**Advocate Aurora Health**

**AUTHORIZATION TO USE AND DISCLOSE INFORMATION**

**FOR RESEARCH PURPOSES**

**[NOTE to User: you may not change any of the language in this document. Any change, without authorization from the AAH RSPP Office will constitute noncompliance.   
DELETE all instructions highlighted in blue before use.]**

|  |  |
| --- | --- |
| **Abbreviate Study title for Participant use** | **[*Include abbreviated study tile only if provided by sponsor – delete row in chart if not provided. Do not duplicate below.***] |
| **Study Title** | <<title (must match protocol)>> include sponsor protocol ID number |
| **Study Investigator** | <<principal investigator name>>  <<PI’s address>>  <<phone number (daytime)>>  <<phone number (24-hour contact number)>> |
| **Sponsor<<delete row if no sponsor>>** | <<insert name>> |
| **Research Site(s) (optional)** | ***[List research sites in authorization if required by study contract – delete row if not needed*.]** |

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.

*<<use when subjects are adult – delete if not needed>>*

**Authorization Signature section when subjects are adults**

By signing this form, I acknowledge that I have read this authorization form describing the researchers’ access to and use of my personal data in its entirety. I have spoken to the investigator or his/her representative and have had all questions answered to my satisfaction. I will receive a completed signed copy of this document. My signature indicates my agreement to voluntarily authorize such access to and use of my personal information as a participant in this study.

Subject signature Date Time

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

Printed Name of Subject

Witness signature (if applicable\*) Date Time

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

Printed name of witness

*\*A witness must be used 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 agreed to participate.*

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*<<Include section when using a legally authorized representative (LAR) – Delete if not needed.>>*

Legally Authorized Representative signature Date

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

Printed name of legally authorized representative (LAR)

Relationship to Subject: Court Appointed Guardian Heath Care Agent

Other Personal Representative 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 on behalf of the subject.***

**Research Representative’s Statement**

My signature below certifies the following:

* The subject has been given enough time and an adequate place to read and review this form.
* This document was 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.
* The subject/LAR will receive a copy of the signed and dated authorization.

Signature of person obtaining authorization Date Time

Printed name of person obtaining authorization Title Phone number

*<<Use when subjects are minors -delete page if not needed>>*

**Authorization signature section when subject are minors**

By signing this form, I acknowledge that I have read this authorization form describing the researchers access to and use of the subject’s personal data in its entirety. I have spoken to the investigator or his/her representative and have had all questions answered to my satisfaction. I will receive a completed signed copy of this document. My signature indicates my voluntary agreement to have the child named below participate in this study.

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Printed Name of Subject

Signature of parent or individual legally authorized Date Time

(LAR) to consent for the child

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

Printed name of parent or individual legally authorized (LAR) to consent for the child

Relationship to Subject: parent Court Appointed Guardian Heath Care Agent

Other Personal Representative per AAH Policy 2453 [define relationship] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***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.***

Witness signature (if applicable\*) Date Time

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

Witness Name (Please print)

*\*A witness must be used 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 agreed to participate.*

**Research Representative’s Statement**

My signature below certifies the following:

* The subject has been given enough time and an adequate place to read and review this form.
* This document was 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.
* The subject/LAR will receive a copy of the signed and dated authorization.

Signature of person obtaining informed consent Date Time

Printed name of person obtaining informed consent Title Phone number