



THE AMERICAN ASSOCIATION OF  
IMMUNOLOGISTS

Submission by The American Association of Immunologists  
to the National Institutes of Health (NIH) regarding its Request for Comments  
on “Notice to Announce NIH Updated Policy Guidance for Subaward/Consortium”

July 5, 2023

[The American Association of Immunologists \(AAI\)](#), the nation’s largest professional association of research scientists and physicians who are dedicated to understanding the immune system through basic, translational, and clinical research, appreciates this opportunity to submit a response to the NIH Request for Comments on its “[Notice to Announce NIH Updated Policy Guidance for Subaward/Consortium](#).” AAI is concerned that this proposed policy could greatly increase administrative burden for both prime and subrecipients and could harm international collaborations, and therefore urges NIH to delay implementation and seek additional stakeholder feedback in order to assess whether this is the optimal way to strengthen NIH oversight efforts.

AAI understands that NIH must enforce the requirement of subaward agreements “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.”<sup>1</sup> Having access to these materials is important to ensuring that there is strong oversight of NIH funds being used by foreign subrecipients.

AAI is concerned, however, about the planned update to section 15.2.1 of the [NIH Grants Policy Statement](#), “Written Agreement,” that states: “[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. 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.”<sup>2</sup> While AAI recognizes the prime recipient’s responsibility to oversee the research being carried out by the subrecipient and agrees that more stringent reporting requirements are necessary for high-risk research, AAI is specifically concerned that requiring the collection of “all lab notebooks, all data, and all documentation” “no less than once every six months” for all foreign subawards could be overly burdensome to both prime recipients and subrecipients in terms of administrative effort, time, and cost. AAI urges NIH to provide clarity on the reasons behind, and benefit of, such frequent collection of the specific items listed above. And if this policy is implemented, it will be important for NIH to fully explain the expectations of prime recipients upon receipt of this extensive data.

---

<sup>1</sup> <https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR031321e29ac5bbd/section-200.332>

<sup>2</sup> <https://rfi.grants.nih.gov/?s=646e6654a8ba09024f09e852>

AAI is also worried that the proposed policy may damage existing international scientific collaborations and discourage future collaborations, especially for under-resourced prime and subrecipients. These partnerships are vital, especially when researching infectious diseases that are emerging or endemic in foreign countries.

AAI therefore recommends delaying implementation to allow more time for stakeholder consultation and exploration of alternative policy changes that preserve scientifically crucial collaborations and impose less burden on prime and subrecipients of NIH grants.