NIH DMS policy, 2023

The National Institutes of Health (NIH) updated their data sharing policy in January of 2023. Researchers must have plans in place for how data will be stored and how data will be shared with other researchers. According to the NIH website this means:

Under the DMS policy, NIH expects that investigators and institutions:

- Plan and budget for the managing and sharing of data.
- Submit a DMS plan for review when applying for funding.
- Comply with the approved DMS plan (NIH DMS Information).

The NIH website has many resources on how to write a DMS plan, and how to write a budget. However, it's important to know that the DMS plan must be part of an NIH grant and must be approved by the NIH.

The implications of this updated policy for HRPP/IRB submissions includes (but is not limited to) obtaining informed consent from participants. At the OHRP conference in September 2023, panelists discussed HRPP/IRB implications:

- Changes to IRB submission consent templates submission forms
- Monitoring/Adherence with plan requirements
- Coordination with organizational/institutional stakeholders
- Education of researchers and relevant organizational/institutional stakeholders (OHRP)

Informed consent means that you give potential participants sufficient information in an understandable format so that they can make a reasonable decision about whether to participate in your research. Telling participants what you will do with their data is crucial. If their data is to become part of a national repository to be shared with other researchers, they will want to know 1) is it required? 2) where will it be stored? 3) what are the security processes in place to ensure my data is not identifiable?

Currently, the NIH provides a list of "best practices" for "protecting participant privacy" while still adhering to this DMS policy (https://sharing.nih.gov/data-management-and-sharing-policy/protecting-participant-privacy-when-sharing-scientific-data/principles-and-best-practices-for-protecting-participant-privacy)

- Apply appropriate de-identification.
- Establish scientific data sharing and use agreements.
- Understand and communicate legal protections against disclosure and misuse.

This policy and supporting guidelines explain much of why we have so many riders in our Informed Consent Template/Process. Carefully consider each rider and whether you need additional signatures from participants for sharing. Consider the need for a DUA, as applicable. Consider your explanation of the reasons for sharing and how data will be shared so participants fully understand what they are agreeing to.