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Biospecimen protocols and dataset specifications

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Biobank sample protocols

The *All of Us* Biobank, operated through the Mayo Clinic in Rochester, Minnesota, is responsible for the storage and management of biospecimens used in the generation of *All of Us* genomic data and for broader research use. **Note** - the following sample collection process provides a high-level overview of standard procedures. Biosample tables available in the Researcher Workbench will be released iteratively and may not initially include all sample types listed.

Participant blood, saliva or urine are collected by our *All of Us* partners, and sent to the *All of Us* Biobank for further processing. Samples collected and stored by the *All of Us* Biobank adhere to standardized collection and storage protocols, as described in the *All of Us* Program protocol here. All samples, like blood or saliva, are prepared at the place where they are collected. The program then keeps the samples at 4ºC during transport to the Mayo Clinic's Biobank, where they are divided into smaller portions, frozen (-80ºC) and stored safely.

The *All of Us* Biobank processes the collection tubes, and stores various aliquot types from each collection tube. Aliquot types can include:

- Plasma (EDTA and PST)
- Serum
- DNA
- RNA (PAXgene RNA)
- WBC
- RBC
- Whole Blood + DMSO (Na-heparin)
- Urine

Sample Collection Process

Blood

HPO or DV Blood collection
Participant blood is collected either on an on-site clinic visit at an HPO site, or direct volunteer (DV). Blood is collected by standard venipuncture using a recommended winged butterfly needle (with an initial no-additive waste tube if needed to prime the tubing), with attention to keeping PAXgene tubes upright to prevent preservative backflow to the participant. A direct needle collection device can also be used, with special care used to ensure there is no backflow of preservative into the participant.

Tubes are drawn in the specified order: 8.5 mL SST, two 4.5 mL PST tubes, 4 mL Na-heparin, 4 mL EDTA, 10 mL EDTA, 10 mL PAXgene Cell Free DNA, and 2.5 mL PAXgene RNA. After collection, tubes are mixed by gentle inversion (SST 5 inversions; PST/Na-heparin/EDTA/PAXgene 8–10 inversions). All collected tubes for a Biobank order except the SST and PST are placed together in a blue biohazard bag and immediately refrigerated at 2–8°C. In difficult draws, collection may be prioritized by drawing the 4 mL EDTA tube first, then collecting remaining tubes as possible (including additional sticks or clearing tubing with a waste tube before returning to SST)

Quest Blood Collection
Blood samples for *All of Us* Research Program can also be collected through operators, such as Quest. A kit is mailed to the participant, after which they can visit a local Quest location for sample collection. Blood is collected by standard venipuncture using a recommended winged butterfly needle (with an initial no-additive waste tube if needed to prime the tubing), with attention to keeping PAXgene tubes upright to prevent preservative backflow to the participant. A direct needle collection device can also be used, with special care used to ensure there is no backflow of preservative into the participant.

Tubes are drawn in this order: SST, two PST tubes, Na-heparin, EDTA 4 mL, EDTA 10 mL , PAXgene Cell Free DNA, and PAXgene RNA. After draw, tubes are mixed by gentle inversions (SST 5 inversions; PST/Na-heparin/EDTA/PAXgene 8–10 inversions), and all tubes except SST/PST are immediately bagged and refrigerated at 2–8°C. SST/PST are processed shortly after collection (SST clot at room temperature, then centrifugation with SST/PST at room temperature), then returned to the same order's biohazard bag and refrigerated at 2–8°C until shipment.

Blood Diversion Pouch
On rare occasions at some HPO site visits, upon enrollment into the All of Us Researcher Program via an inpatient or outpatient clinical visit, blood division pouch sample collection may be used for some blood samples.

Using a diversion pouch blood-collection workflow, staff begin by filling the diversion pouch to capacity (about 60 mL), then seal the diversion pouch tubing and collect any required clinical/infectious disease marker tubes before collecting *All of Us* specimens via the diversion pouch. All *All of Us* Research Program tubes are then collected in a modified order that includes

intermittent no-additive waste tubes (filled ~half volume, ~2 mL) to clear the diversion line: 10 mL EDTA, waste, 8 mL SST, 4 mL EDTA, waste, PST tubes, 2.5 mL PAXgene RNA, waste, 4 mL Na-heparin, and 10 mL PAXgene Cell Free DNA. Tubes are mixed immediately after draw by gentle inversion (SST 5 inversions; PST/Na-heparin/EDTA/PAXgene 8–10 inversions), and all tubes except SST/PST are bagged and refrigerated at 2–8°C. SST/PST are kept at room temperature for processing (SST clots ≥30 minutes), then centrifuged and returned to the same order's biohazard bag for refrigerated storage at 2–8°C until shipment.

Saliva

HPO or DV Saliva collection

Using the Oragene Dx OGD-500 saliva collection kit, participants are instructed to avoid eating, drinking, smoking, or chewing gum for 30 minutes before collection. Saliva is collected by having the participant spit into the kit funnel until the liquid (not bubbles) reaches the "FILL TO" line on the tube. The funnel lid is then firmly closed (until it clicks) to puncture the stabilizer seal and release stabilization liquid into the saliva, which is allowed to fully drain into the tube before the funnel is removed. The tube is capped with the blue screw-top, inverted 8–10 times to mix, and placed in a biohazard bag for subsequent handling/shipment.

Urine

HPO or DV Urine collection

At HPO sites, urine is collected using a labeled 120 mL BD Vacutainer urine collection cup and a labeled 10 mL BD Vacutainer urine tube (no additive). Participants provide an unwitnessed midstream urine sample into the cup (clean-catch is not required) and are instructed not to overfill beyond a visual reference line drawn at ~60 mL. Immediately after collection, staff transfer urine from the cup into the 10 mL tube using the cup's integrated transfer device by inserting the tube upside down and allowing the tube's vacuum to fill it to ~10 mL (at least ~3/4 full) without removing the tube top. Once filled, the tube is removed, and excess urine and the collection cup are discarded per site procedures (the cup is not shipped to the Biobank).

Direct volunteer (DV) urine collection follows similar protocols as noted above. A visual reference line is drawn at ~60 mL on the cup, and at least ~20 mL must be collected to enable transfer via the integrated transfer device. Immediately after collection, staff transfer urine from the cup into the 10 mL tube by inserting the tube upside down into the transfer device and allowing vacuum fill to ~10 mL (at least ~3/4 full), without removing the tube top. The cup/excess urine are discarded (the cup is not shipped), and the filled urine tube is placed in the biohazard bag with the other specimens from the same kit and kept refrigerated at 2–8°C until packaging/shipping.

Sample Storage Temperatures

Aliquot Generated	Final Storage Condition	Collection Cohort
Plasma	-80°C	Adult, Pediatric

WBC	-80°C	Adult, Pediatric
RBC	-80°C	Adult, Pediatric
DNA	-80°C	Adult, Pediatric
Serum	-80°C	Adult, Pediatric
Whole Blood +DMSO	LN2	Adult, Pediatric
RNA	-80°C	Adult, Pediatric
Urine	-80°C	Adult, Pediatric

Biospecimen Inclusion Criteria

The following information is the sample inclusion criteria for the samples found in the **3a v8** biosample tables. To learn more, see the biosample release notes and data dictionary see here.

1. Sample is located at Minnesota location (not Florida location)
    a. Mayo_MN location value
2. The participant donated the sample is included in CDR v8
3. Cutoff date of 10/1/2023
    a. I.e. each sample was collected on or before 10/1/2023
4. The participant who donated the sample has provided the following data to the program:
    a. EHR data (any amount at any time, does not need to be current)
    b. Successful WGS or Array sequencing (sample must be included in the latest CDR genomic dataset)
    c. Physical measurements (any, no validation needed)
    d. TheBasics survey
    e. Lifestyle survey
    f. Overall Health survey

Field-specific filtering criteria:

The following information is the filter criteria for the samples found in the **3a v8** biosample tables

1. **participant_id**
    a. Values: XXXXXXXXX
    b. Criteria: none
2. **EDTA Plasma sample availability**
    a. Values: Y/N
    b. Criteria
        i. Yes =100 µl or more (in one tube alone. We will not be combining tubes)
        ii. No <100 µl volume
3. **EDTA Plasma sample date of collection**
    a. Values: Timestamp of collection in UTC

    b. Criteria: none
4. **PST Plasma sample availability**
    a. Values: Y/N
    b. Criteria
        i. Yes =100 µl or more (in one tube alone. We will not be combining tubes)
        ii. No <100 µl volume
5. **PST Plasma sample date of collection**
    a. Values: Timestamp of collection in UTC
    b. Criteria: none
6. **Serum sample availability**
    a. Values: Y/N
    b. Criteria
        i. Yes = 100 µl or more (in one tube alone. We will not be combining tubes)
        ii. No < 100 µl
7. **Serum sample date of collection**
    a. Values: Timestamp of collection in UTC
    b. Criteria: none
8. **DNA from Blood sample availability**
    a. Values: Y/N
    b. Criteria
        i. Yes = 2.5 µg or more dsDNA mass
        ii. No <2.5 µg dsDNA mass
9. **DNA from Blood sample date of collection**
    a. Values: Timestamp of collection in UTC
    b. Criteria: none
10. **DNA from Saliva sample availability**
    a. Values: Y/N
    b. Criteria
        i. Yes = 2.5 µg or more dsDNA mass
        ii. No <2.5 µg dsDNA mass
11. **DNA from Saliva sample date of collection**
    a. Values: Timestamp of collection in UTC
    b. Criteria: none
    c. Note: this may be blank for DV saliva samples, as we do not have a collection date from Biobank/ HPOs for DV saliva samples