Harvard University Area

Harvard University Area IRB Monthly Newsletter

February 2023

NIH DMSP Now Live!

The NIH Data Management and Sharing Policy (DMSP) took effect 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.

Are you ready? If not, here are some resources to get you there.

Harvard University Training Sessions

Our colleagues at Harvard Countway Library are offering some great DMSP training sessions. 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

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

NIH DMSP FAQ

Check out 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/

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/

NIH DMSP Survey to Assess Needs of the Harvard Research Community

The Harvard University NIH DMSP Working Group has developed a survey to better understand the needs of the Harvard research community as they implement the NIH Data Monitoring and Safety Policy (DMSP) into their work.

The Working Group will utilize these responses to understand the policy's effect on research at Harvard and to develop additional resources and services. Please set aside 10 minutes to share your thoughts about the NIH policy and how the university can support data management and sharing. Please submit your survey by end of the day **Tuesday, February 28.**

Here is the link to the survey:
https://hms.az1.qualtrics.com/jfe/form/SV_cGxPhtJjj0TuKIm

If you have any questions about the survey, visit the Harvard NIH Data Management and Sharing Policy FAQ, or reach out directly to Julie Goldman, Harvard Library Research Data Services.

Do You Speak IRB?

Determination versus Approval

In our January 2023 newsletter, we talked about engagement and how this impacts the IRB's review of multi-site or collaborative studies. In this

discussion, we explained that only non-exempt research was applicable when we were determining engagement. Non-exempt research is research with human subjects that is reviewed at the level of expedited or convened IRB review.

What's so special about non-exempt research?

Non-exempt research is different because the entirety of the federal regulations only applies to research that is non-exempt. For example, non-exempt research must have a consent process where the consent form contains all the elements of consent. If not, a waiver of consent is required. Non-exempt research must also meet the IRB's regulatory criteria for approval.

Non-exempt research is reviewed by the IRB. This review might be at a monthly convened IRB meeting if the study's risk profile might be "greater than minimal risk" or where the risk is unknown, or this review might be carried out by a designated member of the IRB if the research is considered "no greater than minimal risk" and fits into an expedited review category. At the HUA IRB, expedited reviews are carried out by qualified staff who are also IRB members and who have been designated to carry out such reviews.

What about all other types of reviews?

At the HUA IRB office, we often provide not human subjects research (NHSR) and exempt determinations. The key word here is **determinations**. Determinations are not IRB approvals. Determinations are made by IRB staff too, however, these determinations are not made under the authority of the IRB. Rather, these determinations are made under the authority of the institution. It is up to each FWA-holding institution to regulate how these

determinations are reviewed. At the Harvard University Area, determinations are made by the HUA IRB office.

The difference between NHSR and Exempt Determinations

If you receive a not human subjects determination from the IRB office, you can be assured (and have documentation) that the research activity that you are conducting does not involve human subjects and therefore no further review is required. Not sure if your research involves human subjects? Check out the section "Do You Need IRB Review and Why" in our IRB Lifecycle Guide.

On the other hand, an exempt determination means that human subjects ARE involved however the research is of such low risk that the research is **exempt** from federal regulations. To determine whether research is exempt, it must fit into one or more designated exempt categories. Although this research is exempt from federal regulations, there are still some requirements that must be met. For example, those that take part in exempt research should be provided with information about the study using the template "HUA Exempt Human Research Consent Script" also known as HRP-502c (found in the ESTR Library).

NHSR and Exempt Research Flexibility

NHSR and exempt determinations do not have an expiration date and if there are no substantial changes, there is no need to check in with the IRB office again. Substantial changes include a change or addition of funding, change in scope, change in population, or a change in procedures. See page 8 of the HUA Investigator Manual for more information.

But what about changes to the study team? Do I need to notify the IRB

office? The quick answer is “no” if those study team members are affiliated with the Harvard University Area. If you are adding individuals from another institution (including those from the Harvard Longwood Campus), you will need to contact the HUA IRB office. Also know that while you may not need to make any changes to your existing exempt determination from the HUA IRB for study team changes, there are other university offices that are not able to offer the same flexibility. For example, changes to a data use agreement (DUA) and a data safety plan (DAT) will require you to get in touch with that respective office.

Questions? Contact us!