**Guidance: Customizing consent form provided by sponsor or cooperative group to submit to University of Chicago BSD IRB.**

It is recognized that sponsors and cooperative groups invest significant resources into the preparation of written consent forms. As such, instead of attempting to transition the sponsor consent form into the University of Chicago template, the goal of this document is to allow a sponsor/cooperative group consent form to be utilized with a few revisions.

There are a few sections of the consent form that **must** include University of Chicago prepared language. These sections are noted below and appropriate template text is included at the end of this document.

1. University of Chicago Header (Appendix 1)
2. Key Information Section (Appendix 2)
3. University of Chicago Costs Section (Appendix 3)
4. University of Chicago Research Related Injury statements (more than minimal risk research) (Appendix 4)

In addition, please note the following Dos and Don’ts for utilizing a previously prepared consent form:

|  |  |
| --- | --- |
| **Do Include** | **Do not include (Remove from sponsor template)** |
| Utilize University of Chicago Header (Appendix 1) | Sponsor header, footer, Logo |
| Add University of Chicago protocol # |  |
| Add University of Chicago PI name, address (with MC), and contact Phone # | Utilize overall study PI/phone number |
| Include UChicago version date |  |
| Add Key Information section if one is not included (OHRP/UCHICAGO requirement) (Appendix 2) |  |
| Include page numbering if not present to include the total number of pages (e.g., “pg. 7 of 10”)  |  |
| Tables designed for the subject may be included | Use tables from the protocol  |
| Use lay language explanations | Use REFERENCES, FOOTNOTES, Table of Contents, etc. |
| Use UChicago Costs language (Appendix 3) | Sponsor costs language |
| Use UChicago Research Related Injury Language (Appendix 4) | Sponsor research related injury language |
| HIPAA authorization language from sponsor may be used IF university of Chicago is included/added | Reference to separate stand-alone authorization agreement. If authorization language is not included, utilize information on Appendix 5 |
|  | Exculpatory langue and language that waives or appears to waive subjects’ legal rights |
| Contact Information for UChicago BSD IRB  |  |

**Appendix 1: UNIVERISTY OF CHICAGO HEADER**

***(This should replace sponsor/cooperative group header and logo)***

### The UNIVERSITY OF CHICAGO

### The Division of the Biological Sciences • The University of Chicago Medical Center

**CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL**

*(remove “Authorization” if the form is not a HIPAA authorization)*

Protocol Number: *[insert #]* Name of Subject: Medical History Number:

## **STUDY TITLE**: *(insert study title)*

Doctors Directing Research: *[include PI & at least 1 other investigator]*

Address: *(insert complete mailing address, including mail code if applicable)*

Telephone Number: *(insert complete telephone number)*

**APPENDIX 2: KEY INFORMATION TEMPLATE**

*(This information should be included at the beginning of the consent form)*

**INSTRUCTIONS**: To use this template, complete all required sections (substituting appropriate language for any *italicized red text*) and any applicable optional sections (marked in *[highlighted red italicized brackets]*). Following this, ensure to delete all instruction boxes, italicized instructions, brackets, and omitted optional sections prior to submitting this form.

**KEY INFORMATION**

## *[The Key Information section is intended to provide subjects with a quick snapshot of what their participation will entail. Only very brief descriptions should be included in this section.*

*Note, information that is included in the Key Information section does not need to be duplicated in the Detailed Information section, as long as sufficient information is provided]*

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

***Why am I being invited to take part in a research study?***

We invite you to take part in a research study because . *[Fill in the circumstance or condition that makes subjects eligible for the research.]*

***What should I know about a research study?***

* Someone will explain this research study to you.
* Whether or not you take part is up to you.
* Your participation is completely voluntary.
* You can choose not to take part.
* You can agree to take part and later change your mind. Leaving the study will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
* Your decision will not be held against you.
* Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
* You can ask all the questions you want before you decide.

***Why Is This Study Being Done?***

*[Briefly tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]*

***How long will the research last and what will I need to do?***

People who agree to join the study will be asked to attend *[number of visits]* visits over *[Duration]*. You will be asked to *[include a high‐level summary of the procedures that will be done. In this description include any descriptions of drugs to be administered, including placebo, if appropriate and randomization or blinding]*

***What are my other options?***

*[This section should describe alternatives to participation.]*

*[For studies involving healthy volunteers or other studies for which the study is proposed as an alternative to treatment, the following language may be appropriate. If not, delete.]*

Your participation in this study is voluntary. You may choose not to participate in this study.

*[OR List alternatives including commonly used therapy. If the study drug can be given in a clinical setting (including off-label), please list here]*

***Is there any way being in this study could be bad for me?***

*[This beginning section of the consent form should briefly identify the most important risks, e.g., life-threatening risks of a drug study or emotional distress resulting from a series of questions in a social‐behavioral research project but with a particular emphasis on how those risks are changed by participating in the study]*

*[OR]* We don’t believe there are any physical risks from participating in this research. Whenever data are collected, there is always a risk of loss of privacy.

More detailed information can be found in the Detailed Risks section later in the consent form.

***Will being in this study help me in any way?***

*[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document.]*

*[Include if there are benefits to participation. Otherwise delete.]* We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include . *[First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]*

*[Include for a study with no benefits to participation. Otherwise delete.]* There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include . *[Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]*

## [Include this section if there is an identified Conflict of Interest to disclose the nature of any financial or proprietary interests. Otherwise Delete.]

***Researcher Financial Interests in this Study***

*This section should identify the researchers or research staff by name and study role.*

*[Example of language to indicate the interest in an entity or the product:] [Name of person with external relationship]* a researcher on the study team, has a financial interest in *[name of company]*, *[the company paying for this study; the company that will manufacturer the study drug; the company that will sell the drug, and/or the company conducting part of this study]*.

*[Example of language if the interest is other than a financial interest in an entity, e.g., in the product being tested:] [Name of person with COI]* a researcher on the study team, has a financial interest in the *[product, drug, device, name of company]* being studied.

## [Example of language to describe the interest:]

* *[Name of company and relevance of company to study, e.g., sponsor]* is paying

*[Name][describe payment, e.g., consulting fee, salary]*.

* *[Name]* is being paid to be a scientific advisor to *[name of company and relevance of company to study]*.
* *[Name]* is an unpaid member of the Scientific Advisory Board of *[name of company and relevance of company to study]*.
* *[Name]* is on the board of *[name of company and relevance of company to the study]*.

## [Name] is the [title] of [name of company and relevance of company to study].

*[Example of language to describe significant stock ownership in a publicly traded company, stock ownership in a non‐publicly traded company, and/or holder of stock options:]*

* *[Name]* owns stock in *[name of company and relevance of company to study]*.

## [Name] is a [founder or majority or minority shareholder] of [name of company and relevance of company to study].

* *[Name]* has a stock option from *[name of company and relevance of company to study]* and may receive income in the future.

## [Example language for the inventor:]

* *[Name]* invented the *[drug, device]* being studied and may benefit financially if it is marketed. In the event that the *[drug, device]* is marketed, the University of Chicago would may also receive financial benefit.
* *[If possible, elaborate on the information provided. For example: “The consulting income [Name] receives is in addition to her salary from the University.”]*

*[Example language:]* This disclosure is *[or, these disclosures are]* made so that you may determine whether this relationship *[or, these relationships]* affect your willingness to participate in this study. If you have questions, please inform the study coordinator, and they will put you in touch with someone to talk to.

**APPENDIX 3– COST SECTION TEMPLATE LANGUAGE**

Please utilize the language outlined below based upon the study type. If you have any questions regarding the study type, please reach out to the Office of Clinical Research for assistance.

WHAT ARE THE COSTS?

*[Clinical Trial Template]*

Clinical services provided during a clinical trial are either research-related or considered part of usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as ‘usual medical care’. ‘Research-related’ is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical trial.

You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. This often includes regular visits with your doctor, lab tests and imaging used to measure your response to treatment, and other tests and procedures deemed medically necessary by your care team. Financial responsibilities for routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study and would not be performed if you were not participating in this clinical trial. This will often include the cost of the investigational drug you are receiving as part of this clinical trial or additional tests performed to answer a research question but not required for your routine clinical care.

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT ARE THE COSTS?

*[HemOnc Template]*

Clinical services provided during a clinical trial are either research-related or considered part of usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as ‘usual medical care’. ‘Research-related’ is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical trial.

You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. This often includes regular visits with your doctor, lab tests and imaging used to measure your response to treatment, administration of medications and other tests and procedures deemed medically necessary by your care team. Financial responsibilities for routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study and would not be performed if you were not participating in this clinical trial. This will often include the cost of the investigational drug you are receiving as part of this clinical trial or additional tests performed to answer a research question but not required for your routine clinical care.

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT ARE THE COSTS?

*[All SOC- clinical research]*

Clinical services provided during a clinical research study are either research-related or considered part of usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as ‘usual medical care’. ‘Research-related’ is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical research study.

All of the tests, procedures, and activities you will undergo as part of your participation in this clinical research study are considered part of your usual, ongoing medical care. Thus, you or your insurance will be financially responsible for the costs of your usual, ongoing medical care. Financial responsibilities from routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

If you have questions about the financial aspects of your usual medical care, please speak to your physician.

WHAT ARE THE COSTS?

*[All Research]*

Clinical services provided during a clinical research study are either research-related or considered part of the usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as ‘usual medical care’. ‘Research-related’ is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical trial.

All of the tests, procedures, and activities you will undergo as part of your participation in this clinical research study are considered research-related. You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study. However, this does not include visits or care received at the University of Chicago Medicine (or affiliate sites) that is not related to your participation in this clinical research study. You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. Financial responsibilities from routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT ARE THE COSTS?

*[Investigational Device Template – procedure SOC and device provided for free]*

Clinical services provided during a clinical trial are either research-related or considered part of usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as ‘usual medical care’. ‘Research-related’ is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical trial.

You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. This often includes regular visits with your doctor, lab tests and imaging used to measure your response to treatment, surgical procedures necessary to implant a device, and other tests and procedures deemed medically necessary by your care team. Financial responsibilities for routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study and would not be performed if you were not participating in this clinical trial. This will often include the cost of the investigational device you are receiving as part of this clinical trial or additional tests performed to answer a research question but not required for your routine clinical care.

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT ARE THE COSTS?

*[Device- research billed procedure]*

Clinical services provided during a clinical trial are either research-related or considered part of usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as ‘usual medical care’. ‘Research-related’ is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical trial.

You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. This often includes regular visits with your doctor, lab tests, imaging used to measure your response to treatment, and other tests and procedures deemed medically necessary by your care team. Financial responsibilities for routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study and would not be performed if you were not participating in this clinical trial. This will often include the cost of the investigational device you are receiving, procedures needed to use or implant the device as part of this clinical trial, or additional tests performed to answer a research question but not required for your routine clinical care.

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT ARE THE COSTS?

*[General clinical research study (non-investigational)]*

Clinical services provided during a clinical research study are either research-related or considered part of usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as ‘usual medical care’. ‘Research-related’ is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical research study.

You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. This often includes regular visits with your doctor, lab tests, and other tests and procedures deemed medically necessary by your care team. Financial responsibilities for routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study and would not be performed if you were not participating in this clinical research study. This may include additional tests to answer a research question that are not required for your routine clinical care.

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

**APPENDIX 4: RESEARCH RELATED INJURY STATEMENTS**

*[Include for studies with a commercial sponsor:]*

The sponsor of the study, *[insert sponsor name]*, has agreed to pay for the care of certain injuries directly resulting from this research. If you think that you have suffered a research-related injury, you must contact *[insert PI/study doctor name]* right away. The study doctor can help you obtain more information about the sponsor’s agreement to pay for research-related injuries.

## [One of the following two paragraphs should be included for all studies with an intervention:]

## (1) For studies with any therapeutic intent (including Phase I and II trials):

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, you may receive such emergency medical treatment at the University of Chicago Medical Center, UChicago Medicine Ingalls Memorial Hospital, UChicago Medicine Northwest Indiana, UChicago Medicine AdventHealth Bolingbrook, UChicago Medicine AdventHealth Glen Oaks, UChicago Medicine Advent Health Hinsdale, or UChicago AdventHealth LaGrange at no cost to you. You must notify *\_\_\_\_\_\_\_\_\_\_\_ [insert PI/study doctor name]* as promptly as possible after your injury in order to receive this care. An injury is “unanticipated” if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance or the study sponsor in the ordinary manner. If you think that you have suffered a research related injury, you must let *\_\_\_\_\_\_\_\_\_\_\_\_ [insert PI/study doctor name]* know right away.

*or (2) For studies involving healthy volunteers:*

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, you may receive such emergency medical treatment at the University of Chicago Medical Center, UChicago Medicine Ingalls Memorial Hospital, UChicago Medicine Northwest Indiana, UChicago Medicine AdventHealth Bolingbrook, UChicago Medicine AdventHealth Glen Oaks, UChicago Medicine Advent Health Hinsdale, or UChicago AdventHealth LaGrange at no cost to you. Costs of related non-emergency care for an unanticipated research injury will be covered if that care is provided at the University of Chicago Medical Center. You must notify *\_\_\_\_\_\_\_\_\_\_ [insert PI/study doctor name]* as promptly as possible after your injury in order to receive this care. An injury is “unanticipated” if it is not one of the known effects of a study drug, medical device or procedure. If you think that you have suffered a research related injury, you must let *\_\_\_\_\_\_\_\_\_\_ [insert PI/study doctor name]* know right away.

*For all studies*

In the event of an emergency, you should seek care at the nearest emergency room or call 911.

**APPENDIX 5: HIPAA AUTHORIZATION LANGUAGE**

***HIPAA‐Covered Data***

Federal law provides additional protections of your medical records and related health information. During this study, Dr. *[insert PI name]* and *[his/her/their]* research team will collect information about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. This information will include information within your medical record, which could include your medical history and new information collected as a result of this study. The information to be used on this study includes *… [Please specify all individually identifiable to be collected and used for this research study by the University of Chicago research team AND provide a meaningful explanation as to why this information is being collected/used. This description should include all PHI collected during the screening process as well as during the study. Please ensure that all PHI that is collected from the subject’s medical record, if applicable, is listed as well as data that is generated during the study. For example: “The information to be used on this study includes your name, medical record number, contact information (phone number, email number, address), social security number, and dates (including date of birth, dates of medical procedures and tests, and dates of clinic visits). We will use these identifiers to schedule visits, check on your health status, and collect safety data, and for long term follow up.” ]* In addition, we may collect information and results of tests, procedures, or examinations that have been done for purposes outside of this study.

*[For any studies for which information about the subject is being sent outside of the University of Chicago, also include the following paragraph:]*

As part of the study, Dr. *[insert PI name]* and their research team will share information about you as well as the results of your study-related procedures and tests with *[Include all persons/entities outside of the U of C with whom this information will be shared or disclosed, including the Sponsor, outside labs, cooperative groups, DSMB, etc.]*. These include *[specify all individually identifiable elements to be shared and briefly describe in lay terms information that will be disclosed to the study sponsor (e.g. “research test results”)]*. This information is being sent because *[describe why this information is being sent (each purpose)] . (If different information will be shared with different entities, please explain each disclosure separately, e.g. “Your name and phone number will be shared with X University for follow up purposes. Your date of birth, dates of study procedures, and dates of side effects will be shared with ABC Pharm Company for data analysis and safety tracking purposes.”)*

*(if applicable include)* The study sponsor or their representatives, including monitoring agencies, may also review the entirety of your medical record (for example, in the event of an audit). If the medical record is accessed, it is possible that all of the information on this study would be viewed, including your name.

*[Include for cancer studies:]*

Your health information may be shared with governmental agencies, including the National Cancer Institute, for federally mandated reporting purposes.

*[Include for all studies:]*

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Food and Drug Administration (FDA) *[FDA may be removed if the study does not involve any FDA-regulated drugs, devices, or biologics.]*andOffice of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

*[Include for all studies:]*

Once information is shared outside the University of Chicago, please note that your identifiable health information may be shared with someone else. The same laws that the University of Chicago must obey may not protect your health information.

*[Include the following paragraph for most studies. NOTE: As per the HIPAA regulations, the consent form must state whether subjects have access to their medical records. Access to research records is not the subject of this paragraph]*

During your participation in this study, you will have access to your medical record. Dr. *[insert PI name]* is not required to release to you research information that is not part of your medical record.

*[If access to the medical record will be denied due to single-blinding or another reason, contact the IRB for sample language. Note that justification for denying access must be provided to the IRB]*

*[Include for all studies]*

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team *[for a length of time or “until completion of this study”]*.

At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results.

*[Include for all studies]*

Data from this study may be used in medical publications or presentations. Your name and any other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time. We may also share de-identified data with collaborators or others for research purposes.

*[Include for all studies involving samples]*

We are collecting your tissue and/or blood as part of this study. We may use your samples for other research studies, including genetic testing, without contacting you, including sharing your samples with others for research purposes here and outside University of Chicago. It is possible that these samples may be shared with a for profit company for research.

*[Include for clinical trials – Per FDA regulations, the exact wording is mandatory and cannot be altered]*

*ClinicalTrials.gov*

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.

*[If your study will involve HIPAA covered data, please include the following language. Otherwise delete.]*

***HIPAA covered research***

The University of Chicago/University of Chicago Medical Center will not withhold treatment or refuse treating you based on whether you sign this Authorization or revoke your authorization at a later time.

If you do not sign this form, you will not receive the research-related intervention(s).

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. *[insert PI name]* in writing at the address on the first page. Dr. *[insert PI name*] may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your health information does not have an expiration date.