

## **Informed Consent to Participate in Research and Authorization to Collect, Use, and Share your Health Information**

**Sponsor / Study Title:**

**Protocol Number:**

**Principal Investigator:  
(Study Doctor)**

**Telephone:**

**Address:**

**Instructions:** To use this template, complete all required sections (substituting appropriate language for any *italicized blue* text) and any applicable optional sections, then delete all instructions, brackets and omitted optional sections.

**KEY INFORMATION** *[Please note: This Key Information section is required under the revised Common Rule and is intended to provide subjects with the pertinent information they need to decide whether to participate in the research.]*

You are invited to take part in a research study. The purpose of the study is to *[insert brief summary of the study purpose in lay language and the expected duration of participation]*.

*[In lay language, describe key information about the study. Consider the following questions when writing your key information:*

- What are the main reasons a subject will want to join this study?*
- What are the main reasons a subject will not want to join this study?*
- What is the research question the study is trying to answer? Why is it relevant to the subject?*
- What aspects of research participation in this particular study are likely to be unfamiliar to a prospective subject, diverge from a subject's expectations, or require special attention?*
- What information about the subject is being collected as part of this research?*
- What are the types of activities that subjects will do in the research?*
- What impact will participating in this research have on the subject outside of the research? For example, will it reduce options for standard treatments?*
- How will the subjects' experience in this study differ from treatment outside of the study?*
- In what ways is this research novel?*

***Additional notes on key information:***

- *The presentation must be concise and focused.*
- *The standard is to provide the information that a reasonable person would want to have in order to make an informed decision about whether to participate.*
- *The information should be provided in sufficient detail and organized and presented in such a way that helps subjects think about why they might or might not want to participate.*
- *Rather than a list of isolated facts, the goal is the help people process the information they're given and make it easier for them to make an informed decision.*
- *Note that if information included in the key information section also satisfies the basic elements or additional elements of informed consent (under 45 CFR 46.116[b] and [c]), this information doesn't need to be repeated later in the body of the informed consent.]*

***[If Legally Authorized Representatives may be asked to provide informed consent, include the paragraph below:]***

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. When the subject cannot legally consent to take part, pronouns “you” and “your” should be read as referring to the subject rather than the person (legally authorized representative) who is signing this form for the subject. In cases where the subject’s representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent will be obtained from the subject and the subject offered the ability to leave the study if desired.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form.

**DETAILED STUDY INFORMATION**  
**BACKGROUND AND PURPOSE**

You are being asked to participate in this research study because you have ***[disease/condition]. [In lay language, describe relevant background information and rationale for conducting this study.]***

About ***[xxx]*** subjects will participate in this study at North Memorial Health. ***[If the study includes multiple sites, add the following statement: A total of [number of subjects] individuals will participate in this study at all sites.]***

**WHAT WILL HAPPEN DURING THE STUDY?**

Your participation in this study will last approximately ***[xxx (weeks/months/years)]*** and will include approximately ***[xx number]*** study visits to North Memorial Health.

*Explain in lay terms what will happen during the study. Make sure your explanation addresses what is being performed as standard of care and what is being performed strictly as part of the research. Explain what may happen at each study visit and at what intervals study visits will occur. Explain the study visit timetable – you may include a table or timeline if helpful. Explain what the subject will need to do before the first study visit, if anything. For example: You will need to fast (go without food) for 8 hours before your visit.*

At each visit, you will be asked to:

- *Describe the tests and procedures that will be performed, including the purpose of each. If there are multiple visits with different procedures occurring at each visit, it is suggested to list each in a separate paragraph and/or as bulleted items.*
- *If blood will be drawn, indicate the amount (in English units) and frequency.*
- *Explain the questions that will be asked and/or interviews/surveys that may be conducted.*
- *Explain the drug, device, or biologic and how it will be administered.*
- *List experimental procedures and therapies and identify them as such.*
- *Explain whether subjects' regular treatment will change if they take part in the research and if so, how it will change.*
- *If the final visit is different from the others, explain what will happen at that visit.*
- *If audio- or videotaping will be used, the subject must be informed of taping and, if applicable, given the option to agree to be recorded. Explain who will have access to these tapes, whether the information will be identifiable, how long the tapes will be maintained, and how they will be destroyed.*

## **RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS**

The following risks may occur:

- *[List each risk in bulleted form and include lay explanations for each one. When possible, categorize by likelihood of occurrence (for example, ranges of frequencies or other quantifiable risk information). Note where risks may be life-threatening and may be irreversible.]*
- *When applicable, list and explain risks related to breaches of confidentiality, including risks to employability, insurability and/or criminal or civil liability.*

## **RISKS OF STUDY PROCEDURES**

- Blood samples: Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
- Electrocardiogram (ECG): Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used.
- Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.
- *[Insert bulleted list of side effects for additional procedures specified above.]*

## **ALTERNATIVES TO PARTICIPATION**

*[Use whichever statement is applicable:]*



You do not have to participate in this research study. *[This statement is sufficient if there are no alternatives for the subject.]*

*[Or]*

Alternatives to participating in the study include: *[If there are alternatives, describe the procedures/treatments/interventions that the subject could receive such as taking a different course of treatment, etc.]*

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

You can decide after signing this informed consent document that you no longer want to take part in this study for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can so that we can tell you how to stop safely. There may be reasons we will need to withdraw you from the study even if you want to continue. You may be taken out of this study if we find out it is not safe for you to stay in the study or if you are not coming for the study visits when scheduled. We will let you know the reason for withdrawing you from this study.

## **NEW FINDINGS**

Any new important information that is discovered during the study that may influence your willingness to continue participation in the study will be provided to you.

## **BENEFITS**

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

*[OR replace the previous sentences with the following for a non-treatment study:]* This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

## **COMPENSATION FOR PARTICIPATION**

*[If compensation for participation is available, include the dollar amount per visit and payment upon study completion of study activities. Explain any other costs you may be able to remunerate, such as parking fees, bus or taxi fare; childcare costs, or time away from work.]*

You will be paid up to a total of \$xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- \$xx.xx for Visits xxx.
- \$xx.xx for Visits xxx.
- \$xx.xx for Visits xxx.



If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid \_\_\_\_\_ *["following each completed visit", "monthly", "quarterly", "at the end of your participation in the research study", "following each completed visit or at the end of your participation in the research study, whichever you prefer"]*.

*[Investigators must include the following paragraph for studies where compensation is more than \$600 per calendar year:]* To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not tell them what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

If you have any questions regarding your compensation for participation, please contact the study staff.

*[OR]*

You will not receive any monetary compensation for your participation in this study.

## **CONFIDENTIALITY**

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Principal Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

*[If this is a clinical trial add:]*

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.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- a limited number of representatives from the study sponsoring drug company (namely its monitors and auditors),
- the research ethics review board – Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants),



- government regulatory authorities including the US Food and Drug Administration (FDA) and other regulatory agencies.

Your study records, including confidential information about you collected during the study, will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

### **AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.
- ***[Please list any other PHI that may be used or disclosed, if applicable]***

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users.

Authorized users may include:

- Representatives of ***[sponsor name, if applicable]***.
- Representatives of ***[CRO name, if applicable]***.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other U.S. federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.
- ***[Please list any other authorized users, if applicable.]***

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the ***[study drug/device]*** works and is safe.
- To compare the ***[study drug/device]*** to other ***[drugs/devices]***.
- For other research activities related to the ***[study drug/device]***.





- *[Please list any other uses, if applicable.]*

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will not expire unless you revoke (withdraw) it in writing.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

#### **COMPENSATION FOR INJURY**

*[This Compensation for Injury section must be included for all studies that are greater than minimal risk; if your study is minimal risk, you may delete this entire section.]*

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

*[If a study is industry-sponsored, please include the following language.]* The sponsor of this research has agreed to pay North Memorial Health for the cost of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness or injury as a direct result of participation in the study in accordance with the protocol. Any costs not reimbursed by the sponsor or your health insurer will be billed to you.

*[If the study is investigator initiated or not sponsored, please include the following language.]* The cost of illness or injury that may result from your participation in research will be billed to your insurance company or to you in the event you do not have health insurance.

*[Include for all studies regardless of funding/sponsor]* Before you agree to take part in this study, you may want to find out whether your insurance will cover injuries that result from taking part in research. You may be responsible for any deductible, co-insurance, or co-payments that result from such care. If you are injured, North Memorial Health has also not set aside money for lost wages, discomfort, or disability you may experience as a result of a research-related injury. By signing this form, I acknowledge North Memorial Health will not pay for the costs of medical care and treatment, or any associated costs such as lost wages, due to injury arising from participation in this study. You do not give up your legal rights by signing this form. In addition to contacting the study investigator, you should also contact the **North Memorial Health Office of XXXX** if you believe you have been injured as a result of taking part in this study.

## COSTS

*[Use only the following statements that apply to your research]*

It *[will / will not]* cost you *[amount / anything]* to take part in the study.

*[If the costs of the research are being paid by the study sponsor, the following statement is required:]*

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

*[If there are costs associated with the study:]*

You or your insurance company will be expected to pay the costs for the following: *[list all procedures which will be the responsibility of the subject outside of routine care.]*

## FUTURE RESEARCH STUDIES

*[For research that involves the collection of identifiable private information or identifiable biospecimens, include one of the following statements as applicable to this study:]*

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and **could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent.

*[OR]*

Your private information or biospecimens collected during this study **will not be used or distributed for future research studies**, even if identifiers are removed.

*[Include for studies involving biospecimens:]* **COMMERCIAL PROFIT**

Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and **you will not share in this profit**.

*[OR]*

Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and **you will share in this profit**.

*[Include for studies with clinically relevant research results:]* **CLINICALLY RELEVANT RESULTS**

Research results that are clinically relevant, including individual research results, **will be disclosed to you** under these conditions: *[describe conditions]*

*[OR]*





Research results that are clinically relevant, including individual research results, **will not be disclosed to you.**

#### **WHOM TO CONTACT ABOUT THIS STUDY**

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Principal Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

**Please contact the Principal Investigator at the telephone number listed on the first page of this consent document.**

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:  
Study Subject Adviser  
Advarra IRB  
6100 Merriweather Dr., Suite 600  
Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: [adviser@advarra.com](mailto:adviser@advarra.com)

Please reference the following number when contacting the Study Subject Adviser:  
**Pro000XXXXX.**

#### **VOLUNTARY PARTICIPATION / WITHDRAWAL**

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

***[Add any consequences for withdrawing and procedures for orderly termination/withdrawal.]***

The Principal Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:



- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the Principal Investigator may ask you to have some end-of-study tests for your safety.

**PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION**

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

**YES** (If yes, please complete the information below)

**NO**

Name and address of family doctor or primary health care provider:	Name:
	Address:
Telephone and Fax Number:	Tel:
	Fax:



**CONSENT TO TAKE PART IN RESEARCH and AUTHORIZATION FOR THE COLLECTION, USE AND DISCLOSURE OF HEALTH INFORMATION**

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study and authorize that my health information as agreed above, be collected/disclosed in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

\_\_\_\_\_  
Subject's Printed Name

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of the Person Conducting the  
Consent Discussion

\_\_\_\_\_  
Signature of the Person Conducting the  
Consent Discussion

\_\_\_\_\_  
Date

*[If applicable, add:]*

\_\_\_\_\_  
Printed Name of Legally Authorized Representative

\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Authority of Legally Authorized Representative to act on behalf of Subject

**WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ**

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject



by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

\_\_\_\_\_  
Printed Name of Impartial Witness

\_\_\_\_\_  
Signature of Impartial Witness

\_\_\_\_\_  
Date

**FOR CHILDREN WHO BECOME ADULTS**

I have been told that my parents/legal guardian agreed for me to participate in this research study as a minor. I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to continue to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

\_\_\_\_\_  
Subject's Printed Name

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date