Policy

Biospecimen Access

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Contents

List of Abbreviations

BID: Biobank Identifier

CAPS: Committee on Access, Privacy, and Security

DRC: Data and Research Center

DUCC: Data User Code of Conduct

ELSI: Ethical, Legal, and Social Implications

IRB: Institutional Review Board

MTA: Material Transfer Agreement

NIH: National Institutes of Health

PID: Participant Identifier

QC: Quality Control

RAB: Resource Access Board

Section 1: Introduction

The mission of the *All of Us* Research Program is to "Accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us." *All of Us* provides a rich and unique resource of biological specimens (biospecimens) and related information voluntarily contributed by the program's participants. This resource can be used to study a wide range of scientific questions to improve our knowledge of health and well-being and improve health outcomes. *All of Us* is committed to responsible stewardship of this valuable resource by enabling meaningful and high-quality scientific research that is conducted in a manner respectful of our participants.

1.1 Purpose and Scope

This policy applies to researchers accessing biospecimens for the purpose of partnered research studies and to any data generated by the study, including data stored and/or analyzed outside of the Researcher Workbench.

This policy establishes the framework and principles governing access to *All of Us* biospecimens (Section 1). It further details the eligibility, application, and researcher requirements (Section 2) and the processes for reviewing and approving requests for access to *All of Us* biospecimens (Section 3). The policy also provides a list of responsibilities that researchers are held accountable to after receiving *All of Us* biospecimens (Section 4).

The following principles have guided the development of a framework for access to *All of Us* biospecimens:

- Participants are research partners.
    - Participant privacy must be protected to the greatest extent possible, in accordance with the PMI Privacy and Trust Principles.
    - Participants' biospecimens and data must be kept secure, as dictated by the PMI Data Security Policy Principles and Framework.
    - Participants' biospecimens may not be used for research purposes that could potentially harm or stigmatize them or groups to which they belong. Refer to the *All of Us* Policy on Stigmatizing Research.
- The program will be transparent about approved studies and the requirements for receiving approval, as defined by the policy.
- Participants must be able to access information on the research purposes that *All of Us* biospecimens are being used for, and by whom.
- Biospecimens are a scarce and finite resource. As such, researchers can only use *All of Us* biospecimens after they are authorized and for research uses that are scientifically sound, high priority, non-duplicative, and have the potential to contribute to knowledge that improves human health and well-being.

The following safeguards will be afforded to *All of Us* biospecimens:

- Identifiable, sensitive information will be protected from disclosure by Certificates of Confidentiality, with which all researchers accessing *All of Us* biospecimens and data must comply.
- Applications for biospecimen access will undergo a coordinated review process (see Section 1.2) for scientific merit and adherence to research ethics principles and *All of Us* core values. Applications will also be assessed for potential for benefit and for harm to relevant individuals, groups, and communities beyond *All of Us* participants.
- Researchers must sign the Material Transfer Agreement (MTA).
- Researchers and all other authorized biospecimen users must sign the Biospecimen Access Code of Conduct, which specifies the terms of use for *All of Us* biospecimens. The signed copies of the Code of Conduct must be retained within the researcher's records.
- *All of Us* biospecimens may not be used to establish immortalized cell lines and other derivatives that perpetuate the use of *All of Us* biospecimens beyond the period of approved research (see Section 4.8).
- Researchers and all other authorized biospecimen users cannot share, loan, give, sell, or otherwise redistribute *All of Us* biospecimens to anyone outside the research team on the approved research protocol. This includes other approved researchers of *All of Us* biospecimens that were not included in the research protocol.
- *All of Us* biospecimens and data cannot be used for advertising or marketing purposes.

Furthermore, to protect the privacy of participants, re-contact of participants will be allowed only with explicit approval from the relevant governance bodies detailed in Section 1.2 and can only be carried out through the *All of Us* Research Program.

1.2 Governance of Biospecimen Access

This section describes the framework for biospecimen access governance and is consistent with other *All of Us* policies for access to data and participants.

Biospecimen access requests will undergo a review process outlined in the Partnered Research Studies Handbook, including review by the *All of Us* Partnered Research Access Board. The Partnered Research Access Board will:

- Provide recommendations on which requests should be approved and conduct required follow-up on all biospecimen access requests.
- Be composed of a diverse group of subject matter experts to evaluate scientific merit and ethical, legal, and social implications (ELSI) considerations related to biospecimen access.
- Include participants.
- Escalate reviews as needed to the Resource Access Board (RAB) to assess for compliance with *All of Us* resource access and use policies.
- Escalate potential violations of the Data User Code of Conduct, Biospecimen Access Code of Conduct, and MTA, and recommend appropriate actions against violators to the RAB.
- Review applications in consultation with community partners, participant representatives, and other *All of Us* governance bodies as necessary, to seek additional input on biospecimen access and use-related issues (such as community research needs, perception of benefit and harm to communities, and research proposals requiring direct contact between researchers and participants).

The policies defining the activities of the governance review bodies, including the RAB, are overseen by the *All of Us* Committee on Access, Privacy, and Security (CAPS) in coordination with the *All of Us* Policy Office.

Section 2: Researcher Eligibility and Application Requirements

All of Us biospecimen requests will undergo a review that will include ethical considerations, availability and technical suitability of biospecimens, scientific approach, qualifications of the researcher or research team, and the research facility's capabilities. Researchers must submit a complete application package, which must be approved before access can be granted. This section of the policy details eligibility and application requirements for biospecimen access.

2.1 Researcher Eligibility to Apply for Biospecimen Access

No research team will have privileged access to *All of Us* biospecimens, in accordance with the program's Core Protocol. An application package will be required from all partnered research studies requesting *All of Us* biospecimens, including those based at institutions participating in the *All of Us* Research Program. The application package assessment will be based on the information provided by the research team (see Section 2.2), and approval will be based solely on review criteria determined by the program (see Section 3.1).

To be eligible for biospecimen access, the researcher must:

- Be an authorized Controlled Tier data user of the Researcher Workbench.
- Provide consent for public display of their name and affiliations alongside a plain language description of their research project(s).
- Provide consent for public release of their name and institutional affiliation if the program finds that they have violated the program's policies.
- Provide a signature via the Biospecimen Access Code of Conduct to affirm that the applicants have read, understood, and agree to abide by the relevant *All of Us* policies, including but not limited to the Biospecimen Access Policy.

Annually, researchers and authorized biospecimen users must re-attest to the Biospecimen Access Code of Conduct using procedures established by the program. Each approved researcher must also review their contact information, institutional affiliation(s), conflict(s) of interests declaration, and research purpose description(s) annually and provide updates if they have changed.

2.2 Application Requirements

Researchers will be given templates with which to complete their biospecimen request application, which includes the following sections:

- Abstract (written for a general audience)
- Research rationale, highlighting the *novel and/or crucial* need to utilize biospecimens from the *All of Us* cohort and particular subpopulations requested
- Main hypothesis/hypotheses
- Research aims
- Anticipated benefits of the study, including how it might add to the *All of Us* scientific resources, benefit particular subpopulations (e.g., groups underrepresented in biomedical research), or potentially reduce health disparities
- Brief overview of statistical power of analyses anticipated
- General performance metrics of the proposed assay(s) (specificity, sensitivity, reproducibility, etc., as applicable)

- Plan, proposed funding, and timeline for dissemination of products and results (e.g., abstracts, publications, other research dissemination products, and knowledge products for participants) and return of data to *All of Us* via deposition to the *All of Us* Data and Research Center (DRC)
- Plan, proposed funding, and timeline to potentially return individual research results to participants, if appropriate
- Qualifications of the proposed laboratory/facility, describing how biospecimens will be secured/stored, and a brief description of past efforts on similar research, where applicable
- Discussion of any potential risks to participants or other individuals, and any potential harms posed to groups or specific communities whose biospecimens are being requested
- Proposed measures to mitigate potential harms to individuals, groups, and specific communities, such as steps to prevent risk of stigmatization
- Declaration of all conflicts of interest, whether financial or not. Any conflict(s) of interest must be described, including how the research design and protocol will mitigate the influence of such conflict(s)

2.3 Supplementary Materials

The supporting materials detailed below are to be provided to the Partnered Research Access Board during the biospecimen access application process:

- Justification for the types (e.g., whole blood, white blood cells, serum, plasma, DNA, urine) and volumes of biospecimens
- Proof of grant funding or financial support for the proposed research. If funding is contingent upon access approval, the program will grant conditional approval until funding is secured
- Credentials of the researcher (biosketch or curriculum vitae)
- The names of individuals who will have access to or use of *All of Us* biospecimens in the course of the research detailed in the application

Research proposals will be reviewed according to the criteria laid out in Section 3.1. Biospecimen access will be granted if the application package is found satisfactory after review. Biospecimens will only be shipped to the researcher ***AFTER*** the researcher signs the MTA and the Biospecimen Access Code of Conduct. Requests for additional biospecimens to support an approved biospecimen request will be linked back to the original request application for review; this may not necessitate a full review if the scope of the study and study objectives remain the same.

Section 3: Adjudication

3.1 General Review Criteria/Guiding Principles

As applicable for the project proposed, applications will be evaluated according to the following criteria:

- Is the research scientifically sound and non-duplicative (no duplication of effort between applicants, as determined during scientific review of proposals), and does it have the potential to significantly contribute to knowledge that improves health and well-being?
- Does the research align with the overarching *All of Us* mission and core values? Does the proposed project represent a unique value-add to *All of Us*?
- Is the research an appropriate and justified use of this scarce and finite biospecimen resource? Projects should be fit for purpose such that biospecimens and data from the program are essential to answer the proposed research question. Criteria for prioritization of multiple requests for the same biospecimens will be established in line with programmatic priorities.
- Is the research team sufficiently qualified for the proposed research? Does the laboratory have infrastructure suitable for the proposed research and necessary to securely handle and store the requested biospecimens?
- Is the proposed analysis suitable to produce high-quality data from the requested biospecimens? Is the initial power analysis sufficient to create meaningful data outcomes?
- What safeguards are in place to prevent participant or group harms or stigmatization at any stage of the project, including dissemination of findings, such as scientific papers/ publications?
- Does the application provide a robust plan for biospecimen and data security in accordance with the PMI Data Security Policy Principles and Framework?
- Does the application provide a plan, including timeline, for the return of project data/assay results to the DRC? Does the plan account for formats and curation sufficient to integrate the project data/assay results with other *All of Us* data?

3.2 Periodicity of Review

The periodicity of review of applications will be determined by the *All of Us* Research Program. In addition to regular meetings, ad hoc meetings may be called for as needed to review special requests, such as requests for biospecimens from American Indian and Alaska Native participants.

Studies should follow the research plan reviewed and approved by the program, recognizing that there may be additional analyses needed. Major deviations from the proposed research

plan or expansion of the scope of the study will need additional approval by the review committee. Amendments to the proposal must be submitted and reviewed separately.

3.3 Review of Requests for American Indian and Alaska Native Biospecimens

Any proposal that requests the use of biospecimens from American Indian and Alaska Native individuals must follow additional requirements set forth in program policy, including, but not limited to, the Policy on Respectful Research Involving American Indian and Alaska Native (AI/AN) Populations.

3.4 Periodic Audits

Periodic audits will be conducted to review compliance with the terms for biospecimen use. Individuals found to have violated the Biospecimen Access Code of Conduct may be subject to punitive action, including termination of access to *All of Us* Research Program resources, posting on a publicly accessible list of violators, notification of the National Institutes of Health or other federal agencies about the violation, or other penalties.

3.5 Appeals

If biospecimen access is denied, the researcher will be given the opportunity to submit an appeal for reconsideration of the proposed research, according to the appeals process defined by *All of Us*.

Section 4: Requirements of Researchers

4.1 Reporting

Researchers accessing *All of Us* biospecimens must submit or update:

1. The status of their project that details whether study aims, progress, study design, and measures for return of value to participants have remained consistent with how the aforementioned items were outlined within their approved proposal, as well as citations for any dissemination products (e.g., abstracts, publications) generated from use of *All of Us* biospecimens, at timepoints established in the approved Partnered Research Study Protocol.
2. Biospecimen status and plans every six months to the Biobank.
3. Incidents related to participants, including potential breaches of privacy/confidentiality and/or other relevant reports from ethical oversight bodies, in accordance with the

timeline and process established by *All of Us*, in addition to any reporting activities required by the Researcher's institution or other applicable policies.

Reports must comply with expectations of timeliness, completeness, and honesty set in the Biospecimen Access Code of Conduct. Failure to report or noncompliance with reporting expectations will be shared with *All of Us* oversight bodies and/or leadership and may lead to significant consequences, punitive actions, and/or loss of good standing with the program and NIH.

4.2 Data Sharing and Linkage to Phenotypic Data

1. Authorized Biospecimen Users will receive requested biospecimens in a coded manner, where requested biospecimens and any associated Quality Control (QC) samples are indexed and labeled with a unique Biobank identifier (BID). The key linking the Biobank ID with the PID is held by the DRC and not released to biospecimen-only partnered research study investigators
2. Linkage between the BID and the Research ID (RID) utilized to index phenotypic data will be conducted by the DRC and resultant dataset provided to Authorized Biospecimen Users on the Researcher Workbench.
3. Researchers accessing *All of Us* biospecimens must return assay data indexed by BID generated by approved research to *All of Us* within a timeframe established by *All of Us* and in accordance with standards set by the program for data quality and formatting. Data shared back with the program should be of sufficiently high quality to validate and replicate research findings.
4. Returned datasets will be held for a period of up to one year or first publication before the datasets are released for general access in the Researcher Workbench, to allow the approved researcher exclusive rights to their data.

4.3 Publication Guidelines

Researchers must notify *All of Us* about any dissemination products and must acknowledge *All of Us* and its research participants in all dissemination products (e.g., publications, presentations, patent applications, conference abstracts, etc.) that result from the use of the *All of Us* biospecimens and data, per the *All of Us* Research Program Publication and Presentation Policy.

4.4 Cost

- Approved researchers may be expected to pay a minimal processing fee for access to biospecimens. The fee will be set by the biobank and *All of Us* and made publicly available.

- The fee would be used to cover the costs associated with assembly of requested biospecimen sets, production of appropriate QC samples, biospecimen shipment, and analysis of QC results.
- *All of Us* is committed to ensuring that fees are reasonable for approved researchers and will review the fee structure every two years to ensure it is within the scope of common funding mechanisms.

Additionally, researchers requesting biospecimen access should budget for the following costs, depending on the scope of work:

- Preparing the dataset for submission to *All of Us*
- Preparing any associated documentation (e.g., protocols, data dictionaries)
- Supporting researchers/data users for data curation and quality control

4.5 Disclosure of Affiliations/Conflicts of Interest

Researchers approved for biospecimen access will disclose all relevant affiliations, interests and partnerships, as well as any financial and other conflicts of interest. The program will review applications from all entities requesting biospecimen access using criteria set forth in Section 3.1 and consult with interested parties (including participants, community partners, patient advocates, and others), as appropriate and at its discretion, for approving such access.

4.6 Destruction or Transfer of Unused Materials

- Biobank operations staff will ensure that only the approved minimum necessary volume of biospecimen is distributed.
- As part of the QC process, any residual biospecimens not consumed in carrying out the approved research must be destroyed in accordance with procedures of the researcher's organization.
- Researchers are expected to attest to having fulfilled the disposal or transfer requirements (and to share documentation as required by *All of Us*).
- If biospecimens are received and approved research is aborted, biospecimens must be destroyed in accordance with the procedures of the researcher's organization or transferred, as directed by *All of Us*.
- Separate procedures for handling biospecimens from withdrawn participants are referenced in the *All of Us* Research Program Operational Protocol. Biospecimens of participants who withdraw from the program are to be disposed of at the biobank if the biospecimens have not yet been shipped out. Biospecimens that have already been shipped out will not be retracted from researchers' institutions; any data collected until that point will be stored by the DRC.

4.7 Commercial Use/Access

- *All of Us* is dedicated to providing biospecimens to support research that provides maximal output, gains, and data usability for the broad research community.
- *All of Us* will evaluate commercially-funded and publicly-funded access requests utilizing the same criteria.
- Use of biospecimens for commercial research is permitted if proposed research meets the established evaluation criteria AND the commercial entity accepts the full MTA terms, Biospecimen Code of Conduct terms, data sharing terms, and all terms of this and other applicable *All of Us* policies.

4.8 Prohibition of Generation of Immortalized Cell Lines and Other Derivatives

All of Us does not permit the production of immortalized cell lines or other derivatives from *All of Us* biospecimens that perpetuate the use of these biospecimens beyond the period of approved research. This extends to current and future techniques that may be developed for such purposes.

4.9 Intellectual Property

No restrictions are placed on using *All of Us* resources to develop commercial products and tests to meet public health needs. *All of Us* claims no intellectual property rights on commercial products developed from research use of *All of Us* data and biospecimens.

All of Us supports and recommends that commercial products and services emerging from secondary research using *All of Us* data and biospecimens be accessible broadly and equitably. This broad and equitable access may be part of the return of value plan included in the application.

Section 5: Monitoring And Evaluation

The program will provide overviews of biospecimen access approvals and study updates to the relevant oversight and governance bodies. Relevant oversight bodies will review reports (Section 4.1) and audit projects, as necessary, to ensure compliance with expectations set forth in the Biospecimen Access Code of Conduct and relevant *All of Us* policies.

Glossary of Terms

***All of Us* Partnered Research Access Board (PRAB)**: The board responsible for recommending which biospecimen access requests should be approved. The PRAB is also responsible for monitoring activity, reviewing potential violations of *All of Us* Biospecimen Access Policy, and recommending appropriate remedial actions.

***All of Us* Research Program (*All of Us*):** A national longitudinal research initiative that aims to engage at least one million participants living in the United States. Participants contribute health data and biospecimens (blood, urine, saliva) to a repository that includes health, behavioral, genomic, and other data. *All of Us* is a key component of the Precision Medicine Initiative, which aspires to leverage advances in genomics and health information technology to accelerate biomedical discoveries.

***All of Us* Resource Access Board (RAB)**: The board that operationalizes decisions regarding resource access, including data access to biospecimens. Its responsibilities include overseeing registration procedures for new Authorized Data Users, conducting Workspace audits, responding to Authorized Data User inquiries around compliance with the *All of Us* research resources terms of use and policies, and reviewing potential violations of said terms and/ or policies.

Authorized Biospecimen User: For the purposes of this policy, the researcher(s) and other individuals who will have approved access to or use of *All of Us* biospecimens in the course of the Research.

Biospecimen Access Code of Conduct (BACC): An agreement between the *All of Us* Research Program and authorized users of the *All of Us* biospecimens. The BACC sets out the terms with which authorized biospecimen users must comply, to gain and maintain approved access to *All of Us* biospecimens.

Committee on Access, Privacy, and Security (CAPS): The committee that develops and assists in the development of the policies and implementation of resource access for the *All of Us* Research Program; CAPS is overseen by the *All of Us* Steering Committee.

Conflicts of Interest (COI): For the purpose of this policy, a COI may occur when a person's or entity's vested interests, financial or otherwise, raise a question of whether their actions, judgment, and/or decision-making can be unbiased. This may extend to situations where the person or entity who potentially benefits from actions or decisions made in their official capacity may also have undue influence (real or perceived) on the decision-making process.

Controlled Tier:. The Controlled Tier, made accessible for biomedical and health research through the *All of Us* Researcher Workbench, contains minimally obfuscated individual-level participant data, including genomic data, that builds upon the data types available in the Registered Tier, including data from electronic health records, wearables, surveys, and physical measurements. Access to the Registered and Controlled Tiers both require Authorized Data Users to log in to and interact with the data through the *All of Us* Researcher Workbench.

Data and Research Center (DRC): The entity that acquires, organizes, and provides secure access to the *All of Us* Research Program dataset. The center also provides research support for the scientific data and analysis tools for the program.

Data User Code of Conduct (DUCC): An agreement between the *All of Us* Research Program and authorized users of the *All of Us* data resources. The DUCC sets out the terms with which authorized data users must comply, and prospective data users must sign the DUCC to gain access to the Researcher Workbench.

Participant: An individual enrolled in the *All of Us* Research Program who has completed the consent process.

PMI Data Security Policy Principles and Framework: Building from the existing PMI Privacy and Trust Principles, these security policy principles and framework guide decision-making by organizations conducting or participating in precision medicine activities.

Research: Research to be conducted in part or in full using *All of Us* biospecimens and that has been reviewed and approved by the *All of Us* Partnered Research Access Board as documented in the approved study protocol.

Researcher: The individual(s) authorized in the MTA to carry out the approved research using *All of Us* Research Program biospecimens.