**Medical College of Wisconsin**

**AUTHORIZATION TO COLLECT, USE, AND SHARE HEALTH INFORMATION IN RESEARCH**

***Only the institution(s) at which the project is planned to occur should be listed below.*** *Please note, this section is for the institution involved rather than individual sites covered under the below institutions at which minor activities may occur.*

Froedtert Menomonee Falls Hospital

Froedtert West Bend Hospital

Froedtert and The Medical College of Wisconsin Community Physicians, Inc.

Froedtert Hospital

Medical College of Wisconsin

<Title>

<Principal Investigator>

<Department>

<Telephone Number>

* Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee WI 53226

OR

* Froedtert Hospital

9200 W. Wisconsin Avenue

Milwaukee, WI 53226

The purpose of this form is to give your signed written permission to the research team to collect, use, and share your health information in accordance with the details contained in this form.

### **PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION**

**E1. What health information will be collected and used for this study?**

To be in this research study, the study team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the study.

Health information from your medical record known as protected health information (PHI) comes from services you will or have received at one or more of the following locations: Medical College of Wisconsin (MCW); Versiti, Inc.; Children’s Wisconsin (CW); any Froedtert Health Affiliate- Froedtert Hospital (FH), Inc.; Froedtert Menomonee Falls Hospital; Froedtert West Bend Hospital;  Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

**The health information to be collected and used for this study is described below:**

***List here the types of information to be collected or used for the research study, including the time period from which they were collected.***

* [Medical records of the care you receive for this study]
* [Medical records dating from when you join this study until you die]
* [CT scan taken when you were first diagnosed with <specific disease/condition>]
* [Past medical records related to care and treatment of your disease/condition]

## E2. Who will see the health information collected for this study?

The only MCW/Froedtert Hospital/Versiti, Inc. employees allowed to handle your health information are those on the study team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital’s rules are followed and only where necessary billing personnel if the cost of any treatment during the study is to be billed.

***Delete this section if no one outside MCW/FH will access identified data***

The study team may share your information with people who don’t work at MCW/Froedtert Hospital/Versiti, Inc. because they planned, pay for, or work with us on this study. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital/Versiti, Inc. For this study, we plan to share information with those doctors, researchers or government representatives working with us on this study at the institutions or companies listed here:

***Here list*** (***name), institution, city and state for each sponsor or collaborator needing access to identified data or source records. It is NOT necessary to list Sponsors who do not need access to data or source records.***

***The information in this section should be specific, but the following inclusive phrases (or equivalent) may be used:***

- “Sponsor” includes any persons or companies that are working for or with the sponsor or are owned by the sponsor

- Government agencies in other countries that monitor [research, research drugs, etc.] for those countries

 [Industry Sponsor, City, State]***(Delete if not applicable)***

 [CRO, City, State]***(Delete if not applicable)***

 [Multisite Coordinating Center, City, State]***(Delete if not applicable)***

 [NCI Cooperative Group, City, State]***(Delete if not applicable)***

 [Dr. X, Y University, City, State*]* ***(Delete if not applicable)***

In addition, if the cost of any treatment arises out of the study is required to be billed to insurance, we will need to disclose to the insurer for those purposes.

***If the study involves drugs or devices, please insert the following:***

Because this study involves the use of drugs, devices, and/or biologics the FDA also has the right to inspect all study records.

***The following two paragraphs are required if data and/or biospecimens are being collected as part of the research.***

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record or Versiti, Inc. blood donor record.  As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your health information for a different study without your permission or the permission of a research review board (IRB). Once all personal identification is removed from your health information and/or biospecimens, the information and/or biospecimens may be used for future research studies or released to another investigator for future research studies without additional permission or consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the study may be presented in public talks or written articles, but no information will be presented in any way that identifies you.

**E4. How long will you keep the health information for this study?**

If you sign this form, we plan to keep your information [for xxx years / for 10 years after the research study ends / without any end-date] in case we need to check it again for this study.

## E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to <Principal Investigator> at *specify address*. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study.We may still have to use the information we have already collected.

E6. Access to clinical records

***Insert this section if access to records will be prohibited for reasons other than blinding***

You may not be able to see, or copy, your project-related health information until after the project has been completed; otherwise, it could affect the study. *[The following text may be deleted, but it cannot be edited.]* <<You may ask the <researcher/ research doctor/ research director> for updated information on what data he/she has recorded for you, and you can request corrections of any errors in the recorded data.>>

**AUTHORIZATION TO COLLECT, USE, AND SHARE HEALTH INFORMATION**

**By signing my name below, I confirm the following:**

* I have read (or had read to me) this entire authorization document. All of my questions have been answered to my satisfaction.
* I agree to let the study team use and share the health information and other information gathered for this study as described in this form.

**IMPORTANT:** You will receive a signed and dated copy of this authorization form. Please keep it where you can find it easily.

***Signature line instructions:***

*Generally the subject's signature is sufficient. Thus, the following signature lines are* ***optional*** *to include: Legally Authorized Representative, Witness, Principal Investigator or designated representative. These should only be included when the Investigator chooses to include them, or when required by the Sponsor.*

***Date or Date & Time: Time is optional to include; if included, must be completed by each signer.***

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| --- | --- | --- |
|  |  |  |
| **Subject's Name** *please print*  | **Subject's Signature** | **Date** OR **Date**/**Time** |

|  |
| --- |
| **Consent of Parent(s)/Guardian(s) of Minor Subject**  |
|  |  |  |
| **Name of Parent/Guardian** *please print*  | **Signature of Parent/Guardian** | **Date or Date/Time** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Second Parent/Guardian** *please print* | **Signature of Second Parent/Guardian** | **Date or Date/Time** |
| **If the signature of the second parent/guardian cannot be obtained, please indicate the reason:**[ ]  Second parent/guardian is deceased[ ]  Second parent/guardian is not reasonably available[ ]  Second parent/guardian is incompetent[ ]  Only one parent/guardian has legal responsibility for the care and custody of the minor[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Legally Authorized Representative, if applicable***please print*  | **Signature of Legally Authorized Representative** | **Date** |
|  |  |
| ***Name of Subject*** *please print* | ***Relationship to Subject*** *(e.g. Court-appointed guardian, healthcare power of attorney, next of kin, etc.)* |

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| **Name of Witness, if applicable** *please print* | **Signature of Witness** | **Date** |
| **Rationale for Use of Witness**[ ]  Subject has limited/no literacy[ ]  Subject has limited English proficiency[ ]  Subject has limited/no vision | [ ]  Sponsor requirement[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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|  |  |  |
| **\* Name of person discussing/ obtaining consent** *please print*  | **Signature of person discussing/obtaining consent** | **Date** |

*\* A member of* *the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol.* *The Principal Investigator is responsible and accountable for the research project.*

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| **Name of Principal Investigator** *please print* \_\_ I participated in consent process\_\_ I acknowledge enrollment of this subject into the project | **Signature of Principal Investigator** | **Date** |

***Attachment 1 is optional. Delete if not needed***

Attachment 1 – Details of project schedule and procedures