Thinking Points:
The Pros and Cons of Implementing the 'Three Less-Burdensome Provisions'

On June 19, 2018, HHS formally delayed the general compliance date of the revised Common Rule to January 21, 2019. Within the rule formalizing the delay, three 'less burdensome' provisions were included that institutions 'may' choose to apply in the interval from July 19, 2018 through January 20, 2019.

Institutions must pay attention to the details of the effective/compliance dates as well as the domino effect associated with implementing the three provisions. Examples of this domino effect are addressed in this document.

Below are some thinking points for institutions considering whether to implement these provisions.

Studies that do <u>NOT</u> have to comply with the revised Common Rule on January 21, 2019

- Studies that were approved or determined exempt **prior to** January 21, 2019.
- Studies that are not subject to the Common Rule (i.e., not conducted or supported by a Common Rule department or agency) when an institution has adopted flexibility and does not commit to apply the Common Rule to all research.

Studies that <u>DO</u> have to comply with the revised Common Rule on January 21, 2019

- Studies that are subject to the Common Rule (whether due to support or organization policy) and for which any of the following apply:
  - Studies **approved or determined exempt on or after** January 21, 2019
  - Studies that were **transitioned to the new rule** between July 19, 2018 and January 20, 2019 by implementing the three available 'burden-reducing' provisions:
    a) Definition of research, although the core definition is unchanged ('a systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge'), has an addition to it:

'For purposes of this part, the following activities are deemed not to be research:

(i) Scholarly and journalistic activities; see ___.102(l)(1) of the new rule for details

(ii) Public health surveillance activities; see ___.102(l)(2) of the new rule for details

(iii) 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; ___.102(l)(3)

(iv) Authorized operational activities (as determined by each agency (in support of intelligence, homeland security, defense, or other national security missions' ___.102(l)(4)

b) Revised certification requirement that **eliminates IRB review of the (grant) application or proposal** (see ___.103 [d] for details)

c) Exceptions to mandated **continuing review**; see ___.109(f)(1)(i) and (iii) of the new rule, specifically:

Research eligible for expedited review in accordance with ___.110; and

Research that has progressed to the point that it involves only one or both of the following, which is part of the IRB-approved study:

- Data analysis, including analysis of identifiable private information or identifiable biospecimens or
- Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

Please note:

Although the revised Rule presents these three provisions as a 'package,' an institution can adopt a more stringent standard for any or all of the provisions in its SOPs. For example, an institution could establish a requirement for continuing review even when not required under the revised Common Rule as institutional policy.

PROS AND CONS OF ADOPTING THE PROVISIONS

***a) Revised definition of research*:**

Pros: Alleviation of burden for investigators, IRB staff and IRB members. The revised definition provides direction where there was subjectivity previously for certain activities.

Cons: Without guidance, institutions and investigators may not have a clear understanding of the intended scope and parameters for each excluded activity.

Consideration: The modified definition formalizes OHRP's position that certain activities are not research. Theoretically, the activities deemed 'not research' in the new definition should not be considered research today so long as the research is fully consistent with the descriptor and constraints outlined for each activity in the revised rule. As an alternative to adopting the revised definition of research prior to January 21, 2019, institutions could supplement their current materials and tools to list these activities as examples of activities that are not research but delay modifying the actual definition of research until the rule goes into effect.

b) Revised certification requirement that eliminates IRB review of the (grant) application or proposal:

Pros: The burden is removed from the IRB to ensure congruence between the grant and the IRB materials.

Cons: Who will ensure congruency? The institution still needs, in some manner, to ensure that the actual research is consistent with what the grantor approved and that all human subject activities have been reviewed and approved by the IRB. Who will ensure that IRB approval is in place before funds are expended or that consent forms are consistent with the information outlined in the grant (e.g., risks, benefits, procedures, payments to subjects, etc.)? Although the onus can be on the investigator, bias and motivation to move the research forward quickly are concerns. Ultimately the institution is accountable for compliance with the terms of a grant, as the institution is the award recipient. Removal of the congruency review as an IRB responsibility may impact other offices within an organization (e.g., when those offices may have to pick up additional responsibilities or modify their processes).

c) Exceptions to mandated continuing review:

Pros: Alleviation of burden for investigators, IRB staff and IRB members.

Cons: The institution is still responsible for the oversight and conduct of research being conducted under the auspices of the institution. Alternative mechanisms may need to be put into place to ensure ongoing knowledge of research activities the organization is engaged in and responsible oversight of research.

How will institutions know which studies are still active for:

- Post-approval monitoring
- Providing an accurate list of protocols, including status, to a regulatory or accrediting body if requested
- Internal reporting and metrics
- Internal recordkeeping purposes (e.g., will studies remain open in an electronic system for an indefinite period of time?)?

Without the reminder of continuing review, will investigators forget or overlook their other reporting responsibilities? Will they monitor the literature and report when new information has become available that suggests the risks or benefits are different than previously understood? That another study or studies have been published that alter the merit or relevance of the research? Will they report study closure?

Other Considerations:

If an institution decides to apply the three less-burdensome provisions, this means that the study(s) **MUST** be transitioned to comply with the revised Common Rule **in its entirety** on January 21, 2019. The only additional aspects of the revised rule that may be applied prior to January 21, 2019 are those that do not conflict with the current rule. But, per Dr. Jerry Menikoff, the Director of OHRP at the July SACHRP meeting, institutions should be cautious about early implementation because revisions may need to be made once guidance is issued.

Processes and therefore SOPs, submission forms, reviewer checklists, etc. must be updated for the period of time in which only the three provisions are being implemented. Materials would then need to be updated again for the full compliance with the revised rule effective January 21, 2019.

The decision whether to adopt the provisions is an institutional decision. The decision may be for all studies, a subset of studies (e.g., all minimal risk studies), or on a study-by-study basis. The institutional decision must be documented and dated by either appropriate institutional officials or the IRB. The date the decision is documented becomes the de facto compliance date (per an OHRP representative attending the SACHRP meeting July 10-11, 2018.)

All studies under the new provisions (one or all) must be tracked and steps taken to ensure compliance with all other applicable provisions of the revised rule **ON** January 21, 2019 (not even a day after, and not implementing anything that conflicts with the current rule prior to that date).

Compliance with the revised rule means that these studies will need to be re-reviewed, for example:

- To determine whether the study now qualifies for or no longer qualifies for exemption
- When consent is being obtained, to determine whether the new requirements for informed consent (process, elements, and documentation) are satisfied

- To determine whether a study is a clinical trial according to the definition in the revised rule (the revised rule includes a requirement for posting clinical trial consent forms to a 'to be determined' public website)
- To determine whether previously granted waivers of consent are still permissible (the revised rule contains an additional criterion: '(iii) If the research involves using identifiable private information or biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format')
- To determine whether the new criterion for waiver of documentation of consent applies, i.e., (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 (when a waiver has been requested by the investigator)

Institutions will need to carefully evaluate which regulations apply to each study to ensure compliance with all applicable rules (e.g., studies that are regulated by both the Common Rule and the FDA, studies with Dept. of Justice/National Institute of Justice support (signatory on the current rule but not currently a signatory on the revised rule), studies supported by new signatories on the revised Common Rule (e.g., Dept. of Labor, Consumer Product Safety Commission).

Institutions must consider recordkeeping for studies no matter which path you choose. Institutions must maintain SOPs for all studies including:

1. Those under the current rule that will continue under it through completion (will not be voluntarily transitioned to comply with the revised rule);
2. Those for which the three less burdensome provisions are adopted between July 19, 2018 and January 20, 2019 and then must fully comply with the revised rule on January 21, 2019;
3. Pre-existing studies that will be voluntarily transitioned to comply with the revised rule on or after January 21, 2019;
4. Those studies that are approved or determined exempt on or after January 21, 2019.