**Instructions:**

* **Use this Caregiver Information sheet when a caregiver will be helping the subject follow study requirements, but where no data is gathered about the caregiver. If data about the caregiver is gathered, then the caregiver is also a subject and you should use the Caregiver Informed Consent template 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.**

# Aurora Health Care, Inc.<<or other institution name>>

# Research Study Information Sheet for Caregivers

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

Subject Name:

What am I being asked to do?

The person listed above has been enrolled in this 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.” In some research studies, a subject may need help with certain study activities or study requirements. The person who helps the subject is called a caregiver.

You are being asked to act as caregiver for the subject listed above. You can choose whether or not you want to do this. This information sheet will tell you what you would need to do. Please take your time to decide.

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.

What is involved in being a caregiver?

As a caregiver, you will be asked to do the following things to assist the subject participating in this study: <<Include any/all of the below, as applicable. Add any other responsibilities.>>

* Read this Caregiver Information Sheet and the consent form(s) the subject reads and signs.
* Tell us if the subject wants to stop being in the study or you want to stop serving as caregiver.
* Attend study visits with the subject
* Tell us information about the subject. This includes completing the study diary for the subject, if needed.
* Tell us if the subject shows or tells you about any unexpected or unusual symptoms, physical changes, behavior, or other signs of changes

<<Delete if n/a>> **You must come with the subject to all study visits.** If you can’t make it to a study visit with the subject, you must be available to answer questions over the phone about the study diary and the subject’s usage of study drug.

<<Delete if n/a>>You must have contact with the subject at least once each day. Someone else cannot take your place. That is why, before you agree to act as the caregiver, you need to make sure you can do what is required for the study. If you become unable to personally do what is required, tell us immediately.

After the study is over, you should talk to the study doctor about the subject’s future <<disease or medical condition>> treatment**.**

How long will I be involved in this study?

Your involvement in this study will last <<insert duration>>*.* The study staff will tell you and the subject about the study visit schedule.

The whole study is expected to last for <<insert duration>>.

<<Delete if n/a>>If you can no longer assist the subject in this study, the subject must have a new caregiver in order to stay in the study.

What about confidentiality?

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

Will it cost anything to be a caregiver?

There will be no costs to you as a caregiver.

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

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 a caregiver in this study is the right decision.

Who do I contact?

|  |  |  |
| --- | --- | --- |
| **If …** | **You should contact** | **Contact information** |
| The subject is harmed by the research | <<investigator name>> | <<phone number (daytime)>> << 24-hour contact number if different than the above)>> |
| You have questions about the research subject’s rights | 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>>orAurora IRB office | <<phone number>>or414-219-7744 (outside Milwaukee: 877-219-7744) |