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Dear Dr. Lauer and Dr. Wolinetz,

The Council on Governmental Relations (COGR), the Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU) and the Association of American Medical Colleges (AAMC) are writing with respect to the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NIH sIRB Policy) which is scheduled to take effect on May 25, 2017. COGR, AAU, APLU and AAMC are seeking a one-year extension to the implementation date to address a number of complexities as detailed in this letter. This would require universities to comply with the policy no later than May 25, 2018.

Proposed revisions to the Federal Policy for the Protection of Human Subjects, the Common Rule notice of proposed rulemaking (NPRM), included provisions to mandate use of a single IRB review for cooperative research. The proposed compliance date for this provision is three years from the publication of the final rule. As indicated in the NPRM, the proposed date reflects concerns "regarding implementation logistics, and the time necessary to establish new policies, procedures, and agreements." The effective date of the NIH policy is 11 months following issuance, and policy details and guidance, excepting costing guidance for which we feel additional discussion and clarification is needed, have not yet been made available. Given the policy applies to all competing grant applications with receipt dates on or after May 25, 2017, we believe all issues would need to be resolved and all related guidelines would need to be issued immediately in order to comply by the current implementation date.

Institutions are currently laying the groundwork to implement the NIH sIRB Policy. This includes assessing the capacity to act as the reviewing IRB; assessing what IT, personnel and operational changes will have to be

made and cost analyses; developing SOPs, forms, checklists and processes; educating staff; and establishing fee schedules or, for those seeking to partner with a commercial IRB, working with that IRB to develop processes and fees. This is a complex process and, as detailed in the letter COGR sent on September 23 and attached here, a number of costing issues require clarification. Among the issues, that the NIH guidance does not explicitly indicate that institutions can include the full cost of the review in the proposal budget for those institutions for which the IRB is not included in their indirect cost pool; removal of these costs with respect to Appendix III C.8.b. of the Uniform Guidance and the NIH sIRB policy; and the flexibility afforded by the Uniform Guidance to direct charge administrative costs that are unique and identifiable to the award. As institutions reorganize their IRB enterprise to comply with the new NIH policy, it will be imperative that the maximum costing flexibility is provided. We look forward to continued discussion on these issues and the NIH cost guidance. Institutions would also like to discuss whether additional funding will be made available by NIH to cover budgeted IRB costs for NIH funded multisite studies so that investigators' funding for research is not reduced.

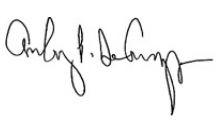
As a result of the NIH Policy many institutions will incur significant infrastructure costs to re-work and/or supplement their IT systems in order to serve as both the reviewing and relying IRB, even if they elect to use a commercial IRB. Managing all of the institution's protocols that are being reviewed by dozens of other institutions, and the individual review and correspondence requirements for each study, will require additional IT costs for all parties. We would like to discuss whether NIH would consider IT infrastructure grants, as it has in the past, to upgrade or replace IRB systems to accommodate the NIH sIRB Policy.

For the reasons indicated above, most institutions are still unsure of how they will implement this policy, that is, whether they will use a commercial or other institutional IRB, should the latter become an option, and, if acting as the reviewing IRB, how they will structure their IRB, what software and personnel changes they will make and how they will structure the fees to cover the cost of review. Universities do not yet know what the costs will be to conduct their own review or what the cost will be for a commercial entity to conduct the review.

Additional time is needed to address the concerns raised above and COGR, AAU, APLU and AAMC are therefore requesting a one-year extension of the implementation date to May 25, 2018. This will ensure that the NIH Single IRB Policy is implemented in a measured and thoughtful manner and will facilitate a successful transition to the policy.

Thank you for reviewing our concerns and we look forward to working with you to develop the best approach to address the issues raised in this letter.

Sincerely,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