Research Consent Form

Greater Than Minimal Risk Study

Instructions

- Enter all information below as it relates to your study. Sample text is provided; text should be adjusted as needed so that it is appropriate for your study. If any of the required elements of consent (see appendix) will not be included, request an "Alteration of Consent" from the IRB.
- Throughout this template, red text is instructions and sample language. Change the font color to black, and delete the examples and other instructions before submitting this form to the IRB.
- A 1-inch margin must be maintained at the top of the page for the IRB stamp and the "patient sticker" field must be maintained unless a copy of the consent will not be added to the medical record.

Study Title

[INSERT THE FULL TITLE OF THE STUDY.]

Investigator

[INSERT THE INVESTIGATOR'S NAME AND HIS/HER HOSPITAL/CLINIC/ORGANIZATION.]

If applicable, indicate that the study is being conducted as part of an undergraduate project, graduate student project, thesis, or dissertation and include the student's name and affiliation in addition to the PI's.

Key Information about this Study

This section is required for any studies approved by the Allina IRB on or after 01/21/2019 and should be specific to the research. When writing the "Key Information" section, include information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. Information should be organized in a way that facilitates comprehension. The IRB Office has provided a draft below that should be modified for the research. Additional information that may be appropriate to address in the key information section include:

- Essential study design elements such as randomization, the use of placebo, etc.
- How treatment in a trial is different from the clinical care the subject would receive if they do not participate in the trial
- Significant costs that could incur as a result of participation
- Compensation for injury
- Study sponsor

Information presented in this section may be repeated in subsequent sections of the form but does not have to be.

You are invited to participate in a research study. The purpose of the research is to [INSERT STATEMENT DESCRIBING PURPOSE OF RESEARCH]. You are invited to be in this study because [INSERT EXPLANATION FOR WHY SUBJECT IS BEING ASKED TO PARTICIPATE]. Your participation in this

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research will involve [INSERT NUMBER OF VISITS] visits and last about [STATE DURATION IN HOURS, DAYS, OR MONTHS].

Participation in this study will involve [E.G., INSERT INFORMATION COLLECTED, PROCEDURES, OTHER RESEARCH ACTIVITIES]. All research studies involve some risks. Some risks to this study that you should be aware of are [LIST MOST IMPORTANT RISKS DUE TO FREQUENCY OR MAGNITUDE]. You (MAY/MAY NOT) benefit from participating in this study by [LIST MOST LIKELY POTENTIAL BENEFITS, IF ANY].

Your participation in this study is voluntary. You do not have to be in this study if you do not want to, or you can stop being in this study anytime. You will not lose any services, benefits, or rights you would normally have if you choose not to participate or stop being in the study. There may be other choices if you do not want to participate. Some of those other choices may include [INSERT ALTERNATIVES, IF ANY].

The rest of this form contains more information about being in this study. Please read this whole form carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is [PRINCIPAL INVESTIGATOR]. If you have questions or concerns or want to leave the study, you should let [PRINCIPAL INVESTIGATOR] know by contacting (HIM/HER) at:

[INSERT CONTACT INFORMATION]

If you have any questions about your rights as a volunteer in this research, contact the Allina Health Institutional Review Board Office at 612-262-4920.

If you are interested in learning more about this study, please continue to read below.

Funding

If funded, identify the sponsor or funding agency. Include a conflict of interest statement from the Conflict Management Plan, if applicable. If there is no funding, then delete this section.

Why are you being asked to participate in this research study?

If this study has been approved to use Legally Authorized Representatives (LAR) to consent on behalf of a prospective subject for the subject's participation in the research or if children have been approved to be enrolled, insert the following [If you are a parent or guardian of a child under 18 years old or the legally authorized representative of an adult, the word "you" in this form refers to the child or adult who will be in the study].

We are asking you to take part in this research study [INSERT CONDITION OR MODIFY THIS STATEMENT ACCORDING TO RESEARCH TOPIC]

This is a [INSERT STUDY TYPE/DESIGN], e.g. Clinical Trial, a type of research study. Your study staff will explain the [INSERT STUDY TYPE/DESIGN] e.g. Clinical Trial, to you. Please take your time to make your decision about taking part. You may wish to discuss your decision with others (for example, your friends or family). You can also discuss it with your health care team. You should have all the information you need to be comfortable with your decision, if you have any questions, you can ask the study doctor or staff for more explanation.

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If you decide to take part in the study, you will be asked to sign this form. Your signature means that you have been told about the study, including the risks and possible benefits and you want to take part in this study.

If this is a clinical trial that presents more than minimal risk insert the below text verbatim:

Research Subject's Bill of Rights

People who volunteer to participate in an experiment (also called a research study or clinical trial) need to understand what is expected of them and why the research is being done. As you think about whether or not to volunteer, it is important that you know you have rights in place to help protect you. These rights, listed below, will be further explained as you read this consent form.

If you are asked to participate in a research study, you have the right to the following:

- Be told the purpose and details of the research study.
- Have the drugs or devices (implants, instruments, or tools) used in the research study described to you.
- Have the procedures of the research study and what is expected of you explained to you.
- Have the risks, dangers and discomforts of the research study described to you.
- Have the benefits and advantages of the research study described to you.
- Be told of other drugs, devices, or procedures (and their risks and benefits) that may be helpful to you.
- Be told of medical treatment available to you if you are injured because of the research study.
- Have a chance to ask questions about the research study.
- Quit the research study at any time without it affecting your future treatment.
- Have enough time to decide whether or not to take part in this research study and to make that decision without feeling forced or required to participate.

Be given a copy of this signed and dated consent form.

Why are we doing this research study?

We want to learn more about how to help people who have [INSERT CONDITION OR MODIFY THIS STATEMENT ACCORDING TO RESEARCH TOPIC]. This study will help us learn more about [INSERT SPECIFICS]. We are inviting people like you who have [INSERT CONDITION] to help us.

[INSERT BACKGROUND INFORMATION ABOUT THE STUDY AND APPLICABLE DEFINITIONS] "This study has 2 parts, the first part of this study is Phase I and has been completed, so you will be part of the second part of this study (Phase II). Clinical research studies are often labeled as Phase I, Phase II, Phase III or Phase IV. Phase I and II studies are conducted primarily to see if a new treatment is safe and to see what effect, if any, the treatment may have on a particular condition. Phase I and II studies do not include very many people. This is a Phase II study; that means there is limited information available

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about how this treatment may affect you and your condition. You should take this into account when deciding whether to participate in this study."

[INSERT DRUG/DEVICE INFORMATION, INCLUDING FDA STATUS, AND INVESTIGATIONAL STATUS, IF APPLICABLE], "XXXXXX is approved/not approved by the US Food and Drug Administration (FDA) for XXXXX. XXXXX is approved by the US Food and Drug Administration (FDA) for XXXXXX but is currently not approved for XXXXXX. Therefore, the use of XXXXXX in this study is considered investigational."

[INSERT VERBATIM LANGUAGE FOR FDA-REGULATED STUDIES THAT ARE REQUIRED TO BE REGISTERED ON CLINICAL TRIALS.GOV]:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

How many people will take part in the research study?

[INSERT THE NUMBER OF ANTICIPATED SUBJECTS WHO WILL PARTICIPATE]

Who can take part in this study?

[INSERT IMPORTANT ELIGIBILITY CRITERIA AND EXCLUSION CRITERIA, IF APPLICABLE]

How long will participating in the study take?

[INSERT LANGUAGE EXPLAINING HOW MUCH TIME IT WILL TAKE TO COMPLETE PARTICIPATION IN THE STUDY, CONSIDER ADDING A TABLE REGARDING ACTIVITIES, QUANTITY, AND TIME FOR EACH ACTIVITY IF COMPLEX]

"You will be asked to come to the clinic for 6 appointments, each of these will last around 1 hour and will require lab work at the conclusion of each visit, which may last approximately 20 minutes."

What happens if I say, "Yes, I want to be in the research study"?

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time. If you decide not to participate in the study or leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

[INSERT LANGUAGE EXPLAINING, PREFERABLY IN CHRONOLOGICAL ORDER, WHAT WILL HAPPEN TO SUBJECTS DURING THE STUDY]

Screening:

To make sure that you are eligible for this research study you will need to have the following exams, tests, and/or procedures. This process is called "screening". If you had some of these done recently, they may not need to be repeated.

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- [Include *screening exams, tests, and procedures. Use bulleted and/or table format if there are more than a few]*

Random Assignment:

If subjects are being assigned to a treatment, include information about the probability and mechanism for random assignment to each treatment option (e.g. flip of a coin, one-in-three). "If the exams, tests and procedure show that you can be in the study, and you choose to take part, you will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. Neither you nor your doctor can choose or know the group you will be in. For this study, it is twice as likely that you will be placed in group 2 as opposed to group 1.

Blinding:

Neither you nor the study doctor or staff will know which study drug/procedure you are receiving. We can find out if we ever need to know to protect your safety.

The following applies to everyone in the study (in all groups):

- *[Insert exams, tests, and procedures preferably by study visit. Use bulleted and/or table format if there are more than a few]*

(Table example):

When	**What happens**
Screening Day 1	Meet with study staff and fill out health survey
Screening Day 2	Blood tests ECG (Electrocardiogram)
Study Day 1	Begin taking _____ once a day. Do this every day until the study doctor tells you to stop.
Study Day 14	Physical Exam Answer health questions

If you are in study group 1 the following will happen:

- *(List exams, tests, and procedures preferably by study visit. Use bulleted and/or table format if there are more than a few)*

If you are in study group 2 the following will happen:

- *(List exams, tests, and procedures preferably by study visit. Use bulleted and/or table format if there are more than a few)*

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Suggested text (non-randomized studies):

If you are found eligible for this study you will have the following exams, tests, and procedures:

- *(List exams, tests, and procedures in order of occurrence and preferably by study visit. Use bulleted and/or table format if there are more than a few)*

Include the following as applicable to the study:

Genetic Testing:

This study includes *(insert optional or required)* genetic tests. Information about this testing is explained in a section towards the end of this document.

Infectious Disease Testing (or other testing/results that are required to be reported to MN Department of Health:

This study includes tests to determine if you may have XXXXXXXX. Information about this testing is explained in a section towards the end of this document.

Sub-study(ies):

In addition to this research, the (*insert sponsor or investigator*) has additional studies that they would like to perform in order to learn about (*insert simplified description such as how your body processes the investigational drug).* Information about this is explained in a section towards the end of this document.

When will my participation in the study be over?

[INSERT LANGUAGE THAT EXPLAINS WHEN THE PARTICIPANT CAN EXPECT TO HAVE COMPLETED THE STUDY, INCLUDING ON-GOING EXAMINATIONS OF MEDICAL RECORDS] "Your active participation in the study is expected to take two years, the study team will continue to collect information from your medical record for an additional 5 years after your participation. Most subjects will complete their participation in 7 years. The entire study is expected to last 10 years."

What happens if I say, "No, I do not want to be in the study"?

Your participation in this study is voluntary.

If you say no, no one will treat you differently. You will not be penalized and you will not lose any benefits you are entitled to.

[REMOVE THIS STATEMENT IF SUBJECTS ARE NOT PATIENTS]The care you get from your doctor or Allina Health will not change.

What happens if I say, "Yes," but change my mind later?

You can stop being in the study at any time. You will not be penalized and you will not lose any benefits you are entitled to. Tell the study doctor or study staff if you are thinking about stopping or decide to

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stop, they will tell you how to stop safely. You can contact the study team at [INSERT CONTACT INFORMATION].

If patients are not being recruited, delete or replace with an appropriate sentence: The care you get from your doctor [or Allina Health] will not change.

If you do decide to withdraw from the study, the researchers may ask you to come in for follow up visits, to call you to find out how you are doing, and/or to continue to review and record information from your medical records. Any continued follow up is voluntary, you can choose not to without any penalty.

If subjects can withdraw data that has already been collected from/about them from the research, describe how to do so and any restrictions. Please note that this is not allowed for FDA-regulated studies (i.e. data that has already been gathered must be retained).

For more information on subject withdrawal from research, see these guidance documents:

- https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-withdrawal-of-subject/index.html
- http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf

[IF APPROPRIATE, INSERT LANGUAGE DESCRIBING RECOMMENDED PROCEDURES TO SAFELY MANAGE SUBJECT WITHDRAWAL].

[IF APPROPRIATE, INSERT LANGUAGE DISCLOSING THE CONSEQUENCES OF A SUBJECT'S CHOICE TO WITHDRAW] e.g., they will not receive any remaining payments, or will lose access to treatments/services only offered by the study.

[INSERT LANGUAGE IF THE INVESTIGATOR MAY CHOOSE TO END A SUBJECT'S PARTICIPATION INDEPENDENTLY AND INCLUDE A STATEMENT DESCRIBING THE ANTICIPATED CIRCUMSTANCES UNDER WHICH THE SUBJECT'S PARTICIPATION MAY BE TERMINATED BY THE INVESTIGATOR.] e.g., because they are not attending enough visits or the investigator feels it is in the subject's best interest)

[INSERT LANGUAGE DISCLOSING THE CONSEQUENCES OF A SUBJECT'S CHOICE TO WITHDRAW] e.g., they will not receive any remaining payments, data will be retained, or will lose access to services only offered by the study

What side effects or risks can I expect from being in the research study?

[DESCRIBE FORESEEABLE RISKS, OR DISCOMFORT TO SUBJECTS IN CLEAR, SIMPLE, CONCISE TERMS, IF POSSIBLE STRATIFY RISKS BY CATEGORIES AND INTERVENTION] e.g., confidentiality, study drug, procedures, or other interventions.

The following is sample text:

Risks associated with study drug:

- The most common side effects (occurring in more than 10% of patients) are:
  - Upset stomach, headache, and dizziness
- Less common side effects (1-10% of patients) are:
  - Muscle weakness, trouble with memory, and rash

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Risks associated with skin biopsy:

- Biopsies will be collected directly from the affected skin using a small scalpel and a local anesthetic. A biopsy may cause pain, bleeding, bruising, soreness, and on rare occasion, infection.

Reproductive Risks

[If the study involves or may involve currently unforeseeable including reproductive risks to either males or females or fetuses, or if the subject is or may become pregnant, please include a statement to that extent.]

How will those involved in the research decrease the risks of this study?

[Explain how the risks are monitored or reduced; consider using bullet points to improve readability. Alternatively, include a bullet titled "Safeguard" under each risk describing the procedures that will be implemented specifically to mitigate the risk.]

We will do the following to decrease the risks of this study:

- (Describe protective measures here).

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers about any injuries, side effects or other problems you have during the study.

If anything happens or we learn of anything that might impact your decision to stay in this study, we will let you know.

We will do our best to protect your privacy and confidentiality.

Will being in this study help me in any way?

[INSERT LANGUAGE DESCRIBING ANY BENEFITS OR THAT THERE ARE NO DIRECT BENEFITS THAT THE SUBJECT MAY REASONABLLY ACCRUE AS A RESULT OF PARTICIPATING IN THE STUDY. COMPENSATION SHOULD NOT BE DESCRIBED AS A BENEFIT]

Being in the study will not help you, but may help people with [INSERT CONDITION] in the future.

[FOR STUDIES THAT OFFER A TREATMENT OR POTENTIAL BENEFIT, INSERT A DISCLOSURE OF APPROPRIATE ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT, IF ANY, THAT MIGHT BE ADVANTAGEOUS] e.g., disclose if the treatment or benefit is available without participating.

What other choices do I have if I do not take part in this research study?

You do not have to be in this study to receive treatment for [INSERT CONDITION].

[INSERT LANGUAGE DESCRIBING OTHER TREATMENT CHOICES THE PATIENT MAY HAVE] e.g. standard treatment options, taking part in other research studies, receiving the same treatment but not as part of

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a research study (if applicable), or no treatment. When applicable, note if the intervention is available without participating in the research.

Talk to your doctor about your choices before you decide if you will take part in this study.

Who will see my information?

Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions:

- [INSERT SPONSOR NAME AND ANY OTHERS INFORMATION MAY BE SHARED WITH, e.g., FDA, Data Centers, Manufacturer]
- Data Monitoring Committee (DMC) or Data Safety Monitoring Board (DSMB), which is an independent group who will be reviewing the data from this research group throughout the study (if applicable, otherwise remove]
- Persons within Allina Health with responsibilities for the administration or oversight of the research may inspect or review records.

We may be required by law to report some information (for example; certain infectious diseases, suspected abuse) to Minnesota Department of Health for public health or safety reasons.

How will my information and privacy be protected?

Allina Health has rules in place to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study, who might see or use it and what precautions will be taken to protect your privacy and confidentiality.

The people working on the study will collect information about you. [INSERT LANGUAGE DESCRIBING THE PRECAUTIONS BEING TAKEN TO PROTECT PARTICIPANT'S PRIVACY AND CONFIDENTIALITY OF THEIR INFORMATION] e.g., "Your study visits will take place in a private exam room in the _____ offices. When we call you we will verify your identity by _____. Your study file will be stored in a secure area in ___. Information sent to the study sponsor and research laboratories will not include information that can directly identify you such as your name and address, instead your name will be replaced by a code."

[INSERT LANGUAGE IF PHOTOGRAPHS, AUDIOTAPES, OR VIDEOTAPES WILL BE TAKEN OR UTILIZED, DESCRIBING WHAT, WHEN, WHY, AND THE PRECAUTIONS TO BE TAKEN TO PROTECT THE PARTICIPANT'S PRIVACY AND CONFIDENTIALITY]

[INSERT LANGUAGE DISCLOSING IF THE SUBJECTS RESEARCH PARTICIPATION AND PERTINENT INFORMATION WILL BE SHARED WITH THEIR PRIMARY CARE OR OTHER HEALTH CARE PROVIDER, AND INCLUDE WHAT INFORMATION MAY BE SHARED AND WHY. WHENEVER POSSIBLE THIS SHOULD BE PRESENTED AS AN OPTION]

We will not put your research records into your medical record. [REMOVE THIS STATEMENT IF INFORMATION WILL BE RECORDED IN THE MEDICAL RECORD]

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[INCLUDE THE FOLLOWING LANGUAGE VERBATIM IF THE EXCELLIAN RESEARCH FUNCTIONALITY WILL BE USED]:

Your participation in this study will be documented in Allina Health's electronic medical record system. This documentation provides health care providers with basic information about the study and information so that they can contact the study team to learn more, if important for your care. It can also be used by the study team and Allina Health Research Administration to assist with administrative processes such as tracking enrollment and participation in the study.

When we share the result of the study [INSERT DETAILS HERE, E.G. IN MEDICAL JOURNALS OR PRESENTATIONS] we will not include your name. We will do our best to make sure no one else will know you are part of the study.

[INCLUDE CERTIFICATE OF CONFIDENTIALITY, LANGUAGE VERBATIM AS APPLICABLE:]

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, [except as explained below].

Use the following language as applicable, if not applicable, remove:

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

[Language such as the following should be included if researcher intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others.] The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of [list what will be reported, such as child abuse and neglect, or harm to self or others].

Will my information or specimens be used for other purposes?

[INSERT STATEMENTS BELOW THAT ARE APPLICABLE TO THE RESEARCH]

If the research involves biospecimens, describe whether the research will (if known) or might include whole genomic sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

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If the study will produce any clinically relevant research results, describe whether these results will be given to the subjects, and if so, under what conditions. Describe whether and how subjects can opt out of receiving results.

For any research involving the collection of identifiable private information or identifiable biospecimens, a statement must be included regarding future use of the information or specimens.

If you will never use information and specimens from this study for future research, insert the following, or similar, language:

The information and/or biospecimens collected as part of this research will not be used or distributed for future research studies.

If it is possible that information and/or biospecimens from this study will be used for future research, insert the following, or similar, language:

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

If there are plans to store or share data and/or specimens for future research, such as submitting the data to a repository, describe those plans here including whether identifying information will be shared and the purposes for which the data and/or specimens will be used.

Consider whether biospecimens collected for this study may ever be used for commercial profit. Consider all sources of profit for this study and future uses. If biospecimens (whether identifiable or deidentified) may be used for commercial profit, insert the following language:

The specimens we collect as part of this research may be used for commercial profit. [INSERT ONE OF THE FOLLOWING:]

There is no plan to share this profit with you OR there is a plan to share this profit with you.

Will it cost me anything to be in the study?

[INSERT LANGUAGE DESCRIBING THE COSTS THE SUBJECTS MAY INCUR AS A RESULT OF PARTICIPATING IN THE RESEARCH, OTHERWISE IF NO COSTS, SIMPLY STATE "NO"]

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You may be responsible for some costs, such as: [INSERT A LIST OF POSSIBLE COSTS SUCH AS CO-PAYS, LOSS OF INCOME WHEN TAKING TIME OFF FROM WORK, OR TRANSPORTATION COSTS OTHERWISE DELETE THE STATEMENT.]

[INCLUDE THIS BILLING ERROR STATEMENT VERBATIME WHEN THE RESEARCH INVOLVES PROCEDURES WHICH MIGHT ORDINARLY RESULT IN A BILL TO THE SUBJECT OR THE SUBJECT'S INSURER]

If you believe you have received a bill in error during the research study, contact the investigator or study staff at the phone number listed on page [INSERT PAGE NUMBER] of this form.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

Will I receive any payments for participating?

[INSERT LANGUAGE DESCRIBING COMPENSATION IF YOU ARE COMPENSATING SUBJECTS, IF NOT, DELETE THIS SECTION OR STATE NO]

Examples:

Yes, you will receive [describe] for each visit to help cover your travel expenses.

Yes, you will receive [describe compensation and insert detail, e.g., at the end of the survey today] even if you decide [DESCRIBE WHAT HAPPENS IF SUBJECT QUITS, AT WHAT POINT].

[INSERT THE LANGUAGE BELOW VERBATIM IF YOU ARE COMPENSATING SUBJECTS AND THEY MAY RECEIVE MORE THAN $600.00]

If the research includes compensation, include the following (adjust appropriately if the compensation is $600 or greater):

Because you are being compensated for participating in this study, your name, address, and social security number may be released to the Allina Health Accounting Office. If you receive payments that total $600 or more from Allina Health in a year, you will receive a W9 tax form to complete and the payments will be reported to the Internal Revenue Service (IRS) as income.

What happens if you are injured as a result of taking part in the study?

[If the research is sponsored or supported by an external grant, contact OSP for review of this language.]

If you experience an illness or injury while in this study, please contact your study doctor and if needed, seek medical care at Allina Health (if possible). If immediate treatment is needed, call 911 or seek care at the nearest emergency or urgent care center. There is no commitment by Allina Health, [INSERT GROUP PRACTICE NAME], or your physician to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. [INSERT PI'S NAME] at [INSERT PI's PHONE NUMBER] during regular business hours and at [INSERT PI'S 24 HOUR PHONE NUMBER] after hours and on weekends and holidays.

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What if I have questions?

For questions about the study or research-related injury, contact Dr. [INSERT PI'S NAME] at [INSERT PI's PHONE NUMBER] during regular business hours and at [INSERT PI'S 24 HOUR PHONE NUMBER] after hours and on weekends and holidays.

The Allina Health Institutional Review Board (IRB) has reviewed this research study. If you have any concerns about your rights in this study or want to speak to someone outside of the study team, please contact the Allina Health IRB at 612-262-4920 or IRB@allina.com.

Do I have to sign this document?

No. You only sign this document if you want to be in the study.

What should I do if I want to be in the study?

You should make sure your questions and concerns have been answered, and then you sign this document. We will give you a copy of the document to keep.

STATEMENT OF VOLUNTARY CONSENT

I have read this form or have had it read to me. I have been told what to expect if I take part in this study, including possible risks and possible benefits. I have had a chance to ask questions and have had them answered to my satisfaction. I have been told that the people listed in this form will answer any questions that I have in the future. By signing below, I am volunteering to be in this research study.

Participant's Name (Print): _____

Signature: _____ Date: _____ Time: _____

_____

[INSERT ONLY IF APPROVED FOR LAR OR UNDER 18 YEARS OF AGE]

If someone is signing this form for the subject as a "legally authorized representative (LAR) or representative (e.g., parent(s), guardian or conservator), explain why:

_____

_____

_____

Name of legally responsible person (please print)

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Signature: _____ Date: _____ Time: _____

Relationship: _____

_____

If a witness was required:

Witness's Name (Print): _____

Signature: _____Date: _____

Reason for Use of Witness: _____

(Witness signatures are required whenever the participant or representative cannot read or sign the form themselves; (for example, due to a medical condition or language barrier)). The witness signature is used to verify that the participant was provided with and understood the information in the consent form. The witness must be impartial and cannot be a member of the research team. If a witness is necessary, a detailed note describing the process used to obtain informed consent must be kept with the consent in the research file.)

If an interpreter was used:

_____

Name of interpreter (please print)

_____ _____

Signature of interpreter Date

STUDY REPRESENTATIVE STATEMENT

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: _____ Time Consent Obtained: _____

You will receive a copy of this form after it has been signed and dated

HIPAA AUTHORIZATION TEMPLATE

- **This HIPAA authorization must be used for studies under the oversight of the Allina IRB or an external IRB under contract with Allina (e.g., Advarra, Western IRB).**

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- **The HIPAA authorization should be attached to the end of the consent form after the signature lines for consent.**
- **This template includes instructions in red for creating the form. Prior to uploading this form for IRB review, delete or replace all template instructions (including these introductory instructions), and reformat the document so that the entire form is in black. (To do this, press Ctrl + A at the same time. In the menu bar, select black as the font color.)**

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HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Research Study: [insert study title]

Subject Name: _____

Use and Disclosure of Your Health Information
By signing this form, you are authorizing the use and disclosure (release) of your health information in connection with your participation in the above named research study. Your information will be used only in accordance with the provisions of this authorization as outlined in this form or as required by law.

What Information Will Be Used or Disclosed?
The health information that we may use or disclose (release) for this research includes: **[Insert specific description of health information to be used or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, x-rays, MRIs, or certain health information indicating or relating to a particular condition]. [Optional: It also includes all information you may provide us through [insert other information that may be obtained from patient (e.g., surveys), or otherwise.]**

Who Will Receive, Use, and/or Disclose the Information?
The following person(s), class(es) of persons, and/or organization(s) may use, receive, and/or disclose the information connected with this study listed below. These persons are authorized to use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law. **[Add requested information on names/classes of recipients of PHI. Delete all categories that do not apply. Note that when the specific individual may change over the course of the project it is preferable to list their class as opposed to specific names. For example reference the "research coordinator" as opposed to the name of the current individual performing that role.]**

- The following health care facilities or research site(s) and research staff involved in this study: _____ **[list]**
- Health care providers at Allina Health System
- Laboratories and other individuals and organizations that analyze your health information used in this study as outlined in the study protocol
- The following research sponsors: _____ **[list]**
- The United States Food and Drug Administration (FDA)
- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Attach Patient Sticker Here

- A Data Safety Monitoring Board or Committee (A DSMB or DSMC is an independent group who will review study data throughout the study)
- The members and staff of the Institutional Review Board (IRB) that approved this study
- Principal Investigator: _____ **[name]**
- Additional members of the Research Team **[individual names not required]**
- All persons and entities engaged by the Provider, Allina Health System, or the Research Team to assist in managing, analyzing, storing, or transmitting the information.
- Personnel within Allina Health System who are responsible for the administration or oversight of research.
- Others: _____

We cannot prevent re-disclosure of your health information by anyone who receives the information under this authorization, and the information may not be covered by state and federal privacy protections after it is released.

How Will the Information be Used and Disclosed?
Your health information will be:

- Used and disclosed for purposes of the study, including [**describe how information will be used and disclosed for the study (for example, gathering information for the study, monitoring your safety and the overall safety of the study, and for analyzing study data.**]
- **[Insert the following, if applicable: *The researchers conducting this study would like to use your health information for future research purposes. Authorizing use of your health information for these additional purposes is voluntary and does not impact your ability to participate in this study. Please initial here to authorize the use of your health information for these additional purposes: _____ (Patient's Initials)*]**;
- Combined with information about other people who participate in the study;
- Placed in your medical record at Allina Health Systems; and
- Disclosed to persons listed in this authorization for purposes of the study or as otherwise permitted or required by law.

In order to participate in this study, you must agree to share your information with the groups above by signing this Authorization. You do not have to sign this Authorization, but if you do not, you will not be able to participate in this research study. Refusing to sign this authorization will not affect your current or future care at Allina Health System and will not cause any penalty or loss of benefits to which you are otherwise entitled.

When Access to Your Information May Be Limited
[Choose appropriate language]
[*Your right to access your medical record is not affected by your participation in this project.*]
OR
[*You have the right to review and copy your health information related to this study for as long as the Research Team or institution holds this information. However, to ensure the scientific integrity of the study, you will not be able to review or copy some of the study information until after the study has been completed.*]

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The Notice of Privacy Practices, available in the **[hospital, clinic, or office]** where this research is being conducted, provides general information on your rights to review, copy, and correct your health information.

Revocation (cancellation)
If you decide to end your participation in the study or if you are removed from the study by the principal investigator, you may cancel your authorization to use or disclose your health information by notifying **[insert individual to be contacted to terminate authorization]** in writing at **[insert address for contact]**. Your cancellation will be effective after the date it is received. Any health information about you that has already been collected may still be used or disclosed to maintain the integrity or reliability of the research.

Expiration
This authorization for the use and/or disclosure of your health information will not expire unless or until you revoke it.

_____	_____
Printed name of participant or participant's personal representative	If applicable, description of the personal representative's authority to sign for participant
_____	_____
Signature	Date
_____	_____
Printed name of person obtaining authorization	Role in study
_____	_____
Signature of person obtaining authorization	Date

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Consent Riders

The following pages are consent riders, or addendums, to the primary consent form. Riders are used to address special topics and for optional studies or components of studies that require distinct consent and/or authorization for reasons of law or policy.

- *Please select the riders that are appropriate to your research and delete the remainder (and this instructional page) prior to submission to the IRB.*

Currently Available Riders (in order of appearance):

1. *Child Assent*
2. *Continuing Participation*
3. *Genetic Testing*
4. *Sub-Studies and Corollary Studies*
5. *Future Research*

Please contact the HRPP/IRB office if you have suggestions for additional riders or if you need guidance on how to best address a topic not covered in the main consent or these riders.

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(Consent Rider for Pediatric Assent)

CHILD'S ASSENT FORM FOR BEING IN A RESEARCH STUDY

[INSERT AGE RANGE]

Assent forms should at a minimum document the assent process - that the child has been told about the research, and any risks and benefits, that they understand, and that they know that it is okay to say no or change their mind, and that they agreed to take part before any research activities took place. Alternatively, an assent form can be structured to explain important information about the study, similar to a consent form, but in simpler terms and using diagrams or pictures to enhance understanding.

The assent form should be reflective of the child's age, knowledge of disease or illness, and maturity. A 15-year old who has managed type I diabetes for several years may have a very high level of understanding and desire more detailed information than a 7 year old who was recently diagnosed.

Study Title

[INSERT THE FULL TITLE OF THE STUDY.]

Why am I being asked to be in this study?

We are asking you to take part in a research study because we are trying to learn more about [INSERT LANGUAGE REGARDING THE PURPOSE OF THE STUDY]

What happens if I say, "Yes, I want to be in the research study"*?*

If you agree to be in this study [DESCRIBE WHAT WILL TAKE PLACE FROM THE CHILD'S POINT OF VIEW]

What risks are there for being in the study?

[DESCRIBE ANY RISKS TO THE CHILD THAT MAY RESULT IN PARTICIPATION IN THE RESEARCH]

What benefits are there for being in the study?

[DESCRIBE ANY BENEFITS TO THE CHILD, OR THE LACK THERE OF, THAT MAY RESULT IN PARTICIPATION IN THE RESEARCH]

What happens if I do not want to be in the study?

[INSERT LANGUAGE DESCRIBING WHAT WILL HAPPEN IF THE CHILD DOES NOT WANT TO BE IN THE STUDY].

Your doctors will continue to treat you whether or not you participate in this study.

If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop

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[INSERT NAME OF STUDY STAFF] has talked to me about what research is and what will happen if I am in this study and answered my questions. I know that being in this research study might not help me to feel better. I know that I do not have to be in this study, being in this study is up to me and my doctor won't be mad at me if I don't join. I can change my mind later and stop being in the study. My parent or guardian can also take me out of the study at any time. Signing my name on this form means that I agree to be in this study.

Participant's Name (Print): _____

Signature: _____ Date: _____

If a witness was required:

Witness's Name (Print): _____

Signature: _____Date: _____

Reason for Use of Witness: _____

(Witness signatures are required whenever the participant or representative cannot read or sign the form themselves; (for example, due to a medical condition or language barrier)). The witness signature is used to verify that the participant was provided with and understood the information in the consent form. The witness must be impartial and cannot be a member of the research team. If a witness is necessary, a detailed note describing the process used to obtain informed consent must be kept with the consent in the research file.)

If an interpreter was used:

_____

Name of interpreter (please print)

_____ _____

Signature of interpreter Date

STUDY REPRESENTATIVE STATEMENT

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I have explained in terms understandable to this child all of the following: the purpose of the research, the study procedures, the possible risks and discomforts, and the possible benefits. I have answered all of the child's and his/her parent(s') or guardian(s') questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: _____ Time Assent Obtained: _____

You will receive a copy of this form after it has been signed and dated.

Attach Patient Sticker Here

(Consent Rider for Continuing Consent)

CONSENT FOR CONTINUED RESEARCH PARTICIPATION

This form must be included with studies in which subjects may turn 18 during the course of the study. It must also be included with studies in which it is likely that consent will be obtained from a legally authorized representative. For example, when the subject is temporarily incapable of providing consent.

The form should document that the person is aware that they are a subject in a research study, that they understand what the research entails including any risks and benefits that they understand continuing to participate is voluntary and that they won't be penalized now or in the future if they decide to withdraw from the research. The main consent form should be reviewed with the subject, and their questions answered, before they are asked to sign this form.

Suggested Text:

You have been taking part in the research study: [INSERT TITLE OF RESEARCH STUDY]. Consent for your participation was initially obtained from your parent(s) or legal representative because you were either a minor or were unable to provide consent at that time. We are now asking for you to consent to continue being in the study. Your continued participation is entirely voluntary. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care, any legal rights, or any benefits that you are otherwise entitled to.

STATEMENT OF VOLUNTARY CONSENT

I have read this form and the attached consent or have had them read to me. I have been told what to expect if I take part in this study, including risks and possible benefits. I have had a chance to ask questions and have had them answered to my satisfaction. I have been told that the people listed in this form will answer any questions that I have in the future. By signing below, I am volunteering to continue to be in this research study.

Participant's Name (Print): _____

Signature: _____ Date: _____

(If Required) Witness's Name (Print): _____

Attach Patient Sticker Here

Signature: _____ Date: _____

Witness to: ☐ Discussion ☐ Signature

Reason for Use of Witness: _____

(Witness signatures are required whenever the participant or representative cannot read or sign the form themselves; (for example, due to a medical condition or language barrier)). The witness signature is used to verify that the participant was provided with and understood the information in the consent form. The witness must be impartial and cannot be a member of the research team. If a witness is necessary, a detailed note describing the process used to obtain informed consent must be kept with the consent in the research file.)

If an interpreter was used:

_____

Name of interpreter (please print)

_____ _____

Signature of interpreter Date

STUDY REPRESENTATIVE STATEMENT

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: _____ Time Consent Obtained: _____

You will receive a copy of this form after it has been signed and dated

Attach Patient Sticker Here

(Consent Rider for Genetic Testing)

GENETIC TESTING FOR RESEARCH PURPOSES

Why is genetic testing important to the study?

We are asking your permission to conduct genetic testing. (OR) Genetic testing is a required part of this study. The purpose of this testing is to [INSERT LANGUAGE ABOUT THE PURPOSE OF THE GENETIC RESEARCH IN THIS STUDY]

We are asking your permission to conduct genetic testing. The purpose of this testing it to look at your genetic information so your oncologists can prescribe drugs that specifically may match your tumor. An individual's genes carry hereditary information that contribute to characteristics such as hair color, height, and eye color. Researchers are often interested in studying genes to learn about genetic differences and how those differences affect a large variety of traits such as disease, brain processes, and developmental disorders.

What happens if I say, "Yes, I want to have this genetic testing done"? How will my information be protected?

[INSERT LANGUAGE ABOUT THE PROCEDURES FOR THE GENETIC RESEARCH COMPONENT IN THIS PROJECT, INCLUDING IF ADDITIONAL SAMPLES WILL BE REQUIRED AND HOW THEY WILL BE COLLECTED]

The results from the testing will be sent to the study sponsor and to your study doctor. Your study doctor will review the results with you and record the information in your research record and your medical record. If you are found to have the (insert descriptor such as X gene, X mutation, etc.), you will be placed in Study Arm (insert descriptor) and will receive (insert descriptor).

(OR)

Because this type of testing is designed to help us understand more about the drug and is unlikely to provide information that is important to your health, the results will only be provided to the sponsor. Neither you nor your study doctor (or other health care providers) will receive the results.

How will my information be protected?

[INSERT LANGUAGE ABOUT WHERE THE SAMPLES WILL BE SENT, AND HOW CONFIDENTIALITY WILL BE PROTECTED]

[IF THE STUDY IS NOT RECEIVING NIH FUNDS, INSERT THE FOLLOWING LANGUAGE AS APPLICABLE]:

- Genomic information will be coded, and your name and other information that could be used to directly identify you will not be utilized. However, there is always a possibility that then your genomic information is combined with other information available, either now or in the future, they may be able to identify a group you belong to or you personally.
- If you allow us to put your genomic information in the repository, you can change your mind later and ask us to remove it. Keep in mind, however, that we cannot to take back information that other researchers have already obtained from the repository.

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[IF THE STUDY IS RECEIVING NIH FUNDS, INSERT THE FOLLOWING LANGUAGE VERBATIM]:

- This research receives funding from the National Institutes of Health (NIH), we will submit your genomic information to a public repository approved by NIH. NIH is a national research agency and is part of the federal government.
- We will label your genomic information with a code, instead of your name or other information that people could use to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

[ALSO INSERT ONE OF THE FOLLOWING IF NIH FUNDED]:

- Researchers will have *controlled access* to your specific genomic information. Controlled access means that researchers will need approval from NIH in order to obtain genomic information from the repository.

OR

- Researchers will have *unrestricted access* to your specific genomic information. Unrestricted access means that researchers may obtain genomic information from the repository without special approval from NIH.
- If you allow us to put your genomic information in the repository, you can change your mind later and ask us to remove it. Keep in mind, however, that we cannot to take back information that other researchers have already obtained from the repository.

Will the results become part of my medical record or will I be made aware of the results?

[INSERT LANGUAGE ABOUT WHETHER THE RESULTS WILL BECOME PART OF THE MEDICAL RECORD AND IF THE SUBJECT WILL BE INFORMED OF RESULTS AND, IF SO, DESCRIBE HOW, WHEN, AND BY WHOM.]

Will this testing reveal heritable disorders and is there a genetic counselor available?

[INSERT LANGUAGE ABOUT IF A GENETIC COUNSELOR IS AVAILABLE AND, IF NOT, WHAT THE SUBJECT CAN DO FOR ADDITIONAL INFORMATION]

This is not the type of genetic testing that can tell us about whether or not you may have inherited a disease; instead it helps us understand why different people react in different ways to the same treatment. If you have questions please talk to your oncologist or your care team.

(OR)

The genetic testing done for this study could reveal whether or not you (and possibly your family members) have certain genetic traits linked with (insert disease, condition, or trait). Learning the results of genetic tests can be stressful to you and to family members. Counseling to help you understand the meaning of the results and to provide support is available to you, at your request.

What are the risks of genetic testing?

Attach Patient Sticker Here

[INSERT LANGUAGE ABOUT ANY RISKS OF GENETIC TESTING]

Although we will take steps to protect your confidentiality, there is a risk that if your employer or insurer becomes aware that you have had genetic testing, this information could influence their perceptions regarding your health status. If you do not share information about taking part in this study with others, you will reduce these risks.

However, there are some laws that provide protection from genetic discrimination. The Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

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

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

GINA does not apply to the following groups, however these groups have policies in place that provide similar protections against discrimination:

- Members of the US Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)
- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

Will there be any additional costs to participating in this genetic research?

[IF THE SUBJECT MAY INCUR COSTS AS A RESULT OF PARTICIPATING IN THE RESEARCH INSERT LANGUAGE DESCRIBING COSTS, OTHERWISE, SIMPLE STATE "NO"]

You may be responsible for some costs, such as: [INSERT A LIST OF POSSIBLE COSTS SUCH AS CO-PAYS, LOSS OF INCOME WHEN TAKING TIME OFF FROM WORK, OR TRANSPORTATION COSTS OTHERWISE DELETE THE STATEMENT.]

[INCLUDE THIS BILLING ERROR STATEMENT VERBATIME WHEN THE RESEARCH INVOVLES PROCEDURES WHICH MIGHT ORDINARILY RESULT IN A BILL TO THE SUBJECT OR THE SUBJECT'S INSURER]:
If you believe you have received a bill in error during the research study, contact the investigator or study staff at the phone number listed on page [Insert Page Number] of this form.

What happens if I say, "No, I do not want to be in the study" or "I want to stop participating"?

Your participation in this study is voluntary.

Attach Patient Sticker Here

If you say no, or decide that you want to take back your permission no one will treat you differently. You will not be penalized and it will not result in any loss of benefit to which you are entitled.

[REMOVE THIS STATEMENT IF SUBJECTS ARE NOT PATIENTS]The care you get from your doctor or Allina Health will not change.

Your choice will not impact your ability to participate in the main study.

[INSERT LANGUAGE DESCRIBING WHAT WILL HAPPEN TO THE SAMPLE, DATA, AND FUTURE USE OF SPECIMENS COLLECTED IF THEY WITHDRAW]

The information about you that has already been gathered for this study cannot be taken out of the research data set, but no further information will be gathered about you without your permission.

If you would like, you may ask that the specimens that have already been gathered for this study are destroyed. The results from any testing that has already been done cannot be taken back, but no further testing will take place and the remaining specimen(s) will be destroyed.

or

Because we will remove any information that could be used to identify you from the specimen(s) to be used for additional research, we will not be able to locate and destroy your specimen if you were to change your mind about the research.

STATEMENT OF VOLUNTARY CONSENT

I have read this form or have had it read to me. I have been told what to expect if I take part in this study, including possible risks and possible benefits. I have had a chance to ask questions and have had them answered to my satisfaction. I have been told that the people listed in this form will answer any questions that I have in the future. By signing below, I am volunteering to be in this research study.

[INSERT THE APPLICABLE SECTION BELOW]*:*

I understand that genetic research is a required part of this study and authorize the use of my information and specimens for the purposes described in this form.

or

Please indicate whether or not you authorize the use of your information and specimen(s) for the genetic research described in this form by selecting an option below and signing this form.

☐ Yes, I authorize the use of my specimen(s) *(include if applicable: "and associated clinical information")* for the genetic research described in this form.

Attach Patient Sticker Here

☐ No, I don't authorize the use of my specimen(s) *(include if applicable: "and associated clinical information")* for the genetic research described in this form.

Participant's Name (Print): _____

Signature: _____ Date: _____

_____

[INSERT ONLY IF APPROVED FOR LAR OR UNDER 18 YEARS OF AGE]

If someone is signing this form for the subject as a "legally authorized representative (LAR) or representative (e.g., parent(s), guardian or conservator), explain why:

_____

_____

_____
Name of legally responsible person (please print)

_____ _____
Signature Date

Relationship: _____

_____

If a witness was required:

Witness's Name (Print): _____

Signature: _____Date: _____

Reason for Use of Witness: _____

(Witness signatures are required whenever the participant or representative cannot read or sign the form themselves; (for example, due to a medical condition or language barrier)). The witness signature is used to verify that the participant was provided with and understood the information in the consent form. The witness must be impartial and cannot be a member of the research team. If a witness is necessary, a detailed note describing the process used to obtain informed consent must be kept with the consent in the research file.)

Attach Patient Sticker Here

If an interpreter was used:

_____

Name of interpreter (please print)

_____ _____

Signature of interpreter Date

STUDY REPRESENTATIVE STATEMENT

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: _____ Time Consent Obtained: _____

You will receive a copy of this form after it has been signed and dated

Attach Patient Sticker Here

Consent Rider for Sub-Studies and Corollary Studies

Consent for *[insert descriptor]* Research

As with any other research, subject participation in corollary or sub-studies not essential to the primary aims of the research should be on a voluntary basis. This is particularly important when the primary research offers a potential benefit, such as treatment, that might compel the potential subject to agree to something that they otherwise would not.

HIPAA reinforces this ethical principle by explicitly stating that authorization for "unconditioned" activities, for which there is no associated treatment, benefit or other effect on the individual subject associated with participation, cannot be required.

This consent rider should be used whenever sub-studies or corollary studies are proposed in addition to the primary research. As with all consents, sufficient information must be provided for the subject to be able to make an informed choice about participation. As described above, participation in such studies should be optional, unless the proposed analysis has an effect on the individual subject, such as providing information relevant to their safety.

In addition to the main study [insert title], we would like to [insert appropriate descriptor] e.g., "use your specimen(s) and clinical information for additional research" (or) "have you complete 3 questionnaires for additional research"). The purpose of this research is to (describe purpose in lay terms, for example: "to learn more about how different people's bodies process the study drug" (or) "to learn more about how (insert condition) affects the quality of people's lives.").

What happens if I say, "Yes I want to participate in this additional research study?"

[INSERT LANGUAGE ABOUT THE PROCEDURES FOR THE ADDITIONAL RESEARCH COMPONENTS IN THIS PROJECT, INCLUDING IF ADDITIONAL SAMPLES/BLOOD DRAWS/SURVEYS WILL BE REQUIRED AND HOW THEY WILL BE COLLECTED]

[INSERT LANGUAGE ABOUT WHERE THE COLLECTED MATERIALS WILL BE SENT AND STORED, IF APPLICABLE]

You are being asked to let us use the *(insert descriptor such as "information and left over blood samples")* that was already gathered for *(insert applicable text, for example: "this study" or "clinical care")*.

(OR)

You are being asked to *(insert descriptor, such as "have an additional 3 blood samples drawn of about X teaspoons each*" or *"complete 3 additional questionnaires")* for this research. This will take about (*X minutes/hours)* of your time.

Attach Patient Sticker Here

What happens if I say, "No, I do not want to be in the study" or "I want to stop participating"?

Your participation in this study is voluntary.

If you say no, or decide that you want to take back your permission no one will treat you differently. You will not be penalized and it will not result in any loss of benefit to which you are entitled.

[REMOVE THIS STATEMENT IF SUBJECTS ARE NOT PATIENTS]The care you get from your doctor or Allina Health will not change.

Your choice will not impact your ability to participate in the main study.

The information about you that has already been gathered for this study cannot be taken out of the research data set, but no further information will be gathered about you without your permission.

If you would like, you may ask that the specimens that have already been gathered for this study are destroyed. The results from any testing that has already been done cannot be taken back, but no further testing will take place and the remaining specimen(s) will be destroyed.

(OR)

Because we will remove any information that could be used to identify you from the specimen(s) to be used for additional research, we will not be able to locate and destroy your specimen if you were to change your mind about the research.

What are the risks for participating in this additional research study?

[INSERT LANGUAGE ABOUT THE RISKS OF PARTICIPATING IN THE ADDITIONAL RESEARCH STUDY]

Having your blood drawn can be painful and can sometimes cause a bruise. In some people, it can cause fainting. In very rare cases, an infection may occur. Only trained people will draw your blood. Let your doctor know if you have had problems before with blood draws.

(OR)

The questionnaires include some questions that may be sensitive or personal. You are free to skip any question for any reason. *(Insert if applicable: "*It's possible that your answers to the questionnaires could indicate that you may be at risk for a problem such as depression. If this happens we will *(insert description such as "discuss this with you and possibly refer you to X for additional support)")*.

Will this additional research provide any benefit?

[INSERT LANGUAGE ABOUT WHETHER OR NOT THE ADDITIONAL RESEARCH WILL PROVIDE THE INDIVIDUAL SUBJECT WITH ANY BENEFITS]

Will this additional research obtain additional results and will they be shared with me?

Attach Patient Sticker Here

[INSERT LANGUAGE ABOUT WHETHER OR NOT THE ADDITIONAL RESEARCH WILL PROVIDE ADDITIONAL RESULTS AND IF AND HOW THEY WILL BE SHARED WITH THE SUBJECT]

The results of the testing could be important to your health. The results will be sent to the study sponsor and to your study doctor. Your study doctor will review any important results with you and record the information in your research record (insert if applicable: "and your medical record").

It's possible that we could learn something while doing this research that could be important to your health. If this happens, we will contact your study doctor and ask him to share the information with you. Sometimes the tests that are used for research purposes have not been approved yet for clinical purposes or we are unsure of the meaning of the results. If this is the case, your doctor may want you to have some additional testing.

Will there be any additional costs to participating in this additional research?

[INSERT LANGUAGE, IF APPLICABLE, DESCRIBING THE COSTS THAT THE SUBJECTS MAY INCUR AS A RESULT OF PARTICIPATING IN THE RESEARCH, OTHERWISE, SIMPLY STATE "NO"]

You may be responsible for some costs, such as: [INSERT A LIST OF POSSIBLE COSTS SUCH AS CO-PAYS, LOSS OF INCOME WHEN TAKING TIME OFF FROM WORK, OR TRANSPORTATION COSTS OTHERWISE DELETE THE STATEMENT.]

[INCLUDE THIS BILLING ERROR STATEMENT VERBATIME WHEN THE RESEARCH INVOVLES PROCEDURES WHICH MIGH ORDINARILY RESULT IN A BILL TO THE SUBJECT OR THE SUBJECT'S INSURER]:
If you believe you have received a bill in error during the research study, contact the investigator or study staff at the phone number listed on page [INSERT PAGE NUMBER] of this form.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

STATEMENT OF VOLUNTARY CONSENT

I have read this form or have had it read to me. I have been told what to expect if I take part in this study, including possible risks and possible benefits. I have had a chance to ask questions and have had them answered to my satisfaction. I have been told that the people listed in this form will answer any questions that I have in the future. By signing below, I am volunteering to be in this research study.

[INSERT THE APPLICABLE SECTION BELOW]*:*

I understand that *[INSERT DESCRIPTOR]* research is a required part of this study. I agree to participate and authorize the use of my *[INSERT DESCRIPTOR]* for the purposes described in this form.

Or

Attach Patient Sticker Here

Please indicate below whether or not you agree to participate in the additional research activities described in this form and authorize the use of your *[INSERT DESCRIPTOR]* for the research.

☐ Yes, I agree to participate in the additional research activities described in this form and authorize the use of my *(insert descriptor, such as* "information and specimens") for the research.

☐ No, I do not agree to take part in the additional research activities described in this form.

Participant's Name (Print): _____

Signature: _____ Date: _____

_____

[INSERT ONLY IF APPROVED FOR LAR OR UNDER 18 YEARS OF AGE]

If someone is signing this form for the subject as a "legally authorized representative (LAR) or representative (e.g., parent(s), guardian or conservator), explain why:

_____

_____

_____
Name of legally responsible person (please print)

_____ _____
Signature Date

Relationship: _____

_____

If a witness was required:

Witness's Name (Print): _____

Signature: _____ Date: _____

Reason for Use of Witness: _____

Attach Patient Sticker Here

(Witness signatures are required whenever the participant or representative cannot read or sign the form themselves; (for example, due to a medical condition or language barrier)). The witness signature is used to verify that the participant was provided with and understood the information in the consent form. The witness must be impartial and cannot be a member of the research team. If a witness is necessary, a detailed note describing the process used to obtain informed consent must be kept with the consent in the research file.)

If an interpreter was used:

_____

Name of interpreter (please print)

_____ _____

Signature of interpreter Date

STUDY REPRESENTATIVE STATEMENT

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: _____ Time Consent Obtained: _____

You will receive a copy of this form after it has been signed and dated

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(Consent Rider for Future Research Including Banking of Information & Specimens)

Research in the Future

As with any other research, agreement to future contact and use of information and specimens for other research projects should be on a voluntary basis and enough information must be provided for individuals to make an informed choice. This is particularly important when the primary research offers a potential benefit, such as treatment, that might compel the potential subject to agree to something that they otherwise would not.

Why are you asking for [INSERT LANGUAGE ABOUT FUTURE ACTIVITIES] e.g., future contact and/or the storage of data and samples for future research?

[INSERT LANGUAGE DESCRIBING WHY YOU ARE ASKING FOR CONSENT, WHAT YOU WILL BE ASKING PERMISSION FOR, AND INCLUDE WHAT FORSEEABLE OR UNFORSEEABLE WAYS THEIR INFORMATION/SAMPLES MAY BE USED]

Researchers are always trying to learn more about cancer, diabetes, heart disease and other health problems. We are always looking for volunteers for research. Much research is also able to be done using leftover samples, such as blood, and information that has been gathered for another purpose. Through these studies, researchers hope to find new ways to detect, treat, and maybe prevent or cure health problems. Sometimes these studies may be about how genes affect health and disease, or how genes affect response to treatment. Some may lead to new products, such as drugs or tests for diseases.

We are asking you to let us contact you in the future to tell you about other research studies and ask if you might like to participate. We are also asking you for your permission to store any samples left over when this research is complete, and for your permission to gather and store information about you, for use in research projects in the future.

What happens if I say, "No, I do not want to be in the study"?

Your participation in this study is voluntary.

If you say no, or decide that you want to take back your permission no one will treat you differently. You will not be penalized and it will not result in any loss of benefit to which you are entitled.

[REMOVE THIS STATEMENT IF SUBJECTS ARE NOT PATIENTS]The care you get from your doctor or Allina Health will not change.

Your choice will not impact your ability to participate in the main study.

[INSERT LANGUAGE EXPLAINING HOW TO WITHDRAW PERMISSION AND ANY LIMITATIONS, INCLUDING DATA AND SAMPLE RETENTION/DESTRUCTION]

If you change your mind, contact [INSERT NAME OF PI OR STUDY TEAM] to let us know. You can call us at [INSERT PHONE NUMBER] or if you wish, you may write to us at [INSERT ADDRESS]. We may need to call you back to clarify if you want to withdraw some or all permissions, so please leave us your phone

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number.

Sometimes information and samples are provided to a researcher without a code or any other way to link them back to you, if this happens we will not be able to locate your information or samples to stop it from being used.

When researchers use your information or samples for research in the future, it is possible that information from the research could end up stored in another scientific database.

What are the risks for participating in this future research?

[INSERT LANGUAGE ABOUT THE RISKS OF PARTICIPATING IN FUTURE RESEARCH STUDIES]

Having your blood drawn can be painful and can sometimes cause a bruise. In some people, it can cause fainting. In very rare cases, an infection may occur. Only trained people will draw your blood. Let your doctor know if you have had problems before with blood draws.

The questionnaires include some questions that may be sensitive or personal. You are free to skip any question for any reason. *(Insert if applicable: "*It's possible that your answers to the questionnaires could indicate that you may be at risk for a problem such as depression. If this happens we will *(insert description such as "discuss this with you and possibly refer you to X for additional* support.).

There is a risk that someone could get access to the information we have stored about you. There are laws about unauthorized access to and use of personal information, but they may not give you full protection. If your sample is used for genetic research, because your genetic information is unique to you, it is possible that someone could trace the information back to you. We believe the chance that someone will access your information without permission or trace information back to you is small, but we cannot promise that it won't happen.

Your privacy is very important to us and we will make every effort to protect it. Here are just a few of the steps we will take:

- Your sample and information will be labeled with a code instead of your name or other information that directly identifies you. We will keep the list that links the code number to your name separate from your sample and information. This list will be kept in a secure location at Allina Health and will only be shared with those who have a valid reason to see it, such as people who oversee research to make sure that it is done safely.

- Unless you give us permission, researchers who study your samples and information will not be told who you are. Any information or samples provided to researchers will be labeled with the code.

- We will not give information that identifies you to anyone without your permission, except if it is required by law. Information that is shared outside of Allina Health may no longer be protected by the federal privacy law called 'HIPAA'. But it will be protected as described in this form and may be covered by other privacy laws.

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Will this additional research provide any benefit?

[INSERT LANGUAGE ABOUT WHETHER OR NOT THE ADDITIONAL RESEARCH WILL PROVIDE THE INDIVIDUAL SUBJECT WITH ANY BENEFITS]

You will not benefit directly from allowing the use of your information and samples for additional research. Researchers hope the research they do will help other people in the future.

Will this additional research obtain additional results and will they be shared with me?

[INSERT LANGUAGE ABOUT WHETHER OR NOT THE ADDITIONAL RESEARCH WILL PROVIDE ADDITIONAL RESULTS AND IF AND HOW THEY WILL BE SHARED WITH THE SUBJECT]

The results from such research will not be added to your medical records, nor will you or your study doctor know the results.

Occasionally, researchers will find something out that could be important to your health. If this happens, we will try to get in touch with you to let you know and to help you understand what it means.

Will there be any additional costs to participating in this additional research?

[INSERT LANGUAGE, IF APPLICABLE, DESCRIBING THE COSTS THAT THE SUBJECTS MAY INCUR AS A RESULT OF PARTICIPATING IN THE RESEARCH, OTHERWISE, SIMPLY STATE "NO"]

There will be no costs to you or your insurer for any of the tests done for the research projects. You will not be paid for agreeing to the storage and use of your information and samples. There are no plans to pay you for any information or products that result from research using your information and samples.

[INCLUDE THIS BILLING ERROR STATEMENT VERBATIME WHEN THE RESEARCH INVOLVES PROCEDURES WHICH MIGH ORDINARILY RESULT IN A BILL TO THE SUBJECT OR THE SUBJECT'S INSURER]:
If you believe you have received a bill in error during the research study, contact the investigator or study staff at the phone number listed on page [INSERT PAGE NUMBER] of this form.

STATEMENT OF CONSENT:

I understand that I am being asked permission to be contacted in the future for research and to allow the use of my information and leftover samples for research in the future. I understand that agreeing to these activities is completely voluntary and that I can say no or withdraw my permission at any time without any negative impact on me. I've indicated my choices below.

I give my permission for researchers within Allina Health to contact me about future research projects. I understand that my contact information and basic information about me will be shared so that this can happen.

YES _____ (initials) NO _____ (initials)

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I give my permission for researchers outside of Allina Health to contact me about future research projects. I understand that my contact information and basic information about me will be shared so that this can happen.

YES _____ (initials) NO _____ (initials)

I give my permission for the information gathered about me for this research to be stored and used for future research projects. Information that is provided to researchers will not have my name or other information that directly identifies me on it.

YES _____ (initials) NO _____ (initials)

I give my permission for researchers or staff to gather additional information from my medical record for future research projects. I understand that this means that the researchers or staff will have to have access to information that directly identifies me.

YES _____ (initials) NO _____ (initials)

I give my permission for any of my samples that are left over from the main research study to be stored and used for future research. I understand that my samples will be either stripped of all information that could be used to identify me or that my name will be replaced by a code.

YES _____ (initials) NO _____ (initials)

My permission for the use of my samples includes genetic research.

YES _____ (initials) NO _____ (initials)

Participant's Name (Print): _____

Signature: _____ Date: _____

_____

[INSERT ONLY IF APPROVED FOR LAR OR UNDER 18 YEARS OF AGE]

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If someone is signing this form for the subject as a "legally authorized representative (LAR) or representative (e.g., parent(s), guardian or conservator), explain why:

_____

_____

_____
Name of legally responsible person (please print)

_____ _____
Signature Date

Relationship: _____

_____

If a witness was required:

Witness's Name (Print): _____

Signature: _____Date: _____

Reason for Use of Witness: _____

(Witness signatures are required whenever the participant or representative cannot read or sign the form themselves; (for example, due to a medical condition or language barrier)). The witness signature is used to verify that the participant was provided with and understood the information in the consent form. The witness must be impartial and cannot be a member of the research team. If a witness is necessary, a detailed note describing the process used to obtain informed consent must be kept with the consent in the research file.)

If an interpreter was used:

_____
Name of interpreter (please print)

_____ _____
Signature of interpreter Date

STUDY REPRESENTATIVE STATEMENT

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered all questions to the best of my ability.

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Study Representative's Name (Print): _____

Signature: _____

Date: _____ Time Consent Obtained: _____

You will receive a copy of this form after it has been signed and dated

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Below please find the Federal Elements of Consent as a reference. Please delete it from the final version of the consent document.

Federal Elements of Consent

(for researcher reference)

HHS:

Required Elements:
A statement that the study involves research
An explanation of the purposes of the research
The expected duration of the subject's participation
A description of the procedures to be followed
Identification of any procedures which are experimental
A description of any reasonably foreseeable risks or discomforts to the subject
A description of any benefits to the subject or to others which may reasonably be expected from the research
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
An explanation of (1) whom to contact for answers to pertinent questions about the research and (2) research subjects' rights, and (3) whom to contact in the event of a research-related injury to the subject
A statement that (1) participation is voluntary, (2) refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and (3) the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
One of the following statements about any research that involves the collection of identifiable private information or biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research

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studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies
Elements that are required when applicable:
A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
Any additional costs to the subject that may result from participation in the research
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
The approximate number of subjects involved in the study
A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)
A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions

FDA regulated studies:

In addition to the above, the consent form must contain a statement that notes that the FDA may inspect the records.
This statement must be included verbatim for applicable clinical trials as defined in FDAAA 801: *"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*

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