

June 26, 2015

The Honorable Lamar Alexander
Chairman
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

The undersigned members of the Ad Hoc Group for Medical Research, representing patient groups, scientific societies, research institutions, and industry commend you for your leadership and vision undertaking a bipartisan initiative to examine the process for getting safe treatments, devices, and cures to patients and the critical role of the National Institutes of Health (NIH) in that process. As your committee begins to draft legislation to implement recommendations to enhance the role of NIH, we are pleased to offer the following recommendations, which represent the consensus of the undersigned organizations and institutions.

Stabilize the NIH Budget through Sustained Increases in Appropriations – As your committee’s hearings have helped document, we are in a time of unprecedented scientific opportunities and pressing health needs. If we are to achieve the full potential of advances in areas such as precision medicine, neuroscience, digital health technologies, and the other emerging opportunities discussed by your committee, the NIH budget will require sustained, predictable real growth. As you know, the NIH budget has lost nearly 25 percent of its purchasing power since 2003 after adjusting for inflation.

We believe that increases in appropriations of at least 5 percent annually for the next five years would enable thoughtful planning and efficient use of funding. This is similar to the recommendations of the American Academy of Arts and Sciences in its 2014 report “Restoring the Foundation: The Vital Role of Research in Preserving the American Dream.”

Affirm Existing NIH Support for Interdisciplinary Scientific Research – The NIH is authorized to stimulate and support research from basic through the full spectrum of translational, including biomedical, social, behavioral, and health services research. The HELP Committee legislation should reaffirm, rather than narrow, the agency’s existing mandate to support interdisciplinary science and the full spectrum of scientific disciplines.

Grant NIH “Carry-Over” Budget Authority – Because of its one-year budget cycle, compounded by delays in passage of appropriations bills, NIH forfeits a portion of its budget every year. Moreover, the compressed funding cycle creates administrative obstacles for NIH and the extramural community. Other federal research agencies with the ability to carry over funding into the next fiscal year include the National Science Foundation, the Department of Veteran Affairs Medical and Prosthetic Research Program, and the Department of Energy Office of Science.

Ease the Burdensome Travel Restrictions for Federal Researchers – Ideally, this would be accomplished by exempting federal employee attendance at scientific and technical meetings and

conferences from the policies included in Office of Management and Budget (OMB) Memorandum M-12-12. Similar language was included in the text of the draft FY 2015 Senate Labor-HHS Appropriations bill [Sec. 526. (b)].

Address Regulatory Burden – We thank you for your interest in reducing the administrative burden for researchers and institutions, and we share your concern that regulatory burden takes valuable time away from research. We recommend that several steps be taken to reduce administrative burden:

- **Human Subject Protection** – We suggest that Institutional Review Boards (IRB) regulations be tied to risk, exempting certain categories for research and allowing minimal risk protocols – such as public use data from health assessment surveys – to avoid continuing review. The community is awaiting final guidance from NIH on allowing single IRBs to suffice for multi-site studies and reducing the requirements for IRB documentation at the initial proposal stage. Further, greater harmonization between NIH’s human subject protection protocol and HHS’ protocol might reduce administrative time.
- **Financial Conflict of Interest Reporting** – We support the promotion of transparency, and we urge that the three-year review of the reporting requirements called for by the Public Health Service be conducted. Further, this review should include stakeholder meetings to examine ways to reduce this reporting burden without decreasing the effectiveness of conflict of interest reporting.
- **Administrative Burden Is Not Limited to NIH Grants** – In particular, two requirements from OMB are burdensome and duplicative: effort reporting and subrecipient monitoring.

Effort reporting per OMB Circular A-21 requires faculty to regularly identify and certify the amount of time that they and their staff, including unpaid volunteers, expend on individual research grants. The National Science Board’s 2014 report “Reducing Investigators’ Administrative Workload for Federally Funded Research” suggested that institutions’ payroll systems could provide automated time and effort information that could be certified to fulfill effort reporting. We support that recommendation.

Requiring primary grant awardees to monitor subrecipients of grants for compliance is duplicative in the many instances that subrecipients receive federal funds and must already file compliance documentation.

Again, the community thanks you for your leadership in sustaining NIH as a national priority, and we look forward to working with you and your committee as you move forward in drafting legislation.

Sincerely,

AcademyHealth
Alpha-1 Foundation
American Anthropological Association
American Association of Colleges of Nursing
American Association of Colleges of Pharmacy
American Association of Neurological Surgeons and Congress of Neurological Surgeons
American Association of Neuromuscular and Electrodiagnostic Medicine
American Institute for Medical and Biological Engineering

American Society for Microbiology
American Society for Pharmacology and Experimental Therapeutics (ASPET)
American Society of Transplantation (AST)
American Sociological Association
Association for Clinical and Translational Science
Association of Academic Health Sciences Libraries (AAHSL)
Association of Academic Physiatrists
Association of American Geographers
Association of American Medical Colleges
Association of American Universities
Association of American Veterinary Medical Colleges
AVAC
Clinical Research Forum
The COPD Foundation
Federation of Associations in Behavioral and Brain Sciences
GBS/CIDP Foundation International
The Marfan Foundation
Medical Library Association (MLA)
Pulmonary Hypertension Association
National Alopecia Areata Foundation
National Association for Biomedical Research