HOT TOPIC: New NIH "Clinical Trials" Definition to Impact Basic Social and Behavioral Science Research

The National Institutes of Health (NIH) has been working for the last few years to enhance its stewardship of and increase transparency over the clinical trials it funds. The agency, which is the largest funder of clinical trials in the U.S., issued a Notice of Revised NIH Definition of "Clinical Trial" (NOT-OD-15-015) in late 2014 laying out a new, expanded definition to govern which research projects are to be categorized as a "clinical trial" from here on out.

While this change has been in process for the last few years, it wasn't until more recently that the biomedical and behavioral research community started to take notice of the potentially significant impacts this new definition could have on a variety of basic research activities funded by the NIH, which will now be considered clinical trials. Although it was developed with
the traditional NIH biomedical research clinical trial in mind and in response to concerns about study results going unreported, the social and behavioral sciences are impacted as well.

The 2016 notice states that "the revision is designed to make the distinction between clinical trials and clinical research studies clearer and to enhance the precision of the information NIH collects, tracks, and reports on clinical trials." While it further states that the intention is not to "expand the scope of the category of clinical trials," the resulting policy does just that.

Read on for COSSA's full analysis of the changes.

COSSA IN ACTION

**Tomorrow: Social Science Solutions for Health, Public Safety, Computing, and Other National Priorities**

COSSA and SAGE Publishing will host a Congressional briefing on Wednesday, October 4 on Social Science Solutions for Health, Public Safety, Computing, and Other National Priorities. The event will feature authors of past Why Social Science? blog posts, including Representative Dan Lipinski (D-IL); Andrew Bernat, Computing Research Association; Nancy La Vigne, The Urban Institute; and William Riley, National Institutes of Health. The briefing will take place at noon in room 2075 of the Rayburn House Office Building. RSVPs are still being accepted here. For those unable to attend in person, the briefing will be livestreamed on COSSA’s Facebook page.

**Research!America Answers "Why Social Science?"**

This week's Why Social Science? guest post comes from Mary Woolley, President and CEO of Research!America, who writes about how research in the social and behavioral sciences has led to life-saving interventions. Read it here and subscribe.

FEDERAL AGENCY & ADMINISTRATION NEWS

**GAO Recommends Changes to NSF Indirect Cost Guidance**

A new report from the Government Accountability Office (GAO), Actions Needed to Improve Oversight of Indirect Costs for Research, finds that the National Science Foundation (NSF) "does not consistently take steps to ensure it pays no more than its fair share of indirect costs." Indirect costs, also referred to as facilities and administrative (F&A) costs, represent the portion of NSF awards that cover operational costs, such as maintenance, rent, and utilities. The report notes that while NSF has produced guidance for setting indirect cost rates, it is not implemented consistently. The report makes recommendations to ensure NSF staff follow its guidance more reliably, better document the process of setting indirect cost rates, and maintain consistency with the guidance set by other federal agencies. In a letter responding to the report (Appendix I), NSF concurred with GAO's recommendations and outlined the steps it will take to implement them. The complete report and a highlights page are available on GAO's website.

**HHS Requests Comments on Draft Strategic Plan**

The Department of Health and Human Services has invited comments on its draft strategic plan for fiscal years (FY) 2018-2022. The plan describes how the Department plans to advance its...
mission according to five strategic goals: "(1) Reform, Strengthen, and Modernize the Nation’s Health Care System; (2) Protect the Health of Americans Where They Live, Learn, Work, and Play; (3) Strengthen the Economic and Social Well-Being of Americans across the Lifespan; (4) Foster Sound, Sustained Advances in Sciences; and (5) Promote Effective and Efficient Management and Stewardship." HHS is accepting comments through October 26, 2017. More information is available in the Federal Register notice.

**NSF Releases Video on Social Science Research's Importance to Disaster Preparedness**

The National Science Foundation (NSF) released a video on September 15 highlighting the contributions of the social sciences in disaster preparedness and response. The video explains that together with improvements in the science of forecasting, social science has helped more effectively communicate the potential risk of natural disasters and more effectively respond after disasters hit. The video is among a suite of new resource posted to the NSF website highlighting the many contributions of basic science to everyday life.

**NSF Releases Dear Colleague Letters on Research Methodologies for STEM Education and Broadening Participation in Science**

The Education and Human Resources Directorate (EHR) of the National Science Foundation (NSF) released a Dear Colleague Letter on September 19 announcing their intention to support fundamental research on methodologies that support valid inferences in science, technology, engineering, and mathematics (STEM) education. The letter also includes invitations to submit proposals on a variety of aspects of research methodology for a variety of grant types, including conference proposals or early-stage research. More information can be found here.

EHR also released a Dear Colleague Letter on September 26 in partnership with the Social, Behavioral, and Economic Sciences Directorate (SBE) to announce their interest in continuing support of research related to the science of broadening participation in science. In fiscal year (FY) 2018, SBE and EHR will partner to support research proposals that contribute to the overall understanding of the positive and negative factors impacting the participation of underrepresented communities in STEM. More information can be found here.

**NSF Extends Application Deadline for Director of Division of Behavioral and Cognitive Sciences Position**

The National Science Foundation (NSF) is seeking candidates for the Director of the Division of Behavioral and Cognitive Sciences (BCS) within the Directorate of Social, Behavioral, and Economic Sciences (SBE). The BCS Director is responsible for providing leadership and direction to the Division and implementing overall strategic planning. The BCS Division provides funding for research that helps advance scientific knowledge about the brain, human cognition, language, social behavior, and culture. Applications must be submitted by October 29, 2017. The position requirements can be found on USAJobs.

**PUBLICATIONS & COMMUNITY EVENTS**

**National Academies Calls for Nominations for Committee to Assess the Minerva Research Initiative**

The Board of Behavioral, Cognitive, and Sensory Sciences (BBCSS) at the National Academies of Sciences, Engineering, and Medicine announced a new project funded by the Department of Defense to assess its Minerva Research Initiative. The Minerva Initiative is a Department of
Defense-sponsored university-based social science research program that supports basic research to better understand the social, cultural, behavioral, and political forces that shape the world, including international conflicts. BBCSS is seeking applications for committee members who will lead this assessment. More information can be found here, and applications for committee membership can be submitted here.

**SBS Graduate Training Workshop Proceedings Published**

The National Academies of Sciences, Engineering, and Medicine has published the proceedings of a workshop held in June 2017, *Graduate Training in the Social and Behavioral Sciences*. The workshop was convened by the Academies' Board on Science Education and sponsored by the National Science Foundation and the National Institutes of Health. The workshop focused on how graduate education in the social and behavioral sciences can adapt to increasing focuses on interdisciplinarity and changing workforce needs. The workshop summary and a webcast of the workshop are available on the Academies' website.

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**FUNDING OPPORTUNITY ANNOUNCEMENTS**

- NSF: [Cyberlearning for Work at the Human-Technology Frontier](#) (NSF 17-598)

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**EVENTS CALENDAR**

- [Why Social Science? Congressional Briefing on Social Science Solutions for Health, Public Safety, Computing, and Other National Priorities](#), October 4, 2017, Washington, DC
- [The Lunch @ DC: The Promise of Evidence-Based Policymaking: Recommendations of the Commission on Evidence-Based Policymaking](#), October 5, 2017, Washington, DC
- [American Statistical Association Symposium on Statistical Inference](#), October 11-13, 2017, Bethesda, MD
- [National Research Summit on Care, Services and Supports for Persons with Dementia and Their Caregivers](#), October 16-17, 2017, Bethesda, MD
- [The Lunch @ DC: How Evidence Can Transform the Fight Against Poverty](#), October 19, 2017, Washington, DC
- [Council on Social Work Education Annual Program Meeting](#), October 19-22, 2017, Dallas, TX
- [Fall 2017 Henry and Bryna David Lecture - Child Support in the Age of Complex Families: It's Critical, but it's Broken](#), October 26, 2017, Washington, DC
- [Council of Colleges of Arts and Sciences Annual Meeting](#), November 1-4, 2017, Denver, CO
- [Association for Public Policy Analysis and Management Fall Research Conference](#), November 2-4, 2017, Chicago, IL
- [Social Science History Association Annual Meeting](#), November 2-5, Montreal, Canada
- [North American Regional Science Council Annual Meeting](#), November 8-12, 2017, Vancouver, Canada
- [History of Science Society Annual Meeting](#), November 9-12, Toronto, Canada
- [American Society of Criminology Annual Meeting](#), November 15-18, 2017, Philadelphia, PA
- [National Council on Family Relations Annual Conference](#), November 15-18, 2017, Orlando, FL
- [National Communication Association Annual Convention](#), November 16-19, 2017, Dallas, TX
A list of COSSA members' annual meetings and other events can be found on the COSSA events page. COSSA members who have an upcoming event they would like to see listed in the Events Calendar and on our website should send an email to jmilton@cossa.org.
The Consortium of Social Science Associations (COSSA) is a nonprofit advocacy organization working to promote sustainable federal funding for and widespread use of social and behavioral science research and federal policies that positively impact the conduct of research. COSSA serves as a united voice for a broad, diverse network of organizations, institutions, communities, and stakeholders who care about a successful and vibrant social science research enterprise. The COSSA membership includes professional and disciplinary associations, scientific societies, research centers and institutes, and U.S. colleges and universities.

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