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Welcome to



CSSA HEADLINES

A monthly look at what's new and noteworthy in social science policy



- ❑ This Month's HEADLINES
- ❑ This Month's DEEP DIVE: NIH Clinical Trials Policy and Updates from the Office of Behavioral and Social Sciences Research, featuring Dr. Bill Riley, OBSSR
- ❑ This Month's HOMEWORK: What you can do this month



This Month's Experts



Wendy Naus
wnaus@coffa.org



Bill Riley, NIH/OBSSR
william.riley@nih.gov



MEMBERSHIP ORGANIZATIONS

Academy of Criminal Justice Sciences
African Studies Association
American Association of Geographers
American Council of Learned Societies
American Evaluation Association
American Historical Association
American Psychosomatic Society
Association for Behavioral and Cognitive Therapies
Association for Public Policy Analysis and Management
Association of Academic Survey Research Organizations
Association of Research Libraries
Council of Colleges of Arts & Sciences
Council on Social Work Education
Economic History Association
History of Science Society
Midwest Sociological Society
National Association of Social Workers
National Council on Family Relations
North American Regional Science Council
Rural Sociological Society
Social Science History Association
Society for Prevention Research
Society for Research on Adolescence
Society for Social Work and Research
Society for the Psychological Study of Social Issues
Society of Behavioral Medicine
Southern Political Science Association
Southern Sociological Society
Southwestern Social Science Association

COLLEGES & UNIVERSITIES

Arizona State University
Boston University
Brown University
Carnegie Mellon University
Columbia University
Cornell University
Duke University
Fielding Graduate University
George Mason University
Georgetown University
Harvard University
Indiana University
John Jay College of Criminal Justice, CUNY
Johns Hopkins University
Massachusetts Institute of Technology
Michigan State University
New York University
North Carolina State University
Northwestern University
Pennsylvania State University
Princeton University
Rutgers, The State University of New Jersey
Stanford University
Texas A&M University
The George Washington University
The Ohio State University
University of Arizona
University of California, Berkeley
University of California, Irvine
University of California, Los Angeles
University of California, Santa Barbara
University of Colorado, Boulder

University of Chicago
University of Georgia
University of Illinois
University of Iowa
University of Maryland
University of Michigan
University of Minnesota
University of Nebraska, Lincoln
University of North Carolina, Chapel Hill
University of Oklahoma
University of Pennsylvania
University of Pittsburgh
University of Texas, Austin
University of Texas, San Antonio
University of Virginia
University of Washington
University of Wisconsin, Madison
Virginia Tech
West Virginia University
Yale University

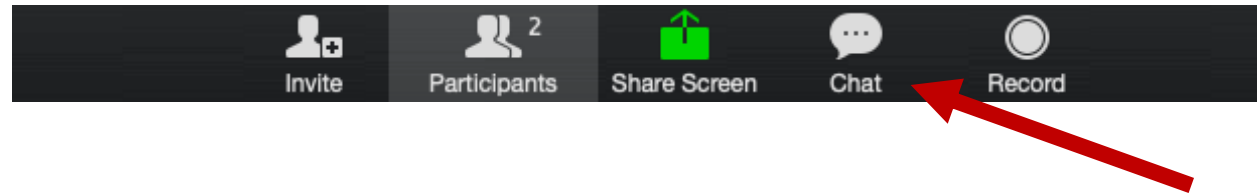
CENTERS & INSTITUTES

American Academy of Arts and Sciences
American Academy of Political and Social Science
Center for Advanced Study in the Behavioral Sciences
Cornell Institute for Social and Economic Research
Institute for Social Research, University of Michigan
Institute for Social Science Research, University of
Massachusetts, Amherst
NORC at the University of Chicago
RTI International
Social Science Research Council



Quick Questions

Use the chat box to ask a question.



More opportunities for Q&A at the end.



This Month's Headlines



CONGRESS

- FY 2019 CR expires 12/21
 - More: www.cossa.org/advocacy/funding-updates
- New day on the House Science Committee
 - Visit: www.democrats-science.house.gov
- Looking ahead

EXECUTIVE BRANCH

- Fate of pending nominations
- White House issues STEM Education Plan
 - Visit: www.whitehouse.gov/articles/america-will-win-global-competition-stem-talent
- Latest NSF “Big Ideas” solicitation
 - www.nsf.gov/news/special_reports/big_ideas/index.jsp
- NIH FOA for Prospective Basic Science Studies Involving Human Participants
 - More: www.grants.nih.gov
- Funding Opportunities
 - More: www.cossa.org/resources/funding-opportunities



COMMUNITY

- NASEM: Advancing Science Communication Research and Practice Standing Committee
 - More: www.sites.nationalacademies.org/dbasse/advancing-science-communication/index.htm
- Reports:
 - More: www.cossa.org/resources/recent-reports

COSSA

- 2019 Social Science Advocacy Day, 4/30 to 5/1
 - Registration opens soon! www.cossa.org/event/2019-advocacy-day
- Why Social Science? – Linguist Claudia Brugman
 - More: www.whysocialscience.com

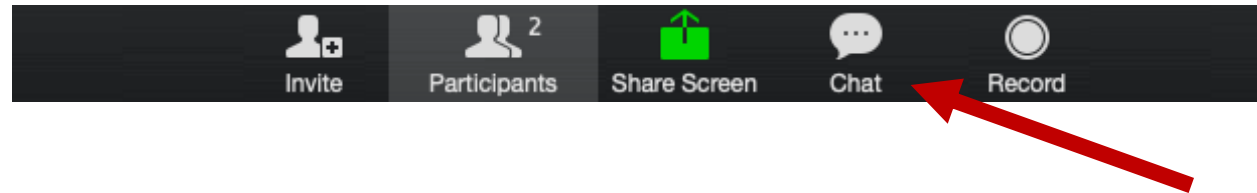


WASHINGTON UPDATE

Subscribe for even more: www.cossa.org/washington-update

Quick Questions

Use the chat box to ask a question.



More opportunities for Q&A at the end or
email me at wnaus@coasa.org





NIH Clinical Trials Policy and Updates from the Office of Behavioral and Social Sciences Research

Today's Guest: Dr. William "Bill" Riley

NIH Associate Director for Behavioral and Social Sciences Research,
and Director of the Office of Behavioral and Social Sciences Research
(OBSSR)





National Institutes of Health
Office of Behavioral and Social Sciences Research



Behavioral and Social Sciences at the NIH

Office of Behavioral and Social Sciences Research
National Institutes of Health

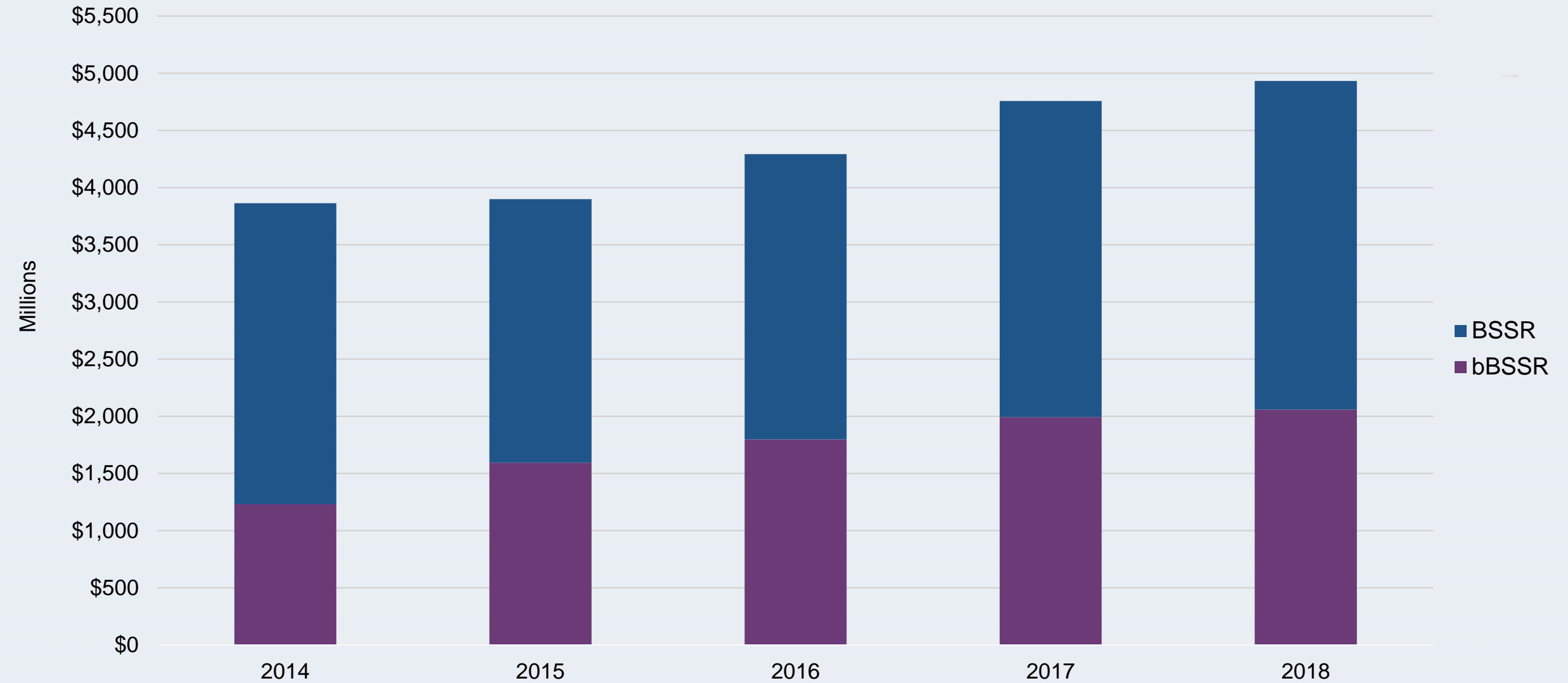
William T. Riley, Ph.D.
NIH Associate Director for Behavioral and Social Sciences
Research
Director, Office of Behavioral and Social Sciences Research

December 13, 2018

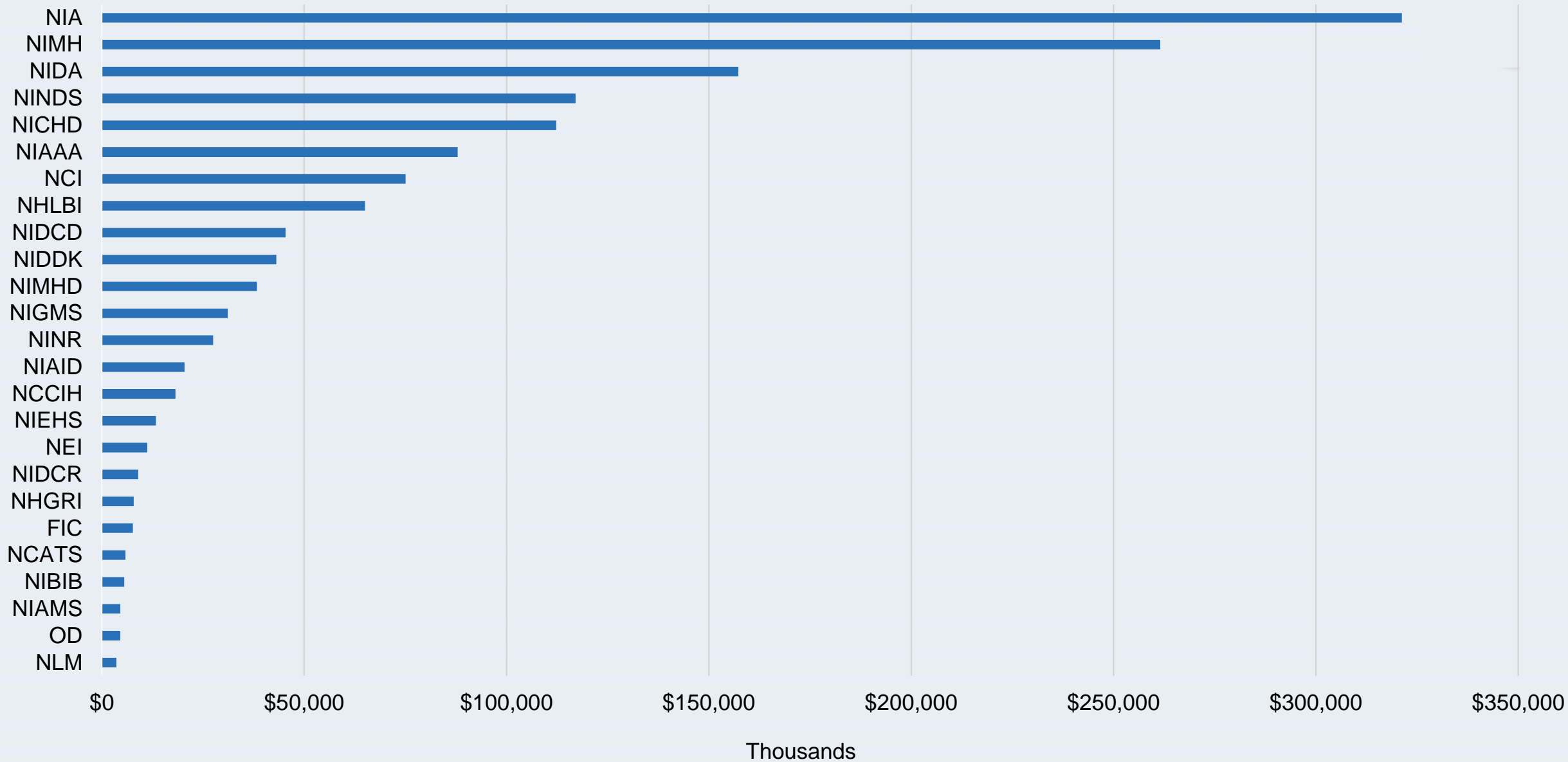
NIH Behavioral and Social Sciences Research Funding

Fiscal Year 2018

Total NIH BSSR and bBSSR Funding by FY (RCDC)



FY18 BSSR Competitive Funding by Institute or Center



BSSR Content Areas

Addictive Behaviors

- Processes / Mechanisms
- Prevention / Cessation
- Risk of Substance Use/Abuse

Attention, Learning & Memory

- Neurobiological/Psychological Processes / Mechanisms of Attention, Learning and Memory
- Disorders of Attention, Learning & Memory (e.g., dementia) & Interventions

Developmental Processes & Family Health

- Developmental Processes from Conception to Death
- Maternal Health, Parental Behavior, Family Dynamics
- Adverse Events that Affect Development

Food Intake & Physical Activity

- Behaviors Associated with Energy Intake & Expenditure
- Treatment of Obesity, Malnutrition

Healthcare & Disease Management

- Healthcare Access
- Provider-Patient Interactions
- Health Literacy
- Medical Errors
- Treatment Adherence
- Disease Management

Language & Communications Disorders

- Communication Processes
- Impairments in Receptive/Expressive Verbal and Nonverbal Communication
- Interventions

Mental Health

- Bio-Psycho-Social Processes Involved in Regulating Mental Health/Illness
- Interventions
- Influences of Mental Health on Other Conditions

Pain, Injury, & Disability

- Functional Impairments that Reduce Quality of Life
- Pathophysiology, Management, and Rehabilitation
- Prevention of Injury and Falls

Sensation & Perception

- Mechanisms of Sight, Sound, Taste, Touch, Smell, Interoception, Balance, Proprioception, Time, Temperature
- Perception / Integration / Interpretation / Response

Sexual Behaviors

- Sexual Attitudes / Behaviors
- Bio-Psycho-Social Influences
- Risky Sexual Behavior
- Interventions

Sleep

- Bio-Psycho-Social Processes
- Sleep Disorders
- Circadian Rhythms
- Effects of Sleep on Performance / Disease Risk
- SIDS

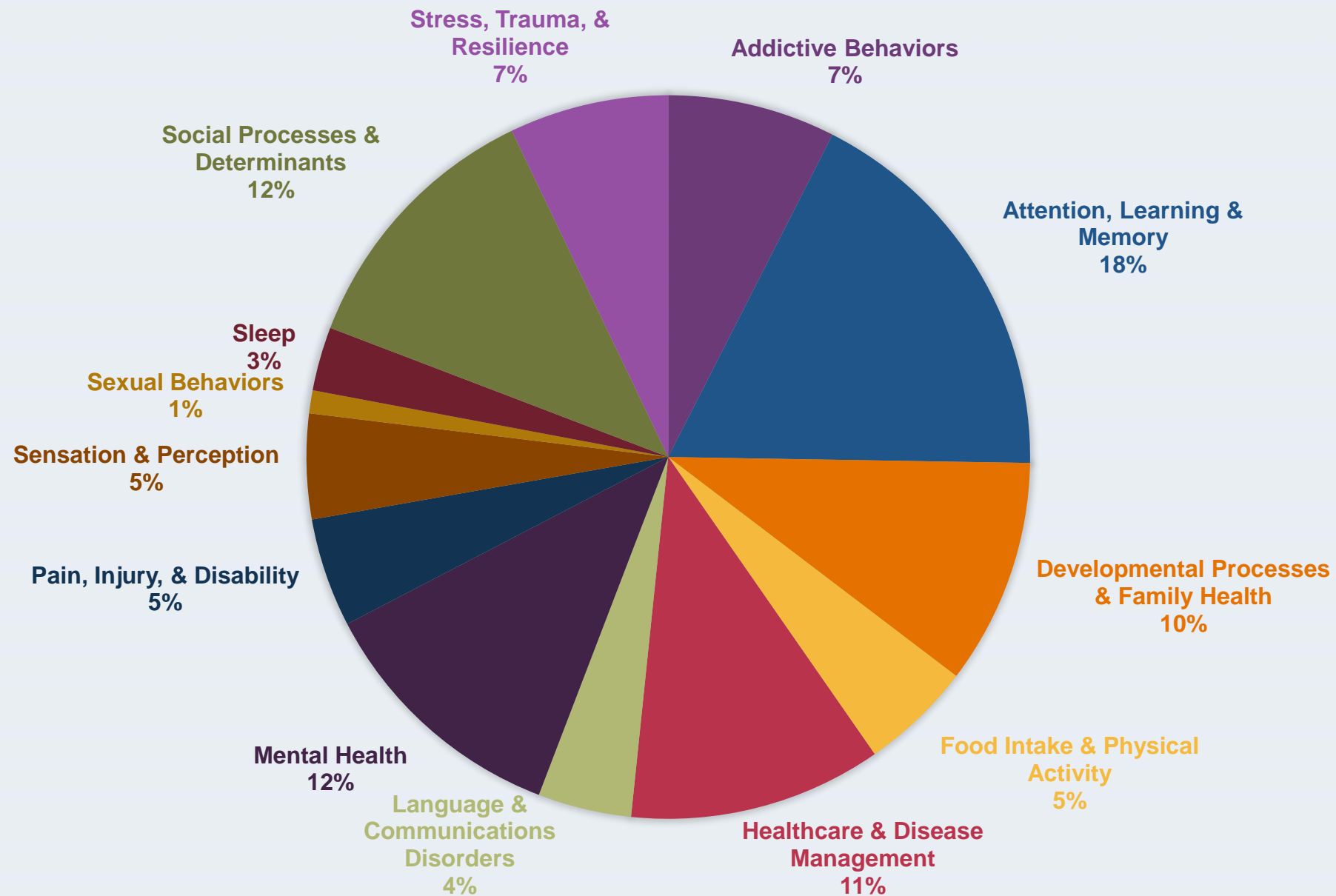
Social Processes & Determinants

- Social / Economic Influences
- Cultural/Community Factors
- Policy Impacts
- Health Disparities

Stress, Trauma, & Resilience

- Effects of Exposure to Stressors/Trauma on Health & Well-Being
- Coping/Resilience
- Interventions

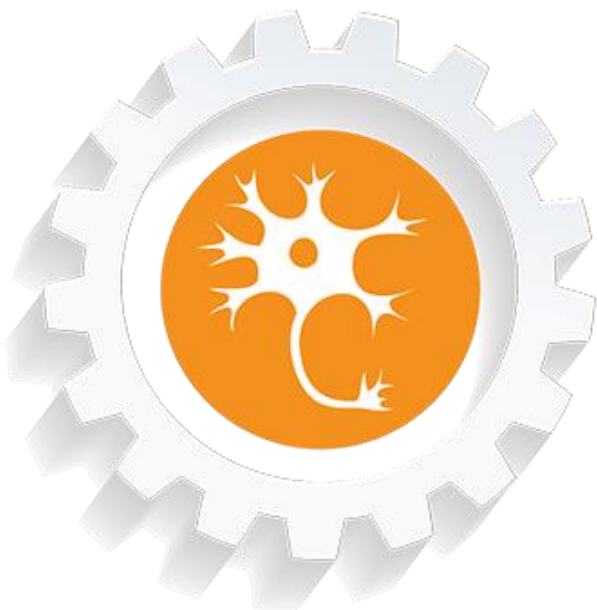
FY18 BSSR COMPETITIVE FUNDING BY CONTENT AREAS



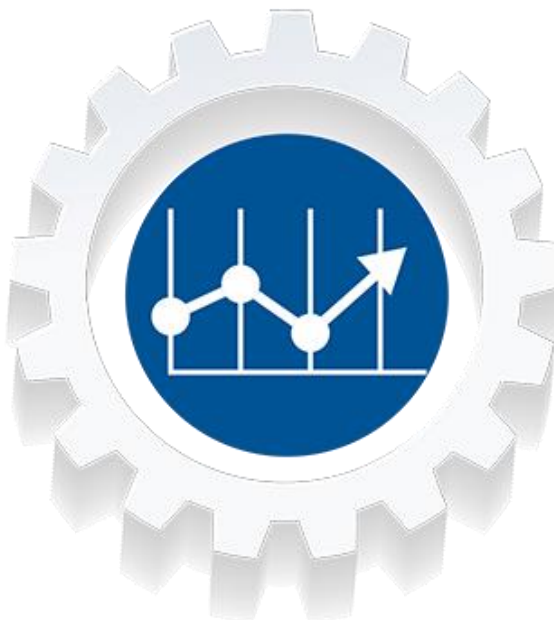
Highlighting a Few OBSSR Activities and Accomplishments

Fiscal Year 2018

**BASIC + APPLIED
RESEARCH SYNERGY**



**METHODS, MEASURES +
DATA INFRASTRUCTURES**



**APPLICATION + ADOPTION
OF BSSR RESEARCH**



COMMUNICATION



**PROGRAM COORDINATION
+ INTEGRATION**



TRAINING



POLICY + EVALUATION

Scientific Priority 1: Improve the Synergy of Basic and Applied Behavioral and Social Science Research



- ▶ Continuing support of OppNet to advance basic behavioral and social science research
- ▶ Brain-Behavior Quantification meeting for BRAIN Initiative



Scientific Priority 2: Enhance the Methods, Measures, and Data Infrastructures to Encourage a More Cumulative Behavioral and Social Sciences

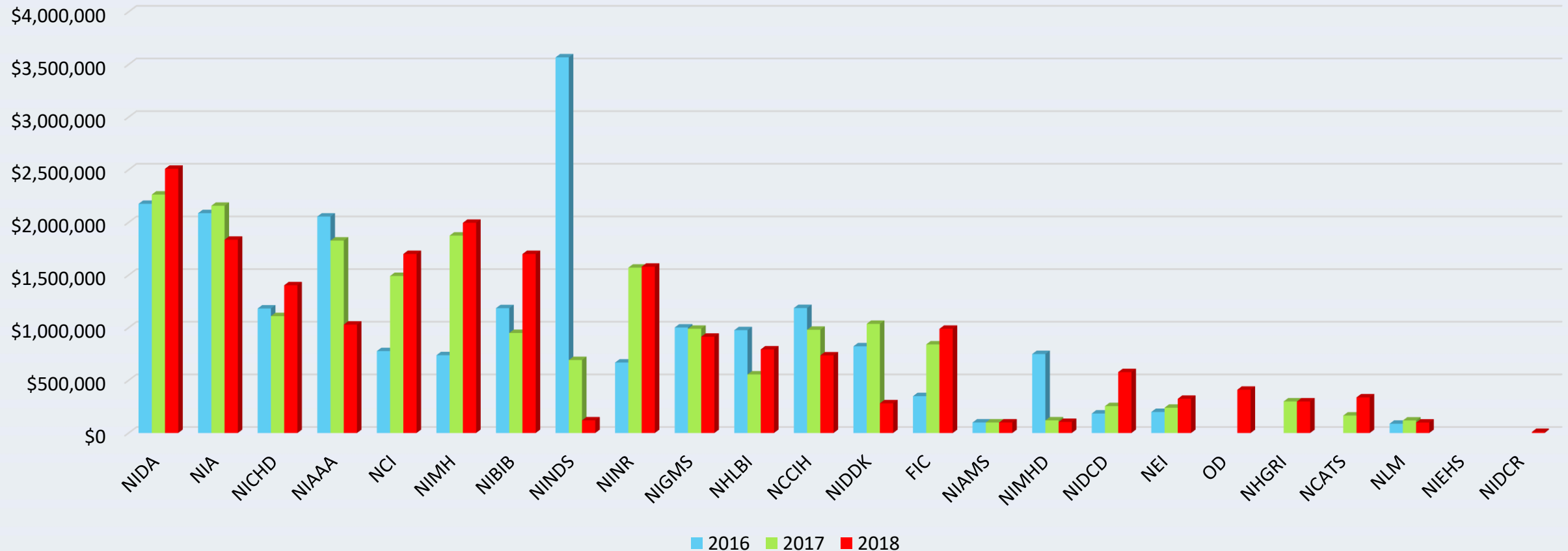
- ▶ Longitudinal Analysis of Health Behaviors
- ▶ OBSSR Methodology Workshop: Predictive Modeling for Behavioral and Social Sciences Health Research

Scientific Priority 3: Facilitate the Adoption of Behavioral and Social Science Research Findings in Health Research and Practice



- ▶ Contributions of Social and Behavioral Research to Addressing the Opioid Crisis (March 5-6, 2018) – integrated the behavioral and social sciences into the NIH HEAL initiative.
- ▶ Coordination of TIDIRH (D&I) Training

Trends in OBSSR Co-funding Support of Grants



2016 N = 101

2017 N = 120

2018 N = 127

*Does not include D43 awards or contracts/IAA



NIH Clinical Trials Policies Update



Imagine . . .

. . . that to increase research transparency and accountability, NIH released an “**experimental studies involving humans**” policy to:

1. Certify that all involved in such research receive online training in participant and data protections.
2. Obtain study information (sample, methods, hypotheses) via form fields in the grant application to monitor and report on these studies
3. Require that investigators register the study protocol within 21 days of first participant, and report primary findings within one year of last data collection point.



. . . and the world will be as one

All of this is true except that this is the “NIH Clinical Trials Policy”

NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

Notice Number: NOT-OD-16-149

Key Dates

Release Date: September 16, 2016

Effective Date: January 18, 2017

Related Announcements

[NOT-OD-15-019](#)

Issued by

National Institutes of Health ([NIH](#))

Purpose

Summary

The National Institutes of Health (NIH) is issuing this policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results information of these trials is submitted to ClinicalTrials.gov. The policy is complementary to the statutory and regulatory reporting requirements. These are section 402(j) of the Public Health Service Act, as amended by Title VIII of the Food and Drug Administration (FDA) Amendments Act of 2007 (FDAAA), and the regulation Clinical Trial Registration and Results Information Submission, at 42 CFR Part 11. Hereafter, we refer to section 402(j) as the statute and 42 CFR Part 11 as the rule or regulation. This [policy](#) as well as the [rule](#) were posted in the Federal Register.

VIEWPOINT

Toward a New Era of Trust and Transparency in Clinical Trials

Kathy L. Hudson, PhD
National Institutes of Health, Bethesda, Maryland.

Michael S. Lauer, MD
National Institutes of Health, Bethesda, Maryland.

Francis S. Collins, MD, PhD
National Institutes of Health, Bethesda, Maryland.



Supplemental content

Clinical trials are the most publicly visible component of the biomedical research enterprise, from the potential human application of novel laboratory findings to the generation of robust evidence about treatments or preventive interventions in routine clinical care. These trials are also the point at which biomedical research most directly engages human participants—dedicated volunteers who trust investigators to uphold the highest standards of scientific rigor and ethical oversight. While clinical trials have evolved and improved over time—producing impressive advances in diagnosis, treatment, and prevention—there are still major challenges. Therefore, fundamental changes are needed to reflect science and society’s movement to increase efficiency, accountability, and transparency in clinical research.

As the largest public funder of clinical trials in the United States, currently investing more than \$3 billion each year, the National Institutes of Health (NIH) takes its stewardship of the nation’s clinical trial enterprise very

The aim is to help ensure that all involved in the clinical trial enterprise have the appropriate knowledge about the design, conduct, monitoring, recording, analysis, and reporting of clinical trials. While GCP training on its own may not be sufficient, it provides a consistent and high-quality standard.

Another important change at the beginning of the clinical trial lifecycle is a new NIH policy that will require all applications for clinical trials to be submitted in response to clinical trial-specific Funding Opportunity Announcements (FOAs). This will mean that applications including one or more clinical trials will no longer be accepted in response to parent funding announcements, which are broad FOAs that allow researchers to submit investigator-initiated applications without specific elements appropriate to describe and evaluate a trial. Under this policy, NIH trial applications will need to contain specific information about protocols and other information necessary for effective peer and program-

Hudson KL, Lauer MS, Collins, FS (2016) JAMA, 316:1353-4.

NIH Revised Definition of a Clinical Trial

Notice of Revised NIH Definition of “Clinical Trial”

Notice Number:

NOT-OD-15-015

Key Dates

Release Date: October 23, 2014

Related Announcements

None

Issued by

National Institutes of Health ([NIH](#))

Purpose

The purpose of this Notice is to inform the research community that NIH has revised its definition of “clinical trial.” 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. It is not intended to expand the scope of the category of clinical trials. No changes have been made to the NIH definition of a “Phase III clinical trial.”

In addition, because clinical trials are subject to additional oversight, a clearer definition will help investigators ensure that they are meeting all of their obligations, and it will help NIH ensure that the additional oversight is occurring when it is needed. For example, NIH policy requires clinical trials to be monitored, and applicants and offerors seeking NIH support are expected to describe their plans for data and safety monitoring in their applications and proposals. Final data and safety monitoring plans must be approved by the NIH prior to award. In addition, throughout the life of the award, NIH staff monitors the clinical trial’s progress to ensure that milestones are met and that any safety concerns are addressed.

A research study¹ in which one or more human subjects² are prospectively assigned³ to one or more interventions⁴ (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.⁵

Blog Post - Implications of Clinical Trials Policy for Behavioral Researchers

“While basic behavioral and social science researchers may not consider their manipulation an “intervention” or their lab research a “clinical trial,” it may be interpreted as such under this definition.”

<https://obssr.od.nih.gov/new-nih-clinical-trials-policies-implications-for-behavioral-and-social-science-researchers/>



New NIH Clinical Trials Policies: Implications for Behavioral and Social Science Researchers

October 18, 2016

Last month, the NIH released new policies and related efforts to improve our stewardship, accountability, and transparency of clinical trials.

NIH is the largest funder of clinical trials in the U.S., and these multi-faceted efforts are designed to address issues at multiple stages of the clinical trials process, from grant application through dissemination of results to the public. Although these policies and efforts were developed primarily with the traditional biomedical clinical trial in mind, they are applicable to social and behavioral trials as well. Therefore, the purpose of this rather lengthy and policy dense blog is to assist the behavioral and social sciences research community in adhering to these policies and efforts, and to highlight OBSSR's efforts to make these policies and efforts fit better with the typical social or behavioral intervention trial. A working group of the NIH Behavioral and Social Sciences Research Coordinating Committee (BSSR-CC), led by Melissa Riddle and Stephane Philogene, is addressing various aspects of these NIH policies to determine whether additional guidance may be needed to facilitate the application of the policies to social and behavioral intervention research.

As a starting point for determining whether the policies are applicable to a social or behavioral intervention trial, it is critically important to understand what is meant by “clinical trial.” The clinical trials policies below are based on the [NIH Definition of a Clinical Trial](#) - “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” Understanding each component of this definition is important for determining if a behavioral or social science study meets the definition of a clinical trial.

Why Require Good Clinical Practice (GCP) Training?

- GCP is an international standard for the conduct and reporting of clinical trials
- Initially developed for industry trials but includes broadly applicable basic research principles:
 - Ensuring the protection of participant rights, integrity, and confidentiality
 - Ensuring data credibility and accuracy
- Requires that all involved with the study complete online training every three years
- OBSSR provides a GCP for behavioral research and is working on a basic science version of GCP

- University of Michigan CTSA produced an online GCP training tailored to social and behavioral research
- OBSSR makes these materials available for download to any LMS
- Institutions and organizations are encouraged to make this training available

The screenshot displays the NIH Office of Behavioral and Social Sciences Research (OBSSR) website. The header includes the NIH logo and the text "National Institutes of Health" and "Office of Behavioral and Social Sciences Research". Below this is the tagline "Healthier Lives through Behavioral and Social Sciences". A navigation bar contains links for Home, Funding, Scientific Initiatives, Training, Events, News, OBSSR Connector, and About Us. The main content area features the title "GOOD CLINICAL PRACTICE FOR SOCIAL AND BEHAVIORAL RESEARCH – ELEARNING COURSE". Below the title, a paragraph states: "In September 2016, the NIH issued a Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>). Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials. The principles of GCP help assure the safety, integrity, and quality of clinical trials. Investigators and clinical trial staff who are competent in GCP principles will be better able to assure that the rights, safety and well-being of human subjects are protected; that clinical trials are conducted in accordance with approved plans and with rigor and integrity, and that data derived from clinical trials are reliable." To the right of this text is a section titled "UPCOMING EVENTS" with a date "08 DEC" and the event name "NIH Behavioral and Social Sciences Research Festival". At the bottom of the screenshot, the URL <https://obssr.od.nih.gov/training/web-based-learning/good-clinical-practice-for-social-and-behavioral-research-elearning-course/> is displayed.

NIH National Institutes of Health
Office of Behavioral and Social Sciences Research

Healthier Lives through Behavioral and Social Sciences

Home | Funding | Scientific Initiatives | Training | Events | News | OBSSR Connector | About Us

GOOD CLINICAL PRACTICE FOR SOCIAL AND BEHAVIORAL RESEARCH – ELEARNING COURSE

In September 2016, the NIH issued a Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>). Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials. The principles of GCP help assure the safety, integrity, and quality of clinical trials. Investigators and clinical trial staff who are competent in GCP principles will be better able to assure that the rights, safety and well-being of human subjects are protected; that clinical trials are conducted in accordance with approved plans and with rigor and integrity, and that data derived from clinical trials are reliable.

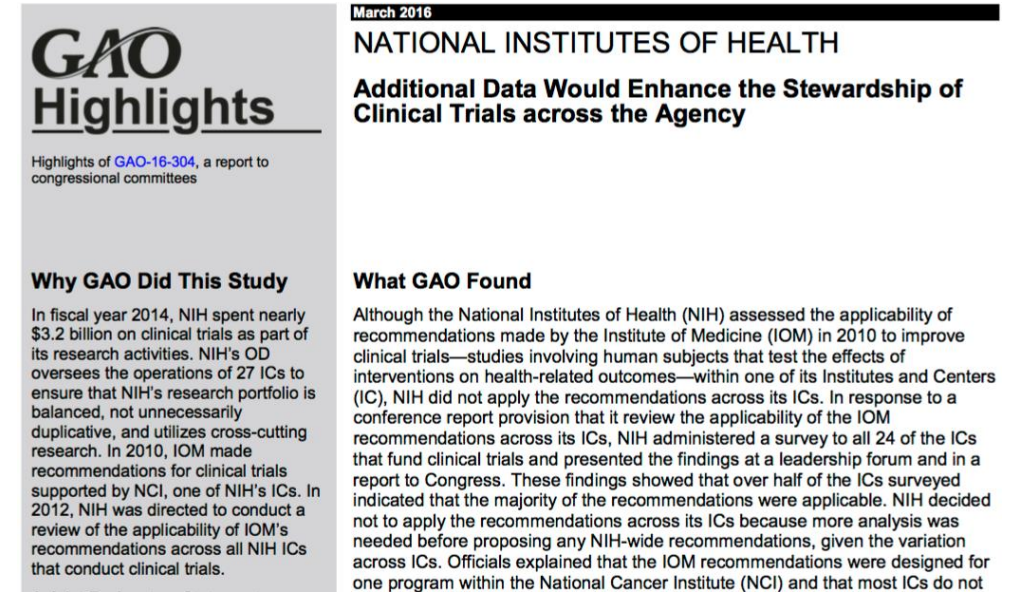
UPCOMING EVENTS

08 DEC NIH Behavioral and Social Sciences Research Festival

<https://obssr.od.nih.gov/training/web-based-learning/good-clinical-practice-for-social-and-behavioral-research-elearning-course/>

Why Require a Separate FOA with Form Fields?

- GAO recommended to Congress that we do a better job reviewing clinical trials data
- Form fields will allows NIH to track and monitor grants subject to the clinical trials policy
- Form fields are the same as in ClinicalTrials.gov (working on automated import from FOA to CT.gov)
- Preliminary report from reviewers that they like the form fields – easily find info



NIH's Office of the Director (OD) reviews some data on clinical trial activity across NIH but has not finalized what additional data it needs or established a process for using these data to enhance its stewardship of clinical trials, as intended by NIH's own recommendations . . . GAO recommends that the NIH OD (1) finalize data on clinical trial activity that the OD needs to collect from ICs, and (2) establish and implement a process for using those data.

Why Registration and Reporting via ClinicalTrials.gov?

- Behavioral and Social Sciences have been leaders in preregistration and open science
 - Registration and reporting minimizes selective reporting and publication bias
 - A third to a half of studies fail to publish in a timely manner.
 - Ethical obligation for sacrifice of participants to benefit scientific progress
- Reviewing responses to RFI regarding alternatives to clinicaltrials.gov
- ClinicalTrials.gov can handle BSSR (basic & applied)
 - Thousands of basic science studies in CT.gov
 - Can receive data from other registries
- Working with CT.gov to improve interface and provide help for researchers

Registered Reports: Peer review before results are known to align scientific values and practices.

The screenshot displays the ClinicalTrials.gov website. At the top, a navigation bar includes links for 'Registered Reports', 'Participating Journals', 'Details and Workflow', 'Resources for Editors', 'For Funders', and 'FAQ'. The 'Registered Reports' section is active, containing text about the format and a list of features for registered reports. Below this, the NIH U.S. National Library of Medicine logo and the 'ClinicalTrials.gov' name are shown, along with navigation links like 'Find Studies', 'About Studies', 'Submit Studies', 'Resources', and 'About Site'. A blue banner states: 'ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.' Below the banner, there is a section titled 'Explore 260,293 research studies in all 50 states and in 201 countries.' followed by a disclaimer and a search interface. The search interface includes a 'Search' button, a 'Condition / Disease' dropdown, an 'Other Terms' dropdown, and a 'Country' dropdown. There are also buttons for 'Find a study to participate in' and 'Search all studies', and a link to 'Advanced Search'.

Registered Reports

Currently, **80** journals use the Registered Reports publishing format either as a **regular submission option** or as part of a single **special issue**. Other journals offer **some features** of the format. This list will be updated regularly as new journals join the initiative. See also our [table](#) that compares the specific features of Registered Reports at different outlets.

For an article type to qualify as a registered report, the journal policy must include at least these features:

- Peer review occurs prior to observing the outcomes of the research.
- Manuscripts that survive pre-study peer review receive an in-principle acceptance that will not be revoked based on the outcomes, but only on failings of quality assurance, following through on the registered protocol, or unresolvable problems in reporting clarity or style.

NIH U.S. National Library of Medicine

ClinicalTrials.gov

[Find Studies](#) [About Studies](#) [Submit Studies](#) [Resources](#) [About Site](#) [Saved Studies \(0\)](#)

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore **260,293** research studies in all 50 states and in 201 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Search (all fields optional)

Condition / Disease: e.g. breast cancer

Other Terms: e.g., NCT number, drug name, investigator name

Country:

[Find a study to participate in](#) [Search all studies](#)

[Advanced Search](#)

Healthier Lives through Behavioral and Social Sciences

Basic Experimental Studies Involving Humans (BESH)

Funding Opportunity Title	NIH Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)
Activity Code	R01 Research Project Grant
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	PA-19-091
Companion Funding Opportunity	PA-19-055 Parent R01 Clinical Trial Required PA-19-056 Parent R01 Clinical Trial Not Allowed
Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.213, 93.866, 93.273, 93.279, 93.173, 93.121, 93.113, 93.242, 93.307, 93.853, 93.361, 93.879
Funding Opportunity Purpose	<p>The NIH Research Project Grant supports a discrete, specified, circumscribed project in areas representing the specific interests and competencies of the investigator(s).</p> <p>This Parent Funding Opportunity Announcement is for basic science experimental studies involving humans, referred to in NOT-OD-18-212 as “prospective basic science studies involving human participants.” These studies fall within the NIH definition of a clinical trial and also meet the definition of basic research. Types of studies that should submit under this FOA include studies that prospectively assign human participants to conditions (i.e., experimentally manipulate independent variables) and that assess biomedical or behavioral outcomes in humans for the purpose of understanding the fundamental aspects of phenomena without specific application towards processes or products in mind. Studies conducted with specific applications toward processes or products in mind should submit under the appropriate ‘Clinical Trials Required’ or ‘Clinical Trial Optional’ FOA.</p> <p>The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions.</p>

Open Mike

Helping connect you with the NIH perspective, and helping connect us with yours

Posted on November 28, 2018 by Mike Lauer and William T. Riley

New Funding Opportunities for Basic Experimental Studies Involving Humans

Over the past year, since we published an essay in *Nature Human Behaviour* on “NIH policies on experimental studies with humans,” NIH has engaged in a discussion with the basic science community to find ways to meet our shared obligations to study participants and taxpayers, while respecting the unique goals and outcomes of basic science. While we are still in the [midst of that conversation](#), we are pleased to announce real progress in the form of new funding opportunity announcements for [Basic Experimental Studies Involving Humans](#).

Since October 2014, the NIH defines a clinical trial as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” ([NOT-OD-15-015](#)). We appreciate that not all studies meeting this NIH definition of a “clinical trial” are “clinical” in nature. Some studies involve preventive interventions with healthy individuals or interventions with patients in settings other than the healthcare system. Other studies constitute basic research, defined as the “systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind.” ([32 CFR 272.3](#)). Indeed, [over 10,000 trials](#) registered in ClinicalTrials.gov indicate that their primary purpose is basic research.



Dr. Michael Lauer is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.



William T. Riley, Ph.D., Associate Director of Behavioral and Social Sciences Research

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In a nutshell, what must investigators proposing experimental research with humans do?

- Complete and certify that you and all research staff have received GCP training within the last 3 years
- If the grant submission is a CT or BESH, submit under the appropriate parent FOA
 - Decision tree will guide which FOA to submit under. If in doubt, discuss with a program officer
 - Complete the form fields as part of the application process
- If funded, register the study in clinicaltrials.gov within 21 days of the first participant enrollment (preferably before the first enrollment)
- Submit protocol to clinicaltrials.gov and to funding IC
- When the study is completed, submit your primary results to clinicaltrials.gov within one year.

NIH is committed to working with investigators throughout this process.

NIH Clinical Trials policy **doesn't** require . . .

- That you must redefine the purpose of your study
 - *If it is a basic mechanistic study, then it is still a basic mechanistic study.*
- That your application will be reviewed by clinical trialists
 - *CSR study section assignment remains the same*
 - *As usual, you can contact the SRO or PO if you believe the assigned study section does not have the expertise to review your proposal*
- That you must submit an extensive Phase 3 Clinical Trial protocol
 - *The extent of the protocol depends on the level of oversight required (e.g., risk to participants, financial investment in the projects).*
 - *Behaviorally oriented protocol template being finalized based on RFI input.*
- That a basic research study will be monitored with the same stringency as a large safety and effectiveness trial
 - *IC procedures for monitoring vary based on participant risk as well as other factors (e.g., size, cost, complexity)*

Benefits of the Clinical Trials Policies

- Clinicaltrials.gov can serve as a source of a broader range of behavioral and social science studies with appropriate filters to focus on the studies of interest
- Meta-analyses now have access to all results, not just published results, via clinicaltrials.gov
- Registration policies encourage preregistration in journals and facilitate publications in journals that increasingly require study registration
- NIH can analyze and report on experimental studies (both applied and funded) by the various form fields in the application
- Applicants still have 12 pages for research strategy in addition to the form field specifications – more room to explain why you are proposing what you propose
- Reviewers can more easily identify specific information in the grant application via the form fields
- Trainees now have access to online training in good clinical practice research
- Aspects of these policies tied to 21 Century Cures Act often ignored:
 - Strengthens expectation that human research use single IRBs for multisite studies
 - Automatically issues Certificates of Confidentiality for NIH-supported research involving humans

Connect with OBSSR

Questions? Bill Riley:
william.riley@nih.gov



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Discussion



Let's hear from you!

If using computer microphone: **raise your hand!**

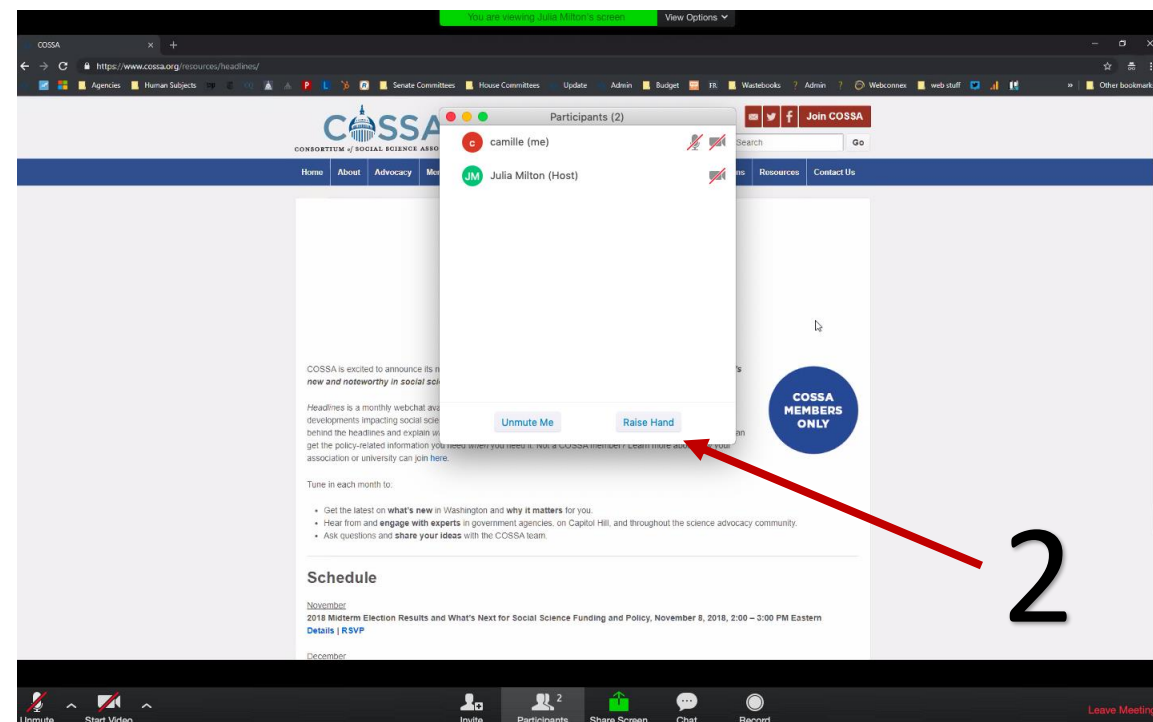
Step 1: select "participants"

Step 2: select "raise hand"

(may be in sidebar)

Step 3: after you're unmuted, ask your question!

If using telephone audio/microphone: **put your question in the chat box!**



Homework



☐ Stay Informed

A MESSAGE to  SSA MEMBERS...



☐ Learn about your new Members of Congress and their committee assignments

- House: www.house.gov
- Senate: www.senate.gov

☐ Sign up for Social Science Advocacy Day!

- Registration opens Jan. 4: www.cossa.org/event/2019-advocacy-day





Find this useful?

- ❑ **Tune in** each month – 2nd Thursday
- ❑ Tell your colleagues to **sign up** for COSSA Member Messages and Alerts—MEMBERS ONLY (*email Julia at jmilton@cossa.org*)
- ❑ Encourage other organizations and universities to **Join COSSA** (*email Wendy at wnaus@cossa.org*)
- ❑ **Send us your ideas** for DEEP DIVES (*email Camille at chosman@cossa.org*)



MARK YOUR CALENDAR
January 10, 2018

Next Month:

- ☐ January's HEADLINES
- ☐ DEEP DIVE: COSSA's 2019 Legislative Agenda and Resources for Social Science Advocates



Did you miss last month's Headlines?

❑ Visit: www.cossa.org/resources/headlines



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