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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

WARREN GUNNELS, MAJORITY STAFF DIRECTOR
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www.help.senate.gov

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Dear Stakeholder:

I write today to seek your input on modernizing the National Institutes of Health (NIH).

NIH's work is integral to the health and wellbeing of every American. NIH has enjoyed widespread support from bipartisan members of Congress because of this societal value, and in recent years has received significant and consistent funding increases. However, NIH and its officials became a lightning rod for partisan debates during the COVID-19 pandemic response, eroding public trust in the institution and distracting from its core mission.

Congress should work with NIH and stakeholders to modernize the agency so it is more transparent, nimble, and forward-thinking. As Ranking Member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, I intend to consider policies that would advance these goals.

To inform this work, I invite your input on the topics below, or other topics that are relevant but not mentioned. If you would like to do so, you are welcome to include proposed line edits to current law or other legislative text as a supplement to your narrative response.

Please submit comments to my staff by email at NIHModernization@help.senate.gov no later than close of business on Friday, October 27th.

Increasing the Pace of Science

Overarching Questions

1. How has the conduct and dissemination of science changed in recent years, particularly due to COVID-19? What role can NIH play in speeding up the pace of science and quickly disseminating high-quality research findings?
2. What specific policies or systems would better expedite open sharing of NIH-funded data and analyses?
3. In your view, what would be the appropriate balance between basic, translational, and clinical research at NIH? How can NIH continue to prioritize truly fundamental research while improving outcomes for translational and clinical projects?
4. How can NIH improve collaboration between the academic research community and the private sector? What barriers or challenges make this difficult to achieve?
5. In your view, how successful are NIH's Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs? What are your specific

recommendations as to how NIH could better leverage these or other programs to bridge the “valley of death” between basic research and clinical development?

6. What lessons can be learned from individual NIH Institutes and Centers (ICs) related to the conduct of clinical research? How can clinical trials be conducted more efficiently and effectively? What types of trials should NIH conduct, and what types are more appropriate for industry to undertake?

Extramural Research Program

1. How do the R01 and other common NIH funding mechanisms support or discourage transformational science? How could these funding mechanisms be improved to prioritize transformational science?
2. How do academic institutions typically fund the salaries of extramural investigators? What benefits and challenges come with this approach? How could this practice be reformed to better support the biomedical research workforce and ensure that NIH dollars, on a per-project basis, accurately reflect the time commitments of each investigator and staff member?
3. What are the benefits and challenges associated with the current approach to negotiating facilities and administrative (F&A, or “indirect”) costs? How could this approach be changed to maximize the proportion of federal funds going toward direct research expenses? How, if at all, does the current process for negotiating indirect cost rates advantage or disadvantage certain institutions over others?
4. Do you see opportunities to improve the current process for structuring peer review committees? What attributes does NIH tend to prioritize when selecting both chartered and ad hoc reviewers?
5. How could NIH change its approach to staffing peer review committees to increase risk tolerance within the research community and encourage funding of more bold proposals, rather than incremental science?
6. Could peer review committees be organized differently to improve NIH’s evaluation of interdisciplinary work?
7. What specific factors cause individuals to leave the biomedical research workforce? How could common NIH funding mechanisms be revised to better recruit and retain high-quality investigators, including young investigators?
8. Which specific aspects of the extramural grant life cycle place the most burden on institutions and investigators? Are there ways to streamline these aspects without negatively impacting project outcomes or undermining the goals of relevant federal requirements?
9. What role do institutions not affiliated with major research universities, such as other types of academic medical centers or community hospitals, currently play in the NIH ecosystem? How could these types of facilities be more effectively leveraged as research partners?
10. In your view, how successful has the Institutional Development Award (IDeA) program been to date? How can this program be improved to distribute extramural research funding more evenly to institutions around the country, particularly in less well-resourced states?

Intramural Research Program

1. How can NIH's intramural research program be better supported and differentiated from NIH's extramural activities? What types of projects are most appropriate for the intramural versus extramural environment?
2. What legal, administrative, or other barriers impede the recruitment of high-quality researchers for the intramural program?
3. How can Congress and NIH incentivize investigators and key staff to routinely move between the intramural research program, academia, and industry, rather than remaining at NIH for the majority of their careers? What would be the benefits and risks associated with this strategy?
4. As clinical trials increasingly move to outpatient settings and utilize remote monitoring tools, how can the NIH Clinical Center be best utilized in both the near and long terms? How, if at all, could the Clinical Center be better leveraged to complement NIH's other intramural and extramural work?
5. What other aspects of the intramural research program are working well or should be improved, in your view? How can Congress or NIH better support or refine these activities?

Organizing NIH for Success

Statutory Structure and Functions

1. Does NIH's current organ- and disease-based structure effectively facilitate the conduct of research? If yes, how? If no, what alternative structure would be more effective in your view? What barriers prevent Congress or the administration from implementing this structure, aside from NIH's statutory authorization and appropriations?
2. How might NIH's mission, strategic goals, and objectives be refined to better reflect and enable its core functions?
3. In your view, could NIH research dollars be better allocated within the agency's portfolio? Are there certain areas of research that are over-funded or under-funded? What strategy should Congress and NIH take in allocating resources to specific areas?
4. How could NIH better prioritize its programs to support core activities, reduce redundancy across its ICs, and ensure activities are appropriately targeted?
5. How would you rate the success of the Common Fund, since its inception? What works well, what could be improved, and how?
6. Could the process for selecting Common Fund projects be changed to improve the impact of Common Fund dollars and more easily integrate, and eventually transition, Common Fund projects into IC-level programs?
7. How effectively is the Foundation for the NIH currently operating, in your view? What is working well, and what could be better supported?
8. How, if at all, should NIH's high-risk, high-reward research portfolio be adjusted now that the Advanced Research Projects Agency for Health (ARPA-H) has launched? What high-risk research should be retained at NIH, and what types of projects are a better fit for ARPA-H?

Administrative Opportunities and Challenges

1. Regarding NIH's interagency collaborations, what currently works well and what could be improved? How can NIH better leverage capabilities that exist within the interagency, particularly for technologies and disciplines outside NIH's traditional scope?
2. What role could novel technologies, such as artificial intelligence and machine learning, play in protecting the privacy of research participants' data or inadvertently making this data more vulnerable? What models or capabilities exist to strengthen privacy protections, while improving the timely dissemination of research findings and underlying data?
3. What are the biggest ethical challenges facing the biomedical research community today? How is, or is not, NIH currently working to address these issues? What more could NIH do to lead in this space?
4. What opportunities exist to harmonize funding applications for research awards across ICs and the interagency?
5. What impact would capping the number of concurrent awards for a principal investigator have on the output of NIH's extramural investments?
6. Are there any specific initiatives, capabilities, or best practices of a particular IC that you believe should be scaled across NIH? If yes, how would you propose most effectively leveraging them across the agency?
7. Do you believe there are any specific projects, platforms, or other broad capabilities that are currently being duplicated in multiple NIH components? If yes, do you believe this duplication has any specific benefit, or do you view it as redundant?
8. Please evaluate the success of NIH's public-private partnerships to date, such as the Partnership for Accelerating Cancer Therapies (PACT), Accelerating Medicines Partnership (AMP), Helping to End Addiction Long-term (HEAL) Initiative, and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV). Do you see any differences in their effectiveness? If yes, what attributes do you believe make a public-private partnership more or less successful?

Improving Transparency and Oversight

1. What specific policy recommendations do you have to improve the transparency of NIH's work, including its accountability to the American people and Congress? Are you aware of any specific mechanisms that have effectively achieved this goal for other federal agencies, including outside of the Department of Health and Human Services (HHS)?
2. Would capping the number of terms that an IC director can serve help or hinder NIH's work?
3. What is your view of NIH's current practices for conducting audits of its intramural and extramural programs? How, if at all, could this be enhanced?
4. Would increasing audits and other oversight mechanisms have an overall positive or negative effect on the conduct of research?
5. How, if at all, should the Office of the Inspector General for the Department of Health and Human Services' oversight of NIH be enhanced?
6. Congress established the Scientific Management Review Board to advise on NIH's structure and management, and the Research Policy Board to advise the Office of Management and


Budget (OMB) and review administrative requirements for extramural research. However, to date, the Executive Branch has not effectively leveraged these entities. What steps could Congress take to encourage full implementation of these statutory requirements, and how could Congress maximize the boards' ability to increase transparency and provide outside recommendations to NIH and OMB?

Other Issues

1. What other policies or issues should Congress consider, aside from those mentioned above?
2. What structural, legislative, or administrative barriers impede Congress or NIH's ability to implement your policy recommendations?

Thank you in advance for your feedback. I look forward to working with you on this important matter.

Sincerely,



Bill Cassidy, M.D.

Ranking Member

Senate Committee on Health,

Education, Labor, and Pensions