This **model consent form** contains sample language and is designed for use by **Public Health Sciences** researchers conducting more than minimal risk research. If you are conducting a clinical trial please use the clinical model. 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>.

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. University of Washington; 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].

We do not know if being in this study will help participants. The study procedures could cause side effects such as [ADD A FEW SIGNIFICANT EXAMPLES], as described below in this form.

You do not have to join this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

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”).

When appropriate, include the approximate number of participants involved in the study. Appropriate when the research involves more than minimal risk.

We are doing this study to examine . We want to know . Since you are , we would like to ask you to join this research study. We will enroll up to people.

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 if you say no. Whatever you decide, your regular medical care will not change.

# What research tests and procedures are part of this study? / What will happen in this study?

Describe the specific research procedures clearly and simply.

Normally it is not necessary to describe eligibility criteria or screening procedures.

Where applicable, indicate the amount of blood to be drawn; types of tissue to be collected; tissue sample storage/use (e.g., banked, used for future research, stored indefinitely, immortalized in a cell line). Identify where the procedures will take place (home, hospital, outpatient clinic, etc.).

Explain duration of each procedure. Depending on the complexity of the study, give treatment time points as part of these descriptions or in a table.

If applicable, state whether patients may participate in some activities/tests only (for example, agreeing to complete a questionnaire but refusing to give a blood sample), or must agree to all activities/tests in order to be in the study.

Use bullets if descriptions will fit in a single paragraph. Otherwise, use subheadings (style: Heading 2).

If the study is complex, consider adding a simple table or figure to illustrate the schedule of procedures.

If you decide to join this study, we will do these tests and procedures:

* **Treadmill test.** A doctor and exercise specialist will test your heart and fitness level. You will walk or run on a treadmill for 5-10 minutes. While walking, you will breathe into a measurement tool.
* **X-ray.** We will perform an X-ray scan to measure your total body fat.
* **Questionnaire.** We will ask you to fill out 3 questionnaires—one when you join the study, another one 6 months later, and another one after the first year. Each questionnaire has questions. Some of the questions may be sensitive. If a question makes you feel uncomfortable, you may choose not to answer.
* **.** .
* **.** .
* 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.]

# How long will I be in this study?

Define total expected time, and then break down into categories (e.g., intervention followed by telephone contact) as appropriate. If there are procedures or consequences for early withdrawal, state them clearly.

We think you will be in this study for/until about .

The total time includes of . After that, we would like you to visit the Prevention Center for . You will visit every for .

When appropriate, explain the anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. Appropriate when there are anticipated circumstances under which the investigator may terminate participation of a participant.

The study doctor or your doctor may take you out of this study at any time. This would happen if:

* They think it is in your best interest to drop out.
* You are unable or unwilling to follow study procedures.
* The whole study is stopped.

When appropriate, explain the consequences of a participant’s decision to withdraw from the research. Appropriate when withdrawal from the research is associated with adverse consequences.

When appropriate, explain procedures for orderly termination of participation by the participant. Appropriate when the research includes such procedures.

If you are thinking about dropping out of this study, please tell us. We will talk to you about the effects of stopping , and about any other follow-up or testing that would help you.

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.

# Risks of being in this study

Use bullets if descriptions will fit in a single paragraph. Otherwise, use subheadings (style: Heading 2). **Do not state that there are no 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).

* **Problems with diet.** At the beginning of each feeding period, you may have mild bloating or stomachache. This is because the study diet has more fiber than your usual diet.
* **Exercise program.** The major risks are fatigue, muscle soreness, and possible joint or skeletal injury. These risks are reduced by proper warm-up and cool-down periods, instruction and monitoring by a trained instructor. Risk of a sudden heart attack is low, similar to that of other activities of daily living.
* **Genetic testing.** 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.
* **.** .
* **.** .

If radiation is involved, insert appropriate language from Radiation Safety Office.

# What are the benefits?

Use third-person language that refers to the study population as a whole (“participants,” “people in this study,” etc.), not to the individual participant (“you”).

We do not know if this study will benefit participants. We hope the information we learn will help people with in the future.

Although the study will not benefit participants directly, we hope the information we learn will improve our knowledge about .

# You have other choices besides this study.

If the only “alternative” is not to participate in the study, omit this section. Adjust the “other choices” as appropriate to the research.

You do not have to join this study. You are free to say yes or no. Your regular medical care will not change. Enrollment in this study may exclude you from other research studies.

If you do not join this study, you have other choices. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about them.

Edit list as needed.

Your other choices may include:

* Another research study.
* A standard exercise program.
* Exercising on your own.
* No exercise program.

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

Some people or organizations may need to look at your research records for quality assurance or data analysis. They 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.
* [NAME OF SPONSOR(S)] (the sponsor of the study) 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.

We will do our best to keep the personal information in your medical record 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 “shorter” 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.

# 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 as appropriate 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 prorated payment].

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 you receive 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.

One approach is to state that there are some extra costs, and list everything (tests, procedures, agents, etc.) that is NOT covered. Another approach is to state that participant or insurer will have to pay costs except for those listed, and list everything that IS covered. **Various examples** are given here. Edit as needed.

There are no extra costs for being in this study.

OR

There may be some extra costs for being in this study. You or your insurer will have to pay these costs. Some insurers will not pay for research. Check with your insurer before you join this study.

The extra costs might be:

Choose all that apply, and delete the rest:

* Cost of tests that are given for the study more often than for standard care.
* Cost of the .
* Paying the people who give you the , and the cost of the equipment they use.
* Cost of people and equipment to give you the . There is no charge for the [INTERVENTION] itself.
* Cost of any other medical care you may need because of this study.

You will **not** be billed for:

* .
* .

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

All consent forms must describe any compensation for injury available to participants.

For studies where the sponsor does not provide compensation (e.g. NIH funded studies) the following 3 paragraphs or their equivalent should be included in the consent. The 911 paragraph is only required if there are potential physical risks to the study.

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.

For all studies involving more than minimal risk, **always** include this statement at the end of the “what if I get hurt” section as a separate paragraph:

You would not lose any legal right to seek payment for treatment if you sign this form.

# Your rights

* You do not have to join this study. You are free to say yes or no. Your regular medical care will not change.
* If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping. Your regular medical care will not change.
* If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.

When appropriate, include a statement that significant new findings developed during the course of the research which might relate to the participant’s willingness to continue participation would be provided to the participant. Appropriate when the research is long term and interim information is likely to be developed during the conduct of the research.

* During the study, we may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn these kinds of information, we will tell you.

# 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 |  | (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 |  |  |

Include emergency number only if it is also listed on the front page. It is required if outpatient treatment is involved or if an investigational new drug or device will be used.

Emergency number (24 hours):

# 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 may be important to your general health or to you disease or condition, they will not 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.]You do not have to donate your tissue or information for future 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 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 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 required under the regulations, IRB directive, or otherwise, please include a second parental signature line. This should be signed by the second parent / legal guardian unless:

- Other parent is deceased

- Other parent is unknown

- Other parent is incompetent to provide permission

- Other parent is not reasonably available

- Or, only one parent has legal responsibility for the care and custody of the child

These situations should be noted on the second signature line as appropriate

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Other 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 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: