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Subject: NICHD Strategic Plan 2025

Dear Dr. Bianchi:

The American Urogynecologic Society (AUGS) appreciates the opportunity to provide input on the 2025 five-year strategic plan for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). As you know, AUGS is a national medical specialty society whose mission is to drive excellence in comprehensive care for women with pelvic floor disorders.

Women's health research has been woefully underfunded. A 2021 study found that NIH funding of disease states that unequally affect one gender are disproportionately allocated to male dominated diseases with approximately 75% of funding provided to male dominated diseases. In addition to the smaller amount of NIH research funding allocated to women's health, the majority goes to research involving reproductive-aged women. Provision of funds to pregnancy and maternity issues has been prioritized over problems which arise in the post-reproductive years.

For example, in a recent September 2024 search via the NIH RePORTER using the terms, "Pelvic Floor Disorders," "Prolapse," and "Incontinence," only 33 NICHD grants funded in 2024 were identified for a total of \$15.8 million. Given that the cost of pelvic floor disorders to society in terms of healthcare system and patient out-of-pocket costs are in the billions, AUGS believes \$15.8 million in annual research funding from NICHD is inadequate. And, while research on reproductive aged women is important, given the potential impact, it is also critical to study women's health disorders across the entire female lifespan.

Furthermore, the Office of Research on Women's Health (ORWH) noted that only 10% of overall NIH research spending by disease, condition, and special initiative from FY 2017 to FY 2019 was allocated to women's health research, and that the vast majority of that money (80%) was spent on research related to contraception and pregnancy rather than conditions that impact women throughout their life course.

With these concerns in mind, AUGS is focusing our comments below on Research Goals #2 and #3 of the proposed five-year NICHD strategic plan.

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**Research Goal #2: Promoting Gynecologic, Andrologic, and Reproductive Health**

*Enhance individuals to manage their fertility and minimize the impact of reproductive health conditions.*

**Opportunities:** Recent gains in scientific knowledge have created opportunities to improve understanding of reproductive stages across the life cycle, with particular emphasis on typical and atypical initiation, timing, and symptomatology of critical windows such as puberty, andropause, and perimenopause. This research also aims to characterize reproductive aging and its impact on reproductive outcomes, particularly infertility. Furthermore, this goal will focus on identifying biologic and environmental factors that can lead or contribute to idiopathic infertility with the goal of applying this knowledge to expand technologies or methods for fertility stimulation, fertility preservation, and contraception. This goal encompasses a broad emphasis on gynecologic conditions, including identifying the mechanisms underlying generalized and pelvic pain in gynecologic conditions. This goal will also identify interventions for the treatment of gynecologic conditions and assess the impact of new and existing treatment approaches on gynecologic health disparities. Finally, this goal will improve understanding of the factors affecting contraceptive use and non-use as well as preferences for specific contraceptive methods. This knowledge will be applied in developing new contraception options and advance understanding of the effects of contraceptives on human health.

**AUGS Recommendations:**

1. We commend NICHD for including “perimenopause” into the categorization of critical windows across the life cycle, and we encourage you to extend the research opportunities for this goal to **postmenopause**, as various reproductive processes influence conditions later in the life cycle.
2. We recommend changing the language from “reproductive aging and impact on **reproductive** outcomes” to “reproductive aging and impact on **gynecologic** outcomes.” This would broaden the scope and allow for research on outcomes related to overall gynecologic health and not just those outcomes that impact future pregnancy(ies).
3. We recommend revising the following sentence to broaden the scope to other conditions that may impact women: “This goal encompasses a broad emphasis on gynecologic conditions, including identifying the mechanisms underlying **generalized and pelvic pain in gynecologic conditions**” to read “This goal encompasses a broad emphasis on gynecologic conditions, including identifying the mechanisms underlying **all pelvic floor disorders such as pelvic organ prolapse, urinary/fecal incontinence, sexual dysfunction, as well as generalized and pelvic pain.**”

Pelvic floor disorders are complex, multifactorial conditions, that are highly influenced by the reproductive health conditions. Combinations of anatomical, physiological, genetic, lifestyle, and reproductive factors interact throughout a woman’s lifespan to contribute to pelvic floor dysfunction. A better understanding of the physiology and pathophysiology of the pelvic floor,

as well as the roles of aging, hormonal influences, and biomechanics on these processes, should therefore be included into this research goal.

4. Adoption of this research goal provides the opportunity to attain a better understanding of how pregnancy and the peripartum period affect the development of pelvic floor disorders through examination of predisposing factors (including genetics, family history, neurologic symptoms, pelvic floor muscle loading function in peripartum/intrapartum states, labor, route of delivery). These are common conditions that are especially prevalent in post-reproductive aged women and can lead to substantial sequential events such as falls, increased utilization of health care and hospitalizations, and significantly impact daily life for potentially up to half of a woman's lifetime. We urge this research goal to encompass this area of focus and specifically recommend that studies be pursued to examine key factors associated with pregnancy and childbirth complications, and their impact on future pregnancies among women in the reproductive stage, to develop an effective treatment algorithm with preventative strategies for managing childbirth sequelae.
5. Furthermore, we urge the NICHD to include research initiatives that focus on critical time points across a woman's lifetime particularly during and beyond the menopausal transition with investigations into events that are likely to impact the genitourinary ecosystem (to encompass microbiome, immune system, hormonal influences physical barriers, environmental factors).

### **Research Goal #3: Setting the Foundation for Healthy Pregnancies and Lifelong Wellness**

*Improve pregnancy outcomes to maximize the lifelong health of women and their children.*

**Opportunities:** This goal is focused on improving outcomes for women and children, including those associated with maternal health conditions, labor and delivery complications, and postpartum conditions. It includes enhancing interdisciplinary collaborations aimed at understanding mechanisms and causes of preterm birth. This goal also includes improving the long-term outcomes of infants born preterm or with aberrant fetal growth. This work includes integrating and analyzing diverse types of data, such as genomic, social and behavioral, and/or exposure data, to inform interventions for adverse maternal conditions and complications of pregnancy, such as preeclampsia, gestational diabetes, and placental anomalies. Furthermore, this requires supporting community-informed research to develop maternal health interventions that are widely applicable and that address health disparities. Continued study of the placenta, including basic and translational science approaches, will play a key role in this opportunity, particularly understanding the role of the placenta in pregnancy outcomes and in the long-term health of the mother and infant. This goal will also support the development of prevention strategies for labor and delivery complications that contribute to maternal morbidity and mortality (such as hemorrhage, infections, and cardiovascular conditions). Moreover, this goal will focus on identifying new approaches to mitigate maternal and paternal risk factors for conditions associated with pregnancy with effects that extend through the postpartum period and beyond.

### **AUGS Recommendations:**

1. We recommend broadening the scope of conditions associated with pregnancy to include prolapse, fecal incontinence and urinary incontinence as follows: “This work includes integrating and analyzing diverse types of data, such as genomic, social and behavioral and/or exposure data, to inform interventions for adverse maternal conditions and complication of pregnancy, such as preeclampsia, gestational diabetes, and placental anomalies, **as well as conditions resulting from pregnancy and childbirth, such as pelvic organ prolapse, as well as urinary and fecal incontinence.**

Integrating pelvic floor disorders including pelvic organ prolapse, urinary and fecal incontinence into the framework of the foundation for healthy pregnancy and lifelong wellness creates a platform that makes the treatment of pregnancy and childbirth the same as any other functional recovery (similar to orthopedic injuries) where rehabilitation and restoration of organ function is the main focus. The inclusion of pelvic floor disorders is critical as these conditions negatively affect quality of life and are highly prevalent.

Research has overlooked how pregnancy and childbirth impact pelvic floor support structures (muscles, ligaments, and soft tissues) and how these in turn contribute to the subsequent development of pelvic floor dysfunction. We urgently need to focus research efforts on understanding the mechanisms of injury related to childbirth and shift our framework of treating this type of injury like any other injury with properly studied and focused rehabilitation efforts.

In addition, incorporating pelvic floor disorders within this goal will help facilitate the development of rigorous prospective data regarding changes in sexual function before, during, and after pregnancy. Patients with pelvic floor disorders have a high prevalence of sexual dysfunction and lack of improvement in sexual function after pelvic reconstructive surgery is viewed by patients as a serious complication. A more thorough understanding of the prevalence of sexual dysfunction among each of the individual pelvic floor disorders is essential.

2. Interdisciplinary collaborations under this goal could include specialists in maternal fetal medicine, urogynecologists, urologists, colorectal surgeons, physical medicine and rehabilitation experts, etc.
3. Urogynecologists should be included in the NICHD study section to enhance efforts to incorporate pelvic floor disorders into studies designed to improve lifelong wellness.

### **Cross-Cutting Themes:**

**Health Disparities:** Understanding the contribution of social, economic, structural, and regional factors is vital to advancing preventive, diagnostic, and intervention efforts. These are essential factors when



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considering and addressing the pervasive disparities that exist in the health of racial/ethnic, rural, low-resource, sexual and gender minority, and other underrepresented populations.

**AUGS Recommendations:**

Health disparities in the care of pelvic floor disorders is a prevalent issue worldwide, notably affecting diagnosis, treatment, symptoms, and financial burden experienced by people suffering from these conditions. While we know these disparities exist, our understanding of the mechanisms of these inequities remains poor given small cohort sizes, lack of data collection on race/ethnicity and social and structural determinants of health, incomplete understanding of patient's perspectives, and the vast differences in research methodologies limiting opportunities for pooled analyses of existing data. Without a sound understanding of the mechanisms driving inequity, development and utilization of interventions to eliminate disparities will be ineffective.

Below are several recommendations related to research design and to types of studies that should be prioritized within the 2025 NICHD Strategic Plan to improve health disparities.

1. Promote racial/ethnic representation in research studies through investments in community partnerships and specialized efforts to recruit representative study populations.
2. Craft research questions and select research methodologies that center populations of interest and allow for investigations of structural determinants of health that can enhance the effectiveness of policy interventions.
3. Utilize a framework within research design that comprehensively captures a broad spectrum of variables (inclusive of social determinants of health as well as biologic, physical, environmental, and demographic factors) that influence health outcomes and policy interventions; this will enrich data used for analyses that can better address research questions aimed to narrow health disparities and achieve health equity. With respect to racial health inequities in particular, frameworks should acknowledge and explore the different experiences of individuals in healthcare settings and the biologic impact of social stressors.
4. Prioritize research that uncovers the mechanisms of disparities and lays the foundation for a path toward equity.

Respectfully Submitted on behalf of AUGS,

A handwritten signature in cursive script that reads "Stacey Barnes".

Stacey Barnes

AUGS CEO

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