



Overview of the Revised Common Rule and Its Impact on the IRB

Focus on Significant Changes in the Rule

Soundia A. Duche, MA, MS
Program Analyst/PRIDE

September 18, 2018

Overview

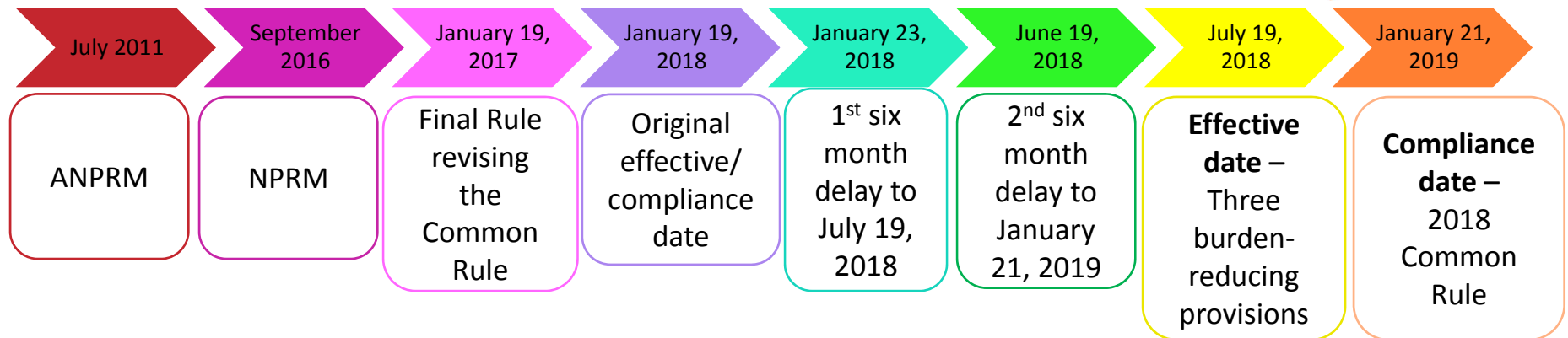
- Provide a Status Update on the Revised Common Rule and VHA Handbook 1200.05
- Provide an Overview of Significant Changes in the Revised Common Rule
- Discuss Considerations and Strategies your IRB can use to Implement the Revised Common Rule



Current Status of the Revised Common Rule and VHA Handbook 1200.05

Timeline

WE
ARE
HERE



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

Burden Reducing Provisions

Beginning July 19, 2018 Institutions can implement the following burden-reducing provisions on projects they designate to transition to the 2018 Requirements on January 21, 2019:

- Apply the revised definition of research, which deems four categories of activities “not research”
- Eliminate the requirement that IRBs review grant applications or other funding proposals related to the research study
- X Eliminate Continuing Review for studies approved by expedited review and studies that have reached a certain point in the research**
- VA policy only allows implementation of the first two provisions during the delay period

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.
- Working timeline is to have VHA Directive issued by late October or early November
- ORD is in the process of developing numerous VA-specific guidances to support VHA Directive 1200.05
- The revised Common Rule will impact other VHA Handbooks that are also being revised
 - VHA Handbook 1200.01, Research and Development Committee
 - VHA Handbook 1200.12, Use of Data and Data Repositories in Research

Transition Provisions

- **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 continue to comply 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.

Transition Provisions: Implications for the IRB

- We will likely be operating under both requirements for the foreseeable future
 - SOPs and certain forms will need to be consistent with two sets of regulations
- Need to determine how to prioritize requests to transition protocols
 - Who will initiate requests (PISC or the IRB)
 - Who will determine whether a protocol should be transitioned and when?
 - Administratively when is the best time to transition a protocol (at CR; next amendment; in groups)
 - How will you document and track that a protocol has been transitioned?
- Determine what changes are required to transition protocols (e.g. consent form changes, waivers, IRB approval criteria):



Overview of Significant Changes in the Revised Common Rule “2018 Requirements”

Definitions: Human Subject

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or **biospecimens** through intervention or interaction with the individual, and **uses, studies, or analyzes** the information or **biospecimens**; or (ii) Obtains, **uses, studies, analyzes, or generates** identifiable private information or **identifiable biospecimens** (38 CFR 16.102(e)).

- Revisions made to (1) include biospecimens in the definition of human subjects and (2) clarify that “obtaining” is synonymous with using, studying, analyzing or generating identifiable private information or identifiable biospecimens
- Federal agencies will reexamine the meaning of “identifiable” within one year of implementation of the revised common rule and every 4 years thereafter.

Definitions: Research

No changes to the definition of research itself, however four categories of activities have been deemed “not to be research”

- Scholarly and journalistic activities
- Public health surveillance activities
- Collection and analysis of information, biospecimens, or records for activities authorized by law or court order for criminal justice or criminal investigative purposes
- Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions

Definitions: Clinical Trial

New Definition

- *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes (38 CFR 16.102(b)).

Additional Definitions that have been Revised in the 2018 Requirements

- Department/Agency Head: Minor clarifications (38 CFR 16.102(c))
- Federal Department or Agency: New Definition (38 CFR 16.102(d))
- Identifiable Biospecimen: New Definition (38 CFR 16.102(e)(6))
- Intervention: Minor clarifications (38 CFR 16.102(e)(2))
- Legally Authorized Representative: Minor clarifications (38 CFR 16.102(i))
- Public Health Authority: New definition (38 CFR 16.102(k))
- Written or in writing: New definition (38 CFR 16.102(m))

Federal Wide Assurance

- Institutions no longer required to designate IRBs on their FWA
 - Institutions remain responsible for ensuring that IRBs that they rely on are registered with OHRP and are appropriately constituted to review and approve their human subjects research
- FWA-holders no longer required to routinely submit up-to-date IRB member rosters as part of the Assurance process
 - IRBs/Institutions continue to be responsible for maintaining a current list of IRB members and their qualifications
- IRBs no longer have to review grant applications as part of the approval process



Exempt Research Categories

Retained and Deleted: Exempt Categories 3 and 6

- Deleted: **Exempt Category 3** which deals with educational tests, surveys, interviews or observation of public behavior involving elected or appointed officials or candidates for public office or where federal statutes require that the confidentiality of the identifiable information be maintained throughout the research and thereafter
 - Majority of this research would be eligible for Exempt Category 2 under the 2018 Requirements
- Retained Unchanged: **Exempt Category 6** involving Taste and Food quality evaluations and consumer acceptance studies

Revised: Exempt Category 1

Exempt Category 1 involving research conducted in established or commonly accepted educational settings involving normal educational practices

- Clarification added that the educational practices are not likely to adversely impact students opportunity to learn required content or the assessment of the educators who provide instruction

Revised: Exempt Category 2

Exempt Category 2 involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior

- Initial two criteria retained: (1) information recorded such that identity of the subject cannot be ascertained; (2) any disclosure of the subject's responses outside the research would not reasonably place the subjects at risk
- Third criteria added allowing the recording of identifiable information provided that an IRB conducts a limited IRB review to determine that adequate measures exist to ensure the privacy and maintain the confidentiality of the subject's data.

Revised: Exempt Category 4

Exempt Category 4 involving the collection or study of existing data, documents, records, pathological or diagnostic specimens if publicly available or recorded such that subjects cannot be identified

- Relabeled as “Secondary research for which consent is not required”
- Requirement that data be existing at the time of approval has been removed
- Two new criteria added:
 - Use of identifiable health information regulated by HIPAA
 - Certain federal research using government-generated or collected information obtained for non-research activities

Revised: Exempt Category 5

Exempt Category 5: Research and demonstration projects conducted by or subject to the approval of department or agency heads designed to evaluate public benefit or service programs

- Minor clarification: Addition of “improve” to clarify that the government conducts such activities to improve the benefits and services provided.
- Requires that each federal department or agency supporting these projects must publish a list of projects that the department or agency supports under this provision prior to commencing research

New: Exempt Category 3

Exempt Category 3 deals with benign behavioral interventions that an adult subject prospectively agrees to

- If identifiable information is collected, the IRB conducts a limited IRB review to ensure that adequate measures exist to protect the privacy and confidentiality of the subject
- Caveat for Research Involving Deception
 - Subject's must agree to being deceived in advance
- Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

New: Exempt Categories 7 and 8

Specific to the secondary storage and use of data and biospecimens for which Broad Consent was obtained:

- **Exempt Category 7** involves the storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary use
- **Exempt Category 8** involves the secondary use of identifiable data and identifiable biospecimens.
- In both instances, an IRB must make certain determinations using the limited IRB review process prior to granting the exemptions.

Applying Exempt Categories to Research involving Pregnant Women, Prisoners, and Children

Pre-2018 Requirements and research involving:

- Pregnant Women: All exemptions apply
- Prisoners: None of the exemptions apply
- Children:
 - Categories 1, 4, 5, and 6 apply
 - Category 2 only applies to research involving educational tests or observation of public behavior when the investigator(s) do not participate in activities being observed.

Applying Exempt Categories to Research involving Pregnant Women, Prisoners, and Children (continued)

2018 Requirements and research involving:

- Pregnant Women: No Changes
- Prisoners: Only applies if research is aimed at involving a broader subject population that only incidentally includes prisoners
- Children: Categories 1, 4, 5, 6, 7, and 8 apply
- Categories 2(i) and 2(ii) only apply to research involving educational tests or observation of public behavior when the investigator(s) do not participate in activities being observed
- Categories 2(iii) does not apply

Strategies for Dealing with Exempt Research

- Remember research that has not transitioned will continue to be subject to its respective regulatory requirements
 - Amendments to research deemed exempt under the pre-2018 requirements must continue to remain exempt under that criteria, unless transitioned to the 2018 Requirements.
- Maintain separate lists of exempt categories for research subject to pre-2018 Requirements and research subject to the 2018 requirements
- Process to conduct exempt review is similar under both sets of requirements
 - SOPs could refer to both exempt category lists depending on the regulations being followed



IRB Membership, Functions and Review of Research

IRB Membership

- No significant changes
- Removal of specific reference to IRBs not consisting entirely of men, women, or members of one profession
 - Requirement that IRB membership reflect members of varying background and diversity, including gender has been retained.
- Inclusion of members with knowledge and experience working with vulnerable populations has been retained
 - Pregnant women and handicapped individuals have been removed from the category of subjects considered vulnerable
 - Term “mentally disabled” has been replaced with “individuals with impaired decision-making”.

IRB Functions and Operations

- No material changes in 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;
 - Meeting space and staff
 - Policies and Procedures to conduct initial and continuing review, changes in research, UAP reporting, and suspensions and terminations

IRB Review of Research: Continuing Review

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.

IRB Review of Research: Expedited Review

- 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

IRB Approval Criteria

Minor change to IRB approval criteria concerning equitable selection of subjects (38 CFR 16.111a(3))

- Pregnant women and handicapped individuals have been removed from the category of subjects considered vulnerable
- Term “mentally disabled” has been replaced with “individuals with impaired decision-making”.
 - Selection of subjects is equitable. In making this assessment the IRB should take into account the purpose of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(38 CFR 16.111(a)(3))

IRB Approval Criteria (continued)

- Addition of 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
 - IRB review is limited to (1) determining that adequate provisions to protect the privacy of subjects and maintain the confidentiality of their data exist and/or (2) Broad consent is appropriately obtained and documented (or waiver of documentation is appropriate)
 - Secretary of HHS to issue guidance on adequate provisions to protect the privacy of subjects and maintain the confidentiality of their data

Suspension/Termination of IRB Approval

- No changes

Cooperative Research

- Compliance date is January 20, 2020
- Single IRB review/approval required for any institution located in the US that is engaged in cooperative research with the following exceptions:
 - When more than a single IRB review is required by law (includes tribal law)
 - When a federal agency determines and documents that use of a single IRB is not appropriate

IRB Records

- Justification required when continuing review is conducted on research no longer requiring CR
- Justification required when research appearing on the expedited review list is deemed more than minimal risk
- IRBs continue to be required to maintain a list of members and their qualifications

Strategies for Implementing Changes

- Continuing Review
 - SOPs need to differentiate CR requirements based on which regulations are being followed
 - IRB needs to determine what, if any, tracking or updates they may wish to require for research no longer requiring continuing reviews
 - Reviewer forms could be revised to include a section for justifications when CR is conducted on research not eligible for CR
- Expedited Review
 - Reviewer Forms could be revised to include section for justification when the IRB determines that a specific project on the Secretary's list is greater than minimal risk

Strategies for Implementing Changes (continued)

- Limited IRB Review
 - Revise SOPs accordingly
 - Revise IRB Approval Criteria to include **111(a)(8)** requirements for limited IRB review, when applicable
 - Consider revising reviewer forms to include criteria required for Limited IRB review, when applicable
 - Revise exempt application and reviewer forms to incorporate information required for the IRB to conduct Limited IRB review, when applicable



Informed Consent

General Requirements for Informed Consent

- 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 of informed consent unchanged
- New 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
- 6 additional elements of informed consent unchanged
- 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 sequenci

Broad Consent: Required Elements

First 4 elements
are from the basic
elements of
Informed Consent

- Specific to storage, maintenance, and secondary use of identifiable data/specimens (collected for other research or non-research purposes)
- Can be used as an alternative to general informed consent requirements

Required Elements:

1. A description of any reasonably foreseeable risks or discomforts to the subject;
2. A description of any benefits to the subject or to others that may reasonably be expected from the research;
3. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
4. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Broad Consent: Required Elements (continued)

Next 2 elements (5 & 6)
are from the additional
elements of Informed
Consent (2018
Requirements)

5. When appropriate, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
6. When appropriate, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
7. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
8. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

Last 6 elements
(7-12) are new
and specific to
Broad Consent

Broad Consent: Required Elements (continued)

Last 6 elements
(7-12) are new
and specific to
Broad Consent

9. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
10. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
11. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
12. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Revised Common Rule: Waiver/Alteration of Informed Consent

- 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))

Revised Common Rule: Waiver of Informed Consent (Caveat)

- IRB cannot waive or alter any of the elements required for Broad Consent (38 CFR 16.116(f)(2))
 - Broad consent is specific to the storage, maintenance, and secondary use of identifiable data/specimens (collected for other research or non-research purposes)
- 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.

Revised Common Rule: Alteration of Informed Consent (Caveat)

- 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

Revised Common Rule: Screening and Recruiting Activities

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))

Documentation of Consent

- 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

Posting Clinical Trial Consent Forms

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

Revised Common Rule: Waiver of Documentation of Consent

Addition of a third option for waiving documentation of informed consent:

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 16.117(c)(1))

Strategies

- Update regular Informed Consent Template with new elements
- Create a template for Broad Consent
 - Can't approve research using Broad consent prior to January 21, 2019
- Revise SOPs to incorporate changes to informed consent and waiver requirements

Strategies (continued)

- Waivers of Informed Consent and Documentation of Informed Consent
 - Revise waiver forms (both investigator forms and IRB reviewer forms) to include the additional criteria but make it clear that consideration of the new criteria is only applicable for research subject to the 2018 requirements (e.g. highlight or use an asterisk stating that it is only applicable when research is subject to the 2018 requirements)
 - Revise SOPs accordingly
- Use of Identifiable Information/Biospecimens without consent for screening and recruitment activities
 - Revise SOPs accordingly
 - Revise Reviewer Forms to include criteria for approval
 - Revise Application Forms to capture new information



Summary

Managing the Process

Determine how to manage and track protocols that transition from pre-2018 requirements to 2018 requirements

- Manage IRB administrative burden when transitioning protocols
- Think about how this will be done and communicate plan (and limitations to investigators)
- May want to create cheat sheet containing list of requirements needed to transition a protocol to the new requirements
- May decide to start rolling out some new forms immediately or determine a date by which all new submissions must use revised forms
- Remember that all studies approved (or deemed exempt) on or after January 21, 2019 must meet all of the 2018 Requirements

Revision and Creation of Key Documents

- Anticipate few changes due to the activities now excluded from the definition of research
- Revise exempt application and reviewer forms to include items specific to limited IRB review and new exempt categories
- Determine how IRB will track studies no longer requiring CR
- Minor revisions to informed consent template
- Development of Broad consent template
- Minor changes to various other forms
- Revise SOPs as needed



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](#)

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	MyhealthVet 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	Transition Provisions and Overview of the revised VHA Handbook 1200.05 <i>or</i> Myth Busters: Common Misperceptions re. VA Research	ORD
20-Nov-18	In-depth Focus on the revised VHA Handbook 1200.05	ORD
21-Nov-18	External IRBs and FWAs	ORO
18-Dec-18	In-depth Focus on the revised VHA Handbook 1200.05	

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

- Cyberseminars conducted by ORD can be found on the PRIDE cyberseminar webpage:
<https://www.research.va.gov/pride/cyberseminars/default.cfm>
- Cyberseminars conducted by ORO can be found here:
 - Overview of the Revised Common Rule:
 - Part 1: <https://www.vapulse.net/docs/DOC-162168>
 - Part 2: <https://www.vapulse.net/docs/DOC-162169>
 - Informed Consent: <https://www.vapulse.net/videos/22977>



Questions?

CATEGORIES OF EXEMPT RESEARCH: PRE-2018 REQUIREMENTS

1. USE OF CATEGORIES

Use of the exemption categories for research subjects who are pregnant women, prisoners, or children is as follows:

a. **Pregnant Women.** Each of the exemptions section may be applied to research involving pregnant women if the conditions of the exemption are met.

b. **Prisoners.** The exemptions at this section do not apply to research involving prisoners.

c. **Children.** The exemptions for Categories 1, 4, 5, and 6 may be applied to research subjects who are children if the conditions of the exemption are met. Exempt category 2 of this section may only apply to research subject to 45 CFR 46 subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

2. CATEGORIES OF EXEMPT RESEARCH

a. **Category 1.** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(1) research on regular and special education instructional strategies, or

(2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b. **Category 2.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(1) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

c. **Category 3.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(1) the human subjects are elected or appointed public officials or candidates for public office; or

(2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

d. **Category 4.** 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

e. **Category 5.** Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(1) Public benefit or service programs;

(2) procedures for obtaining benefits or services under those programs;

(3) possible changes in or alternatives to those programs or procedures; or

(4) possible changes in methods or levels of payment for benefits or services under those programs

NOTE: *The determination of exempt status for research and demonstration projects meeting the criteria in paragraph 5 in this Appendix 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.*

f. **Category 6.** Taste and food quality evaluation and consumer acceptance studies,

(1) if wholesome foods without additives are consumed or

(2) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

CATEGORIES OF EXEMPT RESEARCH: 2018 REQUIREMENTS

1. USE OF CATEGORIES

Use of the exemption categories for research subjects who are pregnant women, prisoners, or children is as follows:

a. **Pregnant Women.** Each of the exemptions section may be applied to research involving pregnant women if the conditions of the exemption are met.

b. **Prisoners.** The exemptions at this section do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

c. **Children.** The exemptions for Categories 1, 4, 5, 6, 7, and 8 may be applied to research subjects who are children if the conditions of the exemption are met. Exempt category 2(a) and (b) of this section may only apply to research subject to 45 CFR 46 subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph 2.b.(3) of this section may not be applied to research subject to subpart D.

2. CATEGORIES OF EXEMPT RESEARCH

a. **Category 1.** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b. **Category 2.** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by paragraph 12.a(7).

NOTE: *The exemption for research involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.*

c. **Category 3.** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by paragraph 12.a(7).

(4) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(5) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

d. **Category 4.** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(1) The identifiable private information or identifiable biospecimens are publicly available;

(2) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily

be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(3) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of health care operations or research as those terms are defined at 45 CFR 164.501 or for public health activities and purposes as described under 45 CFR 164.512(b); or

(4) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities; if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note; if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a; and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

e. **Category 5.** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

(1) Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(2) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

NOTE: *The determination of exempt status for research and demonstration projects meeting the criteria in paragraph e. in this Appendix 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.*

f. **Category 6.** Taste and food quality evaluation and consumer acceptance studies:

(1) If wholesome foods without additives are consumed, or

(2) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

g. **Category 7.** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by paragraph 12.a(8).

h. **Category 8.** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(1) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with paragraph 17.f.

(2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with paragraph 17;

(3) An IRB conducts a limited IRB review and makes the determination required by paragraph 12.a(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph h.(1) of this section; and

The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.