October 3, 2018

Dear Dr. Tabak:

In follow up to our conversations and recent NIH notices, we wish to suggest a path forward that we believe will meet the needs of the National Institutes of Health (NIH) and the basic science community.

We appreciate having had the opportunity to meet with you, and we acknowledge that NIH has taken some positive steps (most recently, delaying enforcement of registering and reporting of basic science in ClinicialTrials.gov). However, we remain concerned about the problematic division of basic human research into clinical trial and non-clinical trial categories. As you know, the NIH released a definition and set of case studies in 2014 that adequately captured the distinction between clinical trials and basic research. *This became problematic and confusing in 2017 when NIH's Office of Extramural Research adopted a very expansive interpretation of terms like "intervention" through new and revised case studies, thereby sweeping large swaths of basic research into the clinical trial category.*

Relabeling basic science as a clinical trial runs the risk of subjecting that science to present and future regulatory burdens that are unrelated to the conduct of basic research. Basic research should be and is regulated, for example through federal, state, and local human participant protection rules. Labeling a subset of basic science as clinical trials creates a confusing and artificial distinction. For example, similar research ideas could be conveyed through different types of NIH grant applications with different registration and reporting requirements. For basic research labeled as clinical trials, the grant forms and reporting requirements can be a poor fit to the science and add significant administrative requirements for investigators and institutions. Moreover, inclusion of basic research in clinical trial portals would be misleading to the public.

We wish to offer a simple, two-part solution that we believe meets the goals of NIH and the needs of the human research community.

First, the fundamental research definition described in NOT-OD-18-212 and NOT-OD-18-217 adequately captures basic science research, and the 2014 definition and case studies adequately capture clinical trials. We urge NIH to return to the 2014 clinical trial case studies.

Second, we have been and remain committed to a registration and reporting system that is appropriately tailored to basic science. We recommend that *all* NIH-funded human research be registered and reported but also that the standards and methods for reporting be beneficial to the public and the research community and not create unnecessary administrative work. Once the comments on the RFI (NOT-OD-217) are collected, the focus should be on developing registration and reporting systems appropriate to basic research. This approach would capture far more research and would go further toward accomplishing the goals we share with NIH: ensuring respect for all human participants,

increasing transparency in reporting research studies and findings, and reducing the regulatory confusion that currently exists.

We firmly believe that our investigators are ready and willing to register and report any NIH-funded experiment undertaken for purposes of publication. We would support development of a registration and reporting framework appropriately tailored to the style of science involved (perhaps through multiple, NIH-approved portals) and minimal in its burden on investigators. This would be useful to the broader scientific community, facilitate the progress of science, and ultimately benefit the tax-paying public. If funding is an issue, we would be pleased to speak to Congress about the need for sufficient resources for NIH to develop such a system for this research.

Sincerely,

American Anthropological Association
American Educational Research Association
American Psychological Association
American Society for Investigative Pathology
American Society for Pharmacology & Experimental Therapeutics
American Sociological Association
Association for Psychological Science
Association of American Universities
Association of Population Centers
Behavior Genetics Association
College of Social Science, Michigan State University
Consortium of Social Science Associations (COSSA)
Council of Colleges of Arts & Sciences (CCAS)
Council on Governmental Relations
Department of Psychology, Southern Methodist University
Federation of American Societies for Experimental Biology
Federation of Associations in Behavioral and Brain Sciences
Harvard University
Linguistic Society of America
National Council on Family Relations
Population Association of America
Princeton University
Psychonomic Society
Soc. for Behavioral Neuroendocrinology
Society for Computers in Psychology
Society for Mathematical Psychology
Society for Personality and Social Psychology
Society for Prevention Research
Society for Research in Child Development
Society for Social Work and Research
Society for Text and Discourse
Society for the Psychological Study of Social Issues

Society of Multivariate Experimental Psychology
The Cognitive Science Society
University of California, Davis
University of Colorado Boulder
University of Maryland Baltimore
University of Maryland, College Park
University of Virginia, Department of Psychology
Vision Science Society