**NIH Data Management and Sharing Policy Human Subjects Research Data FAQs**

1. Is there sample consent language available that addresses the requirements of the NIH Data Management and Sharing Policy?

Yes, the IRB has developed [guidance and sample language](https://research.columbia.edu/sites/default/files/content/HRPO/Policies%20%26%20Guidance/NIH%20DMS%20guidance%20and%20sample%20consent%20form%20language%20V1%20final%5B3%5D.docx) that is posted on the HRPO website and available in the Rascal Consent Form module. This language is based on the sample future use and data sharing language provided by the NIH in the resource, [Informed Consent for Secondary Research with Data and Biospecimens](https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf).

1. I am collecting sensitive human subjects research data. What are the considerations for developing a data management and sharing plan?

Information is considered sensitive if the loss of confidentiality, integrity, or availability could be expected to have a serious, severe, or catastrophic adverse effect on organizational operations, organizational assets, or individuals. [Source: [Guide for Identifying and Handling Sensitive Information at the NIH](https://oma.od.nih.gov/DMS/Documents/Privacy/Guide%20for%20Handling%20Sensitive%20Information%20at%20NIH.pdf)] NIH expects scientific data to be shared to the extent possible, but acknowledges that privacy, security, informed consent, and proprietary issues must be considered. These are particularly relevant when the data include sensitive human subjects research data such as certain genomic data and data about individuals belonging to smaller populations and minority groups who may be more likely to be re-identified and potentially experience greater harm in the event that their data are re-identified. If protective measures such as having a Certificate of Confidentiality or deidentification of the data and biospecimens would not be sufficient to safeguard confidentiality of research participants, and they would be at greater risk of harm as a result, the data management and sharing plan should describe such limitations.

1. Do I need to modify consent forms for my ongoing studies to include future use and data sharing information?

If the research is currently NIH funded, enrollment is open and a competitive renewal is anticipated, the consent forms should be revised to include future use and data sharing information that meets the requirements of the NIH Data Management and Sharing Policy, if not already included. At such time as the renewal is submitted, the Policy requirements apply. It is good practice and will allow the greatest flexibility moving forward if all consent forms, regardless of current funding status, include future use and data sharing information. This is particularly relevant if future NIH funding is anticipated.

1. Does the NIH Data Management and Sharing Policy replace the [Genomic Data Sharing Policy](https://sharing.nih.gov/genomic-data-sharing-policy)?

No, but both invoke requirements for sharing of data so consent requirements are similar. Consent forms for research to which both policies apply must include language that will satisfy the requirements of each policy. The IRB has prepared sample language that can be used in this situation.