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NIH Clinical Trials Update: April 5, 2018

AUTHOR

We are disappointed to report that the instructions from Congress in the FY 2018 omnibus bill to delay the implementation of the new NIH clinical trials definition are not being interpreted by NIH in the spirit in which we believe they were intended. The Institutes have been instructed to continue to enforce the new definition of clinical trials for all new proposals for the time being. Our understanding is that NIH is choosing to interpret the language in the omnibus bill as referring only to reporting and registration guidelines (i.e., post-award procedures), not the submission process. The NIH has 30 days from the passing of the bill (which was on Mar 23) to report back to the House and Senate Appropriations Committees with a plan for consultation, so there may be further developments in the coming weeks. However, for now, NIH program staff have been advised that PIs should assume that any proposal that would be considered a clinical trial under the guidelines implemented in January should still be submitted as a clinical trial study. Please contact your NIH program officer with specific questions, and we will continue to monitor the situation and post updates as new developments occur. We are hopeful that the process will begin moving in the right direction soon, but it is obviously not yet where we need it to be.

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)