

June 8, 2023

## Update: NIH Invites Comments on Changes to Data Requirements for International Research Subawards

On Friday June 2, 2023 Ropes & Gray issued an [Alert](#) regarding the May 19, 2023 updated grants policy guidance from the National Institutes of Health (“NIH”) (the “Updated Policy Guidance”). The Updated Policy Guidance requires, among other things, that institutions that are primary awardees of NIH grant funding 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 at least every three months.<sup>1</sup>

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Following issuance of the Updated Policy Guidance, on June 5, 2023, an associated Federal Register notice was published, inviting public comments on the Updated Policy Guidance, with such comments to be submitted no later than July 5, 2023.<sup>2</sup> The notice reiterates that the “**planned** effective date” of the Updated Policy Guidance is October 1, 2023.<sup>3</sup> Oddly, despite the May 19<sup>th</sup> publication of what then appeared to be final guidance, NIH now appears to be leaving open the possibility that the Updated Policy Guidance might be revised to reflect public comment and that its release might be pushed beyond the October 1, 2023 planned effective date.<sup>4</sup> Ropes & Gray is preparing a draft comment to NIH addressing the challenges that implementation of the Updated Policy Guidance, as written, will pose to institutional recipients of NIH funding. If you would like to receive a copy of Ropes & Gray’s comment in draft form prior to submission to NIH and/or join the comment as a co-signatory, please email [minal.caron@ropesgray.com](mailto:minal.caron@ropesgray.com) to indicate your interest and include “NIH Updated Policy Guidance Comment” in the subject line.

1. [NIH Updated Policy Guidance for Subaward/Consortium Written Agreements](#).
2. [88 FR 36603](#) (June 5, 2023).
3. *Id.*
4. *See id.*; [NIH Updated Policy Guidance for Subaward/Consortium Written Agreements](#).