

Q&A from Presentation 12/7/22

Specific to NIH

Many studies are not able to do final analyses until a while after study completion. Would we be required to make data available before then?

Some data is supposed to be made available by the end of the funding period, if possible after ethical and legal limits are addressed. If it's not to the final analysis, you may want to propose what you can get prepared in time, and then discuss with the program staff during Just In Time (JIT) document revisions.

Do I understand correctly that if study participants do not give permission to share data that it would not get uploaded? How can shared data be used for reproducibility?

You can still submit a Plan, even if the Plan is mostly outlining that you can't share due to consent. Consent takes priority over data sharing for reproducibility. You could consider sharing just data collection and cleaning protocols and other documentation, to help others understand your methods more than what can be addressed in a journal methods section in case they want to attempt a replicate or extend into a new topic. Or you could discuss with your program staff for their recommendations, either now or during Just In Time (JIT) revisions to whatever Plan you submit.

Data plan is required for projects that generate data; what about projects that only process pre-existing data (e.g., EHR)?

A Plan is still required, even if the Plan says that the EHR data license doesn't allow for more sharing, if that's accurate. Or you could propose aggregate or summary data sharing only.

Is there any way to protect the data from being used for "bad" science?

If it's high-risk data, you should describe the ethical or security concerns in the data plan and wait to see what the program staff suggest during Just In Time (JIT) review and revision requests. If you're not sure, discuss with the program staff in advance.

Does the new policy apply to current and/or new awards?

No, unless your program officer asks for it. The new policy is for award deadlines on or after January 25, 2023, only. Competitive renewals will be affected, but existing awards are not.

You mentioned 1/25 is the date this policy goes into effect. Does that mean our DMSP must be finalized by then?

A DMSP needs to be submitted with your proposal whenever you submit if it's for a due date on or after January 25. So, if you're submitting February 5th for the R01 deadline, the DMSP has to be finalized when that submission goes in. The program staff will discuss any need for revisions during Just In Time (JIT) document requests.

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How would this work if you manage a multi-center registry, with a DUA for just participating sites? Would that be excluded under these new rules?

Data sharing is subject to any DUAs, so the DMS Plan would need to describe the DUA situation in Element 5 - Access and Reuse Considerations. It depends also on how much of the registry work is built into the funding. You can try just describing what the DUA covers and what if anything will be shared after those restrictions, like documentation. Or discuss with your program staff, who are the ones making the decisions.