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NIH Clinical Trials Update: April 11, 2019

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NIH Releases Protocol Template for Behavioral and Social Sciences Research Involving Humans

In its latest attempt to respond to concerns regarding the treatment of all experimental manipulations as "clinical trials", NIH recently released a new resource for behavioral and social science researchers to prepare research protocols for human studies measuring a behavioral or social outcome or testing a behavioral or social science based intervention. The Behavioral and Social Clinical Trials Template was derived from the NIH-FDA Phase 2/3 IND-IDE Clinical Trial Template but was adapted to include terminology and approaches used by behavioral and social scientists. The template will be especially helpful for investigators who find themselves adapting protocols that have not previously been considered clinical interventions, to adhere with the clinical trials framework. Reaching out to relevant Program Director(s) may be helpful in obtaining further guidance.

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)