A response to NIH request for information on optimizing funding policies and other strategies to improve the impact and sustainability of biomedical research.

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Abstract

Currently NIH has put out a request for information (RFI) to "Optimizing Funding Policies and Other Strategies to Improve the Impact and Sustainability of Biomedical Research". Here I open my response (unabridged version) submitted to this RFI. With the hope and intention of stimulating the scientific community to submit a response of their own as well as criticize, debate and use as resource, the points in this response.

the WINNOWER

SCIENCE AND SOCIETY

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ABSTRACT

Currently NIH has put out a request for information (RFI) to "Optimizing Funding Policies and Other Strategies to Improve the Impact and Sustainability of Biomedical Research". Here I open my response (unabridged version) submitted to this RFI. With the hope and intention of stimulating the scientific community to submit a response of their own as well as criticize, debate and use as resource, the points in this response.

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Introduction:

On April 2nd 2015 NIH put out a request for information (RFI) to solicit input from the scientific community regarding possible development of new policies and other strategies to improve the impact and sustainability of the NIH-funded biomedical research enterprise (NOT-OD-15-084). The deadline to submit a response is May 17th 2015. More information can be found at Rock Talk blog post. Response need to be submitted atthis website.

NIH intends to maximize the impact of taxpayer investment in biomedical research by A] maximizing the productivity and creativity of the research workforce it funds, B] ensure funding for a broad and diverse group of investigators studying a wide range of important questions. Comments were invited in the following areas:

1. Key issues that currently limit the impact of NIH's funding for biomedical research and challenge the sustainability of the biomedical research enterprise. We welcome responses that explain why these issues are of high importance.

2. Ideas about adjusting current funding policies to ensure both continued impact and sustainability of the NIH-supported research enterprise. We welcome responses that point to specific strengths or weaknesses in current policies and suggest how we can build on or improve them.

3. Ideas for new policies, strategies, and other approaches that would increase the impact and sustainability of NIH-funded biomedical research.

4. Any other issues that respondents feel are relevant.

Submission (unabridged) to NIH:

A*. Key issues that currently limit the impact of NIH's funding for biomedical research and challenge the sustainability of the biomedical research enterprise. We welcome responses that explain why these issues are of high importance.*

1. *NIH grant overhead costs*: In 1980s and 90s NIH grant overhead costs were capped at 25-30% and the universities and institutions were doing well and on a sustainable path (Ledford H. 2014). A change in policy to allow institutions to negotiate the overhead rates coupled with doubling of NIH budget (1998-2003) perhaps led to the unintended consequence of was ballooning of universities and institutional structure, wildly inflated research bureaucracy and administrative costs (Ledford H. 2014). Currently NIH pays around 50-80% in overhead costs which in some cases are as high as 103%!!! NIH pays $5.7 billion per year in overhead costs!!! Moreover, this money is NOT distributed equally to universities because of the independently negotiated rates. This is highly unsustainable and need to be addressed immediately, with a clear message to the institutions to stop expanding and rein in the operational costs and even close things that are not productive and not efficient in the current financial climate.

2. *Soft salary Principal Investigator (PI) positions*: Over the past decade universities and institutions have enforced a steady increase in soft salaries for faculty positions (salaries paid by grant money from NIH), another perhaps unintended consequence of doubling of NIH budget (Tilghman-Rockey report -TRR 2012). This again siphons (public) money away from the research grants to non-research purposes. Essentially, NIH is paying for institutional facilities and their upkeep, administrative costs, PI salaries and research expenses. What is the contribution of the institutions?? They essentially have no skin in the game, yet get the all benefits of discoveries made by PIs on NIH grant money. This is unsustainable and needs to stop!!!!

> "In addition to diverting research money into PI salaries, soft money salaries pose dangerous financial risks for both institutions and faculty, threaten collegiality, destabilize teaching commitments and discourage PIs from tackling creative, innovative but risky projects that are not guaranteed to put food on the table." – Bourne HR. 2012

3. *Funding principal investigators (PIs) in their non-productive years*: Sufficient published evidence exists showing highest creativity and productivity (across ALL fields of research) is between 30-40 years of age, including Nobel Prize winning work (Young Jo 2011, Falagas ME. et.al. 2008, Stephan PE and Levin SG. 1993). Productivity and creativity precipitously drops after age 50. During 1980s-2000 majority of NIH RO1 grants (>60%) were awarded to PIs in their early 30s, leading to major breakthroughs and discoveries. Currently,

majority (>65%) of grants are awarded to PIs over 50-55 age with average age of first RO1 to be 43 years (Rockey S. 2012). What is even more surprising is, a significant increase in number of grants awarded to people over age 65 – least creative and productive section of the research community. In essence NIH is NOT funding the most creative and productive section of the research community!! This funding structure is flawed and inefficient use of NIH (public) money and is skewed against the best interest of science, scientific community and the public interest which funds NIH.

4. *Translational research focus of NIH*: Over the past decade NIH has shifted focus and entered into the area of clinical and translational research. NIH spends 2% per year of its budget (which still is a significant dollar amount) in this area on creating drug libraries and drug screening facilities, which is a significantly redundant and misguided approach (Wadman M. 2012). Understandably NIH's goal is betterment of human health. However significant advances in clinical and translational research can only be built upon the foundation and framework of major basic science breakthroughs. Industries already have much larger drug libraries (millions of compounds with each company) and huge monetary investment (much larger than NIH investment) in drug screening, scaling, their testing and their industrial production. Industries due to their for-profit nature cannot invest in basic science which is high risk with less tangible outcomes. Hence, NIH should be investing in basic science research and not investing in something that the industries are already very efficient, good and better equipped at doing. Such investment is a monetary distraction from basic research which leads to ground breaking discoveries on which clinical and translational research stands. An anecdotal example is discovery of penicillin and antibiotics which was not done through a drug screen but was discovered during a basic science undertaking.

5. *Publishing of negative results*: NIH should acknowledge and take into consideration that it has a huge stake in the publishing of research business. Mainly because NIH is paying for the research publication costs. More important is that there is no outlet for negative results!! It is unimaginable how many times the same experiments and projects are repeated by various investigators across the research landscape just because negative results are not published. This is a waste of time, effort, human capital and precious NIH (public) money (Matosin N. et.al. 2014, Anderson G. 2012).

***B**. Ideas about adjusting current funding policies to ensure both continued impact and sustainability of the NIH-supported research enterprise. We welcome responses that point to specific strengths or weaknesses in current policies and suggest how we can build on or improve them.*

I am addressing these opinions with the assumptions of NO increase in NIH budget in near future.

1. *Capping NIH overhead costs*: Overhead costs on NIH grants are out of control, majority between 50-80% and some as high as 103% (Ledford H. 2014). Overhead costs should

be capped around 20-30% with adjustments for particular area of living. Within a particular geographical area all universities and institutions should have the same overhead amounts, eliminating favoritism and unnecessary negotiation burden and increased bureaucracy. These overhead costs are ONLY for maintenance and upkeep of the research laboratories where NIH funded research is conducted, not for bureaucratic, administrative and geographical expansion of university campuses. This should be implemented in phases over the next 10 years with incremental decrease in cap from 80% down to 30%. Capping overheads to 30% will send a clear message to Universities and institutions to stop and rein in the unsustainable growth at the expense of NIH (public) money. A 30% capped overhead is not unprecedented. This was the case before the doubling of NIH budget and the research enterprise was much healthier then. Other funding organizations like USDA also have a similar 30% capped overhead. Japan has a flat overhead rate of 30%, European Union no longer negotiates overhead rates and enforces a flat 25% overhead and United Kingdom calculates indirect costs on a per-project basis (Schiermeier Q. 2013). NIH should iron out the bureaucratic and administrative costs by implementing streamlined efficient regulatory requirements for grants. With this significant amount of NIH (public) money can then be spent on actual research rather than administration.

2. *Eliminating soft salary PI positions*: In order to make NIH grants more productive and sustainable, NIH grants should stop funding 100% PI salary. Institutions who hire the faculty need to show confidence in their decisions and invest in their own human capital (PIs) rather than in expansion of research facilities. NIH as one of the premier funding agency in biomedical research should exercise its tremendous leverage to push this reform. If an institution or university wants to be an NIH funded institution then at least 50% of its PIs/faculties salary need to be paid by the institution, with a push for 80% pay by hard money. This should be implemented slowly (over the next 10-20 years) with gradually reducing the NIH PI salary supplementation to <30% of the total salary amount. NIH should maintain a provision for supplementing some amount of PI salary (capped at 30% total, through all government funding including NI, NSF, and DOD etc.) for unusual circumstances. This will again ensure that majority of NIH (public) grant money actually goes towards conducting research.

At the end of this implementation period (10-20 years) for both overheads and PI salaries, if institutions fail to comply then they will have to forgo any stake in intellectual property and patents on discoveries made there using the NIH money (either overheads or PI salaries).

3. *Funding PIs in their most productive years*: NIH (Public) money should be granted in a way that is most productive and efficient to get the most bang for buck in order to make this biomedical research enterprise highly productive and sustainable. Scientist are most productive and creative between age 30-40 and productivity precipitously drops after age 50 (Falagas ME. et.al. 2008, Stephan PE and Levin SG. 1993). Hence, RO1s should be split 60-40 with 60% of grants awarded to PIs <50 years and 40% to those between 50-65 years of age. NO NIH grants should be awarded to PIs >66 years as this has been shown to be overall the least productive time of scientific career. Those PIs who are above age 66 and are still highly productive, their track record and their reputation should be enough leverage for them to secure funding from other non-government (private) funding sources. This will also help older PIs ease into retirement. These policies should be implemented gradually over the next 5-10 years. This will ensure that bulk of NIH grant money is going to the most productive and creative section of the

research community.

4. *Divestment from translational research*: Although only 2 % of its annual budget it is still a significant amount of research money that NIH is putting into translational research and drug discovery, an area that is far advanced in terms of technology and drug libraries in the industry sector (Wadman M. 2012). NIH should divest from translational and drug discovery research and invest it in basic science research where NIH is much better poised to make a significant impact.

C. *Ideas for new policies, strategies, and other approaches that would increase the impact and sustainability of NIH-funded biomedical research.*

1. *Personnel costs within NIH grants*: Personnel costs (salaries of post-docs, graduate students, technicians and research staff) forms a major bulk of research grant money. Personnel costs should be handled *independently* of research grant money. Money going for personnel costs should be divided into 2 piles. One should be used to push for employment of technicians and staff scientists collaboratively (in a shared fashion with respect to their expertise) within research clusters (of multiple laboratories). This will provide one possible source of employment for the current vast pool (40-80,000) of post-docs who cannot be absorbed into academia as PIs (Polka JK. et.al. 2015, McDowell GS. et.al. 2014). The second pile should be used to fund (a very limited number of) post-docs and graduate students *ONLY through competitive fellowships* (irrespective of their country of origin as long as they are conducting research work in US, at a US institution) and NOT through research grant money. These fellowships should *mandate* minimum standard living wages ($50,000/-) and benefits with cost of living adjustments depending on geographical area (Powell K. 2015). This should be possible to achieve with the significant decrease in the number of post-docs funded. These fellowships should NOT exceed 5-6 years per person (irrespective of number of post-docs they do). These policies should be rolled out gradually over the next 10 years. These policies will help significantly rein in the personnel costs for NIH grant money and also provide a means to monitor and manage the number of post-doctoral fellows and graduate students per PI and per department to create a more sustainable workforce within the research enterprise.

2. *Significantly reduce number of post-docs and graduate students to a sustainable level*: It is blatantly obvious that one PI training 10s of post-docs and graduate students for an academic career is an unsustainable scientific ecosystem. New policy that one PI should have only one graduate student/post-doc being trained for academic position. Other non-academic “post-docs” should be employed as technicians or staff scientists (employee status) with career goals outside academia. The more diversified portfolio of career goaled people a PI has in his group, the more he/she should be rewarded, and NOT for total number of post-docs and grand students being produced. Enforcement of humanistic living wages and benefits will also aid reducing the rampant employment of post-docs as cheap labor. This will generate a sustainable, balanced and efficient scientific enterprise. A case and point is the changes implemented in New Zealand research enterprise to make it more sustainable (Powell

K. 2015).

3. *Automation of routine procedures*: The engineering and technology industry had greatly benefitted from automation. Research enterprise should also push for use of automation of standardized protocols and procedures that are routinely used in research laboratories in form of core facilities. A very good case and point is the launch of Emerald cloud laboratories. This will significantly reduce personnel costs freeing up large amount of money for more investment in intellectual capital – research projects.

4. *Publishing*: NIH has a vested interest in publishing of the research conducted and in particular getting the negative results published as discussed above. NIH should invest in creating a centralized publishing outlet (free for NIH funded researchers). This will, at least to a large extent, prevent NIH from having to pay thousands of dollars per research article being paid to every single publishing journal. This will particularly help the junior faculty who are currently starved for research money. Also, negative results should be actively encouraged to be published here and serve as a primer go to source for evaluation of research projects and their feasibility for the entire research community. It will save NIH and researcher's money, time and effort.

5. *New tenure rules*: Tenure at universities and academic institutions should be void at the age of 66. This along with no NIH grants after 66 will incentivize the institutions and individual scientist who are not very productive, to retire. On the other hand those who still remain highly productive could be hired by the universities on a contract basis as consultants and/or contract researchers for their expertise and knowhow independent of NIH grants. This will free up significant amount of monetary resources for the universities and institutions which can hire up to two junior faculties for the salary of one retiring faculty member.

6. *Transparency*: Every effort should be made for making this scientific enterprise as transparent and accountable as possible; from knowing the number of post-docs and graduate students (Polka JK. et.al. 2015) to where exactly the overhead dollars are being used by the institutions. What kind of incentives (which are sometimes not very obvious) are provided to the PIs, institutions and researchers and what is their intended goals.

With the combination of overhead costs, PI salary, Personnel costs and publishing costs < 40% of NIH (public) grant money is actually spent on research projects. This is a sorry state of affairs and needs concerted, focused and persistent reform efforts slowly but surely over the next decade to make the scientific enterprise and workforce efficient and sustainable.

Disclaimer: The above opinions are those of this author only and do not represent the views of the Tufts University or any other organization or society this author is associated with.

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