CCPM BIOBANK TEMPLATE LANGUAGE: PURPOSE, APPLICATIONS AND REVIEW

This document provides template language for use by University of Colorado (CU) 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 study 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 is responsible for implementing and routing updates to templated language for review and approval by appropriate stakeholders and submitting the approved document as a change request to update the document on the Access to Biobank Committee (ABC) website.

Acronyms:

ABC – Access to Biobank Committee

CCPM – Colorado Center for Personalized Medicine

CIDA – Center for Innovative Design & Analysis

COMIRB – Colorado Multiple Institutional Review Board

CReST – Clinical Research Support Team

CU – University of Colorado

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:

- Complete all **highlighted** sections as instructed and incorporate the corresponding template language provided below into your study protocol and Informed Consent Form(ICF) prior to submission for regulatory review and approval (e.g., IRB, COMIRB, PRMS).

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 ABC.

- Unmarked language below constitutes approved template language developed by CCPM to ensure consistency and accuracy in the participant recontact process and must not be modified.
    - Approved biobank template language must be used verbatim in all applicable study documents and materials, without modification, additions, or supplemental content.
- Text in *blue italics* indicates guidance for investigators and must be removed from all final study documents.
- Review all sections of this document carefully and ensure content accurately reflects the details of your study.

Note:

- CCPM does not provide coordinator support for the development, management and maintenance of studies.

  For coordination and regulatory support inquiries and pricing, please contact:
    - Oncology Clinical Research Support Team (OCRST) -for oncology indications
    - Clinical Research Support Team (CReST) - for all other indications

CCPM BIOBANK PARTICIPANT RECONTACT TEMPLATE LANGUAGE:

- Ensure that the approved biobank template language is completed accurately and inserted verbatim into your study protocol and informed consent form, as applicable.
- Refrain from modifying the template language or adding any content and references to CCPM or the biobank beyond what is included in the approved text below.
- Confirm that all required biobank-specific template language is incorporated in every section of your study documents where it applies.

A. Language to be included in the Study Protocol:

A1. CCPM Biobank Study Population

*The information and language in this section should be included in **ALL** study protocols.*

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]**.

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A2. Study Design and Strategies for Recruitment and Retention Related to CCPM Biobank

*The following paragraph should be included **ONLY** for studies that will be recruiting participants based on specific genotype (i.e., studies using genetic information to identify and recruit participants).*

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 HDC and RECRUIT processes.

*The following paragraph should be included **ONLY** for studies where participants may be recruited before genotyping, as genotype-specific information may not be required during the recruitment phase and will be aligned with genetic data later through established CCPM ABC processes.*

The study team may request genetic and other necessary data to identify a potentially eligible study cohort. CCPM biobank participants who meet the study's recruitment criteria, but have not yet undergone genotyping, may still be included in the cohort list if all other eligibility requirements are met. This study does not require genotype-specific information during the recruitment phase and will reconcile study data with genetic information at a later stage through established CCPM Access to Biobank Committee (ABC) processes.

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 HDC and RECRUIT 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].**

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The first contact with individuals identified using recruitment lists will be made exclusively using UCHealth My Health Connection (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.

A3. Study PI Responsibilities and Continuity Guidelines

*The following paragraph should be included in **ALL** study protocols.*

In the event of a PI change and/or departure from University of Colorado (CU), CCPM will have the opportunity to choose to manage access to data and results through its established Access to Biobank Committee (ABC) process.

A4. Informed Consent

*The information and language in this section should be incorporated into the Informed Consent section for **ALL** study protocols.*

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.

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B. Language to be included in the Informed Consent Form:

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.

B1. Purpose of research/participation

Include the following language under the section of your study's Informed Consent form(s) 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).

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.

B2. Impact on Colorado Center for Personalized Medicine (CCPM) biobank participation

Incorporate the following language into your study's Informed Consent form(s) 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.

B3. Participant withdrawal from the CCPM biobank

Incorporate the following language into your study's Informed Consent form(s) where appropriate.

You 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.

C. Recruitment Messages Requirements:

The requirements outlined below must be followed by investigators and study teams when developing recruitment messages for biobank participants being recontacted for potential participation in research studies. Recruitment materials containing content that does not align with these requirements will not be eligible for CCPM ABC approval, regardless of prior IRB approval.

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C1. Disclosure of Biobank Genotype Results

Biobank research genotypes should not be disclosed as part of the recruitment process for biobank participants who are being recontacted and invited to participate in a research study.

Investigators and study teams are responsible for ensuring that recruitment materials do not include genotype information derived from biobank research data. Research genotypes used for selection are not generated or validated through the same process that CCPM uses for its return of results program. Recruitment materials can note that genetic factors were a component of a selection process (e.g., “You are eligible to participate in this study because you are enrolled in the biobank at the Colorado Center for Personalized Medicine (CCPM), and, based on your genetics, you may or may not ...”).

Examples of recruitment materials subject to this requirement include, but are not limited to, the Informed Consent Form, UCHealth My Health Connection messages (including RECRUIT Description and Script Templates), email communications, flyers, and other participant-facing recruitment materials.

Please note that recruitment materials returning biobank genotype information to participants outside of CCPM’s established return-of-results process are ineligible for ABC approval, regardless of prior approval by the study’s IRB of record. If such content is identified during the ABC triage or review process, the investigator and study team will be notified and required to revise the materials before the submission can advance for ABC review and approval.

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Title: [XX][1]

Description:

The purpose of this study is to [XX][2].

If you decide you are interested, we may conduct a review of your UCHealth medical record to confirm your eligibility.

You may be eligible if you:

- Are a participant in the CCPM biobank
- [XX] [3]
- [XX] [3]
- [XX] [3]

If you choose to take part, you will:

- [XX] [4]
- [XX] [4]
- [XX] [4]

Individuals who participate will be compensated for their time and effort[5].

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 biobank or if you wish to withdraw, contact the biobank team at CCPM-biobank@cuanschutz.edu or 303-724-9944.

Subject line:
New Research Opportunity "Interested" Follow-Up

Message body:

Greetings @PFNAME@,

Thank you for your interest in the [XX][1] study being conducted at [XX][2]

You may be able to take part in this study because you are enrolled in the biobank at the Colorado Center for Personalized Medicine (CCPM) and because our records show that [XX].

To learn more and review your eligibility with the research team, please reply to this message and provide your preferred contact number and times for us to reach you.

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 biobank or if you wish to withdraw, contact the biobank team at CCPM-biobank@cuanschutz.edu or 303-724-9944.

Sincerely,

@ME@