

# ORWH Interdisciplinary Women's Health Research Symposium

## *Sex Differences Methodology and Reporting: Essentials for High-Impact Health Research*

Thursday, November 6, 2014

Masur Auditorium, Clinical Center (Building 10), NIH Main Campus

- 7:30– 8:00 a.m.      **Registration**
- 8:00–8:05 a.m.      **Welcome and Introduction**  
Janine A. Clayton, M.D.  
Director, Office of Research on Women's Health (ORWH)  
Associate Director for Research on Women's Health  
National Institutes of Health (NIH)
- 8:05–8:15 a.m.      **Opening Remarks**  
Francis Collins, M.D., Ph.D.  
Director, NIH
- 8:15–8:30 a.m.      **Setting the Stage**  
Janine A. Clayton, M.D.  
Director, ORWH  
Associate Director for Research on Women's Health, NIH
- Pamela E. Scott, Ph.D.  
Director of Research and Development, Office of Women's Health  
U.S. Food and Drug Administration
- 8:30–9:10 a.m.      **Keynote Address—Women and Substance Abuse: What Do We Know?**  
Wilson Compton, M.D., M.P.E.  
Deputy Director, National Institute on Drug Abuse (NIDA), NIH
- 9:10–9:50 a.m.      **Keynote Address—Sex and Disease: Do Males and Females Read Their  
Genomes Differently?**  
David C. Page, M.D.  
Director, Whitehead Institute  
Massachusetts Institute of Technology
- 9:50–10:00 a.m.      **Break**

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10:00 a.m.–12:00 p.m. **BIRCWH Scholar/SCOR PI Oral Presentations**  
(10-minute presentations; 5 minutes for Q&A)

**Moderators**

Cora Lee Wetherington, Ph.D.  
Chair, Women and Sex/Gender Differences Research Group  
NIDA, NIH

Leah Miller, Ph.D., M.B.A.  
Health Scientist Administrator, ORWH, NIH

10:00–10:10 a.m. **Sex Differences in Attenuation of Cocaine-Conditioned Cue Reinstatement by the Central Oxytocin Receptor Agonist**  
Carmela M. Reichel (presenting author), Shannon M. Ghee, Luyi Zhou, and Jamie Peters  
*Medical University of South Carolina*

10:15–10:25 a.m. **Sex Differences in the Brain Response to Smoking Cues in Adult Cigarette Smokers**  
Stephen J. Wilson (presenting author) and Shannon L. Henry  
*Pennsylvania State University*

10:30–10:40 a.m. **Sex-Dependent Neurodevelopmental and Behavioral Consequences of Exposure to Concentrated Ambient Ultrafine Particles**  
Joshua L. Allen (presenting author),<sup>1</sup> Katherine Conrad,<sup>1</sup> Marissa Sobolewski,<sup>1</sup> Douglas Weston,<sup>1</sup> Gunter Oberdorster,<sup>1</sup> and Deborah A. Cory-Slechta<sup>2</sup>  
*<sup>1</sup>Department of Environmental Medicine, University of Rochester School of Medicine; and <sup>2</sup>Departments of Environmental Medicine and Pediatrics, University of Rochester School of Medicine*

10:45–10:55 a.m. **Pubertal Hormone Associations with Psychopathology: Dynamic Cyclic and Moderated Effects**  
Michelle M. Martel (presenting author), Tory Eisenlohr-Moul, and Bethan A. Roberts  
*Department of Psychology, University of Kentucky*

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- 11:00–11:10 a.m. **Periconceptional Folic Acid–Containing Supplements and LINE-1 DNA Methylation in the MARBLES Prospective Study of Autism Spectrum Disorder**  
R.J. Schmidt (presenting author),<sup>1,3</sup> F. Cray,<sup>2,3</sup> A. M. Iosif,<sup>1,3</sup> J.E. Dienes,<sup>1</sup> and J.M. LaSalle<sup>2,3</sup>  
*<sup>1</sup>Public Health Sciences and <sup>2</sup>Medical Microbiology and Immunology, University of California, Davis; and <sup>3</sup>MIND Institute*
- 11:15–11:25 a.m. **Inhibition of Cyclooxygenase-2 Prevents Chronic and Recurrent Cystitis**  
Thomas J. Hannan,<sup>1,2</sup> Pacita L. Roberts,<sup>3</sup> Terrence E. Riehl,<sup>4</sup> Sjoerd van der Post,<sup>5</sup> Valerie P. O'Brien (presenting author),<sup>2</sup> Jana M. Binkley,<sup>2</sup> Drew J. Schwartz,<sup>2</sup> Hiroyuki Miyoshi,<sup>1</sup> Matthias Mack,<sup>6</sup> Reto A. Schwendener,<sup>7</sup> Thomas M. Hooton,<sup>8</sup> Thaddeus S. Stappenbeck,<sup>1</sup> Gunnar C. Hansson,<sup>5</sup> William F. Stenson,<sup>4</sup> Marco Colonna,<sup>1</sup> Ann E. Stapleton,<sup>3</sup> and Scott J. Hultgren<sup>2</sup>  
*<sup>1</sup>Department of Pathology and Immunology, Washington University School of Medicine; <sup>2</sup>Department of Molecular Microbiology and Center for Women's Infectious Disease Research, Washington University School of Medicine; <sup>3</sup>Division of Allergy and Infectious Diseases, Department of Medicine, University of Washington; <sup>4</sup>Division of Gastroenterology, Department of Medicine, Washington University School of Medicine; <sup>5</sup>Department of Medical Biochemistry, University of Gothenburg; <sup>6</sup>Department of Internal Medicine, University of Regensburg; <sup>7</sup>Institute of Molecular Cancer Research, University of Zurich; <sup>8</sup>Division of Infectious Diseases, Department of Medicine, University of Miami Miller School of Medicine*
- 11:30–11:40 a.m. **Placental Abruption and Type 2 Diabetes Risk in Women: The Danish Birth Registry, 1980–2010**  
Tamarra James-Todd (presenting author),<sup>1</sup> Grete Skøtt Pederson,<sup>2</sup> Jennifer Stuart,<sup>1,3</sup> Laust Hvas Mortensen,<sup>4</sup> Janet Rich-Edwards,<sup>1,3</sup> and Anne-Marie Nybo Andersen<sup>4</sup>  
*<sup>1</sup>Division of Women's Health, Department of Medicine, Connors Center for Women's Health and Gender Biology, Brigham and Women's Hospital and Harvard Medical School; <sup>2</sup>Department of Epidemiology and Biostatistics, University of Southern Denmark; <sup>3</sup>Department of Epidemiology, Harvard School of Public Health; and <sup>4</sup>Section of Social Medicine, Department of Public Health, University of Copenhagen*

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11:45–11:55 a.m. **Sex Differences in Human Pancreatic Islets: Survival, Function, and Genetic Expression**

Kirstie K. Danielson (presenting author),<sup>1</sup> Yong Wang,<sup>1</sup>  
James J. McGarrigle,<sup>1</sup> Jan Jensen,<sup>2</sup> and Jose Oberholzer<sup>1</sup>

<sup>1</sup>*Division of Transplant Surgery, University of Illinois at Chicago;*  
*and* <sup>2</sup>*Department of Stem Cell Biology and Regenerative Medicine,*  
*Cleveland Clinic*

12:00–1:00 p.m. **Poster Session**  
Masur Auditorium, FAES Terrace

1:00–1:45 p.m. **Lunch** (on your own)

1:45–2:45 p.m. **Special Panel and Workshop: Sex Differences Methodology**  
**Goal:** Examine the practical application of the biological variable sex  
in preclinical research

### **Moderator**

Margaret McCarthy, Ph.D.  
Chair, Department of Pharmacology  
Professor, Department of Pharmacology, Physiology, and Psychiatry  
University of Maryland School of Medicine

### **Speakers**

Frederick Ferris, M.D.  
Director, Division of Epidemiology and Clinical Applications  
Clinical Director  
National Eye Institute, NIH

Kay Dickersin, Ph.D.  
Director, Center for Clinical Trials  
Johns Hopkins Bloomberg School of Public Health

Kathleen Brady, M.D., Ph.D.  
Distinguished University Professor  
Associate Provost, Clinical and Translational Research  
Director, South Carolina Clinical and Translational Research Institute  
Medical University of South Carolina

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Margaret McCarthy, Ph.D.  
Chair, Department of Pharmacology  
Professor, Department of Pharmacology, Physiology, and Psychiatry  
University of Maryland School of Medicine

Rear Admiral Sandra Kweder, M.D.  
Deputy Director, Office of New Drugs  
U.S. Food and Drug Administration

**Part 1:** How can the basic biological variable sex be incorporated into all research projects?

*For example, the panelists will address the following:*

- How do we achieve high-impact research? What are recommendations for the study of sex differences in women's health research?
- What is the difference between sex and hormonal status? Do researchers need to include females in all stages of the estrus cycle?
- What are best practices for including sex in experimental design? How should researchers control for sex?
- Are there circumstances in which sex should be controlled for instead of studied?

2:45–2:55 p.m.

**Break**

2:55–3:55 p.m.

***Special Panel and Workshop: Sex Differences Methodology (continued)***

**Part 2:** What is the impact of including or omitting sex as a basic biological variable?

*For example, the panelists will address the following questions:*

- What are the clinical implications of studying sex in the preclinical space?

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- What are the harms and costs of not including sex?
  - Example: Physician's Health Study and Women's Health Study (practical issues related to sex-related research in aspirin for cardiovascular disease; issues of special populations and sex-based differences; issues related to not having sex-based analyses)
  - FDA's experience with industry
- Is there a lack of fundamental understanding of the effect of sex on outcomes?
  - Examples of errors in interpretation of outcomes without sex as a variable
- Can researchers duplicate sex difference outcomes? Should publishing negative sex-based outcomes be the new norm?

3:55–4:00 p.m.

### **Closing Remarks**

Janine A. Clayton, M.D.

Director, ORWH

Associate Director for Research on Women's Health, NIH

4:00 p.m.

### **Adjournment**