FARA Notice for Data Management and Sharing for FARA-funded research grants

(adapted from Final NIH Policy for Data Management and Sharing link https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html)

Section I. Purpose

FARA Notice for Data Management and Sharing (herein referred to as the DMS Notice) aligns with FARA's commitment to making the results and outputs of FARA-funded research available to researchers through effective and efficient data management and data sharing practices. 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, FARA 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.

Under the DMS Notice, FARA requires researchers to prospectively plan for how scientific data will be preserved and shared through submission of a Data Management and Sharing Plan (Plan). The Plan will be reviewed as part of the FARA grant review process and upon FARA approval of a Plan, FARA expects researchers and institutions to implement data management and sharing practices as described.

Section II. Definitions

For the purposes of the DMS Notice, terms are defined as follows:

Applicable Law: All laws, statutes, regulations, decisions, rulings, sanctions, governmental and regulatory policies and/or mandatory codes of practice which may from time to time be in force anywhere in the world and which a Party is bound to comply with in the exercise of its rights and performance of its obligations under this Agreement, including the Relevant Privacy Laws.

Relevant Privacy Laws: Any legislation, regulation, code or guideline in relation to the collection, use, storage and security or disclosure of any personal information which a Party is legally required to comply with in its performance of this Agreement.

Scientific Data: The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data includes but is not limited to genomic data, sequencing data, omics data, clinical data, MRI data, digital measure data. Scientific data does 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.

Data Management: The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.

Data Sharing: The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository.

Metadata: Data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).

Data Management and Sharing Plan (Plan): A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.

Section III. Scope

The DMS Notice applies to all research, funded in whole or in part by FARA, that results in the generation of scientific data.

Section IV. Effective Date(s)

The effective date of the DMS Notice is July 1, 2025

Section V. Requirements

The DMS Notice requires submission of a Data Management and Sharing Plan at the time of grant submission to FARA, outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations.

Costs associated with data management and data sharing may be allowable under the budget for the proposed project.

The Plan will be assessed by FARA at the time of grant review.

If Plan revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), Plans should be updated by researchers and will be reviewed by FARA.

Section VII. Managing and Sharing Scientific Data

FARA expects that in drafting Plans, researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may affect the extent to which scientific data are preserved and shared. Any potential limitations on subsequent data use should be communicated to individuals or entities (e.g., data repository managers) that will

preserve and share the scientific data. FARA will assess whether Plans appropriately consider and describe these factors.

Considerations for Scientific Data Derived from Human Participants: FARA prioritizes the responsible management and sharing of scientific data derived from human participants. All Applicable Laws that govern research involving human participants and the sharing and use of scientific data derived from human participants should be considered in the Plan. The DMS Notice is intended to support compliance with all Applicable Laws for research involving human research participants and Relevant Privacy Laws. Researchers proposing to generate scientific data derived from human participants should outline in their Plans how privacy, rights, and confidentiality of human research participants will be protected (i.e., through de-identification and other protective measures).

FARA strongly encourages researchers to plan for how data management and sharing will be addressed in the informed consent process, including communicating with prospective participants how their scientific data are expected to be used and shared. Researchers should consider whether access to scientific data derived from humans, even if de-identified and lacking explicit limitations on subsequent use, should be controlled.

Data Repository Selection: FARA strongly encourages the use of established repositories to the extent possible for preserving and sharing scientific data. Examples include Gene Expression Omnibus and Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP®)..

Data Preservation and Sharing Timelines: Shared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication or the end of performance period. Researchers are encouraged to consider relevant requirements and expectations (e.g., data repository policies, award record retention requirements, journal policies) as guidance for the minimum time frame that scientific data should be made available, which researchers may extend.

Section VIII. Compliance and Enforcement

During the Funding or Support Period

During the funding period, compliance with the Plan will be determined by FARA. Compliance with the Plan, including any Plan updates, may be reviewed during regular reporting intervals (e.g., at the time of annual Progress Reports).

The Plan will become a Term and Condition of the Notice of Award and Funding Agreement. Failure to comply with the Terms and Conditions may result in termination of the award and may affect future funding decisions.

Post Funding or Support Period

After the end of the funding period, non-compliance with the FARA approved Plan may be taken into account by FARA for future funding decisions.