**Instructions:**

* **When research data will be collected *about* a caregiver (in addition to data collected about the study subject), the caregiver is also considered a subject. Use this template. If information is not collected about the caregiver, use the Caregiver Information Sheet instead.**
* **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 as a Caregiver in a Research Study

|  |  |
| --- | --- |
| **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>> |

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>>. You are being asked because you are a caregiver of someone who is taking part in this study.

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?

We will ask you to do the following things <<insert list of questionnaires or any other study-related activities the caregiver will need to do>>

You will be responsible for:

* attending all study visits
* following study instructions
* <<insert any other study-specific responsibilities>>

Are there any risks to me?

<<Insert any risks that may apply to the caregiver, such as breach of confidentiality, questionnaires, etc.>>**Questionnaire risks:** You will complete questionnaires in this study. Sometimes the questions can make people uncomfortable or bring back bad memories.

<<OR>>

There are no known risks to you as a subject in this research study.

Are there any benefits to me?

As a caregiver, 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?

There will be no costs to you as a caregiver.

You will not be paid for your involvement in this research study.

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
* <<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.

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

Will personal information be kept confidential?

Any information you provide about yourself or the study subject during this study will be kept confidential, as described in the subject’s consent form.

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.

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) |

# 

**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.*

**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

**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.

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

***v. 11/4/19***