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NIH Clinical Trials Update: June 29, 2018

AUTHOR

In response to Congressional report language (see pages 34-35), and in follow up to a recent meeting among NIH and a group of stakeholders, NIH has developed a plan to "address the shared interests of involved stakeholders" and is preparing to "move forward so that [they] can widely communicate the delayed enforcement and lenient implementation described in the plan." Within the next two weeks, NIH will issue guide notices and a Request for Information (RFI). FABBS will share information as it becomes available and plans to respond to the RFI, working collaboratively with other stakeholders.

The Federation of Associations of Behavioral and Brain Sciencies (FABBS)

Read the full post on the FABBS website

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)