SOP#: RPS-22	**Requesting a Data Management and Sharing Waiver**
Version #: 3.0	**Next Review Date: 08/2025**
Approved Date: 08/2023	**Review Interval Period: Biennial**
NCI Clinical Director Signature/ Effective Date:	James Gulley Digitally signed by James Gulley Date: 2023.08.30 12:07:35 -04'00'

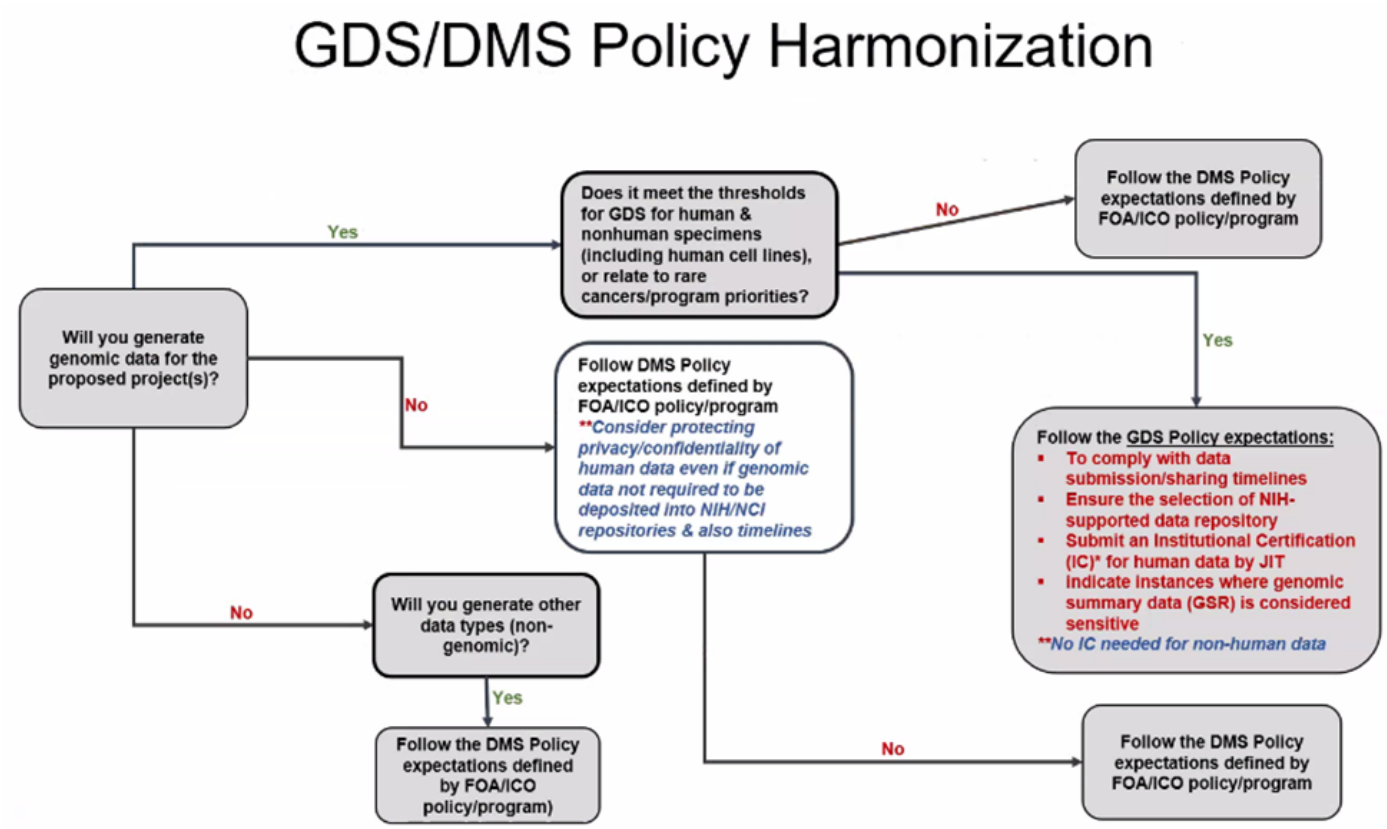
POLICY

The Data Management and Sharing (DMS) Policy applies to all NIH intramural research and was effective January 25, 2023. The Office of Intramural Research has specified that DMSP applies to research associated with a:

- ZIA (human and non-human research)
- Clinical protocol that will undergo IC Initial Scientific Review
- Genomic Data Sharing (GDS) project

The DMS Policy requires sharing scientific data, defined as data of sufficient quality to validate and replicate the research findings[1]. For additional information on the DMS Policy, please refer to the Center for Cancer Research (CCR) DMS Policy Home Page.

The DMS Policy has been harmonized with the Genomic Data Sharing (GDS) Policy. See Figure 1[2]:



To assist in determining which Data Sharing Policies apply to a particular research project, the NIH Office of Science Policy has created an online tool, What Policies Apply to My Research. This process involves answering a few questions about the research, which is submitted to obtain information about which policy or policies apply to a particular research project.

For additional information on the DMSP, please refer to the Center for Cancer Research (CCR) DMSP Home Page.

CCR recognizes that data sharing may not be appropriate in rare circumstances[3]. Examples include:

- Informed consent will not permit or will limit the scope or extent of sharing and future research use;
- Existing consent (e.g., for previously collected biospecimens) prohibits sharing or limits the scope or extent of sharing and future research use;
- Privacy or safety of research participants would be compromised or place them at greater risk of re-identification or suffering harm, and protective measures such as de-identification and Certificates of Confidentiality would be insufficient;
- Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure;
- Restrictions imposed by existing or anticipated agreements (e.g., with third-party funders, with partners, with repositories, with Health Insurance Portability and Accountability Act (HIPAA) covered entities that provide Protected Health Information under a data use agreement, through licensing limitations attached to materials needed to conduct the research);
- Datasets cannot practically be digitized with reasonable efforts[3].

In such a scenario, CCR will consider a Data Management and Sharing Waiver. A written memo requesting and justifying the Waiver and approved by your Branch Chief should be submitted to the Genomic Program Administrator (GPA). All waiver requests will be forwarded to the NCI leadership for consideration. Any request for a waiver must be accompanied by relevant documents for justification.

PURPOSE

To provide instructions for requesting a Data Management and Sharing Waiver.

RESOURCES

- CCR Data Management and Sharing Website
- CCR Data Management and Sharing Project Home (Wiki Page)
- Office of Intramural Research Data Management and Sharing Website
- NCI Office of Data Sharing
- NIH Office of Science Policy Scientific Data Sharing

CCR Genomic Program Administrator (GPA)

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CCR Genomic Program Administrator (GPA)

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PROCEDURES

STEP 1: Initial Consultation and Document Preparation

- Contact the GPA for consultation. As such situations are rare, and there is no hard-and-fast rule to determine the eligibility for a waiver, the investigator should discuss with the GPA to determine eligibility.
- If eligible, the GPA team will help you to write a memo directed to the review committee. The memo will include a summary of the study, the rationale behind the waiver, and fields for the signatures of the review committee.
- The memo should accompany all the relevant documents for waiver justification.

STEP 2: Obtain Branch Approval

- Submit the request form to Branch Chief for approval.
- Branch Chief will indicate endorsement via signature on the memo.

STEP 3: Submit to the GPA

Submit the following to the GPA:

- Waiver requesting memo approved and signed by the branch chief.
- All other relevant documents

STEP 4: Review Process

The GPA will review the Waiver Justification Package and initiate the review process by NCI leadership. They will also track the progress of the review process.

- If the Waiver Justification Package is incomplete or the waiver justification is not adequate, the GPA will return the package to the PI for revision with guidance on what needs to be addressed.
- If Waiver Justification Package is c**omplete and sufficiently justified**:
    - The GPA will forward the package to the CCR Clinical Director.
    - The CCR Clinical Director will make their determination.
    - The CCR Clinical Director will present the Exception Package with the cover memo to the CCR Director.

    - The CCR Director will make their determination and return the signed memo to the GPA.
- If the Waiver is **NOT APPROVED,** the GPA will:
    - Return the Waiver Request Package to the PI and discuss plans compliance with the DMS Policy.
- If the Waiver is **APPROVED,** the GPA will:
    - Return the approved Waiver Request Package to the PI.
- The GPA will track all waiver requests, the rationale for the waiver, and the approval determination.

REFERENCES:

1. 2023 Data Management and Sharing Policy: Policy Scope https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm?anchor=56772, accessed 6/23/2023.
2. NCI Office of Data Sharing Tactic meeting presentation held on May 2023. Author: Emily Boja.
3. What are Justifiable Reasons for Limiting Data Sharing? https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm?anchor=56549, accessed 6/23/2023.