

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

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National Institutes of Health

44th Meeting of the NIH Advisory Committee on Research on Women's Health  
September 13, 2017



**National Institutes of Health**  
*Office of Research on Women's Health*

[orwh.od.nih.gov](http://orwh.od.nih.gov) | [#SABV](https://twitter.com/NIH_ORWH) | [@NIH\\_ORWH](https://twitter.com/NIH_ORWH)

## *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*



# SABV Team



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# 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

## 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

**ANNOUNCE  
SABV  
POLICY  
GUIDE NOTICE**

**IMPLEMENT  
SABV  
POLICY**

**EVALUATE  
&  
REFINE**

**TRANSLATE  
SABV  
FOR HEALTH**

**APPLY  
SABV TO  
SCIENCE**

## THE HEALTH OF EVERYONE

### WHO: PUBLIC

- Patients/Families
- HealthCare Professionals
- Patient Advocacy Groups

### WHAT: TOOLS & RESOURCES

- Media
- Online Health Info
- Practice Guidelines

## 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

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SABV Policy:

**NOT-OD-15-102**

*Release date: June 9, 2015*

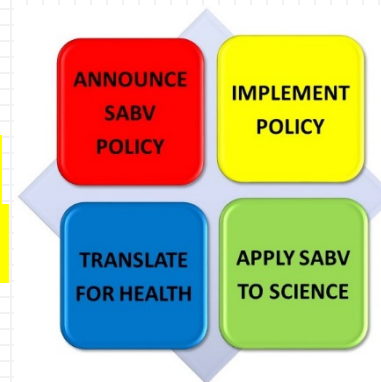
# SABV Policy:

## 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.





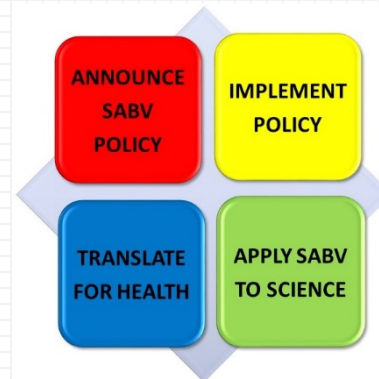
# SABV Policy:

## 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](http://orwh.od.nih.gov/sexinscience/overview/pdf/NOT-OD-15-102_Guidance.pdf).”



# NEW GRANT GUIDELINES

what you need to know

## WHY UPDATE THE GUIDELINES?

The updates focus on four areas deemed important for enhancing rigor and transparency:

1

### PREMISE

The scientific premise forming the basis of the proposed research

2

### DESIGN

Rigorous experimental design for robust and unbiased results

3

### VARIABLES

Consideration of relevant biological variables

4

### AUTHENTICATION

Authentication of key biological and/or chemical resources

Send inquiries to [reproducibility@nih.gov](mailto:reproducibility@nih.gov)

See also NIH Notice NOT-OD-16-011 <http://grants.nih.gov/grants/guide/noticefiles/NOT-OD-16-011.html>

## WHAT ARE THE UPDATES?

### 1 UPDATES TO RESEARCH STRATEGY GUIDANCE

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



Introduction to resubmission and revision applications



Specific aims



Research strategy



Commercialization plan



Biographical sketch

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

- State the strengths and weakness of published research or preliminary data crucial to the support of your application
- Describe how your experimental design and methods will achieve **robust and unbiased** results
- Explain how biological variables, such as sex, are factored into research design and provide justification if only one sex is used

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

From now on, 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:



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 NEW REVIEWER GUIDELINES

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

➔ Is there a **strong scientific premise** for the project?

➔ Have the investigators presented adequate plans to address **relevant biological variables**, such as sex, for studies in vertebrate animals or human subjects?

➔ Have the investigators presented strategies to ensure a **robust and unbiased approach**, as appropriate for the work proposed?



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

Explain how biological variables, such as sex, are factored into research design and provide justification if only one sex is used

ANNOUNCE SABV POLICY

IMPLEMENT POLICY

TRANSLATE FOR HEALTH

APPLY SABV TO SCIENCE

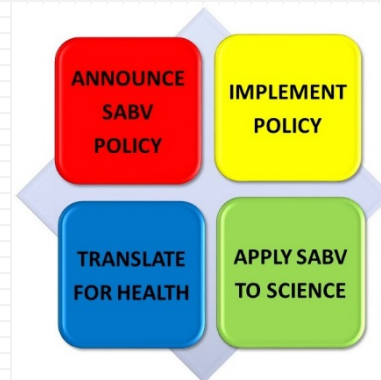
# SABV Policy:

## 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.”



# NIH Community

(Photo: Wikimedia Commons)

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

What does a thorough and complete review of SABV look like?

Tools to evaluate progress reports for SABV?





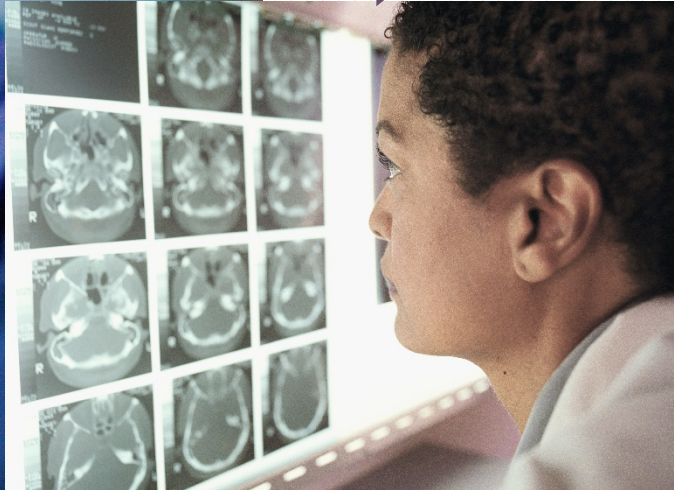
# The Biomedical Community

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?

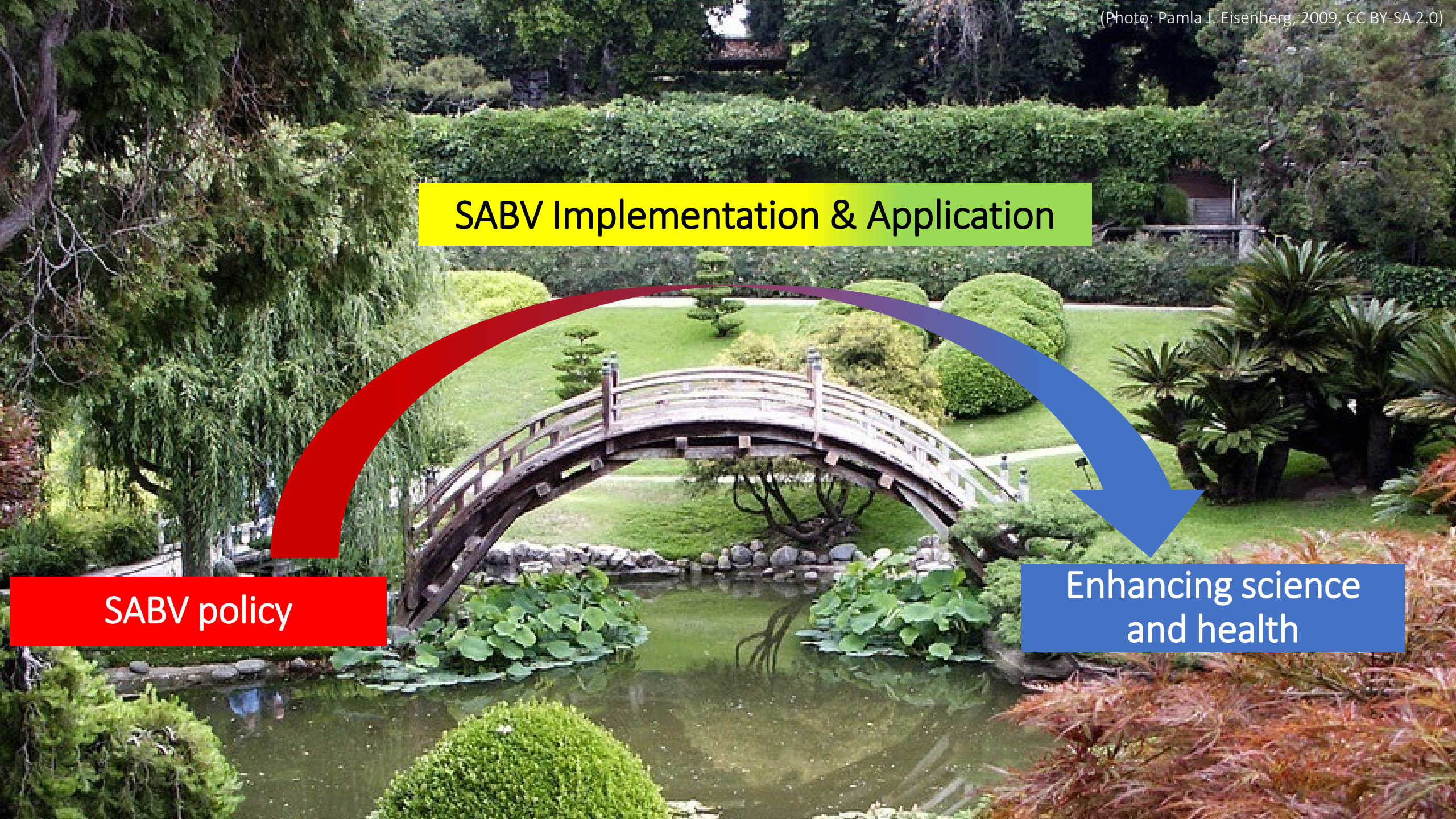
NIH should admit that research costs will increase 2X to consider SABV.



## SABV Implementation & Application

SABV policy

Enhancing science  
and health



# Implementing SABV Policy:

## NIH Business Practices

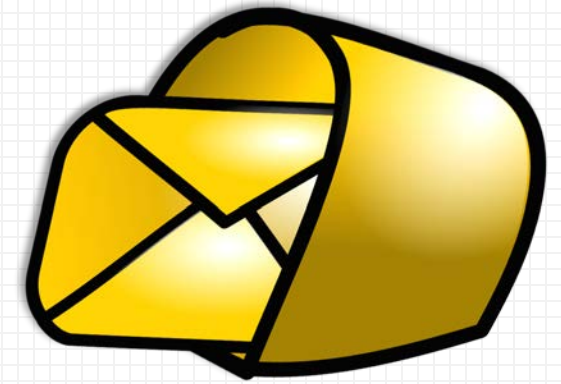


# Implementing SABV Policy:

## 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)



(Photo: Pixabay, CCO Creative Commons)





# Implementing SABV Policy:

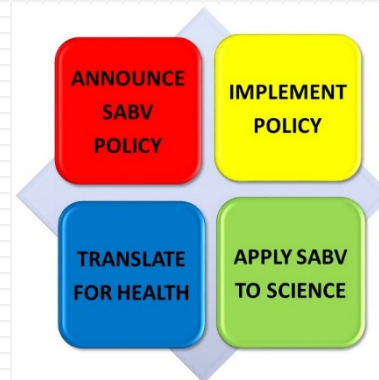
## Trans-NIH SABV Working Group

- 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



(Photo: Pixabay, CC0 Creative Commons)

**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

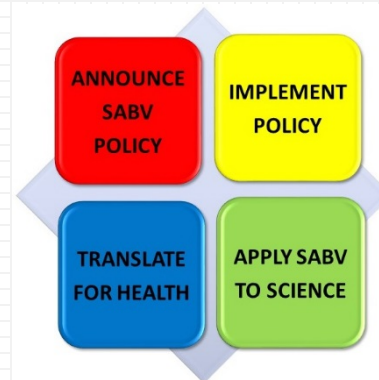


# Implementing SABV Policy:

## NIH Business Practices

### 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



# Applying SABV to Science:

## The Biomedical Research Community

### Recent Presentations:



American College of Laboratory Animal Medicine 2017 Forum, Tucson, AZ, April 24-26, 2017: *Rigor & Reproducibility: Implementation of NIH Policy for Sex As a Biological Variable (SABV)*.



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.*



Am. Acad. of Child & Adolescent Psychiatry, SABV Symposium, Washington, DC, Oct. 23-28, 2017: *Advancing Sex- and Gender-Based Research to Understand Mechanisms and Developmental Trajectories of Depression.*



47<sup>th</sup> 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.*

**FY18 ORWH Seminar Series**

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



Expanding SABV  
in the next  
Trans-NIH Strategic Plan for  
Research on Women's Health

# Translate SABV for Health:

## The Health of Everyone



### Sex and Gender Course Module 4:

- Redesigned to incorporate SABV into each lesson:

- Cardiology
- Neurology
- Endocrinology
- Pulmonology
- Mental Health
- Immunology

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Office of Research on Women's Health

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The Science of Sex & Gender in Human Health  
Online Course Series

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*Thank You!*



## SABV Implementation & Application

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