FABBS Federation of Associations in Behavioral & Brain Sciences

July 12, 2017

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

Dear Dr. Collins,

The Federation of Associations in Behavioral and Brain Sciences (FABBS) is a nonprofit organization representing twenty scientific societies whose scientists share an interest in the sciences of mind, brain, and behavior. Our communities of scientists 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.

According to the Final Rule, a clinical trial is "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 are writing to raise serious concerns about the breadth of this definition and the new policy.

At the outset, we want to be clear that we appreciate and support NIH's effort to enhance stewardship of clinical trials. However, we think that a better approach is warranted, for a multitude of reasons. Our concerns are as follows:

1. **Definition of clinical trials includes basic science research**. We appreciate NIH's effort to capture all research that is a clinical trial, but the definition is so broad that it includes fundamental research that is not aimed at testing an intervention or treatment and should not be considered a clinical trial. In our field, scientists often conduct basic science research to understand the relationship between brain and behavior in the hopes that new knowledge can aid in the development of interventions at a later time (at which time it would be properly classified as a clinical trial).

2. **Basic scientists not consulted, yet impacted.** The new policy was developed without the input of large segments of the basic science community that are now being impacted by it. The Notice of Proposed Rulemaking was titled "Clinical Trials Registration and Results Submission." Basic science researchers were not aware that their research would be swept in under the definition of "clinical trial," so were not on notice that they

should respond to the NPRM. In fact, some NIH staff were caught off guard by the new policy and its reach.

3. **Public confusion about what is included in ClinicalTrials.gov.** If members of the public want to know about NIH-funded clinical trials and visit the clinicaltrials.gov database, they will not be able to distinguish true clinical trials in which they may enroll from basic science research being funded by the agency in which they cannot enroll. Even if there is a menu option that separates the types of research funded by NIH, we are concerned that it may still be confusing and that additional time and money will be required to address the problem. We note that while improvements have been made to the system, it has been described as difficult to navigate, and adding more nonclinical research studies and data to it is not likely to resolve this issue.

4. **NIH policy may decrease funding opportunities for basic scientists.** The new policy will likely make it *more* difficult for basic science researchers to receive funding through NIH because they can only submit grant applications for their research (now a "clinical trial") in response to clinical trial-specific funding opportunity announcements (FOAs). As a result, basic science researchers whose research is now described as a clinical trial "will need to identify an FOA that clearly invites clinical trial applications." Compounding the problem is that the basic science grant applications will now be reviewed by scientists with expertise in clinical trials, using trial-specific review criteria. While clinical trials are important part of the research funded by NIH, basic science research is critical and very much the responsibility of NIH.

5. **Increases burden on investigators without a clear rationale.** The purpose of the regulatory action, as stated in the Final Rule, was to implement provisions of the Public Health Service Act, as amended by Title VIII of the FDAAA, which "were intended to improve public access to information about certain clinical trials of U.S. FDA-regulated drugs, biological products, and devices… and certain pediatric postmarket surveillances of a device." Given this, it is confusing why basic scientists who do not conduct clinical trials are now required to submit research protocols and findings to a clinical trials database. If the goals of the policy are to improve stewardship overall of the research funded by NIH, we encourage you to consider other approaches that are less confusing to the range of stakeholders impacted – and involve *all* scientists affected during the development of these policies.

6. **Penalties for noncompliance are significant.** The penalties for not fully complying with the new policy include criminal and civil judicial actions, civil monetary penalties, and loss of federal funding. We remain concerned that large segments of the basic science research community are only now

becoming aware of the new policy and the penalties of not registering their research in the clinical trials database.

7. **Mandatory training is focused on clinical trials, not the type of research actually being funded and conducted.** The mandatory training for investigators addresses "good clinical practice," but is now required of investigators who do not conduct clinical trials, but instead conduct basic science research using human subjects. This is requiring many hours of additional training time for PI's and research staff (including graduate and undergraduates) that do not conduct clinical trials.

We appreciate NIH's good stewardship of taxpayer dollars, and support additional efforts to be transparent with Congress and the American people. However, we feel that the new policy is currently creating confusion among scientists and has the potential to create confusion among the public and even members of Congress. We urge you to pause implementation of the policy, seek additional feedback from the entire scientific community affected by the policy, and work toward a better policy that can be fully supported by all stakeholders.

Sincerely,

Paula R. Skedsvold

Paula R. Skedsvold, JD PhD
Executive Director