*This form should be used for minimal risk research when a subject reaches the age of majority while enrolled in a research project and the remaining activities do not warrant a full consent form be signed.*

*Please note, the reviewing IRB and/or the Sponsor have the authority to request a full consent form rather than this form, which is considered an alteration of consent.*

**Instructions**

To stand out both on your computer screen and in black/white copies, instructions are in bold, italic, and blue type. Instructions are in gray boxes and should be deleted in final consent.

IRB-required template language is in black type and should not be changed.

Rarely, changes to the required language may be necessary. To petition for a change in required language, submit proposed changes with justification on the “ICF Template Change Form” to the IRB office.

Sample language, which can be used, modified, or deleted as appropriate for your project, is in blue type. Please maintain the blue color to distinguish your project-specific information from the required template language.

* Arrows are used to show alternative choices. In the final consent, arrows can be deleted and the usual margin maintained.

**<Medical College of Wisconsin><Children’s Wisconsin>**

**CONSENT FORM FOR CONTINUED PARTICIPATION IN RESEARCH**

<Title>

<Principal Investigator>

<Department>

<Telephone Number>

Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee WI 53226

(*insert if research activities are occurring at CW*)

Children’s Wisconsin

8915 W Connell Ct

Milwaukee, WI 53226

You are currently enrolled in a research project [titled <Title>/because you have…>. Permission for you to take part in this project was given by your parent(s)/guardian(s) when you were a child. Now that you have reached the age of majority and are considered an adult, we are asking for your consent for continued participation.

***Insert brief overview of project and a description of the subject’s status.***

E.g. “You are currently in the follow-up phase of the project…”

***Insert any additional relevant details relating to the subject’s continued participation at age of majority.***

E.g. <Specify biospecimen(s)> may have already been sent for testing as part of this project. <Your samples can be identified as belonging to you, so they can be removed if you prefer not to have the researchers continue to use them. OR Your <specify biospecimen(s)> is/are no longer identified as yours, so it is not possible to remove it/them from the project.

***Insert appropriate decision choices – the option should not be provided if it is known that samples are no longer identified. This section may be duplicated to address multiple decisions.***

|  |
| --- |
| Initial next to the appropriate statement(s) to indicate your decision |
| **INITIAL** | I AGREE to continue to allow researchers to use my identifiable samples for research purposes. I understand that I can change my mind about participation at any time, and that samples that have already been used cannot be retracted.  |
| **INITIAL** | I DO NOT AGREE to have my identifiable samples stored for future research purposes. I request that my samples be destroyed at the facility where they are presently being stored. I do understand that samples that have already been used cannot be destroyed.  |

***Delete the following section if no identified health information has been or will be collected about the subject.***

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

**What health information will be collected and used for this project?**

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. 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 project.

***If any of the health information to be collected comes from care or services received at a MCW/FH hospital or clinic or from Versiti, Inc., please include the following. If not, please delete. You must include the entire paragraph or nothing at all; please do not edit the phrase or delete the names of some institutions.***

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the 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 we will collect and use for this project is:**

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

* Health information collected during this project, such as, questionnaires
* [Medical records dating from when you join this project until you die]
* [CT scan taken when you were first diagnosed with <specific disease/condition>]

**Who will see the health information collected for this project?**

The only people allowed to handle your health information are those on the research team at MCW/Froedtert Hospital/Versiti, Inc./CW [and at <Community Organization>], those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital’s rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

***Delete this paragraph if no one outside the MCW/FH/Versiti, Inc./CW study team will access identified data***

The research team may share your information with people who are not part of the research team because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital/Versiti, Inc./CW. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project 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)***

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

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

***If research project involvement does not require any clinical tests or procedures at MCW or FH or Versiti, Inc. or CW, and no research information would appear in any MCW/FH/CW medical record, the following paragraph can be deleted.***

We may record your research information, including results of tests, procedures or questionnaires done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record and/or Children’s 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.

***The following paragraph is required for projects occurring at CW.***

A copy of this signed consent/assent and HIPAA authorization will be placed in your Children's Hospital medical record.

***The following paragraph is required if data and/or biospecimens are being collected as part of the project.***

We will not use your personal health information for a different project without your permission or the permission of a hospital 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 or distributed to another investigator for future research without additional informed 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 project may be presented in public talks or written articles, but no information will be presented that identifies you.

**What are the risks of sharing this health information?**

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. If you have questions, you can talk to the research doctor.

**How long will you keep the health information for this project?**

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

**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, wemay/will decide that you cannot continue to be part of the project.We may still use the information we have already collected.

**Access to records**

***Insert this section if access to records will be prohibited***

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 research doctor for updated information on what data he/she has recorded for you, and you can request corrections of any errors in the recorded data.>>

**WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?**

* If you have more questions about this project at any time, you can call <Principal Investigator> at <Telephone number>.
* If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844 or Children’s Wisconsin Human Research Protection Program at 414-337-7133.

***.***

**CONSENT TO CONTINUE PARTICIPATING**

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

* I have read (or had read to me) this entire document, including Attachment 1.
All of my questions have been answered to my satisfaction.
* The project’s purpose, procedures, risks and possible benefits have been explained to me in the main consent form for this project.
* I agree to continue letting the research team use and share the health information and other information gathered for this project.
* I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

**IMPORTANT:** You will receive a signed and dated copy of this document. Please keep it where you can find it easily. It will help you remember what we discussed today.

***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.***

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

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **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.)* |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **\* 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** |

**WITHDRAWAL FROM CONTINUED PARTICIPATION**

I **DO NOT AGREE** to continue my participation in this research PROJECT. I am withdrawing my consent for participation in this project.

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

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

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **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.)* |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **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.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **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