**Instructions:**

* **Use this form to give currently enrolled subjects new information about the research. It may be used instead of re-consenting with the full informed consent form.**
* **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>>

# Addendum to Consent to Participate in a Research Study

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

Summary of changes to the informed consent document

You are currently participating in the above named research study being conducted by << PI name>>. The consent form you previously signed told you that you would be informed of any significant new findings during the research study, such as changes in the risks or benefits of participation, new alternatives to participation, or changes in study procedures. The purpose of this consent addendum is to inform you of changes in the study. All other sections of the original consent form still apply. Please refer to it for any questions you might have.

The following are changes that have been made to this research study since you signed the original consent form:

* <<List changes here. Discuss the impact these changes will have on subjects participating in the research, such as extra time required for additional study visits, changes in medication regimens, the consequences of a newly identified risk or side effect, etc.>>

If you have questions about any of these changes, <<PI name>> will be available to answer them and to provide you additional information so you can decide if you want to continue participating in this research study.

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

Continuing to be in this study is your choice. If you agree to continue, you may withdraw from this study at any time, but before you withdraw, talk with the investigator who will help you withdraw in the safest way. If you withdraw from the study, your decision will not result in a penalty to, or loss of, your benefits, and will not affect your access to health care.

If we learn new things during the study that may affect your health, or your willingness to continue in the study, we will tell you as soon as possible.

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) |

# 

**Subject name:**

* I have read this form and the changes to the research study have 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 addendum 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 the changes to 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

**DOCUMENTATION OF INFORMED CONSENT**:

🞏 All elements of the study contained in this document were discussed with the subject.

🞏 The subject had the opportunity to ask questions, all questions were answered, and the subject expressed understanding.

🞏 The subject gave written informed consent before any research-related procedures began.

🞏 The subject received a copy of the signed and dated consent form.

Signature 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.**

***Form IC 701A v. 11-4-19***

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