



June 21, 2017

Jerry Menikoff, M.D., J.D.  
Office for Human Research Protections  
Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852

Re: Final Rule on the Federal Policy for the Protection of Human Subjects, Federal Register Vol. 82, No. 12, January 19, 2017

Dear Dr. Menikoff,

The Association of American Medical Colleges (AAMC), Association of American Universities (AAU), Association of Public & Land-grant Universities (APLU), and Council on Governmental Relations (COGR), collectively the “Higher Education Associations,” write in regard to the implementation date for the Federal Policy for the Protection of Human Subjects, the “Common Rule,” published on January 19, 2017. The Higher Education Associations’ member institutions are the primary recipients of federally funded human subjects research awards.

The final rule is effective January 19, 2018 for all provisions except cooperative research. Entities conducting federally funded human subjects research are expected to be compliant with the regulations on that date, and generally operating under the current regulations until that time. It is typical for a major rule affecting institutional research practices to be issued with a compliance date that is at least 6 to 12 months later than the effective date, to allow institutions to implement the changes as resources and time allow. As the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) is well aware, the revised final rule includes significant changes. The process for implementing these changes, including new policies, processes, information technology systems and education efforts, takes many months.

On January 20, 2017, the White House issued a memorandum to all executive departments and agencies<sup>1</sup> to freeze new or pending regulations, allowing the new administration time to review them. For regulations that had been published but had not reached their effective date, the memo postponed the effective date for 60 days pending review with the potential that a new notice for reopening the regulation could occur. Although we recognize that no formal action is required for the final rule to be implemented as published, we understand from recent public presentations from OHRP staff that the rule is under administrative review at this time. As a result of the uncertainty surrounding the status of the revised Common Rule over the course of the last five months, and the significant costs involved, universities, medical schools, and other entities have been hesitant to fully move forward in implementing the rule. Further, 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.

Given this uncertainty, the Higher Education Associations are requesting a **one year delay in the compliance date** of the Federal Policy for the Protection of Human Subjects until January 19, 2019, with an effective date for most provisions

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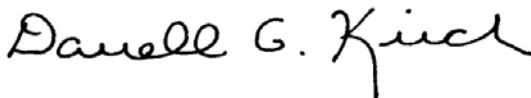
<sup>1</sup> Available at: <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies>.

remaining January 19, 2018. The delay would allow institutions adequate time to come into compliance with all provisions of the revised rule. In addition, we ask that OHRP allow the regulated community to move forward with those provisions that would reduce administrative burden for investigators, one of the stated goals of this regulatory effort, on or before the effective date. These include 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. This flexibility is consistent with a proposal in the Notice of Proposed Rulemaking, *Effective and Compliance Dates of New Rule (NPRM at §11.101(k))*, which would have allowed “a provision that is anticipated to provide additional regulatory flexibility to institutions or investigators” to “voluntarily be implemented 90 days from the publication of the Final Rule.” A one year delay in compliance would account for time lost to the administrative review and allow for effective implementation and compliance while also allowing for more immediate burden reduction.

The Higher Education Associations recognize that as the primary office for human subjects protection issues within HHS, OHRP has the closest connection to the status and implementation of the Common Rule. We also understand that the 15 other departments and agencies that have implemented the rule must be included in this effort. We believe that such a delay in the compliance date of the Common Rule will be beneficial for all affected institutions and relevant agencies. Importantly, this time could be used to advance harmonization efforts to align the FDA’s human subject protection regulations with the Common Rule as required by the 21<sup>st</sup> Century Cures Act.

We remain available to discuss this proposed delay and look forward to hearing from you. Thank you for considering this request.

Sincerely,



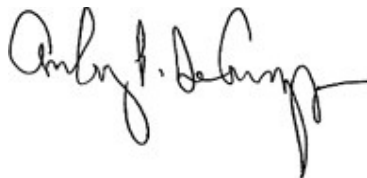
Darrell G. Kirch  
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Mary Sue Coleman  
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President  
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The Association of American Medical Colleges is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 147 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. 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.