Guidance for proposing new studies using CBR resources

Biospecimens donated by CBR participants are available for a broad spectrum of research uses. Annotations from the medical record are accessible via DataDirect. Additional data (e.g., genetic, survey, epidemiological data, etc.) can be made available from other U-M study teams.

Requests for biospecimens must be approved by an Oversight Committee. Necessary IRB applications should be made after Oversight Committee approval.

Basic information
- The CBR catalog of research participants is accessed through the DataDirect self-serve tool at [http://datadirect.med.umich.edu/](http://datadirect.med.umich.edu/)
- You can get counts of CBR participants who meet your inclusion/exclusion criteria straight away, without any kind of review
- Before you can receive CBR biospecimens, you will need approval from a CBR committee
- If you wish to directly access the medical records or identifiable information of participants, you will need IRB review of one kind or another
- Once you have all approvals, you will be able to download individual-level and biospecimen data together
- Generally, your final dataset provided by the Data Office will be coded. Biospecimens and additional data from Study teams will also be coded. Ongoing access to medical records will only be possible through the Data Office.
  - Biospecimens are delivered from the Central Biorepository
  - Biospecimen-derived (e.g., genetic, survey, epidemiological, etc.) data are delivered from the CBR program that generated the data
  - Medical record data are delivered through DataDirect or the Medical School Data Office
  - Coding/honest-brokering is managed by the Data Office

Additional biospecimens from participants who consented to research prior to the CBR or through larger consortium programs may also be available through the CBR. Please see our website for an overview of the entire inventory.

Detailed process
- Log in to DataDirect with Level-2 password
  - You also need to have completed PEERRS training [http://my.research.umich.edu/peerrs/](http://my.research.umich.edu/peerrs/)
- Click “Create a new blank query”
- Name and describe the query and leave the HUM number drop-down as “None Selected.” This will keep the query in Cohort mode.
Central Biorepository

- Under “Starting Population” select “Biorepository.”
- Click “Create new query”
- Filter using your patient and sample inclusion/exclusion criteria by selecting them from within the categories on the left side of the screen
  - “OR” vs. “AND”: If, for example, you click “Diagnoses” and then select two ICD codes and click “Add,” the query will return all CBR participants whose records reflect one diagnosis OR the other. To return only CBR participants who meet the first ICD code AND the other, click “Diagnoses,” select the first code, then click “Add.” Then click “Diagnoses” again, select the second code, then click “Add” again.
- The right side of the screen will update to display the number of CBR participants who meet your criteria.
  If you’d like to request biospecimens or data about the cohort you’ve filtered down to, complete a Use Proposal Form for the CBR available at https://research.medicine.umich.edu/office-research/biorepository/access-biospecimens-data

What happens next
- Your proposal will be reviewed by the CBR committee that has oversight of the materials you’ve requested
- We will get back to you with any changes that the committee requests for the proposal
- If approved by the committee, you will be asked to sign a Memorandum of Understanding that outlines your use of the materials
  - You will have the option to appeal to the CBR Governance Committee if you believe your proposal is unreasonably denied
- If IRB review is necessary, the CBR will provide assistance with making efficient application for the determination or approval you need
- The Data Office will provide or adjust your permissions in DataDirect
- You will be able to log back into DataDirect and re-run your query in “PHI mode.” This will allow you to select and download clinical data of interest for the cohort
- After you complete your work with the clinical data (typically verifying diagnoses, deriving phenotypes, or creating subgroups within the cohort), you’ll send your dataset to the Data Office and discard your working dataset
- The Data Office will generate codes (“Distribution IDs”) and apply them to your dataset, removing any identifiers
- The same Distribution IDs will also be applied to any biospecimens or other data you’ve requested, so that you can collate all your materials and perform your analyses