
Petrice B. Longenecker, MA, PhD, CIP
Senior Regulatory Affairs Officer, PRIDE
June 27, 2018 and July 2, 2018
Important Links

• Final Rule for the Delay (published June 19, 2018)

• Revised Common Rule (published January 19, 2017)

• Current Common Rule

• VHA Handbook 1200.05
Objectives

• Discuss the Final Rule’s delay of the compliance date of the revised Common Rule to January 21, 2019

• Discuss the three burden-reducing provisions described in the Final Rule

• Identify which burden-reducing provisions can be used for VA research and describe considerations for use in VA research
Final Rule for Delay of Revised Common Rule

On June 19, 2018, VA along with 16 other Federal Agencies and Departments issued a Final Rule published by the Office of the Federal Register to:

- delay general compliance date of revised Common Rule (2018 Requirements) to January 21, 2019, and

- allow institutions to implement three burden-reducing provisions starting July 19, 2018.
Background on Common Rule

- The Federal Policy for the Protection of Human Subjects is usually referred to as the “Common Rule”.

- The Common Rule is the Federal regulation Federally funded research must follow if it involves human subjects research.

- Office for Human Research Protections (OHRP) within HHS interprets the Common Rule for HHS and issues Federalwide Assurances (FWAs).

- All non-exempt human subjects research conducted by VA must currently comply with the Common Rule as operationalized by ORD policies in VHA Handbook 1200.05.

- ORD interprets the Common Rule for VA, and ORO has compliance oversight of the Common Rule for VA.
• Does not effect cooperative research provision (single IRB) – compliance date remains January 20, 2020.
What Do We Do in VA Research for the Common Rule Until January 21, 2019?

- Continue to use the pre-2018 Requirements (e.g., the current Common Rule) for all VA research involving non-exempt human subject activities;

- Continue to use VHA Handbook 1200.05 for VA research
  - Major revision is in process for compliance with the revised Common Rule 2018 Requirements for January 2019;

- Follow your VA Facility’s human research protection program standard operating policies and procedures (SOPs) and IRB of Record’s SOPs unless a modification is required because of use of the burden-reducing provisions.
Delay & the Burden-Reducing Provisions

The delay of the general compliance date for the revision of the Common Rule to January 21, 2019 allows for the implementation of three-burden reducing provisions starting July 19, 2018.
Three Burden-Reducing Provisions

Provision #1: Revision to the definition of research such that certain activities are deemed not to be research

Provision #2: Elimination of the requirement that an IRB review the grant or research application or contract proposal

Provision #3: Elimination of continuing IRB review for certain non-exempt human subjects research for certain categories of research
Provisions #3: Eliminating Continuing Review For Certain Categories of Research

Elimination of continuing IRB review for certain non-exempt human subjects research in the following circumstances (§__.109(f)(1)(i) and (iii)):

- Research eligible for expedited review in accordance with the expedited review categories
- Research that has progressed to the point that it involves only:
  - Data analysis, including identifiable data/biospecimens, or
  - Accessing follow-up clinical data

*Provision CANNOT be implemented for VA research before January 21, 2019*
Burden-Reducing Provisions – Not Allowed

• VA Research may not eliminate continuing review (Provision 3).

• VHA Handbook 1200.05, Paragraph 8 requires IRB review no less than annually.

• Provision can only start on January 21, 2019 with newly approved research or studies that transition.
Burden-Reducing Provisions & VA Research

- VA Research may implement two provisions:
  - Provision 1 - Definition of research
  - Provision 2 - Eliminating IRB review of application/proposal

- Starting **July 19, 2018**, ahead of general compliance date

- Institutions can decide individually to implement per study
  - Documentation required by:
    - Medical Center Director or ACOS/R&D, and
    - IRB of Record
Utilizing One of the Burden-Reducing Provisions?

- Those studies **automatically transition** to 2018 Requirements on January 21, 2019 and must comply with all of the 2018 Requirements.

- Documentation is critical
  - Document institution’s decision
  - Document impacted studies
Provision #1
Activities Deemed Not Research

Revision to the definition of research such that certain activities are deemed not to be research (§__.102(l)):

1. Scholarly and journalistic activities
2. Public health surveillance activities
3. Activities for criminal justice purposes by law or court order
4. Activities in support of intelligence, homeland security, defense or other national security missions
Definition of Research

**Current definition**

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

**Revised definition**

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Because this was a legal document, the revised definition might include more specific language and be more precise in its definitions to ensure clarity and consistency.
Provision 1: Activities Deemed Not Research For Institutions, IRBs & Investigators

- VHA does not currently recognize these activities as research under the Common Rule, unless a component of larger study.

- If using the provision, SOPs will have to reflect revision for clarification of these 4 activities.

- VHA Handbook 1200.05 will be updated as part of its major revision of compliance with the 2018 Requirements, but this provision does not contradict what is considered (or not) to be research under either the current or revised Common Rule.
Provision #2: Eliminating IRB Review of Federally Funded Grants

2. Elimination of the requirement that an IRB review the grant or research application or contract proposal (§__.103(d))

Certification of IRB approval will no longer require the IRB to review the grant application, however certification must be submitted as required by the Federal Sponsor of the research.
Certification

Associate Chief of Staff for Research (ACOS/R) Just-In-Time (JIT) Assurance Document

PI Name: [Redacted]
Project Title: [Redacted]
Station Number: 663
Station Location: Seattle, WA

The ACOS/R is responsible for signing the completed assurance form. No other supporting documentation for these two requirements (Committee Review and Eligibility Verification) is needed unless indicated.

A. Committee Reviews. Please fill in the date of R&D Committee approval and check whether subcommittee reviews are complete or not applicable (N/A) for this project.

<table>
<thead>
<tr>
<th>R&amp;D Committee</th>
<th>Approval Date: 7/12/18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcommittee Reviews</td>
<td></td>
</tr>
<tr>
<td>IRB Review</td>
<td>Complete</td>
</tr>
<tr>
<td>IACUC Review</td>
<td>Complete</td>
</tr>
<tr>
<td>SRG and/or IBC Review of Research Protocol Safety Survey Form10-0308</td>
<td>Complete</td>
</tr>
<tr>
<td>...</td>
<td>Complete</td>
</tr>
</tbody>
</table>

Determination that the study does not include safety hazards: Complete

B. Verification that PI is eligible to receive research funding. Please check one box below.

- [x] PI is eligible to receive funds due to a current 5/8th or greater VA paid appointment
- [ ] PI is eligible to receive funds due to an ORD-issued waiver from the 5/8th or greater VA paid appointment
- [ ] PI will be eligible to receive funds once VA hiring or promotion action is complete. Project start date will not be set until PI is hired*

Reminder: Contract employees are not eligible to serve as PI on VA funded projects.

C. By signing this ACOS/R JIT Assurance Document, I am affirming that all VA requirements regarding the conduct of research in VA for this study will be met, training requirements for all research staff are completed, and that records will be maintained in accordance with VA requirements for research.

Signature of ACOS/R&D: ___________________________ Date: 7/12/18

Printed Name: ___________________________

*Note: Once all JIT requirements are met, a system generated email will request the project start date from the station, which will be confirmed by the Research Services funding the project.
Provision 2: Eliminating IRB Review of Federally Funded Grants

- Individual VA sites can choose to implement provision starting July 19, 2018

- Decide per study; determine criteria

- Each individual study must have separate documentation that the IRB has not reviewed the grant application

- Update SOPs

- Inform investigators
Provision 2: Eliminating IRB Review of Grants
General Considerations for VA Facilities

- Does provision reduce burden for particular study?

- Study may need to be re-reviewed in January 2019 to comply with 2018 Requirements if not reviewed according to the 2018 Requirements.

- Consent documents must be revised if the consent form did not meet the 2018 Requirements and subject enrollment continues past January 21, 2019.

- Previously-consented subjects may need to be re-consented if the study is still enrolling as of January 21, 2019 and the informed consent did not meet the 2018 Requirements.

- Coordinate with affiliated institutions, funding agencies, and/or IRBs of Record on issues related to IRB elimination of grant review.
Provision 2: Eliminating IRB Review of Grants
Considerations For Institutions & IRBs

- Individual VA Facility must decide whether to allow elimination of grant review; coordinate with applicable stakeholders (e.g., funding agency, IRB of Record)

- Update SOPs, if needed

- Inform investigators and affiliated institutions of decision to use (or not) Provision #2

- Documentation by IRB and Medical Center Director or ACOS/R&D for studies “earmarked” to transition if using Provision #2
Suggested language to add to letters for studies that utilize the burden-reducing provision of elimination of IRB review of the grant application or contract proposal to document a study that must transition to the revised Common Rule:

The IRB review of this study was conducted without review of the grant application or contract proposal, therefore, as of January 21, 2019, this study must comply with all the 2018 requirements of the Federal Policy for the Protection of Human Subjects (38 CFR 16).
Provision 2: Eliminating IRB Review of Grants
Considerations For Investigators

• Determine what your VA Facility has decided for reviewing grant applications per study

• Determine whether the Federal agency or Department funding the grant is allowing use

• Determine whether or not you will need to submit the grant application for IRB review (if not, mark it as automatically transitioning)
### Which to Transition to 2018 Requirements

<table>
<thead>
<tr>
<th>Possible Consideration</th>
<th>Discourage Consideration or Not Possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Studies that will complete enrollment before January 21, 2019</td>
<td>• Studies that will continue to enroll subjects after January 21, 2019</td>
</tr>
<tr>
<td>• Studies with a waiver of consent</td>
<td>• Studies that are non-exempt as of July 19, 2018 and will be exempt as of January 21, 2019</td>
</tr>
<tr>
<td></td>
<td>• FDA regulated</td>
</tr>
<tr>
<td></td>
<td>• IRB, Institution, and/or Federal Agency does not Permit</td>
</tr>
</tbody>
</table>

Will it reduce the burden of the study to not review the grant application and transition it to the 2018 Requirements?
Provision 2: Eliminating IRB Review of Grants

Example

ORD has funded a merit award that has been awarded to Investigator “Y” at VA Facility X. The ACOS/R&D had decided to allow use of Provision 2 for this ORD-funded non-exempt human subjects study.

A. The IRB of Record for the study agrees to allow it and modifies its SOPs.

B. When the IRB approves the study, the IRB documents in its approval letter that the study must transition to all of the 2018 Requirements as of January 21, 2019.

C. The VA R&D Committee approves the study; notifies the investigator that the study may be initiated because all of the applicable committee and subcommittee approvals have been obtained (VHA Handbook 1200.01, Para. 4(d)).

D. As part of the Just-In-Time Requirements, the ACOS/R&D submits an assurance document that serves the purpose of certifying to the specific ORD funding service that the non-exempt human subjects study has been reviewed and approved by the IRB. The ACOS documents that this study must transition to all of the 2018 Requirements.
• VA Central IRB has decided to not implement the provisions ahead of January 21, 2019 general compliance date

• Maintain current SOPs and practices
• On-going research must comply with pre-2018 Requirements

• New and newly approved research must comply with 2018 Requirements (based on date of IRB approval)

• Studies that took advantage of burden-reducing provisions early must comply with 2018 Requirements

• Existing studies can transition to 2018 Requirements, if appropriate
### VA Research’s Implementation of Final Rule Permitting Institutions to Utilize Three-Burden Reducing Provisions in the Revised Common Rule Prior to January 21, 2019

<table>
<thead>
<tr>
<th>Burden-Reducing Provision</th>
<th>Allowed by Current ORD Policies</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| 1. Revision to definition of research such that certain activities are not considered research | Yes, current practice | • Document decision to use  
• May need to update SOPs |
| 2. Eliminate IRB review of grant application | Yes | • Document decision to use  
• Update SOPs  
• Document studies using provision  
• Studies must transition to all 2018 Requirements on Jan. 21, 2019  
• Communicate with investigators |
| 3. Eliminate continuing IRB review for certain research | No | • VHA Handbook 1200.05, Paragraph 8 requires continuing review no less than once annually |
### ORD/ORO Collaborative Training on the Revised Common Rule: Tentative Schedule

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Lead Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-Jan-18</td>
<td>Records Management</td>
<td>ORD</td>
</tr>
<tr>
<td>20-Feb-18</td>
<td>Engagement in Human Subjects Research</td>
<td>ORD</td>
</tr>
<tr>
<td>20-Mar-18</td>
<td>MyhealtheVet and Secure Messaging</td>
<td>ORD</td>
</tr>
<tr>
<td>24-Apr-18</td>
<td>Continuing Review</td>
<td>ORD</td>
</tr>
<tr>
<td>15-May-18</td>
<td>Expedited Review</td>
<td>ORD</td>
</tr>
<tr>
<td>16-May-18</td>
<td>Overview of the Revised Common Rule</td>
<td>ORO</td>
</tr>
<tr>
<td>19-Jun-18</td>
<td>Working with the VA CIRB</td>
<td>ORD</td>
</tr>
<tr>
<td>17-Jul-18</td>
<td>Waivers: Common Rule, Privacy Rule, and FDA Regulations</td>
<td>ORD</td>
</tr>
<tr>
<td>18-Jul-18</td>
<td>Informed Consent: ICFs; Broad Consent; and Posting of ICFs</td>
<td>ORO</td>
</tr>
<tr>
<td>18-Sep-18</td>
<td>Myth Busters: Common Misperceptions re. VA Research</td>
<td>ORD</td>
</tr>
<tr>
<td>19-Sep-18</td>
<td>Exempt Review and Limited IRB Review</td>
<td>ORO</td>
</tr>
<tr>
<td>16-Oct-18</td>
<td>Transition Provisions and Overview of the revised VHA Handbook 1200.05</td>
<td>ORD</td>
</tr>
<tr>
<td>20-Nov-18</td>
<td>In-depth Focus on the revised VHA Handbook 1200.05</td>
<td>ORD</td>
</tr>
<tr>
<td>21-Nov-18</td>
<td>External IRBs and FWAs</td>
<td>ORO</td>
</tr>
<tr>
<td>18-Dec-18</td>
<td>In-depth Focus on the revised VHA Handbook 1200.05</td>
<td>ORD</td>
</tr>
</tbody>
</table>
Questions?

TWO DATES to REMEMBER:

• July 19, 2018 – can start to implement Provision 1 (revised definition of research) and Provision 2 (elimination of IRB review of the grant application)

• January 21, 2019 – general compliance date of revised 2018 Common Rule

Contact
Petrice Longenecker, PhD
Sr. Regulatory Affairs Officer, PRIDE
Petrice.Longenecker@va.gov
• Questions: vhacoORDregulatory@va.gov
• Website: http://www.research.va.gov/PRIDE/