This material is intended solely for specific, approved purposes. It must not be reused, repurposed for other studies, or shared beyond the scope of approved use without prior consultation and approval from the CCPM PE team.

CCPM BIOBANK TEMPLATE LANGUAGE PURPOSE, APPLICATIONS AND REVIEW:

This document provides template language for use by investigators performing studies that rely on recontacting Colorado Center for Personalized Medicine (CCPM) biobank participants. Templated language ensures consistency, accuracy, and compliance across study documentation, including but not limited to research protocols, informed consent forms, and Institutional Review Board (IRB) applications.

This document will be reviewed and updated by CCPM on an as-needed basis to reflect new information, evolving practices, or changes in regulatory or institutional requirements. CCPM's Participant Engagement (PE) team will email an updated version to the email(s) on file whenever a new version includes significant changes to templated language or processes.

Acronyms:

CCPM – Colorado Center for Personalized Medicine

CIDA – Center for Innovative Design & Analysis

COMIRB – Colorado Multiple Institutional Review Board

CReST – Clinical Research Support Team

EHR – Electronic Health Record

HDC – Health Data Compass

ICF – Informed Consent Form

IRB – Institutional Review Board

MHC – My Health Connection

MRN – Medical Record Number

OCRST – Oncology Clinical Research Support Team

PE – CCPM Participant Engagement Unit

RA – UCHealth (University of Colorado Hospital) Research Administration

RECRUIT – Research in Epic Collaborative Recruitment User Integrated Team

PRMS – Protocol Review and Monitoring System

Investigator Guidance:

- Incorporate the template language below into your protocol and informed consent form (ICF) prior to submitting for regulatory review/approval (e.g., IRB, COMIRB, PRMS).
- Unmarked language below is template language that CCPM has checked for consistency and accuracy and should not be modified.
- Complete **highlighted** sections to produce the draft text for CCPM's Participant Engagement (PE) team to review.

- Text in *blue italics* indicates guidance for investigators. Remove this text from your final study documents.
- Review all sections carefully and ensure content accurately reflects the details of your study. If there may be a need to modify unhighlighted language, contact CCPM's PE team before making changes.

Important Notes:

- CCPM's PE team **must review** all final study-related documents **prior to submission to the IRB of record**.
- CCPM does not provide coordinator support for the development, management and maintenance of studies.

  For coordination and regulatory support inquiries and pricing, please feel free contact:

  - Oncology Clinical Research Support Team (OCRST) -for oncology indications
  - Clinical Research Support Team (CReST) - for all other indications

TEMPLATE LANGUAGE:

1. CCPM Biobank Study Population

Population

Up to **[NUMBER]** people from the Colorado Center for Personalized Medicine (CCPM) biobank will participate in the study.

Inclusion Criteria

- Participants in the Colorado Center for Personalized Medicine (CCPM biobank) **[who have been genotyped]**.

2. Study Design and Strategies for Recruitment and Retention Related to CCPM Biobank

*The following paragraph should be included **ONLY** for studies that are recruiting by genotype.*

The study team will **[request genetic and other necessary data to identify a potentially eligible study cohort list OR use the CCPM-CIDA (Center for Innovative Design & Analysis) partnership (COMIRB Protocol 24-1296) to identify a potentially eligible cohort list]**. Arbitrary IDs for potentially eligible participants will be provided to Health Data Compass (HDC), who provides the UCHealth Research Administration (RA) RECRUIT team with a list of eligible participants, including Medical Record Numbers (MRNs) and other necessary identifiable information, based on recruitment criteria outlined in **[RELEVANT SECTION OF THE PROTOCOL].** Participants who are deceased or are withdrawn from the CCPM biobank will be excluded through standard RECRUIT platform processes.

The following paragraphs should be included for ALL studies.

We will work with the UCHealth Research Administration (RA) team and use the RECRUIT (Research in Epic Collaborative Recruitment User Integrated Team) system, which manages secure and compliant access to UCHealth's Epic EHR (Electronic Health Record) to support patient recruitment and enrollment for clinical research studies. RA will create a list of potential participants using the study's inclusion and exclusion criteria. Study participants will be exclusively recruited from **[genotyped AND/OR non-genotyped]** individuals in the Colorado Center for Personalized Medicine (CCPM) biobank, as genetic data is **[required OR not required]** for **[this study OR this portion of this study]**.

The first contact with individuals identified using recruitment lists will be made exclusively using MHC messages. Once individuals confirm their interest in the study, **[and agree to participate in pre-screening and/or screening assessments]**, additional contact may be made via MHC, phone, or email. This will be done in accordance with the standards, requirements, and approvals of each process.

Individuals will be informed about the eligibility criteria and screening procedure and invited to participate. The study coordinator, or delegated staff, will contact them via their preferred method of contact, provide them with study details, answer any questions, and inquire about their willingness to participate. If participants do not agree to the study, permission may be asked to inquire about the reasons for not participating, and information about barriers to study participation may be gathered.

All aspects of this study will comply with institutional guidelines of the University of Colorado and UCHealth, and Institutional Review Board (IRB) approval will be obtained prior to study initiation. Results sharing and any additional participant information request (such as genetic data) will comply with CCPM's existing processes and partnerships, and with applicable health data privacy and security rules and institutional policies.

3. Informed Consent

3.1 Language for Study Protocol Informed Consent Section – CCPM Biobank

The information and language in this section should be incorporated into your protocol's Informed Consent section.

Study participants will be drawn from the CCPM biobank, which includes individuals who have previously provided consent and agreed to be contacted for future studies.

Participants will be informed that their decision to participate in this study will not impact their enrollment or participation in the CCPM biobank. The consent form will include information on how to contact the biobank team if they have questions or concerns about their biobank participation status. They will be assured that if they choose not to participate in this study, their enrollment and ongoing participation in the biobank will remain unchanged.

This study will not obtain informed consent for the CCPM biobank. **[DESCRIBE YOUR STUDY GROUP(S) HERE]** will be drawn from **[CCPM OR CCPM-genotyped]** biobank

participants who have previously consented to the use of their data for future research. The participants will be followed in accordance with the secondary research use protocol.

3.2 Language for Informed Consent Form (ICF) – CCPM Biobank

The information and language in this section should be incorporated into your Informed Consent form(s). Sections are distinct and do not need to be incorporated consecutively.

Purpose of research/participation

Include the following language under the section of your ICF that covers "Purpose of the research", in addition to your study-specific information. The section header may differ

You are being asked to participate in this research study because you have participated in the biobank study at the Colorado Center for Personalized Medicine (CCPM).

[The primary goal OR One of the goals] of this research study is to help researchers understand how our genes affect health. Your contribution may help further the research needed to improve future medical care. These improvements may help us better fight the diseases that affect you, your biological relatives, future generations, and the community at large.

Impact on Colorado Center for Personalized Medicine (CCPM) biobank participation

Incorporate into your ICF where appropriate

Your choice to participate in this study will not affect your enrollment in the CCPM biobank study. If you decide not to participate, your enrollment and ongoing participation in the biobank study will remain unchanged. For questions about your biobank participation or if you wish to withdraw, you can contact the biobank team anytime at CCPM-biobank@cuanschutz.edu or 303-724-9944.

Participant withdrawal from the CCPM biobank

Incorporate into your ICF where appropriate

Participants may choose to withdraw from the CCPM biobank study at any time, and this decision **[will OR will not]** automatically result in withdrawal from the current study if the withdrawal from the CCPM biobank happens before the end of the current study.

Version History Table

Date	Version Number	Changed by or Reviewed by	Descriptions of Changes/Key Decisions	Approval Status
06/27/25	1.0	Danielle Koffenberger, CCPM PE Manager	Finalized Draft1 and shared for review.	N/A
06/28/25	1.0	Casey Greene, CCPM biobank PI	Reviewed Draft 1 v1.0: provided comments and edits.	N/A
06/30/25	1.0	Danielle Koffenberger, CCPM PE Manager	Implemented Draft 1 v 1.0 edits and reviews. Drafted clean document: Draft 2 v1.0	N/A
07/08/25	1.0	Elise Shalowitz, CCPM PE Sr. CRC	Reviewed Draft 2 v1.0: provided comments and edits.	N/A
07/14/25	1.0	Abi Buell, CCPM-CReST Regulatory Coordinator Erin McDonagh, CResT Program Director	Reviewed Draft 2 v1.0: provided comments and edits. The document was shared with COMIRB for review, and no concerns or edits were raised.	N/A
07/15/25	1.0	Danielle Koffenberger, CCPM PE Manager	Implemented Draft 2 v 1.0 edits and reviews. Drafted clean document: Final v1.0	N/A
07/15/25	1.0	Casey Greene, CCPM biobank PI	Reviewed Final v1.0. Approve.	Approved
09/11/25	1.0	Danielle Koffenberger, CCPM PE Manager	Updated the language in Section 2 to better reflect the build and recontact processes for biobank participants within RECRUIT. Drafted clean document: Final v2.0	N/A
09/11/25	1.0	Casey Greene, CCPM biobank PI	Approve v 2.0.	Approved