

Plan Overview

A Data Management Plan created using DMP Tool

Title: Disparities in Substance Use and Mental Health for Women by Sexual Orientation: Identifying Modifiable Risk and Protective Factors during the COVID-19 Pandemic Using Multiple Sources of Health Data

Creator: Kristie Seelman - **ORCID:** [0000-0002-4064-2927](https://orcid.org/0000-0002-4064-2927)

Affiliation: Georgia State University (gsu.edu)

Principal Investigator: Kristie Seelman, Grace Eau

Data Manager: Grace Eau, Blake McGee

Project Administrator: Kristie Seelman

Funder: National Institutes of Health (nih.gov)

Funding opportunity number: RFA-PM-23-002

Template: NIH-Default DMSP

Start date: 12-01-2023

End date: 11-30-2025

Last modified: 07-08-2024

Copyright information:

The above plan creator(s) have agreed that others may use as much of the text of this plan as they would like in their own plans, and customize it as necessary. You do not need to credit the creator(s) as the source of the language used, but using any of the plan's text does not imply that the creator(s) endorse, or have any relationship to, your project or proposal

Disparities in Substance Use and Mental Health for Women by Sexual Orientation: Identifying Modifiable Risk and Protective Factors during the COVID-19 Pandemic Using Multiple Sources of Health Data

Data Type

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.

Describe data in general terms that address the type and amount/size of scientific data expected to be collected and used in the project (e.g., 256-channel EEG data and fMRI images from ~50 research participants). Descriptions may indicate the data modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing that has occurred (i.e., how raw or processed the data will be)

This project involves secondary data analysis of health data from the All of Us research study; no additional data are generated. The data utilized include survey data and electronic health records. The All of Us data are stored in a common cloud (online) environment, accessible to approved researchers who undergo training about privacy rules and other topics. The present study uses the controlled tier data, which include the most sensitive information that may increase the risk for possible identification of individuals, including sexual orientation information. Researchers are not able to download copies of the data - therefore, the researchers on this team are unable to prepare the actual data for public sharing, but others can access the data through the All of Us Research Hub.

The researchers will manage, preserve, and share:

- (a) A project-specific codebook of variable names, descriptions, and values used in our project from the All of Us dataset;
- (b) A copy of R/Python syntax used for data analysis for each resulting publication.

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.*

Because researchers cannot download copies of the full All of Us dataset, all analysis occurs in the cloud environment, and access to the data is controlled by All of Us, our research team cannot preserve or share actual copies of the data.

We will preserve and publicly share a list of variables used for this study in a project-specific codebook so that others may potentially replicate or build from our analysis in future research. Each variable in the codebook will include a brief description of the item along with the question number and question text from the relevant survey (if applicable), variable name, variable label, value labels, and standard codes for missing values—including codes for non-applicable, “don’t know,” and refusal. Documentation will be provided in portable document format (PDF).

We will preserve and share R and/or Python syntax used for our analyses so that others may potentially replicate or build from our analysis in future research. We will note which versions/packages of

R/Python were used for analysis.

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.

Study protocol for the All of Us research project and copies of surveys used with participants are already made publicly available through the All of Us Research Hub: <https://www.researchallofus.org/>.

Documentation to be made publicly available by our research team for the research community will include a project-specific codebook with univariate statistics for each variable used in our analysis, and study-level metadata following the Data Documentation Initiative specification. Each variable in the codebook will include a brief description of the item along with the question number and question text from the relevant survey (if applicable), variable name, variable label, value labels, and standard codes for missing values—including codes for non-applicable, “don’t know,” and refusal. Documentation will be provided in portable document format (PDF).

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.

We will manage, preserve, and share R and Python syntax used for analyzing the All of Us data for this research. We will publicly share information about the version/packages of R and/or Python that we used for analysis so that procedures can be replicated by others.

The All of Us data are accessed using the cloud environment available to all approved researchers, including Jupyter Notebooks. Additional tools or software are not needed to replicate our study.

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

We will use open file formats (e.g., PDF, TXT, HTML, etc.) to preserve and share our project-specific codebook and R/Python syntax.

Data Preservation, Access, and Associated Timelines

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 [Selecting a Data Repository](#))

Our project-specific codebook with variable names and descriptors and R/Python syntax will be deposited in the Open Science Framework registry.

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.

Open Science Framework provides searchable study-level metadata for dataset discovery. Open Science Framework assigns DOIs as persistent identifiers, and has a robust preservation plan to ensure long-term access. Data will be discoverable online through standard web search of the study-level metadata as well as the persistent pointer from the DOI to the dataset.

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.

All data generated from this project will be made available as soon as possible, and no later than the time of publication or the end of the funding period, whichever comes first. The duration of preservation and sharing of the data will be a minimum of 10 years after the funding period.

Access, Distribution, or Reuse Considerations

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 [Frequently Asked Questions](#) for examples of justifiable reasons for limiting sharing of data.

Because we are not sharing the underlying data, but only a project-specific codebook and R syntax, there are not limitations requiring approval before we publicly share this information.

The All of Us study has its own limitations on availability of data and privacy of participants. The Public Tier of data contains only aggregate data with identifying information removed and is open to the general public for use.

For our project, we are utilizing the Controlled Tier of data, which contains genomic data in the form of whole genome sequencing (WGS) and genotyping arrays, previously suppressed demographic data fields from EHRs and surveys, and unshifted dates of events. According to the All of Us protocol, these data are accessible only to approved, trained researchers. Further, researchers are not able to download the actual data for analysis. These limitations prevent our team from distributing the actual dataset used for our analyses.

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).

Controlled access will not be used for access to our project-specific codebook or R/Python syntax. This information will be shared by unrestricted download.

All of Us data are available by controlled access only. Any individual may receive access to All of Us data resources (i.e., become an “authorized user”) if they follow the appropriate process. An authorized data user is a person who is authorized to access and/or work with registered or controlled tier data from the All of Us Research Program. Authorized users receive a data passport that allows them to create workspaces and conduct research. Initially, a data user’s institution must enter into an institutional data use agreement with the All of Us Research Program for an individual to become an authorized user. Once their institution has entered into the agreement, the individuals must take the following steps to become authorized data users: (1) Provide their identity to the All of Us Research Program; (2) Provide consent for public display of their name and affiliations along with plain language descriptions of their research project; (3) Provide consent for public release of name and affiliation if the RAB finds that they have violated the DUCC. (5) Complete the All of Us Responsible Conduct of Research Training, including modules on data security and participant privacy awareness, and renew this training on an annual basis. (5) Provide a signature that codifies that the user has read, understood, and agrees to abide by the DUCC, and has completed the requisite training.

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).

N/A - The only data being managed and publicly shared by the research team are not human subjects data (i.e., the project does not involve interactions with human subjects, and the data being analyzed are not identifiable). This project will adhere to the All of Us Research program's Data Protection and Privacy standards as well as their code of conduct for responsible data use. All members of the research team involved in direct analysis of study data have undergone the training and registration required by All of Us for access to the controlled tier of data.

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).

PI Kristie Seelman will be responsible for the day-to-day oversight of project management activities and data sharing, while PI Grace Eau will track our final variables list and store copies of our R/Python syntax. Broader issues of the DMS Plan compliance oversight and reporting will be handled by the PIs and Co-Investigators as part of Georgia State University's stewardship, reporting, and compliance processes.
