Breaking News - Revised Rule Now Delayed Until July 19, 2018

A notice of an unpublished document was filed on Thursday, January 17, 2018 at 4:15 pm to announce the January 22, 2018 publication of a “Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects.” As stated in the document:

“This interim final rule delays the effective date and general compliance date of the 2018 Requirements to July 19, 2018. The federal departments and agencies listed in this document are in the process of developing a proposed rule to further delay implementation of the 2018 Requirements. The limited implementation delay accomplished by this interim final rule both provides additional time to regulated entities for the preparations necessary to implement the 2018 Requirements, and additional time for the departments and agencies listed in this document to seek input from interested stakeholders through a notice and comment rulemaking process that allows for public engagement on the proposal for a further implementation delay.”

This interim rule is also unique in that it bypassed the standard rule making process. As indicated in the notice, “…we find that good cause exists to waive normal rulemaking requirements for the delay of the effective date and general compliance date to July 19, 2018. We believe that a notice-and-comment procedure, in this limited instance, is impracticable, unnecessary, or contrary to the public interest.”

*Given this news, the Harvard University IRB will continue to implement the existing federal regulations to all research that involves human subjects until the new Revised Rule implementation date of July 19, 2018.*

We will be posting updates on the [IRB website](https://irb.h.harvard.edu) as new developments arise. Stay tuned.

What Does This Mean for Our Existing Revised Rule Presentations and Initiatives?

Presentations – We will be re-scheduling our remaining Revised Rule presentations to occur nearer to the new implementation date of July 19, 2018. These dates will be posted on our website as well as announced in an upcoming IRB newsletter.

New Forms and Templates – As many improvements aimed at reducing administrative burden and increasing efficiency were incorporated into our IRB Protocol Template and Informed Consent Form Templates, we will be removing the Revised Rule elements and launch these forms and templates shortly.

SOPs, Investigator Manual, and Human Research Protection Plan – Like the improvements that were included with our IRB Protocol Template and Informed Consent Form Templates, we will shortly be implementing a new suite of documents that include:

- Standard Operating Procedures (SOPs): A manual that includes an overview of the nuts and bolts of the IRB review process as well as policy that guides the human subject research review process.
- Investigator Manual (IM): A manual that provides additional guidance and information on various regulatory topics, insight into nebulous areas of IRB review, as well as resources that will assist in navigating the IRB process.
- Human Research Protection Plan (HRPP): This document provides an overview of the Human Research Protection Program at Harvard University. It defines roles, mission, and includes a complete outline of the regulatory requirements that must be adhered to.

Thank you all for your understanding and patience during these uncertain times!

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