**Model Consent R** - To use this consent form, taking the samples must involve no more than minimal risk to research participants.

Use this consent when collecting additional blood prior to transplant in situations where it may not be completely known if, or which, protocol a participant will qualify for and there is more risk of doing a separate sampling than taking extra samples during the clinical intervention in preparation for research.

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>.

Add or subtract institution names as needed. UW Consortium must include the University of Washington in this list.

Fred Hutchinson Cancer Center

University of Washington

Consent to donate extra tissue samples for research during a planned clinical evaluation for blood or marrow stem cell transplantation

Protocol No.:

Protocol Title:

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

*Principal Investigator*: ; Telephone

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.*

# We would like to take extra tissue samples before you join a research 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 being evaluated to see if you can be in a research study using transplantation to treat your disease. During your evaluation, we take samples of your tissue (blood or bone marrow). This procedure is a normal part of the evaluation.

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”).

When we do this procedure, we would also like to take extra samples to use if you join the study. The purpose of the study is .

Why do we want to take extra samples now, instead of waiting for you to join the study? If we wait, we would need to repeat the sampling procedure, which could cause you discomfort. By taking the extra samples now, we can do the procedure only 1 time, not 2 times. There is no other benefit to taking the samples now.

We would take an extra for the study. This will add about to the sampling procedure. We would store the extra samples, and use them if you join the study.

The sampling procedures include: [PROVIDE A BRIEF DESCRIPTION OF THE BLOOD DRAW, BONE MARROW BIOPSY, ETC.]

You do not have to let us take extra samples now. You are free to say yes or no, or to withdraw your tissue after we take it. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

There are no extra costs for having extra samples taken for the study. You will not be paid for giving these extra samples.

When applicable, include the following statement regarding plans for genetic research and/or 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) on samples the participant provides for the research study. Note, genome research might be required by the study sponsor (e.g., [NIH](https://osp.od.nih.gov/scientific-sharing/policies/)).

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.]

# If you join a different study

If you join a different research study, we would use the extra samples for that study instead of this one.

You may be asked to sign a consent form before joining any other study.

# If you do not join a study

If you do not join a research study, we would like you to donate your tissue samples for future research about cancer or other diseases and conditions.

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

# What are the risks?

Use the following statement – UNLESS there is an increased risk by providing additional blood or marrow (e.g. given the volume taken). Then provide a description of the increased risk of the additional sample.

We are already taking samples of your tissue (blood or bone marrow). There is no increased physical risk to having extra samples taken at the same time.

There is a slight risk of loss of confidentiality.

Also consider if the research involves a genetic analysis component, if so add the risk associated with genetic research.

Results of your genetic tests may be released by accident. This risk is very low, because we keep your personal information private. If your results become 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..

# 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, repeat 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.

Delete the FDA from this list if the study is not FDA regulated.

If this is an IND study, add IND sponsor/institution.

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 sponsors and their agents.
* 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.
* Fred Hutchinson Cancer Center, University of Washington, and Seattle Children’s.
* US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, Food and Drug Administration, and other agencies as required.

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

We will do our best to 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.

OR

If this study is considered “Therapeutic” where the primary research objective of the study involves treatment of a disease or other health condition, 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 means that 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 research information if you give 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.

# For more information

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you can talk to are listed below.

In the table below, under “Your rights as a research participant,” include both Fred Hutch and UW contact information if activities are occurring at UW or if the PI’s primary appointment is UW. Otherwise, only include Fred Hutch in that row.

|  |  |  |
| --- | --- | --- |
| If you have questions about: |  | Call: |
| This study (including complaints and requests for information) |  | (Dr. )  () |
| If you get sick or hurt in this study (there are no plans to provide compensation). |  | (Dr. ) |
| Your rights as a research participant |  | 206-667-5900 or email [irodirector@fredhutch.org](mailto:irodirector@fredhutch.org) (Director of Institutional Review Office, Fred Hutchinson Cancer Center)  206-543-0098 (Human Subjects Division, University of Washington) |
| Your bills and health insurance coverage |  |  |

# 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 provide biospecimens. 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 the research 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 the 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 the 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 (entire rest of this section)

If you do not join a study, or if there are some tissues leftover, we would like you to donate your tissue for future research. This may include genetic research. [IF APPLICABLE: We [also] would like to use your information for future research.]You do not have to donate your tissue or information for research. You are free to say yes or no. Your regular medical care will not change.

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 to you or your doctor. 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:

Include this section if there are plans to upload data from this research into a genetic database such as NIH’s Database of Genotypes and Phenotypes (dbGaP).

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 donate tissue samples.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 donate tissue samples.

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

|  |
| --- |
| Include an Impartial Witness signature line on your consent 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.   If a study sponsor or other entity requests inclusion of a witness statement for other reasons, consult the IRO.  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: