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

Re: Docket Number HHS-OPHS-2017-0001, Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects

The Association of American Medical Colleges (AAMC), Association of American Universities (AAU), and Association of Public & Land Grant Universities (APLU) appreciate the opportunity to respond to the Department of Health and Human Services' (HHS) request for comments on the Interim Final Rule (IFR), which delays the effective date and general compliance date of the revised Federal Policy for the Protection of Human Subjects ("Common Rule") by six months, until July 19, 2018. The member institutions of AAMC, AAU and APLU are the primary recipients of federally funded human subjects research awards.

The IFR notes that members of the regulated community expressed significant concerns about whether they would be able to implement the requirements of the revised regulations by the initial compliance date (January 19, 2018). In a June 2017 letter to the Office of Human Research Protections (OHRP), AAMC, AAU, APLU and COGR requested a one-year delay in the compliance date to allow universities, academic medical centers, and independent research institutes additional time to develop the policies, processes, information technology systems and educational materials needed to transition from the current Common Rule in addition to training investigators, IRB members and research compliance personnel.[1] **Consistent with the recommendation in our 2017 letter to OHRP, we strongly recommend further delay of the compliance date of the revised Common Rule for at least one year from the original effective and compliance date (until January 21, 2019).**

[1] AAMC, AAU, APLU, COGR letter to Office for Human Research Protections (June 21, 2017) https://www.aamc.org/download/480840/data/aamcissuesjointletteroncommonrule.pdf

I. One purpose of the HHS six-month delay was to allow the consideration of comments through a rulemaking process that has yet to begin.

On January 17, 2018, just two days before the compliance date of the revised regulations, this IFR was issued to delay the effective and compliance dates by six months. One of the stated purposes of this proposed "limited implementation delay" is "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*." The proposal referenced is apparently the proposed rule which was submitted to the Office of Management and Budget (OMB) on October 7, 2017, entitled "Federal Policy for the Protection of Human Subjects: Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year." As of the date of this letter, this proposed rule is still listed as "pending review" on the Office of Information and Regulatory Affairs (OIRA) website, raising the question of whether the contemplated notice and comment rulemaking process will take place before the new compliance date of July 19, 2018.

It is important to understand that publication of the revised Common Rule in January 2017 was quickly followed by months of confusion and uncertainty, in some cases resulting in institutions halting their implementation efforts in case further changes or delays occurred. The strong suggestion of a proposed delay beginning in October 2017, coupled with earlier statements by federal officials expressing uncertainty about whether and when the revised regulations would take effect, left the research community hesitant to move forward with implementing the regulations. The last-minute delay of the revised regulations have kept institutions in an untenable holding pattern. An additional six-month delay of the compliance date, issued with sufficient notice, would account for the time lost during this period of understandable confusion and give institutions needed additional time to come into compliance with the revised regulations.

II. Agency guidance and clarifying documents have not been provided to the research community by any signatory agency, which has increased uncertainty about how to comply with the regulations.

The IFR acknowledged 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." Meaningful guidance minimizes the potential for the inconsistent application of institutional policy and reduces administrative and financial burden. Specific areas where guidance has not been issued but is critical to the research community and which will have great impact on the management and conduct of clinical trials include: the inclusion of key information in informed consent documents, posting of informed consent documents on a public website, broad consent, 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.

Given the complexity of the revised rule, successful implementation and compliance with its changes requires issuance of agency guidance within a timeframe that allows institutions to develop comprehensive implementation plans and make critical decisions about institutional policies and procedures. Many institutions have to make costly changes to their electronic protocol submission

and review systems to implement the new rule. Making such changes without knowing whether final guidance will require further modifications has consequences for institutional and federal resources, as well as for human subjects.

We strongly recommend that OHRP use the recommended additional six-month delay to move swiftly toward issuing guidance, leveraging available resources such as the recommendations provided by SACHRP.

III. AAMC, AAU, and APLU urge additional time to allow commencement of the rulemaking process to align the Food and Drug Administration's (FDA) regulations on human subject protections with the revised Common Rule.

As directed by Section 3023 of the 21st Century Cures Act (P.L. 114-255, "Cures Act"), the Secretary of HHS is required "to the extent practical and consistent with other statutory provisions, […] harmonize the differences between the HHS Human Subject Regulations (45 CFR part 46, Subpart A) and the FDA Human Subject Regulations" (21 CFR Parts 50 and 56) within three years from the Cures Act's enactment date, by December 13, 2019. An additional delay would provide the FDA with more time to develop and propose regulatory provisions before the revised Common Rule takes effect.

We strongly recommend that HHS delay the compliance date for an additional six months so the FDA may utilize this opportunity to initiate and finalize rulemaking to harmonize its human subject protection regulations at a time when HHS will be issuing critical guidance and clarifying information on key changes to the revised regulations.

We appreciate the opportunity to comment on the IFR and remain available to discuss our recommendations or provide additional information on how an additional delay, announced soon, would greatly help the academic research community most soundly implement the new policies.

Sincerely,

Darrell G. Kirch
President and CEO, AAMC

Mary Sue Coleman
President, AAU

Peter McPherson
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The Association of American Medical Colleges 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 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 235 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.