants.

Element II.2.A. The IRB or EC has and follows written policies and procedures for determining when activities are exempt from applicable laws and regulations, when permitted by law or regulation and exercised by the IRB or EC. Such policies and procedures indicate that exemption determinations are not to be made by researchers or others who might have a conflict of interest regarding the studies.

- (4) When following VA requirements (1200.05, section 10):
- (a) Policies and procedures must designate who is authorized to make exemption determinations.
- (b) Exemption determinations may be made by the research and development committee or a subcommittee, the IRB chair, an experienced voting member of the IRB, IRB administrators, or IRB staff with appropriate qualifications.
- (b) Exemption determinations may not be made solely by the researcher, or someone with a conflict of interest in the research.

TABLE II.2.A.1. for Category 5:

When following VA requirements: The determination of exempt status for research and demonstration projects meeting the criteria for exempt category 5 must be made by the Under Secretary for Health on behalf of the Secretary of VA, after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate.

Element II.2.C. The IRB or EC has and follows written policies and procedures to conduct limited review by the IRB or EC, if such procedures are used.

- (3) When following VA requirements (1200.05 section 10):
- (a) For exempt research activities involving the researcher interacting with human participants or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human participant as applicable in writing or orally:

- (i) The activity is research.
- (ii) Participation is voluntary.
- (iii) Permission to participate can be withdrawn.
- (iv) Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data.
- (v) Contact information for the VA researcher.

- (b) If an exempt activity requires a limited IRB review, the limited IRB review must be completed prior to approval by the R&D Committee.
- (c) Research that has undergone limited IRB review and determined to be exempt requires approval by the R&D Committee and requires continuing review by the R&D Committee unless it is under the oversight of another subcommittee (e.g., Safety Review Subcommittee).

Element II.2.D. The IRB or EC has and follows written policies and procedures for conducting meetings by the convened IRB or EC.

- (2) When following VA requirements (1200.05, section 7):

- (a) When the IRB of record is an affiliate's IRB, policies and procedure indicate that at least one of the VA members has to be present during the review of VA research.

Element II.2.E. The IRB or EC has and follows written policies and procedures to conduct reviews by the convened IRB or EC.

- 1. Element II.2.E.1. – Initial review
- 2. Element II.2.E.2. – Continuing review
- 3. Element II.2.E.3. – Review of proposed modifications to previously approved research

- (3) When following VA requirements (1200.05, section 27):

- (a) Policies and procedures indicate that if a researcher does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date, policies and procedures:

- (i) Stop all research activities including, but not limited to, enrollment of new participants, analysis of individually identifiable data, and research interventions or interactions with currently enrolled participants, except where stopping such interventions or interactions could be harmful to participants.
- (ii) Immediately submit to the IRB chair a list of research participants who could be harmed by stopping study procedures.
- (iii) The IRB chair, with appropriate consultation with the chief of staff, determines within two business days whether participants on the list may continue participating in the research interventions or interactions.

Element II.2.F. The IRB or EC has and follows written policies and procedures to conduct reviews by an expedited procedure, if such procedure is used.

Element II.2.F.1. – Initial review

Element II.2.F.2. – Continuing review

Element II.2.F.3. – Review of proposed modifications to previously approved research

(4) When following VA requirements:

(a) If a researcher does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date, policies and procedures:

- (i) Stop all research activities including, but not limited to, enrollment of new participants, continuation of research interventions or interactions with currently enrolled participants, and data analysis.
- (ii) Immediately submit to the IRB chair a list of research participants who could be harmed by stopping study procedures.
- (iii) The IRB chair, with appropriate consultation with the chief of staff, determines whether participants on the list may continue participating in the research interventions or interactions.

Element II.2.G. The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to participants or others, and for reporting these actions, when appropriate.

(4) When following VA requirements (VHA Directive 1058.01 Sections 5, 7):

(a) Policies and procedures indicate the terms “unanticipated” and “unexpected” refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

(a) Policies and procedures include the following definitions, procedures, and timeframes:

(i) An unanticipated problem involving risks to participants or others (UPIRTSO) in human participants research is an incident, experience, or outcome that is: unexpected; related or possibly related to participation in the research; and indicative of the research placing participants or others at substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized. (VHA Directive 1058.01 Section 3)

(A) The term “unexpected” refers to an incident, experience, or outcome that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

(B) The phrase “related to participation in the research” means a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome.

(C) The phrase “possibly related to participation in the research” implies a lesser degree of certainty about causality and refers to an incident, experience, or outcome for which

there is some evidence to reasonably suggest a causal relationship between study procedures and the incident, experience, or outcome.

(i) A serious adverse event (SAE) in human participants research is an untoward occurrence, whether or not considered related to a participant' participation in research, that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome.

(A) An unexpected SAE that is related or possibly related to participation in human participants research constitutes a UPIRTSO.

(b) For unanticipated problems involving risks to participants or others, members of the VA research community are required to ensure that all unanticipated problems involving risks to participants or others in research are reported promptly to the IRB.

(b) In the event of a local research participant death, VA personnel must ensure that the appropriate IRB of Record is notified:

(i) Immediately (i.e., within one hour) upon becoming aware of any local research death of a human participant that is believed to be both unexpected and related or possibly related to a participant in a VA non-exempt human participant study. VA personnel must also provide follow-up written notification to the IRB within one (1) business day.

(ii) Within one (1) business day after receiving written notification of the death, the IRB Chair or another qualified IRB member must assess and document whether any actions are warranted to eliminate apparent immediate hazards to participants and, if so, initiate those actions.

(iii) In response to the written notification the IRB must:

(A) Review the written notification, the immediate hazard assessment of the IRB Chair or other qualified IRB member, and the actions taken to date at its next convened meeting, not to exceed 30 calendar days after the date of written notification. NOTE: Incidents covered by this paragraph may call for immediate attention and require the IRB to convene an emergency session prior to its next scheduled meeting.

(B) Determine and document within 30 calendar days of the convened IRB's initial review:

(I) Whether the death was both unexpected and related or possibly related to participation in the research; and

(II) What, if any, protocol or informed consent modifications are warranted. If modifications are warranted, the convened IRB must determine and document whether or not researchers must notify or solicit renewed/revised consent from previously enrolled participants; and if so, when such notification or consent must take place and how it must be documented.

(iv) The IRB must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations within five (5) business days after making those determinations.

(v) If the IRB is unable to make a determination on the matter within 30 calendar days of the convened IRB's initial review due to insufficient information or due to a lack of sufficient time to complete its review, the IRB must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing no later than five (5) business days after the determination was due.

(c) In the event of any apparent UPIRTSO, VA personnel must ensure that the appropriate IRB of Record is notified, in writing, within five (5) business days after becoming aware of any apparent UPIRTSO.

(i) Within five (5) business days after receiving written notification of an apparent UPIRTSO, the IRB Chair or another qualified IRB member must assess and document whether any actions are warranted to eliminate apparent immediate hazards to participants and, if so, initiate those actions.

(ii) In response to the written notification, the IRB must (except as provided for in paragraph 7.b.(5)): (a) Review the written notification, the immediate hazard assessment of the IRB Chair or other qualified IRB member, and the actions taken to date at its next convened meeting, not to exceed 30 calendar days after the date of written notification. NOTE: Incidents covered by this paragraph may call for immediate attention and require the IRB to convene an emergency session prior to its next scheduled meeting.

(iii) Determine and document within 30 calendar days of the convened IRB's initial review:

(A) Whether the incident, experience, or outcome was unexpected and related to or possibly related to participation in the research and indicative of the research placing participants or others at substantively greater risk of harm than was previously known or recognized (i.e., whether the incident, experience, or outcome constituted an actual UPIRTSO); and

(B) What, if any, protocol or informed consent modifications are warranted. If modifications are warranted, the convened IRB must determine and document whether or not researchers must notify or solicit renewed or revised consent from previously enrolled participants; and if so, when such notification or consent must take place and how it must be documented.

(iv) If the IRB determines that the incident, experience, or outcome constituted an actual UPIRTSO, it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations within five (5) business days after making those determinations.

(v) If the IRB is unable to make a determination on the matter within 30 calendar days of the convened IRB's initial review due to insufficient information or due to a lack of sufficient time to complete its review, the IRB must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing no later than five (5) business days after the determination was due.

(c) For serious unanticipated problems involving risks to participants or others, within five business days of becoming aware of any serious unanticipated problem involving risks to participants or others in VA research, members of the VA research community are required to ensure that the problem has been reported in writing to the IRB. Serious unanticipated problems involving risks to participants or others include:

- (i) Interruptions of participant enrollments or other research activities due to concerns about the safety, rights, or welfare of human research participants, research staff, or others.
- (ii) Any work-related injury to personnel involved in human research, or any research related injury to any other person, that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individuals, or leads to serious complications or death.
- (iii) Any VA National Pharmacy Benefits Management (PBM) Bulletins or Communications (sometimes referred to as PBM Safety Alerts) relevant to one or more of the VA facility's research projects.
- (iv) Any data monitoring committee, data and safety monitoring board or data and safety monitoring committee report describing a safety problem.
- (v) Any sponsor analysis describing a safety problem for which action at the VA facility might be warranted.
- (vi) Any unanticipated problem involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research participants, research staff, or others.
- (vii) Any problem reflecting a deficiency that substantively compromises the effectiveness of the VA facility's HRPP.

(d) Local unanticipated serious adverse events.

- (i) Policies and procedures indicate that within five business days of becoming aware of any local (i.e., occurring in the reporting individual's own facility) unanticipated serious adverse events in VA research, members of the VA research community are required to ensure that the serious adverse event has been reported in writing to the IRB.
 - (A) This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA regulations).
 - (B) The unfounded classification of a serious adverse event as "anticipated" constitutes serious non-compliance.
- (ii) IRB review of serious unanticipated problems and unanticipated serious adverse events.

(e) Policies and procedures indicate that within five business days after a report of a serious unanticipated problem involving risks to participants or others, or of a local unanticipated serious adverse event, the convened IRB or a qualified IRB member reviewer must determine and document whether the reported incident was serious and unanticipated and related to the research.

(i) "Related" means the event or problem may reasonably be regarded as caused by, or probably caused by, the research.

(ii) If the convened IRB or the IRB reviewer determines that the problem or event was serious, unanticipated, and related to the research, the IRB chair or designee must report in writing the unanticipated problem or event within five business days after the determination to:

(A) Facility director.

(B) Associate chief of staff for research.

(C) The Research and Development Committee.

(f) The facility director must report the problem or event to the appropriate Office of Research Oversight research officer within five business days after receiving such notification.

(g) If the convened IRB or the IRB reviewer determines that the problem or event was serious, unanticipated, and related to the research, a simultaneous determination is required regarding the need for any action (e.g., suspension of activities; notification of participants) necessary to prevent an immediate hazard to participants in accordance with VA regulations.

(i) All determinations of the IRB reviewer (regardless of outcome) must be reported to the IRB at its next convened meeting.

(ii) If it was determined that the problem or event is serious, unanticipated, and related to the research, the convened IRB must determine and document whether a protocol or consent document modification is warranted.

(iii) If the convened IRB determines that a protocol or consent document modification is warranted, the IRB must also determine and document:

(iv) Whether previously enrolled participants must be notified of the modification.

(v) When such notification must take place and how such notification must be documented.

(h) Policies and procedures include a requirement that the report of unanticipated problems involving risks to participants or others be sent to:

(i) The Office of Research and Development, if VA funded.

(ii) The Regional Office of Research Oversight.

(iii) The VA Privacy Office, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.

(iv) The VHA Information Security Officer when the report involves violations of VA information security requirements.

(i) IRBs of academic affiliates and the IRB of record for VA facilities must also follow these requirements when reviewing VA research.

Element II.2.H. The IRB or EC has and follows written policies and procedures for suspending or terminating IRB or EC approval of research, if warranted, and for reporting these actions, when appropriate.

(4) When following VA requirements (VHA Directive 1058.01):

(a) ~~The IRB of Record must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing within five business days of the suspension or early termination of a non-exempt VA human research study by the IRB or IO due to the study not being conducted in accordance with applicable regulations, policies, agreements, or IRB requirements or due to concerns about the safety, rights, or welfare of human participants or others.~~

(a) ~~Policies and procedures include the following definitions, procedures and timeframes:~~

(b) ~~The research and development committee and facility director have the authority to suspend or terminate their approval of research.~~

(c) ~~Reporting of terminations or suspensions of research.~~

(i) ~~Any termination or suspension of research (e.g., by the IRB or other research review committee, or by the associate chief of staff for research or other VA facility official) related to concerns about the safety, rights, or welfare of human research participants, research Staff, or others must be reported in writing within five business days after the termination or suspension occurs to:~~

- (A) Facility director.
- (B) Associate chief of staff for research.
- (C) Research and Development Committee.
- (D) IRB.
- (E) Other relevant research review committee.

(ii) ~~The facility director must report the termination or suspension to the appropriate Office of Research Oversight research officer within five business days after receiving such notification.~~

(iii) ~~Policies and procedures describe the prompt reporting of suspensions and terminations of IRB or EC approval to:~~

- (A) The Office of Research and Development, if VA funded.
- (B) The Regional Office of Research Oversight.
- (C) The Privacy Office, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.
- (D) The Information Security Officer when the report involves violations of information security requirements.

(iv) ~~IRBs of academic affiliates that are the IRB of record for a VA facility must also follow these requirements when reviewing VA research.~~

Element II.2.I. The IRB or EC has and follows policies and procedures for managing multisite research by defining the responsibilities of participating sites that are relevant to the protection of research

participants, such as reporting of unanticipated problems or interim results.

(2) When following VA requirements (VHA Directive 1200.05 Section 15):

(a) Policies and procedures indicate that for a VA multi-site study, not only the principal researcher, but also all local site researchers, must obtain written approvals from the relevant local VA facilities' IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA, and other federal requirements.

(i) Research cannot be initiated at any given site until the local researcher has obtained written notification that the research can be initiated from the local ACS/R&D.

(iv) Policies and procedures indicate that collaborative research may not be undertaken without a signed agreement that addresses the responsibilities of each party, including ownership of data and re-use of data for other research.

(a) Collaborative research is human participants research activities involving researchers from VA and at least one non-VA institution. Collaborative Research includes VA and non-VA institutions.

(i) The protocol or other documentation submitted to their VA IRB of Record must clearly delineate which research activities will be conducted as the VA portion of the overall Collaborative Research study (e.g., by VA researchers on VA time or VA property).

(ii) The VA informed consent document must clearly state when procedures conducted at other non-VA institutions are part of the VA's portion of the study.

(iii) Each institution engaged in the collaborative research must use the informed consent document required by its respective institutional policies for participants recruited from that institution, or procedures requiring participation of the participants at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed under VA's auspices and which will be performed under a non-VA institution's auspices.

(iv) The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom. This includes data from individual participants as well as other data developed during the research such as the analytic data and the aggregate data.

Standard II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.

Element II.3.C. The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants.

- (3) When following VA requirements:
- (a) Policies and procedures have the IRB consider the relevance of the research to the mission of VA and the Veteran population it serves.
 - (b) Policies and procedures have the protocol and related materials justify the inclusion of non-Veterans. Non-veterans may be enrolled in VA-approved research studies, including the provision of outpatient or hospital care for research participants, only when there are insufficient veterans available to complete the study or when the researcher can present a compelling argument to the IRB for the inclusion of non-veterans (e.g., survey of VA employees; study of active-duty military; study involving veterans' family members), and the research is relevant to the care of veterans or active-duty military personnel.
 - (c) To improve veterans' access to non-VA research, advertisements for research not conducted at a VA facility may be posted, provided facility director ensures there is a formal process to review and approve recruiting documents, flyers, and advertisements prior to being posted or distributed.
 - (i) A VA facility may not use Facebook as a method of advertising non-VA studies.

Element II.3.E. The IRB or EC has and follows written policies and procedures to evaluate proposed arrangements for maintaining the confidentiality of identifiable data, when appropriate, preliminary to the research, during the research, and after the conclusion of the research.

- (5) When following VA requirements where research involves a certificate of confidentiality (VHA Directive 1200.01, Section 22):
- (a) For studies that do not involve a medical intervention, no annotation may be made in the medical record.
 - (b) For studies involving a medical intervention, a progress note in the medical record should be made, indicating the individual has been enrolled in a research study, any details that would impact clinical care, and the name and contact information of the researcher conducting the study.
 - (a) For studies in which information about the participant's participation will be included in the participant's VA medical record, information must be given to the prospective participants as part of the consent process that information regarding study participation will be included in the medical record.

(See Element II.3.F. for a required consent disclosure)

Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately document the consent process.

- (4) When following VA requirements (VHA Directive 1200.05, Section :

- (a) The consent document must include all required disclosures, but does not need to use a specific template.
- (b) The consent document must be signed and dated by the participant or legally authorized representative, and by the person obtaining consent. The IRB may waive the requirement for the signature of the person obtaining consent when there is no physical contact with the participant (e.g., where the only contact with the participant is through telephone or mail).
- (c) The consent document must indicate the date of IRB approval, but the date does not need to appear on each page of the consent document.
- (d) Consent may be obtained and documented electronically so long as there are appropriate authentication controls to provide assurance the consent is rendered by the appropriate individual, and the participant dates the consent, or software provides the current date when signed.
- (e) The informed consent for research must include information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes; how the photographs, video, and/or audio recordings will be used for the research; and whether the photographs, video, and/or audio recordings will be disclosed outside VA.
- (e) ~~Consent to take a photograph, video, or audio recording for research cannot be waived by the IRB.~~
- (f) An informed consent to take a photograph, video, and/or audio recording cannot be waived by the IRB.
- (g) The consent for research does not give legal authority to disclose the photographs, video, and/or audio recordings outside VA.
- (f) Consent documents must include additional VA elements of disclosure. (See Table II.3.F.)
 - A statement that VA will provide treatment for research-related injury in accordance with 38 CFR 17.85 (see section 24 of this directive). NOTE: VA's statutory requirements in 38 CFR 17.85 apply regardless of inclusion of the information as part of the informed consent process.
 - For studies with a certificate of confidentiality, the informed consent document approved by the IRB must include a statement that the study has a certificate of confidentiality.

Element II.3.G. The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.

- (4) When following VA requirements:
 - (a) Policies and procedures require the IRB to document the reason when it waives the requirement to obtain written documentation of the consent process.

Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.

Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.

(4) When following VA requirements (VHA Directive 1200.05 Section 19):

(a) Policies and procedures have the IRB find and document in the minutes or IRB records specific findings in accordance with VA requirements.

(b) Policies and procedures indicate:

(i) Research that involves provision of in vitro fertilization services is permitted and cannot be conducted by VA researchers while on official VA duty, or at VA facilities, or at VA-approved off-site facilities.

○ (A) This includes prospective and retrospective research involving provision of or the enhancement of FDA-approved methods of in vitro fertilization for studies involving consenting participants, both male and female, undergoing or who have undergone in vitro fertilization for the treatment of certain forms of human infertility. In vitro fertilization is any fertilization of human ova that occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means.

(ii) Prospective and retrospective studies that enroll or include pregnant participants who conceived through in vitro fertilization or other artificial reproductive technologies are permitted.

(iii) Research in which the focus is either a fetus, human fetal tissue, either in-utero or ex-utero, is not allowed can be conducted by VA researchers while on official VA duty, at VA facilities, or at VA-approved off-site facilities. Use of human fetal tissue and human stem cells shall be governed by the policy set by NIH for recipients of NIH research funding.

(iv) Research involving stem cells shall be governed by the policy set by NIH.

(v) Research involving the creation of a human embryo or embryos solely for research purposes or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498B of the Public Health Service Act (42 U.S.C. 289q(b)) cannot be conducted by VA researchers, at VA facilities, or at VA-approved off-site facilities.

(ii) Research involving the provision of in vitro fertilization services is not allowed.

- (iv) ~~Interventional research involving neonates is not allowed. Prospective observational or retrospective record review studies that involve neonates or neonatal outcomes are permitted.~~
~~VA researchers cannot conduct interventions in research that include neonates while on official VA duty, at VA facilities, or at VA-approved off-site facilities. VA researchers may conduct research involving noninvasive monitoring of neonates if the research is determined by the IRB to be minimal risk. Prospective observational and retrospective record review studies that involve neonates or neonatal outcomes are permitted.~~
- (v) ~~Research involving pregnant women as participants is not allowed unless the IRB determines the requirements in 45 CRR 46.204 are met, and the facility director certifies the facility has sufficient expertise in women's health to conduct the proposed research.~~
- (vi) ~~Research involving prisoners as participants is not allowed unless a waiver has been granted by the chief research and development officer. Research involving prisoners cannot be conducted by VA researchers while on official VA duty, at VA facilities, or at VA-approved off-site facilities unless a waiver has been granted by the CRADO. (VHA Directive 1200.05 Section 20)~~
- (vii) ~~Research involving children as participants is not allowed unless a waiver has been granted by the VA medical facility director. Research involving children may not pose greater than minimal risk to the child. (VHA Directive 1200.05 Section 21)~~
- (viii) ~~Biological specimens and data obtained from children is considered research involving children even if deidentified.~~
- (ix) ~~International research is not initiated unless permission is obtained from the VA facility director.~~
- (ix) Before approving international research involving human participants research, the IRB must ensure that human participants outside of the U.S. who participate in research projects in which VA is a collaborator receive equivalent protections as research participants inside the U.S.
- If the activity involves research involving human participants requiring IRB approval or limited IRB review, the VA medical facility director must approve participation in the proposed international research.
- (x) ~~Research involving adults who are unable to consent may occur only when the IRB determines the proposed research:~~
- ~~(A) Does not present greater than minimal risk, or~~
 - ~~(B) Presents a greater probability of direct benefit to the participant than harm to the participant, or~~
- ~~(C) Poses greater than minimal risk and no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance to understanding or amelioration of the participant's disorder or condition.~~

- (D) In addition, the IRB determines the research cannot be performed solely on adults who can consent, and the focus of the research is the disorder leading to the lack of decision-making capacity, or
(E) Where the participant of the research is not directly related to the participant's lack of decision-making capacity, the researcher has presented a compelling reason for including adults unable to consent.

Element II.4.B. The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.

- (4) When following VA requirements:
- (a) Policies and procedures indicate:
- (i) Consent by a legally authorized representative is limited to situations where the prospective participant is incompetent or has impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note.
 - (ii) Consent from the legally authorized representative of the participant can only be obtained from the following: a healthcare agent (i.e., an individual named by an individual in a durable power of attorney for health care); legal guardian or special guardian; next of kin in this order: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or close friend, unless otherwise specified by applicable state law.
 - (iii) If there is any question as to whether a potential adult participant has decision-making capacity, and there is no documentation in the medical record that the individual lacks decision-making capacity, and the individual has not been ruled incompetent by a court of law, the researcher must consult with a qualified practitioner (who may be a member of the research team) about the individual's decision-making capacity before proceeding with the consent process.
 - (iv) Individuals, who because of a known condition, are at high risk to temporary or fluctuating lack of decision-making capacity must be evaluated by a qualified practitioner to determine the individual's ability to provide consent. This evaluation must be performed as described in the IRB approved protocol.
 - (v) If the individual is deemed to lack decision-making capacity at the time of their participation in the study, a legally authorized representative must provide consent.
 - (vi) If the participant regains decision-making capacity, the researcher must repeat the consent process with the participant, and obtain the participant's permission to continue with the study.
 - (vii) Disclosures to be made to the participant must be made to the participant's legally authorized representative.
 - (viii) The participant's legally authorized representative must be told that that his or her obligation is to try to determine what the participant would do if able to make an informed decision. If the prospective participant's wishes cannot be determined, the legally

authorized representative must be told that he or she is responsible for determining what is in the participant's best interest.

(ix) Have the researcher explain the proposed research to the prospective participant when feasible even when the participant's legally authorized representative gives consent.

(x) Have the practitioner explain the proposed research to the prospective participant when feasible.

(xi) Ensure the study includes appropriate procedures for respecting dissent. Prohibit participants from being forced or coerced to participate in a research study.

Element II.4.C. The IRB or EC has and follows written policies and procedures for making exceptions to consent requirements for planned emergency research and reviews such exceptions according to applicable laws, regulations, codes, and guidance.

(5) When following VA requirements (VHA Directive 1200.05, Section 2):

(a) VA does not conduct planned emergency research.

(b) Policies and procedures do not allow the IRB to waive the requirement to obtain consent for planned emergency research.

Standard II-5: The IRB or EC maintains documentation of its activities.

Element II.5.A. The IRB or EC maintains a complete set of materials relevant to the review of the research protocol or plan for a period of time sufficient to comply with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.

(2) When following VA requirements:

(a) The responsibilities that the VA facility and an organization operating as the VA facility's IRB of Record each will undertake to ensure compliance with requirements for maintaining records must be described in an MOU or an IRB Authorization Agreement or IRB reliance agreement.

(a) Policies and procedures indicate that the required records, including the researcher's research records, must be retained for a minimum of six years.

(b) Codes or keys linking participant data to identifiers must be retained as part of the research record for at least six years.

(c) If a protocol is cancelled without participant enrollment, IRB records are maintained for at least five years after cancellation.

(d) Policies and procedures have IRB records include:

(e) Correspondence between the IRB and the Research and Development Committee.

Element II.5.B. The IRB or EC documents discussions and decisions relevant to a research protocol or plan in accordance with legal and regulatory requirements, Sponsor requirements, if any, and organizational policies and procedures.

- (4) When following VA requirements (1200.05 section 8):
- (a) ~~IRB minutes must be submitted to the research and development committee in a timely manner.~~
- (b) ~~When the IRB of Record for a VA facility is the IRB of a non-VA entity (e.g., IRB of another federal entity, IRB of an academic affiliate), the non-VA entity must either:~~ ~~When relying on an affiliate IRB, the affiliate may either~~
- (i) Provide VA with, or access to, unredacted copies of meeting minutes in a timely manner that allows the R&D Committee to review the IRB's deliberations on VA protocols, or
- (ii) Provide VA with, or access to, redacted minutes in a timely manner that allows the R&D Committee to review the IRB's deliberations on VA protocols. The non-VA entity must permit relevant but allow VA personnel (including, but not limited to, ORO staff, and the local VA research office staff, local research compliance officers, and members of the research and development committee) to review unredacted minutes within two business days of a written request.
- (A) Redacted copies of meeting minutes should include the parts of the minutes related to the IRB's review of VA protocols.
- (b) Minutes must communicate the decision and expedited review category in the minutes of the next available meeting, and in written notification to the researcher and research and development committee.
- (c) When the IRB approves a consent procedure which does not include, or which alters, any of the elements of informed consent, or waives the requirement to obtain a signed informed consent document, it must find and document that all criteria for the waiver have been satisfied.
- (d) The IRB must document its determination on the level of risk either in the IRB minutes or the written communication to the researcher.

Domain III: Researcher and Research Staff

Standard III-1: In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Research Staff have the protection of the rights and welfare of research participants as a primary concern.

Element III.1.B. Researchers and Research Staff identify and disclose financial interests according to organizational policies and regulatory requirements and, with the Organization, manage, minimize, or eliminate financial conflicts of interest.

When following VA requirements:

Researchers must disclose conflicts of interest. This means disclosing to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research, and complying with all applicable VA and other federal requirements regarding conflict of interest.

Element III.1.E. Researchers and Research Staff recruit participants in a fair and equitable manner.

When following VA requirements (VHA Directive 1200.05 Section 5(g)):

- (a) Written materials describe researcher and research staff requirements related to Element II.3.C. that address specific VA requirements.
- (b) ~~Researchers are required to ensure appropriate telephone contact with participants. This pertains to contacting the participant by telephone. Research team members are prohibited from requesting social security numbers by telephone.~~
- (b) During recruitment process, VA researchers are responsible for:
 - (i) Making initial contact with potential participants in person or by letter prior to initiating any telephone contact, unless there is written documentation that the participant is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study.
 - (A) The initial contact must provide a telephone number or other means that the prospective participant can use to verify the study constitutes VA research.
 - (iii) Ensuring that all original or digitalized signed and dated informed consent documents are maintained in the researcher's research files, readily retrievable, and secure.
 - (iv) Creating or updating a VA health record and creating a progress note for all research participants (Veterans or non-Veterans) who receive research procedures or interventions as inpatients or outpatients at VA medical facilities that are either used in or may impact the medical care of the research participant at a VA medical facility or at facilities contracted by VA to provide services to Veterans (e.g., Community-Based Outpatient Clinics or community living centers). Informed consent documents are not required to be in the health record.
 - (c) ~~During the recruitment process, the researcher ensures that the research team makes initial contact with the prospective participant in person or by letter prior to initiating any telephone contact, unless there is written documentation that the participant is willing to be contacted by telephone about the study in question or a specific kind of research (e.g., if the prospective participant has diabetes, the participant may indicate a desire to be notified of any diabetes-related research studies).~~
 - (d) ~~Researchers ensure that in later contact, the research team begins telephone calls to the participant by referring to~~

~~previous contacts and, when applicable, the information provided in the consent document, and ensuring that the scope of telephone contacts with the participant is limited to topics outlined in IRB-approved protocols and consent documents.~~

Element III.1.F. Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.

(7) When following VA requirements:

- (a) Policies and procedures pertaining to Elements II.3.F., II.3.G., and II.4.B. that address specific VA requirements.

Standard III-2: Researchers and Research Staff meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.

Element III.2.B. Researchers maintain appropriate oversight of each research study, as well as Research Staff and trainees, and appropriately delegate research responsibilities and functions.

(4) When following VA requirements (VHA Directive 1200.05, Section 5):

- (i) If the principal researcher or the local site researcher does not personally obtain consent, the researcher must formally and prospectively designate to another research team member in writing in the protocol or the application for IRB approval the responsibility for obtaining consent, whether a waiver of documentation of the consent process has been approved by the IRB.
- (ii) If the researcher contracts with a firm (e.g., a survey research firm) to obtain consent from participants, collect private individually identifiable information from human participants, or be involved in activities that would institutionally engage the firm in human participants research, the firm must have its own IRB oversight of the activity.

Element III.2.D. Researchers and Research Staff follow reporting requirements in accordance with applicable laws, regulations, codes, and guidance; the organization's policies and procedures; and the IRB's or EC's requirements.

(8) When following VA requirements:

- (a) Policies and procedures pertaining to Elements I.5.D., II.2.G., II.2.H., and II.2.I. that address specific VA requirements.
- (b) VA personnel must ensure that the appropriate IRB of Record is notified, in writing, within five (5) business days after becoming aware of any apparent serious and/or continuing noncompliance

with applicable laws, regulations, policies, and agreements pertaining to non-exempt human participants research. This includes, but is not limited to, serious or continuing noncompliance with the Common Rule, local VA medical facility policies and SOPs related to human participants research, if developed, IRB-approved protocols, and the requirements or determinations of the IRB.

(c) In the event of a local research participant death, VA personnel must ensure that the appropriate IRB of Record is notified:

(i) Immediately (i.e., within one hour) upon becoming aware of any local research death of a human participant that is believed to be both unexpected and related or possibly related to participating in a VA non-exempt human participant study. VA personnel must also provide follow-up written notification to the IRB within one (1) business day.

(d) In the event of any apparent UPIRTSO, VA personnel must ensure that the appropriate IRB of Record is notified, in writing, within five (5) business days after becoming aware of any apparent UPIRTSO.

(i) Within five business days of becoming aware of any local (i.e., occurring in the reporting individual's own facility) unanticipated serious adverse event in VA research, members of the VA research community are required to ensure that the serious adverse event has been reported in writing to the IRB.

(A) This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA regulations).

(ii) The unfounded classification of a serious adverse event as "anticipated" constitutes serious non-compliance.

(iii) Researchers are required to report deviations from the protocol to the IRB in a time frame specified in local standard operating procedures.

(iii) Researchers are required to report complaints to the IRB in a time frame specified in local standard operating procedures.