



CONSORTIUM *of* SOCIAL SCIENCE ASSOCIATIONS

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May 21, 2018

Jerry Menikoff, MD, JD
Office of Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Re: Docket No. HHS-OPHS-2018-0007 (Comments submitted electronically via regulations.gov)

Dear Dr. Menikoff:

The Consortium of Social Science Associations (COSSA) appreciates the opportunity to comment on the April 20, 2018 Notice of Proposed Rulemaking (NPRM), “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.” COSSA is a nonprofit advocacy organization working to promote sustainable federal funding for social and behavioral science research and federal science policies that positively affect research and its responsible conduct. COSSA serves as a united voice for a broad, diverse network of organizations, institutions, communities, and stakeholders who care about a productive and vibrant social science research enterprise. The COSSA membership includes professional and disciplinary associations, scientific societies, research centers and institutes, and U.S. colleges and universities.

COSSA supports the changes to the Federal Policy for the Protection of Human Subjects (the Common Rule) announced in January 2017 and recognizes that, while not perfect, they make much-needed modernizations to this policy, particularly as it applies to research in the social and behavioral sciences. In addition, COSSA expects and anticipates that the planned guidance to be developed and issued by the Office of Human Research Protections (OHRP) will further facilitate the implementation of these changes.

COSSA believes that the changes to the Common Rule are long overdue, and that they should be implemented as soon as is feasible—that is, by the current effective date of July 19, 2018. The changes were announced well over a year ago and covered institutions, organizations, and investigators have given time and attention to the transition. The current extension period gave more than sufficient time for further consideration to take place. It is our view that there is much to be gained through proceeding and developing a roster of best practices through implementation. A further delay is not warranted and would only lead to increased uncertainty and confusion among the regulated community.

As stated, we recommend against a further delay. **Were the date proposed in the NPRM of January 21, 2019 to be put in place, COSSA supports allowing institutions to take advantage of the three burden-reducing provisions specified in the NPRM during any further extension period beyond July 19, 2018.**

Thank you for your consideration. Please do not hesitate to contact COSSA if we may be of further assistance.

Sincerely,



Felice J. Levine, PhD
Chair, COSSA Board of Directors



Wendy A. Naus
COSSA Executive Director