ORWH Basic and Translational Section: Update

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46th Meeting of the NIH Advisory Committee on Research on Women’s Health
October 23, 2018
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

FY18 Extramural Awards (as % of Extramural Budget)

- BIRCWH (29%)
- SCOR (17%)
- Sex & Gender Admin. Supp. (14%)
- R56 (6%)
- Admin. Supp. (14%)
- Other IC Co-Funds (25%)
- Co-Funds (25%)

 Hydrocodone

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New Findings from Yale SCOR

Investigator

When it comes to addiction, sex matters. Addicts’ cravings have different roots in men and women.


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
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 (SADII) (NIA)
- Bioenergetic and metabolic consequences of the loss of gonadal function (NIA)
- Sex/gender differences in addictive disorders (NIDA)
- Sex-specific effects of endocrine disruption 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
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

- 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-OD-15-102: “Consideration of Sex as a Biological Variable in NIH-funded Research”, framed in the context of Rigor and Reproducibility policies
• Understand the imperative need 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

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


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

BIRCWH annual meeting
November. 28, 2018

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

HRSA Maternal Mortality Summit
June 19-21, 2018

It takes a village.