ABC Readiness Checklist and Core Review Criteria: Supporting a successful initial submission

The **Readiness Checklist** for CCPM biobank research study resources is designed to ensure that investigators are fully prepared to submit a complete, compliant, and scientifically sound proposal for review. It promotes transparency, ethical stewardship of resources, efficient - committee evaluation, and maximizes the impact of the biobank at the Colorado Center for Personalized Medicine (CCPM biobank) research study resources. *By confirming your proposal meets the included checklist items, you also ensure your proposal complies with the ABC core review criteria.*

Purpose: Investigators can use this checklist to guide their self-assessment prior to proposal submission to the Access to Biobank Committee (ABC). Study teams are encouraged to complete it collaboratively—e.g., during meetings—to ensure responses are accurate and complete. Please do not submit the form until all the required information is gathered.

Need help? If you're not sure what a checklist item requires, how to complete it, or how they apply to your ABC request, contact us for guidance.

About my study

- ❑ The PI or co-PI of this study is one of the following:
  - Affiliated with the University of Colorado or UCHealth system
  - Sponsored by someone affiliated with the University of Colorado or UCHealth system
  - I have a list of all investigators working on this project and can specify both (1) the personnel or partners responsible for conducting the analysis, and (2) the project team members who will interpret and apply the results
- ❑ I have prepared the following about this study for the ABC request:
  - Title
  - A brief description of what I hope to achieve by using the requested biobank resources
  - Funding sources if applicable
  - Study steps (high-level) and timeline (estimated; if applicable)
  - Main hypothesis/research question
  - A rationale for why biobank resources are critical to study aims
  - A brief description of study procedures
  - I can justify how this ABC request meets the core review criteria by providing information about:
    - The importance and scientific relevance of using biobank resources in this study
    - How this study builds on or differs from existing research, and what gap it aims to fill
    - A brief description of the study informatics strategy, statistical methods, and analysis plan which should include:

- Study design
- Inclusion and exclusion criteria
- Data storage plan (including data deletion or duration of storing data).

Approvals required

- ❑ I have appropriate Institutional Review Board (IRB) approval for this request
  - ABC requests require IRB approval if the request contains private health information (PHI)
- ❑ I have engaged with Health Data Compass (HDC) if appropriate. I have a case ID, and am aware of what HDC services I need
  - ABC requests require HDC involvement if CCPM biobank resources will be paired or linked with line level patient medical data derived from the electronic health record (EHR)

Types of requests (choose one that best fits your needs)

I am requesting CCPM biobank cohort counts

- ❑ I have identified who on the study team will receive the data
- ❑ I have a detailed description of the data this study is requesting
- ❑ I am requesting summary statistics generated from CCPM biobank data I have identified who on the study team will receive the data
- ❑ I can outline the study data storage, access, and security plan
- ❑ I have a brief description of how this study will adhere to principles of human genetics and ethical research
- ❑ I have a detailed description of the data this study is requesting

I am requesting CCPM biobank data

- ❑ I have identified who on the study team will receive the data
- ❑ I can outline the study data storage, access, and security plan
- ❑ I have a brief description of how this study will adhere to principles of human genetics and ethical research
- ❑ I have a detailed description of the data this study is requesting
- ❑ I know which data products from which data sets I am requesting

I am requesting a new CCPM biobank datamart

- ❑ I have all the checklist items for requesting CCPM biobank data
- ❑ I can demonstrate the request is complex enough to warrant a CCPM-linkable datamart (view datamart example)

I am requesting CCPM biobank genomic DNA samples

- ❑ I can outline the study specimen and data storage, access, and security plan
- ❑ I have submitted a cohort count request to the ABC and received the results necessary to support my proposal request

  - Note: Cohort counts more than one year old must be updated to reflect the latest CCPM biobank data freeze and available genomic DNA samples data
- ❑ I have identified the specimen quantity and concentration this study will request
- ❑ I have prepared a justification for amount of specimen I am requesting
- ❑ I have determined which speed type will incur any associated costs with this request
- ❑ I have signed all appropriate agreements

I am requesting CCPM biobank participant recontact

- ❑ My study involves genotype-specific recruitment of participants who have been genotyped by the CCPM biobank
- ❑ I have submitted a cohort count request to the ABC and received the results necessary to support my proposal request
  - Note: Cohort counts more than one year old must be updated to reflect the latest CCPM biobank data freeze and available participant data
- ❑ I know the approximate number of participants this study aims to enroll
- ❑ This study will remain open to accrual for a minimum of one year or until recruitment targets are met, whichever occurs first
- ❑ Based on CCPM-approved resources and process as well as guidance from participant recontact materials, I have defined strategies to ensure equitable access to participation in the study.
- ❑ The study follows the CCPM biobank consent and protects participant confidentiality. View the consent form here
- ❑ I agree to recontact biobank participants using UCHealth RECRUIT tools
- ❑ I will obtain a COMIRB protocol number for my study prior to my ABC submission
  - Note: COMIRB does not need to serve as the IRB of record; however, a COMIRB number is required for all biobank participant recontact requests.