

## MEMORANDUM

TO: Xanthia James, Director  
Division of Grants Policy, Office of Policy for Extramural Research Administration  
National Institutes of Health

FROM: **Association of American Universities**  
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**Association of Public and Land Grant Universities**  
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DATE: July 5, 2023

Re: Updates to the NIH Grants Policy Statement (NIHGPS), Section 15.2, outlining the requirements for consortium/subaward agreements on NIH-funded grants [NOT-OD-23-133](#)

The Association of American Universities (AAU) represents 69 leading U.S. research universities, all of whom are longstanding partners in NIH research. Our member universities earn the majority of competitively awarded federal funding for research that improves public health, seeks to address national challenges, and contributes significantly to our economic strength, while educating and training tomorrow's visionary leaders and innovators. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization dedicated to strengthening and advancing the work of public universities. With a membership of more than 250 public research universities, land-grant institutions, state university systems, and affiliated organizations.

AAU and APLU appreciate the opportunity to share our significant concerns regarding proposed updates to the NIH Grants Policy Statement (NIHGPS), Section 15.2, which outlines the requirements for consortium/subaward agreements on NIH-funded grants.

Our member institutions are deeply committed to being good stewards of NIH research funds, which includes employing good data practices to safeguard scientific integrity. AAU and APLU support NIH's efforts to ensure that prime recipients of NIH awards make subrecipients fully aware of their obligation to provide the required data and other associated documentation necessary to substantiate research outcomes described in the NIH progress reports. Ensuring such understanding at the beginning stage of an award is integral to sound scientific stewardship – something our member universities take seriously.

AAU and APLU appreciate the concerns raised in the much more comprehensive comments submitted by the Council on Governmental Relations (COGR) and the Association of American Medical Colleges

(AAMC). We write separately to underscore three specific concerns we have with the proposed updated policy guidance that, we believe, require changes and clarifications prior to implementation:

- 1. Overly broad definition of “Scientific Data” in new guidance:** The scope of “Scientific Data” in NOT-OD-23-133 should be aligned more closely to the [2023 Data Management Sharing \(DMS\) policy](#) and be tied to research outcomes. The [2023 Data Management Sharing \(DMS\) policy](#) does not include laboratory notebook and completed case report forms. Several institutions have expressed concern that complete copies of laboratory notebooks and *all* information in case report forms are not required to confirm, reproduce, and replicate scientific findings and therefore may not be necessary to collect from subrecipients. Stated differently, the scope of “Scientific Data” in NOT-OD-23-133 goes beyond what is needed to ensure the integrity and accessibility of the science, which were considered carefully in crafting the 2023 DMS policy. **We recommend that the requirements align with the data and supporting information required to substantiate research outcomes, which do not have such breadth of expectations for sharing information.**
- 2. Vagueness may lead to confidentiality problems:** Collecting the information outlined in NOT-OD-23-133 may conflict with existing limits on information sharing involving research with patient participants. This is especially true of clinical trials research. The European Union’s General Data Protection Regulation ([GDPR](#)) limits data-sharing requirements in such instances. Under the GDPR, patients must consent to broadly sharing their data with other entities and even encoded data must be shielded and stored with certain protections. **We encourage NIH to provide further clarification on the parameters of the necessary foreign subaward data and documentation required in this regard and ensure that requirements are consistent with international standards on confidentiality.**
- 3. Consistency with current guidance on data storage:** Data storage requirements for the foreign subrecipient information outlined in NOT-OD-23-133 need further clarification. As NIH is aware, AAU institutions have dedicated considerable time, effort, and resources to implement NIH’s 2023 DMS policy. The scope of “scientific data” required to be housed by primary awardees according to NOT-OD-23-133 differs from NIH’s 2023 DMS Policy. As such, **we request NIH clarification and alignment of the retention, storage, and accessibility expectations between these two requirements.**

Further clarification of the issues we have identified above will greatly help our institutions to successfully implement and meet the new requirements. Our associations look forward to continued engagement with NIH as the updated subrecipient policy guidance moves forward.