CCPM Biobank Resource Offerings

The CCPM Biobank houses genetic and biological specimen resources for consenting participants across the UCHealth network. The most current research freeze available to investigators is comprised of over 34,000 genotyped participants.

All CCPM Biobank investigator access requests are reviewed by the Access to Biobank Committee (ABC), a panel of research and regulatory professionals to ensure that: 1) the research aligns with CCPM's goal to promote "predictive, personalized, preventative, and participatory medicine", (2) the research complies with and respects the consent given by participants as defined in the CCPM Biobank Clinical Research Program Consent form, (3) the research complies with the ABC Core Review Criteria.

Investigators interested in obtaining CCPM Biobank resources can request:

- fully de-identified datasets.
- limited datasets.
- datasets that include access to protected health information (PHI).

Investigators can access any combination of the following resources on CCPM Biobank participants:

- Clinical data
- Genetic data
  - Raw genotype data
  - QC'd genotype data
  - Imputed and QC'd genotype data
  - Specific SNP(s) or region(s) of interest
- Genetic data analyses
  - Genotype counts
  - Allele frequencies
  - Genome-wide association study (GWAS)
- Biological specimens
  - DNA from whole blood samples
- Recontact of CCPM Biobank participants
  - Passive/opt-in approach
  - Active/targeted approach

CCPM Biobank Resource Offerings Cont.

Clinical Data

Through a partnership with Health Data Compass (Compass), investigators can pair Biobank data with patient clinical data and demographics such as:

- Demographics
- Diagnoses
- Encounters
- Procedures
- Medications
- Labs
- and more

To learn more about the clinical data available through Compass, click here.

Genetic Data

- **Raw genotype data** – De-identified VCF file(s) of ~34,000 Biobank patients across ~1.8 million variants directly genotyped on MEGA (no quality control) delivered to a Health Data Compass Eureka instance (Google Cloud) or other secure location approved by the Security and Compliance Committee.
- **QC'd genotype data** - De-identified VCF file(s) of ~34,000 Biobank patients across ~1.7 million variants genotyped on MEGA (or subset; with TIS quality control) delivered to a Eureka Google Cloud instance or other secure location approved by Health Data Compass Security and Compliance Committee.
- **Imputed and QC'd genotype data** - De-identified VCF file(s) of ~34,000 Biobank patients across ~50 million variants genotyped on MEGA and subsequently imputed from TOPMed (or subset; with TIS quality control) delivered to a Health Data Compass Eureka instance (Google Cloud) or other secure location approved by the Security and Compliance Committee.
- **Genotype data on specific SNPs or regions of interest** – Imputed and QC'd genotype data can be subset on your SNP(s) or region(s) of interest and delivered to a Health Data Compass Eureka instance (Google Cloud) or other secure location approved by the Security and Compliance Committee.

CCPM Biobank Resource Offerings Cont.

Genetic Data Analysis

- **Genome-Wide Association Studies (GWAS)** – A genome-wide association study (GWAS) aims to detect associations between genetic variants and diseases or traits of interest (Chang et al., 2018). The ABC partners with the Translational Informatics Services unit of CCPM to conduct GWAS on your behalf using a curated SAIGE pipeline. Deliverables include summary statistics, QQ and Manhattan plots for genotyped and imputed autosomal variants.
- **Genotype counts** - The ABC partners with the Translational Informatics Services unit of CCPM to provide counts of participants within your defined cohort. This can be conducted as an aggregate request (does not require formal ABC approval) or paired with clinical or other Biobank resources (requires formal ABC approval).
- **Allele frequencies** - The ABC partners with the Translational Informatics Services unit of CCPM to provide allele frequencies on participant data within your defined cohort. This can be conducted as an aggregate request (does not require formal ABC approval) or paired with clinical or other Biobank resources (requires formal ABC approval).

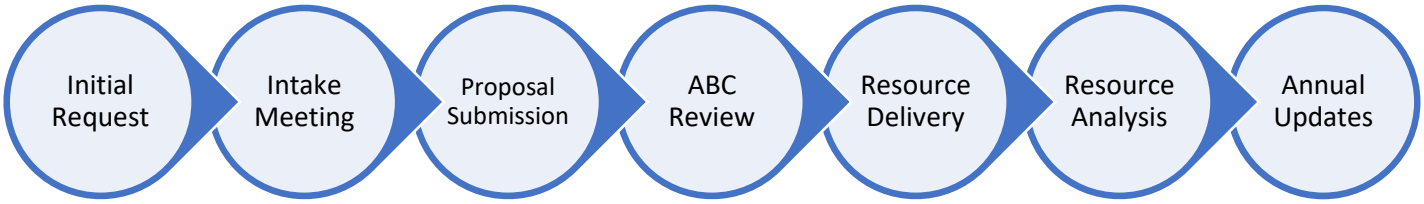
Biological Specimens

- **DNA** – The CCPM Biobank maintains over 50,000 DNA samples obtained from whole blood specimens that can be utilized for approved research purposes.

Recontact of Biobank Participants

- **Passive approach** – The CCPM Biobank offers a passive participant recontact approach wherein the Biobank will email eligible participants to indicate that they are eligible to enroll in a third-party research study. This approach allows the participant to self-select and reach out directly to the third-party investigator for more information.
- **Active approach** – The CCPM Biobank offers an active participant recontact approach wherein the Biobank will request a signed HIPAA Authorization form (via email and/or phone call) to allow the Biobank to forward contact information to the third-party investigator. The investigator is then able to contact those consenting participants directly to enroll in the third-party study.

How do I gain access to CCPM Biobank resources?



Initial request

Initiate a data delivery request through Health Data Compass (Compass).

- All data requests are managed through Compass. Before submitting a CCPM Biobank resource access request, please familiarize yourself with HDC's website and processes: https://www.healthdatacompass.org/.
- Submit a Compass Data Request Questionnaire and make sure to check CCPM Biobank as a data source: https://redcap.ucdenver.edu/surveys/?s=D4WTRF44FJ.
- Once the Compass Data Request Questionnaire is submitted, a Compass liaison will contact you to conduct an intake meeting.

Intake Meeting

Meet with Compass liaison and CCPM Biobank team to discuss your data access request.

- This meeting will address data access specifics such as: cohort inclusion/exclusion criteria, data management and storage plans, IRB coverage, and other attributes directly relating to the resources requested.
- A CCPM Biobank representative will be available during your intake meeting to answer any questions relating to the Biobank access process or what resources the Biobank offers to their clients.
- After the intake meeting, your Compass liaison will supply you with a link to submit a CCPM Biobank Investigator Access Proposal.

ABC submission

Submit CCPM Biobank Investigator Access Proposal to the Access to Biobank Committee (ABC).

- The CCPM Biobank Access Proposal requests specifics on study purpose, cohort, and analytics plans relating to Biobank resources.
- This proposal will be filled out in collaboration with your Compass liaison. There are three distinct sections of the Proposal: investigator information, proposal and access specifics, and Compass documentation. The Compass documentation section will be completed by your Compass liaison, and they will send the Proposal to the ABC for review.
- Ensure that all ABC Core Review Criteria are satisfied within your Proposal in order to expedite the review process.

Proposal review

ABC proposal review and access approval

- The ABC will assess your Proposal to determine if (1) the research aligns with CCPM's goal to promote "predictive, personalized, preventative, and participatory medicine", (2) the research complies with and respects consent given by participants as defined in the Biobank Clinical Research Program Consent form, (3) the research complies with the ABC Core Review Criteria.
- The ABC may either approve, approve with comments, reconsider after the proposal has been revised, or deny access.
- Once a decision has been made by the ABC regarding your Proposal, you will receive an Access Notice letter indicating ABC's decision. Please read this document carefully and respond as necessary.
- Once your Proposal has been approved, a meeting will be initiated to discuss the genetic data delivery and/or analysis specifics.

Resource delivery

Meet with CCPM Biobank resource delivery team to discuss genetic data delivery plan.

- If you requested paired clinical and genetic data, you will receive all clinical data directly from Compass and all genetic data directly from CCPM's Translational Informatics Services (TIS) unit.
- A TIS representative will request a meeting to address the specifics of how you would like the Biobank resources delivered. If you requested data analysis in your proposal, a data analyst will curate an analysis pipeline and deliverables for your study at this time.

Resource analysis

Receive CCPM Biobank resources and begin analysis.

- The requested Biobank resources should now be in your possession, and you are free to conduct research!
- Please remember that the CCPM Biobank requests annual progress updates, so please be sure that you document any achievements/presentations/publications as you continue your research.

Annual updates

Submit annual progress reports until the study has concluded

- One year after the initial CCPM Biobank access proposal is submitted, you will receive a brief CCPM Biobank Annual Progress Report survey. Please complete this survey each year that the study is active and ongoing.
- This survey should only take 5-10 minutes and will consist of documenting any achievements/presentations/publications that utilized CCPM Biobank resources, as well as any clerical updates to the proposal itself.
- If the study has concluded, you will be sent a one-time CCPM Biobank Final Progress Report survey. Once this survey is submitted, you will no longer receive annual progress report surveys.

CCPM Biobank ABC Core Review Criteria

The overall proposal must:

- ❑ contain a clear statement of nature and rationale for the study.
- ❑ clearly state the importance/relevance for using CCPM Biobank resources.
- ❑ clearly outline informatics and analysis plans or utilize a bioinformatic partnership to analyze CCPM Biobank resources.
- ❑ supply all necessary/required documents requested by Health Data Compass and the Access to Biobank Committee.
- ❑ have active and appropriate IRB approval, where required.
- ❑ in the case of an umbrella IRB protocol, submit a protocol describing the use of CCPM Biobank resources as well as describe and justify any differences between the ABC proposal and IRB protocol.
- ❑ respect the principle of the minimum resources necessary to complete a study.
- ❑ consider partnering with other investigators if the proposal overlaps with a pending or approved investigator's study proposal.

The study population must:

- ❑ be clearly and adequately defined and consistent with the information submitted on the study's Compass documentation.
- ❑ contain justification for the requested study population.
- ❑ define inclusion and exclusion criteria for the requested study population.
- ❑ comply with the participants' CCPM Biobank Clinical Research Program Consent forms and respect participant consent and confidentiality.

If requesting biological specimens, the proposal must also:

- ❑ contain a concise storage and handling plan.
- ❑ contain a clearly defined and justified sample number/amount/volume.
- ❑ justify the importance of using biological specimens in the requested study.
- ❑ have an adequate level of scientific merit.

If requesting participant recontact, the proposal must also:

- ❑ indicate how the participants selected for recontact have been defined and if information on selection criteria will be made available to participants.
- ❑ clearly define the recontact process after initial contact by the Biobank has been achieved, e.g how will the study be discussed with an interested participant
- ❑ supply copies of all IRB-approved documents to be used in capturing participant recontact information (consent forms, HIPAA A forms, transcripts, surveys, etc.).
- ❑ have an adequate level of scientific merit.