

November 22, 2021

Karen Parker, PhD, MSW
Director, Sexual & Gender Minority Research Office
National Institutes of Health
6555 Rock Spring Drive
Bethesda, MD 20817

RE: Request for Information on Research Opportunities and Operational Activities Related to the NIH Strategic Plan to Advance Research on the Health and Well-Being of Sexual & Gender Minorities Fiscal Years 2021-2025

Dear Dr. Parker,

On behalf of the Endocrine Society, thank you for considering our comments on the research opportunities and operational activities related to the National Institutes of Health's (NIH) Strategic Plan to Advance Research on the Health and Well-Being of Sexual & Gender Minorities Fiscal Years 2021-2025. Founded in 1916, the Endocrine Society represents approximately 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 our understanding of, and improving care for vulnerable populations including transgender individuals and other sexual and gender minority (SGM) populations.

Through our advocacy and education, the Society strives to ensure that transgender individuals have access to science-based health care services provided by clinicians who appreciate their unique needs.

Below, we offer the following recommendations on research and operational activities related to the NIH Strategic Plan to Advance Research opportunities on the Health and Well-Being of Sexual and Gender Minorities:

Research in Chronic Diseases and Comorbidities

We support the theme in the strategic plan recognizing that chronic diseases and comorbidities are critical drivers of overall poor health in SGM populations. Further research is needed to better understand how chronic conditions intersect with hormonal therapies leading to disparate outcomes in transgender patients. Additionally, it will be important to understand to what extent comorbid conditions and chronic diseases are themselves exacerbated by persistent discrimination faced by SGM populations, including potentially by providers themselves. We support additional investment in research that



includes basic research to understand basic physiological changes associated with transgender treatment regimens across the lifespan, as well as outcomes research to better understand the effects of treatment. This includes its impact on chronic diseases, morbidity, and multiple human organ systems (cardiovascular, GI, liver, renal, brain, lung immunity/ ID, endocrine and others).

Because some of the health outcomes associated with hormonal therapies may overlap with the missions of certain institutes and even other agencies, we urge NIH to consider supporting collaborative studies to better understand the effects of hormonal therapies on e.g., metabolic outcomes and bone health, as well as studies to understand potentially serious effects of hormonal therapies, such as venous thromboembolic disease.

Clinical Research

We recognize that the SGM community has traditionally been underrepresented in clinical trials and research. We commend the NIH's commitment to increasing their enrollment in clinical research and we stand ready to partner with SGMRO to increase access to clinical research for these patient communities.

In support of this goal, we urge the NIH to prioritize large-scale, multi-center cohort studies to further understand SGM needs and identify research gaps. To capture important life course effects for longitudinal studies, we encourage NIH to design studies that include children and adolescents, and with input from families of individuals with differences of sex development (DSD) and families of transgender and gender diverse (TGD) individuals. For example, the All of Us research program could be leveraged to include assessments for individuals who are TGD and subsequently initiate hormonal therapy for gender-affirming care.

Methods and Measurement Research

The NIH is a prominent leader in research methods and procedures and supports the inclusion of Scientific Theme 4. However, we acknowledge that there are inconsistencies as to how agencies and researchers collect sexual orientation and gender identity information in research and non-research surveys. Universal collection of data on gender identity is likely to require strong guidance from research funding agencies, and data will need to be collected in a thoughtful way e.g., via a 2-question approach that includes the sex marker on the original birth certificate. We are therefore pleased that the NIH is working with the National Academies of Sciences, Engineering, and Medicine on standardizing questions to address this information collection issue and we look forward to the release of the report "Measuring Sex, Gender Identity, and Sexual Orientation for the National Institutes of Health." Our members stand ready to work with your office to disseminate the findings of the report and implement best practices to improve the



research community's ability to identify and address the specific needs of these populations.

In addition to the research opportunities highlighted in the draft strategic plan, we recommend that the NIH prioritize research to improve clinical assays for hormones and to develop standardized reference ranges for SGM populations who are treated with exogenous hormones. Standardized reference ranges based on strong evidence are especially important for clinicians to provide optimal treatment regimens. Reference ranges are also important for researchers to better understand the basis for positive or adverse treatment outcomes and to identify future improvements.

Conclusion

We thank the NIH for continuing to prioritize research on the health needs of sexual and gender minority communities and we support many goals in the current strategic plan.

Thank you for considering these comments and for prioritizing SGMR at the NIH. Should you be interested in additional information on any of these recommendations as you build out the full strategic plan, please contact Grace Kranstover at gkranstover@endocrine.org.

Sincerely,

A handwritten signature in black ink that reads "Carol H. Wysham". The signature is written in a cursive, flowing style.

Carol Wysham, MD
President, Endocrine Society