Cornell University

Office of the Vice President
for Research and Innovation
Krystyn J. Van Vliet, Ph.D.
Vice President for Research & Innovation
222 Day Hall
Ithaca, New York 14853-2801
t. 607.255.7200
krystyn.vv@cornell.edu

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Submitted electronically

TO: https://rfi.grants.nih.gov/?s=646e6654a8ba09024f09e852
Xanthia James, Director
Division of Grants Policy, Office of Policy for Extramural Research Administration
National Institutes of Health (NIH), Bethesda, MD 20817

RE: Cornell University comment submitted in response to NIH Request for Comment on NIH Grants Policy Statement (NIHGPS), Section 15.2 (88 FR 36603)

The U.S. National Institutes of Health (NIH) published plans to update NIH Grants Policy Statement (NIHGPS) Section 15.2, which outlines the requirements for consortium/subaward agreements on NIH-funded grants. The proposed update to Section 15.2 imposes new requirements on international subawardees of NIH agreements to "turn over all records to the primary recipient at an agreed upon frequency." The policy statement refers to international subawardees as foreign subrecipients, and gives examples of that record turnover to occur "no less than once every six months, or more frequently based on risks."[1]

Cornell University appreciates the intent of requirements for responsible data sharing and technical reporting among all sponsored research participants, including for NIH-sponsored research consortia. Cornell also understands and is committed to fulfilling obligations to research sponsors, including processes that ensure the integrity of the research and promote the positive societal impact of the research outcomes. We support the NIH policy requirements of formal written agreements among parties participating in sponsored research, including signatures by the principal investigators (PIs) at each participating institution of a sponsored research consortium. At the same time, we recognize that like all top U.S. research universities, Cornell's researchers come from all over the world to conduct research in the U.S., and Cornell researchers also collaborate appropriately with and recruit top researchers from other U.S. research institutions and international research institutions. Thus, Cornell – as a research university that includes NIH-sponsored research led by faculty principal investigators in the Cornell University colleges, Cornell Tech, and Weill Cornell Medicine – offers comments to convey concern with the policy as described.[2] Cornell also supports the comments and concerns expressed by the Council on Governmental Relations (COGR)[3] on behalf of over 200

[1] https://www.federalregister.gov/documents/2023/06/05/2023-11897/notice-to-announce-nih-updated-policy-guidance-for-subawardconsortium-written-agreements

[2] https://rfi.grants.nih.gov/?s=646e6654a8ba09024f09e852

[3] https://www.cogr.edu/sites/default/files/Response%20to%20NIH%20subaward%20notice%20June%2030%202023%20-%20FINAL_0.pdf

public and private U.S. research institutions including Cornell.

The policy update as drafted includes significant new requirements of information sharing frequency and specificity, only for international subrecipients rather than all subrecipients domestic and international. This provision is stated as item 11 in the proposed update[1]:

> "For foreign subrecipients, a provision requiring the foreign subrecipient to provide copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report. These supporting materials must be provided to prime recipient with each scientific update (no less than once every six months, or more frequently based on risks) in line with the timelines outlined in the agreement."

Cornell offers three areas of concern associated with this provision, regarded as an unnecessary additional requirement because of its:

1. Chilling effect on international research collaborations, with anticipated negative effects on U.S. research excellence and impact as well as on the wider pool of international scholars contributing to U.S. research over decades. Focusing this requirement only on international subawardee organizations, rather than on both U.S.-based and international subawardees of research consortia, appears inconsistent with the risk mitigation intent of the new requirement. While it is reasonable to expect all subrecipients to provide the prime recipient with appropriate documentation to support research outcomes, it is not clear why risk is mitigated by limiting this requirement to international subrecipients for a given research consortium. The anticipated reaction from international experts and research sites to an implicit signal of distrust and perceived high-risk based on research site location (i.e., categorization as a foreign subrecipient) will be to recede from such research collaboration opportunities.

   This is not a hypothetical reaction; many current international research teams comprising PIs located at multiple U.S. institutions and international research institutions have shared concerns about the eroded trust and uneven impact on their research teams. Imagining this requirement to be reciprocated by another country for subawardees at U.S. research institutions, the reaction among U.S.-based PIs and those responsible for promoting translation of research outcomes within the U.S. is sharply negative. This reaction is shared even and especially when the participation of the international subrecipient is key to the research outcomes of the U.S. prime recipient, and when all members of the research team agree that timely sharing of technical report summaries is best practice and an understood obligation of NIH-sponsored research.

   Cornell respects the requirements to meet sponsor obligations whether as the prime recipient or the subrecipient, and also finds that international research collaborators are increasingly important to advance human health-related research and research outcomes. This policy change as proposed appears contradictory to NIH's championing of a biomedical research workforce that is, in the words of NIH, "greatly enriched and strengthened by scientists working together from many parts of the world".

2. Implementation resource burden, particularly for international collaborators from less well-resourced countries and institutions. Whether this requirement were to be added to international subrecipients or to all subrecipients of NIH-sponsored research consortia, the suggested policy update is overly broad, vague, and burdensome in the type of and frequency of information reporting required.
    a. To the extent that in 2023 NIH already updated the data sharing mechanisms with plans required at the proposal stage, these can be utilized for risk-based assessment of sufficient data sharing plans during proposal and annual monitoring stages. Some research project plans may merit more detailed data sharing plans or more frequent than annual technical updates, but that subset of sponsored research could be assessed by NIH at time of proposal and upon annual monitoring under current policy.
    b. Increasing the frequency of reporting beyond annual milestones requires additional time of the researchers who generate the data as well as research support teams or systems that communicate those data. This represents real additional costs associated with additional technical reporting materials and increased frequency, over and above the required data sharing plans, for the prime recipient and the subrecipients; for existing recipients, such costs were not included in the original project budget.
    c. For international subrecipients that also receive limited financial support of indirect costs (8% of modified total direct costs), this requirement also imposes additional financial strain. Moreover, it is not uncommon that international subrecipients in health-related research consortia are located in countries or regions (e.g., the African continent) in which it is practically difficult and expensive to transmit research information by secure electronic communication through wired network connections or physical transfer; there is no economy of scaling to do so with increased frequency in these under-resourced yet valuable research collaboration sites.
    d. The types of data and information required as stated are vague, and perhaps misaligned with the intent of risk mitigation and research integrity assurance. Access to raw data or lab notebooks may result in high information volume but less substance than the technical reporting and annual sharing of curated, validated, annotated, and processed data products (i.e., *scientific data* used to support research outcomes, even if unpublished). Simply put and as NIH is aware, the information gathered may not be of sufficient quality to validate research findings or mitigate other perceived risks.
    e. Lab notebooks are not considered *scientific data* per se, even though part of the practice of research. It is also acceptable research practice to manage lab notebooks in local languages, and the potential for error propagation in translating or interpreting such information is high; curated and synthesized data in annual technical reports can provide more insight and opportunity for risk mitigation as warranted.

3. Convolution with reasonable data privacy concerns associated with sharing primary data and notebooks, rather than research outcomes and data required of specific research data integrity investigations. NIH sponsors extramural research ranging from

"basic" study of fundamental molecular and cellular mechanisms of health and disease to population science and translational science (among other topics). Research collaborations, international and domestic, can proceed effectively without direct sharing of primary data related to human subjects. Data use agreements can enable this among research collaborators both domestic and international, and these take time and care to negotiate in order to enable collaborative research. Creating new, additional, and broad data sharing requirements may also create confusion among parties, elicit conflicting expectations, and delay research progress when considering data to which privacy concerns attach for human subjects and/or technology.

Cornell supports an approach by NIH to use existing NIH policies and NIH review of data sharing based on NIH's risk-based assessment (of the proposed research scope, proposed data sharing plan, and specific research locations). We appreciate the opportunity to provide comment on the proposed policy change.

Sincerely,

Krystyn J. Van Vliet, Ph.D.
Vice President for Research & Innovation
Cornell University