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Office of Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
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Submitted electronically at www.regulations.gov

Re: Docket Number HHS-OPHS-2018-0007, Federal Policy for the Protection of Human Subjects: Proposed Six Month Delay of the General Compliance Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period

The Association of American Medical Colleges (AAMC), Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), and Council on Governmental Relations (COGR), collectively the "Associations," write in response to the Department of Health and Human Services' (HHS) request for comments on the Notice of Proposed Rulemaking (NPRM), published in the Federal Register on April 20, 2018 on the revised Federal Policy for the Protection of Human Subjects ("revised Common Rule"). The member institutions of AAMC, AAU, APLU, and COGR are the primary recipients of federally funded human subjects research awards.

This proposal would maintain the current effective date of July 19, 2018 for the revised Common Rule, and delay the general compliance date for an additional six months, to January 21, 2019, to "provide additional time to regulated entities for the preparations necessary to implement the 2018 requirements." Through the transition provisions in the proposed rule, regulated entities would be required to follow the requirements of the current regulations until the general compliance date, with the exception of three burden-reducing provisions which could be implemented voluntarily after the effective date of July 19, 2018.

The Associations support the proposal to delay the general compliance date of the revised Common Rule until January 21, 2019 and the proposal to allow the voluntary adoption of three "burden reducing" provisions in the 2018 requirements during the six-month delay period. We also underscore the urgent need for prompt issuance of guidance.

The most important outcomes of this rulemaking process are 1) having certainty within the research community about when compliance with the revised Common Rule will be required and 2) having the ability to implement the regulations consistently and correctly, an outcome that relies on the issuance of guidance and adequate time for institutions to adapt their policies, procedures, and technology in response to that guidance before the compliance date.

I. This long and complex rulemaking process should close swiftly to allow institutions adequate time and certainty to plan for implementation.

After the revised regulations were published in January 2017, months of confusion and uncertainty about the rule's status led some institutions to halt their implementation preparation efforts. The interim final rule (IFR) issued January 17, 2018, just two days before the revised Common Rule's compliance date, followed by this NPRM's proposal to again delay the regulations has left institutions in an untenable holding pattern, resulting in heightened confusion, frustration, and exhaustion with the rulemaking process. **We urge OHRP to conclude this rulemaking process as quickly as possible following the conclusion of the comment deadline to provide the regulated community with certainty about the effective and compliance dates.**

II. Given the complexity of the revised Common Rule and the noted ambiguities in the rule, successful implementation requires prompt issuance of agency guidance, well in advance of the proposed general compliance date.

In June 2017, the Associations submitted a letter requesting a one-year delay of the compliance date of the revised regulations.[1] Citing the uncertainty about the status of the rule and the need for guidance from the Common Rule agencies, the letter stated, "there are still a number of outstanding guidance documents and templates on which institutions will rely to set their own policies that have not yet been issued by the departments and agencies implementing the rule." *Nearly a year later, no such guidance documents have been released.* **The Associations support a delayed general compliance date of January 21, 2019 with the assumption that the delay period will in fact result in the timely availability of promised guidance.**

In response to the IFR,[2] the Associations had requested that the Common Rule agencies delay the compliance date of the revised Common Rule until January 21, 2019, allowing institutions an additional year to come into full compliance. The IFR included the statement that "[w]ithout a delay, and *without guidance*, institutions that have expected a delay who hastily attempt to implement the revised rule without adequate preparation are bound to make mistakes, the consequences of which may jeopardize the proper conduct of research and the safety and wellbeing of human subjects." The current NPRM asserts that the additional six-month proposed timeframe would allow Common Rule departments and agencies to "issue relevant guidance documents that will better enable the regulated community to comply with the revised rule." The need for guidance is well recognized and well documented by the Common Rule departments and agencies, and the failure to have draft guidance on any of the key provisions this many months after the revised Common Rule was issued as a final rule has prevented institutions from making many policy and IT changes necessary to implement the rule.

Although many areas of the revised Common Rule would benefit from guidance, we urge OHRP to issue guidance first in these specific areas where guidance is urgently needed: the inclusion of key information in informed consent documents, posting of informed consent documents on a public website, benign behavioral interventions, and training resources. In addition, the Secretary's Advisory Committee on Human Research Protections (SACHRP) has recommended that several of the new exemption categories require guidance in order to be implemented effectively and consistently. We

[1] https://www.aamc.org/download/480840/data/aamcissuesjointletteroncommonrule.pdf (June 21, 2017).
[2] Available at: https://www.aamc.org/download/487712/data/aamccommentsonifr.pdf.

recommend that HHS leverage SACHRP's recommendations and resources to assist with the swift vetting and publication of guidance.

III. The usefulness of the proposed flexibility with respect to the three burden reducing provisions will depend on an institution's research activities and on a common understanding of the ramifications of implementing these provisions.

The Associations appreciate the flexibility provided by the proposed option to implement three burden reducing provisions prior to the general compliance date and support this proposal. Institutions will have to determine whether to implement these provisions on a study by study basis, considering the need to make changes to policy and IT systems. It is imperative institutions also clearly understand that by electing to implement one or more of the three burden-reducing requirements during the delay period, the institution has committed that study to compliance with *all* of the requirements of the revised Common Rule beginning on January 21, 2019 for the duration of that study. Research studies that do not implement any of these provisions could otherwise have remained under the current Common Rule requirements through the conclusion of the research. We note that these consequences of electing to take advantage of this proposed flexibility are not equally well understood across all institutions. To minimize confusion and prevent unintended consequences for institutions, **we recommend that OHRP issue clear communications to the regulated community (in the form of a flow chart or other document) that set forth the implications of the institution's decision to adopt the identified burden-reducing provisions, either for a single study or all research at the institution.** We would welcome the opportunity to assist with the development or dissemination of such a communication.

We appreciate the opportunity to provide HHS with our comments and remain available to provide additional information or discuss our recommendations.

Sincerely,

Darrell G. Kirch	Mary Sue Coleman	Peter McPherson	Anthony P. DeCrappeo
President and CEO, AAMC	President, AAU	President, APLU	President, COGR

The Association of American Medical Colleges (AAMC) is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems; and more than 80 academic societies. The Association of American Universities (AAU) is an association of 60 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization with a membership of 237 public research universities, land-grant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico, that is dedicated to strengthening and advancing the work of public universities. The Council on Governmental Relations (COGR) is an association of over 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.