Data User Code of Conduct

All of Us Research Program

This Data User Code of Conduct describes how *All of Us* Research Program data can be used under the User Institution *All of Us* Research Program Data Use and Registration Agreement.

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.

Before accessing and/or working with *All of Us* Research Program data, authorized data users must:

1. complete the *All of Us* Research Program research ethics training; and
2. read and acknowledge this Data User Code of Conduct.

As an "Authorized Data User" of the *All of Us* Research Program data, I will:

- read and adhere to the *All of Us* Research Program core values.
- follow all laws and regulations regarding research involving human data and data privacy that are applicable in the area where I am conducting research.
    - In the US, this includes all applicable federal, state, and local laws.
    - Outside of the US, other laws will apply.
- conduct research that follows all policy requirements and conforms to the ethical principles upheld by the *All of Us* Research Program
- respect the privacy of research participants at all times.
    - I will **NOT** use or disclose any information that directly identifies one or more participants.
        - If I become aware of any information that directly identifies one or more participants, I will notify the *All of Us* Research Program immediately using the appropriate process.
    - I will **NOT** attempt to re-identify research participants or their relatives.
        - If I unintentionally re-identify participants through the process of my work, I will contact the *All of Us* Research Program immediately using the appropriate process.
        - If I become aware of any uses or disclosures of *All of Us* Research Program data that could endanger the security or privacy of research participants, I will contact the *All of Us* Research Program immediately using the appropriate process.
- use the *All of Us* data ONLY for the purpose of biomedical or health research.
- provide a meaningful and accurate description of my research purpose every time I create an *All of Us* Research Program Workspace.
    - Within each Workspace, I will use the *All of Us* Research Program data or any external data I upload for the research purpose I have provided.
    - If I have a new research purpose, I will create a new workspace and provide a new research purpose description.

- take full responsibility for any external data, files, or software that I import into the All of Us Research Workbench and the consequences thereof.
  - I will know and follow all applicable laws, regulations, and policies regarding access and use for any external data, files, or software that I upload into my Workspace.
  - I will NOT upload data or files containing personally identifiable information (PII), protected health information (PHI), or identifiable private information (IPI).
    - "PII" means information that can be used to distinguish or trace the identity of an individual (e.g., name, social security number, biometric records etc.) either alone, or when combined with other personal or identifying information that is linked or linkable to a specific individual 2 CFR § 200.79.
    - "PHI" means individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium (45 CFR § 160.103).
    - "IPI" means private information for which the identity of the subject is or may readily be ascertained by the investigator, or associated with the information (45 CFR § 46.102).
  - I will use any external data, files, or software that I upload into my Workspace exclusively for the research purpose I have provided for that Workspace.
  - I will NOT use external data, files, or software that I upload into my Workspace for any malicious purpose.
  - If any import of data, files, or software into my Workspace results in unforeseen consequences and/or unintentional violation of these terms, I will notify the *All of Us* Research Program as soon as I become aware using the appropriate process.
- use a version of the *All of Us* Research Program database that is current at or after the time my analysis begins.
  - Archived versions of the database are maintained for the sole purpose of completion of existing studies or replication of previous studies. New work may not be initiated on archived versions of the database.
- follow all provisions of the *All of Us* Publication and Presentation Policy

As an "Authorized Data User" of the *All of Us* Research Program data, I will:

- **NOT** share my login information with anyone, including another authorized data user of the *All of Us* Research Program.
  - I will not create any group or shared accounts.
- **NOT** use *All of Us* Research Program data or any external data, files, or software that I upload into the Researcher Workbench for research that is discriminatory or stigmatizing of individuals, groups, families, or communities in accordance with the *All of Us* policy on stigmatizing research.
  - I will contact the *All of Us* Research Program Resource Access Board (RAB) for further guidance on this point as needed.
- **NOT** attempt to contact *All of Us* Research Program participants.
- **NOT** make copies of or download Highly Granular Data or otherwise remove it from the *All of Us* Research Program environment.
  - Highly Granular Data means all participant-level data, and aggregate statistics in buckets of fewer than 20 participants.

- ■ I will not take screenshots or attempt any other way of copying of Highly Granular Data.
- ■ I will not redistribute or publish Highly Granular Data without written approval from the *All of Us* Research Program.
- ○ **NOT** redistribute or publish registered or controlled tier data, including summary statistics aggregated to buckets of 20 with the intent of reproducing the *All of Us* database or part of the *All of Us* database outside of the *All of Us* Researcher Workbench.
- ○ **NOT** attempt to link registered or controlled tier *All of Us* Research Program data at the participant-level with data from other sources.
- ○ **NOT** use *All of Us* Research Program data or any part of the Research Hub for marketing purposes.
    - ■ "Marketing" means a communication about a product or service that encourages recipients of the communication to purchase or use the product or service (US 45 CFR §164.501).
- ○ **NOT** represent that the *All of Us* Research Program endorses or approves of my research unless such endorsement is expressly provided in writing by the *All of Us* Research Program.

Data Disclaimer:

The *All of Us* Research Program does not guarantee the accuracy or availability of the data in the *All of Us* Research Program database. The *All of Us* Research Program does not guarantee the performance of the software in the *All of Us* Research Program database. The *All of Us* Research Program does not warrant or endorse the research results obtained by using the *All of Us* database.

Terms and Definitions:

- The **[*All of Us* Research Program](#)** is a national longitudinal research initiative that aims to engage one million or more participants living in the United States. Participants contribute health data and specimens (blood, urine, saliva) to a repository that includes health, behavioral, genomic, and other data. The *All of Us* Research Program is a key component of the Precision Medicine Initiative, which aims to leverage advances in genomics and health information technology to accelerate biomedical discoveries.
- There are **three data access tiers** within the *All of Us* Research Program.
  - **Public tier**: The resource tier containing only summary statistics and aggregate information that poses negligible risks to the privacy of research participants; the Public Tier can be accessed by anyone without logging into the *All of Us* Research Platform.
  - **Registered tier**: The resource tier that contains data elements that have a lower risk of unapproved re-identification, thus carries minimal risk to the privacy of research participants; Registered Tier data can only be accessed after logging into the *All of Us* Research Platform; all access will be logged and may be audited.
  - **Controlled tier**: The resource tier that contains data elements that may not, in their own right, readily identify individual participants, but may increase the risk of unapproved re-identification when combined with other data elements; such data includes participant-level genomic data, clinical notes, and narrative data; users must be appropriately accredited and granted approval to access the Controlled Tier, and all access will be logged and may be audited.
- 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 data users must complete the *All of Us* Research Program research ethics training and attest to this agreement.
- The **Committee on Access, Privacy, and Security (CAPS)** is the committee that directs the policies and implementation of data access for the *All of Us* Research Program; CAPS is overseen by the *All of Us* Steering Committee.
- The **Resource Access Board (RAB)** is the board that operationalizes decisions regarding data access, with review by the CAPS; responsibilities include: administration of user registration and approval, conduct of Workspace audits, and review of potential violations of data access principles; the RAB reports to CAPS and the *All of Us* Steering Committee.
- *All of Us* **Workbench** is the cloud-based research platform that the *All of Us* Research Program has created, where Authorized Users can request access to the data, and once approved, create project-specific Workspaces in which to access and analyzed the data.
- **Workspace**: A user-created analytical sandbox within the Workbench platform where users can virtually pull in subsets of data from the *All of Us* Research Program database and perform analyses;

Authorized Users must create a new Workspace for each research project using *All of Us* data and provide a plain language description of the research project, as well as other project information, that will be published publicly on an *All of Us* website.