ImmPort Comments and Example Text are provided to aid researchers considering ImmPort for Data Management and Sharing (DMS). In order to draft a robust DMS plan, researchers should consider all applicable NIH guidance, university-specific guidance, and/or other best practices and regulations in addition to repository-specific information. NIH guidance for writing a DMS plan is located <u>here</u>.

DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on <u>sharing.nih.gov</u>. The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001 and 0925-0002). Do not return the completed form to this address.

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:

Summarize the types and estimated amount of scientific data expected to be generated in the project.

ImmPort Comments:

- ImmPort is designed to accommodate the preservation of large data sets
- Up to 512 MB of data can be uploaded directly to the ImmPort system in a single upload
- A no-cost tool, Aspera Connect, is utilized for uploads larger than 512 MB
- A listing of data types and formats that ImmPort accepts is located here
- **B.** Scientific data that will be preserved and shared, and the rationale for doing so: Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

ImmPort Comments:

- ImmPort does not receive HIPAA designated content or protected genetic data
- All human subject data should be de-identified in accordance with federal, state, local, and any university-specific regulations prior to submitting to ImmPort
- If scientific data will be deposited in multiple repositories, ImmPort supports linkages to associated data stored in outside repositories to enhance findability

C. Metadata, other relevant data, and associated documentation:

Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

ImmPort Example Text:

Descriptive metadata will be captured in accordance with the ImmPort data submission templates (repository where scientific data and metadata will be archived) and preserved within the ImmPort record associated with the scientific data. Any documentation or other relevant data required to interpret the scientific data will be associated via link or attached file within the ImmPort record.

Element 2: Related Tools, Software and/or Code:

State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

ImmPort Comments:

• ImmPort supports the preservation of applicable links and attached files which are preserved along with the scientific data in the associated ImmPort record

Element 3: Standards:

State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

ImmPort Comments:

- ImmPort utilizes multiple data standards and ontologies within the <u>data model</u> to enhance interoperability and reusability of scientific data
- Researchers are also encouraged to format their data in accordance with other applicable data standards specific to their research or scientific data type

ImmPort Example Text:

The following data standards and ontologies within the ImmPort data model will be used wherever possible to enhance the reusability and interoperability of scientific data: Cell Ontology (CO), Clinical Data Interchange Standards Consortium Study Data Tabulation Model (CDISC SDTM), Clinical Measurement Ontology (CMO), Disease Ontology (DO), Gene Ontology (GO), Human Immunology Project Consortium (HIPC), Human Phenotype Ontology (HPO), Immuno Polymorphism Database-ImmMunoGeneTics/Human Leukocyte Antigen Database (IPD-IMGT/HLA), Medical Dictionary for Regulatory Activities (MedDRA), National Cancer Institute Thesaurus (NCIT), National Center for Biotechnology Information (NCBI) Taxonomy, Ontology for Biomedical Investigators (OBI), Protein Ontology (PRO), Uber-Anatomy Ontology (Uberon), and Vaccine Ontology (VO).

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived: Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see <u>Selecting a Data Repository</u>).

ImmPort Example Text:

Data resulting from this research will be shared via the Immunology Database and Analysis Portal (ImmPort), a NIH-supported domain-specific repository.

B. How scientific data will be findable and identifiable:

Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

ImmPort Example Text:

The ImmPort repository provides standardized metadata, assigns unique persistent identifiers (DOIs), and follows FAIR data principles to ensure data is findable and identifiable for long-term access. Additionally, ImmPort integrates with PubMed and NCBI via LinkOut records and supports linkage to applicable related data within other repositories for enhanced findability. The ImmPort repository is supported by NIH and datasets are available via free registration upon acceptance of the Data Use Agreement.

C. When and how long the scientific data will be made available:

Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

ImmPort Example Text:

Data will be shared as soon as possible and will be deposited in ImmPort prior to submission of a manuscript for publication or before performance end, whichever comes first, to allow time for curation

and sharing in alignment with publication and performance timelines. ImmPort is a CoreTrust Seal certified repository and employs best practices for long-term preservation and persistence of data.

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See <u>Frequently</u> <u>Asked Questions</u> for examples of justifiable reasons for limiting sharing of data.

ImmPort Comments:

- ImmPort does not receive HIPAA designated content or protected genetic data
- All human subject data should be de-identified in accordance with federal, state, local, and any university-specific regulations prior to submitting to ImmPort
- ImmPort templates and processes are designed to accept only de-identified human subject data
- Users of ImmPort are required to register and agree to a <u>Data Use Agreement</u> prior to uploading or downloading shared data

B. Whether access to scientific data will be controlled:

State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

ImmPort Comments:

- ImmPort shared data sets are available for users to download after a free registration process and agreement to the Data Use Agreement
- Please contact ImmPort_Helpdesk@immport.org if you have controlled access requirements

C. Protections for privacy, rights, and confidentiality of human research participants:

If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

ImmPort Comments:

- ImmPort does not receive HIPAA designated content or protected genetic data
- ImmPort only accepts de-identified human subject data

Element 6: Oversight of Data Management and Sharing:

Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).

ImmPort Comments:

- ImmPort provides private workspaces in an access controlled environment for data upload
- Researchers may request access for others within their team or institution to support data upload or monitoring of activity within the private workspace