This **model consent form** is designed for **Public Health Sciences** researchers conducting **minimal-risk research.** The Fred Hutch IRB recommends the sample language with the understanding that the authors of consent forms will edit the language to fit their studies. Please make consent forms as **simple**, **clear**, and **short** as you can **while still including the required elements**.

The prospective participant, parent or guardian, or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate.

Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant’s, parent or guardian’s, or legally authorized representative’s understanding of the reasons why one might or might not want to participate.

All consent forms must address the OHRP general requirements for informed consent described in 45 CFR 46.116, available online at <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116>. See also http://www.hhs.gov/ohrp/policy/consentckls.html.

Consent forms for FDA-regulated studies must also address the elements of informed consent described in 21 CFR 50.25, available online at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25>. See also http://www.fda.gov/oc/ohrt/irbs/appendixb.html.

**Note:** this model is intended for research involving minimal/low risk, and so some of the optional elements of informed consent described in 45 CFR 46.116 and 21 CFR 50.25 are not addressed in this model. The IRB may determine that other elements are appropriate for the research study and must be included.

Add institution names as needed. Include institutions anticipated to participate in this study, even if IRB approval is still pending.

Fred Hutchinson Cancer Center

Consent to take part in a research study:

If the study uses different consent forms for different populations, identify the population group as the subtitle of the study. Otherwise delete line:

The Fred Hutch IRB requires only that the PI be listed on the consent form. Others may be added if necessary.

*Principal Investigator*: Chris Doe MD PhD, Fred Hutchinson Cancer Center

If this consent *might* be signed by a legally authorized representative, parent or guardian on behalf of the study participant, add the following statement. Otherwise delete.

*If you are serving as a legally authorized representative or are a parent/guardian providing permission for a child in this study, the terms“participant”, “you” and “your” refer to the person for whom you are providing consent or parental permission.*

# Important things to know about this study.

The consent form must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant, legally authorized representative, or parent or guardian in understanding the reasons why one might or might not want to participate in the research. The following is an example of key information that can be included, but should be edited based on the study.

For additional guidance, visit: <https://extranet.fredhutch.org/en/u/irb/informed-consent.html#requirements>

You are invited to participate in a research study. The purpose of this research is [STATE PRIMARY PURPOSE AS BRIEFLY AS POSSIBLE].

People who agree to join the study will be asked to attend [NUMBER OF VISITS] over [DURATION]. The study involves [STATE THE PROCEDURES INVOLVED IN THE STUDY AS BRIEFLY AS POSSIBLE].

You do not have to join this study. Although the study will not benefit participants directly, we hope the information we learn will help people with [DISEASE OR CONDITION] in the future. The study procedures could cause side effects such as [ADD A FEW SIGNIFICANT EXAMPLES], as described below in this form.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

# We would like you to join this research study.

Define the research question clearly and simply. Keep background information minimal. When describing the purpose of the research, refer to the patient population, not the individual (e.g. “to study people with cancer” not “to study your cancer”).

We are doing a research study to examine . We want to know if .

Since you are , we would like to ask you to join this study. We will enroll up to people. Although the study will not benefit participants directly, we hope the information we learn will help people with in the future.

If you agree to be in this study, will do the following: , ***[revise examples to suit your study; include duration of participation either here or elsewhere in the form if any of the procedures are not standard of care, indicate that such procedures are experimental 46.116(a)(1)]***

* **Questionnaire:** The questionnaire asks you about your family history of cancer. You may complete the questionnaire at your clinic visit today or at home. The questionnaire takes about 10-20 minutes to complete.
* **Interview:** Within 2 months after you fill out the questionnaire, a genetic counselor or research assistant will interview you by phone about your family history of cancer. We will call you at a time you tell us is convenient. The interview takes about 30 minutes.
* **Interview you for about 45 minutes by telephone.** We will ask you about your lifestyle and your medical history. Your answers will be kept strictly confidential.
* **Medical records review:** We will review your medical records for information about your family history of cancer.
* **Blood sample:** A person trained to draw blood will insert a needle into a vein in your arm and draw 50 cc (about 2 ounces) of blood. The blood draw may briefly cause you to feel faint, lightheaded, or nauseated. There is a rare chance of infection at the needle site.
* **Buccal swab (cheek scraping):** We will give you a soft paper stick (similar to a lollipop stick) with a small piece of cardboard on the end. We will ask you to rinse your mouth with water, rub the swab gently on the inside of your cheek, and then place the swab in a test tube and hand it to the doctor or nurse. The cheek swab is sterile and non-invasive (it shouldn’t even break the skin).
* **Saliva collection:**
* **Ask some participants for a small sample of blood or saliva.** If you provide a blood sample, you will receive $25. If you provide a saliva sample, you will receive $10.
* **Urine collection:**
* **Review your past diagnostic and treatment information.** We will send you a letter explaining how we do this, and a consent form to sign and return.
* **Invite some of your relatives to join the study.** We will contact your relatives only if you give us permission. They do not have to participate, but family members are a very important part of this research. In our experience, 96% of family members contacted agree to participate.
* During a scheduled visit for the main study, **we will take 2 saliva samples.** Your personal participation in the sub study would end here.
* Your study doctor will store the saliva samples until the main study is finished, then ship them to . **Scientists at will study the DNA in your saliva samples.**
* We may store your samples, or the data produced, for up to 25 years, for **future research on .**

If you agree to be in this study, we will give you a questionnaire about your family history of cancer. You may complete the questionnaire at your clinic visit today or at home. The questionnaire takes about 10-20 minutes to complete.

We will also conduct genetic testing on your tissue. Your tissue contains DNA. DNA makes up the genes that serve as the "instruction book" for the cells in our bodies. By studying genes, researchers can learn more about diseases such as cancer. There are many different types of genetic tests. [IF APPLICABLE: The testing on your tissue samples [WILL OR MIGHT] include genetic testing called whole genome sequencing. Whole genome sequencing looks at all the genetic information in your cells.]

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits for saying no or dropping out. Whatever you decide, your regular medical care will not change.

If the participant withdraws from the study for any reason, the data already collected before the participant withdraws remains with the study records and is included in any subsequent analysis.

If you leave the study, your test results and information cannot be removed from the study records.

# Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

Some organizations may need to look at your research records for quality assurance or data analysis. These include:

Edit list as needed.

If this is a multicenter trial and Fred Hutch is the coordinating center, add all institutions listed at the beginning of the consent Only if they will have access to patient-specific data or records from Fred Hutch participants in the study. If Fred Hutch is the coordinating center, collaborating center consents should list Fred Hutch as having access to their patient-specific data/records.

Delete the NIH/NCI if this study is not federally funded.

Add FDA to this list if the study is FDA regulated.

Add pharmaceutical companies or representatives if the study is industry sponsored.

Add cooperative group (SWOG, COG, etc.) where applicable.

Add statistical research center if statistical analysis is done and coordinated offsite.

* Researchers involved with this study.
* The study sponsor and their agents.
* Fred Hutchinson Cancer Center and University of Washington.
* Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
* US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.

We will assign a random number to your blood and cheek cell samples. The researchers doing experiments on your samples will not have access to your name or other personal information. They will know the random number only. Thus the risk of someone connecting any study information with you as an individual is unlikely. However, results of genetic tests on your samples may be released by accident. If your results become known, you may have problems with family members or insurance.

In the paragraph below, the last 3 sentences (beginning with “For example…”) are optional; revise or delete as appropriate.

We will keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you about lab tests. Or a court may order that study information be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

If this is an NIH-funded clinical trial or an FDA-regulated applicable clinical trial to be registered with [www.clinicaltrials.gov](http://www.clinicaltrials.gov), include the following statement in the consent form.

A description of this clinical trial will be available on [*http://www.ClinicalTrials.gov*](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 the research involves the use of clinical services, items, or tests through UW Medicine, UW Physicians (UWP) (this includes most uses of the UW Clinical Research Center (CRC)), or Fred Hutch, include the following statement.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

If you are obtaining a federal Certificate of Confidentiality, insert the following 3 paragraphs. If your research is NIH-funded and you have been issued a Certificate of Confidentiality, you must include this language in the consent form.

At the start of the study, this research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information. The Certificate may not last the duration of the research. Talk to the study doctor if you have questions about this.

We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

* To a member of the federal government who needs it in order to audit or evaluate the research.
* To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
* To the federal Food and Drug Administration (FDA), if required by the FDA.
* To someone who is accused of a crime, if they believe that our research records could be used for defense.
* To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

If Protected Health Information (PHI) is used for research, see <https://extranet.fredhutch.org/en/u/irb/hipaa-compliance.html> for HIPAA compliance forms.

Genetic Information Protection – GINA defines a *genetic test* as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes. Routine tests that do not detect genotypes, mutations, or chromosomal changes, such as complete blood counts, cholesterol tests, and liver enzyme tests, are not considered genetic tests under GINA. Also, under GINA, genetic tests do not include analyses of proteins or metabolites that are directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

If this research involves genetic testing include the following additional confidentiality section regarding GINA:

# How is my genetic information protected?

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect your genetic information.

GINA restricts access to your genetic information so that it can not be used for health insurance coverage decisions. GINA won't allow health insurance companies or group health plans to:

* ask for your genetic information you have provided in research studies.
* use your genetic information when making decisions regarding your eligibility or premiums

GINA **does not** help or protect you against genetic discrimination by companies that sell life, disability or long-term care insurance.

# Financial conflicts of interest

Delete this section if not applicable.

**UW Conflict of Interest** – If this research study is subject to a UW Conflict Management plan, add the required UW conflict disclosure language. Reference UW GIM Policy 10, and the UW Human Subjects division template consent form, or the following link <http://www.washington.edu/research/hsd> for more information.

**Fred Hutch *Key Personnel* Conflict of Interest** – If this research study is subject to a Fred Hutch Conflict Management plan, add the required conflict disclosure language.

**Fred Hutch Institutional Conflict of Interest (ICOI**) – If this research is subject to the Fred Hutch ICOI policy, contact the Office of General Counsel for the appropriate financial disclosure language to be included here.

# Will you pay me to be in this study?

If compensation is involved, state the value of such compensation, method of payment and payment schedule (such as mailed to participants, given to participant in person, etc.). If payment is prorated, describe the prorated scale if the participant decides to withdraw or is withdrawn by the researcher.

Modify language to fit your study.

If the study is reimbursing actual travel expenses, include a statement about the requirement to provide copies of the receipts to be reimbursed.

There is no payment for being in this study.

OR

If you complete this study, we will mail you a check for $. If you drop out of the study, or if we take you out of this study, we will mail you a partial payment based on the following schedule [DESCRIBE].

OR

We will pay you $ after each study visit you complete.

OR

The study will reimburse you for out-of-pocket costs to you [*if applicable*: up to $[#] per day]. This would include: [*include only those that apply and/or add as approrpiate*]

* Transporation costs to the clinic or hospital for study tests and visits, up to $[#] per visit.
* Costs of hotel stays necessary while you are undergoing study tests and visits, up to $[#] per day.
* Cost of meals during the time of your study visits.
* Costs of child care during the time of your study visits.

IMPORTANT: You will need to give us receipts that clearly show your costs.

If Fred Hutch will be issuing participant compensation: If total compensation is expected to exceed the threshold for IRS 1099 reporting on individuals for Miscellaneous income ($600 as of 2017 tax year) include the following statement at the end of the payment section. (This is not required for reimbursements of actual travel expenses.)  
  
If UW will be issuing the compensation: For studies in which subjects are likely to earn $600 or more at UW sites during the calendar year, include a statement that the University is required to report subject payments of $600 or more as miscellaneous income to the IRS.(Template language included below can meet both Fred Hutch and UW HSD requirements.)

Note: Study team should keep the social security information separate from the research records.

Payments for being in the study may be taxable. Payments that exceed $600 in a single calendar year are reported to the IRS on form 1099-MISC. For this reason, we need to collect your social security number. You can choose not to give us your social security number, but then we cannot pay you.

# How much will this study cost me?

State protocol-specific information about costs to participants. Inclusion of additional costs to the participant that may result from participation in the research is appropriate when it is anticipated that participants may have additional costs. The description of costs should state clearly what the participant is or could be responsible for, and what the institution and/or sponsor will pay for.

There are no costs for being in this study.

# What if you get sick or hurt after you join this study?

All consent forms for studies with physical procedures (blood draw, nasal swab, etc.) must describe any compensation for injury available to participants. Studies without physical procedures do not need to include this section in the consent form.

For studies with physical procedures where the sponsor does not provide compensation (e.g. NIH funded studies) the following 3 paragraphs must be included in the consent:

If the research study has a Sponsor who has agreed to pay for study related injury, revise the wording in paragraphs two and three as necessary per the Clinical Trial Agreement (e.g. industry sponsored studies, or other sponsors who may offer compensation for injury).

For a life threatening problem, call 911 right away or seek help immediately.  Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact [FILL IN AS APPROPRIATE].  They will treat you or refer you for treatment.  You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family.  State or national law may give you rights to seek payment for some of these expenses.  You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

# Other information.

After about [insert time period], your personal information in the database will be destroyed. However, if you choose to donate your samples for future research (see below), your samples and research record will be stored indefinitely.

If you have questions or complaints about this study, please call Dr. at . If you have questions about your rights as a research participant, call the Director of the Fred Hutch Institutional Review Office at 206-667-5900 or email [irodirector@fredhutch.org](mailto:irodirector@fredhutch.org). [*If study activities are occurring at UW, also include:* You can also call the University of Washington Human Subjects Division at 206-543-0098.]

The physical risks of this study are minimal. However, you may feel uncomfortable about genetic testing. Or you may worry about how genetic differences affect your health or risk of disease. Future research may identify links between the genes being tested for this study and health or disease, but you will not be told your test results.

We will keep the sub study information confidential. Results are stored in a secure location with restricted access. The DNA samples and genetic information are kept separate from your name. The chance that your genetic data (which contains information about you and your family) could be accidentally released is very small. If this happens, it could result in discrimination by employers or insurance providers. However, laws and procedures are in place to protect your privacy and keep your DNA information confidential. The results could cause stress or anxiety in family members who learn about their own risk of developing disease.

*OPTIONAL TEMPLATE LANGUAGE:*

Further suggested language for various topics is provided below. Use the headings if (a) you’re using headings already, or (b) if leaving them out would make the consent form confusing. A good rule of thumb: a consent form of more than 3 pages (including signatures) should probably have headings.

To suggest other topics for this section, contact the [IRO](mailto:IRO) at 667-5900.

## How did you get my name?

We found you through the Cancer Surveillance System (CSS), a registry of the Washington State Department of Health and the National Cancer Institute. By law, cases of cancer in Washington state are reported to the CSS. The CSS only releases patient information to accredited investigators doing research, in compliance with regulations to protect human research participants.

## How did you get my name?

We are studying patients from the UW Kidney Transplant Clinic. The doctor treating you thinks you may be eligible for this study.

## Do I have to participate in the whole study?

Each part of the study is completely voluntary. You may choose to join all, some, or none of the study activities. You may stop the telephone interview at any time, or choose not to answer some questions.

## Will you contact me in the future?

About every 6 months, we will send you a newsletter about the study. We will also send you educational materials. Every year or two, we will contact you for short surveys so we can keep your address, phone number and health information current.

## How will you contact my relatives…and why?

Family members are an important part of our research. To get the most complete information, we would like to study all members of a family, especially if more than one has had cancer. However, your relatives do not have to join the study.

We will send your relatives a letter like the one we sent you, then call them on the telephone. We must tell them we got their name from you. We will not tell them any answers from your interview.

# What will my information and/or tissue samples be used for?

The language in this section is intended to inform prospective participants of the required use of their information and/or biospecimens that will occur as a result of their consent to participate in the study. Modify the first sentence as needed to provide specificity about how information and tissues are used in this study.

Your information and tissue samples (such as blood and tumor cells) will be used for the purposes of this study. [DESCRIBE USES.]

Your tissue samples might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.Include one of the following statements regarding research results, and describe the conditions under which results will be shared, if applicable:

During this study, if the researchers learn new information that may be important to your general health or to your disease or condition, they will share that information with you. [DESCRIBE CONDITIONS FOR SHARING RESULTS.]

OR

During this study, if the researchers learn new information that could possibly be important to your general health or to you disease or condition, they will not be able to share that information with you [DESCRIBE WHY, FOR EXAMPLE: because the tests are investigational OR because the results will not be linked to your identity OR because the results will only be general, not specific to you, ETC].

OR

During this study, we do not expect any test results that would affect your care, so we do not plan to return results to you.

# Will my information and/or tissue samples ever be use for future research?

**You must include one of the following three options regarding future research** (option 1 is for when *no* future research will occur).**Option 3 is recommended.** Use the terms “information”, “samples”, “tissues”, or “specimens” as appropriate for the study, but consistently.

Option 1: If you (and the sponsor, if applicable) can guarantee that no future research will ever occur, use this option. The information and biospecimens should not ever be used outside this specific protocol (not even for later retrospective reviews). If you include this consent option, you should ensure mechanisms are in place to destroy/discard all tissue and identifiable data at the end of this study.

Option 2: This addresses the possibility that future research might occur without additional informed consent from the subjects if the information and/or biospecimens are de-identified. This option means you are *not* allowing participants to say “no” to future research—but you must first de-identify all materials before using or sharing them for other projects outside this research.

Option 3: Generally, you should choose this option, which allows participants to choose whether or not to allow future research on their information and biospecimens. This choice is especially important if the study holds the prospect for direct benefit to the participant. Mandating agreement to storage and sharing may be considered coercive if the participant does not want to agree to sharing of data and biospecimens but feels compelled to agree anyway in order to join a possibly beneficial clinical trial. Ensure you have mechanisms in place to document and track participants’ choices so the tissue and information from anyone who says “No” can be appropriately destroyed or discarded at the end of this study.

Option 1

Your information and tissue samples (even if made anonymous) will not be used for any research other than this study.

Option 2

In addition to the planned uses described above, we might remove all identifiers and codes from your information or tissue samples. We could then use or share them with other researchers for future research. If you do not want your anonymous information or tissue samples used for other projects, you should not participate in this study.

If we do share your information or tissue with others, we would not be able to stop the future research, even if you asked later. There will be no way to link the information or tissue samples back to you. We will not contact you or otherwise inform you before we share your information or tissue for future research.

Option 3

After we do tests on your tissue in this study, some tissue may be left over. We would like you to donate this leftover tissue for future research. This may include genetic research. [IF APPLICABLE: We [also] would like to use your information for future research.]

Some of your information may be included with the tissue when used for future research.

You do not have to donate your tissue for research. You are free to say yes or no. Your regular medical care will not change if you say no.

If you say “no,” your tissue and information (even if made anonymous) will **not** be used in future research.

If we want to use your tissue and information for other research or share it with other scientists for research, an ethics review committee (IRB) will review the request. The IRB will decide if we need to ask for your consent to do the research.

Your donated tissue and information will be stored in a secure location. It will be used for research only. This research may be done by for profit companies. Researchers will not report their results to you or your doctor. The research results will not appear in your health record. They will not affect your care.

Research on your tissue and information may help develop new products. If these products make money, there is no plan to share the money with you.

If you donate your tissue and information for research, you can change your mind anytime. Just call Dr. at and tell us you do not want us to use your tissue. There is no penalty for changing your mind. Your regular medical care will not change. However, if you do change your mind, we cannot return donated tissue. We may be able to destroy tissue we know is yours. But if it is stored or shared anonymously (without any label saying who it belongs to), we cannot destroy it. In this case it would still be used for research, but no one would know it was yours.

Read each question and think about your choice. When you decide on each question, please circle yes or no.

Do you agree to donate your tissue and information to study cancer?

(circle one)

YES NO Initials: Date:

Do you agree to donate your tissue and information to study other health problems, such as diabetes, Alzheimer’s disease, or heart disease?

(circle one)

YES NO Initials: Date:

Is it OK if someone contacts you in the future to ask you to donate more tissue or information for research?

(circle one)

YES NO Initials: Date:

# Future genetic research databases:

Delete this section if not applicable.

Several genetic databases are available to help researchers understand different diseases. These databases contain DNA information and other data helpful to study diseases. DNA comes from cells in your body and contains all your genetic information. As part of this study we would like to put your genetic information into these databases. Your information may benefit future research.

All of your personal information would be removed. Your name, address, etc will not be in the database. Only genetic information and information about your condition will be sent to the database.

There is a small risk that your genetic information could be matched against other genetic databases to get your name. Once we release your data to the central database we are no longer in control of the information.

Is it OK if we send your genetic information to one or more databases for future research?

(circle one)

YES NO Initials: Date:

Signatures

Adjust the “(age 13+)” for the appropriate range (e.g., age 13 to 17) to reflect inclusion criteria for teens in this study who would provide documented assent by signing the main consent form in addition to their parent(s) who provide parental permission for the teen. Do not reflect an age lower than 13+ in the main consent. If only adults will be enrolled, remove the “Age” from the signature line.

Please sign below if you:

* have read this form (or had it read to you);
* had the opportunity to ask any questions you have;
* had the opportunity to discuss the research with the person obtaining consent; and
* agree to participate in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Participant (age 13+): | | | | |
|  |  |  |  |  |
| Printed Name |  | Signature |  | Date |

If this consent form might be used to obtain parental permission, one parental signature line should be included.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parent or legal guardian: | | | | |
|  |  |  |  |  |
| Printed Name |  | Signature |  | Date |

If consent *might* be obtained from a legally authorized representative, include the following statement and signature line.

*Note: Use of legally authorized representative to consent on behalf of participants who lack the capacity to provide legally effective informed consent must be prospectively approved by the IRB.*

Legally Authorized Representative: Please sign below if you:

* have read this form (or had it read to you);
* had the opportunity to ask questions;
* had the opportunity to discuss the research with the person obtaining consent; and
* agree to consent on behalf of the participant for him or her to participate in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Legally authorized representative: | | | | |
|  |  |  |  |  |
| Printed Name |  | Signature |  | Date |
|  | | | | |
| Relation to the participant | | | | |

|  |
| --- |
| Include an Impartial Witness signature line on your consent only if a witness is required by federal regulations.  The two contexts in which a witness to the consent discussion is required by federal regulations are:  1) English speakers who have barriers to reading the consent (medical, visual, literacy, etc.), and  2) Non-English speakers who cannot read English, when a “short form” consent process is being used.  Impartial Witness: A person independent of the trial, who cannot be unfairly influenced by people involved with the trial and who attends the informed consent discussion if the participant or the participant's legally authorized representative cannot read the informed consent form that describes the study. |

If you were a witness for a participant who was not able to read this written consent form, sign below to indicate (1) you were present at the consent discussion in person, (2) you witnessed the verbal presentation of the written consent form, and (3) the participant had the opportunity to ask questions and agreed to take part in the study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Impartial Witness: | | | | |
|  |  |  |  |  |
| Printed Name |  | Signature |  | Date |

# Researcher’s statement

|  |
| --- |
| The Researcher’s statement and signature is mandatory in the case of studies needing to comply with ICH guidelines (typically required by Industry sponsors). Unless you need to comply with ICH, this statement and signature is not required. A pre-signed consent form is not acceptable.  If you have a research statement and signature line on your IRB approved consent form, you are required to have the person conducting the consent discussion sign the researcher statement. |

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Person obtaining consent signature: | | | | |
|  |  |  |  |  |
| Printed Name |  | Signature |  | Date |

Protocol:

Current consent version date:

Previous consent version date:

Copies to: