



July 13, 2021

Vajra Ma
Women's Human Rights Campaign USA
P.O. Box 317
Wolf Creek, OR 97497-0317

Dear Vajra Ma:

Thank you for your letter dated March 17, 2021, addressed to Dr. Francis S. Collins, Director of the National Institutes of Health (NIH), on behalf of the Women's Human Rights Campaign USA. In the letter, you express your organization's concerns related to NIH's implementation of Executive Order 13988, "Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation." Your letter articulates your concerns that the biological category of sex will be replaced by gender identity and that defining sex to include gender identity may negatively impact women and girls. As the NIH Associate Director for Research on Women's Health and Director of the Office of Research on Women's Health (ORWH), I appreciate the opportunity to respond to your letter and address the concerns expressed therein.

Executive Order 13988 includes sexual orientation and gender identity within the definition of sex for purposes of protection against unlawful discrimination. It does not replace sex with gender. Consequently, all three are protected under law—sex, sexual orientation, and gender identity. Moreover, the Executive Order affirms and codifies sex based rights of everyone, including women and girls. Your point concerning a potential impact is well taken, and we will be mindful to conduct routine impact assessments on the Executive Order at NIH.

Studying both sex and gender is essential to understanding human health. Applying knowledge gained through rigorous consideration of sex and gender is key to the NIH mission to enhance health, lengthen life, and reduce illness. NIH defines sex as a biological variable, determined by the chromosomal complement, gonads, sex hormones, external genitalia, and internal reproductive organs. Like many in the biomedical and socio-behavioral research communities, NIH usually categorizes sex as male or female, although variations regularly occur (in humans, these are sometimes described as either intersex conditions or differences in sex development (DSD)).

Without attention to sex-based factors, the rigor and reproducibility of biomedical research can be compromised. You may be aware of the NIH policy on the consideration of sex as a biological variable (NOT-OD-15-102), which went into effect in January 2016. This policy outlines the NIH expectation that sex as a biological variable (SABV) will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex. ORWH, with support from the National Institute for General Medical Sciences, developed a free, online [SABV Primer](#) to help the biomedical research community—including researchers, NIH grant applicants, and peer

reviewers—account for and appropriately integrate SABV across the full spectrum of biomedical sciences.

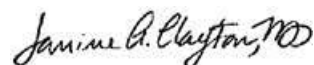
Gender is a multidimensional variable that refers to socially constructed roles, behaviors, norms, and expressions of girls, women, boys, men, and gender diverse people. A nuanced understanding of gender exists among the research community, with the recognition that social, cultural, environmental, and behavioral factors can each shape gender. When studying gender, one might focus on gender identity (as noted in your letter), but also on gender norms, gender-related traits, gender dynamics, gender roles, or gender inequality.

Federal law and NIH policy require applications that propose to involve human subjects to address the inclusion of women, minorities, and individuals of all ages in the proposed research. The NIH Sexual & Gender Minority Research Office (SGMRO) coordinates sexual and gender minority (SGM) health-related research and activities by working directly with the NIH Institutes, Centers, and Offices (ICOs) to advance rigorous research on the health of SGM populations in both the extramural and intramural research communities. As you note in your letter, gender identity can present measurement challenges. To address these challenges, SGMRO and 18 ICOs are supporting a NASEM consensus study on [Measuring Sex, Gender Identity, and Sexual Orientation](#) that will develop recommendations and guiding principles for collecting non-binary sex, sexual orientation, and gender identity information in research and non-research surveys, medical, and administrative records. This report will be vital in expanding standardized data collection efforts and it will have significant implications for advancing the field of SGM health research.

Sex differences in immunity have impacted COVID-19 outcomes. Gender must be considered as an additional dimension relative to health outcomes. As one COVID-related example, gender differences in the workforce (70 percent of frontline healthcare workers are women) place women at increased risk for acquiring COVID-19. As another example, mothers—[even those in egalitarian-oriented mixed-gender partnerships](#)—are disproportionately expected to manage household needs while also attending to their professional careers, increasing stress and its related health concerns.

Your letter expresses concern that gender identity will replace biological sex in NIH regulations, policies, and guidelines. Accounting for gender in health does not preclude a rigorous examination of sex-based differences. Rather, attending to sex, gender, and their intersections enables a nuanced understanding of health outcomes relevant to our communities. I would like to assure you that NIH and the Federal Government remain committed to the constitutionally protected rights of all.

Sincerely,



Janine A. Clayton, MD, FARVO
NIH Associate Director for Research on Women's Health; Director of the NIH Office of Research on Women's Health