Advarra Mandatory Language Document

For

Advocate Aurora Health

Consent To Take Part In A Clinical Research Study

And

Authorization To Disclose Health Information

|  |  |
| --- | --- |
| **Sponsor / Study Title:** | **Sponsor Name / “Protocol Title”** |
| **Protocol Number:** | **Protocol Number** |
| **Principal Investigator:**  **(Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Address:** | **«PiLocations»** |

**Additional notes for Advarra:**

* AAH will be inserting language, Advarra to do a compliance check and revise the language to match what we have on file.
* MLD applies to all forms as applicable
* No specific formatting requirements, header and footer should be in all forms

**Add only if AAH employees are part of the required subject population**

**Advocate Aurora Health employee participation**

Your participation in this research is not a part of your Advocate Aurora Health duties and declining to participate will not affect your employment with Advocate Health Care, or the benefits, privileges, or opportunities associated with your employment at Advocate Health Care. You will not be offered or receive any special consideration if you participate in this research.

**COMPENSATION FOR RESEARCH INJURY SECTION:**

[IF THE STUDY DOES NOT INCLUDE THE POTENTIAL FOR PHYSICAL OR MENTAL HARM TO THE SUBJECT OF THE RESEARCH THE SUBJECT INJURY LANGUAGE MAY BE REMOVED FROM THE CONSENT. However remember that even a simple blood draw may result in physical injury to the subject.]

The AAH language should replace the sponsor’s language, and MUST be consistent with the AAH executed contract:

**OPTION 1:** Use this paragraph for industry sponsored or investigator-initiated studies.

If you get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the study doctor as soon as possible. You will not have to pay for medical treatment of any illness or injury that is caused by your participation in this study. No funds have been set aside by Advocate Aurora Health as compensation for research related injury or associated non-medical costs. You do not waive any of your legal rights by signing and dating this form.

**OPTION 2:** Use this paragraph for federally funded studies, or studies where Aurora Sponsored Programs states that costs cannot be covered.

If you get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the study doctor 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. No funds have been set aside by Advocate Aurora Health as compensation for research related injury or associated costs. You do not waive any of your legal rights by signing and dating this form.

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**RISK SECTION**

Include this risk if there is testing for HIV or Hepatitis done as part of the research study:

Risk of HIV/Hepatitis testing:

There are certain risks associated with the testing for HIV or hepatitis. A positive test result may cause you significant anxiety. A positive test may result in uninsurability for life, health, or disability insurance policies for which you may apply in the future. Although prohibited by law, discrimination in housing, employment, or public accommodations may result from disclosure of a positive test result.

Certain organizations and individuals may be notified of positive test results. These are discussed in more detail in a later section of this document.

**Include the following paragraphs if the research includes genetic testing and not already included by the external IRB consent:**

Genetic Testing:

**If WI sites involved in the research, add:** 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.

**Include for all AAH sites:** There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that 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 insurance.

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**CONFIDENTIALITY SECTION:**

**Add the following information if appropriate to the research and not already included in the consent:**

**This study has a Certificate of Confidentiality.**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

**Add the following if there is testing for HIV required by the research study:**

**What about the confidentiality of the results of the HIV Test performed for this research study?**

In order to participate in this study your blood will be tested for HIV infection, and you will be provided with the results. You may decide that you do not want this test performed, but if you do, you will not be able to take part in this research study.

You will be informed if your test results are positive. If results are positive, the results, along with your identifying information, will be sent to the public health department for the purpose of providing surveillance or control of the communicable disease. The health department may contact you with resources for counseling and medical care if you need them and want them; and you may be asked about sex and/or needle-sharing partners. You should ask the study doctor for more information on mandatory reporting to the state authorities.

*Add the following text to the end of the Advarra WHOM TO CONTACT:*

If you have general questions, problems, concerns, information, input or complaints, and want to speak to someone at Advocate Aurora Health who is unaffiliated with the study, please contact the Human Protections Administrator in the AAH Research Subject Protection Office (RSPP) at 414-219-7744 (outside Milwaukee: 877-219-7744) or via email at [irboffice@aah.org](mailto:irboffice@aah.org) .

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**HIPAA: NO changes are allowed without prior approval by the AAH RSPP office**

**Information about Confidentiality and HIPAA Authorization**

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 and date 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. |
| Advarra IRB | 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 and dating 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 and dating this form or you cannot be in the study.

The study doctor 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 study 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 at the address listed on the first page of this form. 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.

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**CONSENT/AUTHORIZATION SIGNATURE PAGES:**

**Language in this section is to replace the language in IRB’s approved consent/authorization subject signature section. Subject signature should not be in the consent document twice.**

* **Choose one or more signature blocks as needed.**
* **Each signature block should start a new page.**

**SIGNATURE OF CAPABLE ADULT**

**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 and date 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 and dating this form.

Subject signature Date Time

Use the following signature line when the subject cannot read the consent (for example, subject is blind, or illiterate) or of there is a witness present for the consent process. 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 has his/her questions answered.

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Printed Name of Witness (if applicable\*)

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.*

**Signature Of person obtaining consent:**

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 **before** research-related procedures began .
* The subject has had a chance to ask questions and receive answers about this study.
* The subject expressed understanding of the study.
* The subject will receive a copy of the signed and dated consent form.

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

Signature of person obtaining informed consent Date Time

***[****Instructions****:*** *Include the following section if only using a Legally Authorized Representative to enroll potential subjects into the research.* ***The use of LAR in the research must be approved by the IRB.]***

**SIGNATURE FOR AN ADULT UNABLE TO CONSENT**

I have read this consent form or had it read to me. My signature documents that I provide permission for the subject to take part in the research.

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Printed Name of Subject

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Printed name of individual legally authorized representative (LAR) to

consent to the named subject’s general medical care

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Signature of individual legally authorized representative (LAR) to Date

consent to the named subject’s general medical care

Relationship to Subject: Court Appointed Guardian Heath Care Agent Other per AAH Policy

2453 [define relationship]

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Note: Investigators are to ensure that individuals acting as the subject’s representative can demonstrate their legal authority to consent to the individual’s general medical care. Contact legal counsel if any questions arise.**

**Signature Of person obtaining consent:**

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 **before** research-related procedures began .
* The subject has had a chance to ask questions and receive answers about this study.
* The subject expressed understanding of the study.
* The subject will receive a copy of the signed and dated consent form.

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

Signature of person obtaining informed consent Date Time

*[Instructions: Include this page only if including children in the research study. To be signed by the parent/legal guardian* *of the child.]*

**PERMISSION FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY**

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I agree to have the child named below participate in this study.

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Printed Name of Child/Subject

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of parent(s) or legal guardian to

consent to the named subject’s general medical care

Signature of parent(s) or legal guardian to consent to the child’s general medical care

Relationship to Subject: Parent(s) Legal guardian to consent to the

child’s medical care (see note below)

**Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise.**

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Printed Name of Witness (if applicable)

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.*

*Add the following signature block if documenting assent of children.*

**Assent of the Child**

|  |  |
| --- | --- |
| Assent | * Obtained * Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted. |

|  |  |  |
| --- | --- | --- |
| Your signature means you agree to take part in this research. | | |
|  |  |  |
| Printed name of subject |  | Age |
|  |  |  |
| Signature of subject |  | Date |

**Signature of person(s) conducting the informed assent discussion**

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 **before** research-related procedures began.
* The subject has had a chance to ask questions and receive answers about this study.
* The subject will receive a copy of the signed and dated assent form.

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

Signature of person obtaining informed assent Date Time (optional)

***[The following section must be included in all research consent documents for studies that meet the following criteria: 1) the study is being conducted in WI and 2) the study includes a clinical intervention for which state law requires a physician to provide risks/benefits/alternatives for that intervention.]***

The following section must be completed by a physician investigator if the study is being conducted in WI, and includes a clinical intervention for which state law requires a physician to provide risks/benefits/alternatives for that intervention.

**Risk/Benefit/Alternatives Discussion**

I have explained and discussed with the subject [include if appropriate - 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 AND DATED COPY OF THIS FORM IN THE PATIENT’S MEDICAL RECORD (if applicable).**

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

**v.03/30/21**