THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

Response of The American Association of Immunologists (AAI) to the National Science Foundation (NSF) "Request for Information (RFI): Reducing Investigator's Administrative Workload for Federally Funded Research"

Submitted on June 6, 2013 to the
National Science Board's (NSB) Task Force on Administrative Burdens
(via email to: *Administrative-Reform@nsf.gov*)

Dear members of the NSB Task Force on Administrative Burdens:

The American Association of Immunologists (AAI), the largest professional association of immunologists in the world, appreciates this opportunity to submit comments to the National Science Board's (NSB) Task Force on Administrative Burdens. AAI is pleased that the NSB is undertaking this effort, since the problems associated with a heavy and growing administrative burden increasingly impede the productivity, efficiency, and morale of the nation's scientific researchers.

AAI members are funded by a wide range of federal agencies, including the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Defense (DOD), the Department of Agriculture (USDA), the Department of Veterans Affairs (VA), and the Department of Energy (DOE); many members receive grants from multiple agencies over the course of their careers. As a result, AAI hopes that this NSB initiative will identify problems government-wide and foster coordination among the many federal science agencies.

AAI realizes that the Task Force requested responses from individual researchers who currently receive federal funding, and we have encouraged our members to respond. Although AAI, as a professional society, cannot respond to all of the questions posed by this RFI, we do wish to convey the general sentiment of our members and respond to those questions which we believe are within our purview as a membership organization.

In addition, we wish to call to the Task Force's attention the detailed and thoughtful response to this RFI of the Federation of American Societies for Experimental Biology (FASEB), of which AAI is a charter member. In developing its response, which AAI endorses, FASEB conducted a

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survey and received a robust response from AAI members, who are deeply concerned about the impact of administrative burden on NSF grantees and on grantees of every other federal agency which funds scientific research.

AAI recognizes that federal grantees are stewards of taxpayer dollars, and knows that our members take this responsibility seriously. As a result, AAI understands that a certain amount of administrative work is necessary to foster both accountability and the implementation of proper procedures. Because an important part of our stewardship responsibility is to ensure that federal dollars are well spent and that taxpayers receive as much benefit from their investment as possible, we are particularly concerned about excessive administrative activities that divert scientists' time and attention away from research and publishing activities, the fundamental goals of federally funded research. AAI offers the following comments in that spirit.

- **Institutional Animal Care and Use Committee (IACUC) application/approval process**

For immunologists who utilize animal models, the excessive and redundant paperwork associated with IACUC applications and approval delays research progress, effectively reducing the efficacy of grant funding. Specific problems and accompanying recommendations include the following:

- Requirements that investigators exactly match animal protocols with proposed research stated in grants and project for all years of the grant, prior to grant award, ignore the fact that research objectives are continually refined and honed as new data are obtained and the field advances. AAI recommends that the IACUC approval period match the time frame of the funded grant, keeping the current three year period for grants of three years or less, so that principal investigators (PIs) do not have to submit new IACUC protocols merely to complete the grant period.

- Federal agencies, such as the NIH, require all experiments to be predetermined in strain and statistically justified as to exact animal numbers, projected for a three year period. Thus, investigators are forced to project animal numbers years into the future, and then continually file amendments subject to re-approval for each minor modification that must be made as investigators strategically capitalize on the newest findings in the field. AAI recommends that funding agencies allow changes to the exact number of animals required to be approved through a simplified administrative process rather than through additional IACUC approval.

- IACUC approvals for studies on one funded grant are not directly transferable to other institutions funded by the same grant or to other grants that have functional similarity including species, strain, and procedures for animal manipulation. Rather, funded grants generally require separate IACUC protocols, each of which is subject to individual approval, individual revision amendments, and individual annual re-approval. AAI recommends, therefore, that funding agencies adopt a streamlined approach in which one IACUC approval satisfies all institutions funded by the same grant and enables small changes to protocols to be approved through a simplified administrative process.

AAI also recommends further examination of the following topics:

- Whether IACUCs should provide blanket protocols for which individual PIs can be approved across all funded grants;

- When animal care and use documents should be submitted; and

- Whether IACUCs should be required to use similar guidelines (best practices), perhaps via a standard federally developed template that is consistent for all research facilities.

- **Institutional Review Board (IRB)**

For those who conduct clinical research, the IRB process can be as burdensome as the IACUC process is to bench scientists. Developing national standards for IRB approval, for example, could streamline the process and result in a partnership between individual institutions and researchers. AAI urges the Task Force to reach out to clinicians of all disciplines, many of whom are not funded by NSF and who may be unaware of the NSB's solicitation for information on this important matter.

- **Training**

AAI recognizes that training is essential for diverse topics ranging from research integrity to sexual harassment. Frequent training is currently required in myriad areas including, but not limited to, the following: radiation safety, right-to-know, hazardous waste disposal, blood borne pathogens, human subjects, chemical hygiene, occupational health, animal welfare and biosafety. PIs are often required to conduct annual laboratory self-audits that confirm compliance.

AAI members have found that too much time is devoted to training, much of which is duplicative. For example, some investigators funded by more than one agency must attend a training session on the same topic by multiple agencies. AAI recommends developing standardized training across the government so that completion of a course required by one agency satisfies the requirements of all other agencies.

Annual refresher courses, which are often required, are unnecessary since changes from year to year in a specific area are either non-existent or minimal at best. Such courses are highly time-consuming for the PI, especially if a lab requires multiple certifications. AAI recommends that refresher courses be required only when significant changes have occurred or at extended time intervals (i.e., every 3-5 years); lab personnel could be informed of more minor updates or changes in procedure by the PI or lab manager, who would receive notifications from the agency. This type of system would obviate the need for complete retraining of lab personnel while ensuring that new advances are effectively communicated.

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- **Biosafety/Laboratory Safety Training**

Currently, much time is devoted to training for biosafety or general lab safety, in part because of federal, state and institutional requirements, many of which overlap, and requirements that grantees take training courses offered by each entity. AAI recommends coordination among the federal government, state government, and grantee institutions so that one course addresses all applicable requirements.

There are also some safety rules which unnecessarily impede the pace of research. One such example involves the shipping, and therefore sharing, of biological reagents. Some samples require obtaining a permit from the U.S. Department of Agriculture, a process which can take months. AAI recommends that federal agencies review all safety rules to foster streamlining, avoid duplication, and expedite processes which cause harmful delay.

- **Conflict-of-Interest**

AAI members recognize the public's right to assurance that the recipients of federal grant funding are free from conflicts of interest. Our members have found, however, that the interpretation by some institutions of the new conflict of interest rules has resulted in excessive reporting requirements and time-consuming paperwork. Some institutions are now requiring the listing of every honorarium received, talk sponsored, and stock owned (even if the amount is small), etc. for every grant application. AAI recommends that the federal science funding agencies re-assess what information must be reported to prevent conflicts of interest and develop clear guidance for institutions so they do not feel the need to require intrusive or excessive reporting.

- **Effort Reporting**

The Office of Management and Budget (OMB) currently requires PIs to periodically submit an effort report of all individuals compensated on federally sponsored projects. This requires PIs on grants to certify the amount of effort that they and their students, postdocs, and technicians spend on sponsored activities. In order for effort reporting to be accurate, PIs must document how their staff allocates its time among research, teaching and other university-related activities. This requires frequent and time consuming conversations that, while not impacting the quality of work being done, certainly impacts the quantity. AAI encourages the Task Force to recommend less frequent reporting and to recommend less onerous ways for PIs to report effort, recognizing that the PI is, in fact, accountable for ensuring that the federal dollars are properly spent and accounted for.

- **Cumulative Burden**

In addition to evaluating the impact of individual requirements on administrative workload, the cumulative burden must be considered. In recent years, the cumulative burden has been compounded by changes in the grant application process and reductions in available funding. AAI members find the current process of grant application preparation more rigid, detailed,

and time consuming than in the past; many PIs spend the vast majority of their time writing, revising, or preparing to write grants. And with success rates at the lowest point in history, scientists are forced to submit many more applications in order to improve their chances for funding.

In some instances, PIs hire or utilize laboratory staff to handle compliance and other administrative matters. In other instances, institutions may hire such staff. The workload of such staff must be included in assessing cumulative burden and cost; when these staffers are supported by research grants, the time they devote to administrative work effectively reduces the funding available to advance the laboratory's ongoing research.

Conclusion

AAI greatly appreciates this opportunity to submit comments and would be pleased to answer any questions the Task Force might have. Kindly contact me or Lauren Gross, AAI Director of Public Policy and Government Affairs, at lgross@aai.org, if we can be of assistance.

Sincerely,

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