

52nd Meeting of the National Institutes of Health (NIH)
Advisory Committee on Research on Women's Health (ACRWH)
Office of Research on Women's Health (ORWH)
Bethesda, MD
November 2, 2020

Members Present

Wendy R. Brewster, M.D., Ph.D.
Stacie Geller, Ph.D.
Sabra Klein, Ph.D.
Louise D. McCullough, M.D., Ph.D.
Alyson McGregor, M.D.
Judith Regensteiner, Ph.D.
Elena Rios, M.D.
Michelle Robinson, D.M.D.
Susan F. Wood, Ph.D.
Kimberly J. Templeton, M.D.

ORWH Leadership Present

Janine Clayton, M.D., Director, Chairperson
Samia Noursi, Ph.D., Associate Director for
Science Policy, Planning, and Analysis, Executive
Secretary
Chyren Hunter, Ph.D., Associate Director for
Basic and Translational Research

Call to Order

Samia Noursi, Ph.D., ACRWH Executive Secretary and ORWH Associate Director for Science Policy, Planning, and Analysis, called the online meeting to order at 3:05 p.m. Committee members introduced themselves.

Introduction

Janine Clayton, M.D., NIH Associate Director for Research on Women's Health and ORWH Director, stated the purpose of the meeting: To approve two concept clearances—one for the renewal of the Request for Applications (RFA) for the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program and the other for the Supplements to Promote Reentry into Biomedical Research Careers Funding Opportunity Announcement (FOA)—that will advance women in biomedical careers on two fronts. She reviewed the history of NIH and ORWH initiatives to advance women in science, including the Reentry Supplements in 1992, the founding of BIRCWH in 2000, the creation of the Working Group on Women in Biomedical Careers in 2007, the establishment of the Specialized Centers of Research Excellence on Sex Differences (SCORE) in 2018, and the Challenge Prize for Enhancing Faculty Gender Diversity in 2020, among others.

Barriers: Although there is finally sex/gender equity in education—approximately 50 percent of new M.D. and life sciences Ph.D. degrees are earned by women—at every step of academic career progression beyond the degree, women comprise an ever smaller proportion of the workforce. The barriers to career advancement were laid bare in *Promising Practices for Addressing the Underrepresentation of Women in Science, Engineering, and Medicine* (2020) from the National Academies of Science, Engineering, and Medicine: “Underrepresentation of women in STEMM—including at leadership levels—is driven by a wide range of structural, cultural, and institutional patterns of bias, discrimination, and inequity that do not affect men of comparable ability and training.”

Among women of color, the impact is more pronounced. The greatest proportion of “underrepresented race in medicine” (URiM) women faculty is at the assistant professor and instructor ranks. URiM women make up only 15 percent of women chairs in basic science and clinical science departments.

Coronavirus Disease 2019’s (COVID-19) Impact: The current COVID-19 pandemic is negatively impacting women’s careers. Short-term, it has led to a publications gap that impedes women’s tenure path and has accelerated departures from the scientific workforce. Long-term, this may mean fewer women biomedical researchers and less sex as a biological variable (SABV) study, as well as missed opportunities to address issues such as flexibility in tenure, reentry, and leave policies.

COVID has also highlighted the need for an integrative, whole person approach to biomedical research, as outlined by Helen Langevin, Ph.D., National Center for Complementary and Integrative Health, who spoke at the 51st ACRWH meeting.

To inform policy and program decisions as it seeks to identify ways to continue to support the biomedical research enterprise in the future, NIH is conducting two surveys about the impact of COVID, one for institutions and one for individual researchers. Results are expected in the near future.

Concept Clearance for the Re-issuance of the BIRCWH RFA-OD-16-013

Dr. Clayton introduced Lisa Begg, Dr.PH, RN, Senior Research Program Officer, ORWH, who presented a concept clearance proposal for re-issuance of the Building Interdisciplinary Research Careers in Women’s Health (BIRCWH) Program ([RFA-OD-16-013](#)). BIRCWH is one of ORWH’s two signature programs, focusing on career development of junior faculty (called BIRCWH Scholars). Its purpose is to expand support for training/career development in interdisciplinary, basic, translational, behavioral, clinical and/or health services research relevant to the health of women. Where appropriate, such research should include both sexes to better understand the influence of sex as a variable in health and diseases. There are currently 22 BIRCWH programs geographically dispersed across the United States.

BIRCWH Accomplishments: Over 700 Scholars have been trained with the Program. A recently-completed evaluation of the Program covering 2000-2018 indicated that approximately 70 percent of BIRCWH Scholars received at least one successful R-level grant. Research areas for BIRCWH have included cardiovascular disease, aging, cancer, neurosciences, musculoskeletal conditions, autoimmunity, mental health, reproductive health, health disparities, and infectious diseases/emerging infections, including HIV/AIDS.

The evaluation also revealed that BIRCWH Scholars have achieved high levels of success as recipients of funding from various sources for health research projects, and most have published in multiple medical- or health-related journals. Most Scholars went on to pursue women’s health-related research following participation in the BIRCWH program. The Program also had an impact on the institutions where the Program was located. Principal Investigators (PIs) reported that their institutions have benefited through increased interdisciplinary research and an increased number of women in academic leadership positions, and that participation in the BIRCWH program has resulted in the development of new programs and courses or revised content in existing courses. The BIRCWH program has also been instrumental in providing mutually beneficial mentor–mentee relationships.

Re-issuance: Re-issuance of RFA-OD-16-013 will allow the BIRCWH Program to continue to operate without a gap in funding; currently, funding extends to Fiscal Year 2022. The mechanism will continue to be a K12 institutional career development award and the Program will continue to partner with several Institutes and Centers (ICs) at NIH. Clinical trials can be included, i.e., Scholars can lead a clinical research project that falls under the new NIH definition of clinical trials.

Rationale: The BIRCWH Program is the only trans-NIH training/career development program that focuses broadly on the health of women. Initiated as a Congressionally-designated program in 1999, it remains a priority area as specified in the 21st Century Cures Act. Finally, BIRCWH supports the 2019-2023 Trans-NIH Strategic Plan for Women’s Health Research, strategic goal 4: To promote training and careers to develop a well-trained, diverse, and robust workforce to advance science for the health of women (Objectives 4.1, 4.2, 4.3, 4.4, 4.5).

Q&A: Discussion addressed the impact of BIRCWH participation on the career trajectories of PIs and mentors, who are generally mid-career women; whether the presence of BIRCWH has expanded the inclusion of a sex and gender perspective in curricula for the health professions at funded institutions; the strong positive impact that BIRCWH has had on women’s careers and institutions; if schools of public health are eligible to participate in BIRCWH; the feasibility of adding a requirement that institutional change addressing gender diversity be added as a requirement of the Program, perhaps after consideration by a task force; and the need for expanded funding of the Program.

Member Vote: BIRCWH Concept Clearance: Approved, with eight in favor and one abstention.

Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers

Dr. Noursi introduced Lynn Morin, M.A., Health Scientist Administrator, ORWH, who presented the concept clearance for Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers ([PA-18-592](#)). Its purpose is to support individuals with high potential to re-enter an active research career (that falls within the mission of NIH) after an interruption for family responsibilities or other qualifying circumstances. These supplements to existing NIH research grants support full-time or part-time research by these individuals to update their existing research skills and knowledge.

The current FOA is supported by 26 ICs, and supports over 50 activity codes including Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR), Cooperative Agreements, Pioneer, and Innovative awards. The supplements should not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary study to a clinical trial, but does allow for research experience in a clinical trial led by a mentor or co-mentor.

Ms. Morin presented usage data covering the past 10 years that demonstrated the Reentry Supplements are widely used with moderate funding success. Generally, women have submitted more applications and achieved a higher success rate than men. The National Cancer Institute (NCI) and the National Institute of General Medical Sciences (NIGMS) support the majority of the applications, followed by the National Center for Advancing Translational Sciences and the National Institute of Environmental Health Sciences.

Changes to the FOA: The new FOA includes updated language to address recommendations from the NIH Advisory Committee to the Director’s Working Group on Changing the Culture to End Sexual Harassment report, i.e., an example of a qualifying circumstance will include “leaving a research position because of an unsafe or discriminatory environment.” Other changes include revision of the minimum allowed duration of the career interruption from one year to six months. There are additional flexibilities regarding duration of interruption, postdoc eligibility, and other factors as determined by each IC. ORWH will strive to conduct outreach about these changes.

Q&A: Discussion addressed the sensitive nature of some of the proposed changes, e.g., sexual harassment, and how NIH could appropriately support such applicants; the need to support women who want to reenter a research career after spending time on service activities; and the requirement that there be a primary grant with a PI who approves the supplement application.

Member Vote: Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers: Approved unanimously, nine in favor.

SABV Primer Preview

Dr. Noursi introduced Chyren Hunter, Ph.D., Associate Director for Basic and Translational Research, ORWH, who provided a “sneak peak” at the new Sex as a Biological Variable (SABV) Primer that is expected to be available in November 2020. The Primer has been developed in partnership with NIGMS. Its goals are to clarify the SABV policy to create a better buy-in and greater compliance in the biomedical community by providing an educational resource to support NIH applicants and the scientific community in applying SABV with a “science first” focus.

The Primer consists of four modules: 1: SABV and Health of Women and Men; 2: SABV and Experimental Design; 3: SABV and Analyses; 4: SABV and Research Reporting. Each module consists of a minimum of three to four lessons. All modules include knowledge checks; those who successfully complete all four modules will receive a certificate of completion. There is also a companion Instructor’s Guide.

Dr. Hunter demonstrated a live version of Modules 1 and 3, followed by screenshots of Modules 2 and 4. She noted features such as written learning objectives in each module; links to more extensive information and complete references in all lesson content; and interactive features, such as opportunities to conduct a statistical power analysis to detect sex differences in a study design or a “red pen” exercise in which a learner is presented with an example of scientific writing and asked to select the correct assessment of its presentation of sex and gender terminology.

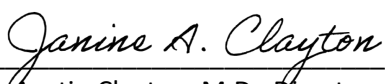
Q&A: Dr. Clayton asked Committee members about how the SABV Primer might be used in their institutions. Suggestions included sharing it with all BIRCWH Scholars and persuading journal editors to make it “required reading” for all editors and reviewers.

Closing Remarks


Dr. Clayton reminded Committee members of the next ACRWH meeting on April 14, 2021, which will be virtual. Dr. Clayton adjourned the meeting at 4:40 pm.

Certification

We certify that the contents above are accurate and complete.



Janine Austin Clayton, M.D., Director
Office of Research on Women’s Health



Samia Noursi, Ph.D., Executive Secretary
Advisory Committee on Research on Women’s Health

Date 2/5/2021

Date 1/25/2021