

Q&A Session: The Revised Common Rule

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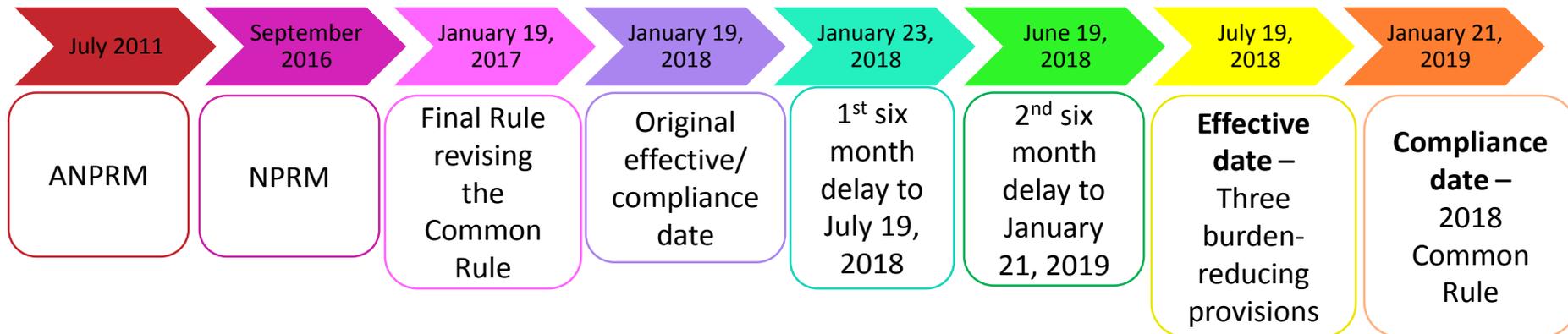
October 18, 2018

Overview of Session

- ORD and ORO will provide responses to unanswered questions from the following cyberseminars:
 - Overview of the Revised Common Rule (September 18, 2018)
 - Exempt Review and Limited IRB Review (September 19, 2018)
- The Revised Common Rule and FDA-Regulated Research
- Open Q&A session addressing additional questions on the 2018 Requirements/Revised Common Rule

The 2018 Requirements/Revised Common Rule: Status Update

WE
ARE
HERE



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



Unanswered Questions from September 2018 Cyberseminars

Transitioning Studies

Status of ORD Handbooks and Directives

Q1: What is the current timeline for updating VA guidance and requirements to synchronize with the Revised Common Rule? What's the current feeling in the various DC offices of the potential of this policy actually going into effect on January 21, 2019?

Status of VHA Directive 1200.05 and Supporting Guidance Documents

Response:

- VHA Directive 1200.05 is in concurrence.
- Working timeline is to have VHA Directive 1200.05 issued early November
- ORD is in the process of developing numerous VA-specific guidance documents to support VHA Directive 1200.05 and plans to release them starting in November.
- ORD and ORO are also working with the other Common Rule agencies on supporting guidance for implementation of the 2018 Requirements/Revised Common Rule.

Status of VHA Directives 1200.01 and 1200.12

Q2: When are the changes being made to 1200.01 and 1200.12?

Response:

- Both Handbooks are in active revision.
- VHA Directive 1200.01 is undergoing concurrence.
- VHA Directive 1200.12 is in active revision and will be issued in 2019.

Studies Approved by the IRB under the pre-2018 Requirements

Q3: Our current IRB-approved studies do not have to be transitioned to the 2018 Requirements/Revised Common Rule, correct?

Studies Approved by the IRB under the pre-2018 Requirements

Response:

- There is no requirement to transition any study approved by an IRB prior to January 21, 2019 UNLESS:
 - the study is transitioned to the 2018 requirements and the IRB documents this decision.
 - the study approved by the IRB prior to January 21, 2019 utilized one of the burden-reducing provisions during the transition period of July 19, 2018 thru January 20, 2019. If the research study utilized one of the eligible burden-reducing provisions during the transition period, it is automatically designated for transition to the 2018 Requirements and must comply with all of the 2018 Requirements (with the exception of the Cooperative Research Provisions) on January 21, 2019.

Transitioning Studies: Reclassifying Studies

Q4: Might studies involving data analysis or retrospective chart review only (i.e. using VINCI) that were approved under the pre-2018 requirements now qualify for exemption under the 2018 Requirements? If not, could they be reclassified so that they no longer require continuing review?

Transitioning Studies: Reclassifying Studies Involving Data Analysis or Retrospective Chart Reviews

Response:

- **Expedited to Exempt:** It is possible that research previously approved by the IRB (likely expedited) may qualify for an exemption under the 2018 requirements (e.g. Exempt Category 4 for studies involving chart reviews). IRB review would be required to determine if the exemption criteria under the Revised Common Rule are met. If the criteria are met, the IRB would need to document that the research has been transitioned to the 2018 Requirements.
- **Expedited (pre-2018 Requirements) to Expedited (2018 Requirements):** If the research previously approved by the IRB does not qualify for exemption under the 2018 Requirements, IRB review and approval is required to ensure that all revised approval criteria have been met. The IRB would need to document that the research has been transitioned to the 2018 Requirements in order to take advantage of the 2018 Requirements, to include removal of the requirement to conduct Continuing Review for studies approved by expedited review.

Transitioning Studies: Recommendations

Q5: Can you recommend some general steps we can take to transition a study that was expedited under the pre-2018 Requirements?

Response:

Transitioning Studies that were Expedited under the pre-2018 Requirements:

1. If study qualifies for an exemption under the 2018 Requirements, IRB would need to determine that the exempt criteria have been met, to include performing limited IRB review when applicable.
2. If study continues to qualify for expedited review, IRB must review all study materials and ensure that all 2018 approval requirements, to include informed consent requirements and waivers, have been met.
3. IRB must document that the study has been transitioned to the 2018 Requirements.

Transitioning Studies: Waivers of Informed Consent

Q6: If a study involving a retrospective chart review is going to be transitioned to the 2018 Requirements, would we have to obtain a new waiver of consent containing the new waiver criteria stipulating that the research could not be conducted without using identifiable private information?

Criteria for Waivers of Informed Consent for Minimal Risk Studies

(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)).

Transitioning Studies: Waivers of Informed Consent

Response:

- Yes. The IRB would need to document that the study met the additional waiver of informed consent criterion if the study involves using identifiable private information or identifiable biospecimens.
- Any research study that is transitioned to the 2018 requirements on or after January 21, 2019 must follow all of the requirements of the 2018 requirements, to include ensuring that all of the criteria for the waiver of informed consent provisions in the 2018 Requirements are met if applicable to the research study.



Informed Consent

Informed Consent and Future Use of Data and Biospecimens

Q7: If a study approved under the 2018 Requirements is collecting identifiable information or biospecimens for the current study AND the investigator is seeking permission to store the data for future use, are two separate consent forms required:

- (1) Regular ICD with required new elements for current use, and
- (2) Broad consent for storage for future use?

Informed Consent and Future Use

Response:

- The 2018 Requirements do not require two separate consent forms to allow future use of identifiable data and/or biospecimens.
- Broad consent is an **option** that can only be used for the secondary use and storage/maintenance of identifiable data and/or biospecimens.
- Broad consent **cannot replace the informed consent required by the IRB (informed consent document or waiver of documentation of informed consent) used for the initial collection of data/biospecimens.**

Informed Consent and Future Use

Response (cont.):

- Advantage of obtaining broad consent is that it would facilitate the use of the new exempt categories 7 and 8 for future research studies using identifiable data and/or identifiable biospecimens collected under Broad Consent.
- Limitations of using broad consent for future use is the requirement to track subjects who refuse to provide Broad Consent and ensure that their identifiable data and/or identifiable biospecimens is not used for future research, even under IRB waivers of informed consent.

Broad Consent

Q8: Broad consent refusals are difficult to monitor. Can an investigator simply exclude individuals who refuse to provide broad consent?

Response:

- If broad consent for future research of identifiable biospecimens and/or identifiable data was offered at the same time that informed consent was obtained for a current research study, the researcher cannot exclude individuals from the current study if they refuse to provide broad consent for future research unless the future use of the identifiable biospecimens and/or identifiable data is a required component of the study and approved by the IRB.

Broad Consent

Q9: Does Broad consent have to be documented in CPRS?

Response:

- There is no current requirement in ORD policy that informed consent must be documented in a VHA Health Record when informed consent is obtained for storage and future use of biospecimens and/or data.

Exempt Review

Revised Common Rule: Exempt Category 4 and Waivers of Informed Consent and Waivers of HIPAA Authorization

- Q10: Would all retrospective chart reviews using data in CPRS collected for clinical purposes now qualify for exemption under Category 4? If so, would they no longer require a waiver of informed consent? Would they still require a HIPAA waiver?

Revised Common Rule: Exempt Category 4: Applicable Regulatory Text in § 104(d)(4)

Secondary research use of identifiable private information or identifiable biospecimens if:

- Identifiable private information or identifiable biospecimens are publically available, OR
- Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects or re-identify subjects, OR
- Investigator's use is regulated under HIPAA as "health care operations," "research," or "public health" OR
- Research is conducted by, or on behalf of, a Federal agency using data collected or generated by the government for non-research purposes, and the information is protected by federal privacy standards

§ 104(d)(4)

Exempt Category 4 and Waivers of Informed Consent and HIPAA Authorization

Response:

- Retrospective chart reviews using identifiable data collected for clinical purposes would likely qualify for exempt category 4 under the Revised Common Rule.
- Exempt research is not subject to the requirements of the Common Rule and therefore is not required to meet the requirements for informed consent, to include waiver of informed consent.
- VHA is a covered entity and is subject to the requirements of HIPAA. VA as a Federal Agency is also required to follow the Privacy Act of 1974. A HIPAA Authorization or Waiver of HIPAA is required for research conducted at the VA using personally identifiable information.

Revised Common Rule: HIPAA Waivers and the R&D Committee

- Q11: Will R&D Committees be able to provide HIPAA waivers or will IRB's need to continue doing this?

Response:

- R&D Committees that are constituted to meet the requirements of a Privacy Board could approve waivers of HIPAA authorization in alignment with VHA Directive 1605.01 policies.

Revised Common Rule: Exempt Category 5

Q12: For Exempt category 5, would we need CRADO approval and who from VA would publish the list?

Revised Common Rule: Exempt Category 5: Applicable Regulatory Text from § 104(d)(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.
- Provides examples of the types of public benefit and service programs covered by the exemption.
- 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

§104(d)(5)

Revised Common Rule: Exempt Category 5

Q12: For Exempt category 5, would we need CRADO approval and who from VA would publish the list?

Response:

- Exempt category 5 is used extremely rarely within VHA. The Department or Agency Head referenced in exempt category 5 regulation for VHA is the Secretary of the Department of Veterans Affairs.
- In VHA, exempt category 5 activities are those exempt research activities conducted by or subject to the approval of the Secretary of VA designed to evaluate public benefit or service programs of VHA.

Revised Common Rule: Exempt Category 7

Q13: In Exempt Category 7, what is meant by “maintenance” for secondary use?

Exempt Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required (§104(d)(7))

- This category is for the storage of identifiable biospecimens and identifiable private information, prior to secondary analysis.
- The storage and maintenance may be exempt if the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and that broad consent is obtained and appropriately documented.

Response:

- They are synonymous terms

Revised Common Rule: Exempt Category 8

Q14: Regarding Category 8, what are examples where the law requires returning research results to subjects?

Revised Common Rule: Exempt Category 8

Category 8 allows the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived.

§104(d)(8)

- IRBs must determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data as noted in 46.111(a)(7), and that the use is within the scope of the broad consent.
- Category 8 also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.

Revised Common Rule: Exempt Category 8

Q14: Regarding Category 8, what are examples where the law requires returning research results to subjects?

Response:

The issue is not whether a law requires returning research results to subjects but rather does a research subject have the right to request research results. Right to access laws whether they be state or federal could be applicable. This is a topic that continues to have multiple discussions among multiple federal and non-federal groups, including public advocacy groups.

Exempt Studies: ISO/PO Responsibilities

Q15: Are ISO/PO reviews required for exempt studies?

Response:

- Exempt research is human subjects research. All VHA human subjects research must be conducted in compliance with all applicable requirements. If there is a privacy and/or information security issue applicable to the exempt activity, those issues must be addressed and resolved prior to the approval of the exempt research activity.

Exempt Studies: Reporting Requirements

Q16: Please clarify: It seems that more studies with PII/PHI will be considered exempt. If there is an Information Security/Non compliance issue that is determined by R&D to be serious, per FWA requirements, these do not have to be reported to OHRP because the research study is exempt, correct?

Response:

- Exempt (generally) means not subject to the requirements of the Common Rule and as such, reporting to OHRP would not be required.
- However, VHA Handbook 1058.01 requires reporting of information security incidents and other serious non-compliance issues to the Office of Research Oversight, irrespective of whether the study is exempt from the Common Rule.

Limited IRB Review

Limited IRB Review: Procedures

Q17: Who does the limited IRB review? Who is the reviewer?

Response:

- Limited IRB Review can be done by expedited review (§110(b)(1)(iii)), which can be done by the IRB chair, or designee from among experienced IRB members (§110(b)(2)).

Limited IRB Review: Procedures

Q18: Is Limited IRB review only required at the time of the initial review or will the study continue to require limited IRB review at continuing review?

Response:

- Continuing Review is not required for research reviewed by limited IRB Review (certain exempt research ((§109(f)(1)(ii))).

Limited IRB Review: Documentation Requirements

Q19: Is there a requirement for documentation of limited IRB review/approval criteria?

Response:

- Yes, it is analogous to the same requirements that the IRB document that the IRB approval criteria have been met.

Limited IRB Review: Documentation Requirements

Q20: If limited IRB review can be done in an expedited fashion, to move it forward to the R&D Committee, does it need to wait until the convened IRB meeting (and documented in IRB minutes)?

Response:

- The Common Rule requires that all IRB members be informed of studies that are approved by expedited review. The current method used by your facility for expedited approvals should be used for limited IRB reviews conducted by expedited review (e.g. continued use of an expedited listing).

Limited IRB Review: ISO/PO Responsibilities

Q21: For limited IRB review, I assume that is not just the IRB reviewing the privacy and confidentiality requirements, but also the PO and ISO?

Response:

- The revision of VHA Directive 1200.05 will address limited IRB review. All VA research must be conducted in compliance with all applicable requirements and regulations. If there is an issue requiring ISO and/or PO review to ensure that the research is conducted in compliance, those groups should be consulted.

Continuing Review

Continuing Review: R&D Committee Responsibilities

Q22: Will the R&D Committee be required to conduct CR [continuing review] for expedited research approved under the 2018 Requirements in cases where the IRB no longer is required to conduct CR?

Response:

- No. Research not requiring continuing review by an IRB is still overseen by the IRB and would not require continuing review by the R&D Committee unless required by local policy.

Continuing Review: R&D Committee Responsibilities

Q23: Will the R&D Committee be required to conduct CR for exempt research approved under both the current and the Revised Common Rule?

Response:

- ORD cannot yet comment on the revision of VHA Directive 1200.01, but current ORD policy in VHA Directive 1200.01 requires that the R&D Committee is the oversight committee for any research not overseen by another committee (VHA Handbook 1200.01, Paragraph 10(c)). The R&D Committee conducts continuing review if the research is not assigned to another committee.

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.



The Revised Common Rule and FDA Regulated Research

The Revised Common Rule and FDA-Regulated Research

- FDA-Regulated Clinical Investigations conducted at the VA are subject to both the Common Rule and FDA Regulations.
- In cases where the regulations differ, the regulations that offer the greater protection to human subjects should be followed.
- FDA recently issued a new guidance document titled, “Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations”:
<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM623211.pdf>
- FDA intends to undertake rule making to harmonize, to the extent practicable, with the 2018 Requirements. In the meantime, the guidance document clarifies the impact of certain provisions of the 2018 Requirements on FDA-regulated clinical investigations

Impact of Certain Provisions of the 2018 Requirements on FDA-Regulated Research

- Informed Consent
 - FDA-regulated research can use the same informed consent form template and processes as research subject to the 2018 Requirements
 - 2018 Requirements related to the content, organization, and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent are not inconsistent with FDA's current policies and guidance.
 - Note, no reference is made to allow use of the Broad Consent Provisions for FDA-regulated research.
- Expedited Review
 - FDA-regulated research approved on or after January 21, 2019 must continue to comply with the current requirements for expedited review.
- Continuing Review
 - FDA-regulated research must continue to undergo continuing review at intervals appropriate to the degree of risk, but not less than once per year.

Resources

Resources: Educational Opportunities

Q24: Where can we find links to the previous cyberseminars?

Resources:

- ORD-led Cyberseminars
<https://www.research.va.gov/pride/cyberseminars/default.cfm>
- ORO-led Cyberseminars
 - 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>
 - Exempt and Limited IRB Review:
<https://www.gotostage.com/channel/380fe4c2ab964476b715ed7446f60d23/recording/6b6d0e1b4e1d486892d7e0bd44846a85/watch?source=CHANNEL>

Resources: Primr

Q25: Will the PRIM&R conference include any VA sessions beyond lunch with the VA on the first day?

Response:

- ORD and ORO will be leading a joint session on November 15, 2018 from 11:45 a.m. to 1:00 p.m.: A Dialogue with the VA.
- Additionally, ORD and ORO will be hosting office hours on November 16, 2018 at 4:30 p.m.
- Separately, ORO is leading a pre-conference for RCOs on November 14, 2018.

Resources: Tools and Templates

Q26: Will anyone be submitting a revised Informed Consent Document Checklist that will include the identified changes that the field can use when reviewing the ICD for the IRB?

Response:

Please review ORD's September cyberseminar on the Overview of the Revised Common Rule. Slide 39, "General Requirements of Informed Consent" outlines the differences in the Common Rule elements under the pre-2018 Requirements and the 2018 Requirements and can be used to create a checklist.

Resources: Tools and Templates

Q27: Will ORD/ORO develop some sample protocol templates that could be used by investigators that include the information needed for exempt research?

Response:

ORD and ORO are not working on protocol templates because protocols vary greatly among the different exempt categories. However, we are working on guidance documents for the exempt categories.

Open Q&A Session

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	Q&A Session on the Revised Common Rule	ORD/ORO
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