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OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

Summary of Significant Changes to VHA Directive 1200.05
Requirements for the Protection of Human Subjects in Research

Summary of changes: Harmonization with the revised Common Rule and elimination of most VA-specific requirements that are not based on existing policies or regulations.

Topics *(listed alphabetically)*	**Paragraph in 1200.05**		**Summary & Rationale for Significant Changes in VHA Directive 1200.05**
	Version 11-12-2014	**Version 1-7-2019**	
Accreditation of Human Research Protection Programs	27	NA	Requirements have been deleted from Directive.
Applicability of 2018 Requirements	NA	6	Describes when a research project will be subject to the pre-2018 Requirements and when a research project will be subject to the 2018 Requirements.
Assuring Compliance with this Policy	5	5f	Majority of contents are now listed under VA Medical Facility Director Responsibilities.
Background	2	2	Revised to incorporate reference to the 2018 Requirements.
Certificates of Confidentiality	21	22	1. Revised to be consistent with new requirements and protections for Certificates of Confidentiality that became effective with the passing of the 21st Century Cures Act. 2. VA Investigators are no longer prohibited from placing Informed Consent Forms in the Medical Records of Research Subjects participating in studies that have been issued a Certificate of Confidentiality (CoC). 3. Includes requirement if information about the subject's participation will be included as part of the subject's VHA medical record that information must be given to the prospective subject as part of the informed consent process that information regarding study participation will be included in the medical record. 4. In instances where a written informed consent form is used, inclusion of a statement that the study has been issued a CoC is required.

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Collaborative Research	13	15	1. Removal of redundancies regarding written HIPAA authorizations. (reduction of information about HIPAA authorization). 2. Adds requirements that protocol, addendum, and/or IRB application must describe how transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom.
Definitions	4	3	1. The following definitions have been revised to be in line with the Revised Common Rule: Human Subject, Intervention, Legally Authorized Representative, and Research. 2. The following definitions have been removed from the Directive: Accreditation, In Vitro Fertilization, Multi-site Research, and Serious Adverse Events. 3. The following definitions are new to the Directive: Clinical Trial, Federalwide Assurance, Identifiable Private Information, Identifiable Biospecimens, Sub-Investigator, Signatory Official, Program Office Employee, and Program Office. 4. The following definitions have undergone minor revisions: Adverse Event, Assurance, Certificate of Confidentiality, Children, Clinical Investigation, De-identified Information, Collaborative Research, Fetus, Human Research Protection Program, Institutional Official, Institutional Review Board, Intervention, Investigator, VA Investigator, Nonprofit Research and Education Corporations, Pregnancy; Private Information, , Research Records, Research and Development Committee, Research Protocol, and VA Research.
Exempt Review	3.d	10	1. Addition of new exempt categories for research subject to the 2018 Requirements (see Appendix B in the Directive). 2. Requires information to be given orally or in writing for exempt research activities involving interacting or obtaining information by education tests, survey or interview procedures, or behavioral interventions. 3. Inclusion of limited IRB review requirements for specific exempt categories. 4. Requires that exempt determinations are made by the IRB Chair, an experienced IRB member, or qualified administrative staff with expertise in applying human research exempt determinations.

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Expedited Review	9	11	1. Expedited review categories remain unchanged. 2. For research subject to the 2018 Requirements, expedited review requirements have been updated to be consistent with the Revised Common Rule. a. Activities found on the expedited review list are presumed to be no greater than minimal risk, and as such should be reviewed by expedited review. b. Justification is required if the IRB deems a research activity found on the expedited review list greater than minimal risk. c. Limited IRB review can be conducted by expedited review.
Informed Consent			Significant revisions related to the 2018 Requirements.
General requirements	15.a	17.b	For research subject to the 2018 Requirements, 1. the prospective subject or the LAR must be provided with the information that a reasonable person would want to have to make an informed decision about whether to participate, and an opportunity to discuss that information; 2. informed consent must begin with a concise and focused presentation of key information about the research study; and 3. informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.

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Elements of Informed Consent	15.b-d	17.d-e	1. For research subject to the 2018 Requirements, a new basic element of informed consent has been added: a. For all studies that involve the collection of identifiable private information or identifiable biospecimens, inclusion of a statement on whether specimens if subsequently de-identified will be used for future research or not. 2. For research subject to the 2018 Requirements, three new additional elements of informed consent have been added: a. Inclusion of a statement whether specimens may be used for commercial profit and if subject will share in the profit b. Inclusion of a statement whether clinically relevant research results will be disclosed to subjects and if so under what conditions c. Inclusion of a statement whether research might include whole genome sequencing 3. The following required VA-specific elements of informed consent have been eliminated: a. Any payments the subject is to receive for participating in the study b. Any real or apparent conflict of interest by investigators where the research will be performed

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Broad Consent	NA	17.f	1. For research subject to the 2018 Requirements, Broad Consent specific to storage, maintenance, and secondary use of identifiable information or identifiable biospecimens can only be obtained when data or biospecimens are collected solely for research purposes. a. Specific elements of Broad Consent are provided and cannot be waived or altered by the IRB. b. An IRB cannot subsequently waive consent for the storage, maintenance, or secondary use of identifiable information or identifiable biospecimens if a subject has refused to agree to Broad Consent. 2. If obtained, Broad Consent must be documented (an IRB cannot approve waiver of documentation of broad consent for VA-approved research). 3. The Broad Consent form can be either a separate consent form or combined with a study-specific informed consent form. a. If combined, the information provided to subjects for Broad Consent must be clearly discernable from the study-specific consent form.
Documentation of Informed Consent	16	18	1. VA-specific requirement to obtain the signature of the individual obtaining consent has been eliminated. a. IRB waiver of the signature of the individual obtaining consent in instances where no physical contact with subjects occurs has been deleted because of the above. 2. Waiver of documentation of informed consent requirements have been updated to be consistent with requirements in the revised Common Rule, specifically: a. For research subject to the 2018 Requirements, inclusion of an additional option for waiving documentation of informed consent for subjects who are members of a distinct cultural group or community in which signing forms is not the norm.

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Waiver of informed consent	15.e	17.g-h	For research subject to the 2018 Requirements, the following additional requirement has been added for waivers of informed consent for minimal risk research: 1. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

Alteration of informed consent	15.e	17.g(3)
		17.h(3)
			IRBs cannot approve a consent procedure that omits/alters any of the general requirements of informed consent found in 38 CFR 16.116(a). Specifically, the consent process must ensure the following:
			• Legally effective informed consent is obtained under circumstances that
			  • provide the subject/LAR sufficient opportunity to decide whether to participate;
			  • minimize coercion/undue influence and
			  • does not include any exculpatory language through which the subject/LAR is made to waive/appear to waive their rights or releases/appears to release the investigator, sponsor, institution or its agents from liability for negligence
			• Information is provided to subjects/LARs in a language they can understand
			• Sufficient information is provided to allow them to make an informed decision
			• A short summary of key information related to participation in the study is provided upfront as part of the consent process

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Screening, recruiting, or determining eligibility	NA	17.i	1. For research subject to the 2018 Requirements, an IRB can approve the use of identifiable information or identifiable biospecimens without the subject's informed consent for the purpose of screening, recruiting, or determining eligibility of prospective subjects provided specific requirements are met. *Note – a waiver of HIPAA for recruitment/screening purposes continues to be required in such cases.*
Photography, Video, and/or Audio Recording for Research Purposes	16.f	17.k	Requirements remain unchanged.
Posting clinical trial consent forms	NA	5.g(20)	1. One IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department conducting the clinical trial on a publicly available Federal website after the last study visit by any subject and no later than 60 days after the last study visit by any subject. 2. Consent forms must be posted on either https://clinicaltrials.gov or a docket folder on http://Regulations.gov (Docket ID: HHS-OPHS-2018-0021). 3. Information on who is responsible for posting the consent form has been included in the Directive.
HIPAA Authorization	23	23	Major revision on removing restriction against combining an informed consent form with a written HIPAA authorization.
Written Authorization	23.a	23.a	The restriction on combining informed consent forms with HIPAA Authorizations Forms has been eliminated. However, VA Form 10-0493 continues to be required if a standalone HIPAA Authorization Form is used.
Waiver of HIPAA Authorization	23.b	23.b	Clarifies that PHI obtained in research for which the IRB of Record or Privacy Board has waived the requirements to obtain a HIPAA authorization may not be disclosed outside VA unless the VA facility PO ensures and documents VA's authority to disclose the PHI to another institution. A waiver of HIPAA authorization by itself is not sufficient to fulfill the requirements of other applicable privacy regulations and statutes such as the Privacy Act of 1974 (5 U.S.C. 552a).

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Preparatory to Research Activities	23.c	23.c	No changes.
International Research	26	25	No changes.
IRB Approval	10	12	1. Updated to be consistent with the approval criteria included in the revised Common Rule, to include limited IRB review and Broad Consent. 2. The requirement that IRBs specifically document the justification of inclusion of non-veterans in research and use of SSNs as part of the approval criteria has been eliminated. ORD plans to move this to an institutional responsibility for the VA R&D Committee in the revised proposed VHA Directive 1200.01. 3. The requirement that the IRB ensure that mechanisms are implemented to manage, reduce, or eliminate Conflicts of Interests (COIs) has been eliminated. This was done because IRBs were being placed in a position of evaluating financial conflict of interest forms, and that is not the role of the IRB nor the original intent of ORD's prior national policy. However, IRBs are responsible for evaluating whether risks to subjects are minimized, risks to subjects are reasonable in relation to anticipated benefits, if any to subjects, selection of subjects is equitable, and ensuring that the possibility of coercion or undue influence is minimized. In addition, the IRB may require that additional information be given to subjects when in the IRB's judgement the information would meaningfully add to the protection of human subjects (38 CFR 16.109(b)). Investigators are required to disclose to the IRB any potential, actual, apparent, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research, and comply with all applicable VA and other Federal requirements regarding conflict of interest (Paragraph 5.g.7). 4. The VA-specific IRB approval criteria pertaining to relevance of the research to the mission of the VA and Veteran population has been eliminated. *Note, Investigators are still required to submit protocols that have relevance to the Veteran population.*

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IRB Functions and Operations	7	8	For multisite studies, an IRB of a non-affiliated medical or dental school can serve as the IRB of Record for a VA facility if that IRB has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facilities.
IRB Membership	6	7	The requirement that a VA Facility Director must appoint VA staff as voting members to an external IRB or another VA Facility that serves as the IRB of Record for a VA facility has been eliminated.
IRB Records	14	16	For research subject to the 2018 Requirements, the IRB must document the following: 1. Justification for conducting continuing review of research that does not require continuing review by the IRB 2. Justification when the IRB determines that research appearing on the expedited review list is greater than minimal risk.
IRB Review of Research	8	9	For research subject to the 2018 Requirements, the following have been added: 1. Limited IRB review for certain exemptions. 2. Elimination of continuing review for certain categories of research: a. Research eligible for expedited review b. Research reviewed by limited IRB Review (certain exempt research) c. Research that has progressed to the point that it involves only one or both of the following: i. Data analysis, inclusive of analysis of identifiable private information or identifiable specimens, and/or ii. Access to follow-up clinical data obtained from procedures that subjects undergo as part of clinical care 3. The IRB must document their justification for conducting continuing review of non-exempt human subject's research that does not require continuing review. *Note – the R&D Committee is not required to conduct continuing review of such research as it is still under the oversight of the IRB.* The IRB must also keep documentation specifying the responsibilities that the VA facility and an organization operating as the VA facility's IRB of Record each have, such as a Memorandum of Understanding or an IRB Reliance Agreement.

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Participation of Non-Veterans as Research Subjects	24	NA	This paragraph has been eliminated from the Directive.
Privacy Officer and Information Security Officer Duties	22	NA	This paragraph has been eliminated from the Directive, however, Privacy Officers and Information Security Officers continue to serve in an advisory capacity to the facility's IRB as either non-voting members or as consultants (Paragraph 7.i.).
Purpose	1	1	Stipulates that the Directive will become effective on January 21, 2019.
Records Management	NA	27	New addition to the Directive. States that records created because of this Directive must be managed per the VHA Record Control Schedule (RCS) 10-1.
Research Involving Children as Research Subjects	19	21	1. No significant changes in VA policy regarding research involving children. 2. Clarification added that research involving children does not include neonates. 3. Research involving neonates must follow ORD's requirements for research involving neonates as described in VHA Directive 1200.05, Paragraph 19.
Research Involving Pregnant Women, Human Fetuses, and Neonates as Subjects	17	19	1. VA Medical Facility Director certification required for: a. Interventional studies or invasive monitoring of pregnant women as subjects, and b. Neonatal research. 2. Research that involves provision of *in vitro* fertilization services can be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities. 3. Research in which the focus is either a fetus, either in-utero or ex-utero, can be conducted by VA investigators 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.

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Research Involving Prisoners as Subjects	18	20	1. Instructions for obtaining a waiver from CRADO for research involving prisoners have been added. 2. Exempt research that is subject to the 2018 Requirements can involve prisoners if the research is aimed at involving a broader subject population that only incidentally includes prisoners.
Responsibilities	NA	5	
VA Investigators	29	5.g	The following new responsibilities have been added: 1. VHA Program Office Employees serving as investigators must prospectively document their research with their supervisor in writing; 2. Submitting exempt protocols that require limited IRB review to the IRB for limited IRB review/approval; and 3. For clinical trials, posting a copy of the informed consent form used to enroll subjects after the clinical trial has closed to recruitment and no later than 60 days after the last study visit by any subject as described in the IRB-approved protocol.
VA Medical Facility Director	5.b	5.f	1. The requirement to appoint VA-compensated staff to serve as voting members of external IRBs of record or other VA Facilities' IRBs used by the VA facility has been removed in its entirety. 2. The VA Medical Facility Director must ensure that a documented procedure is in place for determining when a research activity approved by the IRB prior to January 21, 2019, can transition to the 2018 Requirements. 3. For Multi-site studies, a facility may also use an IRB from a non-affiliated medical or dental school that has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facility. 4. Ensuring that external IRBs of Records that the facility relies on hold current IRB registrations with FDA/OHRP. 5. Requesting CRADO approval if the facility wants its internal IRB to serve as an IRB of Record for a non-VA entity.
Review by Institution	11	13	Clarification that research cannot be initiated until the Investigator receives written notification from the ACOS/R&D.

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Scope	3	2 and 4	Requirements have been Incorporated into paragraphs titled, "Background" and "Policy"
Student and Other Trainee Research	28	NA	This paragraph has been eliminated from VHA Directive 1200.05. However, the requirements for conducting student and trainee research have not changed and can be found in Paragraph 10 of VHA Directive 1200.02, "Research Business Operations".
Subjects Lacking Decision-Making Capacity	20	NA	This paragraph has been eliminated from this Directive. IRB's continue to be required to take into consideration any additional protections that are required when involving subjects lacking decision-making capacity in research when determining if the following two IRB approval criteria are met: "selection of subjects is equitable" and "risks to subjects are reasonable in relation to anticipated benefits".
Suspension or Termination of IRB Approval	12	14	Clarification added that ORD can suspend or terminate research it funds.
Training Requirements	29.a	26 and 5.g	This topic has been divided in the new Directive. "Research training requirements" can be found in paragraph 26 and "Credentialing and Privileging requirements" for researchers and staff can be found in Paragraph 5.g., VA Investigator Responsibilities.
Treatment of Research-Related Injuries	25	24	Requirements remain unchanged.

This worksheet is not an all-inclusive list and does not replace VHA Office of Research and Development policy requirements in VHA Directive 1200.05.