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NIH Clinical Trials Update: July 30, 2019

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Another incremental victory for behavioral scientists whose work is an uncomfortable fit for the NIH Clinical Trials registering and reporting requirements: In response to pressure by researchers, research associations such as SRCD, and Congress, NIH staff undertook an examination of published NIH-funded basic behavioral research (which NIH calls "BESH" –Basic Experimental Studies Involving Humans). This assessment seems to have helped them to understand more concretely why this is a "square peg in a round hole" problem. In recognition of the incompatibility of ClinicalTrials.gov with some NIH funded BESH research, NIH has announced a further delay in enforcement of the requirement to use ClinicalTrials.gov for reporting of basic behavioral research. Note that alternative registration and reporting platforms are required during this postponement. The new deadline for implementation (by which time they will hopefully have a more suitable alternative registration and reporting platform) is September 24, 2021. This is definitely a victory, but societies and associations like ours intend to continue vigilance and engagement. We must ensure that any alternative platforms are developed in consultation and collaboration with actual behavioral scientists effectively fit our community's needs.

As many of our members are aware, the National Institutes of Health (NIH) recently instituted a new definition of clinical trials that directly impacts many researchers in the behavioral and brain sciences. In in the service of improving reporting and compliance for those conducting clinical trials (typically of a medical or pharmaceutical nature), Dr. Francis Collins, Director of the NIH, redefined a clinical trial to include *any*

study that involves manipulation of a variable. Suddenly (and apparently unwittingly on the part of NIH), a large number of researchers who are not the target of Dr. Collins' reforms and have never conducted research previously construed as clinical trials, are now required to adhere to clinical trials guidelines. SRCD is addressing this problem in two ways:

- Society leadership has partnered with other behavioral science organizations including the Consortium of Social Science Associations (COSSA) and the Federation of Associations in the Behavioral and Brain Sciences (FABBS), reaching out to both NIH leadership and sympathetic members of Congress regarding the unintended consequences of this change in definition of clinical trials. We have underscored that the change creates significant additional burden both on investigators *and* on the scientific review process at NIH. Although Dr. Collins has remained steadfast in his commitment to this new definition, the scientific review staff are experiencing first-hand the consequences of this decision. We are hopeful that both pressure-from-within and Congressional pressure may result in some adjustments to the definition in the coming months.

- For those members who find themselves having to navigate these new and unchartered waters, we have listed (below) available resources on how to apply for NIH funding under current guidelines. We will continue to update this resource list and will disseminate additional information as it becomes available. Assuming the guidelines are not adjusted in the near future, we are also planning webinars with NIH staff to better equip developmental scientists who are weathering this change.

Quick Links

- **NIH's New Definition of a Clinical Trial**
- **Is my study a clinical trial according to NIH? Some Case Studies**
- **Clinical Trials FAQ**
- **Guidance on completing NIH forms under the new definition**
- **NIH Director's motivation for altering clinical trials definition**

Petitions and Open Letters to NIH

- **Letter to Congress** encouraging collaboration with NIH to redefine what constitutes as a clinical trial and to put in place a registration and reporting framework to prevent unnecessary duplication (PDF)
- **Open Letter to NIH Director Francis Collins, outlining concerns that the new policies will harm American science and public health (ipetitions)**

- **Joint Letter** to NIH by the Association of American Medical Colleges, Association of American Universities, Association of Public and Land-grant Universities and Council on Government (PDF)

Of Interest

- **NIH delays controversial clinical trials policy for some studies** (*Science Magazine*)
- **NIH's new clinical trial policy kicks in despite concerns from basic behavioral researchers** (*Science Magazine*)
- **Struggles with NIH Clinical Trial Policies Continue For Basic Scientists** (FABBS)