



Harvard University Area IRB Monthly Newsletter

November 2022



Are You Ready for the New NIH Data Management and Sharing Policy?

The effective date for the [NIH Policy for Data Management and Sharing Policy](#) is approaching! Will you be ready on January 25, 2023?

The purpose of the [NIH Policy for Data Management and Sharing \(DMSP\)](#) is “to promote the management and sharing of scientific data generated from NIH-funded or conducted research.”

Although NIH has always promoted the sharing of data, the new policy requires specific requirements for the management and sharing of data. Some items to take note of:

- Replaces the 2003 NIH Data Sharing Policy, which only required a Plan for projects over \$500K in annual direct costs.
- Costs associated with management & sharing may be allowable in proposal/award budgets.
- The policy is relevant to data produced at Harvard and data acquired from external sources.
- Plans can be revised throughout the project (NIH prior approval may be required).
- Plans may be made publicly available, so should not include proprietary or private information.
- The plan should be two pages or less.
- Practices should be consistent with FAIR data principles.

Not ready yet? Here are some resources to get you there.

Harvard University Training Sessions

Our colleagues at Harvard Countway Library are offering some great training sessions during the Fall. Topics include *Ask an Expert: NIH Data Management and Sharing Policy*, and *Writing a Data Management Plan with DMP Tool: Tools, Tips, and Tricks*, among others. Sessions are held via Zoom or in person. Check out the training schedule here:

<https://libcal.countway.harvard.edu/calendar/countway/?cid=9718&t=d&d=0000-00-00&cal=9718&ct=41820&inc=0>

Slides and Video Recordings from the Harvard Summer RDM Mini-

Workshops

Did you miss the amazing Harvard Research Data Management Mini-Workshop series that took place over the summer? Fear not, slide decks and recordings are available! You can check them out at this link: <https://osf.io/tg6nf/wiki/home/>

Harvard Training Request Form

Would it be helpful to have a training for a large group, small group or somewhere in-between? Or are you in need of a consultation? Did you know that you can schedule a training, workshop, or consultation with Harvard data experts? The training request form may be accessed here:

<https://harvard.libwizard.com/f/Data-Services-NIH-DMSP>

Looking for more of a concierge experience? You can request a 30-minute consultation with a Harvard Data Librarian to get initial help with the policy and writing a Data Management Plan here:

<https://libcal.countway.harvard.edu/appointments/rdm>

Harvard NIH DMSP FAQ

The Harvard Countway Library has even more to offer! They've put together this FAQ that includes Harvard-focused answers based on current NIH guidance. You can find the FAQ here: <https://asklib.hms.harvard.edu/nih-dmsp/>

If you are looking for more information or resources, we've got you covered:

Need Help creating a data management plan? Check out the DMP Tool that was created through a university consortium. The DMP Tool can be found here: <https://dmptool.org/>

Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant

Data: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-213.html>

"The purpose of the Supplement is to support and assist researchers in responsible data sharing by establishing 1) operational principles for protecting participants' privacy when sharing scientific data, 2) best practices for implementing these principles, and 3) points to consider for choosing whether to designate scientific data for controlled access."

Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American

Indian/Alaska Native Participant Data:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-214.html>

"The purpose of the Supplement is to support researchers in the submission of a Plan under the DMS Policy with appropriate data management and sharing when conducting research with AI/AN Tribes; promote an understanding of Tribal sovereignty; recognize the historic harms to AI/AN Tribes in relation to inappropriate data use and misuse and participant risks; provide best practices to mitigate potential risks (e.g., group harm, stigmatization, and privacy vulnerabilities) to AI/AN Tribes; and facilitate respectful, sustained, mutually beneficial, and equitable partnerships between AI/AN Tribes, researchers, and the biomedical research enterprise."

CITI Training Completion Now Available in the Harvard Training Portal



The [Harvard Training Portal](#) is a platform that brings together all your compliance and professional development training in one place.

As of October 2022, Harvard-affiliated CITI training courses will appear on your [Harvard Training Portal](#) "Me" page. You will be able to see if training is assigned because it expired, or if it is approaching expiry.

Note that you will still need to access the [CITI portal](#) to take the CITI training as this feature is not yet available in the HTP.

Do You Speak IRB?



Study Team Members

Did you know that not **all** individuals working on your study are “study team members”? While some federal agencies are only interested in knowing about the “key personnel” in a study, here at Harvard we use a different set of criteria to determine who is a study team member. Our criteria are largely based on the regulatory concept of “engagement” such that if a person working on your study: a) has contact with human subjects, b) has access to data that is identifiable; or c) is responsible for the design, conduct, or reporting of the research, they are considered a study team member and will need to be listed in your IRB submission.

IMPORTANT REMINDER! Once you add these study team members, there is also the responsibility to **keep this study team list up to date.**

Instructions on how to add study team members may be found [here](#). Just scroll down to the heading “SmartForm Section: (Local) Study Team Members” found on page 9.

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