**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.

*U of C template version 1/15/25*

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 and, if possible, at least 1 other investigator]

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

Telephone Number: (insert complete telephone number)

**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.* ***Key information must include:*** *any descriptions of drugs to be administered, including placebo, and describe any randomization or blinding if those will occur]*

***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.

**DETAILED INFORMATION**

The following is more detailed information about this study in addition to the information listed above.

***What is the purpose of this research?***

*[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others. This section should provide more detail than the Purpose found in the Key Information section. Include number of subjects locally and if applicable, at all sites.]*

***How long will I take part in this research?***

*[Include the length and duration of visits and procedures]*

***What can I expect if I take part in this research?***

*[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]*

* *A time‐line description of the procedures that will be performed. If practical, prepare a time‐ line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits*
* *With whom will the subject interact*
* *Where the research will be done*
* *When the research will be done*
* *How often procedures will be performed*
* *Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)*
* *When applicable indicate that the subject will be contacted for future research.*
* *Whether the procedures are solely related to the research study, or whether some are part of usual medical care (and thus will be billed to the subject themselves)*

***What happens if I say yes, but I change my mind later?***

You can leave the research at any time; it will not be held against you.

## [When applicable, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects but may agree to undergo follow‐up procedures and data collection.]

***Is there any way being in this study could be bad for me? (Detailed Risks)***

There are some risks you might experience from being in this study. They are *[Describe physical, psychological, privacy, legal, social, and/or economic risks, if appropriate. If known, describe the probability and magnitude of the risk. If possible, please describe the risks in categories of “very likely,” “less likely,” and if necessary “less likely but serious.” If possible, list risk categories in accordance with expected risk frequency (e.g. if ‘very likely’ equals 20% or greater, please indicate this). Do not describe risks in a narrative fashion. Highlight or otherwise identify effects that may be irreversible, long term, fatal, or life threatening. Please ensure that* ***life-threatening*** *or* ***potentially-fatal*** *risks are bolded]*

* *Risk*
* *risk*

*[For Clinical Trials, please use the following]*

In this part of the consent form, we describe the side effects we expect from the tests and treatments in this study. *[Name of study product]* could cause side effects we do not know about yet. We carefully watch everyone in the study for side effects.

There may be other side effects that are unknown or not anticipated. If you join this study, we would tell you if we discover new side effects that could affect you.

*Add examples to the following paragraph. Also, if the paragraph would make more sense* ***after*** *the description of individual drug risks, consider moving it there.*

This form lists side effects of individual drugs. Other side effects could occur when we use these drugs together.

*If appropriate, remove “risk of death” sentence in the following paragraph.*

Side effects may be mild or very serious. Medicines could be given to help lessen side effects. Many side effects go away soon after you stop taking *[name of study product]*. In some cases, side effects can last a long time or never go away. There also is a risk of death.

*Describe any foreseeable risks, stresses or discomforts to be expected. If a side effect may be irreversible, long-term or life-threatening, say so.* ***Do not state that there are no risks.***

*If applicable, divide risks into likely, less likely, and rare but serious. There are no standard definitions for these categories. As a guideline, “likely” can be viewed as occurring in > 20% of patients and “less likely” in < 20% of patients. Adjust these levels for specific study agents.*

*For cancer studies, sample language for specific drug risks is available in the NCI website:*[*http://ctep.cancer.gov/protocolDevelopment/sideeffects/drugs.htm*](http://ctep.cancer.gov/protocolDevelopment/sideeffects/drugs.htm)*.*

*In the “likely” and “less likely” categories, identify those side effects that may be ‘serious.’ ‘Serious’ is defined as side effects that may require hospitalization or may be irreversible, long-term,* ***life-threatening****, or* ***fatal****.*

*Side effects that occur in < 3% of participants do not have to be listed unless they are serious, and should then appear in the “rare but serious” category.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Likely (more than % of patients) |  | Less likely (-%) |  | Rare but serious (less than %) |
|  |  |  |  |  |

*[ITEM]*

Likely side effects of *[ITEM]* are:

* *[ITEM]*.
* *[ITEM]*.

Less likely side effects of *[ITEM]* are:

* *[ITEM]*.
* *[ITEM]*.

Rare but serious side effects of *[ITEM]* are:

* *[ITEM]*.
* *[ITEM]*.

***Reproductive risks***

*When appropriate, include a statement that if the participant was or became pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which were currently unforeseeable. Appropriate when the research involves individuals of childbearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known.*

*If the protocol mandates the specific birth control methods allowed/required for participants: Include a table addressing those specific requirements.*

*If the protocol only indicates that effective birth control is required, even if it suggests methods: The consent must include language directing participants to discuss effective methods with the study doctor.*

Taking *[name of study product]* may involve unknown risks to an embryo, fetus (unborn baby) or nursing infant. Therefore, you could not join this study if you are pregnant, if you are planning to become pregnant, or if you are breast-feeding.

If you join this study, you would have to use an effective method of birth control from the time this form is signed until at least *[duration]* after the last dose of *[name of study product]*. You should discuss this with the study doctor or a member of the study staff.

*[INCLUDE IF THE PROTOCOL MANDATES METHODS]* Birth control methods required on this study for individuals who could get pregnant include: *[LIST APPROPRIATE OPTIONS FROM PROTOCOL]*

If you became pregnant after joining this study, you would have to notify the study doctor immediately. Participation in this study would end, and you would receive counseling and follow-up throughout the pregnancy and for about 6 months after the child is born.

The effects of *[name of study product]* on a pregnancy you could cause are also unknown. If you could get someone pregnant, you must also agree to use one or more forms of effective and acceptable birth control from the time this form is signed until at least *[duration]* after the last dose of *[name of study product]*. You should discuss this with the study doctor or a member of the study staff.

*[INCLUDE IF THE PROTOCOL MANDATES METHODS]*  If you can get someone pregnant, birth control methods required on this study include: *[LIST APPROPRIATE OPTIONS FROM PROTOCOL]*

*If minors are planned to enroll, also address state law requirements related to pregnancy testing.*

For minor participants: If you join the study and have a positive pregnancy test on study, we would tell you about the test results. You must give your permission before we can share the results with a parent or guardian. *[IF APPROPRIATE, ALSO INCLUDE THE FOLLOWING]* If you have a positive pregnancy test, we would ask you to leave the study. This means even if we did not tell your parent or guardian, they might find out you were pregnant.

***Non-physical risks***

*If disclosure of pedigree or genetic testing results has the potential to pose a risk to insurability, damage familial relationships or cause psychological harm, indicate measures (such as counseling, confidentiality protections) to be taken by participant and study doctor to minimize these risks. This section should relate the risks of genetic testing performed as part of the research, if applicable. If optional genetic research is planned, discuss the risks of that testing in the applicable section on optional research (see sample section in this template below).*

If you join this study, non-physical risks are:

* You might not be able to work.
* Results of genetic tests might be released by accident. This risk is very low, because we keep personal information private. If these results became known, you could have problems from others knowing about your genetic test results. For example, the results could cause stress or anxiety in family members who learn about their own risk of developing disease, or you could have problems with insurance because of your health status. There is also a risk that these test results could be combined with other information to identify you.
* *[ITEM]*.
* *[ITEM]*.

***Other possible side effects***

Some people who received *[name of study product]* have reported other side effects. We do not know if *[name of study product]* caused these side effects. They are:

* *[ITEM]*.
* *[ITEM]*.

Some people who received *[name of study product]* have reported *[side effect]*. We do not know if *[name of study product]* caused *[side effect]*.

*[OR]* We don’t believe there are any risks other than the risk of a loss of privacy. *[If the only potential risk is loss of confidentiality/privacy and this was stated in the “Key Information Section”, delete this section, including the header.]*

## What Happens If I have an Injury?

## [Please include this section for all greater than minimal risk studies. This section may be removed for studies that are minimal risk].

*[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.

***If I take part in this research, how will my privacy be protected? What happens to the information you collect?***

Efforts will be made to limit the use and disclosure of your Personal Information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the Office of Clinical Research, and other representatives of this organization. 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.]* and Office of Human Research Protections (OHRP).

*[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities. Examples:*

*“By law, the study team must release certain information to the appropriate authorities if at any time during the study there is concern that child abuse or elder abuse has possibly occurred or you disclose a desire to harm yourself or others.”*

*[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained. Otherwise delete]*

*[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements. Otherwise delete.]*

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

OR

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

*If the study includes HIV or hepatitis testing*

***HIV and Hepatitis Test Results***

For this research study, you will be tested for HIV *and/or* hepatitis.  HIV is the term used for the virus that produces HIV infection and may ultimately lead to AIDS.  Hepatitis is a virus that can damage your liver.  The results of these tests will become part of your medical record.  You have a right to know the results of these tests.  The study doctor must report positive HIV and hepatitis tests including your name, address and telephone number, date of birth and demographic information (age, sex, and race/ethnicity) to the Illinois Department of Public Health (IDPH).  The IDPH keeps track of all persons in the state with positive HIV and hepatitis tests.  The database that keeps track of this information is labeled with a unique identification number so that your name does not appear with your HIV or hepatitis status.  This helps keep your name private.

## [If a Certificate of Confidentiality has or will be obtained for this study, please include the following language. Please note if the study has NIH funding, this language must be included as a Certificate of Confidentiality will automatically be granted. Otherwise delete.]

***Certificate of Confidentiality***

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

*[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws*.] The Certificate of Confidentiality will not be used to prevent reporting of abuse and neglect, or harm to self or others disclosure as required by federal, state, or local law of *[…] [List what will be reported, such as child abuse and neglect, or harm to self or others]*.

## [If your study will involve genetic research, please include the following language. Otherwise delete.]

***Genetic Research***

*[Please use simple language to describe genetic research to be conducted. If you need assistance on drafting this section, please see the Informed Consent Resource hosted by the National Human Genome Research Institute, as well as in the NIH Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy for appropriate language to use in such studies and insert in this section. If submitting data from this study to a federal repository (dbGaP, GEO, etc.) the consent should also include an explanation about whether participants’ individual‐level data will be shared through unrestricted‐ or controlled‐access repositories.]*

## [For NIH‐supported studies, participation infers an acknowledgement that investigators may aggregate and analyze the data generated through the study. NIH expects that consent processes and other information explain that such analyses or other summaries of study information (including genomic study results (GSR) may be shared in the scientific literature and/or through other public scientific resources, such as data sharing resources that provide broad or unrestricted access to the information.]

***The Genetic Information Nondiscrimination Act (GINA)***

 The Genetic Information Nondiscrimination Act (GINA) is a federal law that may help protect you from health insurance or employment discrimination based on genetic information. GINA is a federal law that will protect you in the following ways:

* Health insurance companies and group plans may not request genetic information from this research;
* Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
* Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.  GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

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

***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.

## [Include this section if removal from the research without the subject’s “OK” is a possibility. Otherwise delete.]

***Can I be removed from the research without my OK?***

*[Include for research where this is a possibility. Otherwise delete.]* The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include *[describe reasons why the subject may be withdrawn, if appropriate. Examples include]*

* *You are unable to meet the requirements of the study or your medical condition changes;*
* *The study drug is no longer available;*
* *New information becomes available that indicates that participation in this study is not in your best interest; or*
* *If the study is stopped.*

*[Include for research where new information is a possibility. Otherwise delete.]* We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

***What else do I need to know?***

*[Include for sponsored research. Otherwise delete.]* This research is being funded by *[Insert name of funder]*.

*[Include if subjects will be paid. Otherwise delete.]*

***Compensation ‐***

If you agree to take part in this research study, we will pay you *[indicate amount]* for your time and effort. *[Indicate if the amount is pro‐rated for research visit completion.] Suggested language:*

*[If compensation exceeds $100 per occurrence, or total compensation will meet or exceed $600 please include the following language:]*

As policies at the University of Chicago require that these payments be given in the form of a check, you will need to complete a tax form. We will need to ask for personal information about you including your name, address, and social security number.  In addition, because the process for requesting a check often takes several weeks, we will mail your check to you when it is ready.  Please note that it may take 3-4 weeks after your participation end in order for you to receive your payment.

 *[Include if there is a potential for Commercial Profit. Otherwise Delete]*

*Commercial Profit ‐* Your information and samples (both identifiable and de‐identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans *[or replace with plans when using identifiable information/samples]* to tell you, or to pay you, or to give any compensation to you or your family.

***Potential Costs to You ‐***

Taking part in this research study may lead to added costs to you. *[See Appendix 1 for University of Chicago standard Costs language.]*

*[Include if clinically relevant research results, including individual research results, are possible as part of the study. If results will be disclosed, please describe under what conditions they will be disclosed. If results are possible but will not be disclosed, please state why not. If clinically relevant results will not be found as part of the study, delete]*

***Clinically‐Relevant Results ‐***

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers *will/will not* contact you to let you know what they have found. *(add detail of how/when/what results are shared as applicable)* If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re‐done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

***Who can I talk to?***

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *[Insert contact information for the research team]*

*[If the study does not involve ANY physical intervention, this paragraph may be removed.]*

If you have a research related injury, you should immediately contact *[insert appropriate name and telephone number – ensure that the number listed in this section will provide access to someone 24 hours a day, 7 days a week]*.

This research has been reviewed and approved by the BSD/UCMC Institutional Review Board (“IRB”). You may talk to them at (773)702-6505 or bsdirb@bsd.uchicago.edu if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You cannot reach the research team.
* You want to talk to someone besides the research team.
* You have questions about your rights as a research subject.
* You want to get information or provide input about this research.

***[Omit the signature page if there is no written documentation of consent.]***

# *Signature Block for Adult subject*

Your signature documents your permission to take part in this research.

Signature of Subject

Printed Name of Subject

Date: Time: AM/PM (Circle)

**Person Obtaining Consent**

I have explained to  *(study team should insert name of subject/parent/guardian when obtaining consent)*  the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject. *[or, if appropriate substitute:]* I will give a signed copy of the consent form to the subject and family.

Signature of Person Obtaining Consent:

Date: Time: AM/PM (Circle)

*[Include for More than Minimal Risk Research. Otherwise Delete]*

**Investigator:**

Signature of Investigator/Physician

Date: Time: AM/PM (Circle)

 [*STOP: Only include the following if the inclusion criteria in the protocol does not specify decisional capacity or if the protocol includes children]*

*[Include for Studies Involving Children or Individuals who will require a Legally Authorized Representative Revise sub-heading as needed. Otherwise Delete]*

**Parent/Guardian/Or Legally Authorized Representative:**

I give my permission for my child/relative/the person I represent to participate in the above described research project.

Signature of Parent/Guardian/ or Legally Authorized Representative: \_\_\_\_\_\_\_

Date: Time: AM/PM (Circle)

*[STOP: Only include the following if proxy consent is being requested/approved for this study. Also attach the “Health Care Surrogate Act Certification Concerning Research”]*

***Proxy/Surrogate Consent***

The subject on whose behalf I consent has no legally authorized representative or that person is unavailable despite efforts to contact him/her. I believe my proxy decision on behalf of the subject conforms as closely as possible to what the subject would have done or intended under the circumstances. This decision takes into account what I believe are the subjects’ personal, philosophical, religious and/or moral beliefs and ethical values relative to the purpose of life, sickness, medical procedures, suffering and death. As soon as is possible, the subject will be made aware of his/her/their involvement in this research protocol. These issues have been discussed by the doctors directing this research and myself.

Signature of Individual Providing Surrogate consent:

Relationship to Subject:

Date: Time: AM/PM (Circle)

*[Add the following block if a witness will observe the consent process. A witness may be appropriate in the event a short form translated consent accompanies this form, etc. ]*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of Witness to Consent Process Date

Printed Name of Witness to Consent Process

**APPENDIX 1** – **COST SECTION TEMPLATE LANGUAGE** *[Please remove these pages before finalizing your consent]*

*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?***

*[Studies with no physical risk]*

There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

***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 Standard Of Care - 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.