



Submitted via Regulations.gov

March 16, 2018

Dr. 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: Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects (82 FR 7149)

Dear Dr. Menikoff,

The Council on Governmental Relations (COGR) is an association of over 190 leading research universities and affiliated academic medical centers and independent research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. We appreciate the opportunity to comment on the Interim Final Rule (IFR), [“Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects”](#), published on January 22, 2018, which delayed the effective and general compliance dates of the 2018 requirements to July 19, 2018. We look forward to the opportunity to comment on the proposed rule referenced in the IFR that would further delay the 2018 requirements.

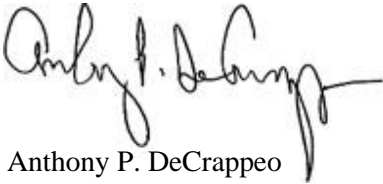
The interim final rule cites a June 21, 2017 [request from AAMC, AAU, APLU, and COGR](#) to delay the implementation of the revised final rule. The request from COGR and the other higher education associations was for a one-year delay in the general compliance date for all provisions, with no delay in the effective date. A one-year delay of the compliance date alone would have allowed institutions to move forward with implementation of certain provisions of the revised final rule and to delay implementation where additional guidance and education is needed. This would have been particularly helpful as institutions had to be prepared to move forward with the revised rule prior to the publication of an IFR. With a delay in the effective date, as indicated in the notice, “regulated entities are not allowed, prior to July 19, 2018, to comply with the 2018 Requirements in lieu of the pre-2018 Requirements.”

A delay of both the effective and compliance dates within 48 hours of the effective date, while well-intentioned, presented a challenge to institutions which had strived to comply with the revised final rule by January 19, 2018 as required by regulation prior to the publication of the IFR. As of this writing the revised effective date is only four months away and an NPRM has not yet been published. Given the need for agreement by all Common Rule agencies and required review by the Office of Information and Regulatory Affairs, and since a comment period, review and consideration of comments, and agreement on and review of any final regulatory action would be necessary, the timeline is likely to again result in the publication of a revised rule just prior to the current July 19, 2018 effective date. This would likewise again require institutions to move forward on implementation of the rule with the possibility of further delay just prior to the effective date. Decoupling the effective and compliance dates would allow institutions to move forward where prepared to do so.

We recognize that a concern may be the absence of guidance that agencies believe is necessary to properly implement the rule. At the same time, guidance is likely to be more effective with input from the community. So where does that leave us with respect to the current July 19, 2018 effective date? It would be optimal if OHRP were to create necessary guidance with input from the community, and publish the guidance prior to the effective date. Also, decoupling the compliance and effective dates, retaining the July 19, 2018 effective date and implementing a July 19, 2019 compliance date would be most practical for the research community. Page 2889 of the federal register notice indicates that most provisions “would not have required significant guidance from Common Rule departments or agencies in order to implement the provisions”. Per the notice, the exceptions include “(1) Excluding activities from the Common Rule because they are not research; and (2) the expansion of research activities exempt from full IRB review.” We would suggest that OHRP therefore prioritize guidance in these areas to allow for retention of the July 19, 2018 effective date and a delay of the compliance date to July 19, 2019. We further encourage prompt publication of guidance on the definition of benign behavioral interventions, limited IRB review, and data security criteria.

We appreciate the opportunity to comment. If you have questions, please direct them to [Lisa Nichols](#) at COGR.

Sincerely,

A handwritten signature in blue ink, appearing to read "Anthony P. DeCrappeo". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Anthony P. DeCrappeo

President

Council on Governmental Relations