

# NIH & AHRQ Rigor and Reproducibility Policy

( 1 )

# Presenters

Stephanie F. Scott, MS, CRA

Director of Policy and Research Development

Sponsored Projects Administration (SPA)

[sfs2110@columbia.edu](mailto:sfs2110@columbia.edu)


 @steph\_f\_scott

Michelle Benson, PhD

Assistant Director for Research Integrity and Compliance

Office of Research Compliance & Training (ORCT)

[mb3852@columbia.edu](mailto:mb3852@columbia.edu)

 @ReaDI\_Columbia

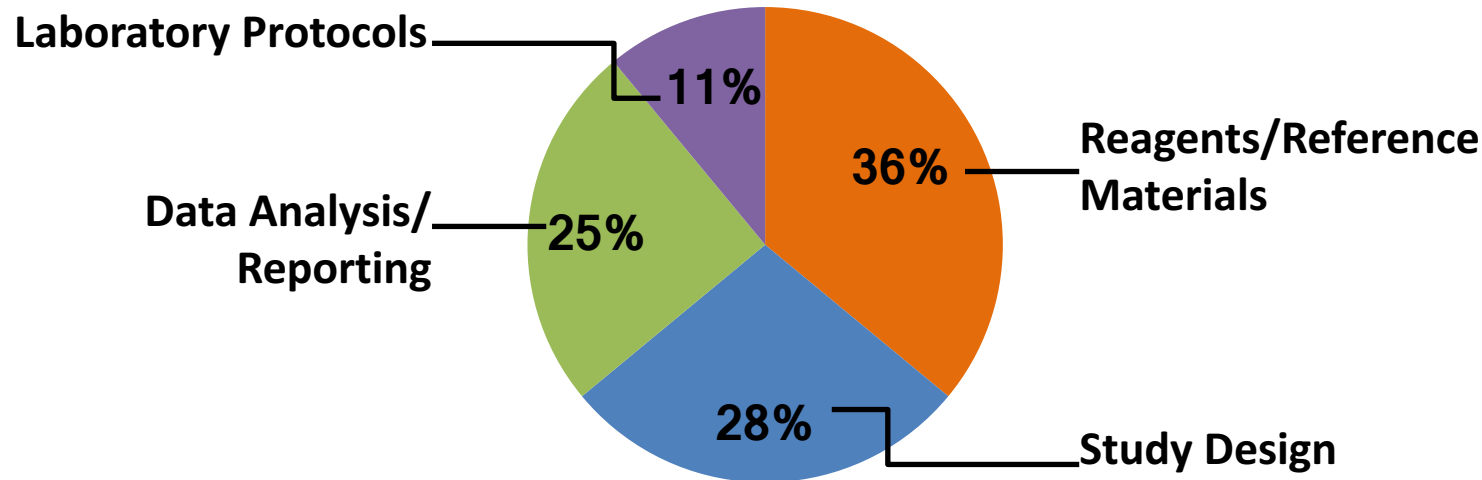
 ReaDI Program at Columbia University

# Outline

- Why Rigor and Reproducibility requirements?
  - NIH's initiative
- Policy implementation
  - What grants are included and what are not
  - Formal training for training grants
- Four areas to address within the application
  - Each area will be defined, applications instructions discussed, reviewer criteria, and examples on how to meet requirement will be provided
- Other categories of research (innovative/qualitative)
- Resources
- Future of reproducibility
- *Information in this presentation is primarily from NIH*

# The NIH Initiative: Enhance Research Rigor and Reproducibility

- Retrospective analysis of preclinical research shows more than 50% are not reproducible = ~\$28 billion/year spent<sup>1</sup>



- NIH introduced initiative in October 2013 highlighting the importance of unbiased experiments and reproducible results<sup>2</sup>
- January 2014 Dr. Francis Collins and Dr. Lawrence Tabak published commentary in Nature<sup>3</sup>
- June 2014 workshop hosted by NIH with Nature publishing group and Science in attendance<sup>3</sup>
- January 2016 NIH Rigor & Reproducibility policy takes effect

1: <http://www.sciencemag.org/news/2015/06/study-claims-28-billion-year-spent-irreproducible-biomedical-research>

2: [http://www.niams.nih.gov/News\\_and\\_Events/NIAMS\\_Update/2013/Tabak\\_letter.asp](http://www.niams.nih.gov/News_and_Events/NIAMS_Update/2013/Tabak_letter.asp)

3: [http://www.niams.nih.gov/News\\_and\\_Events/NIAMS\\_Update/2015/reproducibility.asp](http://www.niams.nih.gov/News_and_Events/NIAMS_Update/2015/reproducibility.asp)

# Phase I – went into effect 1/25/16

## Rigor & Transparency

- Impacted most RESEARCH and CAREER DEVELOPMENT grants
- To enhance reproducibility of research findings through increased scientific rigor and transparency
- See [NOT-OD-16-011](#) and
- [NOT-OD-16-012](#)

## What Changed

- The application instructions for preparing the research strategy attachment
- New "Authentication of Key Biological and/or Chemical Resources" attachment
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications

# Phase I - Progress Reports (RPPRs)

## Section B - Accomplishments

### B.2 What was accomplished under these goals?

- Include the approaches taken to ensure robust and unbiased results.

### B.6 What do you plan to do for the next reporting period to accomplish these goals?

- Discuss efforts to ensure that the approach is scientifically rigorous and results are robust and unbiased.

{ 6 }

# Special Notes and Exceptions

## Research grants excluded

- C06, G08, G11, G12, G13, G20, R13, S06, S10, S21, SB1, U13, U55, UB1, UC6, UC7, UG4, UH4, X02, and 333

## Career Development Awards excluded

- K02, K05, and K24, as candidates for these awards are expected to have independent, peer reviewed research support at the time the career award is made.
- [NOT-OD-16-012](#)

## Special Note on Research Resource and Related grants

- P30, P40, P41, P2C, R24, R28, U24, U41, U42, and U2C may have slightly revised review language; please refer to the Funding Opportunity Announcement.

\*R25: not subject at this time, but must read FOA carefully!

## Phase II - Formal Instruction on Rigor

- See notice [NOT-OD-16-034](#) issued 12/17/15
- **Advance notice:** NIH & AHRQ to **require formal instruction** in scientific rigor and transparency to enhance reproducibility for all individuals supported by:
  - Institutional training grants: D43, T15, T32/TL1, T34, T35, T36, T37, T90/R90, and U2R
  - Institutional career development awards: K12/KL2
  - Individual fellowships: F05, F30, F31, F32, F37, F38, and FI2



# Four Key Areas to Address: Research and Career Development Applications

Key Area	Application Instructions
Scientific Premise	Research Strategy: Significance (scored)
Scientific Rigor	Research Strategy: Approach (scored)
Consideration of Relevant Biological Variables, such as sex	Research Strategy: Approach (scored)
Authentication of Key Biological and/or Chemical Resources	Separate Attachment (not scored): to be saved as a single file named “Authentication of Key Resources Plan” <b>attached in FORMS-D, and FORMS-E,</b> “Other Research Plan Sections”:  *Only required if Key Biological and/or Chemical Resources are mentioned in the research strategy

# Calling out the Review Criteria

Review Criterion	Proposal Sections
Significance	Research Strategy
Investigator	Biosketch
Innovation	Research Strategy
Approach	Research Strategy
Environment	Facilities and Other Resources

# Page Limits

- Watch out for page limitations:
- [http://grants.nih.gov/grants/forms\\_page\\_limits.htm](http://grants.nih.gov/grants/forms_page_limits.htm)
- Note that the application instructions in specific Funding Opportunity Announcement (FOA) *supersedes* the SF 424 Application Instructions, in case there are conflicts.
- Note: K-awards **Candidate Information and Goals for Career Development and Research Strategy**: 12 pages

# Four Areas to Address Scientific Rigor

## Scientific Rigor

### Reduce bias

- Different/multiple individuals recording assessments
- Define terminology in advance
- Use independent and blinded assessors
- Etc.

### Robust results

- Well-controlled experiments
- Reproducible results when repeated using the details reported in experimental design under well-controlled conditions

**Area 1: Scientific premise**

**Area 2: Rigorous experimental design**

**Area 3: Relevant biological samples**

**Area 4: Authentication**

# Four Areas to Address Scientific Rigor

## Scientific Rigor

### Reduce bias

- Different/multiple individuals recording assessments
- Define terminology in advance
- Use independent and blinded assessors
- Etc.

### Robust results

- Well-controlled experiments
- Reproducible results when repeated using the details reported in experimental design under well-controlled conditions

## Research Strategy

Area 1: Scientific premise

Area 2: Rigorous experimental design

Area 3: Relevant biological samples

Area 4: Authentication

# Area 1: Scientific Premise

Significance  
Prospective analysis

Scientific Premise  
Retrospective consideration

- Often times, cited literature demonstrates the feasibility of the proposed experimental approach (positive)
  - Wasted resources
  - Incorrect conclusions
  - Unnecessary risks for trial subjects/unjustifiable clinical trials
- Describe strengths and weaknesses of prior research
- May include assessment of the rigor applied to previous experimental designs (including investigators own research—published or unpublished)
  - Identify and acknowledge shortcomings in rigor, or reporting on rigor and include plans to address issues in future
- For exploratory grant applications include a critical assessment of the literature that either supports or contradicts research question
- Identify relevant biological variables and state how key resources will be authenticated

# Area 1: Scientific Premise

## Application Instructions

- **Research Strategy – Significance:**
  - Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- **Review criteria (quotes from the Reviewer Guidance):**
- “Reviewers will evaluate scientific premise as part of the Significance criterion for research grant applications or the Research Plan criterion for mentored career development award applications.
  - Consider whether the applicant has discussed the strengths and weaknesses of the foundational data.
  - A weak scientific premise, or the failure to address scientific premise adequately, may affect criterion and overall impact scores.
  - The page limit is not an acceptable excuse for an applicant to not address scientific premise.”

# Area 1: Scientific Premise

## How do I write about it?

Might consider clear headers and sub headers. Be consistent throughout application in formatting:

### SIGNIFICANCE

#### Scientific Premise:

Strengths and Weaknesses of Published Research/Preliminary Data:

Consider having more subsections as necessary, such as an overall scientific premise, and a premise for each aim.

“These past studies have focused largely on\_\_\_\_\_”

“However, we’re looking more closely at \_\_\_\_\_”

“We found some conflicting results in our analysis of the past literature\_\_\_\_\_”

- The premise may involve assessing rigor, consideration of relevant biological variables, and/or resource authentication.
- The premise leads to the hypothesis.



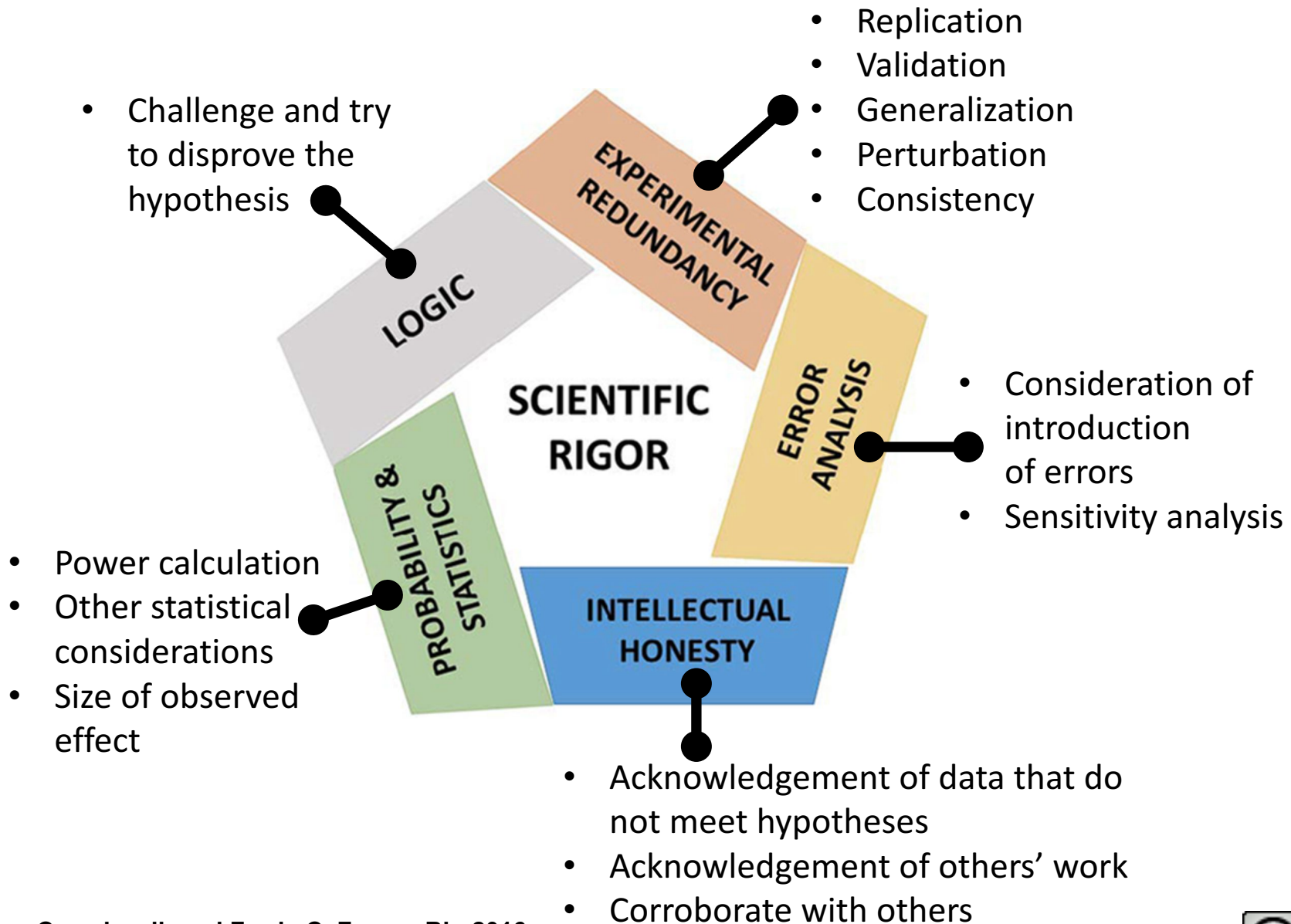
# Area 2: Rigorous Experimental Design

- Full transparency of experimental details are expected in grant applications
- Robust approach might include descriptions of:
  - Use of standards
  - Sample size estimation
  - Randomization
  - Blinding
  - Appropriate replicates
  - Controlling for inter-operator variability
  - Statistical methods planned
  - Inclusion and exclusion criteria
  - Subject retention and attrition
  - How missing data will be handled
  - Any other information as appropriate to the science

( 17 )

**Transparency and consideration on how to avoid inherent bias is key!**

# How to write “Rigorously”



# Area 2: Rigor

## Application Instructions

### Research Strategy – Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. **Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.** Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- **Review Criteria:**
  - Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
  - Scientific rigor pertains to the proposed research (statistical procedures, data analysis, precision, subject inclusions and exclusion criteria, etc.). Different research fields may have different standards or best practices for scientific rigor.

# Area 2: Rigor

## More on Review Criteria

- The applicant should describe experimental controls, plans to reduce bias (blinding, randomization, subject inclusions and exclusion criteria, etc.), power analyses, and statistical methods, as appropriate.
- Reviewers will assess scientific rigor as part of the Approach criterion for research grant applications and the Research Plan criterion for mentored career development award applications, as well as the overall impact score.
  - **The Vertebrate Animal Section no longer requires a justification of animal numbers ([NOT-OD-16-006](#)). Inadequate vertebrate animal numbers should be reflected in the score and will not result in a block to funding.**
- Reviewers will assess information concerning numbers of animals according to the section where it is included in the application.

## Area 2: How much detail should I include in my application regarding rigor?

- Every detail is not expected.
- State succinctly what is planned.
  - For example: "10 males and 10 females will be randomized to blinded treatment and control groups, giving 80% power to detect a treatment effect size of 65% compared to a baseline response of 5% at a significance level of 0.05."
- NIH suggests looking at the guidelines of specific funding opportunities
- Examples of guidance that may be helpful
  - [NINDS Guidance](#), [NOT-MH-14-004](#), and [NOT-DA-14-007](#).
  - Past funding opportunities, see [PAR-13-023](#) (R21) and [RFA-NR-15-001](#) (R01).
- Investigators should be aware of the [guidelines for publishing preclinical research in journals](#), which are similar in intent to the new application instructions.

## Area 2: Rigor

### See NIH Examples in Awarded Applications (*Biomedical/Lab examples*)

- <https://grants.nih.gov/reproducibility/index.htm#guidance>
- NIH provided four examples
- Selected based on high overall impact scores and positive reviewer comments specific to rigor.
- Show how elements of rigor and transparency have been *succinctly* provided in applications.
- May not represent all of the aspects and may still have room for improvement, recognizing that many things go into the full review of applications.

# Area 2: Rigor

## How do I write about it?

### APPROACH

Scientific Rigor:  
(NIH example)

“Aim 3: Male and female mice will be **randomly allocated** to experimental groups at age 3 months. At this age the accumulation of CUG repeat RNA, sequestration of MBNL1, splicing defects, and myotonia are fully developed. **The compound will be administered at 3 doses (25%, 50%, and 100% of the MTD) for 4 weeks, compared to vehicle-treated controls.** IP administration will be used unless biodistribution studies indicate a clear preference for the IV route. **A group size of n = 10 (5 males, 5 females) will provide 90% power** to detect a 22% reduction of the CUG repeat RNA in quadriceps muscle by qRT-PCR (ANOVA,  $\alpha$  set at 0.05). The treatment assignment will be **blinded to investigators** who participate in drug administration and endpoint analyses. This laboratory has previous experience with **randomized allocation and blinded analysis** using this mouse model [refs]. **Their results showed good reproducibility when replicated by investigators in the pharmaceutical industry [ref].”**

# Area 3: Relevant Biological Samples

“Explain how relevant biological variables, such as sex, are factored into research designs and analyses or studies in vertebrate animals and humans.”

- Choice of animal model or human population to be included will vary with the scientific topic of the proposed research
- Biological variables that may affect the outcome should be considered
  - Sex
  - Age
  - Life stage
  - Weight
  - Underlying health conditions
- Applies to basic, preclinical, and clinical research
- It is expected that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies



# Sex as a Biological Factor Background

- Preclinical research historically has focused mainly on male animals<sup>1</sup>
- The results of mostly single-sex studies contributes to ambiguous information on how sex-based differences may influence outcome<sup>2</sup>
- There is increasing evidence of sex-based differences in basic genetics, cellular and biochemical organization<sup>1,2</sup>
- Exclusion of females from preclinical studies has led to treatments with adverse effects that are more common or severe in women than men<sup>3</sup>

1: Janine Austin Clayton. Studying both sexes: a guiding principle for biomedicine *FASEB J February 2016 30:519-524*

2: Brian J. Prendergast, Kenneth G. Onishi, Irving Zucker, Female mice liberated for inclusion in neuroscience and biomedical research, *Neuroscience & Biobehavioral Reviews*, Volume 40, March 2014, Pages 1-5,

3: W.A. Rogers, A.J. Ballantyne Australian gender equity in health research group 2008. Exclusion of women from clinical research: myth or reality?

Mayo Clin. Proc., 83 (2008), pp. 536–542 Attribution-NonCommercial 4.0 International License.

# Methods to Incorporate Sex as a Biological Factor

Considering SABV is **NOT** the same as looking for differences based on sex

## Strategies for accounting for sex:

- Literature review on the influence of biological sex (using key words like sex, gender, male/female, etc.)
- Formulation of research questions
- Taking into account the influence of sex in study design
- Incorporating males and females into studies or providing strong justification for a single-sex study
- Stratified randomization of males and females into experimental conditions
- Characterization of study results for males and females
- Examine the treatment or toxicity effects for each sex separately
- Consider influence of sex in the interpretation of study results
- Make generalizations of research findings, when appropriate
- Rationale for number of study subjects now to be explained in Research Strategy

# Data Treatment and Reporting

## Data Treatment and Sample Size

- At a minimum, develop a data analysis plan that provides for the collection of data disaggregated by sex
- Investigators may need larger sample sizes, especially if expecting sex to influence the results
  - Typically these studies are generated from preliminary data/hypothesis that hint that sex may influence results
  - Differentiate sex effects: **MAY** require larger numbers of animals, or equal numbers of both sexes to ensure adequate statistical power

## Reporting of Results

- Report the sexes of animals and collect/analyze sex-based data, even if study is not powered to detect male-female differences

## Reporting one Sex

- Provide justification from the scientific literature, preliminary data, or other relevant considerations
- Without strong justification, it is expected that both males and females will be included in research

# But What If...

## Higher prevalence in one sex?

- Acceptable justifications may include the study of sex-specific conditions or phenomena, or investigation in which the study of one sex is scientifically appropriate

## Small sample/population availability?

- Scarce resources may be considered adequate justification based on evidence of scarcity

## Secondary Analysis? (such as a dataset i.e. Clinical Data Warehouse)?

- Be aware the limitations in the data available which thereby influence the types of questions that can be asked along with the generalizability of the research
- Limitations in existing clinical data sets, grantees should provide strong justification including evidence of the scarcity of this type of data
- *Consider* relevant biological factors when possible

# Issues Specific to Animal Research

- Justification that the species are appropriate for the proposed research in vertebrate animals section
- Report on the characteristics of the research animal's environment<sup>1,2</sup>
  - E.g. temperature, group housing, etc.
- Clearly describe study population and do not generalize findings of entire population (ex: adult animals vs. young/juvenile adults and aged adults)<sup>1</sup>
- Non-human primates are considered a scarce resource<sup>3</sup>
- IACUC is not required by federal regulations to request justification of the choice of sex(es) proposed in studies, but may ask for justification in studies with only one sex

1: Janine Austin Clayton. Studying both sexes: a guiding principle for biomedicine *FASEB J* February 2016 30:519-524

2: Brian J. Prendergast, Kenneth G. Onishi, Irving Zucker, Female mice liberated for inclusion in neuroscience and biomedical research, *Neuroscience & Biobehavioral Reviews*, Volume 40, March 2014, Pages 1-5,

3: <http://orwh.od.nih.gov/sexinscience/overview/pdf/NOT-OD-15-102-Guidance.pdf>

# Cell Lines

- Sex should be considered when using cells or tissues taken **DIRECTLY** from the animal or human
- *Consider* the possible role of sex in research
- Established cell lines:
  - NIH recognizes the difficulty in determining sex
  - Continuing to work on enhancing strategies and techniques to address challenges
  - At this time, cell lines are **not** explicitly covered by this policy **BUT** the NIH notice encourages investigators to consider SABV and be transparent in reporting of cells (when known) and relevant sex-specific data

# Area 3: Application Instructions: Also in *Approach*

## Consideration of Sex and Other Relevant Biological Variables

- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
- If your study(s) involves human subjects, you are expected to explain how relevant biological variables are important to the proposed experimental design and analyses. The sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample.
- Please refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

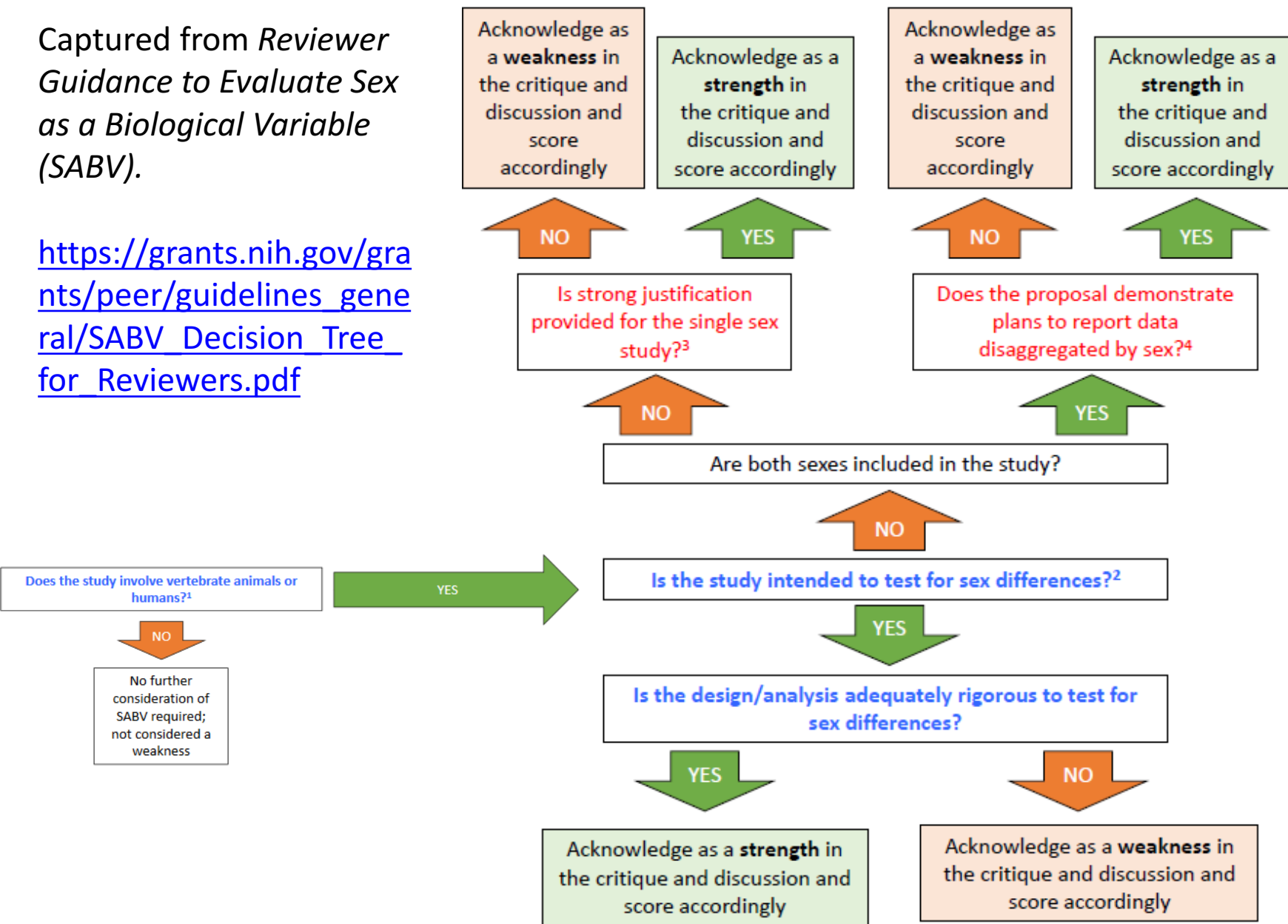
## Area 3: Review Criteria

- Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Decision Tree for Reviewers:  
[https://grants.nih.gov/grants/peer/guidelines\\_general/SABV Decision Tree for Reviewers.pdf](https://grants.nih.gov/grants/peer/guidelines_general/SABV_Decision_Tree_for_Reviewers.pdf)



Captured from *Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)*.

[https://grants.nih.gov/grants/peer/guidelines\\_general/SABV\\_Decision\\_Tree\\_for\\_Reviewers.pdf](https://grants.nih.gov/grants/peer/guidelines_general/SABV_Decision_Tree_for_Reviewers.pdf)



# Area 3:

## How do I write about it?

- Refer to Michelle's list. Slide 26!
- Can pull ideas from here, and just explain it.
- Can be an expansion of your rigor description.
- Demonstrate you have reviewed literature that supports how you considered sex and/or other biological variables in the design of your study.

# The Reduced Criteria for the Vertebrate Animals Section (VAS)

- A description of veterinary care is no longer required
- Justification for the number of animals has been eliminated
- A description and justification of the method of euthanasia is required only if the method is not consistent with AVMA Guidelines for the Euthanasia of Animals

See VAS Worksheet and Checklist:

[http://grants.nih.gov/grants/olaw/vertebrate\\_animal\\_section.htm](http://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm)

---

VAS: Only state the sex of the animals

**Research Strategy** (Approach): must address how sex is factored into the research design

VAS: only state total # of animals proposed

**Research Strategy** (Approach): justification on # of animals is an element of rigor

# More on VAS

Typically, all of the required elements for the VAS can be addressed within 1-2 pages. **The VAS must not be used to circumvent page limits.**

- Source:

[https://grants.nih.gov/grants/olaw/vertebrate\\_animal\\_section.htm](https://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm)

# Area 4: Authentication of Biological and/or Chemical Resources

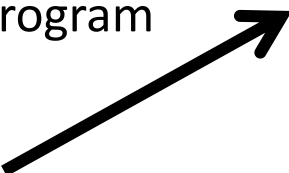
- Sometimes irreproducible results are due to inaccurate reporting of resources used
- Investigator determines what is a “key resource”
- Describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies, including prior to use and frequency of authentication
- What is a key resource?
  - May differ from laboratory to laboratory, over time
  - May have qualities or qualification that could influence results
  - Integral to the proposed research
  - Include resources that are not generated by NIH funds
  - Ex: cell lines, specialty chemicals, antibodies, other biologics, etc
  - Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Ex: buffers, common chemical or biological reagents

# Authentication Plan Examples

- Cell line authentication might include short tandem repeat (STR) profiling and mycoplasma testing
- Chemical authentication might include liquid or gas chromatography, or mass spec, NMR, etc.
- Genetically modified animals or cells might include PCR amplification or Southern blot to confirm genome modification

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-068.html>

# Writing an Authentication Plan

- Depends upon the research discipline
- Investigators should describe how they will authenticate their resources based upon their scientific experience and judgment
- There may be additional resources for authentication procedures
  - Check with NIH program director
  - **ReaDI Program**   
[research.columbia.edu/readi-program](https://research.columbia.edu/readi-program)

## Reproducibility Topics and Guidelines by Research Field

Expand all C

- Antibody Validation
- Biological (Biomedical) Sciences and Research
- Cell Line Authentication
- Health Science and Clinical Research
- Image Manipulation
- Sex as a Biological Factor
- Social Sciences
- Statistics and Methodology (Various Disciplines)
- Computational Science

# Do I Need an Authentication Plan?

## Key resources purchased or obtained from outside source?

- It is *expected* to include a plan to independently verify the identity and activity of product before use
- If product used long-term, consider the stability of the product and how validity of the product will be assessed over time
- Data sets and databases are not a “key resource” (see below)

## An outside party is performing analyses? (Centers, LabCorp, etc.)

- If they’re using a “key resource,” may request information of authentication and include within own authentication plan

## Proposing to establish a new resource?

- Research conducted for resource development, including plans for validating the resource, should be described in Research Strategy section

## Secondary analysis of data collected through means of a “key resource?”

- NO- data sets, databases, machinery, or electronics are not a “key resource”



# Do I Need an Authentication Plan?

## Primary cell cultures?

- Proposing to collect primary cells for short-term culture as part of research, the activities (including plans for authentication identity of cells) should be described in Research Strategy
- If obtained from another laboratory, an authentication plan should be provided

## Collecting biologics as part of research?

- One-time analysis/sample? Do **not** need authentication plan
- Storing samples for repeated use/using stored samples? Authentication plan needed

## Imaging a key part of research?

- Using a “key resource” as part of imaging process? Authentication plan needed
- Otherwise, the parameters to ensure reproducibility of imaging needs to be addressed as part of rigorous experimental design in Research Strategy

# Area 4: Resource Authentication: the Attachment

- **Authentication of Key Biological and/or Chemical Resources:** Briefly describe methods to ensure the **identity and validity** of key biological and/or chemical resources used in the proposed studies.
- If the Research Strategy does not propose use of key biological and/or chemical resources, the Authentication Plan attachment may include a brief statement indicating that no key biological and/or chemical resources will be used in the activities proposed in the application.
- Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.
- Information in this section **must focus only** on authentication and/or validation of key resources to be used in the study as described above. All other methods and any data must be included within the page limits of the research strategy. ***Applications identified as non-compliant with this limitation will be withdrawn from the review process***

## Area 4: Reviewer Critique

- The plan should be **brief** (one page or less for the entire plan), and should not include authentication data. The plan may reflect existing guidelines for some resources or the need for a community to develop a plan for other resources.
- Review of this attachment will occur after scoring; comments on key resource authentication **should not affect scores**. Reviewers will comment on the **adequacy** of the plan for key resource authentication; comments can be addressed by the applicant prior to award for meritorious applications.
- After scoring of the application is complete, Scientific Review Groups (SRGs) will comment on the plans for resource authentication in a manner consistent with the scientific goals of the research. Any concerns raised about the adequacy of the plans for resource authentication should be resolved by the program official before the application/proposal is funded.
- Best practices will emerge from continued discussion and deliberation on this topic

# Other Categories of Research

- **Innovative Research**

- Greater level of risk due to novelty
- Identify risk and incorporate strategies to reduce bias and methods to ensure robust results
- Even innovative research is expected to produce reproducible results

- **Qualitative Research**

- Premise
  - Choice in population
  - Literature review, including quantitative studies
- Rigorous Experimental design
  - Sample strategy and size – theoretical saturation and recruiting methods
  - Data collection methods
    - In-depth interviews (or guided conversations) – Discussion guides
    - Focus groups - Consider things that could positively or negatively impact. Consider novices/experts, strangers/acquaintances, race, gender, income, power differentials
    - Observational
    - Document review – categorization/classification of data, missing data
  - Data Analysis – adequate documentation and transparency is key!
  - Methods to reduce bias
  - Sex as a biological factor

# Videos

Training video meant for NIH staff (33 minutes):

[https://grants.nih.gov/reproducibility/module\\_1/presentation.html](https://grants.nih.gov/reproducibility/module_1/presentation.html)

NIGMS and nine other ICs issued an R25 RFA for educational activities focused on developing the skills of graduate students, postdoctoral fellows and beginning investigators with respect to conducting reproducible research.

The training products resulting from those grants will be housed at the “Clearinghouse for Training Modules to Enhance Data Reproducibility”

<https://www.nigms.nih.gov/training/pages/clearinghouse-for-training-modules-to-enhance-data-reproducibility.aspx>

# Guidance for Reviewers

- [https://grants.nih.gov/grants/policy/review\\_templates.htm](https://grants.nih.gov/grants/policy/review_templates.htm)
- Read the Reviewer Guidance on Rigor and Transparency:
- [https://grants.nih.gov/grants/peer/guidelines\\_general/Reviewer\\_Guidance\\_on\\_Rigor\\_and\\_Transparency.pdf](https://grants.nih.gov/grants/peer/guidelines_general/Reviewer_Guidance_on_Rigor_and_Transparency.pdf)
- Consider becoming a peer reviewer:
- [https://grants.nih.gov/grants/peer/becoming\\_peer\\_reviewer.htm](https://grants.nih.gov/grants/peer/becoming_peer_reviewer.htm)
- Contact: [ReviewerVolunteer@mail.nih.gov](mailto:ReviewerVolunteer@mail.nih.gov)
- Send a brief description of your area of expertise in the body of the email (1-2 sentences) and a copy of your biosketch as an attachment.

# Resources

- <https://research.columbia.edu/ReaDI-Program>
- <http://www.nih.gov/research-training/rigor-reproducibility>
  - PLEASE refer to this website
  - See the training resources and application instructions.
- R&R FAQs: <http://grants.nih.gov/reproducibility/faqs.htm>
- Email questions to [reproducibility@nih.gov](mailto:reproducibility@nih.gov)

# Another Resource of Interest

- Free for any Columbia personnel with valid UNI
- Unlimited storage
  - Unlimited number of notebooks
  - Max file upload into notebook is 4GB
- Features:
  - Secure, backed-up
  - Collaboration space
  - Customizable
  - Searchable
  - Audit trail and version control
  - Protects IP
  - Cloud-based: ability to access from anywhere
- **Approved only for use in research (other than research studies involving the provision of health care services for which study subjects are billed)**
- More information at: [labnotebooks.columbia.edu](https://labnotebooks.columbia.edu)



# labarchives



# The Future of Reproducibility

- In June 2014, NIH, Nature Publishing Group and Science discussed scientific publishing and how to enhance rigor and ensure research that is reproducible, robust, and transparent
- Adopted principles and guidelines for reporting preclinical research
  - Rigorous statistical analysis
    - Journal have method to check statistical accuracy
  - Transparency in reporting
    - No limit or generous limit for methods sections
    - Require authors to fill out a checklist to state where required information is in manuscript
  - Data and material sharing
    - Require datasets be made available upon request (where appropriate)
    - Recommend sharing datasets in a public repository
  - Consideration of refutations
    - Policy stating that if journal publishes paper, assumes responsibility to consider publication of refutations of that paper
  - Considering establishing best practices
    - Image based data
    - Description of biological materials
- Endorsed by 150+ Journals

<http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research>

# Thank You



This work is licensed under a Creative Commons Attribution-NonCommercial 4.0 International License.

Please cite as:

Benson, M.B.; Scott, S. F. (2018). *NIH & AHRQ: Rigor and Reproducibility Policy*. [PowerPoint slides]. <https://research.columbia.edu/content/reproducibility-resources-and-guidelines-topic>