



**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

**ORD GUIDANCE ON THE FINAL RULE FOR THE FEDERAL POLICY FOR THE
PROTECTION OF HUMAN SUBJECTS:
SIX MONTH DELAY OF THE GENERAL COMPLIANCE DATE WHILE ALLOWING THE USE
OF TWO BURDEN-REDUCING PROVISIONS DURING THE DELAY PERIOD**

Date: July 27, 2018

This is a new guidance document.

For questions on the content of this guidance, email the VHA Office of Research and Development at vhacoordregulatory@va.gov.

BACKGROUND: On January 19, 2017, the Department of Health and Human Service (HHS) and fifteen other federal agencies and departments published a Final Rule revising the Federal Policy for the Protection of Human Subjects (“revised Common Rule”) with an effective and compliance date of January 19, 2018, herein referred to as the 2018 Requirements. The 2018 Requirements represents a significant revision of the Federal Policy for the Protection of Human Subjects. An Interim Final Rule (IFR) was published on January 22, 2018, to delay the effective and compliance date of the 2018 Requirements to July 19, 2018. It also stated that the federal departments and agencies listed in the IFR were in the process of developing a notice of proposed rulemaking (NPRM) seeking public comment on a proposal for further delay in the required implementation of the revised Common Rule. This delay would allow the regulated research community additional time to prepare for successful implementation of the 2018 Requirements. The NPRM was published on April 20, 2018.

On June 19, 2018, HHS and sixteen other federal agencies and departments published a final rule to further delay the general compliance date of the 2018 Requirements to January 21, 2019, but to allow the optional implementation of three burden-reducing provisions ahead of this general compliance date, effective July 19, 2018.

SCOPE: The following guidance is issued to assist the VA research community and the Institutional Review Boards (IRBs) reviewing VA research by explaining how some of the burden-reducing provisions can be applied to VA research. This guidance applies to all non-exempt human subjects research conducted or supported by the VA. The Final Rule issued on June 19, 2018, extends the general compliance date for the 2018 Requirements to January 21, 2019, while allowing the implementation of three burden-reducing provisions as of July 19, 2018. Institutions, VA Research and Development Committees, and Institutional Review Boards (IRBs) reviewing VA human subjects research must be knowledgeable about issues impacting whether the burden-reducing provisions can be implemented with VA research ahead of the general compliance date. ORD offers guidance on the following questions:

1. How does the delay in the general compliance date of the 2018 Requirement impact VA research?
2. Will the final rule effective on July 19, 2018, delaying the general compliance date of the 2018 Requirements also delay the compliance date of the cooperative research provision?
3. What are the three-burden reducing provisions allowed to be implemented on July 19, 2018 by the Final Rule?
4. Can all three-burden reducing provisions apply to VA research activities as of July 19, 2018?
5. Is an IRB or institution required to use the burden-reducing provisions as of July 19, 2018, for applicable activities?
6. Who documents whether or not a VA study has taken advantage of one of the burden-reducing provisions in the final rule effective on July 19, 2018?
7. Is there a possibility that VHA Handbook 1200.05's policies regarding continuing review may change prior to January 21, 2019, to allow for the elimination of continuing review for certain categories of research (§ 38.109(f)(1)(i) and (iii))?
8. How does the revised definition of research in the Final Rule, effective on July 19, 2018, impact the VA?
9. Do studies that take advantage of elimination of IRB review of grant or contract proposals prior to January 21, 2019, have to comply with the 2018 requirements on January 21, 2019?
10. If a determination is made and documented for a federally supported VA study to take advantage of the use of the burden-reducing provision to eliminate IRB review of the grant application, is a grant review required by the VA R&D Committee?
11. What are the general institutional or IRB responsibilities if the decision is made to allow use of the burden-reducing provisions permitted by ORD?
12. How should the Associate Chief of Staff for Research and Development (ACOS/R&D) or IRB document that a study has utilized one of the burden-reducing provisions?

1. HOW DOES THE DELAY IN THE GENERAL COMPLIANCE DATE OF THE 2018 REQUIREMENT IMPACT VA RESEARCH?

The delay of the general compliance date of the 2018 Requirements of the revised Common Rule does not negatively impact ongoing VA research involving human subjects. It provides additional time for VA human research protection programs and the IRBs serving as IRBs of Record to prepare for implementing the 2018 Requirements. Until January 21, 2019, human subjects research must comply with the pre-2018 Common Rule requirements. All non-exempt VA human subjects research must be reviewed by the IRB in accordance with the current

Common Rule unless a study utilizes the burden-reducing provision eliminating IRB review of the grant application or contract proposal. Implementing the burden-reducing provision that deems certain activities not to be research does not impact VA research because those four (4) activities currently do not meet the definition of research involving human subjects under the pre-2018 Requirements.

2. WILL THE FINAL RULE EFFECTIVE ON JULY 19 2018, DELAYING THE GENERAL COMPLIANCE DATE OF THE 2018 REQUIREMENTS ALSO DELAY THE COMPLIANCE DATE OF THE COOPERATIVE RESEARCH PROVISION?

The compliance date of the cooperative research provision (use of a single IRB for most multi-site research) described in the 2018 Requirements at §__.102 remains unchanged, i.e., January 20, 2020.

3. WHAT ARE THE THREE-BURDEN REDUCING PROVISIONS ALLOWED TO BE IMPLEMENTED ON JULY 19, 2018 BY THE FINAL RULE?

The Final Rule issued on June 19, 2018, delays the compliance date of the 2018 Requirements to January 21, 2019, while allowing the implementation of three burden-reducing provisions effective on July 19, 2018. The three burden-reducing provisions are as follows:

- (1) the 2018 Requirements' definition of "research" at §__.102(l), which deems certain activities not to be research,
- (2) the elimination of the requirement that an IRB review the grant application related to the research at §__.103(d) of the 2018 Requirements, and
- (3) the allowance for no annual continuing review of certain categories of research at §__.109(f)(1)(i) and (iii) of the 2018 Requirements.

Revised definition of "research" (§__.102(l))

The 2018 Requirements does not change the definition of research but specifies four areas of activities that are deemed not to be research for the purposes of the Common Rule. At §__.102(l), the 2018 Requirements clarify that the following activities are deemed not to be research:

(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, onsets of disease 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.

Elimination of the requirement that an IRB review the grant application (at §__.103(d))

At §__.103(d) of the 2018 Requirements, IRBs are no longer required to review the grant application or contract proposal when reviewing the study protocol and other related IRB materials.

Elimination of continuing review for certain categories of research (§__.109(f)(1)(i) and (iii))

The pre-2018 Requirements require IRB review and approval no less than annually for all non-exempt human subjects research subject to the Federal Policy for the Protection of Human Subjects. In VA, all non-exempt human subjects research is subject to the Federal Policy for the Protection of Human Subjects. The 2018 Requirements identify certain categories of research that will no longer require continuing IRB review after the initial IRB approval.

Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

- research eligible for expedited review in accordance with the expedited review categories; and
- research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - (A) data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - (B) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

4. CAN ALL THREE-BURDEN REDUCING PROVISIONS APPLY TO VA RESEARCH ACTIVITIES AS OF JULY 19, 2018?

No, VHA cannot implement all three-burden reducing provisions as of July 19, 2018. VA non-exempt human subjects research cannot currently utilize the burden-reducing provision for elimination of continuing review for certain categories of research as part of the three-burden reducing provisions. ORD policy in VHA Handbook 1200.05, § 8.e requires that the IRB conduct continuing review of all VA non-exempt human subjects research at intervals appropriate to the degree of risk, but no less than once per year. ORD requires that continuing review by the IRB of Record must continue for all VA non-exempt human subjects research must continue until January 21, 2019, including studies relying on an external IRB.

VHA can implement the updated definition of research that deems certain activities not to be research as this does not differ from VA's current policy. VHA can also implement the discontinuation of the IRB review of the grant application or contract proposal as discussed below.

5. IS AN IRB OR INSTITUTION REQUIRED TO USE THE BURDEN-REDUCING PROVISIONS AS OF JULY 19, 2018, FOR APPLICABLE ACTIVITIES?

No. An IRB or individual institution may elect to use the revised definition to clarify that certain activities are not considered research under the Common Rule or choose to discontinue IRB review of the grant application or contract proposal. If an institution or IRB decides to discontinue the IRB review of the grant application or contract proposal, ORD recommends that the decision be made on a study-by-study basis rather than a decision applicable to all studies. ORD's recommendation is based upon the consideration that studies that use the provision will be automatically to transition to all of the 2018 Requirements on January 21, 2019. The decision to use the provision and thus transition a study should be made with the consideration of whether use of the provision ultimately reduces the burden.

If a study is reviewed by the IRB without review of the grant or contract as of July 19, 2018, there should be clear documentation of that decision. The IRB should maintain appropriate records to track those studies that are reviewed using this burden-reducing provision prior to January 21, 2019, as these studies will be required to transition to all of the 2018 Requirements on January 21, 2019.

Studies approved by the IRB prior to January 21, 2019 and that do not use the provision must continue to comply with the pre-2018 Requirements unless specifically transitioned to the 2018 Requirements after January 21, 2019. ORD also wishes to reinforce that there is no ORD policy requirement to transition any non-exempt VA human subjects study approved prior to January 21, 2019 to the 2018 Requirements, even after January 21, 2019.

6. WHO DOCUMENTS WHETHER OR NOT A VA STUDY HAS TAKEN ADVANTAGE OF ONE OF THE BURDEN-REDUCING PROVISIONS IN THE FINAL RULE EFFECTIVE ON JULY 19, 2018?

ORD recommends that documentation of an institution's decision to implement and apply the permitted burden-reducing provisions should be made by the IRB and the institutional official who has the authority to make the determinations on behalf of the institution. For research subject to IRB approval, the IRB should document as described in standard operating policies and procedures when it utilizes the burden-reducing provision so that it is clear that the study must transition and comply with all of the 2018 Requirements on January 21, 2019.

7. IS THERE A POSSIBILITY THAT VHA HANDBOOK 1200.05'S POLICIES REGARDING CONTINUING REVIEW MAY CHANGE PRIOR TO JANUARY 21, 2019, TO ALLOW ELIMINATION OF CONTINUING REVIEW FOR CERTAIN CATEGORIES OF RESEARCH (§ 38.109(f)(1)(I) AND (III))?

No. There is no plan to amend VHA Handbook 1200.05 for the sole purpose of allowing elimination of continuing review for certain categories of research ((§ 38.109(f)(1)(I) and (III)). VHA Handbook 1200.05 is currently undergoing a major revision to incorporate the 2018 Requirements.

8. HOW DOES THE REVISED DEFINITION OF RESEARCH IN THE FINAL RULE, EFFECTIVE ON JULY 19, 2018, IMPACT THE VA?

The specific exclusion of the activities deemed not to be research does not impact VA research activities. These activities were already not considered to be research by VA.

9. DO STUDIES THAT TAKE ADVANTAGE OF ELIMINATION OF IRB REVIEW OF GRANT OR CONTRACT PROPOSALS PRIOR TO JANUARY 21, 2019, HAVE TO COMPLY WITH THE 2018 REQUIREMENTS ON JANUARY 21, 2019?

Yes. Individual studies that are reviewed by the IRB prior to January 21, 2019, without reviewing the grant application or contract proposal (burden-reducing provision at §__.103(d)) must be in compliance with all other requirements of the current pre-2018 Requirements but must automatically transition to all of the 2018 Requirements on January 21, 2019. This impacts key issues for the approved study, such as the informed consent document, if applicable. For example, Study A is to be reviewed by the IRB between July 19, 2018, and January 20, 2019, and the IRB decides not to review the grant application with the protocol. At the time of IRB review, Study A must comply with the pre-2018 Requirements for the general requirements for informed consent found at §46.116. The PI writes the consent form in accordance with current practices and standards. On January 21, 2019, Study A will automatically transition to the 2018 Requirements and thus must comply with all of the 2018 Requirements, including the general requirements for informed consent at §46.116 in the revised Common Rule. There may be significant differences in the requirements for informed consent for Study A. If the PI neglects to update the consent form, Study A may be out of compliance with the 2018 Common Rule.

IRBs should have a plan to track all studies that implement the allowable burden-reducing provisions and a plan to transition those studies to the 2018 Requirements on January 21, 2019. Those studies may need to be re-reviewed to determine if they are in compliance with the 2018 Requirements.

Investigators should be made aware of the institution's decision to discontinue the IRB review of the grant application or contract proposal and whether it is done for all non-exempt human subjects research or a decision made per study. For institutions that decide to discontinue the IRB review of the grant application, ORD recommends that the investigator make the applications available upon request.

10. IF A DETERMINATION IS MADE AND DOCUMENTED FOR A FEDERALLY SUPPORTED VA STUDY TO TAKE ADVANTAGE OF THE USE OF THE BURDEN-REDUCING PROVISION TO ELIMINATE IRB REVIEW OF THE GRANT APPLICATION, IS A GRANT REVIEW REQUIRED BY THE VA R&D COMMITTEE?

No. There is no VA policy that requires the R&D Committee to review the grant application or contract proposal. However, if this is the standard practice at a local VA Medical Center, then it can continue.

11. WHAT ARE THE GENERAL INSTITUTIONAL OR IRB RESPONSIBILITIES IF THE DECISION IS MADE TO ALLOW USE OF THE BURDEN-REDUCING PROVISIONS PERMITTED BY ORD?

These are ORD's recommendations of general responsibilities of VA Facilities and IRBs if a decision is made to utilize the burden-reducing provisions after July 19, 2018. ORD wishes to reinforce that it is optional to utilize the burden-reducing provisions. There is no requirement by ORD or the regulations to utilize the burden-reducing provisions.

- **Document** – The institutional official, either the Medical Center Director or the ACOS/R&D, should document the institution’s decision to implement and apply the burden-reducing provisions. IRBs should also document which individual studies will make use of the burden-reducing provision and therefore must transition to all of the 2018 Requirements on January 21, 2019.
- **Update SOPs** – IRBs will need to update or revise their standard operating procedures to allow for the elimination of the IRB review of the grant application or contract proposal.
- **Plan** – IRBs should determine a plan for transitioning ongoing studies reviewed using the burden-reducing provision from the pre-2018 Requirements to the 2018 Requirements. This plan should become part of a new or updated standard operating procedure by January 21, 2019.
- **Communicate** – IRBs and/or the VA institutional officials (Medical Center Director, ACOS/R&D) should ensure that all applicable individuals and groups within the VA Facility’s Human Research Protection Program are aware of whether the burden-reducing provision eliminating the IRB review of the grant application or contract proposal will be utilized, either for all protocols or on a protocol-specific basis.

12. HOW SHOULD THE ASSOCIATE CHIEF OF STAFF FOR RESEARCH AND DEVELOPMENT (ACOS/R&D) OR IRB DOCUMENT THAT A STUDY HAS UTILIZED ONE OF THE BURDEN-REDUCING PROVISIONS?

The Final Rule does not dictate a specific manner. ORD recommends that standard language be added to the IRB letter for the approval of the non-exempt study and/or the ACOS letter to the investigator notifying the investigator that the research may be initiated to identify and communicate which studies must transition on January 21, 2019. For example:

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.