Society for Women's Health Research

January 27, 2023

Arati Prabhakar
Director
White House Office of Science and Technology Policy
Washington, D.C. 20500

Comments submitted electronically to emergencyclinicaltrials@ostp.eop.gov.

Re: OSTP Request for Information (87 FR 64821); Clinical Research Infrastructure and Emergency Clinical Trials

Dear Director Prabhakar:

The Society for Women's Health Research (SWHR), a more than 30-year-old national nonprofit dedicated to promoting research on biological sex differences in disease and improving women's health through science, policy, and education, is pleased to offer comments in response to the Office of Science and Technology Policy (OSTP) Request for Information (RFI): Clinical Research Infrastructure and Emergency Clinical Trials.

As an organization whose work and mission revolves around the representation of women and subpopulations of women in clinical trials and supporting these populations in areas, including federal policy, SWHR appreciates that OSTP—in partnership with the National Security Council (NSC)—recognizes the role of clinical trials in responding to outbreaks of disease and other emergencies as well as the importance of ensuring that there is diversity within these clinical trials and among clinical investigators. Guaranteeing that our federal research infrastructure has the capacity to respond to such situations in the future is vital for protecting the health, well-being, and safety of all Americans.

As OSTP and NSC explore ways to enhance U.S. clinical trial infrastructure, SWHR would like to raise the following items for consideration.

I. **Ensure the Inclusion of Pregnant and Lactating Populations in Clinical Trials**

SWHR implores OSTP and NSC to ensure that the U.S. clinical trial infrastructure prioritizes the inclusion of pregnant and lactating populations in clinical research, including during times of emergency. The failure to include these populations in trials can lead to harmful gaps in evidence for both mother and baby.

During a recent webinar hosted by the Coalition to Advance Maternal Therapeutics (CAMT), for which SWHR serves as the administrator, panelist Anne Lyerly, MD, MA,

a professor in the School of Medicine at the University of North Carolina, Chapel Hill discussed the negative unintended downstream effects of excluding pregnant populations from clinical trials. Specifically, she noted that without adequate evidence, pregnant persons may be given drugs at the wrong dose, resulting in either exposure to disease (when dosed too low) or toxicity (when dosed too high); may be given drugs with unacceptable risk; or may be denied access to beneficial drugs.

The COVID-19 pandemic served as a stark reminder of this unnecessary reality. Due to the exclusion of pregnant populations in early COVID-19 clinical trials, women and their health care providers were left to make decisions about whether to get the COVID-19 vaccine without any kind of data to support their decision. This left women and their children vulnerable and their health care providers at risk of making an incalculable recommendation. Further, the absence of data likely allowed vaccine hesitancy to grow and misinformation to proliferate. In other words, this exclusion was dangerous at both an individual and population level.

As we now know from mounting evidence,[1] the COVID-19 vaccine *is* safe and effective for pregnant and breastfeeding populations and is not, as early speculations indicated, associated with fertility problems. Further, data has shown pregnant women and women who were recently pregnant are more likely to get severely ill from COVID-19, demonstrating the harm that can result from women not being vaccinated against the virus. Including pregnant and lactating women at the outset of these trials would have led to having this beneficial information sooner, and thus resulted in better outcomes for mothers and babies across the country sooner.

SWHR supports incorporating pregnant and lactating populations at every level of our federal research infrastructure. This includes, but is not limited to, identifying ways to increase recruitment among these populations, ensuring that the workforce of clinicians and researchers include those with expertise in obstetric and lactation pharmacology and therapeutics, and providing incentives or financial support to those sites that enroll these populations.

II. Enhance Representation of Underrepresented Populations in the Research Workforce

African Americans, Hispanics, Native American/Alaska Natives, and Native Hawaiian/Pacific Islanders are expected to form more than half of the U.S.

[1] Safety and Effectiveness of COVID-19 Vaccination During Pregnancy. COVID-19 Vaccines While Pregnant or Breastfeeding, Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html#anchor_1628692520287 Accessed 26 January 2023.

population by 2050.[2] However, these populations, along with women and people with disabilities, remain underrepresented in the biomedical workforce.[3]

SWHR strongly believes that having more diverse research teams results in better science. Research has shown that having more diversity among researchers can help promote trust toward precision medicine research[4] and that research is of higher quality with diverse teams in place.[5] Therefore, ensuring that our federal research infrastructure prioritizes the recruitment and retention of a diverse biomedical research workforce is of critical public health importance. It is through a diverse workforce that we can better reflect the perspectives of all populations and their unique health needs, including in, but not limited to, times of emergency.

SWHR encourages OSTP and NSC to ensure that underrepresented minority populations are fully integrated within the research workforce and to take steps to increase the involvement of these populations, including:

a. Integrating strategies to improve representation across the educational and institutional systems that exist for training, funding, executing, and publishing research;
b. Encouraging federal research institutions to continue assessing the barriers to equity that exist within them and actively engaging to correct course; and
c. Prioritizing opportunities for underrepresented minorities for mentoring, coaching, and collaborating with principal investigators who have federal funding.[6]

III. Supporting Participation of Different Communities Through Clinical Trial Site Locations

Finally, as mentioned within the RFI, conducting clinical trials during a national emergency will involve needing to establish trial sites across the country. As OSTP and NSC explore the target number and location of various sites, it will be vital to consider how to best promote access to these sites for a diversity of populations.

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[2] Vishwanatha JK, Basha R, Nair M, Jones HP. An Institutional Coordinated Plan for Effective Partnerships to Achieve Health Equity and Biomedical Workforce Diversity. *Ethnicity & Disease*. 2019;29(Suppl 1):129.
[3] Ibid.
[4] Kraft SA, Cho MK, Gillespie K, Halley M, Varsava N, Ormond KE, Luft HS, Wilfond BS, Soo-Jin Lee S. Beyond Consent: Building Trusting Relationships With Diverse Populations in Precision Medicine Research. Am J Bioeth. 2018 Apr;18(4):3-20. doi: 10.1080/15265161.2018.1431322. PMID: 29621457; PMCID: PMC6173191.
[5] Campbell LG, Mehtani S, Dozier ME, Rinehart J. Gender-heterogeneous working groups produce higher quality science. PLoS One. 2013 Oct 30;8(10):e79147. doi: 10.1371/journal.pone.0079147. PMID: 24205372; PMCID: PMC3813606.
[6] Hemming J, Eide K, Harwood E, et al. Exploring Professional Development for New Investigators Underrepresented in the Federally Funded Biomedical Research Workforce. *Ethnicity & Disease*. 2019;29(Suppl 1):123.

For example, OSTP, to the greatest extent possible, should seek to spread trial sites out geographically so that trials are not limited to certain geographic areas, such as urban areas. Additionally, limiting trial sites to hospitals rather than including other potential independent centers could place rural populations at a disadvantage from participating in research.

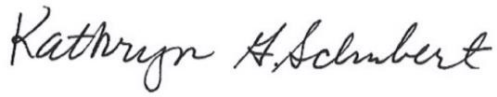
Finally, SWHR would encourage OSTP and NSC to consider how to provide incentives or financial support for individuals who enroll in emergency-related clinical trials. This support will be particularly beneficial for patients who either lack resources or support to travel for these trials.

SWHR commends OSTP for releasing this RFI to determine how to best ensure successful coordinated, large-scale clinical trials that can be activated effectively and efficiently in the event of an emergency. Time and again, we have seen the critical role that research plays in the health and well-being of our society. Prioritizing our federal research infrastructure, assessing it for weaknesses, and ensuring it has the capacity to adeptly respond to new and emerging threats is of the utmost importance.

If SWHR—or our network of peer experts—can be of assistance to OSTP and NSC as they work to build out these emergency clinical trials protocols, we stand ready to assist. Please contact me at kathryn@swhr.org or SWHR Chief Advocacy Officer Lindsey Horan at lindsey@swhr.org if you have questions or if you need additional information.

Thank you for your time and consideration.

Sincerely,



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