



May 1, 2019

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: Interpretation of Compliance Dates for Cooperative Research Under the Revised Common Rule

Dear Dr. Menikoff,

The Association of American Medical Colleges, Association of American Universities, Association of Public and Land-grant Universities and Council on Governmental Relations are concerned about recent communications from the Office for Human Research Protections (OHRP) regarding the application of the cooperative research requirement under the revised Common Rule.

As you know, the final revised Common Rule (2018 Requirements) indicates that the rule is effective July 19, 2018 with a general compliance date of January 21, 2019 and a compliance date of January 20, 2020 for cooperative research. The research community understood this to mean that studies approved by an IRB on or after January 20, 2020 would be subject to the requirements for cooperative research, that is, use of a single IRB. OHRP staff have recently suggested in email correspondence, however, that cooperative research studies subject to the 2018 Requirements (beginning on or after January 21, 2019) are required to come into compliance beginning January 20, 2020, such that studies that have already been approved by local IRBs and may be ongoing would need to be identified, paused, and undergo a new single IRB review.

The preamble to the 2017 final rule explained the purpose of the three-year delay in the compliance date of this provision as follows: “this transition period is intended to allow the regulated community appropriate time and flexibility in adjusting to this new model.” Nothing in the preamble suggested that multisite studies should be rereviewed or transition from review by many IRBs to a single IRB review. Had the general rule gone into effect on January 19, 2018 as

initially proposed this new interpretation of the cooperative research compliance date would have resulted in the re-review of two-years' worth of cooperative research studies.

We note that in none of the many public presentations about the cooperative research provision or implementation of the Common Rule has any OHRP staff member suggested that multisite studies initiated after the general compliance date would need to be transitioned to a single IRB review by the cooperative research provision compliance date. Recent draft guidance entitled The Revised Common Rule Compliance Transition Provision, issued in January 2019, did not address this issue. We believe that such an interpretation is contrary to the original intent of the revised rule as suggested by the language in the preamble. It is certainly contrary to the facilitation of federally funded research. If this interpretation persists, and without regulatory or related changes in guidance, research will be interrupted, and administrative burden and costs will significantly increase, without benefit to the protection of research participants.

We ask that OHRP and Common Rule agencies find a means to expeditiously address this issue. In the absence of prompt and clear guidance, institutions will be forced to begin complying with an interpretation that runs counter to the best interests of the federal government and the U.S. research enterprise or will be out of compliance beginning January 20, 2020.

We do not believe that the OHRP interpretation of this provision is warranted or required and would ask that it be reassessed. However, we note that the provision itself includes a mechanism through which all Common Rule agencies could unambiguously resolve the issue. Section __.114(b)(2)(ii) provides that research “for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context” is not subject to the provision. A timely communication or guidance document could be issued stating that for cooperative research projects approved after the Common Rule’s effective date but prior to the compliance date for § __.114(b) and approved by multiple IRBs, the requirement of a single IRB is not appropriate.

We appreciate OHRP’s openness to ongoing communications regarding the implementation of the revised Common Rule and are happy to have further discussions if that would be helpful. Please contact Lisa Nichols at COGR (lnichols@cogr.edu) or Heather Pierce at AAMC (hpierce@aamc.org) with questions.

The Association of American Medical Colleges (AAMC) is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 154 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 (AAU) 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.