

such as general perceptions of risk, the adoption of risk reduction behaviors, and perceptions framed by scientific controversy or misinformation.

The following statements are provided to obtain feedback to fill existing gaps in DW CEC knowledge and practice in these research areas. Please comment on:

1. The critical, impactful research questions and topics that should be addressed in order to better protect American public health in regard to DW CEC.

2. Research priorities within each of the four areas described below.

3. New or innovative tools, technologies, software, modeling, methods, data/information sharing, etc. that should be developed or employed to address these research areas.

This RFI is for planning purposes only and should not be construed as a solicitation for applications or proposals, or as an obligation in any way on the part of the United States Federal government. The Federal government will not pay for the preparation of any information submitted or for the government's use.

Additionally, the government cannot guarantee the confidentiality of the information provided.

Dated: June 28, 2021.

**Christopher P. Weis,**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Request for Information: Inviting Comments To Inform the Women's Health Consensus Conference (WHCC)

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Request for information.

**SUMMARY:** The National Institutes of Health (NIH) Office of Research on Women's Health (ORWH) is planning a Women's Health Consensus Conference (WHCC) in October 2021, in response to a Congressional request to address NIH research efforts related to women's health research as well as the following specific conditions, rising maternal morbidity and mortality rates, increasing rates of chronic debilitating conditions in women, and stagnant cervical cancer survival rates. The ORWH is seeking comments and

testimonies from the extramural scientific community, professional societies, and the general public regarding the topics mentioned above to assist with identifying research gaps, pitfalls in clinical practices, and obtaining real-life testimonial experiences (direct or indirect) caused by any or all of the listed public health issues.

**DATES:** The Women's Health Consensus Conference (WHCC) Request for Information is open for public comment through September 15, 2021. Comments must be received by September 15, 2021, to ensure consideration.

Comments received after the public comment period has closed may be considered by the Office of Research on Women's Health.

**ADDRESSES:** Submissions must be sent electronically to Elizabeth Barr, Ph.D., [WHCC@od.nih.gov](mailto:WHCC@od.nih.gov).

**FOR FURTHER INFORMATION CONTACT:** Questions about this request for information should be directed to Elizabeth Barr, Ph.D., Office of Research on Women's Health, 6707 Democracy Boulevard, Suite 400, Bethesda, MD 20817, [WHCC@od.nih.gov](mailto:WHCC@od.nih.gov), 301-402-7895.

**SUPPLEMENTARY INFORMATION:** ORWH was established at NIH on September 10, 1990. The Office was reaffirmed by statute in congressional legislation by the NIH Revitalization Act of 1993 (Pub. L. 103-43, Section 486) to serve as the focal point for women's health research at NIH, reporting directly to the NIH Director, and working in a collaborative partnership with the Institutes, Centers, and Offices. ORWH is convening the Women's Health Consensus Conference in response to significant items (SI) in H.R. 7614—Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (2021). The SIs require that a consensus forum assessing research on the health of women be held by the fall of 2021.

*Goals and Requirements.* Both the House and Senate directed NIH to evaluate research underway related to women's health and provide an update on priority areas for additional study to advance women's health research, including reproductive sciences. In preparation for the WHCC, ORWH, and partners from other NIH Institutes, Centers, and Offices will assess the current state of NIH-supported women's health research; delineate research gaps and, in turn, opportunities related to research on the health of women; and set contemporary priorities for research on the health of women. The following specific topics, among others, will be

addressed: Maternal morbidity and mortality,<sup>1,2</sup> the rising rates of chronic debilitating conditions in women<sup>3</sup> and stagnant cervical cancer survival rates.<sup>4</sup> To inform the WHCC meeting and discussion, ORWH seeks comment and testimony on current research efforts on the health of women.

#### 1. Maternal Morbidity and Mortality

Birthing people in the United States are dying during the postnatal period from conditions that can be treated, such as cardiovascular disease, hypertension, thrombotic pulmonary embolism, and hemorrhage, among others. An estimated six in ten maternal deaths are preventable.<sup>5</sup> The public health challenge is to reduce U.S. maternal mortality rates (17.2 per 100,000 live births in 2011–15)<sup>6</sup> to be comparable with or lower than other first world countries such as United Kingdom, Germany, France, and Canada (rates all below 9.2 per 100,000 live births in 2015).<sup>7</sup>

Individual, behavioral, and structural factors influence incidence of maternal morbidity and mortality.<sup>5</sup> Structural racism,<sup>5</sup> implicit bias,<sup>6</sup> & racially biased policies and practices<sup>7</sup> contribute to significant and persistent racial disparities in maternal morbidity and mortality. From 2011–2015 non-Hispanic Black and American Indian/Alaska Native women had the highest incidences of pregnancy-related deaths. Black women are three times more likely to die from a pregnancy-related cause than White women,<sup>6</sup> in New York City, Black women are twelve times more likely than White women to die from pregnancy-related causes.<sup>8</sup> Similar racial disparities exist in maternal morbidity.<sup>9</sup> Neither education nor higher socioeconomic status mitigates the elevated risks of severe maternal morbidity and maternal mortality among Black women.

#### 2. Chronic Debilitating Conditions in Women

Chronic Debilitating Conditions include diseases that occur in both men and women such as diabetes, cardiovascular disease, cancer, and autoimmune diseases as well as sex-specific conditions such as fibroids and endometriosis. In the United States, six in ten adults have a chronic disease; chronic disease is the leading cause of death and disabilities.<sup>10</sup>

Rates of many chronic diseases in women are rising, for example COPD in women,<sup>11</sup> and new discoveries related to sex-difference and molecular mechanisms of disease are being published every day.<sup>12</sup> Biomedical and socio-behavioral understandings of sex

and gender influences on mechanisms and outcomes of chronic diseases are incomplete, reducing the specificity, sensitivity, and efficacy of diagnostic tests and treatments for women. Research on rare diseases that are more prevalent in women or only occur in women faces similar challenges.

### 3. Stagnant Cervical Cancer Survival Rates

In the United States it is estimated approximately 12,000 new cases of cervical cancer occur each year. Human papillomavirus (HPV) is the cause of cervical cancer as well as a large percentage of cancers of the vulva, vagina, penis, anus, rectum, and oropharynx.<sup>13</sup> Despite cancer prevention efforts through HPV vaccination and cervical cancer screening, incidence and mortality from this malignancy have been stable for the last two decades. Communities historically under-represented in medicine are disproportionately burdened by this disease. The incidence rate of cervical cancer is 30 percent higher in Black women<sup>14</sup> and Black women persistently present at later stages at diagnosis.<sup>15</sup> The overall 5-year relative survival rate for cervical cancer among Black women is 56 percent, compared with 68 percent among White women.<sup>14</sup>

### Information Requested

This Request for Information (RFI) invites the scientific community, health professionals, professional societies, and the general public to provide comments and testimonies on research gaps, pitfalls in clinical practices, and obtaining real-life testimonial experiences (direct or indirect) related to any or all of the listed public health issues. Responses are welcome from associations and professional organizations as well as individuals.

This RFI is for planning purposes only and should not be construed as a solicitation or an obligation on the federal government, the National Institutes of Health, or individual NIH Institutes or Centers. Responses to this RFI Notice are voluntary. The NIH will use the information submitted in response to this RFI at its discretion. NIH will analyze the information submitted and may share it internally or in reports. The information may or may not be reflected in future solicitations, as appropriate and at the government's discretion. NIH advises respondents the government is under no obligation to acknowledge receipt of the information provided and will not provide feedback to respondents. The federal government will not pay for the preparation of any

information submitted or for the government's use. NIH will not consider submitted information confidential. Additionally, the government cannot guarantee the confidentiality of the information provided.

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Dated: June 25, 2021.

**Lawrence A. Tabak,**

*Principal Deputy Director, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** David Yang at 240-695-6406 or [yangp3@mail.nih.gov](mailto:yangp3@mail.nih.gov). Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows:

### Pre-Biotic Formulation of Topical Chemicals for Use on Human Skin

*Description of Technology:* Atopic dermatitis (AD) is a common, recurrent, chronic inflammatory skin disease that is a cause of considerable economic and social burden. It is one of the most prevalent skin disorders, affecting ~25% of children in developed and developing countries and is expected to continue to escalate. This increased rate of incidence has changed the focus of research on AD toward epidemiology, prevention, and treatment.