DRAFT NIH Policy for Data Management and Sharing

I. Purpose

The NIH Policy for Data Management and Sharing (herein referred to as the Policy) reinforces NIH's longstanding commitment to making the results and outputs of the research that it funds and conducts available to the public. Data sharing enables researchers to rigorously test the validity of research findings, strengthen analyses through combined datasets, reuse hard-to-generate data, and explore new frontiers of discovery. In addition, NIH emphasizes the importance of good data management practices, which provide the foundation for effective data sharing and improve the reproducibility and reliability of research findings. NIH encourages data management and data sharing practices consistent with the NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research and the FAIR (Findable, Accessible, Interoperable, and Reusable) data principles.

To promote effective and efficient data management and data sharing, NIH expects researchers to manage scientific data resulting from NIH-funded or conducted research and prospectively plan for which scientific data will be preserved and shared. Under this Policy, individuals and entities would be required to provide a Data Management and Sharing Plan (Plan) describing how scientific data will be managed, including when and where the scientific data will be preserved and shared, prior to initiating the research study. Shared data should be made accessible in a timely manner for use by the research community and the broader public. This Policy is intended to establish expectations for Data Management and Sharing Plans upon which other NIH Institutes, Centers and Offices (ICO) may supplement as appropriate.

II. Definitions

For the purposes of this Policy, terms are defined as follows:

- **Data Management and Sharing Plan (Plan):** A plan describing how scientific data will be managed, preserved, and shared with others (e.g., researchers, institutions, the broader public), as appropriate.

- **Data Management:** The process of validating, organizing, securing, maintaining, and processing scientific data, and of determining which scientific data to preserve.

- **Data Sharing:** The act of making scientific data available for use by others (e.g., researchers, institutions, the broader public).

- **Metadata:** Data describing scientific data that provide additional information to make such scientific data more understandable (e.g., date, independent sample and variable description, outcome measures, and any intermediate, descriptive, or phenotypic observational variables).

- **Scientific Data:** The recorded factual material commonly accepted in the scientific community as necessary to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses,

completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens. NIH expects that reasonable efforts will be made to digitize all scientific data.

III. Scope

This Policy applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants, contracts, intramural research projects, or other funding agreements regardless of NIH funding level or funding mechanism.

IV. Effective Date(s)

The effective date of this Policy and subsequent implementation deadlines are dependent upon feedback on this proposal. This Policy is proposed to be effective for NIH-funded or conducted research, including:

- Competing grant applications that are submitted to NIH for a future receipt date or subsequent receipt dates (date yet to be determined);
- Proposals for contracts that are submitted to NIH on or after a future date (date yet to be determined);
- NIH Intramural research conducted on or after a future date (date yet to be determined); and
- Other funding agreements (e.g., Other Transactions) that are executed on or after a future date (date yet to be determined), unless otherwise stipulated by NIH.

V. Requirements

This Policy would require:

- Submission of a Data Management and Sharing Plan (Plan) outlining how scientific data will be managed and shared, taking into account any potential restrictions or limitations.
- Compliance with the NIH ICO-approved Plan, prospectively describing effective management and timely sharing of scientific data (as appropriate) and accompanying metadata resulting from NIH-funded or conducted research.

The funding NIH ICO may request additional or specific information to be included within the Plan in order to meet expectations for data management and data sharing in support of programmatic priorities or to expand the utility of the scientific data generated from the research. Costs associated with data management and data sharing may be allowable under the budget for the proposed project (Supplemental DRAFT Guidance: Allowable Costs for Data Management and Sharing).

VI. Data Management and Sharing Plans

Researchers with NIH-funded or conducted research projects resulting in the generation of scientific data are required to submit a Plan to the funding NIH ICO as part of Just-in- Time for extramural awards, as part of the technical evaluation for contracts, as part of the NIH Intramural Annual Report, or prior to release of funds for other funding agreements. Plans should explain how scientific data generated by a research study will be managed and which of these scientific data will be shared. Plans may be updated by researchers (with appropriate NIH ICO approval) during regular reporting intervals if changes are necessary or at the request of the NIH ICO to reflect changes in the previously documented approach to data management and data sharing throughout the research project, as appropriate. NIH encourages shared scientific data to be made available as long as it is deemed useful to the research community or the public. Plans should also identify strategies or approaches to ensure data security and compliance with privacy protections are in place throughout the life of the scientific data. NIH may make Plans publicly available.

NIH prioritizes the responsible management and sharing of scientific data derived from human participants. Applicable Federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies dictate how research involving human participants should be conducted and how the scientific data derived from human participants should be used. Researchers proposing to generate scientific data derived from human participants should outline in their Plans how human participants' privacy, rights, and confidentiality will be protected, i.e., through de-identification or other protective measures. NIH recognizes that certain factors (e.g., legal, ethical, technical) may limit the ability to preserve and share data. Plans should include consideration of these factors, when applicable, in describing the approach to data management and data sharing. NIH encourages the use of established repositories for preserving and sharing scientific data.

Plan Elements: Consider addressing specific elements outlined in Supplemental DRAFT Guidance: Elements of An NIH Data Management and Sharing Plan

Plan Assessment: The funding NIH ICO will assess the Plan, through the following processes:

- Extramural Awards: Plans will undergo a programmatic assessment by NIH staff within the proposed funding NIH ICO. NIH encourages potential awardees to work with NIH staff to address any potential concerns regarding the Plan prior to submission.
- Contracts: Plans will be included as part of the technical evaluation performed by NIH staff.
- Intramural Research Projects: Plans will be assessed by the Scientific Director (or designee) or Clinical Director (or designee) of the researcher's funding NIH ICO.
- Other funding agreements: Plans will be assessed in the context of other funding agreement mechanisms (e.g., Other Transactions).

VII. Compliance and Enforcement

During the Funding or Support Period:

During the funding period, compliance with the Plan will be determined by the funding NIH ICO. Compliance with the Plan, including any Plan updates, will be reviewed during regular reporting intervals (e.g., at the time of annual Research Performance Progress Reports (RPPRs)) at a minimum.

- Extramural Awards: The Plan will become a Term and Condition of the Notice of Award. Failure to comply with the Terms and Conditions may result in an enforcement action, including additional special terms and conditions or termination of the award, and may affect future funding decisions.

- Contracts: The Plan will become a Term and Condition of the Award, and compliance with and enforcement of the Plan will be consistent with the award and the Federal Acquisition Regulations (FAR), as applicable.

- Intramural Research Projects: Compliance with and enforcement of the Plan will be consistent with applicable NIH policies established by the NIH Office of Intramural Research and the applicable NIH ICO.

- Other funding agreements: Compliance with and enforcement of the Plan will be consistent with applicable NIH policies.

Post Funding or Support Period

After the end of the funding period, non-compliance with the NIH ICO-approved Plan may be taken into account by the funding NIH ICO for future funding decisions for the recipient institution (e.g., as authorized in the NIH Grants Policy Statement, Section 8.5, Special Award Conditions, and Remedies for Noncompliance (Special Award Conditions and Enforcement Actions)).