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August 16, 2024

The Honorable Cathy McMorris Rodgers
Chair
House Energy & Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515
Email: NIHReform@mail.house.gov

Dear Chairwoman Rodgers,

The American Urogynecologic Society (AUGS) is a national medical specialty society whose mission is to drive excellence in comprehensive care for women with pelvic floor disorders. AUGS appreciates your interest in exploring ways to improve and strengthen the National Institutes of Health (NIH), so it remains in the forefront of scientific discovery and provides the foundation for America's global leadership in biomedical research. We are eager to work with you to achieve these objectives.

AUGS strongly believes that input from researchers, medical specialty societies, patient advocacy organizations and other stakeholders is critical to this process. We commend you for inviting comment on the proposal to reform the NIH framework. This is an important first step in what should be a thoughtful, deliberative and transparent process that incorporates ongoing dialogue with the biomedical research community. It would be premature to enact the proposed NIH framework in its current form without expert testimony, review by congressional authorizing committees, *and* a full vetting of the proposal by medical research experts and independent lay review as it evolves.

Women's health research is 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. While research on reproductive aged women is important, it is critical to study women's health disorders across the entire female lifespan.

The Office of Research of 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 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, we appreciate the opportunity to provide the following comments on the current framework for discussion:

- AUGS supports creating greater efficiencies within NIH to maximize equitable allocation of federal research dollars and recognizes the importance of evaluating the conditions women face throughout their lives, including conditions that become more prevalent in the post-reproductive years. There is an urgent need to prioritize and increase the amount of research funding directed towards women's health beyond maternity and reproductive care. Research on women's health should encompass the full life span, including conditions affecting pre-, post-reproductive and geriatric women, who are the fastest growing segment of the U.S. population.

- AUGS has long expressed concern about NIH's limited investment in research on conditions unique to or occurring predominantly in women, such as menopause, pelvic floor disorders, and urinary tract infection. Women make up more than half the population of the United States but investment in conditions affecting them has not kept pace with the need and equitable allocation, leading to substantial scientific and healthcare disparities.
- Ideally NIH funding should be proportionate to the prevalence of a condition in the U.S. population. We advocate for identifying ways to support highly prevalent conditions that currently lack funding.
- AUGS recognizes that there are inefficiencies and silos that result in deprioritized funding of conditions that do not fit neatly into one institute. Science follows the patient, not an institutional structure. While efforts to reduce silos are welcome, we have concerns about conditions that may be difficult to fit into the proposed new institute structure, such as menopause (post-reproductive state). Specifically, we have the following concerns related to consolidating the existing Institutes and Centers (ICs) into new ICs:
 - We are concerned that combining the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) into the National Institute on Body Systems Research will deprioritize funding critical research of conditions that impact qualitative priorities such as quality of life.
 - Combining the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute on Deafness and Other Communication Disorders (NIDCD) into a National Institute for Disability Related Research eradicates the home for much non-disability related impactful research addressing women's and children's health currently funded by the NICHD.
 - Changing the National Institute of Aging (NIA) to the National Institute of Dementia fails to recognize the breadth of science about aging outside of dementia that is currently supported by NIA.

We share our specific comments on each section of the framework on the attached following pages. Thank you for the opportunity to provide input.

Respectfully submitted,



Stacey Barnes
Chief Executive Officer

On behalf of the American Urogynecologic Society

Comments from the American Urogynecologic Society (AUGS) on Reforming the National Institutes of Health (NIH) - Framework for Discussion

*Energy & Commerce Committee Framework recommendations are in bold, followed by AUGS Comments

Structural Reform

- ***The proposed structural framework seeks to break down silos between the National Institutes of Health's (NIH's) Institutes and Centers (ICs) by collapsing the 27 (ICs) into 15, to facilitate each Institute using a life-stage approach throughout its activities, grant funding decisions and research priorities.***

AUGS Comments: The American Urogynecologic Society (AUGS) supports creating greater efficiencies in the NIH to maximize federal research dollars and recognizes the importance of evaluating the conditions women face throughout their lives. There is an urgent need to prioritize and increase research funding directed towards women's health beyond primarily addressing maternity and reproductive care. Women's health care should encompass the full life span, including conditions affecting post-reproductive and geriatric women, the fastest growing segment of the U.S. population.

We recognize that silos in our research space result in deprioritized funding of conditions that do not fit neatly into one institute. As an example, research questions related to urgency urinary incontinence (leakage associated with a strong urge, as in "overactive bladder") and stress urinary incontinence (leakage associated with strong pressure on the pelvic floor, as in coughing or lifting) currently must be submitted to two different institutes. This does not allow for consideration of research proposals that address patients with mixed urinary incontinence (symptoms of both urgency and stress urinary incontinence), which is the most common type of incontinence in some studies of women. Science follows the patient, not an institutional structure. As such, efforts to reduce silos would be welcome. Even with fewer numbers of institutes, we still have concerns about conditions that may be difficult to fit into an institute structure, such as menopause.

Specifically:

- We have the following concerns with the framework's proposal consolidating existing ICs into new ICs:
 - We are concerned that combining the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) into the National Institute on Body Systems Research will deprioritize funding critical research of conditions that impact qualitative priorities such as quality of life.
 - Combining the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute on Deafness and Other Communication Disorders (NIDCD) into a National Institute for Disability Related Research eradicates the home for much non-disability related impactful research addressing women's and children's health currently funded by the NICHD.
 - Changing the National Institute of Aging (NIA) to the National Institute of Dementia fails to recognize the breadth of science about aging outside of dementia that is currently supported by NIA.
- AUGS has long expressed concern about the NIH's limited investment in research on conditions unique to or occurring predominantly in women, such as menopause, pelvic floor disorders, and urinary tract infection. Women make up more than half the population of the United States but investment in conditions affecting them has not kept pace with the need, leading to substantial scientific and healthcare disparities.
- While we recognize the proposed framework intends to support life course research, personalized medicine, and moves away from population-specific Institutes and research endeavors, we are particularly concerned that as written, it will undermine investments in women's health research across the lifespan and ultimately continue to widen the gender health gap and lead to worse outcomes for

women. To have a complete understanding of women's health and the conditions that affect them, a lifespan approach that includes the pre- and post-reproductive years is needed. NIH struggles to support this approach now, and the changes outlined in the proposed framework, have extremely high potential for many important stages of a woman's life to be ignored.

- We suggest exploring ways to grant NIH more legislative authority for the ability to create transdisciplinary funding mechanisms, workshops and conferences.
- NIH funding should be proportionate to the prevalence of a condition in the U.S. population. We advocate for identifying ways to support highly prevalent conditions especially in women, that currently lack funding.
- While we appreciate that there are opportunities for efficiencies with reform, no disease state should be funded at less than its current level. One goal of reform should be increased funding for certain diseases with high prevalence that currently lack funding.
- We request clarification on what would happen to the existing offices at the NIH, including the Office for Research on Women's Health (ORWH), as this is not addressed in the framework.

Policy Reform

- ***Initiate and Complete a Comprehensive Review of the NIH – establish a congressionally mandated commission to lead a comprehensive, wholesale review of the NIH's performance, mission, objectives, and programs. Such review should include regular, timely public reports and updates and conclude with clear, actionable recommendations for improvement. The commission should include a sunset to require Congress to revisit the recommendations and subsequent implementation, to avoid a similar outcome as the SMRB.***

AUGS Comments: AUGS agrees with this recommendation. The oversight of the NIH should be provided by a combination of bipartisan and bicameral governmental, academic, and independent entities to ensure a comprehensive and unbiased approach. The U.S. Department of Health and Human Services (HHS) is the primary government body responsible for overseeing the NIH. Within the legislative branch, Congressional committees related to healthcare and science play a role in the oversight process through budget approvals and hearings but should not be the sole fiscal oversight. Additionally, independent review boards, including ethics committees, the Office of Research Integrity, and real-world independent taxpayer and lay perspectives, should contribute to monitoring research practices. Collaboration between these entities ensures that oversight is thorough, balances innovation with ethical considerations, and reflects the interests of varied stakeholders including the scientific community, research participants, and the general public.

- ***Support Innovation – ensure the NIH is committed to and focused on promoting and bolstering innovation of new treatments and cures, including by encouraging public-private partnerships and collaboration. Resist the use of misguided tactics to pursue a specific agenda and manipulate commercial markets, thus derailing and stifling America's leadership in biomedical innovation.***

AUGS Comments: We agree that NIH should remain committed to promoting and bolstering innovation in medical research, which leads to the development of groundbreaking treatments, effective cures, and better diagnostic tools, directly contributing to improved health of millions worldwide. To achieve these objectives, the NIH should actively encourage and facilitate public-private partnerships and collaboration. These collaborative efforts bring together the diverse strengths and resources of the public and private sectors, including funding, expertise, and technology, accelerating the pace of medical innovation. By fostering environments that support cooperative research and development initiatives, the NIH should not only help amplify the potential for significant medical breakthroughs but also ensure a more efficient and cost-effective translation of scientific discoveries into practical healthcare solutions. To bolster innovation, policies should be specifically designed to nurture a culture of creativity and risk-taking in scientific investigations.

Specifically, we recommend:

- Developing a tiered funding model that allocates resources not only to projects with high potential for groundbreaking discoveries but also to high-risk, high-reward research that might not have traditional metrics of success but could lead to significant scientific breakthroughs
- Implementing policies that facilitate easier collaboration with industry, academic institutions, and international researchers to bring new perspectives and technologies into NIH projects
- Establishing NIH innovation incubators, dedicated spaces where researchers from various disciplines can collaborate on solving complex health problems with cutting-edge technology and unconventional methods
- Creating an internal review board tasked with identifying and reducing bureaucratic hurdles that impede swift progress in research to ensure that innovative projects move forward more efficiently

These policy changes, by providing both the resources and the institutional support necessary for pioneering research, would significantly enhance the NIH's ability to lead in scientific innovation and discovery.

- ***Introduce Term Limits for I/C Leadership – limit every I/C Director to a five-year term, with the ability to serve two consecutive terms, if approved by the NIH Director.***

AUGS Comments: AUGS is supportive of the concept of term limits for leadership positions within the NIH institutes and centers. Term limits along with an active review of leadership's accomplishments can help to ensure the infusion of fresh perspectives and ideas in medical research, where adaptability and responsiveness to new scientific discoveries and technological advancements are crucial. Term limits and/or reviews can also mitigate the risk of stagnant leadership and enhance opportunities for individuals from varied backgrounds, disciplines, and experiences to contribute to strategic decision-making processes. Finally, they encourage accountability and motivate leaders to achieve meaningful impact and legacy during their term.

AUGS also recognizes the importance of recruiting and retaining leadership of a high caliber prior to or in coordination with establishing term limits, given historical challenges filling and retaining I/C Leadership roles. It needs to be more attractive to work at NIH and competitive pay will help recruit the best of the best, otherwise term limits may hinder the ability to maintain high caliber leaders. With these current challenges, flexible term limits with consideration for I/C director performance, and/or research project status, could be considered in which comprehensive internal and external reviews of each I/C Director are required. These could result in a proposal to continue, or not continue, the Directors' term as determined by the NIH Director. Overall, flexible term limits for NIH leadership could strengthen the vitality and effectiveness of institutes and centers to ensure that they remain at the forefront of global health and scientific innovation.

- ***Eliminate Silos Between ICs – require every I/C to issue a biennial report outlining how the individual I/C is utilizing a life stage approach throughout its activities, grant funding decisions, and research portfolio and priorities, including appropriately considering distinctions and factors related to sex and age, as well as rare diseases within each center's purview.***

AUGS Comments: AUGS is in support of this recommendation. Eliminating silos between the Institutes and Centers of the NIH is crucial for fostering a comprehensive and interconnected approach to health research, which more accurately reflects the complex nature of human health and disease. By incorporating a life stage approach throughout its activities, grant funding decisions, and research priorities, the NIH can cater to the specific health needs and challenges that arise at different stages of an individual's life, while also considering crucial distinctions such as sex and age. This holistic approach enhances the potential for groundbreaking discoveries and the development of targeted interventions, as insights from one area can inform and strengthen others, leading to more nuanced and effective healthcare solutions.

Furthermore, the importance of follow-up and action planning, as part of an annual report or strategic planning process by each NIH institute, cannot be overstated. Such practices ensure accountability and enable a data-driven assessment of how well funding allocations match the actual prevalence and burden of diseases or conditions within the population.

Specifically:

- Annual reporting and strategic planning processes should rigorously analyze and justify discrepancies between funding levels and disease prevalence, considering both potential impact on public health and opportunity for scientific advancement. This reflective practice facilitates transparent, rational, and equitable allocation of resources, guiding the NIH towards investments that can yield significant public health benefits.
- Regular reassessment and planning are essential for adapting to emerging health threats and evolving scientific landscapes, ensuring that the NIH remains a dynamic force in advancing medical science and improving health outcomes.

Additional considerations to enhance inter-institute collaboration include:

- Dedicated funding streams to incentivize cross-disciplinary and inter-institute research projects could significantly encourage collaboration. We suggest creation of grant programs specifically designed for multi-institute proposals, valuing the integration and application of diverse scientific perspectives.
- Establishing a centralized platform to share findings and resources across institutes will foster a culture of open communication and collaboration, including shareholder participation in strategic planning. We suggest regular inter-institute meetings, workshops, and symposia to facilitate networking and the exchange of ideas among researchers from different disciplines.
- Developing clear guidelines and support systems for collaborative research efforts will help alleviate administrative burdens that may hinder cross-institute projects.
- Creating leadership development and recognition programs that reward collaboration and the breaking down of silos can motivate NIH staff at all levels to engage in and prioritize inter-institute partnerships.

Additional considerations to ensure that current ICs within the NIH more effectively incorporate a holistic, lifespan approach to research, while accounting for distinct factors such as sex and age include:

- Instituting a policy that requires all research proposals to explicitly address how they will consider the impact of sex and age on their research questions and methodologies could be pivotal. This could include mandating comprehensive analysis plans that detail how data will be disaggregated by age and sex, ensuring that research findings are relevant across the lifespan and for both males and females.
- Policies could encourage or require the inclusion of lifespan and sex-based analysis as criteria for funding decisions, promoting a culture where such considerations are not only valued but deemed essential.
- Training programs could be developed and made mandatory for researchers and peer reviewers, focusing on the importance of lifespan and sex-based research considerations, providing the knowledge and tools needed to conduct and evaluate research through this lens effectively. Finally, representation in the I/C leadership should reflect the US sex and age distribution. Implementing these policy changes would encourage a shift towards more inclusive and representative biomedical research, ultimately leading to health care solutions that are more effective and equitable across all populations.

These policies combined will foster an environment that actively encourages innovative and comprehensive approaches to addressing complex health challenges.

- ***Enforce Financial Disclosure and Transparency Requirements – ensure NIH officials are held to and abide by financial transparency requirements and standards and require appropriate reporting and disclosure of royalty payments and other third-party financial benefits, including support from and affiliations with foreign institutions.***

AUGS Comments: AUGS is in support of this recommendation. The integrity and trustworthiness of the NIH rest significantly on the financial transparency of its officials. It is crucial for NIH officials to be held to, and to abide by, stringent financial transparency requirements and standards. Such transparency is fundamental not only for preventing conflicts of interest but also for maintaining the public's confidence in the NIH's research and its outcomes. When officials transparently disclose their financial relationships, it allows for an open evaluation of whether these connections could influence research priorities or the allocation of funding. Furthermore, in the context of increasing globalization and international collaboration in scientific research, clear disclosure of foreign affiliations is essential to safeguard national interests and security. These practices ensure that NIH activities are conducted with the highest ethical standards, fostering an environment where science progresses in the best interest of public health unimpeded by undue external influences.

- ***Address Misconduct and Expect Accountability – ensure the NIH is issuing and implementing comprehensive policies and procedures that enable full and robust oversight of investigations into allegations of misconduct, including sexual harassment, in both intramural and extramural research programs, as well as ensuring NIH whistleblower protections, trainings, and processes are sound. This should include clear processes for accountability and responsibility for actions, including designating appropriate chains of command and facilitating accessible reporting mechanisms.***

AUGS Comments: AUGS is in support of this recommendation. Ensuring the NIH remains a paragon of scientific integrity and trust necessitates the enactment and enforcement of comprehensive policies and procedures tailored to enable full and robust oversight of investigations into allegations of misconduct, including sexual harassment, within both its intramural and extramural research programs. Integral to upholding this standard is safeguarding NIH whistleblower protections, alongside instituting sound training and processes designed to empower individuals to report wrongdoing without fear of retribution. Clear processes for accountability and responsibility for actions are essential, requiring the designation of appropriate chains of command and the facilitation of accessible reporting mechanisms. These steps are necessary to create a transparent environment where all parties understand their roles and responsibilities in reporting and addressing misconduct.

- ***Improve Transparency from Partners – consider additional disclosure reporting and transparency requirements for donors, partners, and activities supported by the FNIH, including any conflicts of interest related to leadership, funding, or project determinations.***

AUGS Comments: AUGS is in support of this recommendation. Considering additional disclosure reporting and transparency requirements for donors, partners, and activities supported by the Foundation for the National Institutes of Health (FNIH) is pivotal in maintaining the integrity and public trust in its endeavors. Such measures would ensure that any potential conflicts of interest, especially those related to leadership decisions, funding allocations, or project determinations, are openly acknowledged and addressed. Implementing rigorous transparency protocols for disclosing the financial and in-kind contributions of donors and partners, as well as the specifics of how these contributions influence the foundation's activities, can help mitigate the risk of undue influence on research priorities and outcomes. This level of transparency is not only vital for upholding the ethical standards expected of a leading biomedical research institution but also for reinforcing the confidence of the public and the scientific community in the impartiality and objectivity of the FNIH's work. By fostering an environment where activities and affiliations are transparently reported, the Foundation can ensure that its collaborations advance scientific and public health goals free from conflicts of interest, thereby enhancing the overall impact of its contributions to medical research and innovation.

Funding Reform

- ***Restore Congress’s Role in Directing Funding – repeal authorization for the Public Health Service (PHS) Evaluation Set-Aside, also known as the “PHS Evaluation Tap,” under Section 241 of the Public Health Service Act to ensure transparency and accountability in funding decisions.***

AUGS Comments: The Public Health Service (PHS) Evaluation Set-Aside allows the Secretary of Health and Human Services (HHS) to redistribute a portion of eligible PHS agency appropriations across HHS for research, evaluation, and data collection activities. In FY 2024 the maximum set-aside level was 2.5% of eligible appropriations, or approximately \$1.2 billion of NIH funding.

While AUGS supports the need for greater accountability in funding decisions, we strongly suggest that direct funding decisions be left to I/C directors and their staff, as they are experts who understand which research will have the greatest impact on human health and/or science in each respective field.

We are very concerned that repealing the PHS evaluation set-aside will further politicize biomedical research by granting a sometimes highly polarized Congress enhanced authority to direct NIH spending. Frequent changes in the majority parties in Congress could prove very disruptive to advancing biomedical research as each newly elected governing party moves to assert their priorities rather than allowing the science and potential for scientific advancement to govern decisions. Members of Congress do not have the necessary training and expertise to make research funding determinations. Research funding decisions should be based on science and where the greatest research opportunity and overall need are present, including the prevalence of disease and the cost to our nation’s healthcare system.

We support the authority of the NIH to make decisions about investing appropriated funds by engaging in discussion and gathering input from experts in the field through the peer review process and by internal strategic planning and priority-setting processes, such as workshops, conferences, and requests for information. These mechanisms have served the NIH well, which has made the U.S. the global leader in biomedical research.

- ***Reexamine Indirect Costs – consider alternative mechanisms to limit indirect, or F&A, costs, such as tying the indirect cost rate to a specific percentage of the total grant award, either universally or for certain designated entities; capping indirect costs at a graduated rate dependent on a recipient’s overall NIH funding***

AUGS Comments: AUGS supports reforms in indirect or F&A costs to reduce costs and administrative burden. Consideration to tailoring or capping indirect costs based on grant size, scope, specific infrastructure needed, or related to a recipient’s overall NIH funding may be reasonable. Limiting indirect costs on subcontract budgets is one example of a reform that may reduce overall costs while increasing the direct support of research activities. AUGS does not support funding grants based solely on potentially lower indirect cost rates, as this approach would jeopardize funding the highest quality or most impactful science. Policies that streamline and simplify processes to reduce the administrative burden on researchers would allow for more time to be dedicated to research activities.

The NIH could create a more supportive and efficient administrative environment, fostering greater focus and productivity in scientific research, through the following suggestions:

- Digitizing and centralizing administrative tasks through an integrated online platform where researchers can manage grant applications, reporting, and compliance requirements efficiently in one place.
- Implementing standardized forms and procedures across all NIH ICs, reducing the time researchers spend navigating different systems and requirements.

- Developing policies that promote a shift towards longer grant cycles could alleviate the constant pressure of reapplication, allowing researchers to focus more on the science rather than on continuous grant writing.
- Training programs and dedicated support staff for administrative tasks could ensure researchers have the necessary resources and assistance to handle administrative duties swiftly.
- Regular reviews of administrative processes with direct input from the research community could help identify unnecessary burdens and areas for improvement.
- ***Demand Transparency on Indirect Costs – require any entity receiving grants or awards to report publicly and make searchable their indirect F&A costs, including fixed capital costs, administrative overhead, and labor costs.***

AUGS Comments: AUGS agrees that NIH funding reforms should include efforts to promote greater transparency in the use of indirect funds.

- ***Prevent Waste and Fraud – ensure the NIH is properly accounting for and recovering misused taxpayer dollars.***

AUGS Comments: AUGS agrees that NIH funding reforms should include efforts to reduce waste and fraud.

Grant Reform

- ***Grant Recipients Must Remain Dynamic – focus on providing grants and awards only to primary investigators that do not have more than three ongoing concurrent NIH engagements.***

AUGS Comments: We enthusiastically agree that grant recipients must remain dynamic to increase diversity of thought and enhance science and innovation but disagree with the framework’s recommendation to limit grants and awards only to primary investigators that do not have more than three ongoing concurrent NIH engagements. A restriction of the number of total grants an investigator may receive will discourage investigators from applying for small grants which are critically important for new discovery where preliminary data do not yet exist.

While a total dollar amount per principal investigator may be a more effective way to ensure that resources are allocated equitably, it is important to acknowledge that the current NIH cap does not align with physician scientist salaries. These limits could make it impossible for surgeon-scientists to be PIs on research projects, losing a pool of experts that brings tremendous value to the biomedical research enterprise.

We agree that it is important to support early-stage investigators and recommend that the committee consider alternative proposals, such as requiring established investigators to include an early-stage co-investigator at a minimum of 10-15 percent effort on each large (R or U) grant. We recommend ongoing assessment to identify characteristics and expertise that are under-represented among funded investigators to ensure that we continue to foster diversity of thought to advance science. Finally, we recommend that the committee continue to support existing workforce training programs, such as the Building Interdisciplinary Research Careers in Women’s Health (BIRCWH) and K-Awards, for example.

- ***Research Must Be Credible, Reliable, and Timely – consider opportunities to continue to bolster and support early-stage investigators; Encourage systematic replication studies across research portfolios and fields; and prevent research and data waste, fraud, and misconduct***

AUGS Comments: We agree that systematic replication studies to prevent waste, fraud and misconduct are important, but recommend that the investment be in building and maintaining infrastructure to support publicly available and usable data for analysis by other investigators.

- ***Support Independent Community Review Oversight Boards – require grant recipients conducting research involving potentially dangerous agents to establish community oversight boards to review and approve protocols, ensure proper compliance with regulations and guidelines impacting the surrounding community, and create processes for regular community access to information.***

AUGS Comments: We agree that supporting independent lay-community oversight review boards is important, not just for research involving potentially dangerous agents, to support inclusion of those who are currently under-represented in biomedical research, and funds should be made available to support these boards, similar to the mechanisms available through the Patient Centered Outcomes Research Institute (PCORI).