



# ORWH Basic and Translational Section: Update

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*Associate Director, Basic and Translational Research Program*  
Office of Research on Women's Health  
National Institutes of Health

46th Meeting of the NIH Advisory Committee on Research on Women's Health

October 23, 2018



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

[orwh.od.NIH.gov](http://orwh.od.NIH.gov) | #SABV | @NIH\_ORWH

# Basic and Translational Section Staff Members



Rajeev Agarwal, Ph.D.



Adam Apostoli, Ph.D.



Rebecca DelCarmen-Wiggins,  
Ph.D.



Melissa Ghim, Ph.D.



Elena Gorodetsky,  
M.D., Ph.D.



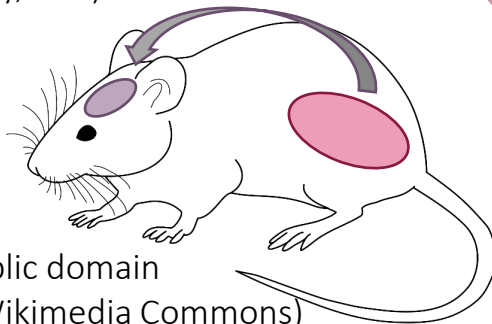
# ORWH supports women's health research through a variety of co-funding programs



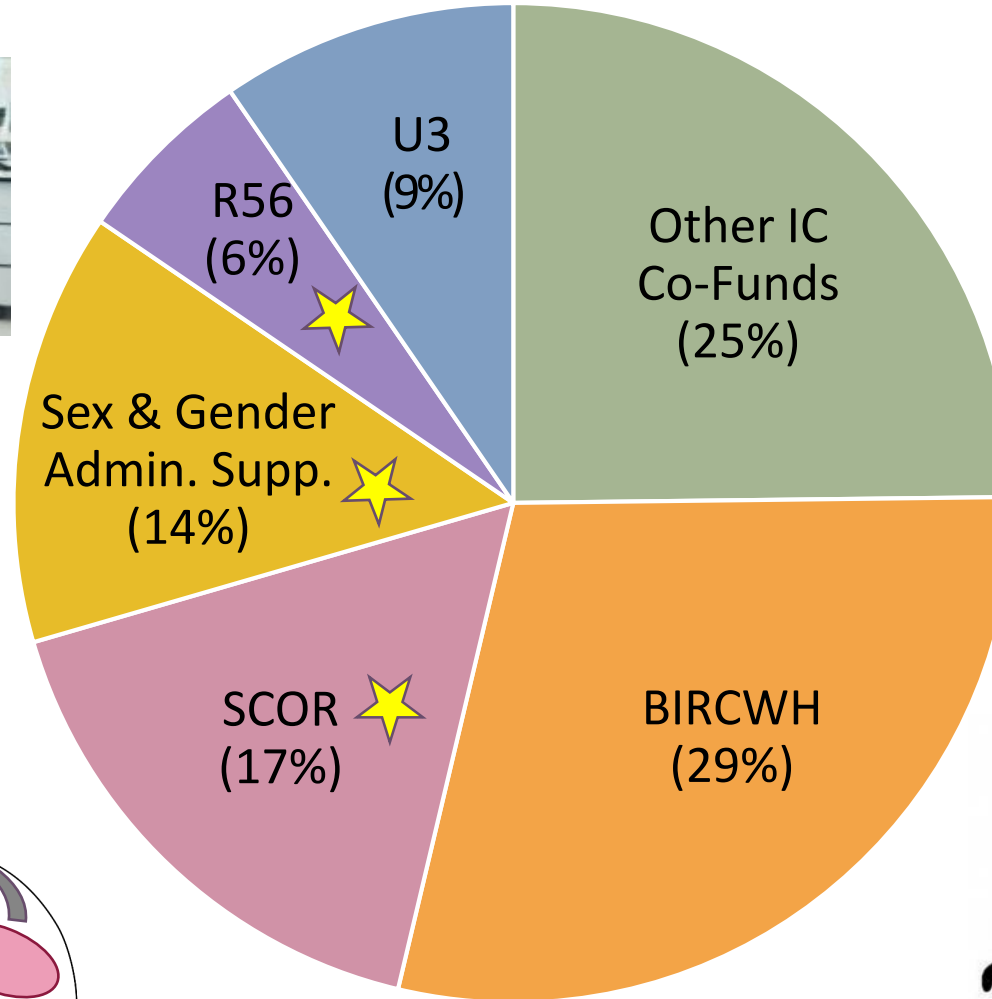
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(Photo: Pixabay, CCO)



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**FY18 Extramural Awards**  
(as % of Extramural Budget)



(Images: PublicDomainPictures.net & Pixabay, CCO Creative Commons)

# SCOR program renamed SCORE in FY18: Specialized Centers of Research Excellence on Sex Differences

*Drs. Rajeev Agarwal and Rebecca DelCarmen-Wiggins*

**The only NIH Center program  
supporting disease- agnostic research  
on sex differences**



## **FY18:**

- Program name changed to SCORE
- Career Enhancement Core (CEC)  
now required, to educate the scientific community and train the next generation of researchers in the study of sex differences



[certipath.com](http://certipath.com)





# SCORE U54 Centers of Excellence:

*function independently and collectively as a national resource with the capacity to:*

- ✓ **Lead** as a regional / national center of research excellence on sex differences and the health of women
- ✓ **Serve** as a potential resource and repository for data, bio- specimens and sex and gender research tools
- ✓ **Educate** the scientific community and train the next generation of biomedical and behavioral researchers
- ✓ **Disseminate** information on sex differences and the health of women





# FY 18 Specialized Centers of Research Excellence (SCORE) take sex differences research to the next level

## RFA-OD-18-004

- 7 IC partners
  - NIA, NIAAA, NIAMS, NIDA, NIDDK, NIEHS, NIMH
- Special Emphasis Panel / 55+ reviewers
- Robust response: > 30 applications
- 6 U54 awards
- Diverse scientific topic areas



## SCORE U54 - diverse scientific topics supported in collaboration with NIH IC partners

- Sex and age differences in immunity to influenza (SAH)
- Bioenergetic and metabolic consequences of aging on mitochondrial function (NIA)
- Sex differences in the regulation of the immune system (NIA)
- Sex-specific effects of environmental factors on aging and Alzheimer's disease (NIA)
- The influence of biological sex on the outcomes of infectious diseases (NIA)
- Sex differences in Metabolic Syndrome (NIDDK)



**NOT-OD-18-232**  
**Notice of Intent to Publish a (SCORE)**  
**on Sex Differences (U54 Clinical Trial Optional)**



# Sex / Gender Administrative Supplement program

*Dr. Rajeev Agarwal*



- Funds supplemental research on NIH grants
- Supports preclinical, clinical, translational or behavioral studies within the scope of the parent project
- Majority of NIH mechanisms eligible for supplemental funding
- Must have 18 months support remaining on the grant term
- Funding supports three main approaches:
  - Add new sex / gender to single sex / gender research
  - Add subjects to an existing study to increase power
  - Comparative analysis of existing samples / data sets







## **ORWH Sex and Gender Supplement Program: 2013 - 2018**

Total investment = \$38.3 Million  
360 Principal Investigators supported  
NIH ICs and OD Office co-sponsors





# ORWH Collaborates with DPCPSI to support R56 short-term awards

*Dr. Elena Gorodetsky*

- Sponsored by three offices under the NIH Office of the Director, Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI):
  - Office of Research on Women's Health (ORWH)
  - Office of Dietary Supplements (ODS)
  - Office of AIDS Research (OAR)
- Supports innovative, potentially high-impact research
- Application score falls outside of NIH IC pay lines
- Successful implementation could advance the mission of OD offices

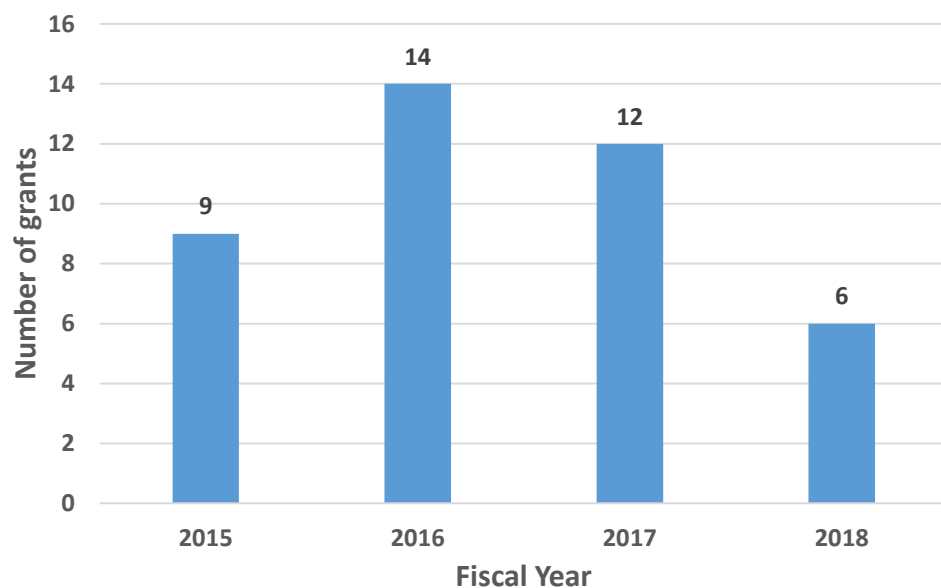
NIH Internal-Only solicitation of applications



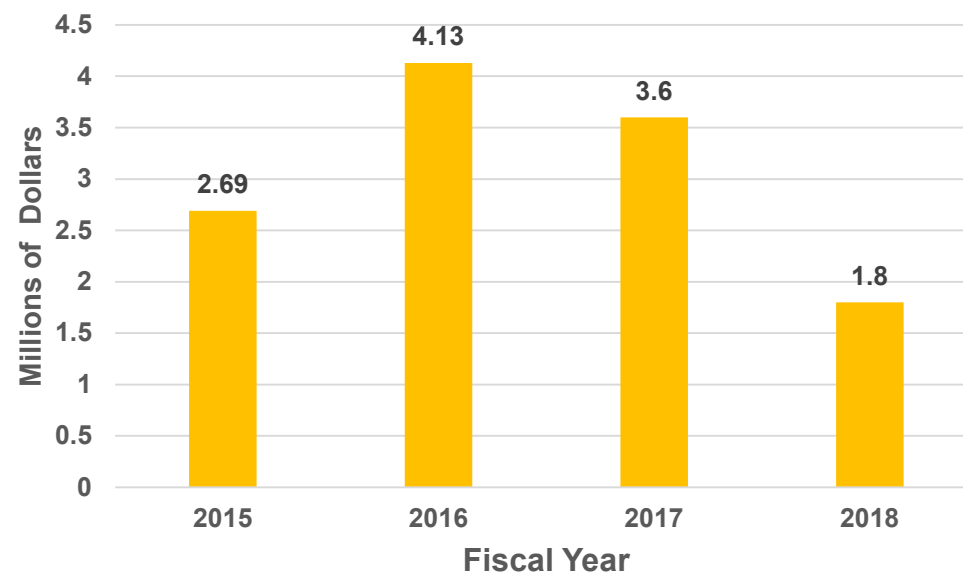
# ORWH R56 Program: supporting investigators in the study of women's health


**ORWH investment FY 15 –FY 18:  
support for 41 investigators / \$11.8 million**

**Funding (#appl), by Year**



**Funding (\$ millions), by Year**





# Achieving our mission through engagement with our stakeholders

- SABV FAQs  
<https://grants.nih.gov/reproducibility/faqs.htm#IV>
- Didactic course content and resources
- Presentations to stakeholders in the biomedical community and at the NIH

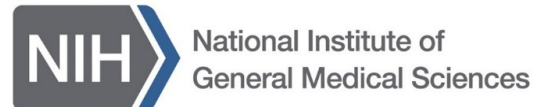


# ORWH and NIGMS establish a new partnership to develop a primer for SABV

*Dr. Melissa Ghim*

PARTNERSHIP

- An interactive, e-learning course to enhance and improve the consideration of SABV in research design, analyses, and reporting
- A resource for designing research studies, preparing NIH grant applications, and training the next generation of investigators
- Audience: researchers of any level, from predoctoral trainees to senior faculty
- Developed by an ORWH-designated contractor with the input of NIH and NIH-designated subject matter experts
- Designed as independent, interrelated modules, with an instructor guide, glossary and references





# SABV Primer provides an understanding of SABV policy as applied to research

## Learning Objectives:

- Understand NIH Policy NOT to consider Sex as a Biological Variable in research, framed in the context of community policies
- Understand how to consider SABV
- Understand how to apply the SABV policy to research
- Provide guidance and examples for the investigator who is not quite sure how SABV should be applied, what resources (s)he should consult for a clearer understanding

**Proposed Launch  
August 2019**



# ORWH Scientific Presentations:



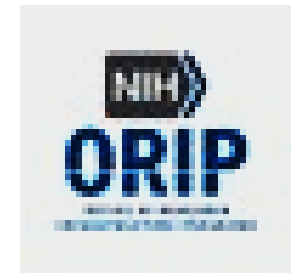
Adolescent Brain Cognitive Development (ABCD) Annual Meeting, SABV Presentation, San Diego, CA, November 1, 2018: *Applying the NIH SABV (Sex as a Biological Variable) Policy to ABCD Research*



Women in Medicine & Science Seminar Series Wake Forest School of Medicine October 17-18, 2018 *Advancing Understanding of Sex and Gender in Health and Disease*



NIH Non-Human Primate Expert Panel Forum. August 23, 2018. *Sex As a Biological Variable (SABV) Policy: Implications for Non-Human Primate Research*



American Psychological Association (APA), Poster, San Francisco, CA, August 9-12: *NIH/ORWH Programs to Support Early Career Psychologists in Biomedical Research. Rebecca DelCarmen-Wiggins, PhD, Melissa Ghim, PhD, & Chyren Hunter, Ph.D. (Best Poster Award for Early Career Information Session)*



ORWH staff collaborate to engage the biomedical community  
and achieve our mission

**NIH Scientific Interest Group:  
Sex and Gender in Health and  
Disease**

**NIH Research Festival  
September. 10-12, 2018**

***It takes a village.***

**BIRCWH annual  
meeting  
November. 28, 2018**

**HRSA Maternal  
Mortality Summit  
June 19-21, 2018**

**Task Force on Research  
Specific to Pregnant  
Women and Lactating  
Women (PRGLAC)  
February & May 2018**





Thank you



