

October 27, 2023

Bill Cassidy, M.D.
Ranking Member
Senate Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, DC, 20510

Electronically submitted via NIHModernization@help.senate.gov

Dear Senator Cassidy,

The Society of Gynecologic Oncology (SGO) is pleased to provide input in response to your request for information on modernizing the National Institutes of Health (NIH).

SGO is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. Our more than 2,000 members include physicians, advanced practice providers, nurses and patient advocates who collaborate with the Foundation for Women's Cancer to increase public awareness of gynecologic cancers and improve the care of those diagnosed with gynecologic cancers. Our primary mission focuses on supporting research, disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies, and collaborating with other organizations dedicated to gynecologic cancers and related fields. All with the ultimate vision of eradicating gynecologic cancers.

In 2023, it is estimated that over 114,000 women would be diagnosed with a gynecologic cancer and more than 34,000 would die. The incidence of gynecologic cancers is increasing, and we are seeing stark health care disparities and disproportionate impacts on our most vulnerable and minority populations. Significant advances have been made in the field of gynecologic oncology, through research and collaboration with patients eager to be involved. However, there is still much more work to do to improve prevention, early detection, and treatment of these devastating diseases. This is why it is essential to ensure that the NIH has the necessary resources and support to maintain its role as a transparent, nimble, and forward-thinking institution, allowing it to continue pioneering research and addressing the evolving healthcare needs of all Americans.

Increasing Diversity

Significant health disparities exist in gynecologic cancers; race and ethnicity, socioeconomic status, and payer status continue to play an outsized role in women's health outcomes. One way to address these disparities is to ensure people from diverse backgrounds who have a cancer diagnosis participate in clinical trials. Strict clinical trial requirements and the complexity of clinical trial participation are barriers that affect the racial, cultural, ethnic, economic, and geographic diversity of clinical trial enrollment. They also limit the representativeness of the clinical trial results, forcing clinicians to speculate as to whether the results can be extrapolated to their real-world patients. The NIH has worked to improve clinical trial diversity in recent years; however, more must be done to optimize enrollment of diverse populations that truly represent all patients.

The NIH should work to restructure clinical trial eligibility, requirements, and protocols to accommodate patients from different communities and social circumstances. For example, clinical trials should have the necessary resources to maximize the use of telemedicine, off-site testing opportunities, and other more flexible measures, rather than required in-person visits. These measures would ensure adequate follow-up without deviating from protocols. There must also be meaningful accountability to enroll underrepresented patients in trials. Funding of clinical trials should require demonstrated inclusion of minority participants with a methodology that may apply more readily to the real-world population.

Furthermore, the NIH should increase the diversity of leadership teams, selection committees, and fellowship placements by having accountable goals related to hiring, promotion and retention, and bridging community and academic partnerships. Congress should encourage the NIH to create pipeline programs for underrepresented minorities, offering research mentorship and insight into grant processes and funding mechanisms. Additionally, prioritizing racial equity is important in obtaining health equity. For example, the grant selection process should be revised to include equity as a criterion alongside scientific expertise. Moreover, program officials and reviewers should be held accountable to expectations around bias and disparities during the application process and trained accordingly.

Trial Design

SGO appreciates your interest in how clinical trials can be conducted more efficiently and effectively. Adaptive designs and the incorporation of synthetic controls for comparison are innovative approaches to enhance the efficiency, flexibility, and accuracy of clinical trials. The requirement to enroll additional participants when they represent populations with known response rates might seem excessive; however, with an innovative trial design we can overcome this inefficiency and enroll fewer participants while leveraging prior knowledge of response rates from external controls. Incorporating innovative trial designs is particularly important when pursuing avenues like breakthrough designation and accelerated approval and could be referenced as a sensitivity analysis against real-world interventions for regular approval applications – particularly to improve diversity and address other SDOH. Additionally, incorporating feedback loops and triggers into the trial design to continuously monitor participant accrual rates in real-time is vital. It is also important to note that the timeline for securing approval may vary between pharmaceuticals. This variability emphasizes the need for flexible and adaptive trial designs that cater to the unique characteristics of clinical trials, and we encourage Congress to support these trial characteristics.

Peer Review Process

The NIH has made efforts in recent years to simplify the peer review framework for research project grant applications and better facilitate the identification of the strongest, highest-impact research, including releasing an RFI seeking input on the topic in March 2023 and announcing a [“Simplified Review Framework for NIH Research Project Grant Applications.”](#) SGO appreciates these efforts as the peer review process ensures the quality of research by subjecting it to rigorous evaluation.

SGO was pleased to see that the new framework aims to reduce reviewer burden by shifting policy compliance activities to NIH staff. This change will help improve reviewers’ focus on the scientific impact, research rigor, and feasibility of the proposed research. Streamlining the peer review process by reducing administrative burdens not only accelerates review cycles, enabling quicker feedback and funding decisions for researchers, but also empowers reviewers to provide more comprehensive

assessments of the scientific impact and quality of research proposals, benefiting both researchers, reviewers, and the advancement of science.

However, the NIH should consider implementing a requirement in the applicant's cover letter that would instruct the applicant to state why their proposal is responsive to the request for application (RFA) or request for proposal (RFP). We believe this would provide an additional level of clarity and transparency for the administrative office and reviewers. This will also ensure that research and resources are directed towards fulfilling the specific objectives outlined in the funding opportunity announcement.

Thank you for the opportunity to submit these comments. Your dedication to seeking input and from stakeholders in the research community demonstrates a proactive and inclusive approach to shaping health policy. Should you have any questions or wish to discuss our comments further please contact Erika Miller at emiller@dc-crd.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Angeles', with a stylized flourish at the end.

Angeles Alvarez Secord, MD, MHSc
President, 2023-2024