

Higher Education Association Meeting with OIRA and Federal Agency Staff on Proposed Delayed Implementation of the Common Rule

December 12, 2017

- **The Common Rule should be delayed one year.** Universities, academic medical centers and independent research institutes strongly support a 1-year delay of the implementation of the Common Rule with a strong preference for a 1-year delay of the *compliance date alone* rather than the effective date *and* compliance date. This would allow institutions to move forward with implementation of certain provisions (in particular with respect to provisions that reduce investigator burden such as certain exclusions and exemptions, elimination of the continuing review requirement for certain types or stages of research and elimination of IRB review of grant applications), and to delay implementation where additional guidance and education is needed. We are concerned that a delay has not yet been implemented as the current effective date is just over one month away.
 - **Only the compliance date should be changed.** Currently, both the effective date and the compliance date of the rule are January 19, 2018. Delay of *just the compliance date* provides a one year period during which institutions can modify the policies, electronic systems, forms, and processes needed to make the change from the current Common Rule and also train investigators, IRB members, and research compliance personnel.
 - **It is unusual for a rule change of this magnitude to have a simultaneous effective and compliance date.** It is difficult for institutions to come into compliance with a new regulation on the same date that the regulation becomes effective and therefore very beneficial to have separate effective and compliance dates. An example of the latter is the revised Public Health Services conflict of interest regulations which were issued on August 25, 2011, became effective September 6, 2011, and had a compliance date of “no later than August 24, 2012.”
 - **It appears that HHS has proposed a more complicated implementation plan, which could be very difficult to implement.** The title of the proposed change, “Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year,” gives us pause because it suggests that both the effective and compliance dates of the rule itself will be delayed for one year while certain provisions will either have different effective dates or through some other mechanism be allowed to be implemented earlier.
 - **Concerns from agencies about the work that has already been done could be addressed through guidance or through a transitional implementation year.** We understand that agency forms may include the new exemption categories. If a 1-year delay is implemented, we believe from conversations with agency staff that this could be addressed through notice or guidance.
 - **There could be another mechanism for extending the compliance date besides notice and comment rulemaking.** Given that the effective and compliance dates are now almost a month away, with many institutions closed a week or more for the holidays, the issuance of a proposed rule with a notice and comment period and then final rule issued within days of the compliance date would cause significant anxiety and confusion. Already institutions are not clear as to whether the delay has gone into effect. A number of news stories and announcements from organizations declared that the rule wasn’t going into effect until 2019, resulting in some institutions halting their preparations. If the compliance date could legally be changed in the absence of rulemaking and a notice and comment period for the sake of expediency, that would be ideal.

- **Critical guidance from the agencies has not yet been issued.** Guidance, assistance, and other clarifying information about the revised rule has not been provided by OHRP or any other signatory agency to the research community, presumably given the uncertainty surrounding regulations issued at the very end of the prior administration. The lack of OHRP engagement has led to uncertainty about how to proceed in order to be in compliance (partially amplified by OHRP statements on their uncertainty about whether and when the rule would take effect).
 - Planning and training is a challenge absent guidance, which is viewed as essential to successful implementation. Examples of anticipated guidance include guidance on:
 - The format of the revised consent document (Institutions do not want to redesign their consent forms only to find that they are inaccurate once guidance is published, a situation that would be confusing to investigators and participants);
 - Expedited categories;
 - Broad consent;
 - The announcement of where informed consent documents must be posted;
 - Training resources; and
 - A decision tree for determining whether research is exempt or subject to review.
 - SACHRP, IRB consulting firms, and other for-profit entities have created extensive guidance, literature, and webinars on the revised rule, however a consistent and vetted approach is lacking and information from sources other than OHRP can only be viewed as opinion.
 - Having a one-year delay would provide institutions needed time to construct a comprehensive plan, based on agency guidance, that includes revision or creation of institutional policies, guidance, and forms; implementation of revisions to the IRB submission process, including electronic systems; training of IRB staff and the research community; and to engage the IRB community in a discussion about best practices with the goal of harmonization across IRBs.
- **Uncertainty about the status of the Common Rule has left institutions to implement a complex rule during a time of significant change across the research community.** Institutions are currently in the process of educating researchers, in what is already a busy time of the academic year, on the NIH Single IRB Policy; NIH revised Certificate of Confidentiality (CoC) Policy; investigator support for the HHS and NIH requirements to register and report on clinical trials; NIH's broadened interpretation of what constitutes a "clinical trial" and associated policies and requirements; and the release of new FDA guidance such as the "minimal risk" waiver of consent; some of which are being implemented in January 2018.
- **Uncertainty about the status of the Common Rule has made institutions hesitant to implement costly changes to their systems, in case there are further changes mandated or enacted that require these changes to be redone.** It should be noted that changes to electronic systems to accommodate regulatory and policy changes can be costly (e.g., on the order of \$1-1.5 million per institution with respect to the Common Rule) and institutions hesitant to make these changes in the absence of needed guidance. Further, institutions are regularly having to make significant changes in response to federal regulations and policies such as the NIH Single IRB and CoC policies.
- **Research regulated by the Common Rule and the FDA will be under two sets of unharmonized regulations, as the FDA is not a signatory to the Common Rule and hasn't started the rulemaking process yet.** A 1-year delay would also allow more time for HHS and the Food and Drug Administration to harmonize differences between their human subject protection rules as directed by Section 3023 of the 21st Century Cures Act (Pub. L. 114-255). The FDA already agreed to update its similar but separate human subject protection regulations to align with the Final Rule. A delay, however, would provide FDA time to draft and propose regulatory provisions prior to the Common Rule taking effect, adding to the overall streamlining and efficiency of human subjects research and enhancing protections. A delay might also allow the Research Policy Board, created under the Cures Act, to review NIH, HHS, FDA and other agency regulations and policies for the purposes of harmonization. This would result in far less confusion on the part of investigators. It would also require fewer changes to institutions' processes and systems.