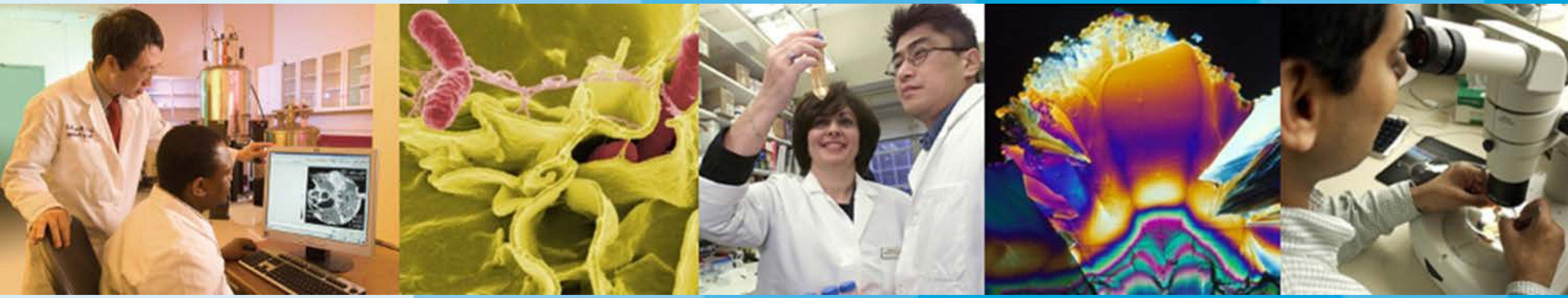
NASEM Workshop – September 25th, 2019

Cultivating Transparent Reporting in Biomedical Research

An NIH Perspective



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Data Sharing and Results Reporting:

An Essential Component

Responsible Sharing – *Why transparency matters…*

SCIENTISTS

- Raises the bar for ensuring rigorous research
- Maximizes investment by reducing unnecessary duplication
- Allows data and results to be combined in unconventional ways

The PUBLIC

- Publicly funded research accountable to taxpayers
- Transparency for greater trust
- Stewardship of research funds (less duplicating existing data, more advanced research)

RESEARCH PARTICIPANTS

- Brings research to your community
- Enables society to contribute to improving health
- Maximizes volunteer contribution
- Ensures **YOU** are represented in research

Carrots, Sticks, & the Golden Rule

Clinical Trials Results Reporting

VIEWPOINT

Toward a New Era of Trust and Transparency in Clinical Trials

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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,

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

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Home » Policy & Compliance » Clinical Trials » NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

POLICY & COMPLIANCE

Policy Topics

- Clinical Trial Requirements
- Clinical Trial Definition
- Clinical Trial-Specific Funding Opportunities
- Clinical Trial-Specific Review Criteria
- Protocol Templates
- Registration and Reporting
- Good Clinical Practice
- Human Subjects and Clinical Trial

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

The NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information sets the expectation that all NIH-funded awardees and investigators conducting clinical trials will register and report results of their trial in Clinicaltrials.gov. Read the deatils of the policy below.

In 2016, NIH published the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information in NIH Guide Notice NOT-OD-16-149. This guide notice includes a summary, background/supplemental information, and an overview of the public comments and NIH response that shaped the policy.

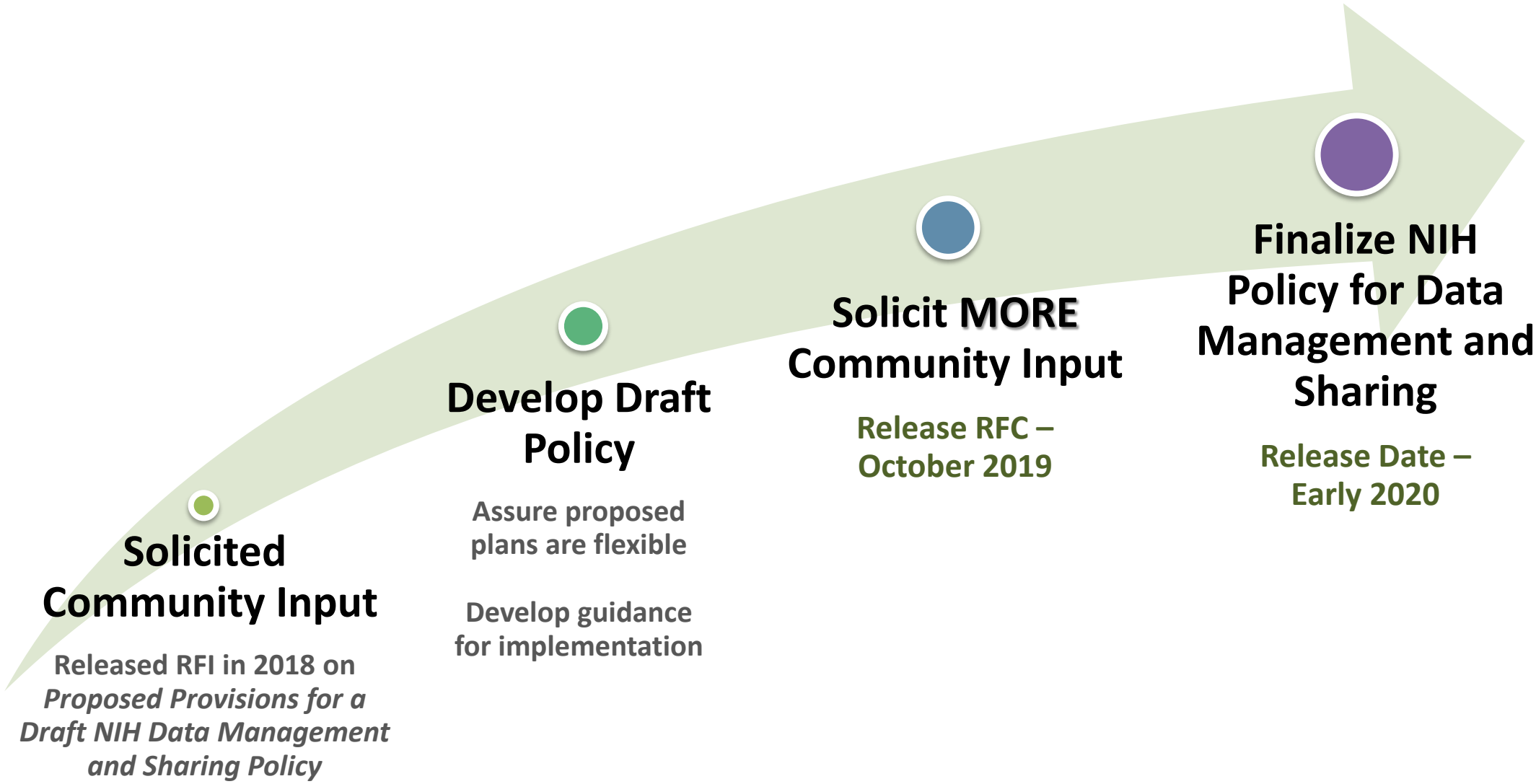
For convenience, we provide the policy itself, excerpted below from NOT-OD-16-149.

NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

Responsible Data Sharing – *Future NIH Policy Aims*

- **Establishes a flexible framework**
  - Sets a “floor” for good practices
  - Accommodates data size and diversity
  - Incorporates human subjects protections
- **Asks researchers how THEY plan to manage and share data**
  - Considers feasibility, including need for exceptions
  - Includes how data *may* and *may not* be shared
- **Includes suggested guidance**
  - Anticipates real world policy implications
  - Can be updated as we learn

Responsible Data Sharing – *NIH Draft Policy Development*



Rigor & Reproducibility (Transparency)

National Institutes of Health
Turning Discovery Into Health

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RIGOR AND REPRODUCIBILITY

Rigor and Reproducibility

- Reporting Guidelines
- Application Instructions
- Training
- Funding Opportunities
- Meetings and Workshops
- Announcements
- Publications
- Resources

Two of the cornerstones of science advancement are rigor in designing and performing scientific research and the ability to reproduce biomedical research findings. The application of rigor ensures robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results. When a result can be reproduced by multiple scientists, it validates the original results and readiness to progress to the next phase of research. This is especially important for clinical trials in humans, which are built on studies that have demonstrated a particular effect or outcome.

Johns Hopkins University students in a laboratory. *Johns Hopkins University*

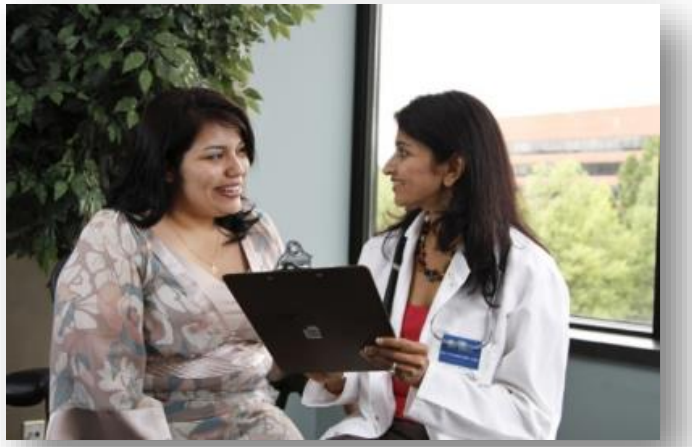
https://www.nih.gov/research-training/rigor-reproducibility

Rigor & Reproducibility – *Continuing to do better….*

ACD Working Group on Enhancing Reproducibility and Rigor in Animal Research

Summary: The ACD Working Group will be charged with assessing and making recommendations to enhance the reproducibility and rigor of animal research by improving experimental design, optimizing translational validity, enhancing training, and increasing the transparency of research studies involving animal models.

Background: Scientific reproducibility and rigor in conducting biomedical research are key to the successful application of knowledge towards improving health outcomes. NIH has taken a number of steps in recent years, including establishment of an ACD working group in response to the 21st Century Cures Act, to improve the reproducibility and rigor of the research it supports. In this way NIH upholds the highest standards of scientific integrity, public accountability, and social responsibility in the conduct of science it supports. As highlighted at a 2014 National Academies workshop, biomedical research involving animal models continues to be compromised in many instances by selection of animals that are not well validated models of the human disease under study, as well as additional problems with suboptimal study design and misapplication of statistical analyses.

NIH...*Turning Discovery Into Health*

www.nih.gov/hope

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