Joint statement of European universities on NIH updated Policy Guidance for Subaward/Consortium

We, the listed European institutions, want to raise our concerns regarding the recently announced additional NIH requirement for foreign subawards, which is due to become applicable to all grants with budget periods beginning on or after 1 October 2023, see RFI (nih.gov).

> *"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."*

We have grave concerns that this new requirement will conflict with institutional, national and regional rules and practices, hence complicating or hindering the further participation of foreign entities as subawards in new and existing NIH grants. More specifically, we wish to highlight the following issues:

1) Legal obstacles:
    a. Personal Data Protection Regulations
        i. In the European Union, the General Data Protection Regulation (GDPR) or equivalent in the UK and Switzerland, imposes restrictions on the processing of personal data and the transfer to third parties. Particular attention is needed for transfers to countries outside the European Union, which in some cases is actually impossible. Extensive legal agreements have to be put in place before any transfer can be made if allowed at all.
    b. Clinical Trial Regulations
        i. When the supporting materials are generated in the context of clinical trials/studies, the original documents would fall under the definition of "source documents" under Good Clinical Practice (GCP). As such, in addition to personal data protection obligations, we will also have to consider, amongst others, GCP guidelines, European and national legislation regarding clinical studies, and the in-house policies of the European institution.
        ii. According to University Hospital policy, the transfer of source documents to third parties, even to the sponsor of a study, is prohibited. Source documents are required to remain on site. Handing over source documents to a regulatory auditor is only allowed if consent is given by the University Hospital and all patient identification has been removed. The latter is often time consuming and difficult to do in practice.

2) IPR constraints:

    Transferring copies of all lab notebooks, all data, and all documentation that supports the research outcomes means that intellectual property or data supporting such intellectual property potentially needs to be shared. If this must be done on a regular basis (at least every 6 months), it will not always be possible to take the appropriate measures to protect such intellectual property. This might jeopardize the exploitation potential of outcomes of NIH-funded research executed by foreign universities, which might also be detrimental to the NIH.

3) Use of the transferred data by the Pass-Through Entity (PTE):
    a. It is not clear who the recipients of this documentation will be and if they are bound by a confidentiality obligation.
    b. What the PTE may use the transferred data for is currently not restricted to audit purposes. This might lead to inappropriate use.
    c. Moreover, analysis of the transferred data by the PTE could result in misinterpretation of the data due to (i) expertise in another field, and (ii) documentation gathered in real time, sometimes under time constraints.
    d. A maximum-defined data-retention period of the documentation by the PTE seems to be lacking.

4) Smooth continuation of ongoing grants may be impacted:
    The new requirement is applicable to all grants with budget periods starting October 1, 2023. Amendments dealing with the extension of the grant after this date will need to include this new requirement. Undoubtedly, this will lead to discussions and uncertainty with the researchers, which could lead to delays or even result in the cessation of further collaboration. This far-reaching measure might impact an excellent collaboration that was already established. Trust between the researchers could be compromised.

5) Dramatic increase of administrative workload of both the PTE and the foreign subrecipient, potentially resulting in decreased resources available for science:
    a. The requested granularity and frequency of sending these data and documents is particularly onerous and is not in line with the frequency of progress reporting.
    b. Most of the supporting material will not be written in English. Translating all the information will be time consuming and costly.

6) Increased costs for the foreign entities
    Facilities and administrative (F&A) costs under NIH grants to foreign organizations are funded at a fixed rate of 8 percent of modified total direct costs. The purpose of these costs is to support the costs of compliance with federal requirements. As European institutes have an actual indirect cost rate well above 8 percent, this additional requirement for foreign Subawards leaves the institutions with an even larger financial deficit.

It is clear that some of the obstacles above can be mitigated by establishing additional legal agreements between the PTE and foreign subawardees. Nevertheless, the establishment of these arrangements will cause significant additional administrative burden, time and costs for both parties.

Multiple existing requirements with the objective of assuring high-quality research are already in place:

1) The current policy guidance states that these data have to be available on request in case of an audit. This obligation can be met provided that the necessary confidentiality agreements are in place, if applicable, at the time of the audit. There is no need to proactively collect and send in all documentation to the PTE.

2) Well-established and recently implemented NIH policies on e.g. peer-reviewed publications, data management and sharing, and invention reporting sufficiently cover the need to evaluate the scientific credibility and outcomes/progress of all NIH-funded research executed at foreign institutions.

3) In addition to the NIH requirement to have approved written policies and procedures in place to prevent research misconduct and to foster research integrity, well-established European institutions also follow the European Code of Conduct for Research Integrity, thus ensuring the necessary internal policies, including training for researchers.

4) The current policy guidance obliges PTEs to perform subrecipient risk analysis and monitoring. The outcome thereof is the basis for deciding on additional requirements for certain foreign subawardees if the risks of non-compliance are considered high.

Conclusion:

Appropriate requirements and policies of the NIH are already in place to ensure that the research performed at domestic and foreign sites is sound and verifiable. The newly proposed requirement is a redundant measure for the many foreign subawards with very high standards and comes with a high cost and potential legal constraints. Moreover, it will complicate and may tarnish existing research collaborations between the US and Europe. Well-established European universities are highly competent in managing public funding and have all the necessary compliance systems in place to deliver high-quality output. Risk management is the responsibility of the PTE and subrecipient monitoring allows them to distinguish between low- and high-risk subawardees, domestic as well as foreign, and to mitigate potential concerns by applying tailor-made measures. We kindly request the NIH to reconsider the implementation of the new requirement and to rely on the existing obligations, which we are confident will safeguard the correct spending of NIH public funding by foreign institutions. We are at your disposal for further discussions.

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