*This template is for projects involving clinical intervention where the MCW IRB defers review to another IRB. The language within this template should be inserted into the applicable areas of the reviewing site’s consent template.*

**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.

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

Language in blue type can be used, modified, or deleted as indicated in the instructional text of each section. 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**

<Title>

<Principal Investigator>

<Department>

<Telephone Number>

Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee WI 53226

**Summary of Procedures:**

***Include the following if research involves infectious disease testing, donating a unit of blood in any Versiti, Inc. donor room, or undergoing apheresis.***

As part of the procedure for donating a unit of blood, your blood will be tested for diseases that can be passed on to other people by transfusion, including AIDS (the disease caused by the HIV virus), syphilis, hepatitis B, hepatitis C and others. If certain tests are positive, Versiti, Inc./we will/may inform you, put your name on a list of ineligible donors, and inform certain government health agencies as required by law. Results of your blood test will be released only to authorized persons as governed by Wisconsin law. A list of persons to be notified and reasons that will cause release of your blood test is available upon request. Results of the blood test will be released to Versiti, Inc. physicians and their assistants/ <<insert appropriate parties>>. Abnormal test results of active military personnel will be forwarded to the military medical authority of the base to which you are assigned, as required by the Department of Defense.

***Include the following or equivalent if the main research project involves genetic testing or whole genome sequencing of biospecimens.***

GENETIC TESTING

In this project, we will do genetic testing on your <specify biospecimen(s)>. Whole genome sequencing may/will be included as part of the genetic testing for this research. This will be collected <identify method and timeframe>. Genetic testing will be done because <include reason for genetic testing>. [insert additional information regarding specific genetic testing occurring in the project.]

This genetic testing is for research only. The purpose is not to discover information that could be used to change your medical care, make or change your diagnosis, or advise you on your risk of diseases.

***Include the appropriate option based on the level of identification.***

Information that can identify you [will / will not] be attached to your <specify biospecimen(s)> // The <specify biospecimen> collected for this part of the project will be coded, which means it will be labeled with numbers and/or letters instead of information that could identify you. Only the research team will be able to link the code to you. 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. Depending on the kind of information being collected, it might be used in a way that could embarrass you.

It is against federal law (Genetic Information Nondiscrimination Act, or GINA) for health insurance companies to deny health insurance, or large employers to deny jobs, based on your genetic information. But the same law does not protect your ability to get disability, life, or long-term care insurance.

***Will the results be given to the subject? Choose one statement and delete the other. If the project allows the subject to receive the genetic test results, allow the subject the choice not to receive them.***

You will not be given your genetic test results.

You will be given your genetic test results. // You will be given the results of [insert test(s)], but you will not be given the results of [insert test(s)]. Dr. <PI> can arrange for you to meet with a genetic counselor. You can request that Dr. <PI> give it to relatives, your personal doctor, insurance companies, etc.

Initial if you do NOT want to receive your genetic test results:

\_\_\_ I do not want to receive my genetic test results.

My decision about the genetic research *[This section may be removed only if genetic testing is a mandatory aspect of the project.]*

***If the subject can still participate in the project whether or not they allow genetic testing, use this set of choices:***

|  |
| --- |
| Initial next to the appropriate statement(s) to indicate your decision |
| **INITIAL** | I do not want genetic testing done on my <blood or specimen> in this project. This means I can still participate in the project.  |
| **INITIAL** | I agree to have genetic testing done on my <blood or specimen> in this project. |
| **INITIAL** | I give Dr. <PI name> permission to give my genetic test results to: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

***If the subject can NOT participate in the project if refusing genetic testing, use this set of choices:***

|  |
| --- |
| Initial next to the appropriate statement(s) to indicate your decision: |
| **INITIAL** | I do not want genetic testing done on my <blood or specimen> in this project. This means I cannot participate in the project. **Stop here** and speak to Dr. <Physician Name>. Do not sign this form. |
| **INITIAL** | I agree to have genetic testing done on my <blood or specimen> in this project. |
| **INITIAL** | I give Dr. <PI name> permission to give my genetic test results to: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

***Will the results be given to the subject? Choose one statement and delete the other. If the project allows the subject to receive the genetic test results, allow the subject the choice not to receive them.***

You will not be given your genetic test results.

You will be given your genetic test results. // You will be given the results of [insert test(s)], but you will not be given the results of [insert test(s)]. Dr. <PI> can arrange for you to meet with a genetic counselor. You can request that Dr. <PI> give it to relatives, your personal doctor, insurance companies, etc.

|  |
| --- |
| Initial if you do NOT want to receive your genetic test results: |
| **INITIAL** | I do not want to receive my genetic test results |

***This template section is to be inserted into the consent form of the main project when banking health information/biospecimens only at a location outside of MCW/Froedtert Hospital (“distant banking”). If banking at MCW/FH, a separate Banking consent form must be used. See the Banking policy for further details.***

***Language in blue text indicates a choice between templated options and/or text that can be edited to specify information. Sections that contain multiple options for required text are in black text, but the options are separated with blue slashes to signal a decision.***

**Optional Project(s)**

**WE WOULD LIKE TO BANK YOUR [HEALTH INFORMATION/SPECIFY BIOSPECIMEN(S)] FOR FUTURE RESEARCH**

“Banking” is storing health information and/or biospecimens for future research projects. A “bank” is the place where it is stored. [PI]/[Sponsor] wants your permission to bank <your health information/your <specify biospecimen(s)>> which were gotten during the main project. // <leftover <specify biospecimen(s)> from the main project> // <specify biospecimen> which will require [insert procedure] only for the purpose of this bank>.

The purpose of the bank is to <collect as much data and/or biospecimens as possible for future research // [insert other reason for banking]>. [PI]/[Sponsor] would like you to take part in this bank because you have [specify disease or condition].

***Blue bullet points contain text that may be deleted if not applicable. If the information is applicable to the project, the text is required.***

**BANKING DETAILS**

* You are free to say yes or no. <No matter what you decide, you can still take part in the main project. // If you decide not to take part in the bank, you cannot take part in the main project.>
* Include the risks of additional procedures performed only for the purpose of the banking: [Insert procedure] is an extra procedure not part of the main project. There [is/are] a [small/high] risk(s) of [state risk of procedure(s)] when collecting your [specify biospecimen] for banking.
* <Data/Biospecimen(s)> will be kept at <insert name of bank and location> for <insert timeframe>. // Since the purpose of this bank is to answer questions in the future, your data and/or samples will be kept for a long time, maybe forever.
* Samples may be transferred to the research sponsor, its collaborators, research partners, designees, or other relevant third parties who may analyze the samples in connection with this project.
* If you agree to allow your <specify biospecimen(s)> to be banked, there is a chance that it/they may be used to study genetic material. Genetic material, or genes, are made up of DNA, and contain all the information which is passed on in families. These projects may look at differences in genetic material that might influence the likelihood of developing a certain disease, or of responding to specific drugs or treatment.
* <Sponsor, other researchers, or research companies> // <Other researchers or research companies> may patent or sell products, discoveries and data or information that result from this research. <Neither the Sponsor nor the <PI> will> // <The PI will not> pay you if this happens. You will not receive any payment or commercial rights for products, data, discoveries, or materials gained or produced from your <health information/specify biospecimen(s)>.
* If you withdraw your consent to take part in the project, you may also request that your <health information/specify biospecimen(s)> be destroyed if they have not yet been used. This request should go through your <researcher/ research doctor/ research director>. Any information processed from your <health information/biospecimen(s)> that occurs before you withdraw your consent will be used by the research sponsor. Insert the following if applicable: <Since your <health information/specify biospecimen> is at <name of bank/laboratory/repository> we cannot guarantee that this will happen.> <If your <health information/ specify biospecimen(s)> is/are no longer identified as yours, it is not possible to remove it/them from the bank.
* If health information/biospecimen(s) sent is/are IDENTIFIED or CODED, insert: Your <health information/specify biospecimen(s)> will be sent to [name of bank] with some personal details. Personal identifiers such as [specify identifiers (e.g. dates, initials, hospital numbers)] could identify you. <Your information will be protected with a code, and only [PI/research team] will have the information to reidentify your data/biospecimens once it/they is/are sent to [bank].> One risk of taking part in research is that more people will handle your personal health information. It is possible that an unauthorized person might see it. If some records include genetic information, it is against federal law for health insurance companies to deny health insurance, or large employers to deny jobs, based on your genetic information. But the same law does not protect your ability to get disability, life, or long-term care insurance. If you have questions, you can talk to the <researcher/ research doctor/ research director> about whether this could apply to you.

If health information/biospecimen sent is ANONYMOUS, insert: Your <health information/specify biospecimen(s)> will be sent to <name of bank> with no personal details, so that researchers at <name of bank> will not know who you are.

**MY DECISION ABOUT THE BANKING PROJECT**

***Insert appropriate decision choices. This section may be duplicated to address multiple decisions.***

Initial either 1 or 2:

|  |
| --- |
| Initial next to the appropriate statement(s) to indicate your decision |
| **INITIAL** | I do NOT want to bank my <health information//biospecimen(s)> in this project. This means I can still participate in the project. // This means that I CANNOT participate in the main project. **Stop here** and speak to Dr. <Physician Name>. Do not sign this form.  |
| **INITIAL** | I agree to bank my <heath information//biospecimen(s)>. |

***If billing for Froedtert services, you must consult with the Office of Clinical Research and Innovative Care Compliance (OCRICC) to determine whether any site-specific language is required in this section.***

**COSTS TO SUBJECTS**

*It is acceptable to use the language provided by the IRB of record.*

***The injury language contained below must be used in its entirety without any additions, or an approved MCW template change request form must be submitted with the reliance request.***

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the <researcher/ research doctor/ research director> right away. Contact information: <PI>, <telephone number>

**Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.**

***The contact language below may be added to the Sponsor’s/coordinating site’s contact information section.***

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.

***The language contained in the “PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION” must be used in its entirety without any additions except for when specific language is used to replace sample blue language, or an approved MCW template change request form must be submitted with the reliance request.***

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.

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 to be collected and used for this project is:**

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

* [Medical records of the care you receive for this project]
* [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 MCW/Froedtert Hospital/Versiti, Inc. employees allowed to handle your health information are those on the research 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.

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 MCW/FH will access identified data***

The research 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 project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital/Versiti, Inc. 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.

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 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 <researcher/ research doctor/ research director>.

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, we may/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 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 project. ***[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.>>

**CONSENT TO PARTICIPATE**

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

* I have read (or had read to me) this entire consent 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.
* I agree to let 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 consent form. 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.*

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

*For projects involving minors, include the applicable signature lines.*

|  |
| --- |
| **Assent of Minor Subject (17 years old or younger)** |
|  |  |
| **Documentation of Assent***Documentation is not specific to a cursive signature and may include whatever the child’s mark is* | **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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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

Attachment 1 – Details of project schedule and procedures