laboratory have a major impact on all downstream analyses. Biobanking must be a well-controlled, well-documented process end-to-end. The expectation is that all samples will be handled and processed the same way with any deviations recorded. The most important factors that create challenges in biobanking processes are summarized in Table 1.

**The Life of a Biospecimen**

The life of a biospecimen begins when a participant signs a consent form and his or her sample is collected (Table 2). Depending on sample type, samples are stabilized at an ambient, refrigerated, or frozen temperature before being routed to the biobank for timely processing. Collection is defined as those specimens obtained from one participant at a given time or visit. The biobank then receives and accesses each collection into the laboratory information management system (LIMS).

Even before recruitment, biobank staff collect study-specific information for processing and storage. This information creates the study in the LIMS and is then activated for sample receipt. Samples arrive with study-specific information and are labeled with a participant identifier. The biobank scans each specimen and follows processing instructions in the LIMS and performs the required fractionation and aliquoting. All aliquots are created in smaller volumes (such as 1 mL in matrix tubes with a two-dimensional barcode at the bottom). Each aliquot from a participant gets a unique repository identification code in the LIMS before it is stored. During their long lifespan in the biobank, specimens’ storage temperature is monitored closely. Facilities have redundant backups to maintain constant conditions.

**Our Experience With a Large-Scale Biorepository**

The Mayo Clinic has a long history of biological specimen and data banking. Since 1907, Mayo Clinic has archived all tissue slides and formalin-fixed, paraffin-embedded blocks and made them available to clinicians to assist in patient care and to researchers with appropriate institutional approval. Investigator-initiated, disease-specific collections are too many to list.

In 2009, the Mayo Clinic Center for Individualized Medicine initiated a large scale biorepository, the Mayo Clinic Biobank, to support a wide array of health-related research studies, especially those with the potential to improve patient care, by recruiting 50,000 subjects. Unlike the clinical biobank paradigm, the Mayo Clinic Biobank is not focused on a specific disease category.

From the beginning, we engaged community members to get recommendations about biobank procedures and guiding principles, including: strong privacy protections, convenient recruitment, data sharing, limited options for return of research results, long-term community oversight, and an easy-to-understand consent document. A key outcome of this engagement was the recommendation to establish a community advisory board.

The Mayo Clinic Biobank is an opt-in biobank. This means that participants actively agree in writing, informed consent to permit use of samples and/or data in multiple studies, provide access to data from a questionnaire and from their medical record (both past and future), provide blood samples drawn specifically for the biobank, and permit access to stored clinical samples. They also agree to permit sharing of de-identified data with other researchers through secured computer databases such as the National Library of Medicine’s database of Genotypes and Phenotypes (dbGaP). Participants also agree to future contact for additional studies.

Our consent document covers privacy protections, the risks involved in participating, and the potential for receiving results from projects that use the biobank. It also provides two checkboxes—included at the suggestion of the community advisory board—allowing the participant the option of 1) not allowing access to stored clinical specimens for research, and 2) not allowing family members access to samples after their death.

Standard blood collection at our institution includes three 10 mL tubes with ethylenediaminetetraacetic acid (EDTA), a 10 mL tube without additives, and a 4.5 mL tube with sodium citrate. Blood samples are fractionated and DNA is extracted from 4 mL of EDTA blood on automated platforms. Unique identification numbers are assigned to each individual container received or created, and barcoded labels are adhered to each container. All demographics are disassociated from the sample record after 3 days to make patient information secure. Over 1.25 million aliquots have been prepared.

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**Pre-collection**

- Obtain study-specific information for collection, processing, and storage
- Study built in LIMS and activated
- Participant consent taken
- Sample collection appointment scheduled

**Collection**

- Study and visit-specific collection information shared with participant
- Biospecimen collection performed based on routine clinical practice
- Tubes labeled and stabilized at correct temperature
- Tubes stored temporarily until transported/shipped to biobank

**Post-collection / Processing**

- Receipt in the biobank
- Accessioned into the LIMS
- Following study-specific protocols samples are fractionated/aliquoted
- Each aliquot receives a unique biobank identification code
- Aliquots stored in freezers

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*LIMS, laboratory information management system