CONSORTIUM of SOCIAL SCIENCE ASSOCIATIONS

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Contact: Julia Milton
jmilton@cossa.org, (202) 842-3525

COSSA Statement on the NIH Definition of "Clinical Trials"

The Consortium of Social Science Associations (COSSA) commends the NIH for its efforts to increase scientific rigor and research transparency, as demonstrated through several steps taken in recent years to ensure that clinical trials supported by the agency meet the highest of standards. These are goals that everyone involved in the biomedical and behavioral research community should strive to achieve. Still, significant concerns remain regarding NIH's broadened definition of "clinical trials" and its impact on basic research involving human participants.

While several of the concerns raised by the basic research community over the last year have been addressed through previously released notices, including the July 20, 2018 Guide Notice: *Delayed Enforcement and Short-Term Flexibilities for Some Requirements Affecting Prospective Basic Science Studies Involving Human Participants* (NOT-OD-18-212), COSSA feels strongly that there is still work to be done to establish a system that benefits transparency and oversight of basic research involving humans without inflicting undue harm on the basic science community supported by the NIH. The unique attributes of basic research warrant a unique process of enhancing transparency and oversight.

Unfortunately, the July 2018 Guide Notice does not address the fundamental concern of the basic science enterprise: the breadth of NIH's definition of "clinical trials" and its impact on fundamental research. Issues of registering, reporting, and Good Clinical Practice training aside, what is most bothersome about the policies rolled out over the last year or so is a unilateral relabeling of countless areas of research across scientific fields as "clinical trials" when they simply are not. While NIH can mitigate some of the adverse impacts by creating new reporting requirements and issuing clinical trials Funding Opportunity Announcements for basic science studies and requiring Good Clinical Practice training, the move to redefine some basic research studies in this way will have unforeseen consequences that reach well beyond the NIH grantee community.

Take for example the public's access to timely and accurate clinical trials information through clinicaltrials.gov. Clinicaltrials.gov is a vital public resource for communicating findings from and opportunities to enroll in clinical trials on a wide range of diseases and disorders. It would be a disservice to the public to muddy clinicaltrials.gov with research findings resulting from basic science studies that were not designed or intended to yield results affecting potential interventions. Unintended adverse impacts could be felt elsewhere, including among IRBs, internal institutional (i.e. university, medical center) policies governing clinical trials, and even on the international stage where the term "clinical trials" is understood to mean something quite different.

The NIH is the world leader in biomedical and behavioral research. In achieving this status, NIH has invested in a broad range of research activities, from fundamental, basic discovery that is built on the testing of hypotheses and innovative new ideas, in turn creating a bedrock for future discoveries, to clinical trials that play the critical role of arbiter for ensuring safety and efficacy of new treatments and interventions. These activities are equally important components of the U.S. biomedical research enterprise. They also serve distinct (albeit connected) purposes and deserve processes and infrastructure that allow both to flourish. In order to best serve the NIH grantee community, and therefore the consumers of NIH research findings (i.e. patients), NIH must put in place an infrastructure that enhances NIH's stewardship of clinical trials at the same time it promotes the future progress of basic science research with human subjects.

COSSA joins with partners in the biomedical and behavioral science communities to continue to urge NIH to revisit the revised definition of "clinical trial" to clarify that research involving human participants is only a clinical trial when clear criteria are met. Specifically, COSSA would like to see NIH take the following steps:

(1) Clarify the definition of an "intervention."
The current definition of an "intervention" is exceptionally broad and can be interpreted as including any prospective manipulation of a subject's environment. A suggested change that could further clarify the definition of "clinical trials" might be: "an intervention that has the *intent* to change the health status of the individual/human subject." Such a change would distinguish studies according to the *intent* of the research or trial, not according to whether subjects are prospectively assigned, regardless of intent relative to health outcome.

(2) Eliminate the new class of basic research called, "prospective basic science studies involving human participants."
In its place, a system should be developed—in consultation with the basic research community—that more appropriately allows for the registering and reporting of all basic science studies involving human participants while not classifying them as clinical trials. The research community does not agree that certain areas of research meet the definitions of both "basic research" and "clinical research," primarily because the intent of basic research studies (including basic behavioral studies) are not to test an intervention or treatment. Creating a third category of research between basic and clinical will cause confusion among the research community, not to mention other potential downstream impacts noted earlier.

We understand that to fully address the community's concerns likely means additional delays in implementation of registering and reporting of basic science studies that involve human subjects and may also require additional resources. However, returning to the more traditional definition of "clinical trials"—perhaps with clarifying changes like those suggested above—coupled with the establishment of an appropriate registering and reporting process for basic research studies involving human participants will serve the NIH grantee community best in the long run.

COSSA hopes NIH will take the long view and work with the research community to develop a plan that not only addresses the transparency concerns of late, but that will prove to significantly enhance NIH-supported basic research for future generations of researchers and patients.

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