



**Summary of Major Changes to Revised [VHA Handbook 1200.05](#) (November 12, 2014):  
 Requirements for the Protection of Human Subjects in Research**

<b>Topics</b>	<b>Revised Version 11/12/2014</b>	<b>Prior Version 05/02/2012</b>	<b>Summary &amp; Rationale for Significant Change in <a href="#">VHA Handbook 1200.05</a> (November 12, 2014)</b>
<b>Advertising Non-VA Research Activities in VA Facilities</b>	Paragraph 5b(5)	Paragraph 5n	<p>VA facilities may post/distribute recruiting documents, flyers, and advertisements for research that is not VA research within or on the premises of a VA Facility following review and approval. The VA Facility Director is responsible for ensuring that a procedure is in place for review and approval of these non-VA recruitment materials prior to posting or distributing.</p> <p>This ORD policy does not allow a VA Facility to use Facebook as a method of advertising non-VA studies. For additional information, please refer to ORD's guidance document on "Advertisement of Non-VA Research in VA Facilities".</p>
<b>Annual Evaluation of Human Research Protection Program (HRPP)</b>	NA	Paragraph 6c	Deleted from <a href="#">VHA Handbook 1200.05</a> . Please refer to <a href="#">VHA Handbook 1200.01</a> , Paragraph 7 for description of ACOS/R&D responsibilities for annual quality assurance reviews.

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<b>Appointment of Local Site Liaison to the VA Central IRB</b>	NA	Paragraph 8b	Deleted from <a href="#">VHA Handbook 1200.05</a> . However, this is required by VA Central IRB Standard Operating Policies (SOPs) for any VA Facility using the VA Central IRB.
<b>Certificates of Confidentiality</b>	Paragraph 21	Not present	Requirements specific to documentation were added to <a href="#">VHA Handbook 1200.05</a> . No annotation can be made in the VA subject's VHA Health Record for VA studies issued a Certificate of Confidentiality (CoC) that do not involve a medical intervention. For studies issued a CoC involving a medical intervention, ORD describes what may be placed in the progress note entry. Subjects' informed consent forms and HIPAA authorization documents cannot be included in the VA subjects' VHA Health Records for studies issued a CoC.
<b>Children</b>	Paragraph 19a	Paragraph 48a	A waiver from the Chief Research and Development Officer (CRADO) to conduct research in VA on children is no longer required. However, approval from the VA Facility Director must be obtained prior to the conduct of VA research involving children. For additional information, please refer to ORD's "Guidance on Conducting Research Involving Children".
<b>Collaborative Research</b>	Paragraph 13	Paragraph 52	Requirements have been streamlined. Collaborative research involving non-VA institutions may not be undertaken without a signed written agreement that addresses such issues as the responsibilities of each party, the ownership of the data, and the reuse of the data for other research (if applicable).
<b>Continuing Review</b>	Paragraph 8e	Paragraph 22	Requirements have been streamlined to maintain consistency with the Common Rule. For additional information, please refer to ORD's "Guidance on Continuing Review".
<b>Emergency Use of a Test Article</b>	Not present	Paragraph 41	Deleted from <a href="#">VHA Handbook 1200.05</a> . ORD has no VA-specific requirements applicable to activities involving emergency use of a test article. ORD continues to not permit planned emergency research as described in <a href="#">21 CFR 50.24</a> to be conducted as VA research.
<b>Engagement in Research/Human Subjects Research</b>	Not present	Paragraphs 50 and 51	Deleted from <a href="#">VHA Handbook 1200.05</a> .

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<b>Exempt Research</b>	Paragraph 7(a)5; Appendix A	Paragraph 16	In addition to the Institutional Review Board (IRB) Chair or an experienced voting member of the IRB, ORD now allows IRB administrators or IRB staff members who have appropriate training and experience to make exempt determinations of human subjects research activities. For additional information, please refer to ORD's "Guidance on Exempt Research Determination".
<b>HIPAA</b>			
<b>HIPAA Authorization Form for Research</b>	Paragraph 23a(1)	Paragraph 37	<p><a href="#">VA Form 10-0493: Authorization for Use &amp; Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research</a> must be used to document authorization. This form is not required to be used for studies approved prior to March 12, 2015.</p> <p>Please also note the following two VA Forms which are not currently required for use as per VA or VHA Handbooks or Directives, but are available.</p> <ul style="list-style-type: none"> <li>• <a href="#">VA Form 10-0521</a>: IRB Documentation of Waiver of HIPAA Authorization for Research is located at <a href="http://vaww.va.gov/vaforms/medical/pdf/vha-10-0521-fill.pdf">http://vaww.va.gov/vaforms/medical/pdf/vha-10-0521-fill.pdf</a>.</li> <li>• <a href="#">VA Form 10-10116</a>: Revocation of Authorization for Use &amp; Release of Individually Identifiable Health Information for VHA Research is located at <a href="http://vaww.va.gov/vaforms/medical/pdf/vha-10-10116-fil-4-11-2014.pdf">http://vaww.va.gov/vaforms/medical/pdf/vha-10-10116-fil-4-11-2014.pdf</a>.</li> </ul>
<b>Human Biological Specimens</b>	Not Present	Paragraph 53	Deleted from <a href="#">VHA Handbook 1200.05</a> .
<b>Human Data</b>	Not Present	Paragraph 54	Deleted from <a href="#">VHA Handbook 1200.05</a> . Please refer to <a href="#">VHA Handbook 1200.12</a> : Use of Data and Data Repositories in VHA Research.
<b>Informed Consent</b>			
<b>Informed Consent Document: Template</b>	Paragraph 16a	Paragraph 33a	Use of <a href="#">VA Form 10-1086</a> to document consent is optional; it is no longer required by ORD. The VA written consent document must include all required elements and additional elements as approved by the IRB.

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<b>Informed Consent Document: Required Signatures</b>	Paragraph 16e(2)(b)	Paragraph 33c	The IRB can waive the signature of the individual obtaining consent on the IRB-approved consent form if no physical contact with the subject will occur.
<b>Informed Consent Document: Documenting Date of IRB Approval</b>	Paragraph 16e(1)	Paragraph 33a(2)	The IRB approval date of the written consent form must be documented on the consent form. Stamping each page of the written consent document is no longer required.
<b>Informed Consent Document: Electronic document</b>	Paragraph 16e(2)(c )	Paragraph 33a	<p>Electronic consent must meet all VHA requirements for documentation of consent, applicable VA requirements, and the identity of the subject and the date the form was signed must be able to be authenticated.</p> <p>In addition, <a href="#">VHA Handbook 1004.05: iMedConsent™</a> requires specific authorization from ORD before iMedConsent™ can be used in VA research; ORD has not given specific authorization to utilize iMedConsent™ in VA research. ORD and other VA and VHA Central Program Offices are working to coordinate issues related to implementing iMedConsent™ across VA Facilities for VA research.</p> <p>Individual VA Facilities cannot contact the iMedConsent™ vendor to implement use.</p>
<b>Informed Consent Document: VA Specific Elements</b>	Paragraph 15c	Paragraph 32b	Numerous VA-specific items are no longer required to be included in the informed consent form.
<b>Informed Consent Document: Consent for Photographs, Audio recordings, or Video recordings</b>	Paragraph 16f	Paragraph 55b	<p>Use of <a href="#">VA Form 10-3203: Consent for Production and Use of Verbal or Written Statements, Photographs, Digital Images, and/or Video or Audio Recordings by VA</a> is no longer required. However, informed consent to take a photograph, video, and/or audio recording cannot be waived by the IRB, and <a href="#">VHA Handbook 1200.05</a> describes what information must be given to prospective subjects.</p> <p>Please note that the consent for research does not give legal authority to disclose the photographs, video, and/or audio recordings outside of VA. All VA subjects must be provided during informed consent information describing any photographs, video, and/or audio recordings that will be taken or obtained for research purposes.</p>

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<b>International Research</b>			
<b>Access to Remote Data on VA Servers</b>	Paragraph 26a(1)	Paragraph 56a	Remote use of data maintained on VA computers within the US or Puerto Rico and accessed via a secure connection is not considered International Research.
<b>Facility Director Approval</b>	Paragraph 26c	Paragraph 56c	With the exception of Cooperative Studies Program activities, a waiver from the CRADO is no longer required to conduct international research. Approval from the Facility Director is required for any other VA research activity meeting the definition of international research activities according to <a href="#">VHA Handbook 1200.05</a> . For additional information on this topic, please refer to ORD's "Guidance on Approval of International Research".
<b>Investigator Responsibilities</b>			
<b>Subject Outreach</b>	Not present	Paragraph 5m	Investigators are no longer required by ORD to distribute the subject outreach brochure, "Volunteering in research - Here are some things you need to know".
<b>Notice of Privacy Practices</b>	Paragraph 24f	Not present	Investigators must follow <a href="#">VHA Handbook 1605.04</a> : Notice of Privacy Practices, to provide notice of privacy practices and acknowledgement for non-Veterans participating in approved VA research activities. Please refer to <a href="#">VHA Handbook 1605.04</a> for specific requirements.
<b>Master List of Subjects</b>	Not present	Paragraph 9i(1)(h)	Investigators are no longer required by ORD to maintain a master list of subjects enrolled in their research studies.
<b>Flagging Health Records</b>	Not present	Paragraph 44	Investigators are no longer required by ORD to flag VHA health records of subjects enrolled in VA research. It is a local HRPP decision as to whether or not they wish to require flagging of VA research studies.

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<b>Human Subjects Training</b>	Paragraph 29a(4)	Paragraph 61a	Individuals involved in the conduct of human subjects research are required to complete training on ethical principles in which human subjects training is to be conducted. ORD has removed training requirements for completion of good clinical practices (GCP) training. Specific information on training requirements can be found at the following ORD website: <a href="http://www.research.va.gov/pride/training/default.cfm">http://www.research.va.gov/pride/training/default.cfm</a> .
<b>Scope of Practice/Functional Statements</b>	Not present	Paragraph 62c	Deleted from <a href="#">VHA Handbook 1200.05</a> , but remains an ORD requirement described in <a href="#">VHA Directive 1200</a> . Please refer to <a href="#">VHA Directive 1200</a> , Paragraph 4(c)(9)(a) for information regarding scopes of practice, functional statements, or other described alternatives.
<b>IRB Functions and Operations</b>			
<b>Communication with Investigators</b>	Paragraph 8d	Paragraph 25a(1)	ORD has removed the requirement that specific types of IRB communication (e.g., initial IRB approval) to the investigator be signed by the Chair or the voting IRB member who reviewed the research has been removed. However, please note that when the IRB approves a waiver of documentation, the signature of the Chair or the IRB, or a qualified voting member of the IRB designated by the Chair, must be present on the HIPAA authorization waiver document.
<b>IRB Audits</b>	Not present	Paragraph 29	This topic has been deleted from <a href="#">VHA Handbook 1200.05</a> .
<b>IRB Meeting Minutes: Drafts</b>	Paragraph 7(c)	Paragraph 28	ORD has removed the requirement that draft IRB meeting minutes be completed in three weeks. ORD emphasizes that the IRB meeting minutes should be completed in a timely manner for the R&D Committee review.
<b>IRB Meeting Minutes: Signature</b>	Paragraph 7(c)	Paragraph 28	ORD has removed the requirement that the IRB Chair sign the final IRB meeting minutes.
<b>IRB Meeting Minutes: VA Specifics</b>	Paragraph 7(c)	Paragraph 28	ORD has removed numerous VA-specific IRB minute requirements to harmonize VA with Common Rule requirements.

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<b>IRB of Record</b>	Paragraph 5d(1)	Paragraph 5e	<p>In addition to using a VA facility's own IRB, the IRB of another VA facility, the VA Central IRB, or the IRB of its affiliated medical or dental school, a VA Facility can now also designate an IRB of another Federal Agency as its IRB of record. Approval from the CRADO is required if a VA facility is changing its IRB of record.</p> <p>Please note that other approvals (e.g., ORO) are also required for changes in a VA Facility's IRB of Record.</p>
<b>IRB Membership</b>			
<b>Appointment of VA members to Another Organization's IRB: Number</b>	Paragraph 5d(2)(b)	Paragraph 7c	With the exception of the VA Central IRB and a Central IRB of another federal agency, research programs with 10 or more protocols must appoint two voting members to an external IRB. Research programs with less than 10 protocols can appointment one voting member and one alternate voting member.
<b>Appointment of VA Members to Another Organization's IRB: Requirements of Members</b>	Paragraph 5d(2)(b)	Paragraph 7c	Voting members appointed to another VA Facility's IRB or academic affiliate's IRB must have at least 1/8th VA appointments. These VA members are no longer required to be scientific voting members.
<b>Membership Tenure for IRB Chairs</b>	Paragraph 6n(2)	Paragraph 12q(2)	Appointment term for IRB Chairs has been increased to up to three years, renewable indefinitely.
<b>ISO/PO Review</b>	Paragraph 22e	Paragraph 38g	Information Security Office and Privacy Officer final review is required only after IRB approval. There is now flexibility as to whether these individuals serve on the IRB or are advisory to the IRB as non-voting members or consultants.
<b>Neonates</b>	Paragraph 17c	Paragraph 45c(2)	Observational and/or retrospective studies involving neonates are now allowed. Interventional studies on neonates continue to be prohibited in VA research. The VA Facility Director must approve the participation of neonates (children) in the proposed VA research activity.

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<b>Non-VA Firms Engaged in Research</b>	Paragraph 29f(1)(a)	Not present	If an investigator contracts with a firm which is engaged in human subjects research activities, the firm must have its own IRB oversight of the activity. In addition, the Privacy Officer must determine that there is appropriate authority to allow disclosure of protected health information to firms wishing to obtain consent from subjects or collect PII from subjects.
<b>Payment to Subjects</b>	Not present	Paragraph 59	Deleted from <a href="#">VHA Handbook 1200.05</a> .
<b>Pregnant Women</b>	Paragraph 17d(4)	Paragraph 46	Women known to be pregnant may be enrolled in research if all the requirements outlined in <a href="#">45 CFR 46.204</a> are met. Additionally, the Facility Director must certify that the facility has sufficient expertise in women's health to conduct the proposed research if pregnant women are enrolled. For additional information on this topic, please refer to ORD's "Guidance on Conducting Research involving Pregnant Women".
<b>Prisoners</b>	Paragraph 18a	Paragraph 47b	A waiver from the CRADO continues to be required prior to enrolling prisoners in VA-approved research.
<b>Serious Adverse Events (SAEs)</b>	NA	Paragraph 42	Deleted from <a href="#">VHA Handbook 1200.05</a> .
<b>Stem Cells</b>	Paragraphs 17b and 17d(4)	Not present	Embryonic stem cells can be used in VA research as governed <a href="#">by the National Institutes of Health's (NIH's) policies</a> .
<b>Student Research</b>	Paragraph 28a	Paragraph 63a	Trainees may not serve as Principal Investigator (PI)/Co-PI on VA research studies but can serve as Investigators of VA-approved research (e.g., VA Advanced Fellows). In addition to those with an educational affiliate agreement with their VA facility, trainees directly appointed to a VA training program that has no external institutional sponsorship can serve as investigators on VA-approved research (e.g. VA Advanced Fellows).

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<b>Women of Child-bearing Potential: Use of FDA Pregnancy Category D or X Drugs</b>	Not present	Paragraph 46	A waiver from the CRADO for use of category D or X drugs in women of child-bearing potential is no longer required.

**Note:** This worksheet is not an all-inclusive list and does not replace Office of Research and Development policy requirements in [VHA Handbook 1200.05 \(November 12, 2014\)](#).