



11 Beacon Street, Suite 710
Boston, MA 02108
Phone: 617-723-6100
Fax: 617-723-6111
www.cobth.org

May 18, 2018

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

Comments submitted via www.regulations.gov: Docket ID No. HHS-OPHS-2018-0007

Dear Dr. Menikoff:

The Conference of Boston Teaching Hospitals (COBTH), an organization of twelve Boston-area teaching hospitals, is appreciative of the opportunity to provide this response to the Department of Health and Human Services' request for comments on the Notice of Proposed Rulemaking on the revised Federal Policy for the Protection of Human Subjects, known as the Common Rule. 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.

COBTH supports 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. **We 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.** 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guidance is well recognized and well documented by the Common Rule departments and agencies, and the failure to have draft guidance on any of the key provisions this many months after the revised Common Rule was issued as a final rule has prevented institutions from making many policy and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 recommend that HHS leverage SACHRP's recommendations and resources to assist with the swift vetting and publication of guidance.

Sincerely,

John Erwin
Executive Director