**UnityPoint Health – Meriter**

**Institutional Review Board**

**CONSENT TEMPLATE**

Version 4 (9/2022)

Complies with 2018 Revised Common Rule Requirements

**Investigator Instructions**

1. ***One size fits all Consent Template***. Use only the portions of the consent that apply to your research. Delete sections that don’t apply.
2. ***Read the comments in the right margin*** for additional guidance. You may have to click on a comment to view the complete comment text.
3. ***Consent font and formatting –*** Make sure the font, color of font and spacing is consistent throughout the document. The template default font is Arial 12 in black.
4. ***Delete comments in right margin*** and ***instructional language*** *(blue italicized text)* in the consent before submitting the consent to the IRB.
5. ***Delete this instruction page*** before submitting the consent to the IRB.
6. ***Version Number and Date*** – Enter this information in the footer. Make sure this matches what is in the electronic IRB submission and review system before you upload this consent.

Name of Company Sponsoring Research or Name of the Funding Agent for the Research

|  |  |
| --- | --- |
| **Research subject information and Consent form** | |
| **TITLE:** | Enter study title here. |

**This consent form contains important information to help you decide whether to participate in this research study.**

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may discuss this consent form with family or friends. Take as much time as you need to decide if you want to be in this research.

* **Being in a study is voluntary – your choice.**
* **If you join this study, you can still stop at any time.**
* **No one can promise that a study will help you.**
* **Do not join this study unless all of your questions are answered.**

**Before signing this consent form, you should be able to answer the following questions.**

* Why is this research study being done?
* What will happen to me during the study?
* What are the possible risks to me?
* What other options could I choose instead of being in this study?
* How will my personal health information be treated during the study and after the  
   study is over?
* Will being in this study cost me anything?
* What to do if I have problems or questions about this study?

**Please read this consent form carefully.**

Consent To Be Part Of A Research Study

## Study title:

## Company or agency sponsoring the study:

## Name, degrees, and affiliation of the Principal Investigator conducting the study:

### 1. Research Summary & Invitation

***Key Information Summary***

We are asking you to choose whether or not to volunteer for a research study about \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {*insert general description of study*}. This key information is to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

**WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**

***Briefly*** *describe the purpose of the study and the procedures to be followed in lay terms. For more information refer to the Detailed Consent that follows.*

By doing this study, we hope to learn \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your participation in this research will last about {*state in hours, days, months, years*}.

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**

*State the most important reason(s) {i.e. potential benefit(s)/rewards} a person may want to volunteer to participate in this study?*

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**

*State the most important reason(s) {risk(s)/disadvantages} why a participant may NOT want to volunteer for this study considering the participant’s perspective.* For a complete description of risks, refer to the Detailed Consent.

**DO YOU HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?**

The person in charge of this study is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{Principal Investigator, PI}* of the University of Wisconsin (or name of other institution), Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {*list department}.* If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: {*PI contact information}*.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact UPH – Meriter Institutional Review Board during business hours, Monday-Friday at 608-417-6411.

You are invited to take part in this research because you\_\_\_\_\_\_\_\_. Your participation is voluntary.

### 2. PURPOSE OF THis STUDY

2.1 **Study purpose:** *Briefly explain in lay-terms at a 6th – 8th grade level, the scientific reason for doing this study. Do not describe the details of the protocol here – that will be done in Section 4 on Study Procedures (below).*

### 3. Information About STUDY participants (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

## 3.1 Who can take part in this study?

*List eligibility criteria* ***in simple lay terms****. Bullet points are fine****. DO NOT*** *Cut and Paste from your protocol. Include a discussion of exclusion criteria, if applicable. Do not list exclusion criteria that would have been used to eliminate potential subjects prior to receiving this consent document.*

*For some studies, investigators may wish to remind potential subjects of the importance of providing complete and accurate information about their health condition/history to ensure that they are safe and appropriate candidates for participation.*

## 3.2 How many people (subjects) are expected to take part in this study?

## Approximately \_\_\_\_ subjects will participate in this study nationally/internationally. \_\_\_ will be enrolled at this institution.

### 4. information about study procedures

## 4.1 What exactly will be done to me in this study? What kinds of research procedures will I receive if I agree to take part in this study?

*Explain in* ***lay terms****, usually in chronological order, research related procedures/treatments. Include a brief description of medical care or procedures that would be performed whether or not the subject participated in the study. Standard procedures must be clearly distinguished from research related procedures.*

## 4.2 How much of my time will be needed to take part in this study? When will my participation in the study be over?

*Describe the time needed in minutes or hours, number of visits, amount of time each visit will take, etc. Include expectations for long-term follow-up, if applicable.*

**4.3 What will happen to my biospecimens or medical information?**

*a) State* ***whether identifiers will be removed*** *from biospecimens or data.*

*b) State whether the subject’s biospecimens may be* ***used for commercial profit*** *and whether the subject may share in commercial profit.*

*c) State whether the research will (if known) might* ***include whole genome sequencing*** *(i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*

***State one of the following:***

*d) if there is a possibility after identifiers have been removed that the subject's biospecimens or information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject.*

*e) if the subject’s information or biospecimens collected as part of this research, even if identifiers are removed, will not be used, or distributed for future research studies.*

**4.4 Will my biospecimens or medical information be used in future research?**

**4.4.1Types of Research**

*Provide a general description of the* ***types of research*** *that might be conducted with identifiable medical information (data) or identifiable biospecimens. Even if biospecimens are not identified, state whether they will be used in future research that involves* ***whole genome sequencing****.*

**4.4.2 What type of identifiable private information and/or identifiable biospecimens are used?**

*Describe the* ***type*** *of identifiable private information and or identifiable biospecimens that might be used in future research.*

**4.4.3 Will my identified biospecimen and/or medical information be shared? Who will you share it with?**

*Explain whether* ***sharing*** *identifiable private information and or identifiable biospecimens might occur and the types of institutions or researchers that might conduct research with the identifiable private information and or identifiable biospecimens.*

**4.4.4 How long could my identifiable private information and/or identifiable biospecimens be stored and used for research?**

*Describe* ***how long you’ll be storing and maintaining*** *the identifiable private information and or identifiable biospecimens and using them for research purposes.*

**4.4.5 Will I be asked whether I want my identifiable private information and/or identifiable biospecimens** **to be included in a specific future research study?**

*State that the* ***subject will not be*** *informed or* ***asked for consent for future research studies*** *on their identifiable private information and or identifiable biospecimens. Explain that they will not be aware of the specific research purposes and that they might not have chosen to consent to some of those specific research studies.*

**4.4.6 Will I find out about the results of future research that is done using my identifiable private information and/or identifiable biospecimens?**

*Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such* ***results may not be disclosed to the subject.***

**4.4.7 Who should I contact if I have questions about my rights and the storage and use of my identifiable private information and/or identifiable biospecimens?**

*You may reference section 10 below if the contacts for the current study are the same as for the future studies. If the contacts are different, please use the format from Section 10 to list separate contacts here.*

### 5. information about RISKS and benefits

## 5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

*Explain the risks and discomforts in clear, simple, concise terms (consider using bulleted format). “None” or “Not Applicable” are not acceptable. Even minimal risk studies have foreseeable risks, such as breach of confidentiality, discomfort or inconvenience.*

*Explain how risks are monitored and reduced. For example, describe how confidentiality will be protected.*

*Federal regulations require listing* ***ALL*** *reasonably foreseeable risks, stresses, and discomforts of* ***ALL*** *aspects of participation in a study, not just the most serious or common side effects of a research intervention or procedure, if applicable. You are encouraged to stratify the risks by categories such as:*

*The most common side effects (occurring in more than 10% of patients) are: …*

*Less common side effects (1% - 10% of patients) are: …*

*Rare side effects (less than 1% of patients) are: …*

*Include risks to a fetus if women of child-bearing potential may participate in the study. It is* ***not*** *necessary to list risks associated with non-research procedures.*

As with any research study, there may be additional risks that are unknown or unexpected.

## 5.2 What happens if I get hurt, become sick, or have other problems as a result of this research? *Delete 5.2 if this is minimal risk research.*

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even when the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers listed in Section 10 of this form.

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, (name) at (phone number) if you are injured or for further information.

## 5.3 If I take part in this study, can I also participate in other studies at the same time?

*Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies*. You should not take part in more than one study at the same time without approval from the researchers involved in each study.

*Delete 5.3 if it’s not applicable to your study.*

## 5.4 How could I benefit if I take part in this study? How could others benefit?

## You may not receive any personal benefits from being in this study.

## 5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

*State whether* ***clinically relevant research results****, including individual research results,* ***will be disclosed to subjects****, and if so, under what conditions.*

*If new information might affect the eligibility of subjects to continue to participate in the study, address that possibility.*

### 6. Other options

## 6.1 If I decide not to take part in this study, what other options do I have?

*Describe alternatives to participation (e.g., what is usually done to treat the condition or disease). For non-therapeutic studies, in which there is no “alternative” or standard treatment, state,* “There is no alternative. Participation is voluntary. There is no penalty if you choose not to participate.”

### 7. ENDING THE STUDY

## 7.1 If I want to stop participating in the study, what should I do?

## You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please notify one of the persons listed in Section 10 “Contact Information” (below).

## 7.2 Could there be any harm to me if I decide to leave the study before it is finished?

*Describe any dangers of terminating from the study abruptly.*

## 7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

* The researcher believes that it is not in your best interest to stay in the study.
* You become ineligible to participate.
* Your condition changes and you need treatment that is not allowed while you are taking part in the study.
* You do not follow instructions from the researchers.
* The study is suspended or canceled.

### 8. Financial Information

## 8.1 Will taking part in this study cost me anything? Will I or my insurance company be billed for any costs of the study? If so, which costs? What happens if my insurance does not cover these costs?

*State if participation will be at no cost to the subject. Describe any reimbursement for participation-related expenses (e.g., mileage, parking, etc.). For studies involving treatment intervention(s), clearly explain which costs will be billed to the subject's insurance company, and who (the subject? the study sponsor?) will be responsible for payment of any costs not covered by the insurance.*

Ask the researchers if you have any questions about bills, fees, or other costs related to this study.

## 8.2 Will I be paid or given anything for taking part in this study?

*Include the amounts and conditions of payment. Incentive payments for completing the study, or disproportionately high levels of payments, might constitute enticement and should not be offered.*

## 8.3 Who could profit or financially benefit from the study results?

*State if no person or organization has a financial interest in the outcome of the study and delete all sub-headings.*

*Address all financial interests of any person or organization involved in the conduct of this study. Some of the items may not apply to your research.*

*How is the research supported or financed?*

*Where and by whom was the study designed (i.e., industry-sponsored versus investigator-initiated)?*

*Do individuals or the institution receive any compensation that is affected by the study outcome?*

*Do individuals or the institution*

*have any proprietary interests in the product (including patents and licensing agreements);*

*have an equity interest in the sponsor;*

*receive significant payments of other sorts (e.g., grants or consultant retainers); and/or*

*receive payment per participant or incentive payments?*

*If applicable, include the following language under this heading:* You will not receive any proceeds, profits, or other benefits from any commercial product that may result from this study.

The company whose product is being studied:

*State if a company or other organization has an ownership or other financial interest in the product or technology under study and might profit or otherwise benefit from the outcome of the study. DELETE this sub-heading if it does not apply.*

The researchers conducting the study:

*If any of the investigators on the study have an ownership, consulting, or similar financial relationship with the sponsor, they should disclose it here. Delete this sub-heading if it does not apply.*

The University of Wisconsin:

*State if the University of Wisconsin owns the investigational technology (for example if there is a technology transfer agreement). DELETE this sub-heading if it does not apply.*

### 9. confidentiality of subject records

Meriter Hospital, Inc. policies require that private information about you be protected. This is especially true for your personal information.

On the other hand, sometimes the law allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

## 9.1 How will the researchers protect my privacy?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

## We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. *{Insert description of procedure(s) used for protecting confidentiality of data, including paper records, computer records, jump drives, and portable storage devices.}*

*Add the following information if REDCap is being used as a survey or storage instrument for your research:* We are using REDCap, a secure, web-based program to capture and store research data at the University of Wisconsin - Madison. We will make every effort to safeguard your data in REDCap.

## 9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

There are many reasons why information about you may be used or seen by the researchers or others during this study. Examples include:

* The researchers may need the information to make sure you can take part in the study.
* The researchers may need the information to check your test results or look for side effects. *Delete this bullet if researchers will not be doing this.*
* Meriter Hospital, Inc. IRB and other government officials may need the information to make sure that the study is done properly.
* Organizations that are funding the study may need the information to make sure that the study is done properly. *Delete this bullet if you are not receiving funding from an organization that is monitoring how your study is executed.*
* Safety monitors or committees may need the information to make sure that the study is safe. *Delete this bullet if you do not have an external safety committee or monitoring board.*
* Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study. *Delete this bullet if your study doesn’t involve billing for research procedures.*
* The researchers may need to use the information to create a databank of information about your condition or its treatment. *Delete this bullet if you are not creating a databank.*
* UW Madison Research Oversight Offices. *Delete this bullet if you are not a UW researcher.*

The results of this study could be published in an article but would not include any information that would let others know who you are.

### 10. Contact Information

## 10.1 Who can I contact about this study?

## Please contact the researchers listed below to:

* Obtain more information about the study
* Ask a question about the study procedures or treatments
* Report an illness, injury, or other problem (you may also need to tell your regular doctors) caused by this research.
* Ask about the storage and use of your identifiable information or identifiable *{insert name of biospecimen if applicable, for example cord blood and placenta}* sample(s) and your rights. *You may delete this bullet if it doesn’t apply to your research.*
* Leave the study before it is finished
* Express a concern about the study

Principal Investigator:

Mailing Address:

Telephone:

Study Coordinator:

Mailing Address:

Telephone:

You may also express a concern about a study or find out about your rights as a research subject by contacting the– Meriter Hospital, Inc. Institutional Review Board at:

**608-417-6411**

Meriter Hospital, Inc.

202 South Park Street

Madison, WI 53715

*When you call or write about a concern, please provide as much information as possible, including the name of the researcher and details about the problem. This will help Meriter Hospital, Inc. officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

### 11. record of Information provided

**11.1 What documents will be given to me?**

Your signature in the next section means that you have received copies of all of the following documents:

This Consent document to be Part of a Research Study.

*Note: A copy of this document will be stored in a separate confidential research file.*

*We will /will not enter this consent into your medical record.*

Other (specify):

### 12. SIGNATURES

**Research Subject:**

I have discussed this study, its risks and potential benefits, and my other choices. My questions so far have been answered. If I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I will receive a copy of this form at the time I sign it and later upon request. If my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: Date:

Subject Name (Print legal name):

Date of Birth:

Person Explaining Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Explaining Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Legal Representative (if applicable):**

Signature of Person Legally

Authorized to Give Consent Date:

Name (Print legal name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address:

Check Relationship to Subject:

Parent Spouse Child Sibling Legal Guardian Other:

**Researcher: Enter a signed copy of this consent in the subject’s electronic medical record.** Use the same method you would use for other signed consent forms.