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the Field of Transplantation

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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, and behavioral 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 nearly 1 percent of its budget every year. The Department of Veteran Affairs Medical and Prosthetic Research program operates under two-year and "available until expended" appropriations, and returns only 0.02 percent of its yearly budget. With similar budgetary flexibility, NIH could retain \$294 million of the \$300 million it forfeits annually. Other federal research agencies with the ability to carry over funding into the next fiscal year include the National Science Foundation and the Department of Energy Office of Science.

NATIONAL OFFICE

1120 Route 73, Suite 200 • Mt. Laurel, NJ 08054
856.439.9986 • Fax: 856.439.9982 • info@myAST.org • www.myAST.org

GOVERNMENT RELATIONS

William Applegate, Director of Government Relations • Bryan Cave, LLP
1155 F Street, NW • Washington, DC 20004
202.258.4989 • bill.applegate@bryancave.com

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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 data collection – 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 IRBs 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 suggest that the recommended three-year review of these requirements become mandatory. Further, the mandatory three-year review should include stakeholder meetings to examine ways to reduce this reporting burden.
- **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 research related to individual 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,



James S. Allan
President