Template Informed Consent Form (ICF) Language for Research Conducted at UCHealth Facilities

Overview: This document contains the research informed consent form requirements for research conducted at any UCHealth facility. Please note that it is acceptable to use the sponsor’s consent template. Please incorporate the preferred language below in regards to payment, subject injury, and HIPAA, provided that payment and injury language ultimately align with what is described in the clinical trial agreement (CTA) for the study.

Sample language for the consent form is below; deviations from this text are acceptable to align with the CTA if the premise remains the same (changes may require legal and institutional review). Any changes to these three sections require approval from the COMIRB or External IRB Coordinators. Issues may be escalated to UCHealth.

Instructions are in *light blue italicized text*, template language is in black, and language requiring edits in [bracketed highlighted black].

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

*If there are ANY usual care (i.e. standard of care (SOC)) procedures/assessments/visits on the calendar, always include the language below in the consent form overview.*

Throughout this form, you will see the term “usual care.” Usual care is routine medical care you will receive while you are participating in this study that is considered routine for [indication] and would be recommended whether you are in the study or not. You will also see the term “research related” which refers to medical treatment, procedures, assessments, or visits that are not considered usual care for [indication], but are solely for the purpose of this study.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Will I be paid for being in this study?

*The consent form must include the following information:*

* *Whether the individual will receive a stipend for participation in the study and/or reimbursement of other expenses related to his/her participation;*
* *The amount of the stipend and/or reimbursement amounts;*
* *The total amount that could be received if all study visits are completed;*
* *Payments will be made up to the point of withdrawal from the study.*

***Option 1 – Participant is paid a stipend or provided reimbursement for parking, mileage, etc.***

*Option 1A (used when paid per visit):*

You will be paid [$XX.XX] for each study visit that you complete. *If the amount will vary from visit to visit, state the different amounts and visit types.*

*OR Option 1B (used when one stipend paid upon completion of study):*

You will be paid [$XX.XX] as a stipend for your participation in this study.

*AND/OR Option 1C (use when paid additional stipends for meals, travel, etc.)*:

You will be reimbursed for [XYZ expense such as parking or mileage] related to your participation in this study. [As applicable if payments are per study visit…]

*Always include for Option 1, as applicable:*

This will add up to a total of [$XXX.XX] if you complete all of the study visits.

If you leave the study early, or if we have to take you out of the study, you will be paid only [(for the visits you have completed) OR (a pro-rated portion of the stipend) OR (reimbursable expenses you have incurred related to the visits you have completed)]. *(As applicable; delete if not relevant)* If you receive $600.00 or more in a calendar year for research participation stipends, [CU/UCHealth/CHCO/DHHA] will file a 1099-MISC tax form to report these payments as taxable income in accordance with applicable laws.

***Option 2 – Participant not paid***

You will not be paid to be in the study.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Will I have to pay for anything?

The site must choose one of the following statements that applies; deviations from this text are acceptable to align with the CTA:

*Option 1 – Participant/third party payer not charged. This section* ***cannot*** *be used if there are any SOC procedures/office visits/etc. on the research calendar in OnCore:*

You will not be charged for the study [drug/device]. You will not be charged for any of the research-related procedures or office visits for the study.

*Option 2 – Participant/third party payer charged*

You and your insurance will have to pay for usual care visits, procedures and treatment that are routine for your medical condition. You will be responsible for any co-payments and/or deductibles that are required by your insurance plan. The sponsor will pay for research-related visits, procedures, and care done only for the research; these include, though may not be limited to, [insert high level list of study-funded procedures].

*Also ADD when applicable and accurate for studies with investigational drug. Verify with Research Manager and/or Research Business Specialist which options are in alignment with the CTA, MCA Analysis and Budget:*

You will not be charged for the cost of the study drug. You and your insurance [will be / will not be] billed for preparing and administering the study drug.

*Also ADD when applicable and accurate for studies with investigational device. Verify with Research Manager and/or Research Business Specialist which options are in alignment with the CTA, MCA Analysis and Budget:*

You and your insurance [will be / will not be] billed for the study device and [will be / will not be] billed for the study device implant procedure.

*Always include:*

Questions about costs that will or will not be covered by your insurance should be addressed to the customer care team for [UCHealth Billing, 1.866.429.6045, OR CU Medicine Group Billing, 303.493.7700], who are available Monday-Friday, 8 a.m. to 5 p.m.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

**What happens if I am injured or hurt during the study?**

*Research-related injury language in the ICF must be commensurate with injury and compensation language in the CTA. Deviations from this text are acceptable as long as they align with the CTA language.*

*Add the following text as the first paragraph of the section:*

If you have an injury while you are in this study, you should immediately call the study doctor or study team at [insert phone number].

*Option 1 – used when no research-related injury coverage for the trial in the CTA. If the treatment and procedures in a study are considered usual care (i.e., there are no research-related risks for injury), the risks specific to the treatment itself are not research-related, as they would occur regardless of a person’s decision to participate in the study. In these cases, the risks for the treatment and procedure(s) should be reviewed with the patient by their physician:*

In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. However, you or your insurance company will have to pay for that care.

*Option 2 – used when sponsor/manufacturer is responsible for research-related injury:*

In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care with the provider of your choice. The investigator will determine if your injury or illness is research-related. The term “research-related” illness or injury means an unexpected physical injury caused by the study [drug/device] or procedures required by the study which are different from the usual medical treatment you would have received if you had not participated in the study. Medical treatment for research-related illness or injury will be provided at no cost to you or your insurance company.

*A Sponsor ICF template may have a statement regarding the Medicare, Medicaid and SCHIP Extension Act of 2007 (“MMSEA”). Although not always required, a statement on MMSEA is allowable if it is in alignment with the following example language: “If you receive Medicare benefits and have a research-related injury, UCHealth may provide your personal health information to the Centers of Medicare and Medicaid Services, and it’s agents or contractors, for federal reporting purposes.”*

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

**Who do I call if I have questions?**

*Ensure IRB is defined in the document already. If not, add statement below:*

The Institutional Review Board (IRB) is a group that serves to protect the rights of participants in research trials.

*If using an IRB other than COMIRB, add the following contact information for COMIRB (which still acts as Privacy Board), after the sponsor template language for the Central IRB:*

OR the Colorado Multiple Institutional Review Board (COMIRB) office at comirb@ucdenver.edu

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Who will see my research information?

*Select first sentence of HIPAA Authorization section based on who will be lead site, UCD/CHCO Study Team with CU Anschutz PI OR UCHealth Study team with UCHMedical Group PI.*

[The University of Colorado Denver | Anschutz Medical Campus and the hospital(s) it works with OR UCHealth and its business affiliates] have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it. The institutions involved in this study include: *(delete those below that are not IRB-approved institutions directly involved in the research project)*

* UCHealth and its affiliated facilities *(always include as individual UCHealth facilities are not to be listed)*
* University of Colorado Denver | Anschutz Medical Campus and its applicable CU Medicine clinics *(only include if the site is an IRB-approved institution involved in the project)*
* Children’s Hospital Colorado *(only include if an IRB-approved institution involved in the project)*
* Denver Health and Hospital Authority *(only include if an IRB-approved institution involved in the project)*
* *Add other institutions approved by the IRB (not covered in the above bullets), as applicable*

Both the records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

* Federal offices such as the Office of Human Research Protection and the Food and Drug Administration (FDA) that protect research participants like you
* People at the Colorado Multiple Institutional Review Board (COMIRB) *(always include due to COMIRB serving as the project’s Privacy Board)*
* Relevant operational, regulatory and compliance offices at University of Colorado Denver | Anschutz Medical Campus involved in the oversight of the study*(always include due to OnCore)*
* People at the [name of IRB of Record] *(delete bullet completely if COMIRB is IRB of Record)*
* The study doctor and his/her team of researchers.
* [insert sponsor name], who is the company paying for this research study, and their representatives who assist with the management and/or conduct of the study *Include only if applicable* (for example, Core Laboratories and Contract Research Organizations)

Your information may be used and disclosed, to do the research, to study the results, and to make sure that the research was done right.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research participants, like you, private.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You have the right to request access to your personal health information from the investigator. *Include only if applicable* [To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.]

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside UCHealth and its affiliates may not be covered by this promise and your information may be disclosed without your permission.

We will do everything we can to keep your records confidential. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study’s Principal Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

 [PI Name and Mailing Address]

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

**Information about you that will be seen, collected, used, and disclosed in this study:**

*Delete all that do not apply*

* Name and Demographic Information (age, sex, ethnicity, address, phone number, email, etc.)
* Your social security number
* Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
* Research Visit and Research Test records
* Psychological tests
* Alcoholism, Alcohol or Drug abuse
* Testing for or infection with diseases reportable to the Public Health department, including but not limited to: Human Immunodeficiency Virus (HIV), hepatitis (all forms) tuberculosis, or other sexually transmitted diseases.
* Testing for sickle cell
* Tissue samples and the data with the samples.
* Billing or financial information
* Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**What happens to Data, Tissue, Blood, and Specimens that are collected in this study?**

*The site will delete the types of data (i.e., tissue, blood, specimens) that do not apply, in heading and in the following text.* Deviations from this text are acceptable to align with the CTA.

Investigators involved in this study work to find the causes and cures of disease. The data, tissue, blood, and specimens collected from you during this study are important to this study and to future research. If you join this study:

* The data, or the tissue, blood, or other specimens are given by you to the investigators for this research and so no longer belong to you.
* Both the investigators and any sponsor of this research may study your data and tissue, blood, or other specimens collected from you.
* If data, tissue, blood, or other specimens are in a form that identifies you, the facilities involved in this study may use them for future research only with your consent or IRB approval.
* Any product or idea created by the researchers working on this study will not belong to you.
* There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

*If COMIRB is the IRB of Record, the University of Colorado Denver has standardized language for tissue banking or storage of samples for future use which should be incorporated, if applicable, and can be found at:* [*https://research.cuanschutz.edu/docs/librariesprovider148/comirb\_documents/forms/list-of-additional-standard-language-statements-for-the-consent-form.pdf?sfvrsn=372c2fb9\_2*](https://research.cuanschutz.edu/docs/librariesprovider148/comirb_documents/forms/list-of-additional-standard-language-statements-for-the-consent-form.pdf?sfvrsn=372c2fb9_2)

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

**HIPAA Authorization for Optional Additional Study Procedures**

*If there are no optional procedures in this study or the optional procedures are in the addendum consent form, delete the HIPAA Authorization for Optional Additional Study Procedures below*

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

*(Include the following sentence if applicable; delete if not relevant)* Some of these optional procedures may involve genetic testing or the use of your genetic information.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

\_\_\_\_\_ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

\_\_\_\_\_ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Agreement to be in this study:

*For Children’s Hospital submissions, please see the Children’s Hospital signature line template.*