OHRP Provides Draft Guidance Regarding the Revised Common Rule Implementation Timeline and Transition of Existing Studies

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On January 10, 2019, the U.S. Department of Health & Human Services, Office for Human Research Protections (OHRP) released draft guidance with respect to the timeline for compliance with the revised Common Rule (otherwise referred to as the 2018 Requirements) and implications when institutions elect to transition studies currently subject to the pre-2018 Requirements to the 2018 Requirements.

By way of background, the revised Common Rule was promulgated by the Department of Health and Human Services (HHS) and other federal departments and agencies on January 19, 2017 and was set to become effective one year following, but its compliance date was initially delayed until July 19, 2018, and the compliance date was delayed again until January 21, 2019. Under the most recent Final Rule issued by HHS on June 19, 2018, regulated entities are required to continue complying with the pre-2018 Requirements until January 21, 2019, except that they are permitted to implement the three burden-reducing provisions from the 2018 Requirements during the delay period (anytime between now through January 20, 2019) if otherwise electing to transition to compliance with the 2018 Requirements. Any study initiated after January 21, 2019 must comply with the 2018 Requirements.

Among other things, in this draft guidance OHRP summarizes the implementation timeline for the 2018 Requirements set forth in the rulemaking referenced above, along with examples of impact on studies at various stages and key takeaways. In short:

- By default, a study initiated prior to January 21, 2019 is subject to the pre-2018 Requirements. A study is "initiated" when approved by an institutional review board (IRB), review was waived, or a determination was made that the research was exempt.
- A study initiated on or after January 21, 2019 must comply with the 2018 Requirements (except for the cooperative research provision, which has a later compliance date).
- An institution may voluntarily transition a study initiated prior to January 21, 2019 to comply with the 2018 Requirements instead of the pre-2018 Requirements. Once transitioned, that decision cannot be reversed.
- The draft guidance also addresses rules particular to studies that were transitioned between July 19, 2018 and January 21, 2018. More detail regarding studies that transitioned during this "delay period" is available here.

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OHRP has also posted timelines on its website illustrating this information.

In addition, OHRP's draft guidance includes a question and answer section, along with examples, to address the regulatory implications of voluntarily transitioning a study to compliance with the 2018 Requirements and addressing clarifications sought by the Secretary's Advisory Committee on Human Research Protections (SACHRP). This Q&A section addresses:

- Transition determinations, including who makes and documents the determination that a study will transition to compliance with the 2018 Requirements. For example, the Q&A section notes that the institution has the flexibility to determine who makes transition decisions on its behalf.
- IRB review, including which version of the Common Rule should be used to evaluate a protocol amendment for a transitioned study, applicability of research exemption provisions, and what actions are required to ensure the transitioned study complies with the 2018 Requirements. For example, for studies subject to pre-2018 Requirements, any amendments to that study's protocol should be evaluated under the pre-2018 Requirements regardless of whether the amendment takes place after January 21, 2019.
- Informed consent, including under what circumstances an informed consent that complies with the 2018 Requirements (such as inclusion of a "key information" section at the beginning) must be used with respect to studies initiated prior to January 21, 2019. For example, where an ongoing study is transitioned to comply with the 2018 Requirements, including modification of the consent form, an IRB may use the expedited review procedure to evaluate the consent form changes as long as they represent a minor change to the research. For more information on the updated elements to informed consent, see this firm's September 15, 2018 article, Informed Consent Requirements Under the Revised Common Rule.
- Additional questions and answers regarding the revised Common Rule are posted on the OHRP website.
- Moving forward, HLB encourages clients to carefully analyze the operational implications of transitioning a study before making any determination regarding whether to comply with the 2018 Requirements. As noted by HHS in the Draft Guidance, "[s]uch an analysis could include consideration of whether there might be an administrative benefit or administrative burden created by transitioning a study, and whether there might be additional protections or benefits to subjects participating in a research study."

Hooper, Lundy & Bookman's Academic Medical Center/Teaching Hospital Working Group provides assistance to health care providers and IRBs in all aspects of research compliance. For assistance relating to transition issues, please contact Katrina Pagonis or Andrea Frey in San Francisco at 415.875.8500; Amy Joseph in Boston at 617.532.2700; Kelly Carroll in Washington, D.C. at 202.580.7700, or your regular Hooper, Lundy & Bookman contact.

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