

Francis Collins, PhD, MD, Director  
National Institutes of Health  
One Center Drive  
Bethesda, MD 20892-0160

October 27, 2017

Dear Dr. Collins:

The undersigned organizations applaud NIH for its work to improve transparency in clinical trials. We recognize that concerns have been raised with the agency that not enough data elements are being collected on clinical trials, and that the results of NIH-funded clinical trials are not being published in a timely manner. We understand that these are real problems the agency must address.

We write, however, to share our concerns that basic science research is being redefined as a clinical trial at NIH. We see this as a distinct matter that does not relate to the problems associated with clinical trials the agency is attempting to address. Yet, basic science investigators will be unnecessarily burdened with requirements relating to conducting clinical trials that have nothing to do with their own research. These include limiting research proposal submissions to funding announcements that are specific to clinical trials, subjecting basic research proposals to new and "more rigorous" review criteria for clinical trials, completing new forms, and participating in good clinical practice training. At a time when Congress has asked for reduced burdens on investigators, we are surprised by NIH's actions.

In rolling out the new definition and related policies, NIH created case studies to determine whether a research project will be classified as a clinical trial. We are aware that NIH has revised the case studies to exclude some basic science research, and we see this as a positive step. However, the case studies have not gone far enough, still define a large amount of basic science as a clinical trial, and remain confusing to basic science investigators who have studied them. As a result, we remain concerned that the policies, at least as applied to basic research, may destabilize areas of science over the coming year, areas that are important to the NIH mission.

To be clear, we support the goal of transparency in clinical trials. We also support the goal of transparency (including registration and reporting) in basic science research. We part ways, however, in thinking that labeling basic science research as a clinical trial, and including this research in a clinical trial database, is the best approach. There are alternative ways to collect this information for basic science. In fact, other registration and reporting frameworks have been in development for years and are more amenable to the concerns of basic scientists. With additional attention and input from basic scientists, transparency can be achieved in basic research without eroding trust in the agency.

Our communities of scientists are guided by professional codes of ethics as well as human research protection regulations, both stretching back decades. We owe an ethical obligation to human participants to conduct research that allows us to build upon prior discoveries to advance knowledge. Basic scientists take this obligation seriously. Our interest in building an infrastructure for transparency in basic science that is separate from a clinical trial database should not be misinterpreted as weakening that ethical obligation.

NIH began the process of redefining clinical trials several years ago. Public notices, however, did not signal that basic science research would be redefined as a clinical trial. Regardless, basic scientists are now aware—at least large numbers of them—and are asking NIH to treat basic science as basic science, not as a clinical trial. There may be different pathways to achieving this, and we welcome the opportunity to discuss this further.

We urge NIH to work with the affected basic science communities to identify a reasonable solution.

Sincerely,

American Economic Association Committee on Government Relations  
American Educational Research Association  
American Institute for Medical and Biological Engineering  
American Kinesiology Association  
American Physiological Society  
American Psychological Association  
American Society for Bone and Mineral Research  
American Society for Pharmacology & Experimental Therapeutics  
Association for Psychological Science  
Association for Research in Vision and Ophthalmology (ARVO)  
Association of Population Centers  
Cognitive Neuroscience Society  
Consortium of Social Science Associations  
Department of Psychology, UNC Greensboro  
Federation of Associations in Behavioral and Brain Sciences  
International Congress of Infant Studies  
Linguistic Society of America  
Population Association of America  
Psychonomic Society  
Society for Behavioral Neuroendocrinology  
Society for Computers in Psychology  
Society for Mathematical Psychology  
Society for Personality and Social Psychology  
Society for Psychophysiological Research  
Society of Experimental Social Psychology, Inc.  
The Histochemical Society