

# DMS Plans and Human Subjects: Things to Consider

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# HRPP's Role

- Ultimately, the protection of Human Subjects and their data.
- Ensure responsible sharing of that data- will also be outlined in the IRB protocol.
- Maximize the *appropriate* use of human subjects data.
- When applicable, attach DMS Plan (and subsequent mods) to relevant IRB protocol.



# Appropriate Use and Limits to Sharing

- There may be legal, technical, or ethical factors that limit sharing and would be justified:
  - Restrictions from existing or anticipated agreements with other parties
  - Explicit laws, regulations, or policies that prohibit disclosure (ex: Certificate of Confidentiality)
  - The privacy or safety of human subjects would be compromised, and available protections are insufficient
  - Informed consent will not permit or limits the scope of sharing/use



# Appropriate Use and Limits to Sharing

- Reasons that may not be justifiable to limit sharing:
  - Not having a suitable repository
  - It is anticipated that data will not be widely used
  - Data are considered to be too small



# Other Considerations

- As with normal IRB requirements, take into account Federal, State, Tribal, Local and Institutional laws, regulations, and policies.
- HIPAA / Common Rule



# Other Considerations

- This policy does NOT require you to share your data.
- There may be steps you have to take to be able to share your data (ex: de-identify first).
- There may be reasons you cannot share the data at all (outlined in limits to sharing).



# If it qualifies as scientific data and you decide to share:

## Open Access

- Must have explicit consent to share
- Institutional review may determine it is low risk information

Informed consent process should ensure prospective participants understand how their data will be managed and/or shared.

## Controlled Access

- Sensitive Data
- Vulnerable Populations
- Cannot be deidentified to acceptable standards
- Explicit limitations on subsequent use



# Templates

- Consent language will be available
- Updates to the MSU HRPP Operations Manual will be made and shared with MSU research community
- Goal is to have clear communication of protections, data sharing, and any limitations of future use in the Informed Consent

