Sex As a Biological Variable (SABV) and the Biomedical Research Community

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44th Meeting of the NIH Advisory Committee on Research on Women’s Health

September 13, 2017
Outline

- **Sex As a Biological Variable:**
  - Guiding principles

- **SABV Policy:**
  - A closer look
  - Report from the front lines

- **SABV Implementation:**
  - Crossing the bridge from SABV policy to *enhancing science and health*
Guiding Principle

Enhancing Science and Health with SABV

• Identify stakeholders
• Identify the tools and resources needed to effectively engage each stakeholder group
ENHANCING SCIENCE AND HEALTH WITH SABV

ANNOUNCE SABV POLICY GUIDE NOTICE

IMPLEMENT SABV POLICY

TRANSFORM SABV FOR HEALTH

APPLY SABV TO SCIENCE

EVALUATE & REFINE

NIH BUSINESS PRACTICES

WHO: NIH LEADERSHIP
• Office of the Director
• IC Directors
• IC Councils
• Extramural Community

WHAT: RESOURCES FOR ICs
• IC Roadshows
• OER & ORWH Website Resources
• Online Tools

NIH BUSINESS PRACTICES

WHO: NIH COMMUNITY
• Program Officials
• IRGs/Reviewers
• Grantees/Contractors
• Postdoctoral Fellows

WHAT: TOOLS & RESOURCES
• PGM Guidance
• IRG Guidance
• Tools for Scientists / Grantees / Contractors / Trainees

BIOMEDICAL RESEARCH COMMUNITY

WHO: SCIENTIFIC COMMUNITY
• Investigators
• Editors / Publishers / Reviewers
• Professional Assoc. & Scientific Societies
• Partnerships, Pharma, Public-Private Partnerships
• Federal Partners

WHAT: TOOLS & RESOURCES
• Journal Editor Guidelines
• Research Symposia, Workshops, Roundtables

THE HEALTH OF EVERYONE

WHO: PUBLIC
• Patients/Families
• HealthCare Professionals
• Patient Advocacy Groups

WHAT: TOOLS & RESOURCES
• Media
• Online Health Info
• Practice Guidelines

ENHANCING SCIENCE AND HEALTH WITH SABV

& NIH BUSINESS PRACTICES

THE HEALTH OF EVERYONE

NIH BUSINESS PRACTICES

BIOMEDICAL RESEARCH COMMUNITY

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BIOMEDICAL RESEARCH COMMUNITY
Outline

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  • A closer look
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  Crossing the bridge from SABV policy to enhancing science and health

(Photo: Pamla J. Eisenberg, 2009, CC BY-SA 2.0)
SABV Policy:

NOT-OD-15-102

Release date: June 9, 2015
Consideration of Sex as a Biological Variable in NIH-funded Research
NOT-OD-15-102, Release Date: Jun 9, 2015

Purpose
The National Institutes of Health (NIH) is committed to improving the health outcomes of men and women through support of rigorous science that advances fundamental knowledge about the nature and behavior of living systems. Sex and gender play a role in how health and disease processes differ across individuals... This notice focuses on NIH's expectation that scientists will account for the possible role of sex as a biological variable in vertebrate animal and human studies.
Consideration of Sex as a Biological Variable in NIH-funded Research

NOT-OD-15-102, Release Date: Jun 9, 2015

Background

“NIH expects that SABV will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex. ... Further info. regarding NIH expectations for the consideration of sex as a biological variable is provided at the following website: http://orwh.od.nih.gov/sexinscience/overview/pdf/NOT-OD-15-102_Guidance.pdf.”
Consideration of Sex as a Biological Variable in NIH-funded Research

NOT-OD-15-102, Release Date: Jun 9, 2015

Background

"NIH expects that SABV will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex. …


SABV Policy:

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

Explain how biological variables, such as sex, are factored into research design and provide justification if only one sex is used.
Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications

NOT-OD-16-011, Release Date: Oct 9, 2015

Research Performance Progress Reports

“Research Performance Progress Reports (RPPR) submitted January 25, 2016 or later will be expected to emphasize rigorous approaches taken to ensure robust and unbiased results. ... This includes non-competing continuation reports (Type 5) for grants reviewed and awarded before implementation of the policy.”
What does a thorough and complete review of SABV look like?

What tools should we direct P.I.s to? What about reviewers?

Tools to evaluate progress reports for SABV?
Do we have to identify the sex of early stage embryos?

I have a scarce resource. I can’t afford to consider SABV.

If I’m transparent about the use of one sex is that ok?

Do we have to identify the sex of early stage embryos?

NIH should admit that research costs will increase 2X to consider SABV.
SABV Implementation & Application

SABV policy

Enhancing science and health
Implementing SABV Policy:

NIH Business Practices
Rigor and Reproducibility Mailbox

• Established June, 2015 (under OER)
• Goal: Address applicants’ questions on NIH policy on Rigor and Reproducibility
• SABV queries sent to ORWH SABV Core for a draft response; forwarded to OER for final response
• FY16: 247 inquiries (23 on biological variables)
Trans-NIH SABV Working Group

- Established: September 11, 2014
- Mandate: To inform SABV Policy development
- Chaired by ORWH Director and OER Director
- Members: Senior IC staff nominated by IC Director
- Meetings: Quarterly

Released a Request For Information (RFI): Consideration of Sex as a Biological Variable in Biomedical Research (NOT-OD-14-128) to gather input from the research community and other interested stakeholders
Implementing SABV Policy:

Trans-NIH SABV Working Group Committees

• Established in April, 2017
• Goal: Implementation of SABV Policy into NIH business practices
• Two Committees:
  • Membership: Trans-NIH SABV Working Group members
    • ad hoc expertise, as needed
• Progress Report: September, 2017:
  • Draft of new Research Performance Progress Report (RPPR) language
  • Draft of new Program Staff Progress Report Guidelines
  • Draft language for FOAs
  • NEW and Updated FAQs for NIH and grant applicants
Next Steps:

- Secure NIH Leadership (OER) support for use of new SABV tools for NIH Business Practices
- Finalize and post answers to new FAQ for use by NIH staff and extramural community
- A new round of “IC Roadshows” to disseminate new implementation tools and resources
Applying SABV to Science:

The Biomedical Research Community
The Biomedical Research Community

Applying SABV to Science:

Recent Presentations:


National Primate Research Centers Consortium, Rigor and Reproducibility Working Group Meeting, NIH Campus, Aug. 6, 2017: Rigor & Reproducibility: NIH Policy for Sex As a Biological Variable (SABV).
Applying SABV to Science:

The Biomedical Research Community

Upcoming Presentations:

**Mayo Clinic’s Celebration of Women’s Health Research Symposium, Rochester, MN, Oct. 18, 2017:** Keynote Address – SABV and the Biomedical Research Community.


**47th Annual Meeting of the Society for Neuroscience, Washington, DC, Nov. 11-15, 2017, Poster:** Considering Sex As a Biological Variable (SABV) in Research: A Primer for Neuroscience Investigators.

**NIH Pain Workshop, Bethesda, MD, Dec. 7, 2017:** Sex Difference Research in Pain Treatment & Opioid Addiction.
Applying SABV to Science:

The Biomedical Research Community

SABV Administrative Supplements

ORWH liaison activities at national & international meetings

It takes a village.

NIH Scientific Interest Group: Sex and Gender in Health and Disease (SGHD SIG)

FY18 ORWH Seminar Series

Expanding SABV in the next Trans-NIH Strategic Plan for Research on Women’s Health
Sex and Gender Course Module 4:

- **Redesigned** to incorporate SABV into each lesson:
  - Cardiology
  - Neurology
  - Endocrinology
  - Pulmonology
  - Mental Health
  - Immunology

Translate SABV for Health:

The Health of Everyone
Thank You!

SABV Implementation & Application

SABV policy

Enhancing science and health