

## 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
- Videocasts & Webinars
- Educational Resources

## Director's Messages

- Guest Blog—Intimate Partner Violence: Raising Awareness, Taking Action  
October 1, 2019
- ORWH Contributes \$1 Million to NIH HEAL Initiative to Evaluate Impact of Opioids on Human Development  
September 26, 2019
- Research Shows Us How to Address Underrepresentation of Women in Academic Medicine: Now Let's Finish the Job  
September 24, 2019
- A Game-Changing Pledge to Bring Greater Diversity to Scientific Panels  
July 17, 2019

## Subscribe to Our Communications

To receive updates from ORWH directly to your inbox, please enter your contact information below.

Enter email

Submit



### NIH Office of Research on Women's Health (ORWH)

6707 Democracy Boulevard  
Suite 400  
Bethesda, MD 20817  
Phone: 301-402-1770

Web Policies and Notices  
Freedom of Information Act  
No Fear Act

U.S. Department of Health and Human Services  
National Institutes of Health  
USA.gov - Government Made Easy  
Office of Inspector General

## 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 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 results are accurately communicated.

In preclinical and clinical research, reporting is also essential to ensure that research results are accurately communicated.

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

Videocasts & Webinars  
Educational Resources

### Director's Messages

- Guest Blog – Intimate Partner Violence: Raising Awareness, Taking Action  
October 1, 2019
- ORWH Contributes \$1 Million to NIH HEAL Initiative to Evaluate Impact of Opioids on Human Development  
September 26, 2019
- Research Shows Us How to Address Underrepresentation of Women in Academic Medicine: Now Let's Finish the Job  
September 24, 2019
- A Game-Changing Pledge to Bring Greater Diversity to Scientific Panels  
July 17, 2019

### Public Reporting Burden Statement

OMB # 0925-XXXX  
Expiration Date: XX/XXXX

Public reporting burden for this collection of information is estimated to average 60 minutes per module, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address

Close

### Subscribe to Our Communications

To receive updates from ORWH directly to your inbox, please enter your contact information below.

Enter email

Submit



NIH Office of Research on Women's Health (ORWH)

6707 Democracy Boulevard  
Suite 400  
Bethesda, MD 20817  
Phone: 301-402-1770

Web Policies and Notices  
Freedom of Information Act  
No Fear Act

U.S. Department of Health and Human Services  
National Institutes of Health  
USA.gov Government Made Easy  
Office of Inspector General



## 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.

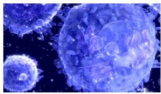
OMB # 0925-XXXX  
Expiration Date: XX/XXXX  
Public reporting burden statement

[View Online Courses Dashboard](#)

### 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:

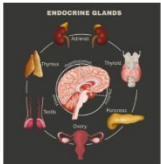
- Recognize sex differences in prevalence, symptoms, and treatment effects for neurological diseases.
- Explain the relationship of sex, gender, and age in neurological diseases.
- Recognize hormonal effects on incidence, disease progression, and treatment outcomes.
- Describe preclinical findings on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



## 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
  - Videocasts & Webinars
  - Educational Resources

## Director's Messages

- Guest Blog—Intimate Partner Violence: Raising Awareness, Taking Action  
October 1, 2019
- ORWH Contributes \$1 Million to NIH HEAL Initiative to Evaluate Impact of Opioids on Human Development  
September 26, 2019
- Research Shows Us How to Address Underrepresentation of Women in Academic Medicine; Now Let's Finish the Job  
September 24, 2019
- A Game: Changing Pledge to Bring Greater Diversity to Scientific Panels  
July 17, 2019

## Subscribe to Our Communications

To receive updates from ORWH directly to your inbox, please enter your contact information below.

Enter email



NIH Office of Research on Women's Health (ORWH)

6707 Democracy Boulevard  
Suite 400  
Bethesda, MD 20817  
Phone: 301-402-1770

Web Policies and Notices  
Freedom of Information Act  
No Fear Act

U.S. Department of Health and Human Services  
National Institutes of Health  
USA gov - Government Made Easy  
Office of Inspector General

## 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 (ORWH) to explore sex- and gender-related differences in key disease areas. Click here for information on course authors, reviewers, and leadership.

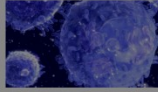
OMB # 0925-XXXX  
Expiration Date: XX/XXXX  
Public reporting burden statement

[View Online Courses Dashboard](#)

### 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 between sex differences and neurological outcomes.
- Describe preclinical research approaches for neurological diseases.



### Module 5: Endocrinology

The Endocrinology module explores two endocrine conditions with pronounced sex differences: osteoporosis and polycystic ovary syndrome (PCOS). 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 differences on the pathophysiology of endocrine and metabolic disorders.
- Detail the knowledge gaps in our understanding of sex differences in endocrine diseases and 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.



## 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
- Videocasts & Webinars
- Educational Resources

## Director's Messages

- Guest Blog - Intimate Partner Violence: Raising Awareness, Taking Action  
October 1, 2019
- ORWH Contributes \$1 Million to NIH HEAL Initiative to Evaluate Impact of Opioids on Human Development  
September 26, 2019
- Research Shows Us How to Address Underrepresentation of Women in Academic Medicine: Now Let's Finish the Job  
September 24, 2019
- A Game-Changing Pledge to Bring Greater Diversity to Scientific Panels  
July 17, 2019

### Public Reporting Burden Statement

OMB # 0925-XXXX  
Expiration Date: XX/XXXX

Public reporting burden for this collection of information is estimated to average 60 minutes per module, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address.

Close

## Subscribe to Our Communications

To receive updates from ORWH directly to your inbox, please enter your contact information below.

Enter email  Submit



NIH Office of Research on Women's Health (ORWH)  
6707 Democracy Boulevard  
Suite 400  
Bethesda, MD 20817  
Phone: 301-402-1770

Web Policies and Notices  
Freedom of Information Act  
No Fear Act

U.S. Department of Health and Human Services  
National Institutes of Health  
USA.gov - Government Made Easy  
Office of Inspector General