

Description

The 45th meeting of the NIH Advisory Committee on Research on Women's Health (ACRWH) convened on Wednesday, April 17-18, 2018 in Bethesda, MD. The closed session was held on April 17, 2018 at the Democracy II Building, Conference Room 849, from 2:30pm until 5:00pm. The meeting was open to the public on April 18, 2018 and was in session from 9:05 a.m. until 1:38 p.m. Janine A. Clayton, M.D., Director, Office of Research on Women's Health, presided as Chair for both sessions.

Recap

DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH ADVISORY COMMITTEE ON RESEARCH ON WOMEN'S HEALTH

MEETING SUMMARY OF THE 45TH MEETING OF THE ADVISORY COMMITTEE ON RESEARCH ON WOMEN'S HEALTH

April 17-18, 2018

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ADVISORY COMMITTEE MEMBERS ATTENDING:

Janine A. Clayton, M.D., Chair
Elizabeth Spencer, Executive Secretary
Jill B. Becker, Ph.D.
Wendy R Brewster, M.D.
Geert J. De Vries, Ph.D.
Carmen R. Green, M.D.
Kimberly Gregory, M.D.
Rachel Jones, R.N., Ph.D.
Carolyn M. Mazure, Ph.D.
C. Noel Bairey Merz, M.D.
David C. Page, Ph.D..
Mary H. Palmer, Ph.D.
Marcia L. Stefanick, Ph.D. (via phone)
Connie Weaver, Ph.D.
Susan F. Wood, Ph.D.

ALSO PRESENT:

Rajeev Agarwal, Ph.D.
CAPT Margaret Bevans, Ph.D., R.N.
Diana Bianchi, M.D.
Roger Fillingim, Ph.D.
Stacie Geller, Ph.D.
Scott Hultgren, Ph.D.
Marjorie Jenkins, M.D.
Ana Langer, M.D.
Amy Paller, M.D.
Judy Regensteiner, Ph.D.
Paris Watson

CLOSED SESSION – April 17, 2018

An April 17, 2018, meeting of the NIH Advisory Committee on Research on Women's Health was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosures under Sections 552b(c){4} and 552b{c}(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2).

OPEN SESSION – April 18, 2018**I. CALL TO ORDER AND OPENING REMARKS**

Janine A. Clayton, M.D., Director, Office of Research on Women's Health, welcomed members and other attendees to the 45th meeting of the NIH Advisory Committee on Research on Women's Health (ACRWH) and called the meeting to order at 9:05 a.m.

Dr. Clayton recognized and thanked four members retiring from their Committee service. The greatly appreciated service of Drs. Jill B. Becker, Carmen R. Green, Mary H. Palmer, and Connie M. Weaver to the Committee was acknowledged, and they were assured that they would remain a part of the ORWH family in the future.

She then officially welcomed the newest Advisory Committee members; Wendy Brewster, M.D., Ph.D.; Kimberly D. Gregory, M.D.; Rachel Jones, Ph.D., R.N.; Marcia Stefanick, Ph.D.; and Susan F. Wood, Ph.D.

II. ADMINISTRATIVE ANNOUNCEMENTS

Dr. Clayton reminded Committee members that as Special Government Employees they are subject to the Standards of Ethical Conduct for Employees of the Executive Branch. She noted that the meeting was being videocast live, photographed, and recorded for archival purposes. The minutes of the September 13, 2017, Advisory Committee meeting were accepted.

III. NIH OFFICE OF WOMEN'S HEALTH PROGRAM UPDATE

Janine A. Clayton, M.D.
Director, Office of Research on Women's Health
Associate Director for Research on Women's Health
National Institutes of Health

Dr. Clayton reviewed the spectrum of current ORWH priorities including collaborations with other NIH Institutes and Centers (ICs) and specific involvement in the NIH Pain Consortium, the Adolescent Brain Cognitive Development (ABCD) Study, the BRAIN Initiative, and the expanding NIH opioid misuse and addiction prevention efforts. Another example of our partnerships with our institutes and centers colleagues is a recent collaboration on increasing the understanding of basic biological pathophysiology and behavioral mechanisms, that's leading to better health for female patients with lung disease.

She stated that the level of ORWH's research program funding remains steady. Almost 37 percent of ORWH's extramural research funds goes directly to NIH Institutes and Centers in support of women's health research programs. Another quarter supports the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program. Eighteen percent of ORWH extramural funds co-fund the Specialized Centers of Research on Sex Differences (SCOR/SCORE) program. Sixteen percent supports the Administrative Supplements for Research on Sex/Gender Differences awards that augment extracting Sex as a Biological Variable (SABV) results from ongoing NIH-funded research. Five percent similarly supports the Research on the Health of Women of Understudied, Underrepresented, and Underreported (U3) Populations program, providing one-year administrative supplements to parent awards addressing these populations of women.

ORWH members tirelessly interact with NIH ICs promoting inclusion of SABV in funded research. Providing tools, publications, and method workshops supporting the incorporation of SABV into preclinical and clinical research is continuing to produce measurable results.

Dr. Clayton noted a couple of updates with the NIH Working Group on Women in Biomedical Careers, she continues to co-chair the working group with NIH Director, Dr. Francis Collins, and reminded the members that the working group was a part of the impetus for the casual factors and interventions funding opportunity announcement that funded 14 grants at the tune of \$16.8 million from 11 ICs, and 4 offices. We are looking at the outcome of that particular funding opportunity. As over 100 publications have resulted, and many PIs have gone on to get additional funding and we are particularly pleased to see that. Additionally, the working group is developing and sharing career advice videos, and hosts symposia encouraging and advising on networking and mentoring among women in science.

IV. LEGISLATIVE & 21ST CENTURY CURES ACT UPDATE

Paris Watson
Legislative Policy Analyst

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

Ms. Watson outlined the 21st Cures Act funding expectations and its commitment to inclusion in both research and workforce. The act requires that women, children, and racial/ethnic minorities across the lifespan are represented in NIH-supported clinical trials and that “valid analysis” of intervention results will be posted to ClinicalTrials.gov.

V. 2019-2023 TRANS-NIH STRATEGIC PLAN FOR RESEARCH ON WOMEN’S HEALTH UPDATE

Captain Margaret Bevans, Ph.D., R.N.
Associate Director for Clinical Research
Office of Research on Women's Health
National Institutes of Health

Captain Bevans described the in-progress development of the “Advancing Science for the Health of Women: 2019-2023 Trans-NIH Strategic Plan.” The plan is addressing the five priorities of research, methods, dissemination, careers, and evaluation. The ACRWH’s participation in the Strategic Plan Working Group made significant contributions to focusing the plan’s strategic objectives. NIH-wide teams are currently working towards an October 2018 launch of the approved plan.

VI. URINARY TRACT INFECTION: COMPLEXITY RESULTS FROM DIVERSITY AT THE BACTERIAL-HOST INTERFACE

Scott J. Hultgren, Ph.D.
Director, Center for Women’s Infectious Disease Research
Washington University School of Medicine
Washington University, St. Louis, MO

Dr. Hultgren is an ORWH SCORE Program PI. He presented an overview of new insights into potential mechanisms and interventions associated with chronic urinary tract infection (UTI) complexity results from diversity of the bacterial host interface, especially prevalent in women. He indicated that we are seeing the headlines in the newspapers lately about superbugs and that there are many UTI patients carrying bacteria resistance, causing the use of antibiotics to be the last resort. Health officials say it could mean the end of the road for antibiotics. With these kinds of depictions, it highlights an urgent need to develop a vaccine or new and better therapeutics. This research into the attachment phenomena of common pathogens suggests several new antibiotic-sparing therapies are on the horizon, some already showing promise.

VII. INSTITUTE UPDATE: INCLUSION OF PREGNANT AND LACTATING WOMEN IN RESEARCH

Diana W. Bianchi, M.D., M.B.A.
Director, *Eunice Kennedy Shriver* National Institute of Child Health

and Human Development
National Institutes of Health

Dr. Bianchi reviewed the pervasive exclusion of children and pregnant or lactating women from current research protocols. More than two-thirds of Phase 3 and 4 clinical studies currently exclude pregnant women. The use of SABV? protocols works to enhance the value of this research, especially as we work to define gestational stressors, opioid use and addiction, and standards of care for neonatal opioid withdrawal syndromes. She confirmed that the NICHD has been actively working on the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) as part of the 21st Century Cures Act (Cures Act) to advise the Secretary of HHS. She discussed a "crowdsourcing resource entitled "Pregsource" and NICHDs efforts in trying to get children included in the NIH "All of Us" Research Program and how as a result of that, pregnant women are also being included now. Also, the NIH overall is funding 683 projects on pregnancy and there is also a category on mental health, a new one breast feeding, lactation and breast milk. Dr. Bianchi indicated that the take-home message is that there is a considerable amount of research going on across NIH and it's not in one specific area.

VIII. CLOSING REMARKS

Dr. Clayton thanked the members and other invitees for their contributions and adjourned meeting.

ADJOURNMENT

The meeting was adjourned at 1:38p.m. on Wednesday April 18, 2018.

10-18-18
Date

Janine A. Clayton
Janine A. Clayton, M.D., Chair

10-18-18
Date

Elizabeth Spencer
Elizabeth Spencer, Executive Secretary

