HARVARD MEDICAL SCHOOL | OFFICE OF The Dean of the Faculty of Medicine

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Francis S. Collins, M.D., Ph.D.
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RE: Feedback on the proposed NIH Grant Support Index (GSI) policy

Dear Dr. Collins:

We appreciate being asked to provide input on the proposed NIH policy that would limit the number of grants that may be held by any individual investigator based on a recently defined Grant Support Index (GSI).

Although we have serious concerns about the proposed policy, which we explain in the four questions at the end of this letter, we strongly agree with the stated goal of the proposed GSI cap. In particular, we agree that there needs to be a greater share of NIH grant funding provided to (i) early-stage investigators seeking a first grant and (ii) mid-career investigators, who risk falling out of the system if their sole grant is not renewed or is significantly delayed.

We believe that an effective solution would be to create a new "targeted mechanism" to direct a guaranteed proportion of NIH's extramural grant funds to specifically support early-stage investigators seeking their first grant and mid-career investigators with a single grant, who are at risk of falling out of the system. Such a policy:

- Would be maximally effective at helping the desired groups;
- Would not create the serious unintended negative consequences that would result from the current proposal;
- Would allow individual NIH institutes the flexibility to manage the allocation of their portfolios; and
- Would maximally retain the value of the current peer review system.

We believe that a "trickle-down approach" such as the proposed GSI cap would have serious drawbacks—as outlined below—and that the targeted, direct funding of early-stage and mid-career investigators would be much more effective in fostering the talent pipeline necessary to maintain the pre-eminence of the United States in biomedical research.

I. Questions and Concerns Regarding the Proposed Policy

We have serious concerns about the proposed policy—specifically:

- The policy is unlikely to be effective in achieving the desired goals, while a targeted mechanism would be more effective in doing so.

- The policy relies on analysis that does not appear to be technically sound.
- The policy relies on analysis that does not appear to be conceptually sound.
- The policy would have major unintended negative consequences for biomedical research.

Our concerns are the results of robust discussion with colleagues on our campus and across the research community. We believe that the NIH should seriously consider the concerns outlined below and instead adopt an alternative, targeted approach.

We consider four questions that capture our concerns.

(1) Will the proposed policy achieve the intended goal, or would a different approach be more effective?

The stated goal of the proposed GSI cap of 21 points is to address a critical concern about the scientific workforce by ensuring that a greater share of grant funding is available to (i) early-stage investigators seeking a first grant and (ii) mid-career investigators, who risk falling out of the system if their sole grant is not renewed or is significantly delayed.

As noted above, we strongly agree with the importance of addressing this problem. However, there is no clear evidence that the proposed "trickle-down approach" would significantly increase funding to those who need it most. Instead, the proposed cap system may simply result in much of the funding that is freed up going to individuals who have stable research programs funded by 1 or 2 NIH grants.

(2) Is the proposed policy based on evidence that is technically sound?

The proposed GSI cap is based on an analysis of the relationship between investigators' level of grant support (as measured by the GSI score) and productivity (as measured by a weighted Relative Citation Index).[1] The analysis has been interpreted as implying that productivity shows dramatically diminishing returns for GSI scores above 21.[2]

However, many technical concerns have been raised about these analyses, including:

a. It is unclear whether the productivity metric actually undergoes a substantial flattening around GSI = 21.
b. The GSI is based on an arbitrary point system with no objective justification,[3] in which the choices can spuriously create or enhance the appearance of a productivity decrease.[4]
c. The analysis combines data from 1996 to 2014 without examining differences across this 18-year time span.

[1] https://nexus.od.nih.gov/all/2017/01/26/research-commitment-index-a-new-tool-for-describing-grant-support/; https://nexus.od.nih.gov/all/2017/02/15/following-up-on-rci-tool-describe-grant-support/.

[2] An online, non-peer-reviewed preprint and supplementary materials containing some of these data were published on May 26, 2017; doi: https://doi.org/10.1101/142554

[3] The point system lacks any objective justification. As noted in Dr. Lauer's blog post, the GSI was "conceived" by a committee of NIH administrators, based on their personal views of the commitment typically required by a PI for each type of grant mechanism. The group was led by the Director of NIGMS, who has been a strong advocate for imposing a cap on grants.

[4] For example, two co-PIs on an R01 are each "charged" nearly the full number of points for the R01, but would each seem to be "credited" with only half the output of the R01.

d. The analysis conflates correlation with causation, without analyzing the internal structure of the data.

(3) Is the proposed policy based on analysis that is conceptually sound?

The NIH analysis is premised on the notion that the Relative Citation Ratio (a newly defined metric that has not been subjected to independent validation[5]) reasonably captures the true value of NIH grants to the US biomedical research enterprise. This assumption is deeply problematic for many reasons, including:

a. It completely ignores other critical contributions of research projects—such as the number of trainees who have gone on to postdoctoral fellowships or to start their own labs; the number of patents or licenses granted as a result of the discoveries; the number of private business ventures that have been initiated based on the funded research; and the number of drugs, diagnostics, or medical devices developed as a result of the work.
b. It assumes that NIH grants under very different mechanisms (R01s, P01s, centers, training grants) can be meaningfully compared on the basis of their RCR per GSI point. Yet, there is no evidence to support this assumption.[6]
c. Even if one focuses only on the citation impact of R01s, it assumes that the value of scientific papers scales linearly with the RCR score.[7]

A conceptually sound analysis of the full impact of NIH grants requires much more than a simple consideration of citation impact. This is especially so when making comparisons across different types of grants.

(4) Will the proposed policy have major unintended negative consequences for biomedical research?

Achieving the NIH's mission requires a diverse portfolio of scientific projects.

The NIH portfolio includes **collaborative projects** (such as center grants, program grants, and clinical networks) and **resource-creation projects** that support the scientific community (such as generating large freely available datasets, developing and maintaining software packages, and creating and maintaining facilities). These efforts are not only essential for overall scientific progress, but such projects also provide major benefits to early- and mid-career investigators by:

a. Providing these investigators with opportunities to participate in cutting-edge efforts and networks, in a manner that enhances their own productivity and exposes them to direct mentorship by colleagues; and
b. Producing community resources that increase their productivity.

[5] The RCR metric was first described in a September 2016 paper by four NIH administrators. The paper sought to validate the metric by comparing RCR scores with various categorical assessments. It is difficult to evaluate the conclusions, because the paper provides only a limited description of the methodology and results. Notably, the authors did not attempt to validate the RCR metric on papers arising from NIH grants *other* than R01s. Given its recent publication, the RCR metric has not yet been the subject of meaningful validation by others.

[6] As noted in the preceding footnote, the paper that introduced the RCR metric did not attempt to validate the method on papers arising from NIH grants other than R01s.

[7] For example, the analysis implicitly assumes that five papers with *n* citations have equal scientific value as one paper with *5n* citations. Alternatively, the *impact* of scientific papers might be better described by a power law of their RCR score.

The NIH portfolio also includes training grants to develop the next generation of scientists (including T32s and other training mechanisms). These grants are crucial to workforce development.

The proposed GSI cap would have a devastating effect on US biomedical research:

- It would discourage interdisciplinary collaborations at a time when team science is increasingly recognized as a key path to discoveries and approaches in the future.
- It would create major disincentives for investigators to lead important efforts that extend beyond their own laboratories and benefit trainees, other investigators, and the scientific community at large—because they would be penalized in their ability to obtain research funding to support their individual laboratories.
- It would discourage more established investigators from collaborating with less established investigators.
- It would seriously impact the ability of senior investigators to lead training grants, which are critical for the development of future generations of scientific leaders.

Moreover, capping these types of grants would not be justifiable as a matter of good public policy, because we have not assessed the impact of these grants on the US biomedical research enterprise (indeed, we currently lack validated metrics that capture their scientific value).

The NIH should not penalize scientists who lead such efforts as centers, program grants, clinical networks, resource-creation grants, and training grants. Such grants should be excluded from any system designed to limit the number of grants.

II. Conclusion and Recommendations

To ensure that the United States continues to lead the world in transformative scientific discoveries, it is essential that the best researchers at all stages of their careers can access the necessary funding to support their research programs. Providing career stability to early- and mid-career investigators is a critical goal.

We need a policy that (i) is supported by strong evidence; (ii) effectively achieves the intended goal; and (iii) does not create major unintended negative consequences.

We have no objection to a policy that focuses on increasing career stability for early- and mid-career investigators.

However, we believe that a "targeted mechanism" is far superior to a policy that limits grants based on a GSI cap because (i) it would be maximally effective at helping the desired groups; (ii) it would not create the serious unintended negative consequences that would result from the current proposal; (iii) it would allow individual NIH institutes the flexibility to manage the allocation of their portfolios; and (iv) it would maximally retain the value of the current peer review system.

We would note that current NHLBI policy provides an example of such a targeted mechanism (https://www.nhlbi.nih.gov/research/funding/general/current-operating-guidelines).

We encourage the NIH to continue to engage the scientific community in discussions to develop a policy that will best fulfill NIH's mandate to serve the nation through support of the best portfolio of scientific projects and responsible development of the scientific workforce.

Sincerely,

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