

## Sex as a Biological Variable: A Primer



### Welcome to the SABV Primer

This course was developed by the National Institutes of Health (NIH) Office of Research on Women's Health (ORWH), with funding support from the National Institute of General Medical Sciences. Click here for information on course authors, reviewers, and leadership.

OMB # 0925-XXXX  
Expiration Date: XX/XXXX  
Public reporting burden statement

The course consists of four independent, interactive modules that are designed to help the biomedical research community—including researchers, NIH grant applicants, and peer reviewers—account for and appropriately integrate SABV across the full spectrum of biomedical sciences. The NIH SABV policy originated in a notice titled "Consideration of Sex as a Biological Variable in NIH-funded Research." It summarizes NIH's expectation that SABV will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.

- Module 1: SABV and the Health of Women and Men
- Module 2: SABV and Experimental Design
- Module 3: SABV and Analysis
- Module 4: SABV and Research Reporting

### Module 1: SABV and the Health of Women and Men

Did you know that female and male differences extend well beyond reproductive organs and hormones or that the lack of consideration or reporting on SABV can have negative effects on health?



As health professionals, we know that good science is important, and we know that no person working in a field that can affect health care would want to jeopardize the health of any patient. That's why the consideration of SABV is a key focus of the NIH initiative to enhance reproducibility through rigor and transparency.

After completing this module, you will be able to:

- Understand how consideration of sex and gender in biomedical research increases rigor of science and improves the health of women and men
- Understand the NIH SABV concept and policy development
- Recognize the meaning and importance of the NIH SABV policy
- Understand the role of SABV across the biomedical research continuum

### Module 2: SABV and Experimental Design

Considering SABV in experimental design of biomedical research is essential to ensure rigor and transparency and to improve generalizability of findings.



When SABV is not considered, there is a risk of an erroneous assumption that results apply to both sexes, poor reproducibility of study results, and lost opportunities for discovering sex differences.

After completing this module, you will be able to:

- Explain what it means to consider and collect data on sex to strengthen science
- Understand how the NIH SABV policy relates to the elements of experimental research design
- Utilize the SABV Checklist to enhance study design
- Recognize common misconceptions about SABV that might influence your thinking
- Recognize how the NIH SABV policy applies across the translational science spectrum

### Module 3: SABV and Analyses

A key component of the consideration of SABV includes characterizing and analyzing sex-based data.



After completing this module, you will be able to:

- Explain the rationale behind characterizing and analyzing sex-based data
- Understand the limitations of analyses that ignore sex influences and differences
- Utilize statistical and power analyses to detect sex differences
- Apply statistical approaches to measure sex influences and differences

### Module 4: SABV and Research Reporting

Full transparency in reporting experimental details, data, and results, including sex-specific reporting, ensures that the biomedical community knows to whom the results of your research apply.



In preclinical and clinical work that aims to develop therapeutic interventions, sex-specific reporting is also essential to determine whether benefits or adverse events differ by sex. This module explores the importance of communicating sex-based data as part of the research process.

After completing this module, you will be able to:

- Recognize the rationale for communicating and reporting data by sex
- Recognize how SABV can be incorporated into the reporting of experimental methodology and results
- Identify the basic elements of guidelines for reporting of sex and gender in research
- Know the guidelines for publishing in scientific journals and ways that communicate sex-based findings
- Know how to share information about sex and gender outside of the scientific community

## Career Development & Education

- Mentored Career Development
- Building Interdisciplinary Research Careers in Women's Health (BIRCWH)
  - Re-Entry into Biomedical Research Careers
- NIH Working Group on Women in Biomedical Careers
- E-Learning
  - Bench to Bedside: Integrating Sex and Gender to Improve Human Health Course
  - Sex as a Biological Variable: A Primer
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- Educational Resources

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- Module 1: SABV and the Health of Women and Men
- Module 2: SABV and Experimental Design
- Module 3: SABV and Analysis
- Module 4: SABV and Research Reporting

### Module 1: SABV and the Health of Women and Men

Did you know that female and male differences extend well beyond reproductive organs and hormones or that the lack of consideration or reporting on SABV can have negative effects on health?



As health professionals, we know that good science is important, and we know that no person working in a field that can affect health care would want to jeopardize the health of any patient. That's why the consideration of SABV is a key focus of the NIH initiative to enhance reproducibility through rigor and transparency.

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- Understand the NIH SABV concept and policy development
- Recognize the meaning and importance of the NIH SABV policy
- Understand the role of SABV across the biomedical research continuum

### Module 2: SABV and Experimental Design

Considering SABV in experimental design of biomedical research is essential to ensure rigor and transparency and to improve generalizability of findings.



When SABV is not considered, there is a risk of an erroneous assumption that results apply to both sexes, poor reproducibility of study results, and lost opportunities for discovering sex differences.

After completing this module, you will be able to:

- Explain what it means to consider and collect data on sex to strengthen science
- Understand how the NIH SABV policy relates to the elements of experimental research design
- Utilize the SABV Checklist to enhance study design
- Recognize common misconceptions about SABV that might influence your thinking
- Recognize how the NIH SABV policy applies across the translational science spectrum

### Module 3: SABV and Analysis

A key component of the research process is the analysis of sex-based data.

After completing this module, you will be able to:

- Explain the rationale for considering sex in data analysis
- Understand the limitations of sex-based data analysis
- Utilize statistical approaches to analyze sex-based data
- Apply statistical approaches to analyze sex-based data

### Module 4: SABV and Reporting

Full transparency in research reporting, ensures that research findings are accurately communicated.

In preclinical and clinical research, reporting is also essential to ensure reproducibility.

This module explores the importance of communicating sex-based data as part of the research process.

After completing this module, you will be able to:

- Recognize the rationale for communicating and reporting data by sex
- Recognize how SABV can be incorporated into the reporting of experimental methodology and results
- Identify the basic elements of guidelines for reporting of sex and gender in research
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## Bench to Bedside: Integrating Sex and Gender to Improve Human Health Course



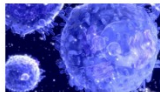
Bench to Bedside: Integrating Sex and Gender to Improve Human Health was developed in partnership with the Food and Drug Administration (FDA) Office of Women's Health (OWH) to explore sex- and gender-related differences in key disease areas. Click here for information on course authors, reviewers, and leadership.

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### Module 1: Immunology

Through a focus on autoimmune diseases, asthma, and vaccine responses (especially the influenza vaccine), this module gives learners the knowledge to:



- Describe key epidemiological data associated with sex differences in the prevalence and outcomes of immunological disease, as well as vaccine efficacy and acceptance.
- Identify the tools available to study sex differences and their outcome measures in preclinical models.
- Describe clinical studies related to sex effects on therapeutic treatments of immunological disease, as well as the efficacy of vaccines.
- Recognize knowledge gaps and biases associated with our understanding of sex differences in immune responses.

### Module 2: Cardiovascular Disease

This module explores sex and gender differences in cardiovascular disease via three major topics: heart failure with preserved ejection fraction (HFpEF), coronary microvascular dysfunction (CMD), and spontaneous coronary artery dissection (SCAD). After completing the module, learners will be able to:



- Identify gaps in research methodologies and public misconceptions associated with sex differences in cardiovascular disease.
- Identify sex differences in the presentation, risk factors, and pathophysiology of representative cardiovascular diseases.
- Describe how sex differences in risk factors and pathophysiology affect cardiovascular patient outcomes and disease management.
- Describe steps required to improve diagnosis and treatment of cardiovascular disease in women and men.

### Module 3: Pulmonary Disease

The pulmonary disease module focuses on sex and gender differences in pulmonary diseases, including idiopathic pulmonary fibrosis (IPF), chronic obstructive pulmonary disease (COPD), and pulmonary arterial hypertension (PAH). After completing the module, learners will be able to:



- Identify sex differences in the presentation, risk factors, and pathophysiology of pulmonary diseases.
- Describe how sex differences in pulmonary risk factors and pathophysiology affect patient outcomes and disease management.
- Identify opportunities to address gaps in knowledge via future research efforts.
- Describe how insights from pulmonary research can inform research design in other fields of study.

### Module 4: Neurology (coming soon)

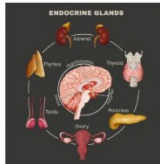
With lessons on ischemic stroke, Parkinson's disease, and epilepsy, this module explores sex differences in neurological diseases. After completing the module, learners will be able to:



- Recognize sex differences in prevalence, symptoms, and treatment effects for neurological diseases.
- Explain the relationship of sex, gender, and age in neurological diseases.
- Recognize hormonal effects on incidence, disease progression, and treatment outcomes.
- Describe preclinical findings on sex differences in neurological diseases.

### Module 5: Endocrinology (coming soon)

The Endocrinology module presents information on sex and gender differences in three conditions: osteoporosis, Type 2 diabetes, and differentiated thyroid cancer. Learners will gain the knowledge to:



- Interpret the epidemiological data on endocrine and metabolic disorders and explain how prevalence and outcomes may differ based on sex.
- Describe preclinical evidence supporting sex differences in endocrine and metabolic disorders and the mechanisms involved.
- Explain the impact of sex differences on the clinical presentation and treatment of endocrine and metabolic disorders.
- Detail the knowledge gaps in endocrine and metabolic research and develop ideas for future preclinical or clinical research studies.

### Module 6: Mental Health (coming soon)

This module explores two mental health disorders with pronounced sex differences: major depressive disorder and autism spectrum disorder. After completing the module, learners will be able to:



- Identify sex and gender differences in the presentation, risk factors, and pathophysiology of mental health disorders.
- Characterize the epidemiology of mental health disorders, with a focus on sex as a relevant biological variable.
- Describe how preclinical models and clinical studies have provided greater understanding of pathology and mechanisms involved in mental health disorders and sex differences.
- Identify gaps in our understanding of sex differences in mental health disorders.

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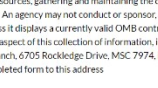
- Recognize sex differences in prevalence, symptoms, and treatment effects for neurological diseases.
- Explain the relationship between sex and neurological diseases.
- Recognize hormonal effects on outcomes.
- Describe preclinical research approaches for neurological diseases.



### Module 5: Endocrinology

The Endocrinology module explores sex differences in three conditions: osteoporosis, diabetes, and thyroid disease. Learners will gain the knowledge to:

- Interpret the epidemiology of endocrine diseases and explain how prevalence differs by sex.
- Describe preclinical research approaches for endocrine diseases.
- Explain the impact of sex on the pathophysiology of endocrine and metabolic diseases.
- Detail the knowledge gaps in endocrine research and ideas for future preclinical or clinical research studies.



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