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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@cossa.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

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George Mason University
Georgetown University
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Johns Hopkins University
Massachusetts Institute of Technology
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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 démocrats-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@cossa.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)
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
# BSSR Content Areas

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<th>Healthcare &amp; Disease Management</th>
<th>Language &amp; Communications Disorders</th>
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<td>Maternal Health, Parental Behavior, Family Dynamics</td>
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<td>Impairments in Receptive/Expressive Verbal and Nonverbal Communication</td>
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<td>Influences of Mental Health on Other Conditions</td>
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<th>Pain, Injury, &amp; Disability</th>
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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 16, 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. This policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that the results of 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 (FDAAA) Act 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.
A research study\(^1\) in which one or more human subjects\(^2\) are prospectively assigned\(^3\) to one or more interventions\(^4\) (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."

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
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 allow 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
Basic Experimental Studies Involving Humans (BESH)

NIH Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)

R01 Research Project Grant

New

None

PA-19-091

PA-19-096 Parent R01 Clinical Trial Required
PA-19-096 Parent R01 Clinical Trial Not Allowed

See Section III.3. Additional Information on Eligibility.

93.213, 93.866, 93.273, 93.279, 93.173, 93.121, 93.113, 93.242, 93.307, 93.365, 93.361, 93.879

Open Mike

New Funding Opportunities for Basic Experimental Studies Involving Humans

Over the past year, since we published an essay in *Nature* Human Behavior 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 ethical 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 conditions (i.e., experimentally manipulated 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.

The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (IC) based on their scientific missions.
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

@NIHOBSSR

@OBSSR.NIH

Sign up for our newsletter and email updates:
https://obssr.od.nih.gov/
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!
Stay Informed

A MESSAGE to COSSA MEMBERS...

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

COSSA WASHINGTON UPDATE

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
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)
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?

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Email: wnaus@cossa.org

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