43rd Meeting of the NIH Advisory Committee on Research on Women’s Health

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

April 4, 2017
Reminder:
Special Government Employees

- Subject to the same ethics rules that apply to government employees
- Rules located in “Standards of Ethical Conduct for Employees of the Executive Branch”
- Real, potential, or apparent conflict of interest
43\textsuperscript{rd} Meeting of the NIH Advisory Committee on Research on Women’s Health

Janine Austin Clayton, M.D.
NIH Associate Director for Research on Women’s Health
Director, Office of Research on Women’s Health
National Institutes of Health

Director’s Report

April 4, 2017
Our Mission:

- Enhance and expand women’s health research
- Include women and minority groups in clinical research
- Promote career advancement
New ORWH Staff

Monica Ramirez Basco, PhD
Associate Director,
Science, Policy, Planning,
and Analysis

Victoria Cargill, MD, PhD
Associate Director,
Interdisciplinary Research

Chyren Hunter, PhD
Associate Director,
Basic and Translational Research
“NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.”

January 25, 2016 (effective date)

NOT-OD-15-102: Consideration of Sex as a Biological Variable in NIH-funded Research
SABV Gets Recognized

The Washington Post

Nathan Davis Award
Feb 27, 2017

Government Science,
Scientific Category

PAPERS AWARD IN THE NEWS

The Scientist
Exploring Life, Inspiring Innovation

National Institutes of Health
Office of Research on Women's Health
Growing Interest in SABV
Implementation is a Team Sport
How Did We Get Here?
SABV Phase II: Intentional Integration
Sex/Gender Influences on Health and Disease

Accounting for Sex as a Biological Variable in Design, Analysis, Reporting

Preclinical Studies

Phase I, II, III, IV Clinical Trials

Basic Science

Clinical Research

Implementation

Bedside to Bench

Healthy Women, Men, Girls, Boys

Education | Health Policy | Health Care

NIH National Institutes of Health
Office of Research on Women's Health
Guidelines Facilitate SABV Application in Scientific Publication


Accessed close to 5,500 times (a/o 04.03.2017)
Studying both sexes: a guiding principle for biomedicine

Janine Austin Clayton

Correspondence: Correspondence: Office of Research on Women’s Health, National Institutes of Health, 6707 Democracy Blvd., Suite 400, Bethesda, MD 20892, USA. E-mail: janine.clayton@nih.gov

Abstract

In May 2014, the U.S. National Institutes of Health (NIH) announced that it will ensure that investigators account for sex as a biological variable (SABV) in NIH-funded preclinical research as part of the agency’s rigor and transparency initiative. Herein, I describe in more detail the rationale behind the SABV policy component and provide additional detail about policy goals. In short, studying both sexes is a guiding principle in biomedical research that will expand knowledge toward turning discovery into health. NIH expects that considering SABV in preclinical research will help to build a knowledge base that better informs the design of clinical research and trials in humans. Integrating the practice of studying both sexes in preclinical research will, over time, expand our currently incomplete knowledge base that plays a critical role in informing the development of sex- and gender--appropriate medical care for women and men.

—Clayton, J. A. Studying both sexes: a guiding principle for biomedicine.
Sex And Gender Equity in Research (SAGER): reporting guidelines as a framework for innovation in an equitable approach to gender medicine

Paola De Castro, Shirin Heidari and Thomas F. Babor

Settore Attività Editoriale, Istituto Superiore di Sanità, Rome, Italy

Babraham Institute, Cambridge, UK

Department of Community Medicine, University of Connecticut, School of Medicine, Farmington, CT, USA

Abstract

Sex and gender are important determinants of health and influence research findings in a variety of ways, yet they are often overlooked and underreported. This oversight limits the generalisability of research findings and their applicability to clinical practice. The objective of this paper is to present and discuss the concept of sex and gender in research and the development of sex and gender reporting guidelines, which can help ensure that sex and gender are considered in research and that the results obtained are generalizable. The text is based on the Sex And Gender Equity in Research (SAGER) guidelines, developed by the European Association of Science Editors (EASE) in 2016 to promote the systematic approach to the reporting of sex and gender in research across disciplines. The paper includes the rationale and basic principles of the SAGER guidelines.

Key words

- sex
- gender
- guidelines

Sex and gender are often overlooked and underreported in research across disciplines. The SAGER guidelines aim to promote the systematic approach to the reporting of sex and gender in research. The guidelines are based on the concept of sex and gender as important determinants of health and influence research findings in a variety of ways.
Supplemental Data

Considering sex as a biological variable in preclinical research

Supplemental Data

- Supplemental Data
FY16 ORWH Research Funding (%) by Program

- SCOR: 27% (6)
- BIRCWH: 23% (2)
- Other Co-Fund: 20% (15)
- R56 Program: 12% (9)
- ADMIN SUPP: 18% (21)

(#) Participating ICs

NIH National Institutes of Health
Office of Research on Women's Health
### The Incorporation of Sex and Gender Influences

**FY2016 ORWH Administrative Supplements**

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<tr>
<th>Study Type</th>
<th>Description</th>
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<tr>
<td></td>
<td>Propose preclinical research</td>
<td>55%</td>
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<tr>
<td></td>
<td>Propose clinical research</td>
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<td></td>
<td>Propose both clinical and preclinical</td>
<td>18%</td>
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<table>
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<th>Approach</th>
<th>Description</th>
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<tr>
<td></td>
<td>Add new sex to single sex research</td>
<td>47%</td>
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<tr>
<td></td>
<td>Add subjects to existing study to increase power</td>
<td>36%</td>
</tr>
<tr>
<td></td>
<td>Analyze existing samples/data sets</td>
<td>17%</td>
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(N=60)
ORWH Invests in 191*
Sex and Gender Influences (SGI) Supplements

*over 3 years

$ in thousands

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<th>Agency</th>
<th>2016</th>
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Executing the NIH Strategic Plan for Women’s Health Research Goals

**GOAL 1:** Increase sex differences research in basic science studies
- **IC:** NIBIB
- **Title:** Preclinical Investigation of a Bioengineered Vascular Graft

**GOAL 2:** Incorporate findings of sex/gender differences in the design and application of new technologies, medical devices, and therapeutic drugs
- **IC:** NIA
- **Title:** Wisconsin Registry for Alzheimer's prevention

**GOAL 3:** Actualize personalized prevention, diagnostics, and therapeutics for girls and women
- **IC:** NIGMS
- **Title:** Integrative informatics approach to develop safe glucocorticoid therapies
ORWH R56 Program for FY 2016

14 apps | 10 ICs

- Internal Applicants
- Short-Term
- High-Priority

Partnership with OAR and ODS
Specialized Centers of Research on Sex Differences (SCOR), FY16

- Interdisciplinary collaborations
- Research on sex and gender factors underlying a priority women’s health issue
- Bridges basic and clinical research
- Partner with FDA

11 Awards
6 ICs
BIRCWH
Building Interdisciplinary Research Careers in Women’s Health

- Annual meeting: October 25, 2017
- NIH Main Campus
- “IC mentoring”, plenary sessions, etc.

Contributing ICs

- National Institute of Arthritis and Musculoskeletal and Skin Diseases
- National Institute on Drug Abuse
- Eunice Kennedy Shriver National Institute of Child Health and Human Development
- National Institute of Environmental Health Sciences
- National Institute of Allergy and Infectious Diseases
- National Institute of Dental and Craniofacial Research
- National Institute on Aging

NIH National Institutes of Health
Office of Research on Women’s Health
ORWH
Amplifying the Message
It was my pleasure to speak at Chicago Med. School at Rosalind Franklin for Grand Rounds! Dr. Mildred M.G. Olivier was a tremendous host.
2nd Annual NIH Vivian W. Pinn Symposium
Putting Science to Work for the Health of Women

HEALTHY WOMEN MAKE HEALTHY COMMUNITIES:
WOMEN AS MAKERS

Wednesday, May 17, 2017, 2:00pm
NIH Main Campus

#NWHW

Ana Langer, M.D.
Harvard T.H. Chan School of Public Health

Afaf Meleis, Ph.D., Dr.P.S., FAAN
University of Pennsylvania School of Nursing

Stephen Woolf, M.D., M.P.H
Virginia Commonwealth University,
## ORWH: Looking Ahead

<table>
<thead>
<tr>
<th>DATE</th>
<th>EVENT</th>
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<tr>
<td>April 27&lt;sup&gt;th&lt;/sup&gt;</td>
<td>NIH-FDA Pre-Conference Symposium at the 25&lt;sup&gt;th&lt;/sup&gt; Anniversary Women’s Health Congress</td>
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<tr>
<td>May 17&lt;sup&gt;th&lt;/sup&gt;</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; Annual NIH Vivian W. Pinn, M.D. Symposium</td>
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<td>June 1&lt;sup&gt;st&lt;/sup&gt;-2&lt;sup&gt;nd&lt;/sup&gt;</td>
<td>Inclusion Across the Lifespan</td>
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<tr>
<td>September 13&lt;sup&gt;th&lt;/sup&gt;</td>
<td>ACRWH Fall Meeting</td>
</tr>
<tr>
<td>October 25&lt;sup&gt;th&lt;/sup&gt;</td>
<td>BIRCWH Meeting</td>
</tr>
<tr>
<td>October 26&lt;sup&gt;th&lt;/sup&gt;-27&lt;sup&gt;th&lt;/sup&gt;</td>
<td>ORWH-Common Fund Symposium</td>
</tr>
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</table>
Later Today . . .
THANK YOU
Implement SABV Policy

Enhancing Science and Health with SABV

WHO: NIH Community
- Program Officials
- IRGs/Reviewers
- Grantees/Trainees

WHAT: Tools/Checklists
- IRG Checklists
- PGM Checklists
- Online tools
The Health of Women in the United States is:
• Poorer than peer countries
• Indicating new areas of worsening health
• Affected by prevailing societal context
• In need of multi-sector AND interdisciplinary solutions
Outline the Challenge:
The Health of Women in the United States is:
• Poorer than peer countries
• Indicating new areas of worsening health
• Affected by prevailing societal context
• In need of multi-sector AND interdisciplinary solutions

Search for the Solution:
• Develop a strategy to set expectations for and facilitate “raising the bar” for the health of women
• Improve health through integrated/collaborative and coordinated framework for:
  o Study / research
  o Communities of practices and care
  o Sharing with partners and stakeholders
## Sex and Gender Influences Across Institutes and Centers by Research Programs

<table>
<thead>
<tr>
<th>ORWH Program</th>
<th>Collaborating ICs</th>
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<tbody>
<tr>
<td>Specialized Centers of Research on Sex Differences Program (SCOR)</td>
<td>NIA, NIAMS, NICHD, NIDA, NIDDK, and NIMH</td>
</tr>
<tr>
<td>Building Interdisciplinary Research Careers in Women’s Health Program (BIRCWH)</td>
<td>NICHD and NIDA</td>
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<tr>
<td>Sex/Gender Administrative Supplements</td>
<td>All except FIC, NCATS, NEI, NIMHD, NLM, and OD</td>
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<tr>
<td>Other Co-Funds</td>
<td>All except NCATS, NCCIH, NIDA, NIDCD, NIDCR, NIEHS, NIGMS, NIMHD, NINR, NEI, NLM, and OD</td>
</tr>
<tr>
<td>R56 Program</td>
<td>NCI, NIA, NIAAA, NICHD, NIDA, NIDCR, NIEHS, NIMH, and NINR</td>
</tr>
<tr>
<td>Conferences and Scientific Meetings</td>
<td>NICHD, NIDA, and NIDCR</td>
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</table>
Executing the NIH Strategic Plan for Women’s Health Research: Goals and Objectives

Goal 1: Increase sex differences research in basic science studies

Goal 2: Incorporate findings of sex/gender differences in the design and application of new technologies, medical devices, and therapeutic drugs

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- **IC: NIGMS**
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