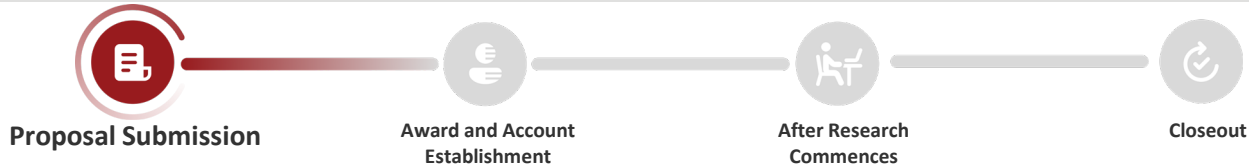




# NIH Data Sharing: Data Sharing Plans (Additional Considerations for Human Subjects Data)



Certain factors may limit data sharing and must be addressed if applicable. These include:

- Informed consent will not permit or will limit the scope or extent of sharing and future research use
- Outline steps researchers will take to protect the privacy, rights, and confidentiality of prospective participants (i.e., through de-identification, Certificates of Confidentiality, and other protective measures)
- Privacy or safety of research participants would be compromised or place them at greater risk of re-identification or suffering harm
- Explicit federal, state, local, or tribal law, regulation, or policy prohibits disclosure

Award recipients must comply with any applicable laws, regulations, statutes, guidance, or institutional policies related to research with human participants and that protect participants' privacy. The DMS Policy encourages respect for participants by encouraging researchers and award recipients to:

- Address data management and sharing plans during the informed consent process to ensure prospective participants understand how their data will be managed and shared
- Existing consent (e.g., for previously collected biospecimens) prohibits sharing or limits the scope or extent of sharing and future research use
- Assess limitations on subsequent use of data and communicate these limitations to the individuals or entities (e.g., repositories) preserving and sharing the data
- Consider whether access to shared scientific data derived from humans should be controlled, even if de-identified. Sharing via controlled access may be specified by certain FOAs or the funding NIH Institutes or Centers.