

APPENDIX B: OPEN-ENDED THEMES AND RESPONSES

At the conclusion of the survey, respondents were given the opportunity to “take a moment to provide us with additional comments.” Given that hundreds of faculty complied, the comments shown in the following pages are intended to be typical of their concerns. All recommendations and agency-specific remarks, however, are included in this appendix.

Faculty Support for, Concerns About, and Recommendations Regarding Direct-Cost Redirection

Support for Direct-Cost Redirection

I am so glad you are looking at this issue. I have been enormously frustrated here by the amount of administrative oversight I need to put in to make sure that even the simplest of things get done correctly. If I could guarantee that there were adequate administrative resources here by putting them into a grant budget I feel it would create an environment that is much more conducive to producing top-quality research.

I spend 2 days a week at least on the activities described in this questionnaire. Federal support for departmental oversight of much of this would improve my productivity dramatically.

I have been an independent investigator (faculty) for 16 years, and have been funded by NIH for almost all of that time. The amount of time I spend on regulations (IACUC, safety, etc.) has increased DRAMATICALLY, and I am positively overwhelmed by the burden. When I hire technicians/lab managers, I seek SCIENTISTS, not people who are skilled at drone administrative tasks. Accordingly, I am stuck with this burden (if I want it done correctly and in a timely manner). Something has to be done!

It is important to note that many of my answers included the concept that many administrative tasks are managed by personnel who report to me. This is absolutely critical to my successful research program. On the other hand, as a result of federal policy a number of years ago ... these individuals are not supported on regular federal grants. We must find ways to find discretionary funds to fund them. Those funds are quickly disappearing and as a result these individuals may disappear. ... At that point my productivity will be drastically affected and the only solution would be if my grants had direct funds for these support personnel.

I currently have 5 percent or so of the grant devoted to administrative support. This is indeed money well spent. Internal audits have validated the accounting and personnel procedures. It is both helpful and reassuring that professionals can deal with the myriad and arcane problems.

I am fortunate enough to have a technician paid for by the college. This relieves me from many of the burdens noted — such as safety plans, safety training, reporting, ordering, etc. I could not survive without this support. Those that do not have in-house support should be able to include it on the proposals. The continuity and time savings is invaluable and frees me to do teaching and research.

Concerns Regarding the Use of Direct-Cost Funds for Administrative Support

Where Are Indirect Cost-Funds Being Spent?

I'm not clear why I was asked about direct-cost allocations for grants administration. Elite universities charge more than 60 percent overhead, which should cover all this administrative stuff. The real question is why do the NIHs (and other funders) allow universities to get away with charging 60 percent overhead and not providing adequate support. In my opinion, its fraudulent; the University charges sky-high overhead, then exaggerates the cost of lights and buildings so that it can subsidize under-funded activities, leaving the faculty with less and less administrative support.

For what it's worth, I think the bigger issue regarding availability of money for administrative support is where does all that overhead go? and that's more of an institution-specific problem. At the same time, though, given agency involvement in setting the accepted overhead rates, it would be nice to see some kind of agency pushback to try to make this aspect more transparent. But, again, I'm not sure any of this is relevant to this particular survey!

Support Personnel Could Not Provide Needed Assistance

The major time issues involve approvals and paperwork required by on campus offices (such as IACUC) that cannot be dealt with by an administrator. I spend a large amount of my time responding to their requests "for clarification" and ensuring that my paperwork actually makes it through their bureaucracy.

I have no confidence that I could find individuals who could accomplish these myriad, unrelated, and rapidly changing tasks expediently. They simply take too long to teach others to do, they are so numerous and idiosyncratic, and they are veritable moving targets (i.e., each time I am asked to document a compliance activity, it has been updated just enough so that the previous iteration I had carefully saved on disk is now of no value).

My Department lacks the in-house staff with the capabilities or skill set necessary to do the grant administration called for in federal grants. Thus I end up not only doing the work I intended to do on the grant but also trying to do what staff should be assigned to do, assuming they were qualified to do so.

Insufficient Direct-Cost Funds to Allocate for Administrative Support

Due to funding caps and across the board budget cuts, my direct costs are insufficient to cover existing expenses, so it would not be possible to reallocate them to cover administrative expenses. That is part of the reason that I have to spend so much of my research time on grant management activities. However, if additional funds were available, or I could use indirect costs that currently do very little to provide a research infrastructure at my institution, I would be extremely grateful and my productivity would be significantly enhanced.

I indicated that I do not want to redirect my grant funds into administration. This was not because I can't use help on administrative stuff but rather because my grants have been cut to the point where I am just barely managing to do the work and I really do not have any fluff in my budgets that could be redirected. So I end up with a choice between spending time on the part of myself and my research personnel to meet the administrative burdens, or taking away personnel money and going to pay some administrator to do the stuff at the cost of reduced research personnel. Neither constitutes an acceptable answer to the administrative burden problem.

Recommendations Regarding Use of Direct-Cost Funds for Administrative Support

It seems that the assumption is that my institution or department will provide quality administrative support. I believe that my institution and department provide much of the services that I need to administer grants — the problem is that the quality is not that good. [I]f I could allocate direct costs to administrative services, I don't for a minute believe that service would improve. ... A real market economy move would be to allow principal investigators to withhold a significant fraction of indirect costs when the institutions don't deliver.

If direct costs were to be permitted for administrative help, it is almost a certainty that the University would further cut back on the little administrative help already provided (faculty would be told to use their own direct costs to cover all administrative needs). As it is, most investigators use their lab techs to perform many administrative duties; as much as 50 percent of a lab tech's time is spent in this fashion for a given grant. This is time taken away from productive research. Without an increase in funds (either direct or indirect), the problem of eroding the time spent in research will not be solved. One potential solution, given the restraints in funding, is to designate a portion of the indirect costs specifically for support of the administrative needs of individual investigators and require institutions to document that those funds are going to support individual investigators (as opposed to getting swallowed up by general university "overhead," which is so far over the heads of faculty that it is of no direct benefit).

I believe that INDIRECT costs should pay for administrative costs, unless a line item in the grant is set aside for administration. I write this because if a percentage is set aside, it will be taken by the department, but administrative support will not be provided. **THIS is a major problem ... v[ery] little access to administrative support.** I guess if I could go back, I would designate a specific sum for administrative support, but I have no guarantee that the department would honor it unless it was a position solely within my lab as a full or part-time. Also, the department would have to allocate space, something they would be loath to do.

A question was asked re: DIRECT costs to be applied from federal grants to assist w/ oversight, but that would mean precious resources away from already strained direct cost budgets. INSTEAD, a more useful approach may be what percentage of indirect costs should be mandated to go toward grant management assistance/personnel, which then is no longer the burden of the PI to ensure, but instead it becomes the institution/college's responsibility to ensure they are meeting federal requirements for providing PI's support.

The term “reallocate” sounds like the total budget would be the same. I would want to be able to propose as part of a grant submission that I hire an administrator as part of the direct and this would increase the budget. The University is not going to lower the indirect rate and they are not going to increase the administrative support staff, so we need to be able to hire direct administrative support staff.

If scientists must compete for money let administrators compete as well. This could easily and reasonably be accomplished by granting the PI the money and letting him negotiate with the institution how much they take.

Faculty Concerns and Recommendations Regarding the Grant Award Process

Grant Proposals Require a Tremendous Amount of Time

The greatest single impediment to effective use of my research time is the wasted weeks spent writing, submitting, and resubmitting proposals to programs that have been bled dry.

I need four grants to do one primary program – wasteful of my time in writing and reviewing proposals, stressful, and wasteful of government sponsor’s time. Not enough dollars per grant. I spend more time writing grant proposals than papers, which is ridiculous.

One of the biggest barriers with federal grants has become the waiting process to obtain funds. It is an enormous time burden for submission and then nearly a 9 month process for a first review which is almost always not funded. So the funding application cycle is typically 1 to 1.5 years at best – then the budget is frequently cut by 15 – 20 percent, meaning that one has to initially pad or remove part of the activities.

By far the largest burden taking away substantial time from research is the low funding level. It forces me to resubmit perfectly good grants. Most recently, I obtained the highest score in a study section on a grant I submitted, but there were insufficient funds to cover the grant, forcing me to resubmit this grant in the next funding cycle. If funding levels are so low that even single percentile scores are insufficient to obtain funding, then all your focus on administrative burden is pointless.

Recommendations Regarding Grant Proposals

Applications

To reduce burden, grant application submission should go to an all electronic format using highly standardized forms that you don't have to piece together. More attention should be paid to requiring home departments to allow a faculty member the time specified on a particular grant. The percentage efforts specified on grants are often no more than a farce, and everyone knows it. For example, my K award specifies a minimum percent effort, but my department requires me to deviate from that for teaching. I am in a hard tenure track line and am paying my own salary with the K award, but the department pockets the salary money that should come to my research program.

One of the most frustrating things with grant applications is that each agency asks for the same information, but uses different forms. Identical electronic forms for each agency would significantly streamline this aspect of grant application (why can't they all copy NSF?).

Too much time is spent on applying for federal research money. In Europe applications are considerably shorter. Also, the time until a funding decision is reached or, if the application is successful, when funding becomes available, is too long.

Review Process

All federal RFPs should include a pre-proposal stage to screen out subjects that have little chance of success. I've had many proposals receive great ad-hoc reviews only to be rejected by the Panel for reasons that should have been identified more explicitly in the RFP.

The biggest difficulty I have as a young professor is the fact that NIH takes so long to review proposals. We typically miss an entire grant cycle waiting for reviews. I would suggest that there be two levels of proposals and two levels of reviews. Small proposals (direct costs < 125K per year) should be reviewed quickly (and could be shorter) while larger proposals would be reviewed in more detail.

The biggest time sink is the preparation of grant applications. Much of this effort is wasted since most grants don't get funded. A more thought-out two-stage process: the bulk of the idea is submitted but the regulatory details and certifications and detailed budgets (which are hugely complicated by ever-changing full cost accounting rules) wait until a proposal is approved (at least provisionally).

It is essential that greater efforts be made to ensure continuity in the review of NIH grants. There is an increasing proportion of cases in which new reviewers are assigned to an A2 application, resulting in completely new sets of criticism that an applicant cannot respond to because A3 applications are not permitted. This is causing serious demoralization and discouraging many junior faculty (as well as graduate students and postdocs who are witnessing the consequences). It would also be very helpful if one of the reviewers assigned to a grant was given the role of

advocate specifically to avoid criticisms that may be unwarranted, and to guard against unfair or inconsistent reviews.

The main problem with NIH grants is that they are so detailed and you know that the study section is going to focus on minor details rather on the science that the preparation time becomes very long. On my last NIH grant I spent three months on grant preparation. In a similar three month period I made significant discoveries that resulted in two high impact papers.

My main concerns with the federal grant application process is related to how reviews are conducted. I've had the experience of responding to a first-round of reviews, only to receive a second-round of reviews that are very contradictory with the first, or that flag concerns that were not raised in the first round. Too much time goes into preparing federal grants to risk not getting the same (or mostly the same) group of reviewers.

In addition to managing those grants received, the time spent waiting for grant review, scores and funding decisions to be made in the first place is a great inconvenience for someone whose career hinges on receiving a grant. This process needs to be sped up or at the very least deadlines should be adhered to more strictly.

Funding Duration and Amount

The 3 year grant cycle is way too short. ... I feel that I am on a short leash, and that I always need to drop risky, long-term projects in favor of less important work that will yield results in the short-term, otherwise my funding will be cut.

A key issue here is grant duration and amount. Because award amounts have been stagnant, and long-term awards are uncommon, many more proposals are being written and reviewed today than before, enormously burdening the research community in the process. If award size and duration increased, research quality will go up. This is worth a try even with static science budgets, because of the trade off between quality and quantity.

You have to have a big chunk of the work finished to write a successful federal grant proposal — this is wrong. A few phone calls and 2 pages of text gets me \$100k/yr from industry — why should I bother with large proposals and closed-minded reviewers at NSF? My university has dismal financial management tools for professors so the burden to me is not federal rules but my employer's reluctance to treat professors as intelligent beings. I need fewer federal regulations on what I spend money on to get the job done.

The time spent in contract administration and proposal writing has increased by at least four times over the last twenty years. This is not necessarily the result of more requirements but of the shrinking funds. The average award per project is actually much less than it was twenty years ago, while all costs have increased dramatically. Research is terribly under-funded and not valued by the federal government. There is a lack of continuity in funding and lack of suitable expertise/manpower in the funding agencies. The government should recognize that many research avenues need to be explored to get to profitable ones. There is no coherent research policy in this country and this is very dangerous for the future. Scientists should spend time

thinking about and working on science rather than on the management of grants. The individuals should have fewer grants with larger amounts. Adding personnel to help with management will have little impact, because often one needs technical competence to manage the research, and such people are not easy to hire.

Wrong Types of Research Being Funded

Excessive emphasis is placed on individual achievement as a principal investigator to ascend the promotion and tenure ladder in academic health science centers (AHSC). Investigator financial independence is no longer a valid criterion for productivity (see IOM (2005) Bridges to Independence) and therefore a basis for justifying award of P&T. The IOM (2005) report clearly states that capacity to produce fundable grant applications and peer-reviewed publications as part of INTERDISCIPLINARY TEAMS OF INVESTIGATORS is the valid criterion by which to judge productivity in the present funding environment. AHSCs that remain wedded to an outdated academic model of personal (vs. team) achievement place extreme pressure on individual faculty to undertake projects with little contributory value, but with higher chances of funding success, in order to cover compensation prior to award of tenure. The average age of such financial independence has risen into the age range 40-45, which falls well into one's period of greatest productivity. Lack of job security is devastating on many faculty members' physical/mental health, and relationships with family and friends. AHSCs, the PHS agencies, and the federal administration have failed to change with the times. They jeopardize the future of the US clinical research enterprise (see COGR reports, Sung (2003) JAMA, and Crowley (2004) JAMA). This crisis is neither inevitable nor unresolvable. The principal barrier at present to implementing solutions is lack of political will.

Some federal funding agencies (e.g., DARPA, DoD) tend to excessively reward operators that run huge research grant programs (or over 10 grants simultaneously). The support of individual investigators is strongly neglected by the federal research funding agencies, which are all moving towards supporting large centers, at the expense of individual investigator grants.

The biggest mistake currently being made in federal funding is the de-emphasis on individual peer reviewed grants, especially in the physical sciences. This applies to both the number and the amounts of funding that can be realistically obtained for supporting research groups and sustain them at cutting edge of their fields. This will adversely affect both the technological base for future INNOVATIVE developments and the standard of higher education that are so important in determining the future economic welfare of this country. Higher education is NOT a business but an investment in the future of this country. The foolish over-emphasis on big projects and center funding, winner take all funding and increased emphasis of commercial exploitation of University intellectual property will prove a catastrophe for this country. The research enterprise at Universities is being totally distorted due to these factors instead of emphasizing innovation. Congress should stop pressuring higher education in this manner. It is simply a terrible mistake in the long run. In addition, the percentage of federal funding that is being mandated and pork barreled without effective peer review is the cause of enormous waste and is counterproductive.

I started my faculty career in Canada (though I'm an American) and have always liked the model they have in NSERC: a significant fraction of funding is small amounts direct to researchers,

rather than projects. This funding forms a reliable base on which one can initiate collaborations that can pursue funding for larger projects. It is amazing how much research is accomplished by having some freedom to pursue promising avenues that were not anticipated.

Faculty Concerns and Recommendations Regarding IRB, IACUC, and HIPAA Regulations

Extent of IRB Burden

Both IRB and HIPAA concerns make the process of developing multi-center studies a morass and often compromise external validity with no concomitant gains by subjects. The process of adhering to an oversight mechanism designed for higher risk research adds unnecessary complexity to the research effort, adds much more frustration than I had previously experienced in my quarter century of research activities, and impedes the research process by adding delays that are 2 to 3 times longer than I have ever seen.

The total impact of the regulatory burden, e.g., IRB, HIPAA, and conflict of interest, are several orders of magnitude greater than when I began clinical research in 1981. These changes over the past 25 years have reduced by ~50%, the amount of research that gets done. The inefficiency is a major factor in my decision to discontinue clinical research next year (2006) and focus on health services research.

As someone within about 10 years of retirement, I find myself thinking of that in terms of how many more projects I will need to fight through the IRB.

One of my major concerns regarding grants management, particularly with compliance issues in biohazard, animal welfare or human subjects, is that the regulations in each of these areas is both ambiguous and continually evolving. This in practice means that they require individuals who really know specific details for the appropriate regs and that they make a concerted effort to keep up with not only federal but state regs. In this institution, this often means completely different people who often give conflicting advice when we have to have compliance that spans both biohazard and human subjects — for instance biohazard and animal welfare or to satisfy OSHA and state requirements. One of the reasons why I indicated that I had minimal animal welfare issues for the year 04-05 is because I had already restructured my research program so that I did not have to maintain my animal IACUC protocol on top of my IRB and biohazard approvals. It probably was not the best decision to make in the interests of science. However, trying to keep up with putting in a new animal or IRB protocol every time I put in a new grant application or a non-competing renewal with slight changes in titles or modifications in protocols or where I would use the same samples or use a common protocol (e.g. making mAb ascities or immunization protocol) but asked a different set of questions just became ridiculous.

Demographic/ethnic distribution requirements of subjects in clinical studies, although good in theory, are unattainable and arbitrary.

The IRB process in this nation is out of control. It is a huge burden for universities to administer and to PIs, especially where non-clinical interventions are concerned. It is costly to administer,

and is on the verge of undermining academic freedom and freedom of speech. I will never do another study involving human subjects again, and I am someone who helps administer IRB policies on my campus. I am the messenger that many faculty members would like to shoot.

The OMB clearance process for human subject research is not only time-consuming but can delay the project by several months. Delays in moving paperwork (submission packets) from the funding agency to OMB add to the delay. These delays add cost for which we are not reimbursed. On two federally funded research projects I have to submit my human subjects research protocols to OMB as well as to 2 or 3 institutional IRBs. A second issue is caused by delays between notification of award and contract finalization — this can often take 3 or 4 months and delays our hiring of research personnel, and the start of the research.

IRB Recommendations

There should be a cap of a fixed number of hours dedicated to compliance/safety training/HIPAA/IRB, etc. It seems that people think of a new requirement and think that just adding another 5 hour mandatory training session is not a big deal. They should be forced to come up with ways to squeeze the training in a fixed number of hours per year.

The costs of the regulatory burden is having such a chilling effect on young clinical investigators that they are turning away from academic research precisely at a moment of unbelievable opportunity. Furthermore, the majority of these new regulatory burdens have added little to the safety of the process they were meant to help. Thus, research administration needs to understand that efficiency is not the enemy of safety. Streamlining the regulatory environment can be done with no loss of safety.

Things are out of control regarding IRB issues for large research domains where it is obvious that human subjects are not in any danger. There should be stratification. Certain lines of research have obvious risks and should be treated separately from other lines of research that are innocuous. The training required in the two cases should also be different.

I think another way to deal with the huge amount of time I spend on IRB applications, amendments, etc. would be to require institutions to use standard forms that are similar — or the same as federal grant application forms — and to encourage institutions to utilize IRB Authorization Agreements more often in the case of multi-site studies.

If there is not an improvement in the IRB process for clinical research, I believe many investigators will abandon this area of endeavor and concentrate on direct patient care. Something has got to be done about the ever changing demands of the IRB and their inconsistent approach to protocol review and informed consent form design.

The major problem with human subjects research is the time involved in IRB approvals/reapprovals, compliance. A National standardized program of IRB approval would greatly aid efforts in multi-site research. I spend the majority of my time working out differences between institutions for IRB compliance on the SAME project. It's a HUGE waste of time.

Extent of IACUC Burden

I am a devout supporter of humane treatment of research animals or any animal for that matter. Having said that, it is my strong opinion that the regulatory laws and paperwork regarding such are hindering research endeavors disproportionately more than they prevent harm to innocent animals. The cost to taxpayers of the regulation in time and real monies is staggering. Many of these animals are considered vermin in society and US laws allow their poison and painful destruction by a variety of methods yet millions of tax dollars are spent on governmental control of their use in research.

The IACUC burden, for me at least, has completely and absolutely overwhelmed all time savings achieved by shorter progress reports and modular grants. Those provide great savings. But, the IACUC protocol I have to write is as long as an NIH grant and a horrible waste of my time, the campus veterinarian's time and the IACUC's time. Moreover, the animal use protocol management is so stringent, that it would be virtually impossible to do any fast moving innovative research following new developments without violating the approved IACUC protocol. This may apply to me more than other investigators because of the species I employ, but the generalities are bound to be true across the board for investigators working on topics involving numerous live animals as subjects.

Focus on federal regulations! As one example, the Animal Care requirements are excessive. Ordering a few more mice (to compensate for a contamination, extra training, or a power failure) takes an amendment that has to be approved. At the end of a protocol period, this actually stops research! Madness! This is just one example. The strong federal reactions to even minor infractions have also developed a no-flexibility mentality. We are turning into FEMA!!! Science requires flexibility, as long as there is a reasonable explanation. However, we are now treated as if we are working in a shoe factory — where everything is predetermined and no adjustments are required. The impact this attitude will have on US science (and our economy) will not be trivial!!

IACUC Recommendations

Dealing with IACUC issues has been a significant burden, which is increasing, not decreasing. The federal government needs to rationalize and streamline the IACUC process and set some clear standards as to what is and what is not the purview of IACUCs. There should be a central, standardized NIH administered IACUC process for basic protocol review. Local IACUCs should be restricted to monitoring compliance. They definitely should not have the authority to pass judgment on the scientific merit of a research project. Particularly in the case of research with non-human primates, IACUC initiated impediments are driving researchers out of the field.

Extent of HIPAA Burden

The addition of a clinical protocol that has to be approved within DMID has added an extra 25% minimum of work to an already very heavy administrative workload. Coordinating between overseas site requirements, NIH requirements and university requirements is very difficult and extremely time-consuming.

HIPAA requirements have also seriously hampered our ability to recruit subjects so they make it even harder to and more expensive to do a project and raise serious concerns about the generalizability of results. When those problems are viewed within the context of the paranoia about OHRP and constantly changing local requirements that plague every annual review and any project amendments, just dealing with the IRB can easily become a full-time job. I work at least 80 hours/week. And my scholarly productivity has suffered because of the number of meetings, task forces, and strategy sessions I have to attend in order to keep a project going and get a proposal submitted.

In my line of research, HIPAA-related requirements have become especially burdensome. Although HIPAA does not preclude us from doing the same type of research we did before HIPAA, it creates tremendous hurdles that require many hours of effort and pleading to overcome. Despite this effort, we are still often unable to get the full cooperation of covered entities that could cooperate with us, and would have cooperated with us prior to HIPAA. The result is that our research has become more expensive and lower quality (because we can no longer obtain fully representative samples across multiple covered entities in the community).

I think HIPAA is one of the biggest problems in limiting accrual. We are severely hampered here by institutions not following HIPAA which allows activities preparatory to research but the hospital does not. We need to rely on busy staff to screen so it either doesn't get done or gets done sporadically. Also the IRBs across sites with different and sometimes competing demands require a person close to 50 percent for multi-site studies. It's become a nightmare.

HIPAA Recommendations

Current NIH policy regarding administrative support for federally funded research is cynical and a joke and everyone knows it! Such support is supposed to come from indirect costs but I know of no institution where that actually happens. Any and all such problems always fall on our (the investigators') shoulders. Plus, with collaborations at multiple medical institutions, I must employ someone full-time just to handle IRB and HIPAA (which some study sections just do not understand), and every hospital we collaborate with is different in their requirements. If there were uniformity, at least it would be easier. HIPAA regulations, which were supposed to deal with the insurance industry, have only made my problems finding appropriate subjects for my research not only harder but have also made it more difficult to stick to rigorous acceptance standards.

The Administrative Burden of University Regulations

University concern about federal auditing requirements has increased our work load noticeably in the past few years.

Our institution places a great deal of regulatory burden on investigators that is NOT required by the federal government. The modular budget for NIH grants, for example, is an excellent policy but doesn't help us here because our University requires detailed budgets. In addition, the regulatory burden with respect to IACUC regulations at this institution far exceeds federal guidelines (NIH and USDA), and border on abusive to investigators. There is a lot of federally funded faculty time going into meeting these burdens that takes away from research.

The university paperwork is overwhelming and the greatest deterrent to time on research.

I actually take more issue with the existing institutional "support" for administrative tasks. It is often not support at all and is often inefficient as well as ineffective. Written policies that are not comprehensible, that change frequently without notice, and the impossibility of obtaining consistent responses to questions necessitating multiple submissions of the same documents for approval, etc., waste a good deal more of my time than the actual requirements imposed by federal funding sources.

Having observed the research administration scene for many years at 3 universities both as investigator and Dean, I am struck by the failure of administration to recognize their duty to facilitate (not impede) faculty research.

Faculty Concerns Regarding the Current Research Climate

Negative Effect of the Current Research Climate on Science

A major problem with administrative/compliance burdens is not simply the time, but also the erosion of creativity and individual initiative. This is hard to address by a survey, but is the most important factor in driving the best students away from scientific careers.

In the face of NIH cutbacks, I am facing my division shifting more grant administrative tasks back to me. I am strongly committed to continuing my research but am very concerned that I am not receiving enough return on my indirects to support the administration of my grants. I am an MD who is R01 funded. My margin is very slim. I see most MDs going into private practice and not seeing research as a viable career choice.

I believe that we are in a crisis situation. As a more senior faculty researcher with over 200 publications and an active, productive lab, I face the very real prospect of having to close down my research program for lack of funds. A recent resubmission to NIGMS was perhaps the best grant application I've ever submitted. It got very positive critiques. Nevertheless, it was triaged. It was noted that it did not show exceptional innovativeness, even though almost all of the proposed experiments were based on new techniques that we have pioneered. There seems to be a serious decreased valuation on study sections for solid, in-depth research and a premium on sexy, trendy, and what I believe is somewhat superficial research. I believe that some of the most

solid researchers in the country, even those of us who have successfully obtained uninterrupted research funding for over 25 years, face the likelihood of closing our labs due to lack of funds. For those of us in our early 60s, this means in effect terminating our research careers. This is a major disaster for the country, crippling the basic science and technology machine just when other countries are becoming much more competitive.

Universities reward and encourage obtaining lots of research funding. The emphasis is clearly on dollar amounts, not on quality of science. The federal government is a willing partner in this graveyard spiral where more and more money is thrown into the system but the quality of science is going down. The emphasis on quantity rather than quality is everywhere: number of research dollars, number of papers, number of graduate students, etc. ... Salaries are directly tied to these numbers. Where is the encouragement for tackling high-risk, high-quality fundamental research? If that research does not take place in Universities then where? Universities have turned into research contractors. Advancing knowledge and understanding and higher education are not the goals anymore. The goal is to have the largest amount of research spending.

Negative Effect of the Current Research Climate on Faculty Motivation and Productivity

I discourage grad students from entering research stream — it is an awful quality of life with many, many evenings and weekend hours spent away from family to do the work that the university should be doing for us. As the fed demands have gone up, the university has not provided any help. It has to come from somewhere. We are picking up the slack — on our own time as there is not enough time in a 40 hour week to come close to meeting all of our commitments. So the 100 percent time is in reality about 150 percent and that is not just for me but for anyone who is successful. I would never have gone into this field if I had known what it would be like, and we talked our kids out of research completely. At this rate we will lose our edge in the next decade or so.

I pity the young faculty members in this day and age who have to work themselves so hard in the face of decreasing federal funding for research and increasing numbers of applicants. The point is rapidly approaching for many faculty members where the effort will no longer be worth the cost to themselves and their families.

I and my colleagues submit more federal grants than ever before, and although I remain committed to academic science, I question that career choice more often than I ever expected that I would.

The diversity of tasks I am expected to carry out has increased to the extent that it is overwhelming and has taken a toll on my personal life. I am exhausted all the time and flit from one badly executed task to the next.

Recent audits at several universities have caused a pendulum swing that has nearly crippled our ability to perform research. Instead of being supported, we are just told no, no, no. But no alternative solutions are provided so we either grind to a halt, or have to spend our time tilting at windmills. Many of us are getting burned out about the whole atmosphere within the university

now. One last thing. My understanding is that auditors are funded by a percentage of the disallowed expenses discovered. That seems to me to be a huge conflict of interest. I hope my information is incorrect, but if not, I think a different funding mechanism for auditors would be strongly advised to remove the perceived conflict of interest.

The Extent of Administrative Burden

Thanks for doing this survey, as the frustration in not being able to hire the administrative help we need is a) making me leave my department, and b) wasting the most productive years of my academic life. I calculate that I waste 35-40 percent of my time doing work that could be done by others. Ultimately this slows down my current research and potential research productivity.

My regular work week is approximately 70 hours. Therefore, my level of effort is well over 100 percent, if one has a base work week of 40 hours. To balance the teaching, service, and other responsibilities with an active research program as I have had for the past ten years, a 40 hour work week is not sufficient.

It is no longer possible for MDs to practice clinically and do research. They have cut out the services that would enable us to get our research done — nurses that take phone calls from parents and outside docs, etc. You need another entirely separate survey to approach the workload issues of medical researchers.

In 1970 I could devote 80+ hours per week to research. Now it is less than 20 hours per week because of all the forms we need to fill out.

The Future of the Academy Is Bleak

Domestic graduate students are far less likely to pursue academic careers than nonresident students. The most common explanation I hear is that the competitive grants program seems daunting to them and they doubt their ability to compete successfully enough to get tenure at an academic institution. The lack of funding is a significant deterrent for domestic students continuing their studies. Consequently, approximately 85 percent of our doctoral students in engineering are international students. The lack of federal funding for research is significantly impacting our ability to attract qualified US residents to graduate school. The current situation, and I am at a top tier university, is critical.

My students and technicians do not see the excitement and joy of science any longer. They simply see regulation and administration. I believe this is going to cause an incredible brain drain in the coming years. The best of the best will simply not be inspired to pursue careers in academic research (especially biomedical). Moreover, I expect that more PIs will opt to retire early, at least from the research component of their responsibilities.

If I were just beginning my career, I would not go into an area of research that involves laboratory animals, nor one that requires such an enormous burden of grant writing. Many of our

doctoral students are making that decision and are turning to other professional opportunities. The scientific manpower problem in this country is going to become a major crisis in coming years as students see the struggles that their mentors go through trying to keep their research funded and elect not to take the same career path. This certainly cannot be news to those who are concerned about these issues, but perhaps this survey will add more weight to the information available to policy makers and the Congress about this very serious matter.

The research burden — i.e., the preparation necessary to perform research, both animal and human (and I do both) — has in my opinion increased exponentially since I began as an assistant professor in 1997 and this burden keeps on being thrust back to the PI in order we are told to have accountability. If this continues it is highly likely that PIs will spend more time on administering research than on the creative aspects of science that are critical if any meaningful research is to be performed in the US in the future. While federal funding in real terms has declined recently, the bureaucracy associated with the funding has continued to increase. Taken to its logical conclusion the future of US science looks very uncertain at this point and I sense that students while they love research are not going to be attracted to academic careers where their future is uncertain and the very thing they entered academia for — the desire to use their curiosity and creativity to further scientific knowledge and advance human health — will become secondary to their ability to survive as administrators. In my opinion we are heading in the wrong direction.

If I was younger, I would bail. Private sector was difficult, but the recognition was based upon objective performance criteria, outcomes were tangible, and pay was higher (in my case 100% greater) than compensation at a university. If this continues, the only individuals interested in research careers will be those looking to emigrate to the United States.

Time spent acquiring and administering grants is an important factor discouraging graduate students from academic careers (particularly women). When they watch what it takes to be successful at a major research university they do not want the low salary and crazy lifestyle.

Back when I started as a PI (1982), the Office of Naval Research was interested in supporting research that trained graduate students. Now they are mission oriented and the funding for core programs has vanished. I can no longer count on funding that will last long enough to train a Ph.D. student, so I can no longer take Ph.D. students that do not have some other source of support. Instead, I can do application oriented research (for which there is much more funding), train MS students, and use professional staff to provide continuity on applied projects. A lot has changed in academic science and engineering, especially in the past decade. It is becoming fairly clear that America's leadership in science and technology is coming to an end.

Gender Issues

I am not sure what is meant by direct costs for federal grant administration. The bottom line is that I don't have a secretary to do anything for me. Thus, I xerox, print out letters, fax, etc., everything. I go to the library to get references. If I am lucky, someone sends out my grant or paper via the mail (although usually I am packing it up and sometimes bringing it to the mail

room). I do all my own referencing of documents/papers/grants. I format my grants and make my own figures for grants and papers. There is no one to delegate all of this to. The research assistant on my grants is busy with research – she does not have time to assist me in this administrative way. My grants office interacts with NIMH, but they aren't going to xerox for me. In part this is a gender issue — I notice more men in my department get more people to do things for them. In part, this is the problem with academic medicine — there are no resources to make things more efficient. You have to do it yourself.

There is an unpleasant gender element that is pretty transparent — in general the males get more grants because they are rewarded by the institution with more resources (they are often the “center” directors) and therefore can generate more NIH funding for all the obvious reasons. The signals being sent to students in the biomedical and life sciences are dreadful and if I were one right now I would sure run the other way unless something changes.

In my institution administrative support and help in grant submission is much greater for male faculty.

Issues Faced by Non-Tenure Track Faculty

Again, my situation is different than many other persons probably responding to this survey. I am a non-compensated affiliated researcher who is supported strictly by soft or grant funds and contract work. In this day and age, there are more people who are not in tenured or tenure track positions who are submitting federal grants or being ** subcontracted ** to implement a grant or act as a subcontractor on a federal grant. This is not acknowledged by this study. For those of us on projects affiliated with the University the entire idea that we are going to get administrative support for the administration and management of a grant is ludicrous. It just means more time at work to get the administrative and management work done in addition to the time to conduct the research or implement the project.

Reporting Concerns

Again, the requirement to post published manuscripts is a waste of valuable time by both PIs and administrative assistants. This should not be encouraged.

Web form entry and other forms are convenient for those receiving the forms, but can be horrific for those completing them. For example, it takes 8 or 9 entries for every publication for NSF Fastlane. Thus, it took a WEEK to enter the publications and other information from just one (very productive) grant. That is just silly and wasteful, and is just one example.

It takes a lot of time to comply with the ever changing requirements to submit proposals and reviews. (Yesterday and this morning it took me over two hours to upload a review to NSF Fastlane; this included an hour of telephone conversation with a Fastlane technician.) Longer term grants alleviate this problem to some extent.

I did not see anywhere in this survey a place to tell you what reporting requirements are completely out of hand. You only asked whether we'd rather do them or whether we'd rather commit more of the very limited federal funding dollars to doing them. This is a ridiculous situation. Examples: We write Prior Research Results sections in every grant proposal. Yet while I have been doing research the NSF has added online final project reporting which asks dozens of separate questions on human resources impact, K-12 education, patents, etc. One of the worst parts is the requirement to separate FINDINGS from ACTIVITIES. (Activity - we did this expts. Findings - we learned such and such. It is completely ridiculous trying to write these in two separate sections when you do a dozen experiments.) Why does our usual Prior Results section in our grant proposals no longer suffice? You are making us write reams of material that NO ONE READS!

My major complaint is not about needing more admin support (which seems to be the focus of this survey). Rather, the number of reporting requirements have changed and become significantly more time-consuming within the last 3 years. a) Travel reporting is burdensome. I would prefer a per diem approach. b) This university radically increased the number of online training certifications. All members of research teams (down to grad students) must carry out an online certification exercise. I find these requirements to be proliferating and do not genuinely promote the claimed goal of education about ethical and fiscal responsibility. We should receive a packet of information. The current system does not transfer much information to us researchers. c) It seems as if our time is being scrutinized more and more. Many of us work well over 60 hours a week, but nonetheless are required to account for our time in terms of hours on research vs. teaching vs. sponsored research, etc. While I can understand that federal payment of summer salary should require careful documentation and be auditable, I don't understand why I have to account for research time that is not drawing federal funding.

The inconsistency across federal agencies in the amount of detail and frequency of progress reports is horrific — truly — since we see them from multiple agencies. ... If they all essentially followed the NIH annual reporting this would be fabulous! Helpful to investigators and the university itself.

I spend too much time filling out progress reports that are read by 2 people (as opposed to real papers that are available to everybody ... hopefully read by more than 2!)

Rather than paying for staff to help with this, the agencies should improve their websites to deal with administration and reporting. NSF has done well in this, but much more is needed.

Accounting/Financial Concerns

Federal funding agencies should force all receiving institutions to treat federal funded research dollars separate from state funding. The stupidity and burden of managing grants often arises when federal research dollars that I raised are treated in the very same way as expenses of the State Correctional Facilities, i.e. purchasing rules, employment rules, etc. There should be federal guidelines and rules that supersede State rules.

Purchase of supplies, travel and equipment could be streamlined by providing researchers with a grant-related credit card with the records going to the grant administrators at the institutions.

In many cases agencies disallow certain expenditures claiming it is part of indirect costs. But yet it may not be and it appears there's no way to rectify that. A catch 22 situation for many PIs. (e.g. our University does not officially support TeX or provide any services, which is the main method use to publish !!! Hence I and my graduate students spend many hours typing in TeX documents, likewise doing illustrations etc. At national labs where I worked in the past this was all part of the support services and I spent my time on research and writing papers — not typing manuscripts etc.)

I think that A21 disallowable expenses are a gigantic problem since there are almost no discretionary funds available in Universities today. What genius thought that a scientist would not need to buy pens, printer cartridges, paper, and lab books with grant funds? Similarly very little money trickles down from indirect costs to pay for secretarial and administrative costs for individual scientists. Both of these rules, i.e A21 circular restrictions and indirect cost calculations providing secretarial and administrative support, are completely unrealistic.

I've been both industrially and federally (mostly DOD) funded throughout my career. The main problem I see with federal funding is the insistence that funding be consumed on schedule regardless of the substantive issues. I quit trying to support grad students for this reason, because I could not plan on suitable students being available to make it worth the trouble of dealing with the hassle with the budget surplus if they weren't.

The summer salary from grants system at NSF is set up as a research disincentive because you can only get 2 months of salary regardless of how many months you work in the summer on grants. They essentially force you to work for free.

I pursue research support from industry rather than the government. The proposal process is much smoother with fewer hassles. The feedback is more direct. Budget allocations and line item transfers are more straightforward.

A big hidden burden comes from the uncertainty of funding EVEN after a grant has been awarded. Not knowing if the support will actually come is nerve racking and disturbs the research greatly. Currently I have a federal grant that has been put on hold in the MIDDLE of the project. ... We hope that the money will come soon but what if it doesn't come? Should we start firing students and staff? or wait? We rarely have the luxury to have backup plans. I consider this a much bigger burden than having to write reports.

Concerns Regarding International Research/International Students

The number of foreign students and postdocs in federally funded research is rising exponentially. Many programs are now more than 60 percent foreign. These students do not qualify for any other federal assistance (REU, etc.) and must be paid for ONLY from federal grants. The administrative load for monitoring INS compliance, obtaining visas, entry permits, permits to

work at national laboratories, work permits, legal help, etc., for these students is staggering. There is no help at the moment in any federal program to deal with this issue.

In this era of ready international communications, I suspect there are many researchers who wish to maintain active studies with collaborators in other countries. Federal regs on grants are a MAJOR barrier to project success, to the extent that they may be interpreted to hold non-US institutions to US rules (e.g., take an English-language ethics exam for the IRB, no reimbursement possible for some international travel, no overhead to international partners, serious conflicts at US customs over research materials, unclear system for international FWA).

I do a lot of international research and administrative support for all kinds of visa applications and processing (especially in post-9/11 environment) as well as general communications. Getting things set up for people going back and forth, etc., is ESSENTIAL. This ought to be considered as a straightforward funding category.

Concerns about Technology Support/Funds

A growing part of the administrative chores is managing computers and information technology. I have a file server for my lab group, 7 desktop computers, and 5 laptop computers. All of these need regular maintenance, software licenses, software upgrades, networking, backup protection, etc. I have to do most of this myself. There is no more admin help for most tasks I do.

Relax the new restrictions on the purchase of computer equipment on direct cost funds. If a PI has no nonfederal funds, it becomes almost impossible to purchase new computer equipment for the lab and for the PI. An up to date laptop for the PI is the most important piece of equipment and is used for everything involved in research program, from writing grants and papers to storing data to writing reports, etc.

Need for System of Best Practices

There does not seem to be a system of best practices for central grant administration, which could help substantially. The people involved could benefit from better training. They could also significantly benefit from automation. They are far too dependent on tedious manual vs. computer based processes. Manually signed forms are required — digital signatures are not used, as they have been for many years in industry.

Agency-Specific Compliments and Recommendations

Compliments Regarding Specific Funding Agencies

The main burden on my time is IRB stuff. The modular budget, etc. — changes made by NIH over the last few years — have been VERY helpful. Now if we can only tone down IRB.

The actual NIH grant submission process has gotten easier over the past decade, and the abbreviated continuation reports required have been a great relief compared to when I started research in the late 1970s.

NSF is very good to work with — its electronic grant submission and administration are efficient and transparent. It would be great if the other federal funders could use NSF as a model.

The more we can couple publishing refereed journal papers with evidence of progress, the better. This is indeed encouraged by NSF and EPA.

NASA and NSF have been exemplary, in my opinion, in allowing P.I.s to get on with research with a minimum of hassle. Our research foundation also has been given authority to handle NASA and NSF grants locally with a minimum of permission-seeking from Washington. This has been very helpful and useful.

The NSF Fastlane system has been marvelous (after a couple of rough start-up years). The time I used to spend on tedious paperwork is much reduced. One improvement I'd like to see is a substantial reduction of the time between notification of grant approval and the arrival of funds.

Hats off to NSF support office for applicants. Their help service was by far the best in helping me foresee administrative needs.

Recommendations

DARPA

DARPA has turned to short term research and development oriented work. Funding for basic research has shown to be a wiser investment in the past. DARPA should get back to that.

VA

The bureaucratic overhead in the Department of Veterans Affairs is a huge drain on time and effort for researchers. Many mandatory activities make little or no sense for researchers, and a one-size-fits-all mentality geared to clinicians and administrators as opposed to researchers dominates decisions. Plus, the fact that VA researchers are hired on a funds-available basis with far less job security than mindless VA bureaucrats fosters a climate of second-class citizenry that makes federal research far less attractive than other university-based research.

NIH

Perhaps the most vexing part of grant management is figuring out how to do the electronic submissions and electronic reporting. For example, I have a single NIH grant (now in its 28th year) and forget from one year to the next how to navigate the Commons web site. There is absolutely no reason to require a new password each year, since this is hardly top secret stuff.

The problem is not so much with tasks that can be turfed to administrators, but tasks that I need to do myself. The most incredible example comes from volunteering to review for an NIH panel. This is an incredible time-sink that I consider a public service, I hate doing these. But what makes it worse is the probably 5 hours I've spent trying to figure out 4 (count 'em) 4 different web-based registration systems just to be able to be reimbursed for airfare. 1. DUNS (Dun and Bradstreet number) 2. CCR (Federal contractor registration) 3. NIH ERA Commons (where you post evaluations) 4. IAR (thread-based comment page)

While I like the idea of saving me time as an investigator, the often confusing staff contacts and assignments at NIH and the constant changes in NIH personnel and paperwork are more frustrating every year.

As for the problem of excessive time spent in writing and re-writing grants, it is essential that greater efforts be made to ensure continuity in the review of NIH grants. There are an increasing proportion of cases in which new reviewers are assigned to an A2 application, resulting in completely new sets of criticisms that an applicant cannot respond to because A3 applications are not permitted. This is causing serious demoralization and discouraging many junior faculty (as well as graduate students and postdocs who are witnessing the consequences). It would also be very helpful if one of the reviewers assigned to a grant was given the role of advocate specifically to avoid criticisms that may be unwarranted, and to guard against unfair or inconsistent reviews.

The amount of wasted time and effort from top to bottom is incredible. The very latest is a 9 page document to follow so the government can pay you \$200 for reviewing NIH grants. I'm just not going to do it anymore. The US government is out of control with this nonsense.

The time I spend working on IRB-related issues, both submitting and renewing protocols and maintaining compliance, is the chief regulatory activity that I spend time on that cannot be delegated to administrative staff. I have delegated about half of the total, but the rest I must do. This time has increased exponentially over the past few years and significantly hampers the ability to get things done. Both because of the time it takes, but also because of all the time lags waiting for either the NIH (for vulnerable subjects) or IRBs to respond/approve. In sum, productivity on my R01 is significantly hampered by IRB issues. Standardized NIH consent forms and protocol format would GREATLY facilitate this process, especially as relates to multi-center human research

I have to submit NIH grant applications under the conditions of my employment. Administrative problems have not increased greatly. Obtaining a good review of an NIH grant application has become much more difficult. Multiple reviewers often go in different directions, and their points of view are not reconciled. I am given three pages by NIH to respond to multiple reviews that have many, many particular criticisms. The bottom line is that the applicant has a much harder time revising an application. Much time has to be spent trying to guess what changes might meet with the reviewers' approval.

Factors that are only partially out of NIH control are leading to a huge windfall for consulting services with corresponding waste of institutional resources on paperwork and ancillary

personnel. Examples include [1] seminars and internal audits for compliance on HIPAA — a law which I believe adds close to zero added privacy protection over civil tort law for me and my patients yet adds a colossal financial burden to my institution, [2] overly strict compliance with limitation of fund use for a given grant proposal. While the latter is perfectly reasonable for a contract, it is inappropriate for grants. Some amount of leeway is necessary to allow free pursuit of the next set of concepts for a lab (egregious cases excepted) without inducing institutional anxiety regarding severe penalties (and resultant resource-wasting associated with hiring consulting firms and compliance related paperwork).

NSF

Since NSF is the major source of funding in my area of research, the extremely low hit ratio (of about 5 percent) is very discouraging. And so is the very questionable decision process, which is steered by Program Managers who have too much power and have been there for far too long.

The biggest problem with federally sponsored research (at NSF) is failure to adhere to review panel rankings, and the strategic over-reliance on NSF to conduct and lead the lion's share of competitive crop-related research, where emphasis on science heavily overshadows the need for application. We need a similarly sized (large or larger!) budget for accomplishing real applied goals, not just chasing scientific rabbits in one direction and then another. That way, both short- and long-term US needs will be addressed.

Requirements for inclusion of education and outreach in, especially, NSF proposals have created not just an extra administrative overhead, but also additional required activities that take away from research. I have seen a relatively low level of return on all this investment.

NSF needs to make the fastlane process for submitting yearly or final progress reports on active or expired grants as easy as it is to submit the proposals for these grants. PIs should be provided the opportunity to upload a single file or set of files of their own design which contain the desired information to complete these progress/annual reports.

PHS (Public Health Service)

Consider eliminating the concordance certification required for PHS grants using animals.

TRIO (Department of Education)

Federal Oversight of TRIO programs has been increasingly oppressive over the past three or so years and this has added a tremendous burden to budget management as Directors nationwide cannot rely that the law, the regulations and EDGAR will be adhered to as they have been written. The Office of TRIO programs seems to be able to make changes in regulations as they see fit without consultation with anyone, and this becomes confusing and has caused an undue hardship in reporting requirements and asking for special permissions for budget transfers that do not adhere to expanded authorities.

USDA

This questionnaire did not ask how much time is taken from research to prepare grant applications that are never funded. This is huge. Combined with the time of reviewers, panel members, etc., the cost of handing out money at the scope which USDA has it available is extremely high. The money would be much more productively used overall if it were simply given in equal shares to those researchers working on agricultural research. This would save enormous overhead time and provide a distribution of returns on investment that would likely be very similar to that obtained with the present system — but there would be significantly more dollars available to research due to the elimination of all the grant-writing and -reviewing overhead costs.

The survey misses the number one waste of academic research effort related to federal grants from the department of agriculture. The department of agriculture has many, many more dollars devoted to in-house research than it does to competitive grant programs. As a result, academic researchers spend a great deal of time, often using limited operating funds, seeking <\$300k multi-year federal agriculture grants with funding rates below five percent. In the meantime, our USDA counterparts, often across the street or even in the same building and doing essentially the same work, are funded at a level of \$350,000 per scientist, annually, on the basis of in-house “proposals” that receive nominal critical review and have funding rates of essentially 100 percent. That’s politics, not research, and you would have a big impact on what research could be accomplished with the public’s money if you could shift more USDA research funds into competitive programs.

Most of my federal research money comes through USDA Co-op agreements, which specifically exclude indirect costs and payment of graduate student tuition. My institution and other educational institutions with which I subcontract have over the past several years changed their policies and now include graduate student tuition remission charges in their fringe benefits calculations. Failure of the universities and the federal government to come to any agreement on handling fringe benefits in a way legally compatible with the USDA co-op regulations means I can no longer hire graduate students at my institution, nor can I subcontract with other institutions to hire graduate students. This has been a major interference with my ability to recruit qualified personnel for my research program, and greatly increases the administrative time it takes me to hire and subcontract with non-student job categories for people with appropriate skills. It also makes my and other institutions less willing than before to encourage seeking co-op agreement funding, rather than other kinds of grants, or to support administration of co-ops. Some change, such as allowing a small amount of indirect costs (even 5 percent would help), or negotiating some general agreement on a way to hire graduate students with a separate fringe benefit rate that does not include tuition, would ease my administrative burden and would make co-op funding through land grant universities more welcome to institutions in general.