

EXAMPLE DATA MANAGEMENT AND SHARING PLAN (in compliance with SF-424 Forms H)

EXAMPLE FOR FLOW CYTOMETRY DATA

ELEMENT 1: DATA TYPE

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

Data will be collected on 50 individuals with AAA during the R34 phase as part of a mock recruitment study. The data type includes individual patient data to determine eligibility for a proposed clinical trial and the likelihood of participation in a proposed clinical trial in tabular data in .csv format. We will also have transcripts from focus groups (.txt files), which will help capture potential barriers and facilitators to participation as well as feedback on meaningful outcomes in a proposed clinical trial.

B. Scientific data that will be preserved and shared, and the rationale for doing so:

We will share all anonymized data and associated metadata to allow other researchers to utilize this information in the design of other studies in the AAA population.

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

We will provide all necessary metadata and documentation (e.g. Readme.txt file, data dictionaries, abstract, methods statement) with the final dataset to ensure that other users can find, understand, and efficiently and accurately use the dataset.

ELEMENT 2: RELATED TOOLS, SOFTWARE, AND/OR CODE

Individual, de-identified patient data will be made available in csv and txt format and will not require the use of specialized tools to be accessed or manipulated.

ELEMENT 3: STANDARDS

We will use standardized survey instruments and the semi-structured interview questions to organize our data, and we will share these instruments and interview questions along with the data.

Specific data formats are anticipated to include:

- Survey data, Data dictionary: .csv
- Protocols, methods, transcripts: .txt

ELEMENT 4: PRESERVATION, ACCESS, DISTRIBUTION AND ASSOCIATED TIMELINES

In compliance with Findability, Accessibility, Interoperability, and Reusability (FAIR) data principles, data will be deposited in the University of Iowa open-access institutional repository, Iowa Research Online. The repository is open access and maintained by the Libraries at the University of Iowa for the preservation and sharing of intellectual work of faculty, students, and staff. Individual patient data will be shared within 1 year of completing the project or upon publication of the data, whichever is sooner. The individual patient data will be maintained in the Iowa Research Online repository for at least 10 years. The datasets will be assigned unique Digital Objects Identifiers (DOIs) that can be incorporated into publications and cited in the literature. Metadata will be included in the data records in the repository through readme files and structured information following the DataCite metadata schema.

ELEMENT 5: ACCESS, DISTRIBUTION, OR REUSE CONSIDERATIONS

To ensure that participants have understood how their data will be used, IRB paperwork and informed consent documents will include language describing plans for data management and sharing, describing the motivation for sharing, and explaining that personal identifying information will be removed.

To protect participant privacy and confidentiality, all identifying information will be removed from the data with each record assigned a numerical code (e.g., R34_###). Transcripts will be reviewed to remove any identifying information (e.g., geographical location).

ELEMENT 6: OVERSIGHT OF DATA MANAGEMENT AND SHARING

Dr. BBB (MPI) will lead execution of this Data Management and Sharing Plan over the duration of the funding period and progress will be reviewed monthly by the Steering Committee, including Dr. CCC (MPI), Dr. DDD (Co-I), Dr. EEE (Consultant), Dr. FFF (Co-I), Dr. GGG (Co-I), and Dr. HHH (Co-I). Dr. BBB will be responsible

Commented [JB1]: These example DMS Plans are provided for educational purposes to assist applicants with developing Plans but are not intended to be used as templates and their use does not guarantee approval by NIH. Do not copy/paste this Plan without modifying it to reflect the types of data that are expected to be generated through your project.

Applicants will need to ensure that their Plan reflects any additional, applicable expectations (including from NIH policies, ICO policies, or as stated in the FOA). If needed, investigators can contact Research Data Services (lib-data@uiowa.edu) if they have questions regarding how to best complete their DMS Plan.

for long-term data management (e.g., change in data repository if needed, serve as point of contact for data) to maintain public access to the data beyond the duration of funding for at least 10 years.

