The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Forum on Drug Discovery, Development, and Translation
Forum on Neuroscience and Nervous System Disorders
National Cancer Policy Forum
Roundtable on Genomics and Precision Health

Enhancing Scientific Reproducibility through Transparent Reporting

A Workshop

September 25 – 26, 2019
National Academy of Sciences Building, Lecture Room
2101 Constitution Ave. NW, Washington, DC 20418

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine is convening a public workshop to discuss the current state of transparency in reporting pre-clinical biomedical research (e.g., disclosure of the availability and location of data, materials, analysis, and methodology) and to explore the possibility of improving the harmonization of guidelines across journals and funding agencies so that biomedical researchers propose and report data in a consistent manner. This workshop is sponsored by the National Institutes of Health, Cell Press, *The Lancet*, and Nature Research.

WORKSHOP OBJECTIVES:

- Highlight current efforts by researchers, institutions, funders, and journals to increase transparency in proposing and reporting pre-clinical biomedical research;
- Consider lessons learned from field-specific best practices for increased transparency in reporting rigor elements (i.e., research design, methodology, analysis, interpretation and reporting of results) that are generalizable across biomedical research domains;
- Discuss journal and funder assessments of researchers' adherence to transparent reporting guidelines, including a discussion of the effectiveness of checklists;
- Discuss opportunities for improving the consistency of reporting guidelines and requirements for rigor and transparency by journals, funders, and institutions across the biomedical research lifecycle; and
- Consider approaches to compare reporting of rigor elements proposed in grant applications to those included in publications.

DAY 1: September 25, 2019

8:00 a.m. Breakfast available outside the Lecture Room

8:30 a.m. **Welcome and opening remarks**
HARVEY FINEBERG, *Workshop Chair*
President
Gordon and Betty Moore Foundation

Highlights and related recommendations from the National Academies report on Reproducibility and Replicability in Science

9:15 a.m. *Q&A with audience*

SESSION I CULTIVATING TRANSPARENT REPORTING IN BIOMEDICAL RESEARCH

Session Objectives:

- Highlight current efforts by researchers, institutions, funders, and journals to increase transparency in proposing and reporting pre-clinical biomedical research
- Discuss the incentives, disincentives, challenges, and opportunities for researchers when it comes to transparent reporting of pre-clinical biomedical research (e.g., pressure to publish, institutional resources, training, funding).
- Discuss experience with implementation of policies to encourage transparent reporting across the biomedical research life cycle.
- Consider the role of stakeholders in supporting a cultural shift towards transparent reporting in preclinical biomedical research.

  For more information on cultural barriers as sources of non-reproducibility, see p. 58, p. 97, and p. 104 of the National Academies' Reproducibility and Replicability in Science report.

9:30 a.m. ***Opening remarks by session moderator***
ALEXA MCCRAY
Professor of Medicine
Harvard Medical School

9:40 a.m. ***A researcher (early career) perspective***
YARIMAR CARRASQUILLO
Investigator
National Center for Complementary and Integrative Health, National Institutes of Health

9:55 a.m. ***A researcher/researcher support perspective***
BRIAN NOSEK
Co-founder
Center for Open Science

10:10 a.m. ***A researcher (later career)/society publisher perspective***
ARTURO CASADEVALL
Professor, Molecular Microbiology and Immunology, Johns Hopkins University
Editor-in-chief, mBio

10:25 a.m. ***An NIH perspective***
CARRIE WOLINETZ
Acting Chief of Staff and Associate Director for Science Policy
Office of the Director, National Institutes of Health (NIH)

10:40 a.m. *Audience Q&A with the panel*

Discussion Questions:

- *What forces are influencing the culture of biomedical research, and how is it changing?*
- *What actions could influence practice and support a cultural shift towards more transparent reporting?*
- *What influence might transparent reporting or required reporting of rigor elements have on grant applications? Is there a role for pre-registration of pre-clinical studies?*

11:10 a.m. **BREAK**

SESSION II ANSWERING THE CALL FOR CHANGE: LESSONS LEARNED AND BEST PRACTICES

Session Objectives:

- Consider lessons learned from institutional and/or field-specific best practices for increased transparency in reporting rigor elements (i.e. research design, methodology, analysis, interpretation and reporting of results) that are generalizable across biomedical research domains.
- Consider available tools and best practices for increased transparent reporting that support researchers and are generalizable across biomedical research domains.
- Discuss the roles of educational institutions, professional societies, researchers, and funders in improving computational reproducibility (*Reproducibility and Replicability in Science* Report Recommendation 6-6).
- Discuss how funding agencies and organizations could invest in research and development of open-source, usable tools and infrastructure that support reproducibility for a broad range of studies across different domains in a seamless fashion, as well as in outreach to inform and train researchers on best practices (*Reproducibility and Replicability in Science* Report Recommendation 6-1).

11:30 a.m. ***Opening remarks by session moderator***
VERONIQUE KIERMER
Executive Editor
PLOS

11:40 a.m. ***A clinical researcher perspective: Lessons from the SPIRIT initiative***
AN-WEN CHAN
Phelan Scientist, Women's College Research Institute
Associate Professor, University of Toronto

11:50 a.m. ***An institution perspective***
GEETA SWAMY
Vice Dean for Scientific Integrity
Associate Vice President for Research
Duke University

12:00 p.m.. ***A funder perspective***
MAGALI HAAS
Chief Executive Officer and President
Cohen Veterans Bioscience

12:10 p.m. *Moderated panel discussion among speakers*

12:30 p.m. *Audience Q&A with the panel*

Discussion Questions:

- *How can challenges with pre-registration, image analysis, cell line authentication, statistical analysis, or other rigor elements be addressed?*
- *What actions can institutions or professional societies take to educate and support their constituents on best practices? How could this information be best provided?*
- *How might funding agencies and organizations invest in development of open-source reusable tools and infrastructure to support transparent reporting seamlessly across different domains?*
- *What actions could funding agencies and organizations take to inform, train, and support researchers on best practices in transparent reporting?*
- *What has been learned from open access mandates and from implementing policies around sharing data in preclinical research? How could those lessons inform transparent reporting guidance and adoption?*

1:00 p.m. **BREAK** (Lunch available Outside the Lecture Room)

SESSION III STAKEHOLDER PERSPECTIVES ON CHECKLISTS AND GUIDELINES

Session Objectives:

- Discuss journal and funder assessments of researchers' adherence to transparent reporting guidelines, including discussion of the effectiveness of checklists.
    - Highlight empirical assessments of checklist application from funders, journals, and researchers; and
    - Consider practical application and effectiveness of checklists and guidelines to encourage or require transparent reporting of pre-clinical biomedical research.
- Discuss how funders could require thoughtful discussion in grant applications of how uncertainties will be evaluated, along with any relevant issues regarding replicability and computational reproducibility (*Reproducibility and Replicability in Science* Report Recommendation 6-9)
- Discuss how journals and scientific societies could disclose their policies relevant to achieving reproducibility and replicability; and how journals could be encouraged to set and implement desired standards of reproducibility and replicability and adopt policies to reduce the likelihood of non-replicability (*Reproducibility and Replicability in Science* Report Recommendation 6-7)

2:00 p.m. ***Opening remarks by session moderator***
BARRY COLLER
Physician-in-Chief, Vice President for Medical Affairs, and David Rockefeller Professor
The Rockefeller University

2:10 p.m. ***The checklist approach at life science journals – challenges and opportunities***
SOWMYA SWAMINATHAN
Head of Editorial Policy
Nature Research

MALCOLM MACLEOD
Professor
University of Edinburgh

2:30 p.m. ***An NIH funder perspective***
SHAI SILBERBERG
Director Research Quality
National Institute of Neurological Disorders and Stroke, National Institutes of Health

2:40 p.m. *Moderated panel discussion among speakers*

3:10 p.m. *Audience Q&A with the panel*

Discussion Questions:

- *How valuable are checklists? How valuable is guidance such as the CONSORT statement? What are observed challenges to adherence, and how could they be addressed?*
- *How could checklists be improved and/or complemented to further encourage transparent reporting?*
- *What resources do researchers need to be able to submit proposals, publish, or otherwise report on specific rigor elements?*
- *How might funders require thoughtful discussion in grant applications of how uncertainties (such as in measurement, computation, knowledge, modeling, or methods of analysis) will be evaluated by researchers?*
- *Should scientific societies be encouraged to develop policies relevant to transparent reporting?*

SESSION IV PART 1 TOWARDS MINIMAL REPORTING STANDARDS FOR PRECLINICAL BIOMEDICAL RESEARCH

Session Objectives:

- Discuss opportunities for improving the consistency of reporting guidelines and requirements for rigor and transparency by journals, funders, and institutions across the biomedical research lifecycle.

4:00 p.m. **Discussion with audience on potential steps stakeholders could take to support harmonizing reporting guidelines**

HARVEY FINEBERG, *Workshop Chair and session moderator*
President
Gordon and Betty Moore Foundation

BENEDICT KOLBER
Associate Professor
Duquesne University

RICHARD NAKAMURA
Former Director (Retired)
Center for Scientific Review, National Institutes of Health

FRANKLIN SAYRE
STEM Librarian
Thompson Rivers University

VALDA VINSON
Editor, Research
Science

5:00 p.m. **ADJOURN WORKSHOP DAY 1**

DAY 2: September 26, 2019

8:00 a.m. Breakfast Available Outside the Lecture Room

8:30 a.m. **Welcome and overview of Day 1**
HARVEY FINEBERG, *Workshop Chair*
President
Gordon and Betty Moore Foundation

9:00 a.m. **Keynote Address**
MARCIA MCNUTT
President
National Academy of Sciences

9:20 a.m. **Q&A Session**

9:30 a.m. **BREAK**

SESSION IV PART 2 TOWARDS MINIMAL REPORTING STANDARDS FOR PRECLINICAL BIOMEDICAL RESEARCH

Session Objectives:

- Consider approaches to compare reporting of rigor elements proposed in grant applications to those included in publications.
- Suggest stakeholder actions to encourage transparent reporting and practical next steps towards establishing minimal reporting standards for pre-clinical biomedical research.

10:00 a.m. ***Opening remarks by session moderator***
HARVEY FINEBERG, *Workshop Chair*
President
Gordon and Betty Moore Foundation

10:10 a.m. ***An early career researcher perspective***
MICHAEL KEISER
Assistant Professor
University of California, San Francisco

10:20 a.m. ***An institution perspective***
MELISSA RETHLEFSEN
Associate Dean, George A. Smathers Libraries
Fackler Director, Health Science Center Libraries
University of Florida

10:30 a.m. ***A research educator perspective***
STEVEN GOODMAN
Professor of Medicine and Health Research and Policy
Co-director, Meta-Research Innovation Center at Stanford
Stanford University

10:40 a.m. *Moderated panel discussion among speakers*

11:10 a.m. *Small group table discussion and reporting*

Discussion Questions:

- *What actions should funders, researchers, institutions, and journals take to drive widespread adoption of minimal reporting standards?*
- *Are reporting categories in guidelines for publishing (such as materials, design, analysis, and reporting) relevant for funders? For institutions? For small publishers/professional societies?*
- *What other information or reporting categories would be relevant?*
- *How should funders instruct reviewers of grant applications to reinforce transparent reporting? How much information should funders request, that is, to what level of detail, in grant applications)? Is it possible to obtain sufficient information about transparent reporting in grant applications without dramatic expansion of the application?*

12:25 p.m. **Workshop wrap up and concluding discussion with audience**

12:30 p.m. **ADJOURN WORKSHOP DAY 2**