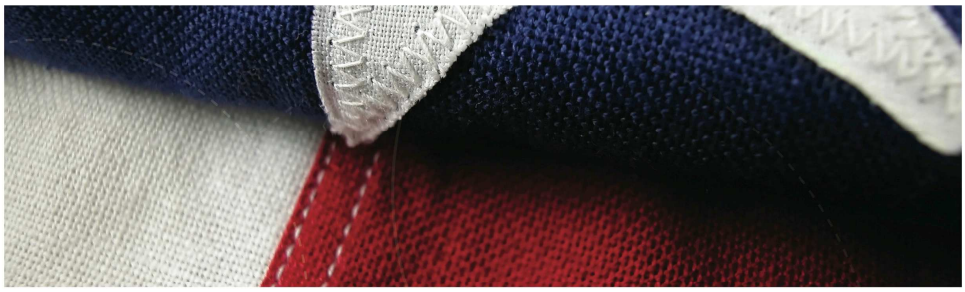

The Revised Common Rule, Proposed VHA Directive 1200.05, and the IRB

Focus on Significant Changes

Dial in: 1 (562) 247-8321
Access Code: 1 (417) 425-757
Slides in "Handout" Tab

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November 29, 2018

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

VA PRIDE Program for Research Integrity Development & Education

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Overview

Dial in: 1 (562) 247-8321
Access Code: 1 (417) 425-757
Slides in "Handout" Tab

- Provide a Status Update on the Revised Common Rule and VHA Directive 1200.05
- VA Research on January 21, 2019
- Significant changes in the Revised Rule, Proposed VHA Directive 1200.05 and its effect on the IRB
  - IRB Operations
  - IRB Review
  - ISO/PO Review
  - Informed Consent and HIPAA
  - Continuing Review

VA PRIDE Program for Research Integrity Development & Education 2

Dial in: 1 (562) 247-8321
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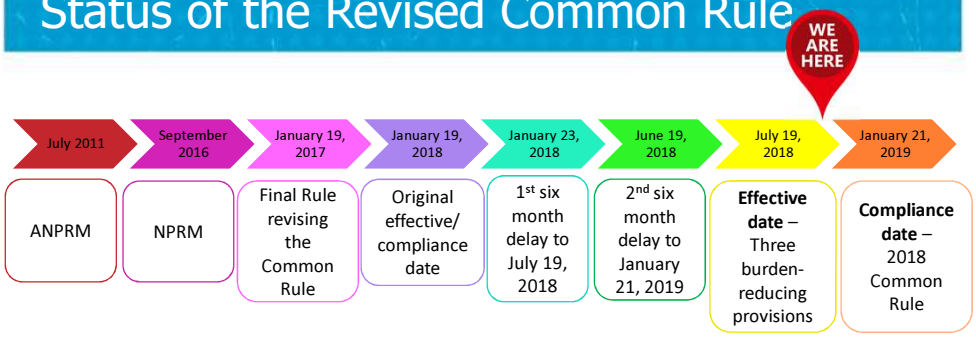
Status of the Revised Common Rule



Cooperative research provision (single IRB) – compliance date remains January 20, 2020.

VA PRIDE Program for Research Integrity Development & Education 3

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Status of VHA Handbook 1200.05

- Will be issued as VHA Directive 1200.05
- ORD's goal is to harmonize as much as possible VA's implementation of the revised Common Rule with other Federal Agencies and Departments, but there will be some VA specific requirements.
- Incorporates VHA Directive 1058.06, "Research Conducted by Employees of VHA Program Offices"
- Directive 1200.05 is in the final stages of concurrence
  - All Program Offices have concurred
  - Currently with VHA Office of General Counsel
  - Office of Labor Management Relations (Union) is final step in the review process once OGC concurs

VA PRIDE Program for Research Integrity Development & Education 4

Case Study 1: January 21, 2019

On January 21, 2019 the following studies must be in compliance with the 2018 Requirements: (select the most appropriate statement)

A. All existing IRB studies

B. Studies approved on/after 1/21/19

C. Studies approved from 7/19/18 - 1/20/19 without IRB review of the grant

D. Both B and C

E. All of the Above

VA PRIDE Program for Research Integrity Development & Education 5

VA Research on/after January 21, 2019

- **New studies approved or deemed exempt on or after January 21, 2019**: Must meet all of the 2018 Requirements (with the exception of the Cooperative Research provisions which go into effect on January 20, 2020).
- **Research approved or deemed exempt from IRB review prior to January 21, 2019**: Must be in compliance with the current Common Rule requirements ("the pre-2018 requirements") unless the study is transitioned to the 2018 requirements and the IRB documents this decision.
- **Research that utilized one of the eligible burden-reducing provisions during the transition period and thus were designated for transition**: Must comply with all of the 2018 Requirements (with the exception of the Cooperative Research Provisions) on January 21, 2019.

➡ **IRBs will be operating under both the 2018 and pre-2018 requirements for the foreseeable future**

VA PRIDE Program for Research Integrity Development & Education

VA Research on/after January 21, 2019

	IRB Approval/Determination on/after 1/21/19 and studies transitioned to 2018 Requirements	IRB Approval/Determination prior to 1/21/19
Exempt Determinations	Must fall into one or more of the Exempt Categories specified in the 2018 Requirements	Review amendments to ensure study activities still fall within the pre-2018 Exempt categories
Non-exempt Approvals	Must meet all 2018 Requirements	Must be in compliance with pre-2018 Requirements. Can incorporate 2018 Requirements that do not conflict with pre-2018 Requirements.
Study-Specific Informed Consent	Must meet all 2018 requirements	Can either continue to adhere to pre-2018 elements of informed consent or amend ICF to incorporate elements of informed consent in the 2018 requirements (as long as no conflict exists)
Broad Consent	Must meet all 2018 requirements and VHA Directive 1200.05 limitations	Not permissable
Informed Consent Waivers	Must meet waiver criteria in 2018 Requirements	Continue to meet pre-2018 criteria
HIPAA Authorization Form	Not impacted by Common Rule. Must meet requirements outlined in VHA Directive 1200.05	Can continue to use HIPAA form existing at the time the study was originally approved

VA PRIDE Program for Research Integrity Development & Education

Case Study 2: Part 1

A new study is undergoing expedited review using forms that incorporate the 2018 Requirements (none of which conflict with the pre-2018 requirements). Comments are sent to the PI on December 15, 2018 and revised documents are received three weeks later. On January 10, 2019, the expedited reviewer reviews the documents received and acknowledges that all issues have been addressed and the study can be approved. The expedited reviewer can (select the correct scenario (one answer only):

The expedited reviewer can

A. Approve the study on 1/10/19. Study is subject to 2018 requirements

B. Approve the study on 1/10/19. Study is subject to pre-2018 Requirement

C. Approve the study on 1/21/19. Study is subject to the 2018 Requirements

D. Either A, B, or C

E. Either B or C

VA PRIDE Program for Research Integrity Development & Education

Case Study 2: Part 2

The reviewer approves the study on 1/10/19. On 1/21/19, the approved study must now follow the 2018 Requirements.

- True
- False

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Case Study 2: Part 3

On 1/21/19 the investigator and IRB may negotiate to transition the study to the 2018 requirements?

- True
- False

Case Study 3

The IRB reviews a protocol and consent form compliant with the pre-2018 common rule requirements on 30 Dec 2018 and approves it with stipulated conditions (conditional approval). The investigator completes all of the required stipulations and the assigned IRB reviewer marks them complete on 22 Jan 2019.

Which set of requirements must the study comply with?

A. Pre-2018 Requirements

B. 2018 Requirements

C. Need more information

VA PRIDE Program for Research Integrity Development & Education

Revised Common Rule/2018 Requirements and Proposed Changes in VHA Directive 1200.05: Significant Changes

VA PRIDE Program for Research Integrity Development & Education 12

IRB Membership, Functions, and Review of Research

VA PRIDE Program for Research Integrity Development & Education 13

IRBs of Record

CURRENT VHA Handbook 1200.05	PROPOSED VHA Directive 1200.05
The facility's IRB(s) of Record may include the facility's own IRB(s), the VHA Central Office IRB (VA Central IRB), an IRB of another VA facility, the IRB's of its affiliated medical or dental school, or an IRB of another federal agency **VHA Handbook 1200.05, Paragraph 5(d)(1)**	The facility's IRB(s) of Record may include the facility's own IRB(s), VHA Central Office IRB (VA Central IRB), an IRB of another VA facility, the IRB(s) of an affiliated medical or dental school, or the IRB of another federal agency. A facility may also use for multi-site protocols an IRB from a non-affiliated medical or dental school if that IRB has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facilities.

VA PRIDE Program for Research Integrity Development & Education

IRB Membership

CURRENT VHA Handbook 1200.05	PROPOSED VHA Directive 1200.05
Ensuring that at least two VA-compensated (minimum 1/8th full-time employee equivalent) staff from the facility are appointed as voting members to each IRB of Record except for the VA Central IRB (see VA Central IRB Standard Operating Procedures (SOP)) or a central IRB of another federal agency (e.g., National Cancer Institute Central IRB). A small VA facility with fewer than ten active protocols is only required to appoint one voting member and one alternate voting member to ensure consistent representation. **VHA Handbook 1200.05, Paragraph 5(d)(2)(b)**	Eliminated

VA PRIDE Program for Research Integrity Development & Education

IRB Functions and Operations

Revised Common Rule

- No material changes in 2018 requirements.
- Majority of items specific to how an IRB operates have been moved from section 103(b)2-5 in the pre-2018 Requirements to section 108(a) in the 2018 Requirements, e.g.:
  - Maintenance of IRB membership rosters;
  - Adequate meeting space and staff to support IRB reviews and record keeping
  - Policies and Procedures to conduct initial and continuing review, changes in research, UAP reporting, and suspensions and terminations

PROPOSED VHA Directive 1200.05

- VHA Directive 1200.05 requirements are aligned with the Revised Common Rule

VA PRIDE Program for Research Integrity Development & Education 16

IRB Records

Revised Common Rule

- Justification required when continuing review is conducted on research no longer requiring continuing review
- Justification required when research appearing on the expedited review list is deemed more than minimal risk

38 CFR 16.115(a)(3)(8)

PROPOSED VHA Directive 1200.05

VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements

VA PRIDE Program for Research Integrity Development & Education

Exempt Research

VA PRIDE Program for Research Integrity Development & Education

Exempt Review

Revised Common Rule

- 2018 Requirements have 8 Exempt Categories
- Exempt Category 6 (Food Quality Studies) is the only category that remains unchanged
- Exempt Categories 2 and 4 likely to be used frequently in VA research
- Current Exempt Category 3 has been deleted (educational tests, surveys, interviews or observation of public behavior involving elected or appointed officials) and replaced with a new Exempt Category 3 that focuses on "benign behavioral interventions"
- Exempt Categories 7 and 8 are new and specific to secondary use or storage if Broad consent was obtained

38 CFR 16.104

PROPOSED VHA Directive 1200.05

VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements

VA PRIDE Program for Research Integrity Development & Education

IRB Review of Research

IRB Approval Criteria

Revised Common Rule

- Revised Common Rule includes a new approval criteria specific to limited IRB review for certain types of activities eligible for exemption (38 CFR 111(a)(8))

Limited IRB Review requirements:

- IRB does not have to ensure that all of the 111 approval criteria are met
- For Exemptions 2(iii) and 3(i)(c) – IRB must ensure that adequate provisions exist to protect the privacy of subjects and maintain the confidentiality of their data
- For Exemption 7: that Broad consent was obtained; broad consent was appropriately documented or waived; and if a change is made for research purposes in the way the identifiable information or specimens are stored, adequate provisions to protect the privacy of subjects and maintain the confidentiality of their data exist.
- For Exemption 8: IRB must ensure that adequate provisions exist to protect the privacy of subjects and maintain the confidentiality of their data and that the proposed research is within the scope of the broad consent

PROPOSED VHA Directive 1200.05

VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements

VA PRIDE Program for Research Integrity Development & Education 21

IRB Approval Criteria: VA Specific Requirements

CURRENT VHA Handbook 1200.05	PROPOSED VHA Directive 1200.05
• The IRB must ensure that mechanisms are implemented to manage, reduce, or eliminate potential, actual, or perceived conflicts of interest related to all aspects of the research, including financial interests, clinical roles (for example, investigator-patient relationships), and other professional or personal roles. (**VHA Handbook 1200.05, Paragraph 10c(3))**	• No longer included as a specific approval criteria, however investigators are still required to inform the IRB of any conflicts of interests.
• Relevance of the research to the mission of VA and the Veteran population that it serves must be considered by the IRB. If non-Veterans will be included, the protocol and related materials must justify the inclusion of non-Veterans. **(VHA Handbook 1200.05, Paragraph 10c(2))**	• No longer a VA-specific approval criteria, however investigator submitted protocol must continue to include this information.

VA PRIDE Program for Research Integrity Development & Education

Privacy Officer/ISO Review

CURRENT VHA Handbook 1200.05

Privacy and confidentiality provisions must take into consideration the requirements of Standards for Privacy of Individually-Identifiable Health Information (HIPAA Privacy Rule), 45 CFR Parts 160 and 164, and other laws regarding protection and use of Veterans' and others information, including the Privacy Act of 1974, 5 U.S.C. 552a; VA Claims Confidentiality Statute, 38 U.S.C. 5701; Confidentiality of Drug Abuse, Alcoholism and Alcohol Abuse, Infection with Human Immunodeficiency Virus (HIV), and Sickle Cell Anemia Medical Records, 38 U.S.C. 7332; and Confidentiality of Healthcare Quality Assurance Review Records, 38 U.S.C. 5705 (see VHA Handbook 1605.1)

VHA Handbook 1200.05, Paragraph 10c(1)

PROPOSED VHA Directive 1200.05

- VA-specific approval requirements has been eliminated.
- POs/IOs continue to serve as advisors to the IRB as either non-voting members or as consultants.
- POs must determine that appropriate authority exists to allow disclosure of individual names and other information to firms an Investigator contracts with to conduct research activities involving human subjects and their identifiable information.

IRB Review of Research: Expedited Review

Revised Common Rule

- Research on the Secretary's list is presumed to be minimal risk
- Justification is required if the IRB deems a study involving only activities found on the list to be greater than minimal risk
- Limited IRB Review can be done by expedited review

38 CFR 16.110(b)(1)

VHA Directive 1200.05

- VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements.
- Note – FDA Regulated Research will continue to be subject to the current expedited review requirements, until further notice is given.

IRB Review of Research: Expedited Review Listing

CURRENT VHA Handbook 1200.05	PROPOSED VHA Directive 1200.05
The (expedited) decision and the expedited review eligibility category must be included in the IRB minutes of the next available convened IRB meeting and in the written notification to the investigator and R&D Committee. **VHA Handbook 1200.05, Paragraph 9d**	The IRB must have a written procedure for informing all IRB members, investigators, and the R&D Committee of the decision and the expedited review eligibility category for any expedited review actions.

IRB Review of Research: Continuing Review

Revised Common Rule

Continuing Review no longer required for the following:

- Research eligible for expedited review
- Research reviewed by limited IRB Review (certain exempt research)
- Research that has progressed to the point that it involves only one or both of the following:
  - Data analysis, inclusive of analysis of identifiable private information or identifiable specimens, and/or
  - Access to follow-up clinical data obtained from procedures that subjects undergo as part of clinical care
- Conducting CR on research that no longer requires CR will require justification that is documented in the study files.

38 CFR 16.109(f)(1)

Proposed VHA Directive 1200.05

- VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements
- Clarifies that the R&D Committee is not required to conduct CR on studies under the oversight of the IRB (to include studies subject to the 2018 Requirements that no longer require CR).

VA PRIDE Program for Research Integrity Development & Education 26

Suspension or Termination of IRB Approval

CURRENT VHA Handbook 1200.05	PROPOSED VHA Directive 1200.05
Not included in current VHA Handbook 1200.05 policy language, but any ORD funding service has always had the authority to suspend or terminate the research it is funding.	ORD has authority to suspend or terminate any research activity it is funding.

VA PRIDE Program for Research Integrity Development & Education

Certificates of Confidentiality

PROPOSED VHA Directive 1200.05

- Updated to bring in alignment with 21st century cures act – requirements for obtaining a COC
- Defines "identifiable sensitive information" per 21st Century Cures Act
- Removes prohibition of placing ICFs in the medical record for studies with a COC, provided subjects are informed of this as part of the informed consent process
- In cases where a written Informed consent form is used, requires inclusion of a statement that the study has been issued a COC.

Informed Consent and HIPAA

General Requirements for Informed Consent

Revised Common Rule

- With the exception of Broad Consent, inclusion of a concise summary at the beginning of the ICF presenting key information that subject should know about the research study
- 8 basic elements and 6 additional elements of informed consent unchanged
- New basic element: For all studies that involve the collection of identifiable private information or identifiable specimens, include a statement on whether specimens if subsequently de-identified will be used for future research or not
- 3 new additional elements required when research involves biospecimens:
  - Statement whether specimens may be used for commercial profit and if subject will share in the profit
  - Statement whether clinically relevant research results will be disclosed to subjects and if so under what conditions
  - Statement whether research might include whole genome sequencing

Proposed VHA Directive 1200.05

- VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements
- The following required VA-specific elements have been eliminated:
  - Any payments the subject is to receive for participating in the study
  - Any real or apparent conflict of interest by investigators where the research will be performed

VA PRIDE Program for Research Integrity Development & Education 30

Broad Consent

Revised Common Rule

- Specific to storage, maintenance, and secondary use of identifiable data/biospecimens (collected for research or non-research purposes)
- Can be used as an alternative to general informed consent requirements
- 12 required elements that cannot be waived by the IRB if use of Broad Consent is approved

38 CFR 16.116(d)

Proposed VHA Directive 1200.05

- Broad consent can only be used when data or biospecimens are collected solely for research purposes
- VHA Directive 1200.05 required elements for Broad Consent are aligned with the Revised Common Rule for research subject to the 2018 Requirements
- Broad consent form can be a separate form or combined with a traditional ICF
  - If combined, information provided to subjects for broad consent must be clearly discernable from the research-specific consent

VA PRIDE Program for Research Integrity Development & Education 31

Case Study 4

A researcher would like to establish a tissue and data repository for future research on a chronic degenerative disease. The researcher would like to collect and store the following on each subject:

- Identifiable blood specimens;
- Identifiable demographic and health information collected from a questionnaire;
- and identifiable health information obtained from CPRS (which is the VHA Electronic Health Care Record)

The researcher plans on obtaining documentation of informed consent from subjects. What should the Investigator submit to the IRB for review:

A. A study-specific ICF for collection, storage and future use

B. A Broad Consent Form covering collection, storage, and future use

C. Either A or B

D. Additional Information is needed

Revised Common Rule: Waiver/Alteration of Informed Consent

Revised Common Rule

- Requirements for waiving/altering informed consent for research involving public benefit and service programs conducted or subject to the approval of state or local government remains substantially unchanged
- Requirements for waiving/altering informed consent for minimal risk research - One additional requirement has been added:
- (i) The research involves no more than minimal risk to the subjects; (ii) The research could not practicably be carried out without the requested waiver or alteration; (iii) 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; (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation (38 CFR 16.116(f)(3))

Proposed VHA Directive 1200.05

VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018

VA PRIDE Program for Research Integrity Development & Education 33

Revised Common Rule: Waiver of Informed Consent (Caveat)

Revised Common Rule

- IRB cannot waive or alter any of the elements required for Broad Consent (38 CFR 16.116(f)(2))
- IRB cannot waive consent for the storage, maintenance, or secondary use of identifiable information or specimens if a subject has refused to agree to Broad Consent (38 CFR 16.116(f))
- With the exception of Broad Consent, the IRB can approve a complete waiver of informed consent if the required criteria have been met.

Proposed VHA Directive 1200.05

VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements

Revised Common Rule: Alteration of Informed Consent (Caveat)

Revised Common Rule

- Alterations: IRBs can not approve a consent procedure that omits/alters the general requirements of informed consent found in 38 CFR 16.116(a). 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 and of 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

Proposed VHA Directive 1200.05

VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements

VA PRIDE Program for Research Integrity Development & Education

Revised Common Rule: Screening and Recruiting Activities

Revised Common Rule

- Use of identifiable information or identifiable specimens without the subject's consent for the purpose of screening, recruiting, or determining eligibility of prospective subjects can be approved by the IRB if the following requirements are met:
  - Investigator obtains information through oral or written communication with the prospective subject, or
  - Investigator obtains identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(38 CFR 16.116(g))

Proposed VHA Directive 1200.05

- VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements
- Note: HIPAA waiver for screening purposes would still be required

VA PRIDE Program for Research Integrity Development & Education 36

Revised Common Rule: Posting Clinical Trial Consent Forms

Revised Common Rule

- 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
- Consent forms must be posted on either https://clinicaltrials.gov or a docket folder on http://Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

38 CFR 16.116(h)

Proposed VHA Directive 1200.05

- VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements

Provides additional details on who is responsible for posting the consent form:

- For any ORD-funded clinical trial, the applicable ORD funding service will be responsible for posting the informed consent form.
- For a clinical trial funded or supported by a Federal agency or department other than VA, the awardee is responsible for posting the informed consent form.
- For a clinical trial funded or supported by a non-Federal agency or department (e.g., university, industry, private nonprofit organization) or not funded, the VA Investigator conducting the clinical trial is responsible for ensuring that the informed consent form is posted.

VA PRIDE Program for Research Integrity Development & Education 37

Revised Common Rule: Documentation of Informed Consent

Revised Common Rule

- No material change to the long form ICF except that regulations now state that a "written" copy shall be given to the person signing the ICF
  - Definition of written: *Written, or in writing* refers to writing on a tangible medium (e.g. paper) or in an electronic format (38 CFR 16.102(m))
- Only change to the short form ICF is inclusion of a statement that key information was presented to the subject prior to presenting other information

38 CFR 16.117

Proposed VHA Directive 1200.05

- VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements
- Requirement to obtain the signature of the individual obtaining consent has been eliminated **(VHA Handbook 1200.05 Paragraph 16e(2)(b))**
- IRB waiver of signature of individual obtaining consent in instances where no physical contact with subjects occurs has also been eliminated as it is no longer necessary **(VHA Handbook 1200.05 Paragraph 16e(2)(b))**

Case Study 5: Part 1

An investigator submits an amendment to remove the signature of the individual obtaining consent from the consent form of a study that is subject to the pre-2018 Requirements. The amendment is submitted after the issuance of the revised VHA Directive 1200.05

Can the IRB approve the request?

A. Yes

B. No

C. Additional information is needed

VA PRIDE Program for Research Integrity Development & Education 39

Case Study 5: Part 2

If the IRB approves the removal of the signature of the person obtaining consent, does the study have to transition to the 2018 requirements?

A. Yes

B. No

C. Additional information is needed

Revised Common Rule: Waiver of Documentation of Consent

Revised Common Rule

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

38 CFR 16.c(1)

Proposed VHA Directive 1200.05

VHA Directive 1200.05 requirements have been aligned with the Revised Common Rule for research subject to the 2018 Requirements

VA PRIDE Program for Research Integrity Development & Education

HIPAA Authorizations

CURRENT VHA Handbook 1200.05

VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for VHA Research, must be used to document the authorization. The authorization may not be embedded in the consent form.

VHA Handbook 1200.05, Paragraph 23(a)(1)

Proposed VHA Directive 1200.05

- The written HIPAA authorization may either be a standalone document or combined with the research informed consent approved by the IRB.
- If a standalone document is used as the written HIPAA authorization, VA Form 10-0493: *Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research* **must** be used.

Case Study 6

In what situation might it be advantageous to combine the informed consent document and the HIPAA Authorization for research?

(Select all that apply)

A. Longitudinal studies in which reconsent is obtained every 2 years

B. A study asking VA employees their opinions about care services

C. A study involving individuals w/impaired decision-making capacity

D. A study assessing obesity and cardiac health in healthy adults

E. None of the above

Vulnerable Populations

Pregnant Women

CURRENT VHA Handbook 1200.05

The VA medical facility Director certifies that the medical facility has sufficient expertise in women's health to conduct the proposed research.

VHA Handbook 1200.05, Paragraph 17(b)(4)

PROPOSED VHA Directive 1200.05

VA medical facility Director certification required for

(1) Interventional studies or invasive monitoring of pregnant women as subjects

(2) Neonatal research

VA PRIDE Program for Research Integrity Development & Education

In Vitro Fertilization Research

CURRENT VHA Handbook 1200.05

Research that involves provision of *in vitro* fertilization services cannot be conducted by VA investigators while on official duty, or at VA facilities, or at VA-approved off-site facilities.

VHA Handbook 1200.05, Paragraph 17(a)

PROPOSED VAH Directive 1200.05

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.

VA PRIDE Program for Research Integrity Development & Education

Fetal and Human Stem Cells

CURRENT VHA Handbook 1200.05

Research in which the focus is either a fetus, or human fetal tissue, in-utero or ex-utero (or uses human fetal tissue), cannot be conducted by VA investigators while on official duty, at VA facilities, or at VA-approved off-site facilities. Use of stem cells shall be governed by the policy set by NIH for recipients of NIH research funding.
VHA Handbook 1200.05, Paragraph 17(b)

PROPOSED VHA Directive 1200.05

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.

VA PRIDE Program for Research Integrity Development & Education

Research Involving Children

CURRENT VHA Handbook 1200.05

- VA research involving children must be no greater than minimal risk and must be relevant to the VA.
- IRB must have appropriate expertise to evaluate VA research involving children
- All requirements of 45 CFR 46.401-46.404 and 46.408 must be met prior to approving research involving children
- Approval from the VA medical facility Director must be obtained

VHA Handbook 1200.05 Paragraph 19

PROPOSED VHA Directive 1200.05

- No significant changes in VA policy regarding research involving children
- Clarification added that research involving children does not include neonates
- Research involving neonates must follow requirements for research involving pregnant women, fetuses, and neonates.

VA PRIDE Program for Research Integrity Development & Education

Individuals with Impaired Decision – Making Capacity

CURRENT VHA Handbook 1200.05

VHA Handbook 1200.05, Paragraph 20 describes VA specific requirements when individuals with impaired decision-making capacity are subjects in VA research.

PROPOSED VHA Directive 1200.05

ORD eliminated the VA specific requirements.

VA PRIDE Program for Research Integrity Development & Education

Research Involving Prisoners

CURRENT VHA Handbook 1200.05

Research involving prisoners cannot be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities unless a waiver has been granted by the CRADO. ***NOTE:*** *Refer to the ORD Web site at http://www.research.va.gov/resources/policies/default.cfm for details on the procedures for waiver applications.*

VHA Handbook 1200.05
Paragraph 18

PROPOSED VHA Directive 1200.05

Waiver requests must be submitted electronically to the CRADO by the VA medical facility Director with the following documents:

- A letter from the VA medical facility Director supporting the conduct of the VA study involving prisoners;
- Rationale for conducting the research involving prisoners to include additional ethical protections taken by the proposed research for prisoners to make truly voluntary and uncoerced decisions whether or not to participate as subjects in research;
- Documentation of the Investigator's qualification to conduct the research involving prisoners, such as a biosketch and a list of all research team members;
- Location of institutions where the research is proposed to be conducted;
- A copy of the IRB approval letter specifically documenting its review determinations according to 45 CFR 46.305(a);
- A copy of the IRB minutes approving the research with documentation that at least one member of the IRB included a prisoner or a prisoner representative for the review of the research;
- A copy of the IRB-approved research study;
- A copy of the IRB-approved informed consent document; and
- A copy of the written HIPAA authorization.

Definitions

Definitions

PROPOSED VHA Directive 1200.05	
Eliminated	In vitro Fertilization; Multi-site research; Serious Adverse Events
New	Clinical Trial; Federal-wide Assurance; Identifiable Private Info.; Identifiable Biospecimens; Sub-investigator; Signatory Official; Program Office Employee; Program Office
Revised per 2018 Requirements	Human Subject (38 CFR 16.102(e)); Intervention (38 CFR 16.102(e)(2)); LAR (38 CFR 16.102(i)); Research (38 CFR 16.102(l))
Minor Clarifications	COC; De-identified info; Fetus; IO; Investigator; VA Investigator; Pregnancy; Private Info.; VA Research
Unchanged	Remaining definitions

Resources

Important Links

- Final Rule for the Delay (published June 19, 2018)
- Revised Common Rule (published January 19, 2017)
  - Pages 7259 to 7274 contain the Text of the Final Rule
- Current Common Rule
- VHA Handbook 1200.05
- ORD Policies and Guidance Documents

VA PRIDE Program for Research Integrity Development & Education 54

ORD/ORO Cyberseminars on the Revised Common Rule

Date	Topic	Lead Office
30-Jan-18	Records Management	ORD
20-Feb-18	Engagement in Human Subjects Research	ORD
20-Mar-18	MyhealtheVet and Secure Messaging	ORD
24-Apr-18	Continuing Review	ORD
15-May-18	Expedited Review	ORD
16-May-18	Overview of the Revised Common Rule	ORO
19-Jun-18	Working with the VA CIRB	ORD
27-Jun-18 and 02-Jul-18	Final Rule: Delay Until January 21, 2019 of General Compliance of the Revised Common Rule and Use of Three Burden Reducing Provisions: What it Means for VA Research	ORD/ORO
17-Jul-18	Waivers: Common Rule, Privacy Rule, and FDA Regulations	ORD
18-Jul-18	Informed Consent: ICFs; Broad Consent; and Posting of ICFs	ORO
18-Sep-18	Overview of the Revised Common Rule and its Impact on the IRB	ORD
19-Sep-18	Exempt Review and Limited IRB Review	ORO
16-Oct-18	Q&A on the Revised common Rule	ORD
26-Nov-18	The Revised Common Rule, Proposed VHA Directive 1200.05, and the IRB: Focus on Significant Changes	ORD
4-Dec-18	External IRBs and FWAs	ORO
18-Dec-18	In-depth Focus on VHA Directive 1200.05	ORD

VA PRIDE Program for Research Integrity Development & Education

ORD/ORO Recorded Trainings on the Revision of the Common Rule Series

Cyberseminars conducted by ORD and ORO as part of the Revised Common Rule series can be found on the PRIDE cyberseminar webpage:
https://www.research.va.gov/pride/cyberseminars/default.cfm

VA PRIDE Program for Research Integrity Development & Education 56

Questions?