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ALERT

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NIH Tightening Grant Requirements for International Subawards: Prime Awardee Obligations to Collect Research Data and Records from Ex-U.S. Subawardees

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On May 19, 2023, the National Institutes of Health ("NIH") released updated grants policy guidance requiring that each primary awardee institution impose on foreign entity subawardees an obligation to provide to the prime awardee all relevant research records (including data and lab notebooks), and to do so at an agreed-upon frequency of not less than every three months.[1] The Updated Policy Guidance, which takes effect on October 1, 2023, adds this new requirement to Section 15.2 of the NIH Grants Policy Statement, specifically targeting subawards to foreign subrecipients.

Informed by audits by the HHS Office of Inspector General and Government Accountability Office, the Updated Policy Guidance is an effort to strengthen the existing requirement that "the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements." These new requirements may be viewed as part of the government's broader effort to impose accountability—including substantive scientific accountability—on prime awardees' stewardship of subawards to foreign entities that largely lie outside of U.S. jurisdiction. These new requirements may also be viewed as limiting the ability of foreign entities to misuse or divert federal research funds. As explained below, prime awardees will need to take steps to ensure compliance with this heightened responsibility, in particular, modifying their contracts with foreign subawardees and stepping up monitoring of those subawardees.[2]

Under NIH Grants Policy Statement Section 15.2 ("NGPS Section 15.2"), NIH funding recipients (*i.e.*, "prime awardees" or "pass-through entities") that seek to utilize subrecipients must enter into "formal written agreement[s]" with those subrecipients, and the associated agreements between the prime awardees and subrecipients (*i.e.*, subawards) must include all provisions set forth in NGPS Section 15.2, including those addressing the ownership and disposition of data produced under the federal project.[3] The Updated Policy Guidance adds a new requirement to NGPS Section 15.2 pursuant to which the written agreement (*i.e.*, subaward) between the prime awardee and the subrecipient must include, "**[f]or 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.**"[4] The Updated Policy Guidance further states that the supporting materials "**must be provided to [the] prime recipient with each scientific update (no less than once every three months) in line with the timelines outlined in the agreement [between the prime recipient and subrecipient]**."[5]

The Updated Policy Guidance details the following additional revisions to NGPS Section 15.2 to emphasize NIH's commitment to conducting oversight of subrecipient arrangements and ensuring compliance with NIH requirements regarding subrecipient arrangements:

- Clarifies that NIH "will not support" any agreement between a prime awardee and a subrecipient that fails to meet the requirements of NGPS Section 15.2, and that any such failure to provide required documentation "may lead to remedies for noncompliance and potential enforcement actions."

- Reiterates NIH's right to request copies of the written agreement between prime awardees and subrecipients as well as any other supporting documentation relevant to NIH's oversight responsibilities, emphasizing that prime awardee failure to provide any requested documentation could lead to "remedies for noncompliance and potential enforcement actions…"

- Encourages prime awardees to "ask potential subrecipients, at the application stage, to submit language in their letters of support indicating their awareness" of the requirements of NGPS Section 15.2 as well as their "willingness to abide by all requirements should an award be issued."

- Clarifies that the written agreement between prime awardees and subrecipients must be (1) signed; (2) agreed to by both parties; and (3) inclusive of all required terms in NGPS Section 15.2.[6]

This update to NIH policy underscores the importance of prime awardees' compliance with existing federal requirements for subawards, as set forth in the Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (the "Uniform Guidance")[7]. Specifically, the revisions to NGPS Section 15.2 reinforce a Uniform Guidance requirement that all federal funding subawards include "a requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part."[8]

Uniform Guidance requirements for subrecipient monitoring and management include reviewing performance and financial reports to ensure compliance with the prime award, following up on any deficiencies identified by the prime awardee to ensure that the subrecipient takes timely and appropriate corrective action, and resolving any audit findings related to the subaward.[9] Prime awardees must also evaluate subrecipients' risk of non-compliance (*e.g.*, looking to subrecipients' prior experience with similar awards and the results of past audits).[10] These monitoring requirements can be more challenging to implement successfully when working with foreign subrecipients as compared to U.S.-based subrecipients. Because they may receive U.S. government research funds only episodically, foreign subrecipients may lack infrastructure to support adequate recordkeeping and records preservation (*e.g.*, compliant accounting procedures, compliant competitive bidding procedures, time and effort reporting) and may have a limited or nonexistent track record on the basis of which a prime awardee could judge the subrecipients' ability to adhere to required federal grants terms and conditions.

The Updated Policy Guidance emphasizes the message that prime awardees must bear responsibility for subrecipient oversight and adds specificity to existing guidance regarding how such oversight must be conducted with respect to foreign subrecipients. The level of granularity imposed on foreign subrecipients—regular provision of "all lab notebooks" and "all data" to the prime awardee—is not often implemented in collaborative research activities funded through subawards. This new requirement will necessarily increase accountability of foreign subrecipients, but prime awardees will bear responsibility for compliance with this new requirement, which effectively serves as a *de facto* requirement that prime awardees regularly monitor foreign subrecipients' source documentation and research data for completeness and proper retention.

Research institutions will need to consider how to implement these new requirements within their existing sponsored programs and principal investigator oversight infrastructure, as the Updated Policy Guidance has implications for both pre-award and post-award processes. For example:

- Instituting more robust processes for vetting potential subrecipients in the pre-award process (in particular, foreign subrecipients subject to these new record-sharing obligations in the Updated Policy Guidance) will help ensure selection of subrecipients that are equipped to handle these record-sharing obligations. Key personnel from the prime awardee, including the principal investigator, will need to understand and be involved directly in the vetting process of each subrecipient, and the subrecipients should be questioned about their understanding of the NGPS Section 15.2 requirements (including the Updated Policy Guidance) and whether they have the appropriate infrastructure to comply with the requirements. Through implementation of a more robust screening process, prime awardees may be more likely to identify and mitigate the possibility of post-award compliance issues (*e.g.*, subrecipients that are not willing or able to comply with NGPS Section 15.2 requirements).

- Prime awardee and subrecipient stakeholders also should consider, at the outset of an engagement, the types of data and records that foreign subrecipients will need to provide to prime awardees in the context of the particular project at issue. The Updated Policy Guidance describes, with broad strokes, the data over which the rule has jurisdiction, yet it may not be possible for a foreign subrecipient to provide *all* data to the prime awardee. For example, "all data" may include human health data whose extraterritorial transfer is not permitted under the terms of the applicable informed consent form signed by research participants or by applicable laws relating to export of such data. On its face, the Updated Policy Guidance does not allow institutions to determine that some data do not need to be provided because of impracticability or other considerations. Therefore, it is particularly important for prime awardees and subrecipients to make a plan for data and records sharing under which the subrecipient will make these transfers to the prime awardee.

- Institutions also must consider applicable record retention requirements, including whether the requirement to provide copies of all lab notebooks and data means that the prime awardee must retain all of this subawardee information for the length of the applicable retention periods and whether the prime awardee should require the subrecipient to do the same.[11]

- Prime awardees should educate principal investigators and other key research personnel and make a plan for the extent to which data received from subrecipients will be scrutinized for completeness, as there are potential individual and institutional risks at play. For example, if investigators working for a foreign subrecipient fabricate data and the principal investigator has failed to secure, at regular intervals, copies of original research data, this could be evidence, in extreme cases, of recklessness, which could have implications in any related research misconduct or False Claims Act proceedings.[12]

The Updated Policy Guidance notes that "[a] Federal Register Notice announcing the updates will be posted in the coming weeks,"[13] which may contain additional guidance that will address some of the open issues it presents and may provide guidance for potential implementation. Through this new requirement, NIH effectively has underscored the importance of subrecipient monitoring as an essential obligation. NIH has also indicated that it may ask prime awardees to provide documentation demonstrating that subrecipient arrangements are consistent with all requirements under NGPS Section 15.2 and that NIH may take action when it deems a prime awardee or subrecipient to be out of compliance with these requirements. Both prime awardees and subrecipients (particularly foreign subrecipients) should use the Updated Policy Guidance as an opportunity to take inventory of their existing approaches for compliance with NGPS Section 15.2 and consider what refinements may be needed to implement these new requirements.

If you have any questions, please contact Mark Barnes, Steve Sencer, Leslie Thornton, Minal Caron, Caroline Himamshu, or your usual Ropes & Gray advisor.

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1. NIH Updated Policy Guidance for Subaward/Consortium Written Agreements (referred to herein as the "Updated Policy Guidance").
2. *Id.*
3. NIH Grants Policy Statement, Section 15.2.
4. NIH Updated Policy Guidance for Subaward/Consortium Written Agreements.
5. *Id.*
6. *Id.*
7. 2 C.F.R. Part 200, codified by the Department of Health and Human Services at 45 C.F.R. Part 75.

8. 2 C.F.R. 200.332(a)(5).
9. 2 C.F.R. § 200.332(d).
10. 2 C.F.R. § 200.332(a).
11. While NGPS Section 15.2 currently requires that written agreements between prime awardees and subrecipients include provisions regarding the way in which recipients will comply with audits necessary to fulfill NIH obligations, there is no explicit record retention requirement for the subrecipients.
12. *See Id.*
13. NIH Updated Policy Guidance for Subaward/Consortium Written Agreements.