Tell SRCD Your Thoughts on the Initial Proposal to Reform the National Institutes of Health

Thank you for your input. SRCD has submitted a response.

On June 14th, 2024, the House Energy and Commerce Committee Chair Cathy McMorris Rodgers (R-WA) circulated a proposal to reform the National Institutes of Health (NIH). Chair McMorris Rodgers provided an opportunity for stakeholders who wish to submit comments on the proposed framework. View the full framework here.

The House Energy and Commerce Committee proposal closely mirrors legislative language included on the fiscal year 2025 Labor, Health and Human Services (L-HHS), which would also change the structure of the NIH, including eliminating the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

On August 16th, SRCD Members and the SRCD Policy Committee joined the SRCD Policy Department to submit a response on this proposal to reform the NIH. Our comments focused on the need for a transparent, timely and evidence-based conversation between the scientific community, bicameral and bipartisan members of the U.S. Congress, and to express our concerns with the reduction of the NIH's 27 Institutes and Centers, and the other reforms on grants, leadership and funding changes. Read our letter and scroll down for the background, summary and context of the proposed reform.

READ SRCD's Response

Background

Two U.S. Congressional House Committees are attempting to dramatically reform and restructure the National Institutes of Health (NIH), including eliminating the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), reducing how many NIH grants a principal investigator can hold, changing grant cost structures, creating term limits for institute directors, and making it more difficult to include international partners on grants, among other substantial changes.

The U.S. House Committee on Energy & Commerce is requesting feedback from the public on a framework to reform the NIH. This follows an interim staff report on the National Institute of Allergy and Infectious Diseases, which purported to find misconduct and inadequate oversight on specific research projects, criticized the agency's handling of the COVID-19 pandemic, and more.

The proposal would consolidate the 27 NIH Institutes and Centers (ICs) into 15. Of great interest to our members, the NICHD would be combined with the National Institute on Deafness and Other Communication Disorders (NIDCD) and renamed the National Institute for Disability Related Research. This initial proposal would not only change the current structure of the NIH, but could also harm the mission, focus and the research that's conducted on each of the NIH ICs.

Here's a helpful diagram, illustrating the changes.

Diagram

This framework also proposes term limits to institute leaders, restrictions on including some foreign participants on grants, and other changes that the U.S. House Committee argues would better support research and innovation and improve transparency and accountability.

SRCD Pushes Back on Similar Efforts

Meanwhile, the U.S. House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (L-HHS) included a similar proposal to restructure the NIH in this year's appropriation bills (FY25) without any consultation or expert input. The appropriation bill also proposes flat funding for the NIH, a nearly 20% cut for the Centers for Disease Control and Prevention (CDC) and a 6.6% decrease for the Institute of Education Sciences (IES) when compared to fiscal year 2024 (FY24) appropriations bill.

SRCD has responded forcefully to the FY25 appropriations proposal. We've joined with our coalition groups and allies, sending letters to U.S. Congressional Leadership to ensure fundings for research and science based federal agencies and to highlight the importance of properly supporting science and research. You can read these letters and SRCD's Policy Engagement on our website.

To what it concerns to the NIH restructure proposal on this year's L-HHS appropriation bill, SRCD sent 242 emails to U.S. Congressional Appropriations staff and joining 223 other allies of the NIH in this letter, opposing this radical and irresponsible change. In the letter, we say:

"Authorizing an entirely new structure for the NIH in an appropriations bill without hearings, data, and review of the impact on biomedical research is a violation of process and procedures...This massive consolidation of NIH's Institutes and Centers amounts to Congress dictating science; it would affect all research conducted at the NIH and be detrimental to the research enterprise. A policy of this magnitude—and one affecting one of our nation's preeminent research institutions—should not be included in an appropriations bill."

Last fall, the Senate's Health, Education, Labor and Pensions (HELP) Committee Ranking Member Cassidy asked for input on NIH reform, which SRCD responded to.

The Political Context

The good news is that these Republican-led proposals are unlikely to pass in a divided U.S. Congress. That said, there is growing bipartisan momentum behind aspects of NIH reform and the political context could change, post-election. As pieces of this initial proposal to reform the NIH might continue regardless of the U.S. Presidential election results, SRCD will continue to work for our members to oppose damaging proposals that would threaten our ability to conduct rigorous and valuable scientific study.

Summary of the Proposed NIH Reforms

In addition to the consolidation of the 27 ICs into 15, the U.S. House Committee on Energy & Commerce's NIH reform also proposes the following changes, divided into three main policy buckets:

Mission and Leadership Reform

- Initiate and Complete a Comprehensive Review of the NIH establish a congressionally
 mandated commission to lead a review of the NIH's performance, mission, objectives, and
 programs. The review process would include regular public reports and updated with
 actionable recommendations that seeks to improve the NIH.
- 2. Support Innovation ensure the NIH is committed and focused on promoting and bolstering innovation of new treatments and cures, including by encouraging public-private partnerships and collaboration. The proposal adds that the purpose of this provision is to "resist the use of misguided tactics to pursue a specific agenda and manipulate commercial markets."
- 3. **Introduce Term Limits for IC Leadership** limit every IC Director to a five-year term, with the ability to serve two consecutive terms, if approved by the NIH Director.
- 4. **Eliminate Silos Between ICs** require every IC to issue a biennial report outlining how the individual IC 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.
- 5. **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.

- 6. 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.
- 7. **Improve Transparency from Partners** consider additional disclosure reporting and transparency requirements for donors, partners, and activities supported by the Foundation for the National Institute of Health (FNIH), including any conflicts of interest related to leadership, funding, or project determinations.

Funding Reform

- 1. **Restore Congress's Role in Directing Funding** repeal authorization for the Public Health Service (PHS) Evaluation Set-Aside, which enable the Health and Human Services Secretary to redistribute funds for research, evaluation, and data collection activities.
- 2. **Re-examine Indirect Costs** consider alternative mechanisms to limit indirect, or the
 Facilities and Administrative (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; or providing incentives or preferences to recipients with established and proven lower indirect costs.

- 3. **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.
- 4. **Prevent Waste and Fraud** ensure the NIH is properly accounting for and recovering misused taxpayer dollars.

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.
- 2. **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.
- 3. Continue Prohibition of Risky Gain-of-Function Research prohibit the NIH from conducting or supporting certain gain-of-function research occurring in countries that have been designated as foreign adversaries and pause any such gain-of-function research of concern until a thorough, comprehensive policy with appropriate guardrails to monitor research that has the potential to pose risks to public health and national security is enacted.
- 4. **Establish Independent Review Entity for the Proposed National Institute on Infectious Diseases** remove final review and approval authorities for certain gain-of-function research proposals from the proposed National Institute on Infectious Diseases, and empower a public, independent oversight entity to review, modify, approve or reject as appropriate, and oversee such research and experiments.

- 5. **Demand Accountability from Grantees** ensure primary grantees are complying with all requirements, including written attestations, to share and provide access to all relevant and supporting information and documentation related to research being conducted by any foreign subgrantee.
- 6. **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.
- 7. **Mandate Foreign Grant Reporting** require each IC to report and publicly post on the IC's website any grant or subgrant occurring in any foreign country.
- 8. **Incorporate a National Security Review** incorporate a specific national security or intelligence community review into the grant and award process for grants that involve research occurring by, or on behalf of, entities or actors that have been designated as foreign adversaries.
- 9. **Prevent Conflicts of Interest** ensure the NIH is appropriately updating, communicating, and implementing conflict of interest policies and requiring the disclosure of information that may indicate potential conflicts, including research support and non-financial conflicts of interest involving foreign activities and resources.
- 10. **Empower Agencies to Suspend Grants** provide the HHS Secretary, in consultation with the Office of the Director of National Intelligence, permanent authority to immediately suspend, pending investigation, a grant determined to be a threat to national security.
- 11. **Ensure Appropriate Oversight of Animal Research** require ethical and judicious standards of care, including appropriate transparency measures, for research involving animals both domestically and abroad.

You can read the full report here. In addition, see press release from the U.S. Committee: Chair Rodgers Unveils Framework for NIH Reform, Requests Stakeholder Input. The deadline to submit comments is August 16th, 2024.

Your Voice Matters

SRCD's Policy Department is preparing a written response. The SRCD Policy Committee's Science Policy Subcommittee will help shape and finalize SRCD's comments. We want to thank all our members for submitting their thoughts on this proposal.