**Instructions:**

* **There are many scenarios where this template could apply (specified/unspecified research, coded/double-coded, sponsor use/other entity’s use of the banked specimens, etc.). Please include details regarding the collection/storage/use as defined in the sponsor’s protocol. If specific details are not available in the main or separate banking protocol, ask the sponsor to provide this information in writing prior to IRB review.**
* **Do not use the term “donate”.**
* **Update the version date in the header each time you make a change.**
* **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**
* **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 Collect and Store <<Blood>> <<Tissue>> <<Other>> for Research Purposes

|  |  |
| --- | --- |
| **Study Title** | <<title (must match protocol)>> |
| **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 are my samples being requested?

Studying biological samples, such as <<blood>> <tissue>> <<other >>, can help researchers better understand how the body reacts to <<disease or condition>>, and why some people’s bodies respond differently to <<disease or condition>> and the therapies used to treat it. Research using<<blood>> <tissue>> <<other >> can also answer other health questions. <<Use one or both of the following sentences, if appropriate>> Some of these may include finding the causes of diabetes, heart disease, or finding genetic links to Alzheimer’s disease. Differences in the way the body handles drugs such as <<drug name>> may explain why some people respond to a treatment and others do not. Researchers are trying to learn more about to <<disease or condition>>, such as what causes it, how to prevent it, how to treat it better, and how to cure it.

You can choose whether or not you want to participate in this portion of the study. The information in this informed consent form will help you decide if you want to take part or not. Please take your time to decide, and talk about this study with your personal doctors, family members, and friends if you like. If you decide you do not want to sign this consent form, you cannot take part in this <<blood>> <tissue>> <<other >> collection portion of the research study.

Why am I being asked to participate?

You are being asked to voluntarily take part in the collection and storing of <<blood>> <tissue>> <<other >> to be used in research about <<Specify – for example: cancer and other health problems>>. You are being asked to take part because you have agreed to participate in the treatment portion of the clinical trial. If you decide that you do not want to participate in this research, you may still participate in the treatment portion. There will be no consequences and you will not be treated differently or lose any benefits to which you are otherwise entitled. The choice to let <<sponsor>> store your tissue is up to you. <<Use the following sentence, if appropriate.>> **No matter what you choose, it will not affect your care or your ability to participate in the treatment portion of the clinical trial.**

<<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 my samples be stored?

The samples will be kept at <<location(s)>>.

How many people will take part in this study?

<<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 in the study?

If you agree to participate, <<specify what samples are being collected and how. State if the samples are being specifically collected only for research purposes or are the samples taken from procedures done for routine care/diagnosis. If appropriate, use one or more of the following sentences.>> The samples will only be stored and used by the sponsor for research purposes. The samples will only be given to researchers approved by the sponsor of this study. The samples will not include your name.

<<Delete if n/a>> The results from future testing of the samples are only for research purposes and have no effect on your medical care. They will not be sent to you or your doctor, will not be used in planning your care, and will not become part of your medical record.

<<***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.>>

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

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>>*.

How long will my samples be used?

Your samples will be used for <<specify length of time>>. <<OR>> The samples will be kept until they are used up or destroyed. Include if appropriate, you can also request to have your samples withdrawn at any time.

<<For tumor samples or other appropriate situations, use the following>>A portion of your samples will be kept at Aurora ACL Laboratories for a minimum of 10 years according to regulatory requirements and will **not** be sent to <<sponsor or location>>.  These samples can be used at a later time for diagnostic purposes or for determining if you are eligible for other research studies.

What are the risks of this study?

There are few likely risks in having your [Specify what samples are to be collected/stored] saved for future research. **[include risks of blood draw if blood is taken specifically for future unspecified research]** The greatest risk is that information about you is released without your permission.**[**Include if appropriate, The sponsor will receive <<limited information that identifies you>> <<**OR>> <<**coded information about you>>. The sponsor will protect your records so that your name and information will be kept confidential. The chance that this information will be given to someone else is very small.

<<Use the following if genetic research is involved>> If information from your research records relating to genetic testing of your samples is released, there is a risk that this information could be used in a discriminatory way against you. However, the researchers will take all reasonable steps to protect your records and assure that your name will be kept private, and the chance that this information will be given to someone else who would use it to discriminate against you is very small.

Wisconsin has laws to protect against genetic discrimination by employers and health insurers. Under employment laws, genetic discrimination in hiring, firing or setting conditions and terms of employment is prohibited. Under state insurance laws, health insurers are prohibited from using genetic information to discriminate in coverage or benefits, and group health insurance plans may not treat genetic information as a “pre-existing condition” without a diagnosis of a condition related to the information.

Also, a federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against people based on their genetic information. Under this law:

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

This law does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Are there benefits to me from participating in this study?

If you agree to allow your samples to be banked and used for research purposes, there will be no benefit to you. We hope the information learned from this future research will benefit other patients with <<disease or condition>> or other diseases in the future.

How much will it cost to participate?

There will be no cost to you if you agree to participate.

<<Moore clause – use if appropriate>> The sponsor may use your <<blood>> <tissue>> <<other >> when developing new tests, procedures and commercial products. If this happens, the sponsor does not plan to share any profits with you.

Will I be paid to participate?

You will be <<paid>> <<reimbursed>> $<<insert amount>> for the use of your samples. <<OR>> You will not be paid for the use of your samples.

**<<*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.

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 research team know. There may be special procedures to follow for your safety.

What are your rights if you take part in this study?

If you decide now that your samples can be kept for future research, you can change your mind at any time. Just contact the investigator and let him or her know that you do not want us to use your samples. Then the samples will no longer be used for research.

Withdraw your permission by writing to: <<insert name, address, etc.>>

<<Include if appropriate>> A portion of <<blood>> <tissue>> <<other >> samples obtained during the course of these studies may be used for research on biochemical markers or genes <<specifically related>> <<not related>> to your medical condition. There <<are>> <<are not>> plans to reveal the results of these studies to you and you doctor.

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.

<<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>>  or  Aurora IRB office | <<phone number>>  or  414-219-7744 (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.

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

Witness signature (if applicable\*) Date

\*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:**

* I have carefully explained to the subject the nature and purpose of this study.
* The subject has been given enough time and an adequate place to read and review this form.
* The subject has had a chance to ask questions and receive answers about this study.

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

Signature of person obtaining informed consent Date

**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.**

***v02.24.21***

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