**Instructions:**

* **If the study is funded by one of the federal agencies that agrees to follow the Common Rule, the prospective subject or the legally authorized representative must be provided with the information that a Reasonable Person would want to have in order to make an informed decision about whether to participate, and have an opportunity to discuss that information**
* **Update the version date in the header each time you make a change.**
* **Blue highlighting: This is for your reference only. Delete before submitting to the IRB.**
* **Yellow highlighting: Insert the requested information, or choose the appropriate response and delete the other options.**
* **Delete all << >> marks in the document as you go.>>**

Subject name: Subject date of birth:

# Aurora Health Care, Inc.<<or other institution name>>

# Consent to Participate in a Research Study

|  |  |
| --- | --- |
| **Study Title** | <<title (must match protocol)>> include sponsor protocol ID number |
| **Study Investigator** | <<principal investigator name>><<phone number (daytime)>> <<phone number (24-hour contact number)>> |
| **Sponsor<<delete if n/a>>** | <<insert name>> |

Summary << *ONLY REQUIRED FOR STUDIES THAT ARE FUNDED BY A FEDERAL AGENCY THAT AGREES TO FOLLOW THE COMMON RULE – YOU MAY DELETE IF NOT APPLICABLE*>>

***<<*** *The 2018 version of the Common Rule requires that consent forms contain a concise and focused presentation of key 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. This part of the informed consent must be organized and presented in a way that facilitates comprehension and presented in a manner that a reasonable person would be able to understand.*

*This section should be entitled “Summary”,* ***MUST BE PLACED AT THE BEGINNING OF THE CONSENT/AUTHORIZATION DOCUMENT****, and address all points below. Try to limit the summary to 2-3 pages in length (length will be dependent on the complexity of the study – a less complex study may allow for a shorter summary, but it MUST address all of the necessary points), and be written in language understandable to a* ***Reasonable Person****.*

*The* ***Summary*** *must contain the following points:*

***(1) the fact that consent is being sought for research and that participation is voluntary;***

**(*2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;***

***(3) the reasonably foreseeable risks or discomforts to the prospective subject;***

***(4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and***

***(5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.***

*In most cases, the information presented in this section should also be discussed later in the consent form in greater detail. The exception to this condition is if the study is no greater than minimal risk, and the general length of the consent document is short in length (this is subjective and will require your interpretation – although your decision may be overridden by the IRB). Only in those cases may the later sections of this template be eliminated from the document and the summary serve in place of the required information discussed later in this template.*

*Remember, all of the required elements of informed consent (see* [*OHRP guidance on informed consent*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html) *or the federal regulations at* [*45 CFR 46.116*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116)*) must be included in this document unless you request a waiver of consent/documentation for those elements. Those additional elements of informed consent (see* [*OHRP guidance*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html)*) that are applicable to your research study should also be included in this document.>>*

Why am I being asked to participate?

You are being asked whether you would like to voluntarily participate in a research study about <<insert one- to two-word description>> because you <<insert a brief description why subject was selected in simple language>>.

This form describes the study and what you would need to do. We will answer any questions you may have so that you can make an informed decision.

What is a research study?

A research study is an experiment, survey, or information collection whose purpose is to answer a specific question, such as:

* Does this work?
* Is it safe?
* What kind of treatment is better?
* How do people think or feel about this?

To answer these questions, doctors and scientists need volunteers to participate in research studies. These volunteers are called “subjects.” The doctors and scientists who run the research study are called “investigators.” Other people who help them run the study are called the “research team.”

<<Delete this paragraph if not an investigational drug/device study.>>Sometimes a drug or device being tested makes research subjects better, and sometimes it doesn’t. When you are a subject, the main purpose is to see if the study drug or device works and if it is safe <<or customize for the particular study>>. There may be side effects or risks to you, including some we don’t know about right now.

<<Delete this paragraph if n/a.>>A research study has specific rules the investigator must follow. The study rules may say that subjects can’t receive certain medications or treatments while they are in the study. We will explain the rules you will have to follow. If you can’t or don’t want to follow these rules, then you should not participate.

What is the purpose of this study?

In this study, we want to find out <<insert research goal in simple language. Include, if applicable, that study drug/device is not approved by FDA for use outside of research studies.>>.

<<Delete this section if there is no sponsor.>>Who is sponsoring this study?

The sponsor for this study is <<insert sponsor name>>. The sponsor <<makes the investigational drug/device, or other brief description>> and also pays for<<PI name>> and Aurora Health Care to run the study.

Where will this study take place?

This study will take place at <<insert name of local facility>>. <<PI name>> expects to enroll about <<insert number>> subjects. <<Delete next sentence if not multi-site>>Investigators at approximately <<insert number>> sites <<in Wisconsin>> <<nationally>> <<worldwide>> will enroll a total of about <<insert number>> subjects.

What is involved?

As a subject, you will be responsible for:

* attending all study visits
* telling the investigator if you are feeling bad or worse than before
* telling the investigator if you have any changes in medications during the study
* following the directions of the investigator and research team
* <<insert any other study-specific responsibilities>>

If you agree to take part in this study, you will sign this consent form before any study-related procedures are performed. The investigator and research team will <<ask you questions>> << and perform tests>> to see if you qualify to be in the study.

<<delete if n/a>>If you meet all criteria to be in this study, you will be randomized to one of <<insert number>> groups. Randomized means being assigned to a group by chance, like flipping a coin or drawing names out of a hat. You have a <<insert probability – 1 in 2, 33%, etc.>> chance of being assigned to each group. <<List randomization groups. Example: Group 1: 50 ml study drug, Group 2: 100 ml study drug, Group 3: placebo>> You cannot choose which group you will be in. <<delete next sentence if n/a >>We will not tell you which group you are in. <<Include, if applicable>> The investigator and research team will not know your group, either. However, we can quickly find out which group you are in if we ever need to know for your safety.

<<delete if n/a>>You may receive a placebo instead of the study drug. A placebo looks like the study drug, but does not have active ingredients. Comparing a study drug to a placebo helps investigators tell how well the drug works.

The following <<tests>> <<procedures>> are part of regular medical care. This means you will have these whether you choose to be in this study or not.

* <<insert general descriptions of standard of care procedures. Avoid complex terms as much as possible. Define them if they must be included.

The following <<tests>> <<procedures>> are for research purposes only. This means you will only have these if you agree to be in the study:

* <<insert general descriptions of procedures being done for research purposes only. If there are any experimental procedures, state clearly that they are experimental. Avoid complex terms as much as possible. Define them if they must be included.

***Examples*** *of general descriptions in simple language:*

***ECG:*** *An ECG is a painless test to measure the electrical activity in your heart. You will have several electrodes placed on your chest, which are connected by wires to a machine. The machine records your heart's electrical signals on a computer screen or on paper.*

***FACT-O:*** *This is a questionnaire that asks how your condition affects daily life. It includes questions about your sex life. You can skip any question that makes you uncomfortable.* >>

<<***ADD AS APPLICABLE IF THE RESEARCH COLLECTS/GENERATES CLINICALLY RELEVANT RESULTS*>>**

Clinically relevant research results [state what these are], including individual research results, will/will not be returned to you. Include conditions under which they will be returned. Upon your request for personal research results, your research team can work with you to understand the type of data available to you.>>

**<<*ADD THE APPROPRIATE STATEMENT BELOW.*>>**

Identifiers may be removed from the <<*list all that apply:* identifiable private information, identifiable biospecimens*>*> collected in this study. After removal of the identifiers, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. <<*Direct the reader on where to find more information on the future research. For example,* “You may find more information on possible future research in a separate research consent.>>**OR**

Your <<*list all that apply:* identifiable private information, identifiable biospecimens*>*> collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.>>

**<<*ADD THE FOLLOWING SECTION IF THE RESEARCH INVOLVES BIOSPECIMENS and GENETIC TESTING >> >>***

Genetic testing can be done on blood and other specimens. In this study, we will do genetic testing on your <<*list all that apply:* blood, other specimens [name]>>. <<*Include the following statement if applicable:* Whole genome sequencing (that is, the process of determining your complete DNA sequence) will be done in this study.>> Your samples will be collected <<*identify method and timeframe*>>.

Genetic testing is being done for research purposes only. The purpose of the testing is not to discover information that could be used to change your medical care, make or change your diagnosis, or advise you or your physician on your risk of disease. Genetic testing will be done because <<*include reason for genetic testing>>*.

What will happen at each study visit?

<<Briefly describe study procedures in a list or table format. Example:>>

|  |  |  |  |
| --- | --- | --- | --- |
| **Visit** | **During this visit, you will** | **How long is this visit?** | **Reminders** |
| Visit 1 (Screening) | * Review and sign this consent form first
* Have a physical exam
* Have an ECG
* Have 3 tubes of blood drawn
 | 2 hours | Do not eat or drink anything except water for 12 hours before this visit. |
| Visit 2 (Randomization) | * Have a physical exam
* Be randomized to study drug or placebo
* Receive study drug and a study diary to take home
 | 1 hour |  |
| Visit 3 (Week 1) | * Have a physical exam
* Have 1 small tube of blood drawn
 | 30 minutes | Bring your study diary and study drug blister packs |
|  |  |  |  |

Are there any risks to me?

There may be risks, side effects and discomforts if you choose to participate in this study. These can be physical, emotional, financial or social. The ones we know about are listed below.

<<Delete this paragraph if not a drug/device study>>There may be side effects from the study <<drug>> <<device>>. Many side effects go away, but sometimes they can be serious, long-lasting, or may never go away. There may be other side effects that we don’t know about yet, so be sure to tell the investigator about any unusual symptoms.

**Risks of <<insert drug or device name>>**

<<List risks. State how common each risk is. Example: “Common (at least 1 in 10 people):” or “Common (greater than 20% chance)”. If multiple drugs/devices, list risks of each separately.

Write risks in simple language. Instead of “hyperglycemia,” say “high blood sugar.” There is a glossary of medical terminology translated into lay language here: <http://humansubjects.stanford.edu/new/docs/glossary_definitions/lay_language.pdf> and also here: <http://med.umich.edu/irbmed/guidance/simplificationterms.html>

State clearly which risks are long-lasting or permanent, if any.>>

<<Example:>>

|  |  |  |
| --- | --- | --- |
| **Common (more than 10 in 100 people)** | **Less common (between 1-10 in 100 people)** | **Rare but serious (less than 1 in 100 people)** |
| * Drowsiness
* Nausea
* Dizziness
 | * Vomiting
* Fainting
 | * Difficulty breathing
 |

<<With relation to an embryo, fetus, or nursing infant, include, if applicable:

* known risks and inconveniences
* a statement that there may be additional unknown risks
* if birth control methods are required, and which are acceptable and during what time period they must be used
* statement that if subject becomes pregnant during the study (or within \_\_\_\_ days of taking study drug), she must tell the investigator immediately
* for male subjects: possible effects of study drug on sperm and birth control requirements >>

<<Insert any known emotional, financial, or social risks. Example: in a study that gathers information about illegal drug use, the information could lead to job loss or problems with friends and family if it is not kept confidential.>>

<<Delete if no questionnaires>>**Questionnaire risks:** You will complete questionnaires in this study. Sometimes the questions can make people uncomfortable or bring back bad memories. <<Add potential confidentiality risks>>

Are there any benefits to me?

You may or may not benefit from being in this study. Your disease or condition could improve in the following ways: <<insert potential benefit; for example, your heart failure symptoms may improve.>>

It is also possible that your condition could stay the same or even get worse. We hope the information learned will help other patients with <<insert condition>> in the future.

<<OR>>

You will not benefit from being in this research study. However, we hope the information we learn will help others in the future.

How much will it cost to participate?

In this study, the sponsor will pay for:

* <<insert list of covered costs. If sponsor is paying for everything, then simply state that.>>

<<Delete if sponsor covers all costs>>You will have to pay for:

* <<insert list>>
* Any insurance copays and deductibles .

<<Delete this paragraph if sponsor covers all costs>>If you have insurance, your insurance may cover some or all of these costs. You will pay any copays and deductibles, as described in your insurance plan. **You will need to contact your insurance company to find out what will be covered.** Ask the research team if you need help.

Will I be paid to participate?

You will be <<paid>> <<reimbursed>> $<<insert amount>> for each study visit, for a total of $<<insert amount>> if you complete all visits. If you do not complete the study, you will only be paid for the visits you completed. <<State whether payment will be after each visit or at the end of the study. Include a schedule of payments, if there is one.>> We may have to report this payment to the IRS.

<<OR>>

You will not be paid to participate in this study.

<<***INCLUDE THIS LANGUAGE IF 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>>***

Your biospecimens (even if identifiers are removed) may be used for commercial profit and you <<will>> <<will not>> share in this commercial profit.

How long will I be in the study?

You will be in the study for <<insert duration>>.

The study may be stopped early by <<customize as needed>> the sponsor, the FDA or the investigator. You could be asked to stop being in the study for any of the following reasons:

* for your safety
* if you do not follow our directions for this study
* <<delete if n/a>> if you become pregnant
* <<insert any other study-specific reasons>>

<<delete if n/a>>If you stop being in the study early for any reason, we will ask you to do the following:

* <<insert any requests for additional safety visit[s] or procedures>>.

Do I have to be in this study?

You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care.

You may decide to participate now, but change your mind and withdraw from the study anytime without penalty or loss of benefits. If you decide to withdraw before the last study visit, let the investigator know. There may be special procedures to follow for your safety.

<<If there are alternate treatments>>If you don’t want to be in this study, your other options include:

|  |  |  |
| --- | --- | --- |
| **Alternate treatment** | **Potential risks** | **Potential benefits** |
| <<insert treatment options>> | <<insert important side effects / risks>> <<required unless sponsor states they do not follow ICH>> | <<insert important benefits>> <<required unless sponsor states they do not follow ICH>> |
|  |  |  |

This is not a complete list. Your doctor can tell you about all your options, and their risks and benefits.

<<OR, if the only choice is not to participate, use this in place of the table above>>

Your only choices are to participate, or not to participate. It is up to you whether you want to be in this study.

<<Delete this section if study is minimal risk, and there is no chance of physical or mental harm to the subject>>What if I am harmed from being in the study?

<<Use this paragraph for sponsored / investigator-initiated studies. This language must be consistent with the contract.>>If you get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the investigator as soon as possible. You will not have to pay for medical treatment of any illness or injury that is caused by research procedures done because of your participation in this study. There is no plan to pay for lost income or any non-medical costs that might result from the illness or injury. You do not give up any of your legal rights by participating in this research study.

<<Delete this paragraph if the study is not industry-sponsored.>>If <<sponsor>> pays for treatment of an illness or injury caused by this research, we will need to collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or social security number. <<sponsor>> will use this information to check your Medicare status. If you are a Medicare beneficiary, <<sponsor>> is required to report the payment to Medicare. The information will not be used for any other purpose.

<<Use this section for federally funded studies, or studies where Aurora Sponsored Programs states that costs cannot be covered. This language must be consistent with the contract.>> There is no money set aside by the sponsor to pay for any medical treatment should you get hurt or sick from being in this research study.

If you get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the investigator as soon as possible. We will bill your insurance, if you have any, and you will have to pay your usual copays or deductibles. If you have Medicare, we may send information that identifies you to Medicare. If you do not have insurance or if your insurance does not cover your treatment, we will bill you for the costs of the treatment.

There is no plan to pay for lost income or any non-medical costs that might result from the illness or injury. You do not give up any of your legal rights by participating in this research study.

Will my records be kept confidential?

Your study records will be kept as confidential as possible. You can find out more in the section “Information about Confidentiality and HIPAA Authorization.”

<<INCLUDE THE FOLLOWING SECTION IF THE STUDY HAS A CERTIFICATE OF CONFIDENTIALITY – If not, you may delete this section.>>

*<<Background: Changes have been made to the* [*NIH Policy for Issuing Certificates of Confidentiality (CoC)*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html)*. This new policy went into effect in October 2017, and affects any research funded by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information. A CoC is automatically issued for these types of studies – no longer does the researcher/sponsor of NIH funded research need to apply for the CoC.*

*Researchers who have been issued a CoC for their study should be aware of the protections afforded to the subject. The* [*NIH COC kiosk*](https://humansubjects.nih.gov/coc/index) *will address any questions you may have. The Aurora RSPP has also published guidance on Certificates of Confidentiality on the RSPP website.* >>

This study has a Certificate of Confidentiality.

To help us protect your privacy, <<we have>> <<the sponsor has>> a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can’t be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding.

There are circumstances where the Certificate doesn’t protect against disclosure of your personally identifiable information:

* when the US government is inspecting or evaluating federally-funded studies
* when information must be disclosed to meet FDA requirements
* if you give someone written permission to receive research information or you voluntarily disclose your study information
* if there is a federal, state or law that requires that the information be released (for example, if you threaten to harm yourself or others, in cases of child abuse, to report cases of contagious disease (such as HIV) to the state.

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

If you want to know the results of the study once it is over, you can ask the investigator.

<<Delete this paragraph if n/a>>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.

Who oversees this study?

The Aurora Institutional Review Board (IRB) has approved this study. The IRB is a group of people who review all research studies at Aurora to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

|  |  |  |
| --- | --- | --- |
| **If …** | **You should contact** | **Contact information** |
| You are harmed by the research | <<investigator name>> | <<phone number (daytime)>> << 24-hour contact number if different than the above)>> |
| You have questions about your rights as a research subject | Aurora IRB office | 414-219-7744 (outside Milwaukee: 877-219-7744) |
| You have questions, problems, concerns, information, input or complaints about this research study | <<investigator name>>orAurora IRB office | <<phone number>>or414-219-7744 (outside Milwaukee: 877-219-7744) |

# Information about Confidentiality and HIPAA Authorization

Note: In this authorization document, “you” and “your data” refer to the subject. If you are a parent or guardian, please remember that “you” refers to the study subject.

Federal law provides additional protections of your medical records and related health information. That law is the *Health Insurance Portability and Accountability Act* (HIPAA). This study’s HIPAA statement is provided below. You are providing your authorization if you sign this form and the accompanying consent or permission form to participate in the study.

Who will see my protected health information?

|  |  |
| --- | --- |
| ***Who may have access to my information:*** | ***Purpose:*** |
| [delete row if there is no sponsor, e.g if the study is investigator initiated research] Any sponsor, including future sponsors, of the study and anyone working on behalf of a sponsor or future sponsor  | To oversee the study and make sure the information is correct. |
| Advocate Aurora Health consultants and employees, including IRB members. | To protect the rights and safety of subjects and make sure the study information is correct. |
| Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries). | To make sure applicable laws are being followed. |
| Organizations that grant accreditation to hospitals and research programs. | For Advocate Aurora Health to remain accredited. |

By signing this form, you are authorizing access to and sharing of personally identifiable health information. This includes direct access to your medical records at Advocate Aurora Health.

Please note that the study doctor or study staff may also share personal information about you if required by law (for example, if the study doctor or study staff suspects that you are going to harm someone or yourself; reporting of communicable disease (HIV, hepatitis, tuberculosis, etc.). If you have questions about this, please ask the study doctor.

***How will my information be used for this study?***

This section explains who will use and share your health information if you agree to be in this study. You must authorize this use and sharing of your information by signing this form or you cannot be in the study.

The study principal investigator and study staff will collect, use, and share identifiable health information about you for the following reasons:

* to conduct this research study;
* to review the study, and to check the safety and results of the study;
* to seek government approval of an investigational study drug, vaccine, device or product if such was involved in the trial;
* to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

* information from your medical records related to the research or your routine medical care;
* information collected about you during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number, social security number *[****ONLY*** *include if collected as part of the study- ask study team representative if collected] ,*health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

***How will my information be kept confidential?***

We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form you were given. Researchers may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves Advocate Aurora Health we cannot control how it is used, and the law may not require outside organizations to protect the privacy of your information.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally will have access to your health information.

If this study is designed so that you are intentionally not told what treatment or study intervention you are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer necessary to keep you blinded. This usually occurs after everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.

***How do I cancel my authorization?***

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

If you cancel your authorization, no new information will be collected without your permission. The study doctor and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study.

***When will my authorization expire?***

[ONLY include ONE of the following statements – Use whichever statement that is most appropriate to this study; delete the other.] This authorization to use and share your information expires at the end of the research study when data analysis is complete, and study records have been destroyed. OR The authorization to use and share your information has no end date.

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

You will receive a signed and dated copy of this form for your records.

**Subject name:**

* I have read this form and the research study has been explained to me.
* I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
* I agree to be in the research study described above.
* I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
* I am not giving up any of my legal rights by signing this form.

Subject signature Date Time

Witness signature (if applicable\*) Date Time

*\*Use when the subject cannot read the consent (for example, subject is blind, illiterate, or does not speak English). The witness must be present for the entire consent discussion. The witness signature means that the information in this document was presented to the subject, and the subject appeared to understand it.*

<<Delete if not requesting LAR>>Legally Authorized Representative signature (if applicable) Date

Relationship to Subject: Court Appointed Guardian Heath Care Agent

**For Site Use only:**

My signature below certifies the following:

* The subject has been given enough time and an adequate place to read and review this form.
* All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began .
* The subject has had a chance to ask questions and receive answers about this study.
* The subject/LAR will receive a copy of the signed and dated consent form/authorization.

Name of person obtaining informed consent (print) Title Phone number

Signature of person obtaining informed consent Date Time

**Risk/Benefit/Alternatives Discussion**

I have explained and discussed with the subject or his/her legally authorized representative

* The nature of the research
* Potential risks and benefits
* The alternate treatments available to the subject and the benefits and risks of each

Name of person providing this information (print) Title

Signature of person providing this information Date

**FILE A SIGNED COPY OF THIS FORM IN THE PATIENT’S MEDICAL RECORD (if applicable).**

**Keep the original in the investigator’s research records.**

***v.02.24.2021***

THIS PAGE IS FOR DOCUMENTATION ONLY. IF GIVEN TO SUBJECTS, IT MAY BE BLANK**.**