

April 23, 2018

The Honorable Roy Blunt  
Chair, Appropriations Subcommittee on  
Labor, HHS, Education & Related Agencies  
U.S. Senate  
Washington, DC 20510

The Honorable Patty Murray  
Ranking Member, Appropriations Subcommittee  
on Labor, HHS, Education & Related Agencies  
U.S. Senate  
Washington, DC 20510

The Honorable Tom Cole  
Chair, Appropriations Subcommittee on  
Labor, HHS, Education & Related Agencies  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Rosa DeLauro  
Ranking Member, Appropriations Subcommittee  
on Labor, HHS, Education & Related Agencies  
U.S. House of Representatives  
Washington, DC 20515

Dear Chairman Blunt, Ranking Member Murray, Chairman Cole, and Ranking Member DeLauro:

As organizations representing researchers and research institutions, we appreciate report language in the omnibus bill focused on NIH's clinical trials definition. The language directs NIH to delay enforcement of its "more expansive interpretation of 'interventions' in relation to fundamental research projects involving humans." It also directs NIH to "consult with the basic research community to determine the reporting standards best suited to this kind of research" and to develop "a plan and schedule for soliciting comments and input from the research community." We believe that engagement with the investigator and institutional community is critical to achieving progress on both the definition and registration and reporting framework.

As you know, NIH revised the definition of "clinical trial" in a [notice](#) published on October 23, 2014. The initial 23 [Case studies](#) published on that date, which operationalized the definition of a clinical trial, seemed to align with the traditional characterization of a clinical trial, and did not raise concern. [Case studies](#) published in the late summer of 2017, however, included an additional 31 studies, and revised existing studies, introducing new ambiguity and generating significant concern and confusion among investigators and their institutions. Unlike the studies published in October 2014, the 2017 case studies include basic science, even following recent revisions, subjecting this research to funding opportunity, training, and reporting requirements that are associated with clinical trials.

Our organizations appreciate the modifications that NIH has made to the case studies to date; however, despite NIH's efforts to work with the community to narrow the 2017 set of case studies, the latest version of case studies remain difficult for investigators, research institutions, and even program officers to interpret. Our primary goal is to seek clarity about what constitutes a clinical trial and to ensure that basic science research is not subject to the range of policies and requirements developed for clinical trials, which simply do not apply to basic research. Our organizations seek continued engagement with NIH on this point. We sincerely appreciate the Committee's assistance with this primary goal, as provided in the report language and continued dialogue.

Another important goal, as noted in the report language, is the development of a registration and reporting framework for basic science that will build a base of knowledge for science and, ultimately, the public good. Our organizations support efforts to make data associated with basic research involving human

participants broadly accessible to prevent duplication, while fostering reproducibility and public access to research funded by the federal government. Any registration and reporting framework should be tailored to basic science research and developed with the involvement of the basic science stakeholder communities, including research institutions. We look forward to interacting with NIH on this issue as well.

We are hopeful that active collaboration between NIH and our organizations and members will allow us to come to agreement on how to: (1) modify the case studies to exclude basic science, and (2) identify a mutually agreeable mechanism to register and report basic research involving humans that does not create undue burden and costs on awardees.

Sincerely,

American Psychological Association  
Council on Governmental Relations  
Federation of Associations in Behavioral and Brain Sciences  
Society for Research in Child Development