Example NIMH Data-Resource Sharing Plan

1. **Grantee Information:**
   * **Project Title:**
   * **Principal Investigator:**
   * **Institution:**
   * **Grant Number**:
   * **Project Period:**

**B. Summary of Project:**

**C. Description of Sharing:**

**Biospecimen and Data sharing with the public:** In compliance with NIH data sharing policies (NOT-OD-14-124, NOT-MH-19-033, NOT-MH-21-265 , <http://grants.nih.gov/grants/sharing.htm>), we will share all permissible de-identified molecular and clinical data and biospecimens collected under this project through NIH-designated data repositories.

**Biospecimens and Accompanying Data:** Biosamples collected as part of the study will be submitted to the NIMH repository and Genetics Resource (NRGR) in compliance with NIMH biospecimen sharing policies. A subset of phenotypic data will also be deposited with NRGR to accompany the biospecimens and facilitate biospecimen sharing. This includes biospecimen related data, demographic data, links to other databases, individual level data from clinical instruments/surveys, etc. All required accompanying phenotypic data will be provided to NRGR at least 6 months prior to the public release date of the biospecimens detailed below. Samples will be submitted in accordance to standard operating procedures as directed by NRGR. We understand that submission of the accompanying phenotypic data is required for biospecimen banking, but that this does not supercede requirements to submit ALL data to NDA and/or dbGaP under NOT-OD-14-124 and NOT-MH-19-033. Double submissions with reformatting may be necessary to fulfill all data submission requirements.

**All Genomic and Phenotypic Data:** The study will be registered in dbGaP and NDA (NIMH Data Archive) and all clinical and molecular data that has been through quality control will be submitted to NDA or other NIMH-designated repositories every 6 months with full compliance with the [terms and conditions for NDA data submission and data sharing](https://ndar.nih.gov/ndarpublicweb/Documents/historical_terms_and_conditions/NIMH%20Data%20Archive%20Data%20Sharing%20Terms%20Effective%2007012015.pdf) as permited by national and internation law and institutional regulation. To comply with NIH GDS policy genomic data will be submitted to an NIH-designated repository after completion of cleaning a quality control, generally within 3 months of generation. Under NIMH purview, extension of time frame for public release can be granted on a case by case basis.

We understand that to deposit data in NDA we are expected to:

* Obtain [**Informed Consent**](https://ndar.nih.gov/contribute_informed_consent.html) that allows for broad sharing of the research subject’s de-identified data.
* Collect Personally Identifiable Information (PII) from research subjects that will allow for the creation of the [**NDA GUID**](https://ndar.nih.gov/standards.html#GUID) (a de-identified subject ID), which is required for submission of data to the NDA. [Note: if GUID generation will be difficult, discuss this term with NIMH program]
* [**Request**](https://ndar.nih.gov/access.html) an NDA Account with access to use the GUID Tool.
* Complete and submit an [**NDA Data Sharing Agreement**](https://ndar.nih.gov/ndarpublicweb/Documents/NDAR+Submission+Request.pdf) (DSA) within six months of the Notice of Award (NoA) issue date.
* Review the [**NDA data definition**](https://ndar.nih.gov/standards.html#Definition) for the measures/experiments expected and define  the project's data definition harmonized to that standard.  For measures not yet defined, work with NDA staff to define the measure following NDA best practices.
* Specify the measures expected to be collected by the project in the Data Expected tab of the NDA Collection and its data sharing schedule within six months of NoA issue date in accordance with the applicable [**terms and conditions**](https://ndar.nih.gov/contribute_data_sharing_regimen.html) of award.
* Create a [**GUID**](https://guid.nih.gov/) for each research subject using the NDA GUID tool.
* Submit data on or before the NDA submission due dates (January 15th and July 15th each year) in accordance with the applicable [**terms and conditions**](https://ndar.nih.gov/contribute_data_sharing_regimen.html) of award.
* Address any post submission [**QA/QC**](https://ndar.nih.gov/policies_standard_operating_procedures.html#sop5) checks that have been identified by the NDA.
* Create an [**NDA Study**](https://ndar.nih.gov/access_ndar_study.html), linking a result from a publication, pipeline, or discovery prior to it being published or made public.
* Specify the Digital Object Identifier (DOI) from the NDA Study in any publication or presentation allowing the result and underlying data to be linked in perpetuity.

**D. Detailed Data/Biospecimen Descriptions:** The details of data and biospecimens to be collected are described below. The all dates provided in these tables are estimates and may be updated by the PI as circumstances require, with the approval of the NIMH program officer. These will be submitted to the the appropriate NIH designated repository (see above) and made available for public distribution the described timeline:

**Table 1: Biospecimens shared with NRGR**

**Instructions:** The details in the following table are provided as an illustrative example. PIs should modify this table to reflect the unique data and samples that will be collected as part of their project. Not all fields will apply.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Project site** | **Number of subjects** | **Type of Biospecimen** | **Timeline for Submission** | **Public Sharing Timeline** |
| Example: U Penn | 20 probands, 20 controls | Whole Blood to be extracted to DNA | Continuous | Up to 6 months after the project end date or at the time of acceptance of initial publication, whichever occurs first |
| Example: CHOP | 5 trios (proband and 2 parents) | Fibroblasts | Stored at sites at sites- shipped at least 1 year prior to end of project period | Up to 6 months after the project end date or at the time of acceptance of initial publication, whichever occurs first |
| Example: CHOP | 20 probands | iPSCs- derived by NRGR | To be derived by NRGR in 2023 | Within 12 months after final delivery from contractor to project team, but not later than 6 months after project end date or at time of publication, whichever occurs first. |
| Example: Yale | 1000 cases; 1000controls | Whole blood to be extracted to RNA | Frozen -batch shipped quarterly | Up to 6 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: U Michigan | 5000 cases; 2000 conrols | Saliva to be extracted to DNA | Stored at sites at RT -shipped 1 year prior to end of project period | Up to 6 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |

We understand that the required accompanying phenotypic data will be released with the biospecimens by NRGR on the timeline described above. We will provide demographic data (gender, ethnicity, age at time of assessment), linking IDs to other data and biospecimen repositories, clinical, and genetic data to NRGR and other data repositories as described below.

**Table 2: Details of data that will be shared**

**Instructions:** Please adjust the table below as needed. Illustrative examples are provided, but this is not an exhaustive list of what may be required. Discuss possible requirements with NRGR and NIMH program.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Data Type** | **Number of subjects, # probands/**  **controls/ sibs/parents etc** | **Submitting Site** | **Timeline Submitted to NRGR** | **Other Repositories** | **Timeine for submission to other repository** | **Public Sharing Timeline at other repository** |
| Example: Demographic Data (gender, ethnicity, age at time of assessment) | 10k cases, 10k controls | CHOP | At least 6 months before public release date of samples described above | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: Overall Diagnosis | 10k cases, 10k controls | CHOP | At least 6 months before public release date of samples described above | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: Diagnostic Instrument- SCID- item level data | 10k cases | CHOP | At least 6 months before public release date of samples described above | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: Family history- FIGS- item level data | 10k cases, 10k controls | CHOP | At least 6 months before public release date of samples described above | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: Screening Questionaire- item level data | 10k cases, 10k controls | CHOP | At least 6 months before public release date of samples described above | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: Genomic data- whole genome sequencing (30x) -BAM fastq | 10,000 cases; 30,000 controls | Yale | N/A | AnViL (dbGaP) | Within 3 months of generation after cleaning and QC | Up to 6 months after data submission or upon publication, whichever comes first |
| Example: Genomic Analysis results (PRS scores) | 10k cases, 10k controls | CHOP | At least 6 months before public release date of samples described above | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: Genomic data- RNA sequencing of iPSC derived neurons | 20 cases, 20 controls | CHOP | N/A | NDA | Within 3 months of generation after cleaning and QC | Up to 6 months after data submission or upon publication, whichever comes first |
| Example: fMRI imaging | 100 cases; 100 controls | CHOP | N/A | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: EEG | 100 cases; 100 controls | CHOP | N/A | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: Electronic Medical Record Derived data ( ICD codes, diagnosis score) | 100k cases; 500k controls | Vanderbuilt | N/A | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: Biospcimen Metadata –(collection time, processing, storage monitoring) | 1000 cases, 1000 controls | UCLA | At least 6 months before public release date of samples described above | NDA | Every 6 months beginning 12/12/2024 | Up to 12 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |

**Table 3: Biospecimens stored at other biorepositories (Linking IDs to specimens stored outside NRGR will be provided)**

**Instructions:** Please adjust the table below as needed to reflect the unique data and samples that will be collected and stores as part of this project. Illustrative examples are provided, but this is not an exhaustive list of what may be required. Discuss possible requirements with NRGR and NIMH program. If all biospecimens will be stored at NRGR, please indicate that no biospecimens will be shared with non-NRGR repositories.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Project site** | **Number of subjects** | **Type of Biospecimen** | **Repository** | **Timeline for Submission** | **Public Sharing Timeline** |
| Example: Broad | 30,000 | DNA | Broad Biorepository | Continuous | Up to 6 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |
| Example: UNC | 5000 | Urine | UNC Biorepository | Continuous | Up to 6 months after the project end date or at the time of acceptance of initial publication, whichever occurs first. |

**Table 4: Milestones and timelines**

**Instructions:** Please complete the table below.

|  |  |
| --- | --- |
| Quarter/year | Data Generation and submission milestones |
| Year 1- Q1 |  |
| Year 1- Q2 |  |
| Year 1- Q3 |  |
| Year 1- Q4 |  |
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