

Irene Avila, PhD Assistant Director Sexual & Gender Minority Research Office National Institutes of Health

December 6, 2022

Dear Dr. Avila:

On behalf of the Endocrine Society, thank you for considering our comments on research opportunities related to the National Institutes of Health (NIH) scientific workshop on gender-affirming care for transgender and gender-diverse populations. Founded in 1916, the Endocrine Society represents over 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders, such as diabetes, hypertension, infertility, obesity, osteoporosis, and thyroid disease. Our members also include scientists and physicians who are advancing evidence-based care for vulnerable populations including transgender individuals and other sexual and gender minority (SGM) populations.

We strive to ensure that transgender individuals have access to science-based health care services provided by clinicians who appreciate their unique needs. We encourage the SGMRO to consider the needs of providers and other healthcare professionals as you frame the workshop. It will be critical not only for interventions to be evidence-based, but also to develop new materials that are science-based to expand access to care by empowering other providers. For example, the pediatric research and care community should be involved in the workshop, as well as representatives from the FDA who can comment on research needs that would inform approvals for treatments. Specialists in behavioral health and clinical psychology would also provide important perspectives.

Below, we offer some specific recommendations on key research opportunities in gender-affirming care for transgender and gender-diverse populations.

- Comparative effectiveness trials for gender affirming treatment regimens, particularly progestogens, including evidence to refine the appropriate sex hormone levels for initiation of treatment and/or maintenance
- Comprehensive studies of organ systems with and without gender affirming hormone treatment
- Social determinants of health, including access to appropriate clinics and care, and how that correlates with morbidity
- Timing on when to begin puberty blockers

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• Longitudinal research on the long-term impacts of gender-affirming medical care for transgender and gender-diverse adolescents on physiological and mental health, including skeletal health, neurocognitive function, and fertility

• Inclusion of racial and ethnic minorities in studies on the impact of genderaffirming medical care with the aim of understanding and minimizing health disparities

- Understanding the unique needs of elderly transgender individuals and guidance on hormone treatment across the lifespan
- Studies on gender non-binary trajectories and hormonal treatment options
- Long term (> 10 years) follow-up studies on biopsychosocial aspects, with focused attention on cardiovascular health including psychosocial aspects as variables

• Understanding of the educational needs for general practitioners and other health care professionals to enable broader access to evidence-based care

• Clinical and biochemical effects of subcutaneous and intramuscular off-label injections of estrogens for feminization, and strategies to enable registered use of sex steroid hormones for treatments

Significant progress has been made to safely provide gender-affirming care for transgender and gender-diverse populations. In addition, the Endocrine Society recognizes that there are research opportunities to further our understanding of this care through the lens of health disparities, how to effectively educate providers, and how to incorporate social determinants of health into research design, among others. We appreciate this opportunity to share our expertise in this field with the NIH to inform the SGMRO scientific workshop. Thank you for considering the Endocrine Society's comments. If we can be of any further assistance, please contact Alyssa Scott, PhD, Manager of Science Policy and Research Affairs at ascott@endocrine.org.

Sincerely,

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Ursula B Kaiser, MD President, Endocrine Society