Research Integrity in Extramural Research at the National Institutes of Health

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Sponsor Influences on the Quality and Independence of Health Research: A Workshop (NASEM)

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Disclosure Statement

- No relationships to disclose

Today's Topics

- Rigor and transparency in applications
- Avoiding bias in funding decisions
- Allegations of research misconduct
- Financial Conflicts of Interest (FCOI)
- Pre-registration and reporting of Clinical Trials
- NIH Data Management and Sharing Policy

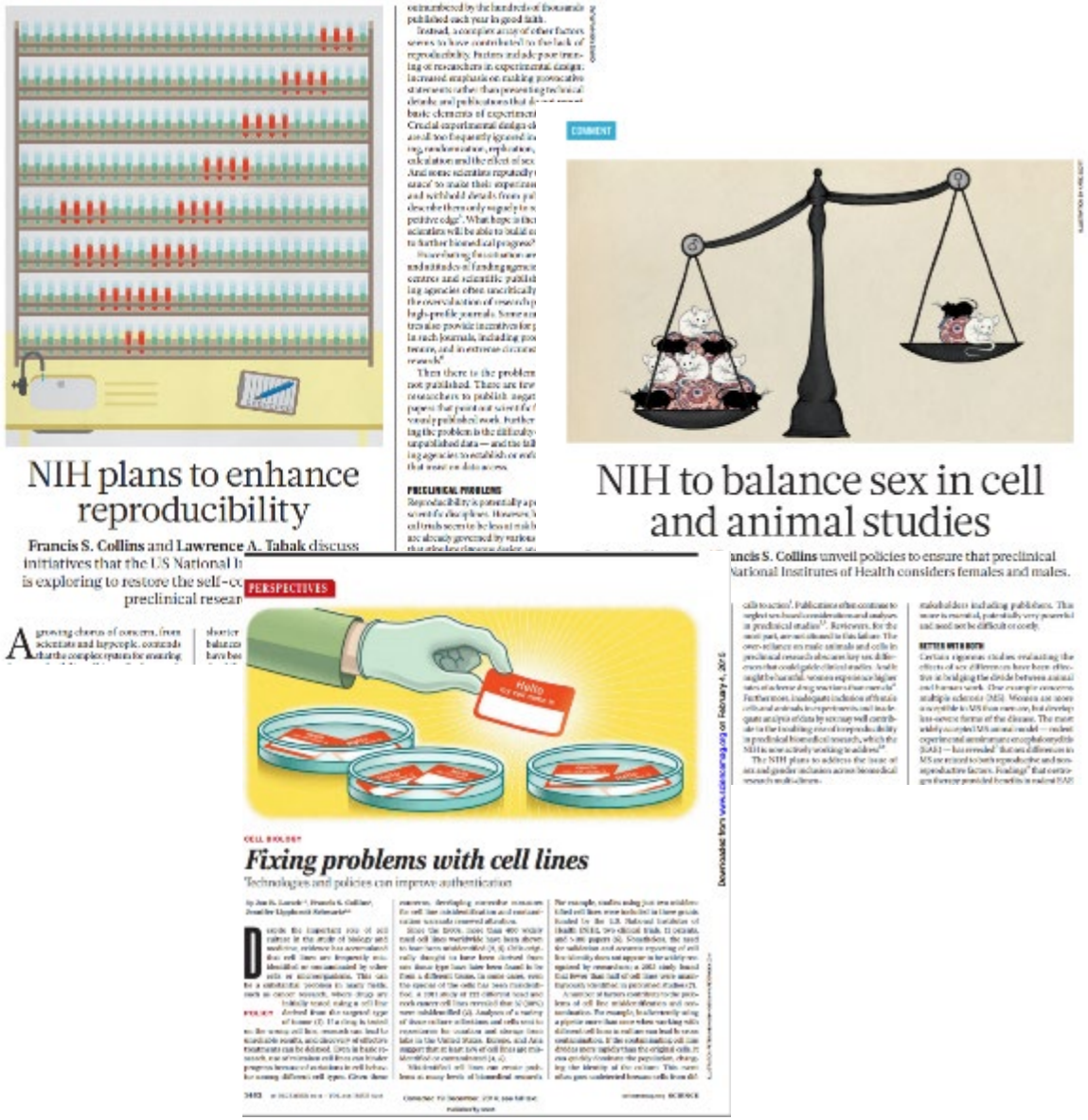
Rigor and Transparency in Applications

Enhancing Reproducibility through Rigor & Transparency

Four areas of clarification

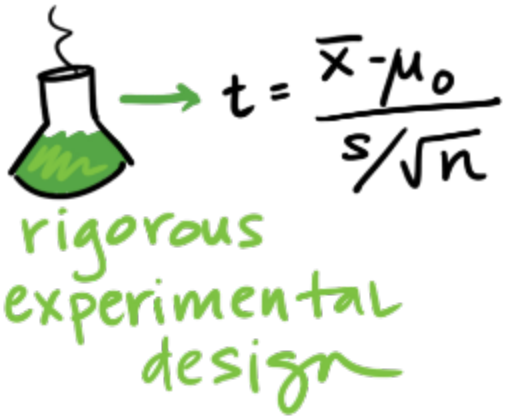
1. Rigor of the prior research
2. Scientific rigor of the proposed research
3. Relevant biological variables, such as sex
4. Authentication of key biological and/or chemical resources

Started with applications due on January 25, 2016



- The strict application of the **scientific method** to ensure **robust and unbiased** experimental design, methodology, analysis, interpretation and reporting of results.

- Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.



https://grants.nih.gov/policy/reproducibility/index.htm

POLICY & COMPLIANCE

Policy Topics

Rigor and Reproducibility

Guidance: Rigor and Reproducibility in Grant Applications

Resources for Preparing Your Application

Training and Other Resources

Notices, Blog Posts, and References

Enhancing Reproducibility through Rigor and Transparency

The information provided on this website is designed to assist the extramural community in addressing rigor and transparency in NIH grant applications and progress reports. Scientific rigor and transparency in conducting biomedical research is key to the successful application of knowledge toward improving health outcomes.

Definition

Scientific rigor is the strict application of the scientific method to ensure unbiased and well-controlled experimental design, methodology, analysis, interpretation and reporting of results.

Goals

The NIH strives to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science. Grant applications instructions and the criteria by which reviewers are asked to evaluate the scientific merit of the application are intended to:

FAQs

RELATED RESOURCES

- For NIH Staff
- Contact: reproducibility@nih.gov

NIH ENHANCING REPRODUCIBILITY GUIDELINES

what you need to know

WHAT ARE THE FOUR ELEMENTS OF RIGOR?

1. RIGOR OF THE PRIOR RESEARCH
2. RIGOR OF THE PROPOSED RESEARCH
3. BIOLOGICAL VARIABLES
4. AUTHENTICATION

Send inquiries to reproducibility@nih.gov

See also NIH Notice NOT-OD-18-228
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-228.html

WHERE IN THE APPLICATION?

1 RESEARCH STRATEGY

The research strategy is where you discuss the significance, innovation, and approach of your research plan. Let's look at an R01, for example:

The **research strategy** guidelines require that you:

- Describe the strengths and weaknesses in the rigor of the prior research that serves as key support.
- Describe plans to address weaknesses in the rigor of the prior research.
- Describe how your experimental design and methods will achieve robust and unbiased results.
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses.

2 ATTACHMENT FOR AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

You must briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

These include, but are not limited to:

CELL LINES
ANTIBODIES
SPECIALTY CHEMICALS
OTHER BIOLOGICS

Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

- **DO NOT** put experimental methods or preliminary data in this section
- **DO** focus on authentication and validation of key resources

3 REVIEW GUIDELINES

Here are the additional criteria the reviewers will be asked to use:

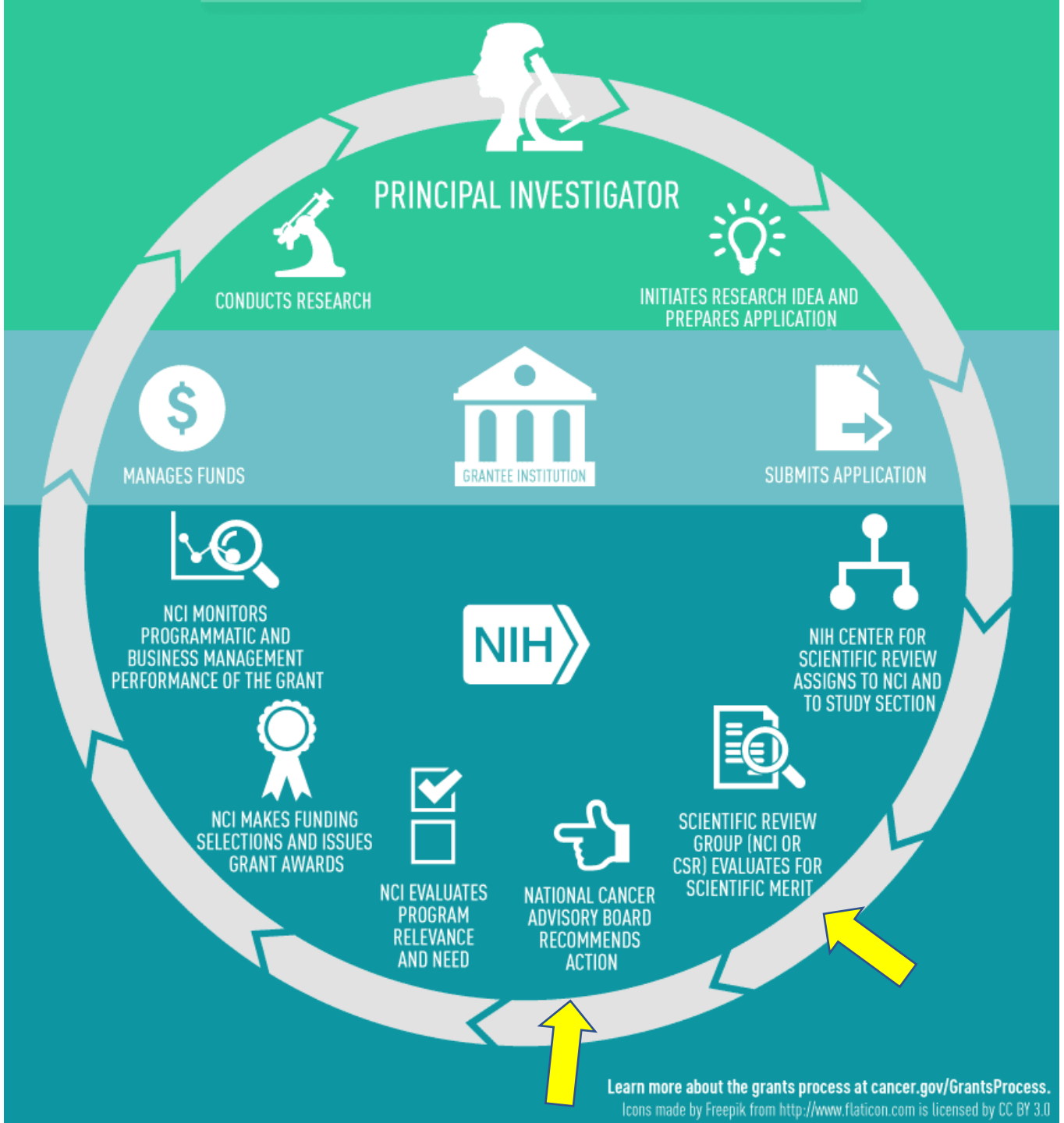
- Is the **prior research** that serves as the key support for the proposed project **rigorous**?
- Have the investigators included plans to **address weaknesses in the rigor of prior** research that serves as the key support for the proposed project?
- Have the investigators presented **strategies to ensure a robust and unbiased approach**, as appropriate for the work proposed?
- Have the investigators presented adequate plans to address **relevant biological variables, such as sex,** for studies in vertebrate animals or human subjects?

Reviewers will also be asked to comment on that new attachment (see **Update 2**)!

Avoiding Bias in Funding Decisions

OVERVIEW OF THE NATIONAL INSTITUTES OF HEALTH AND

NATIONAL CANCER INSTITUTE GRANTS PROCESS



Core Values of NIH Peer Review

The Core Values of NIH Peer Review are:

(1) Expert assessment
(2) Transparency
(3) Impartiality
(4) Fairness
(5) Confidentiality
(6) Security
(7) Integrity
(8) Efficiency

https://grants.nih.gov/grants/peerreview22713webv2.pdf

Impartiality in Peer Review

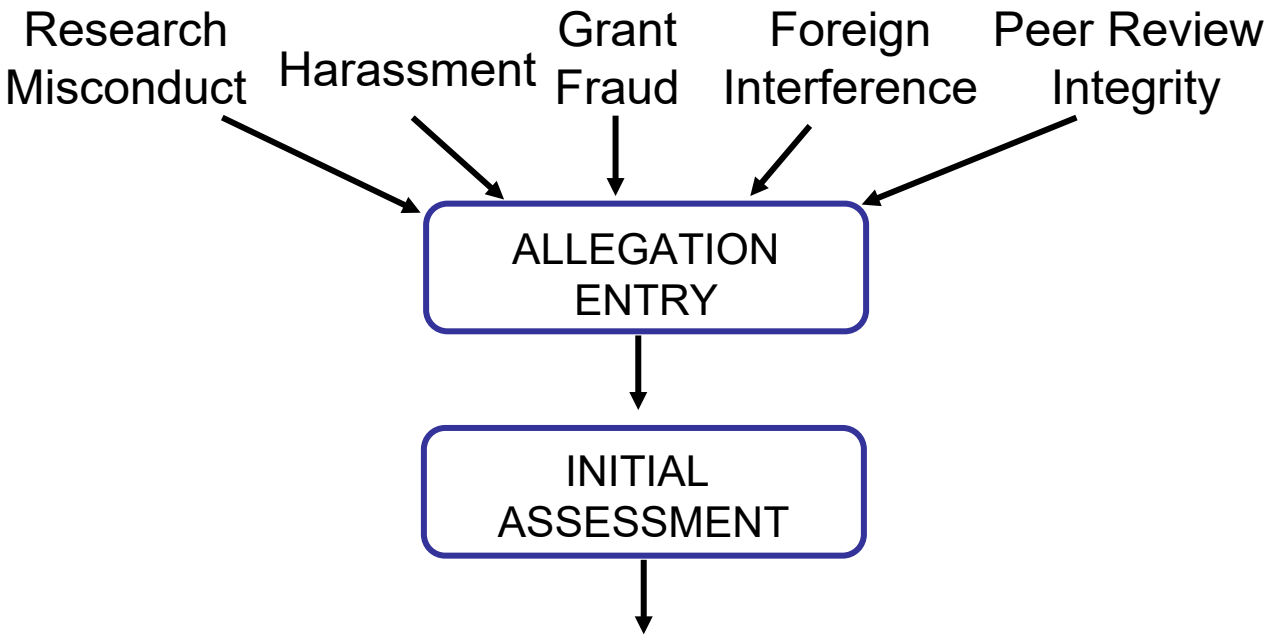
- Manage conflicts of interest, appearance of COI
  - Reviewers certify COI pre- and post-meeting
  - SGEs and Council members adhere also to the Standards of Ethics for Federal Employees
- Lobbyists restricted from serving
- Separation of NIH staff functions (review vs program)
- Policies for managing appeals of initial peer review

Integrity in Peer Review

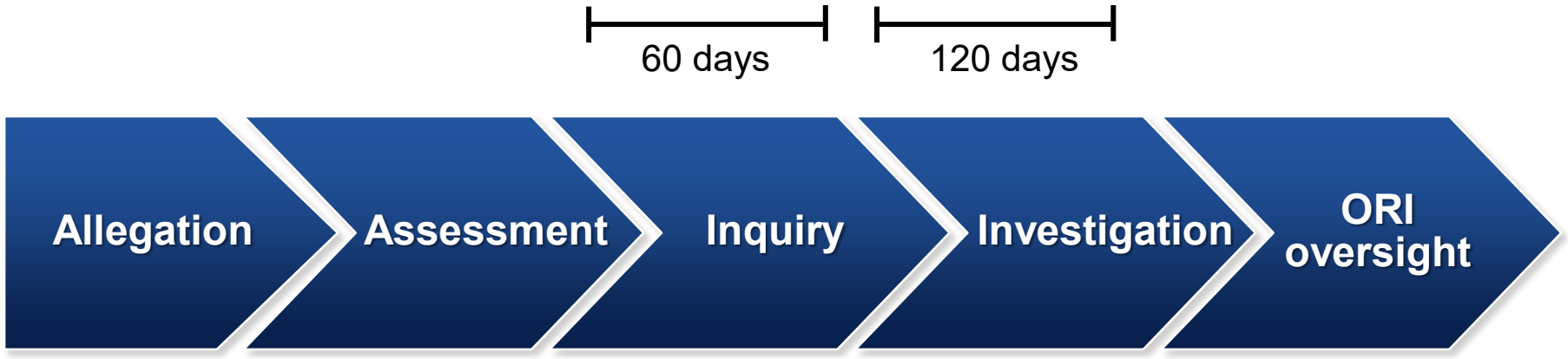
- NIH extramural staff trained in how to handle allegations of research misconduct (RM)
- Reviewers and Council members instructed to report allegations directly to the DFO in charge of the meeting
- DFO will report to assigned Research Integrity Officer
- May defer application from review until the proper authorities can deliberate on the situation
- Allegations of RM referred to HHS ORI

Handling Allegations of Research Misconduct

Overview of OER Allegation Review Process



Research Misconduct Proceedings



42 CFR § 93

NIH Interim Actions for Integrity Concerns

- Protect public, research participants, research, research process, and public funds
- Interim actions include, but not limited to:
  - Specific award conditions
    - Additional supervision
    - Certification of data
  - Request change of PI
  - Restrict funds
  - Suspend or Terminate award
- Also, referral to HHS Office of the Inspector General

Financial Conflicts of Interest (FCOI)

Financial Conflicts of Interest (FCOI)

- HHS regulation 42 CFR Part 50 Subpart F, Promoting Objectivity in Research (FCOI regulation)
  - establishes standards that provide a reasonable expectation that the design, conduct, or reporting of NIH-funded research will be free from bias resulting from any Investigator's conflicting financial interest
- Investigator reports SFI to recipient institution, recipient institution assesses for FCOI and provides management plan to NIH for approval

Registration and Reporting of Clinical Trials

Dissemination of NIH-Funded Clinical Trial Information

- All NIH defined CTs to register and report results in ClinicalTrials.gov
- Regardless of:
  - Study Phase
  - Type of intervention
  - Subject to regulation
- NIH Grants Website regarding CT Registration and Results Reporting

NOT-OD-16-149
FDAAA
42 CFR Part 11

CT Registration and Results Reporting Policy requires:

- Plan in the application outlining compliance with the policy; becomes part of Terms and Conditions
- Statement in the CT consent forms regarding posting of CT information at ClinicalTrials.gov
- REGISTERING in ClinicalTrials.gov no later than 21 days after enrolling the first participant
- REPORTING summary results ClinicalTrials.gov no later than one year after primary completion date

Data Management and Sharing Policy

NIH has a longstanding commitment to making the results of NIH-funded funded research available. Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, and providing accessibility to high-value datasets.

About the Data Management and Sharing Policy →

Planning & Budgeting for Data Management and Sharing

Find out what NIH expects in a Data Management & Sharing plan and what costs are allowed in a request.

Data Management

Proper data management is crucial for maintaining scientific rigor and research integrity. Learn about best practices for scientific data management.

Sharing Scientific Data

Under the NIH Data Management & Sharing Policy, investigators are empowered to choose the most appropriate methods for sharing scientific data. Learn more about methods for

THANK YOU!

NIHResearchIntegrity@mail.nih.gov