



August 7, 2017

Francis Collins, MD Director, NIH
National Institutes of Health
9000 Rockville Pike, Bldg. 1
Bethesda, MD 20892

Dear Dr. Collins,

We write as the President, Past-President, and President-Elect of the International Congress of Infancy Studies (ICIS). ICIS is an international, multidisciplinary, not-for-profit professional organization devoted to the promotion and dissemination of research on the development of infants through its official journal, *Infancy*, and our biennial meeting where researchers and practitioners gather and discuss the latest research and theory in infant development. Members conduct theoretical studies, basic and applied research, and policy analyses to understand and enhance infancy research. Members and attendees include professionals and graduate students in psychology, human development, family studies, education, public policy, sociology, social work, psychiatry, pediatrics, public health, anthropology, speech pathology, and linguistics. Much of the work conducted by our scientists is funded by the NIH, and is consistent with the mission of several of the institutes.

We have recently become aware of NIH's policy that expands the type of research that is included in the definition of "clinical trial" and in the clinical trials database. Although we appreciate and support NIH's effort to enhance stewardship of clinical trials, we have concerns about the Final Rule, in which a clinical trial is defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." We have serious concerns about the breadth of this definition and the new policy. We recognize and appreciate that the NIH is working to improve the stewardship, accountability, and transparency of clinical trials. However, we are concerned that the effect of the new definition and policy on *basic science* may actually work against these goals.

We were pleased to read in the [blog](#) at the NIH Office of Behavioral and Social Science Research of October 18, 2016 that the BBSR-CC working group is considering the definition of an "intervention" and how it might apply to human research not typically considered a clinical trial. To be clear, many of our researchers conduct traditional clinical trials, examining the effect of treatments and interventions on a variety of biobehavioral and health outcomes. However, basic research in developmental science is aimed at understanding the relations between brain and behavior, especially over development. This basic research is a critically important step in designing and conducting clinical trials aimed at testing the efficacy, safety, and appropriateness of interventions or treatments. But, foundational, basic science research has a different focus from clinical trials, and the new policy raises several serious, problems for basic research.



Simply labeling the work as a Clinical Trial is not the main problem. The concerns are the resulting policies and their effect on basic science, and ultimately on the efforts on the part of NIH to improve the stewardship, accountability, and transparency of clinical trials.

This change will negatively impact basic scientists in several ways. One potential impact is that this policy may result in a decrease in funding opportunities for basic scientists. The only funding opportunities available to basic scientists under this new policy is through clinical trial-specific funding opportunity announcements (FOAs). This means that if important basic science is to be conducted, it is critical that FOAs be formed that invite clinical trials that allow us to understand children's development. Moreover, when basic science researchers do submit grant applications, it is critical that the scientists who review those applications not only have expertise in clinical trials, and use trial-specific review criteria, but also have expertise in the basic science. There is no doubt that clinical trials are an important part of the research funded by NIH, but those clinical trials can only succeed when they are based on a strong foundation of basic science research, an area that is very much the responsibility of NIH.

As an illustration, basic science has uncovered how genetics and environmental factors interact across development, providing important insight into the timing and types of interventions that are important for understanding and preventing metabolic conditions, problems associated with stress, and mental health outcomes. Other basic science work has shown how parenting styles interact with child characteristics, such as temperament, and how development of behavior and mental health problems often occurs. Without basic research it would be impossible to design and implement interventions and treatments to help with developmental outcomes related to learning disabilities, obesity, metabolic disorders, mental health, and so on. Clearly, for clinical trials to prove useful and powerful, NIH should continue to support this foundational work.

The new policy also imposes an increased burden of questionable utility on basic science researchers. We acknowledge that the NIH may undertake regulatory action to improve public access to information about true clinical trials—that is, information relevant to FDA-regulated drugs, products and devices. But what is gained by placing basic science that does not involve those drugs, products or devices under increased regulatory burden? Particularly worrisome is that the penalties for noncompliance are significant. Basic scientists who are not conducting clinical trials of drugs, products, or devices would be penalized for not fully complying with the new policy with criminal and civil judicial actions, civil monetary penalties, and loss of federal funding.

The change in policy also has the potential to create confusion for the public. One important role of ClinicalTrials.gov is to give the public access to information about NIH-funded clinical trials. We are concerned that the public will be confused if ClinicalTrials.gov includes both true clinical trials—in which interventions are being tested and the public may be eligible to enroll—and basic science—in which the public is not eligible to enroll. Even with careful adjustments that fully describe basic research on the ClinicalTrials.gov website, including basic research in ClinicalTrials.gov has the potential to reduce transparency for the public on what are true NIH-funded clinical trials.



Finally, these changes were made without significant input from basic scientists. The changes are likely, however, to have a significant impact on many basic scientists. Although the information was made available, the Notice of Proposed Rulemaking was titled “Clinical Trials Registration and Results Submission.” Because basic science researchers do not consider their work to be clinical trials, this Notice did not alert them to the fact that there was a potential policy change. Thus, basic scientists did not respond to this call, and the change was made without their input.

In conclusion, we as developmental scientists request that this change in NIH policy be reversed. We are concerned about the widespread ramifications of the change on the conduct of basic science and on the general public who directly rely upon the information provided to them by ClinicalTrials.gov. This new policy will likely disrupt the key, symbiotic relations between basic science and clinical science. It is also likely to limit funds available to conduct basic science. The lack of basic research will negatively impact the development of successful clinical trials. We urge the NIH to reconsider this policy.

Sincerely,

Kathy Hirsh-Pasek Ph.D.
President

with
Karen Adolph, Ph.D.
Past President

Lisa Oaks
President Elect