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Sally J. Rockey, Ph.D. Deputy Director for Extramural Research National Institutes of Health Building 1, Room 144 One Center Drive Bethesda, MD 20892

by email to <a href="mailto:rockeysa@od.nih.gov">rockeysa@od.nih.gov</a>

Dear Dr. Rockey:

We are writing on behalf of The American Association of Immunologists (AAI), the largest professional association of immunologists in the world, representing more than 7,400 basic and clinical immunologists, in response to your request for input on the use of National Institutes of Health (NIH) resources in this era of fiscal constraints ("How Do You Think We Should Manage Science in Fiscally Challenging Times?" Posted on Rock Talk, on October 17, 2011, by Sally Rockey). We appreciate having this opportunity to comment, because the vast majority of our members depend on NIH funding to support their research and careers. We also appreciate the research that your office has done and posted online, to assist stakeholders in assessing a variety of options that NIH is considering to maximize the use of its resources.

AAI recognizes the challenges faced by NIH as it attempts to ensure an ongoing, robust biomedical research enterprise in the face of challenges from delayed and uncertain appropriations, conflicting demands of Congress, and competing stakeholder priorities. This era of unprecedented scientific opportunity comes at a time of exceedingly limited resources, and AAI appreciates that NIH is seeking counsel on the best use of its resources from a diverse community.

AAI has considered carefully the various options NIH has offered via its Office of Extramural Resources (OER) website. We have also participated in discussions with our biomedical research colleagues, including the Federation of American Societies for Experimental Biology (FASEB), of which AAI is a charter member. In addition to our own comments (below), AAI commends to you the very thoughtful and comprehensive comments submitted by FASEB in its December 7, 2011, letter to you.

AAI believes that the following principles must underlie any changes made in the name of managing its resources.

### • NIH, and the United States, must continue to lead the world in biomedical research and innovation.

NIH is the premier medical research facility in the world, and the world's leading scientists depend on its leadership and funding. Any changes made to address a paucity of resources must ensure that NIH retains its global position and ability to lead.

• NIH should continue to recognize that individual investigator-initiated research yields the greatest advances in biomedical research, and in improving human and animal health.

The system that NIH has supported for more than 60 years – a system in which research applications submitted by investigators are evaluated by independent scientific experts to determine suitability for funding by the NIH – is the underpinning of our successful biomedical research enterprise and should be maintained. Although the ways of research are changing, and there is a place for other funding mechanisms (including RFAs, P01s, etc.), "team science," and large projects, it is essential that NIH preserve the ability for independent investigators to succeed and thrive.

### • NIH should encourage the next generation of scientific leaders.

Within the next decade or two, the baby boom generation will retire. Any steps NIH takes to address its current lack of resources must take into account the need to ensure that there is a generation of well-trained, highly skilled scientists ready to lead. Those future leaders are currently young scientists and students. They must want to enter the field, they must be educated and trained, and they must have opportunities and jobs. Recruitment and retention of young scientists is particularly important as the current funding situation has negatively impacted our graduate population and has deeply discouraged many postdoctoral fellows who remain in academic tracks.

AAI appreciates that the comments sought by OER are designed to elicit suggestions of ways to increase the availability of Research Project Grants (RPGs). With respect to the specific recommendations, AAI offers the following:

### 1. NIH should examine all of its funding, rather than just its existing RPG funding

The options listed by OER consider only the reallocation of funds currently within the RPG budget, rather than looking at the entire budget to determine whether other funds might be moved into the RPG pool. To this end, AAI urges NIH to examine its entire budget (intramural and extramural expenditures), to evaluate ongoing large-scale projects/contracts/centers as to their continued need and efficacy, and to be willing to say that certain projects, while worthy, are not absolutely necessary in difficult fiscal times. With that said, the cost of a project should not determine its value; some important and worthy projects are very costly but should continue to be supported.

As reported by FASEB, the percentage of the NIH budget allocated to both competing and non-competing RPGs has fallen since the mid-1990's. Restoring the RPG budget to the 1994 level, according to FASEB, would significantly increase both the number of awards and the success rate.

# 2. NIH should seek other sources of funds, including reducing indirect costs and limiting the amount of investigator salaries charged to grants, to supplement its research budget

NIH should not only oppose efforts to increase the indirect cost cap on administrative expenses, but also consider whether the current system unfairly reduces the funds available for biomedical research. According to the Government Accountability Office (GAO), indirect (facilities and administrative) costs utilize almost 30 percent of the NIH research grant budget (see <a href="http://www.gao.gov/new.items/d07294r.pdf">http://www.gao.gov/new.items/d07294r.pdf</a>). This is an enormous portion of the budget, and although AAI is not prepared to recommend a specific reduction, AAI does strongly

recommend that NIH examine the fairness of exempting this large expenditure from scrutiny. At the same time, AAI recognizes that many of our members are faculty and students at institutions which receive these indirect costs, and we are concerned that a reduction in cost caps could result in cost-shifting within institutional budgets that would further pressure or harm our members, undermining any benefit from reducing the cost cap. As a result, we recommend that NIH study the impact - on the NIH budget, researchers, and institutions - of a reduction in indirect cost rates, either across-the-board or to correct historical and/or regional discrepancies that may no longer be merited.

NIH should also consider recouping some of the funds lost to institutions that are charging an increasing percentage of researcher salary to research grants. In addition to the loss of funds to NIH, this practice increases the burden on researchers to obtain NIH grants to support their own salaries, leading to further taxing of the NIH system, from increased applications to additional peer review. NIH should examine this practice, and recent trends leading to an increased percentage of investigator salary being charged to grants, with the following goals: 1) using NIH funding for its intended purpose (i.e., research), 2) ensuring fair and adequate investment in its human capital (i.e., researchers and their employees) by institutions, and 3) fostering a better atmosphere for discovery by research scientists employed at these institutions. Any change in the percentage allocated must be phased in over time to avoid the loss of jobs and/or damage to ongoing research.

## 3. NIH should consider limiting the size of grants and/or making it more difficult to secure a large grant

Of the options put forth by OER, limiting the size of grants is the only one that might significantly increase the availability of funds for research. Funds from very large grants may not be spent as efficiently, and therefore such grant applications should, at the least, be more carefully reviewed. One possible option is to institute a reduced payline for larger grants.

## 4. NIH should explore the merits of extending an advantage to young investigators seeking their first renewal and, possibly, their second R01

Young investigators who benefit from the NIH policy giving them a funding advantage on their first RO1 application may be unable to compete with the larger applicant pool at the time of their first renewal or second RO1 application. This is not due to some inherent inadequacy of young researchers, but rather to their inability to demonstrate the results necessary to succeed in competitive review in such a short period of time. Giving young investigators a five year grace period during which they retain a funding advantage may enable them to compete fairly with their more senior colleagues.

#### 5. NIH should not limit the amount of money per Principal Investigator (PI)

Such a limitation would have minimal impact on increasing the funds available for research, but would adversely affect PIs who manage large-scale projects or who are particularly successful and productive. At most, NIH could consider imposing greater scrutiny on those investigators/teams who receive a disproportionate share of funds, to ensure that the funds are being efficiently used. (For example, one NIH institute, the National Institute of General Medical Sciences, requires "special analysis and justification" of applications submitted by "investigators whose total research support from all sources, including the pending award, exceeds \$750,000" in annual direct costs. See

http://www.nigms.nih.gov/Research/Application/NAGMSCouncilGuidelines.htm).

#### 6. NIH should not limit the total number of grant awards per institution

Such a limitation would have minimal impact on increasing the funds available for research, but could drive some private research institutes out of business.

#### Conclusion

AAI believes that most of the options offered by OER, with the exception of limiting the size of grants (as described above), will have negligible positive impact (i.e., will not measurably increase the RPG pool), but may have negative consequences. As a result, AAI does not recommend undertaking those changes, especially absent any analysis from NIH regarding the multivariate impact of the options it promulgated.

AAI does recommend that NIH engage in a broader analysis of its portfolio to determine whether there are additional sources for increased RPG funding, and to adopt a system of dual paylines that funds very large grants at a lower payline than smaller grants.

Finally, in implementing any changes, NIH must balance the need for change against the disruption and harm that even well-intended change can cause to the system. AAI urges NIH to work with its stakeholders to ensure transparency and thoughtful discussion, and to make certain that the implementation process is orderly.

With that said, it is urgent that NIH recognize that the biomedical research community is already in crisis, with many long-productive investigators facing closing their labs, new investigators losing their jobs, and opportunities rapidly shrinking for postdoctoral fellows and students. Although NIH should make thoughtful decisions, any study or phased-in change(s) need to start as soon as possible. Delay is not an option.

AAI stands ready to assist NIH in any way that it can.

Please contact either of us, or AAI Director of Public Policy and Government Affairs Lauren G. Gross, J.D., at <u>lgross@aai.org</u> or (301) 634-7178, if we can be of any assistance.

Sincerely,

Derry C. Roopenian, Ph.D. Chair, AAI Committee on Public Affairs

Leslie J. Berg, Ph.D. President