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

EXAMPLE FOR MRI DATASETS

ELEMENT 1: DATA TYPE

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

Demographic, clinical, MRI, MRS and fMRI imaging data will be acquired from 170 participants with bipolar disorder and 90 matched controls (described in detail in sections C.1 and C.4 of this application). All data will be de-identified prior to receipt by the repository, but the information needed to generate a global unique identifier for the NIMH Data Archive (NDA) will be collected for each subject.

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

Sufficient data from this project will be preserved to enable sharing via NDA data of sufficient quality to validate and replicate research findings described in the Aims. NIMH requires data measured from human subjects to be shared using the NDA.

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

In addition to the subject level data described above, all fMRI task related paradigm designs and experiment definitions will be deposited in the NDA.

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

The clinical data will be analyzed with custom R code written using RStudio employing the following R packages: car, arsenal, emmeans, and tidyverse, all of which are freely available. MRS spectra will be analyzed with LCModel software or AMARES, which are both freely available. fMRI images will be analyzed using fMRIPrep. All locally developed code will be shared on our lab github page and the main readme.md file for the project will also include instructions and parameter choices for the analysis.

ELEMENT 3: STANDARDS

Participant age, sex, ethnicity, height, weight, socioeconomic status, and other demographic data will be collected using the following instruments as defined in NDA:

1) Research Subject and Pedigree (ndar_subject01)
2) Demographics Short Form (demsf01)
3) Ethnic Group Questionnaire (ethgrp01)
4) Height and Weight (height_weight01)
5) Hollingshead Socioeconomic Rating Scale (ses01)
6) Edinburgh Handedness Inventory (edinburgh_hand01)
7) WASI-2 (wasi201).

In compliance with NOT-MH-20-067, the following data will be collected to facilitate aggregation of this data set with other data sets:

1) demographic measures (age, sex at birth)
2) Crosscutting assessment (DSM-5)
3) A measure of impairment (WHODAS)
4) Measures related to anxiety and depression (PHQ-9, GAD-7)
5) RCADS-25 (rcads2501)

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.***

Note that the example DMS Plans may reflect additional expectations established by NIH or specific NIH Institutes, Centers, or Offices that go beyond the DMS Policy. 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).

In addition, these examples may reflect resources or policies that are in place at other institutions but that are not necessarily available at the University of Iowa. If needed, investigators can contact Research Data Services (lib-data@uiowa.edu) if they have questions regarding how to best complete their DMS Plan.

The clinical assessments we plan to collect for this study include:

1) Montgomery-Asberg Depression Rating Scale (madrs01)
2) Young Mania Rating Scale Scale (ymrs01)
3) Beck Anxiety Inventory (bai01)
4) Positive and Negative Syndrome Scale (panss01)
5) Brief Psychiatric History (new data dictionary will be defined in NDA)
6) Barratt Impulsivity Scale (bis01)
7) ASERT (Aktibipo Self-rating) questionnaire (new data dictionary will be defined in NDA)
8) National Health Interview Survey (NHIS): Tobacco Questions (new data dictionary will be defined in NDA)
9) Medication List (new data dictionary will be defined in NDA)

Anatomical MRI, MRS, and fMRI data will be shared with the Image (image03), Imaging Work Flow (iwf01), and Imaging Collection (imagingcollection01) data dictionaries as defined in NDA.

ELEMENT 4: DATA PRESERVATION, ACCESS, DISTRIBUTION AND ASSOCIATED TIMELINES

A. Repository where scientific data and metadata will be archived:

All data will be deposited to NDA starting 12 months after the award begins and will be deposited every six months thereafter following the usual NDA data submission dates.

B. How scientific data will be findable and identifiable:

Data will be findable for the research community through the NDA Collection that will be established when this application is funded. For all publications, an NDA study will be created. Each of those studies is assigned a digital object identifier (DOI). This data DOI will be referenced in the publication to allow the research community easy access to the exact data used in the publication.

C. When and how long the scientific data will be made available:
The research community will have access to data when the award ends. As required by NDA, studies will also be created that contain the data used for every publication. Those studies will be shared when the pre-print is available. NDA studies have digital object identifiers (DOI) to aid in findability. We will include that DOI in relevant publications. NDA will make decisions about how long to preserve the data, but that data archive has not deleted any deposited data up to now.

ELEMENT 5: ACCESS, DISTRIBUTION, OR REUSE CONSIDERATIONS

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

All research participants will be consented for broad data sharing.

B. Whether access to scientific data will be controlled
To request access of the data, researchers will use the standard processes at NDA, and the NDA Data Access Committee will decide which requests to grant. The standard NDA data access process allows access for one year and is renewable.

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

The NDA GUID tool allows researchers to aggregate data from the same research participant without different laboratories having to share personally identifiable information about that research participant.

The NDA data dictionaries do not permit personally identifiable information to be shared. NDA maintains a Certificate of Confidentiality.

ELEMENT 6: OVERSIGHT OF DATA MANAGEMENT AND SHARING

The following individuals will be responsible for data collection, management, storage, retention, and dissemination of project data, including updating and revising the Data Management and Sharing Plan as necessary each year at the time of the Research Performance Progress Report.

PI name, position title, host institution, ORCID, email

Validation Schedule (this section is required by NIMH)

If funded, within 6 months of the Notice of Award date we will submit a Data Submission Agreement signed by the principal investigators and an institutional business official, as well as define and complete the Data Expected section of this project. Uploads of all initial demographic, clinical, and raw structural MRI, MRS and fMRI research data will be completed using the second submission cycle deadline following the Notice of Award date. Subsequent data uploads will be harmonized, validated, and submitted biannually on the standard January 15th and July 15th submission deadlines.

We also plan to use the NDA validation tool as a quality control measure in the laboratory. The data manager in charge of submitting data to NDA will help researchers in the group validate their data once every month.