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Interim Research Product RFI
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To Whom It May Concern,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide input on the use of interim research products in grant applications and reports to the National Institutes of Health (NIH) as proposed in NOT-OD-17-006. FASEB is comprised of 30 scientific societies, collectively representing 125,000 biological researchers and engineers. Member societies and the Federation itself oversee the publication of over 60 peer reviewed scientific journals. Therefore we offer an important perspective as NIH contemplates balancing rigorously reviewed works with "findings in progress" when considering applications for research funding. While we acknowledge the changing landscape of research publications and the successful use of preprints in the physical sciences and mathematics, we do not support the inclusion of preprints or interim research products in NIH grant applications and reports at this time. Our comments highlight five concerns:

1. The lack of a clear definition of "preprint" and a method for distinguishing work that has undergone some form of peer review
2. The risk of an increased workload and burden for study section reviewers
3. Negative effect on rigor and reproducibility of research in absence of peer review
4. Challenges of balancing application criteria to ensure sound science while supporting early career investigators
5. The need to provide stakeholders with ample time to accommodate to potential changes in application policies

The lack of a clear definition of "preprint"

A core challenge will be defining what constitutes a preprint or interim research product. Without a clear definition, there is no way to distinguish between a paper submitted to an archived journal, peer reviewed, and accepted by an editorial board for publication from a self-published document of preliminary ideas. One thing that is clear to our community, however, is that it is a work that is fundamentally different from one that has been subjected to rigorous peer review. In other disciplines, part of the allure of submitting work to preprint servers is the opportunity to share "in progress" findings for collaborative discussion. While FASEB and its member societies encourage and support active discourse about the outcomes of research studies, we also believe that there must be a clear distinction between findings that have withstood the test of peer review and those that are "works-in-progress," albeit subjected to on-line public critique. To be referenced as part of an NIH grant application, preprint and interim research products should already have a permanent digital object identifier (DOI) and be accessible throughout the application and funding process to standardize these entities. Similarly changes or updates to findings resulting from public comment must be recorded and highlighted in subsequent grant reports. Until such systems are mature, we find the use of preprints in peer review to be problematic in that they would be a source of non-uniformity in sourcing and posting of such materials. Similarly, public release of clinical findings that have not been validated in preprints may mislead the public.

On the other hand, large annotated datasets produced from genetic, ribosomal, or proteomic screens represent a form of interim research products that should be considered separately. These data rich resources can be managed in a more uniform manner than preprints for quality and attainment of respective discipline standards. We suggest that NIH issue a separate RFI requesting input regrading large annotated datasets, software, and computational methodologies as a distinct category of interim research product. The remainder of our comments is restricted specifically to preprints as an interim research product.

The risk of an increased workload and burden for reviewers

As NIH contemplates the value of allowing applicants to cite preprint and interim research products in grant applications, we strongly recommend that you consider the impact on an already overly taxed peer review system. At recent meetings of the Center for Scientific Review (CSR) Advisory Council meeting, Richard Nakamura, PhD, CSR Director, reiterated concerns about staff and reviewer workload resulting from steady increases in the number of grant applications. While we acknowledge that typical grant application reviewing practice does not obligate a reviewer to critique supplementary data, reliance on materials that have not been rigorously peer reviewed, such as preprints, may put additional pressure on study sections when considering elements of the proposed research. Thus, we urge you to work with CSR to

determine potential effects on staff and reviewer workloads prior to implementing any changes to application policies. Similarly, we are concerned that preprints and interim research products could be used as a strategy to bypass grant application page limits when describing scientific premise. Therefore, allowing them to be included in grant applications will burden reviewers with the additional responsibility of assessing the merits of a potentially unlimited volume and heterogeneous works in progress submitted in support of a research proposal.

Negative effect on rigor and reproducibility of research

To respond to growing public concerns about the rigor and reproducibility of federally funded research, NIH recently updated its application guidelines. Applicants are now expected to address the general strengths and weaknesses of prior research cited as part of the basis of the proposed research in addition to describing how they will ensure robust and unbiased results, consider sex-based variation, and authenticate key biological and/or chemical resources. Although the research community agrees that these are important checkpoints to include in the application, incorporating preprints and interim research products not subjected to peer review in applications for NIH grants would reduce rigor and reproducibility in the assessment of applications. As previously noted, relying on non-peer reviewed material as a source of data supporting rigor and reproducibility would put the onus on the reviewer to gauge the authenticity and quality of such data.

Challenges of balancing application criteria to ensure sound science while supporting early career investigators

A key component of the success of the U.S. research enterprise is its adherence to stringent peer review of both applications for federal funding and research publications. This is the cornerstone of academic research. Effective review of both grant applications and research publications requires time, and we appreciate that early career investigators may be at a disadvantage in terms of supplementing their proposed work with relevant peer reviewed works. Therefore, the only appeal of the citation of preprints in grant applications is that it may allow early career investigators to demonstrate current progress in support of a broader research proposal.

The need to provide stakeholders with ample time to accommodate potential changes in application policies

NIH's challenge as steward of taxpayers' funds is to balance effective stewardship with minimal regulatory burden. During the past few years, we have seen several changes to the NIH investigator biosketch. The number of pages allowed for a grant application has been reduced

while the amount of information required to sufficiently describe the experimental design has increased. All of these changes have been implemented with limited lead time and communication with the community, leading to confusion and frustration for applicants, administrators, and reviewers. If NIH chooses to change grant application and reporting policies to allow the inclusion of preprints and interim reports, we strongly urge that you clearly communicate the timeline and reasoning for these changes and offer resources, such as guidelines, templates, and training resources to ease the transition to new expectations and formats for both applicants and reviewers.

In conclusion, FASEB does not believe it is appropriate to allow the inclusion of preprints and interim research products in NIH grant applications. Until NIH can provide a clear definition of preprints and the criteria for inclusion in grant applications, ensure that they will not excessively increase reviewer workload, and that they enhance – rather than detract – from the rigor and reproducibility of research activities, we recommend that NIH not change its application policy regarding citation of these products.

FASEB appreciates the opportunity to provide comments on this important issue. Please do not hesitate to contact me if FASEB can provide further assistance.

Sincerely,

Hudson H. Freeze, PhD
FASEB President