Foreign Subrecipients: Access to Data Funded by NIH Grants/Cooperative Agreements

Frequently Asked Questions

What format should the "Implemetion Plan" be in?

The Implementation Plan should be a text document that can be included in a subaward agreement. The Implementation plan should include sufficient information to clarify what data will be made accessible to the Prime institution (Harvard University) by the foreign subrecipient in support of the project aims that will be reported in the RPPR, how that information will be accessible, the timing of access and any other aspects of data access that needs to set forth in order to operationalize the plan.

Why do I need Data Safety approval for my Implementation Plan, how do I get this approval and what do I do with the approval?

Data Safety approval in the Harvard Research Administration Portal will be required by the responsible Data Security Officer to ensure that Implementation plans meet all applicable data security, privacy and IRB requirements. In order to receive approval, investigators will need to initiate a data safety request in the Data Safety tab within the Portal and upload their Implementation plan. Once approval is obtained from Data Safety, the investigator should forward a copy of the approval to their grant manager (to be uploaded into the Sub Agreement Request in GMAS). Foreign subawards under NIH grants or cooperative agreements will not be fully executed by Harvard until Data Safety approval are obtained for the included Implementation plans.

Can I still submit an NIH proposal without a completed Implementation Plan or approved Data Safety record?

Yes, this will not prevent proposal submission. However, a completed Implementation Plan and Data Safety approval are required to issue a foreign subaward. At proposal stage, Harvard requires and has added specific language to Statement of Intent forms for foreign subrecipients that confirms their awareness of the requirements and their willingness to abide by all requirements should an award be issued. At proposal stage, NIH expects PIs to ask potential foreign subrecipients to include language to the same effect in their Letters of Support. The earlier in the process that you work out the Implementation Plan with the foreign subrecipient PI the less challenging and protracted the negotiation with the foreign subrecipient will be at subaward stage.

How does the NIH requirement impact International Training Grants, such as D43 awards?

D43 NIH international training grants are not exempt from this requirement. However, NIH has specified that the Prime Institution only needs access to information pertaining to the research outcomes within the RPPR, therefore it is anticipated the RPPR will be reporting on the training

outcomes, not necessarily the outcomes from the specific research a trainee might be working on as part of the training experience.

What if I already have or anticipate having a DUA/DSA in place, do I still need an Implementation Plan in my foreign subawards under my NIH grant?

Yes. NIH requires that this information be included in the subaward. The implementation plan details technical information that might be left out of DUA.

Does the NIH requirement impact foreign subawards under NIH *contracts*?

No. This requirement currently only applies to foreign subawards under NIH grants and cooperative agreements. This requirement does not apply to foreign vendors that are providing routine goods and services within normal business operations that are ancillary to the operation of the research program.

Do foreign subrecipients have to provide access to <u>all</u> lab notebooks, data, and documentation related to the research?

No, only the notebooks, data, and documentation needed by the Harvard PI to confirm that performance outcomes that are reported in the RPPR are accurate, complete, and properly reflect the programmatic goals stated in the RPPR.

Should PIs request that the notebooks, data and documentation be transferred to Harvard?

Harvard PIs will need access to the data that supports the research outcomes as described in the RPPR; however, the data should remain on the foreign subrecipient's systems. If this is not feasible, contact the local Data Security Officer to discuss receipt and storage of foreign subrecipient materials on Harvard systems.

What if the notebooks, data and documentation are in a foreign language?

As long as the PI can read the materials to confirm the outcomes in the RPPR are accurate, complete, and properly reflect programmatic goals, there is no need to translate into English, unless and until requested by NIH.

How far in advance of the RPPR should the foreign subrecipient provide access to the necessary materials?

The access must be provided in time to allow the Harvard PI to complete their review prior to the due date of the RPPR and in alignment with the timing requirements of other annual technical and progress reports specified in the subaward. In general, we recommend at least 60 days before RPPR due date, and longer if there is a large volume of material.

What if the notebooks, data and documentation contain PHI or PII?

If the PI believes that access to PII or PHI is needed to confirm that the performance outcomes reported in the RPPR are accurate, complete and properly reflect the performance goals stated in the RPPR, or if NIH requests access to unredacted records containing PII or PHI, unredacted records may be requested. If the foreign subrecipient indicates that providing such PII or PHI would violate applicable data privacy law, the PI should contact the Office of General Counsel

who can work with the foreign subrecipient to evaluate whether there is a mechanism for records containing PII or PHI to be provided in accordance with applicable data privacy law. Moreover, in the case in which a request for unredacted records containing PII or PHI originates with NIH, the PI could point NIH to NIH's own FAQ guidance, which states that personally identifiable information can be redacted to protect participant privacy (see FAQ #9). This may allow the PI to avoid providing unredacted records to NIH, thus avoiding any conflict with applicable data privacy laws.

Do existing subawards to foreign subrecipients need to come into compliance with the Policy/NIH requirements?

Yes, if the subaward will be active on June 30, 2024 (Harvard received an extension until June 30, 2024, to bring existing subawards into compliance). If the subaward cannot be brought into compliance, then NIH guidelines would require that Harvard terminate the agreement.

In order to ensure that my NIH foreign subaward is in compliance with this policy when does my completed Implementation Plan need to be submitted?

For existing subawards already in place Harvard strongly encourages that Harvard PIs have their final Implementation Plans approved by Data Safety and to their submitting office before April 1, 2024. Please be mindful that review by the Data Safety Officers will take time. Further, depending on the agreement terms, your central reviewing office may request that this information be received sooner.

For new subawards, an updated scope of work, subrecipient budget, and completed implementation plan approved by Data Safety will be required to initiate the subaward negotiation process.

See NIH FAQs for additional information on retention periods, expectations for PI review, and the provision of subrecipient materials to NIH.