*This template is for projects where a subject was enrolled as a minor and must be consented at the age of majority. The template provides guidance for sections that may be deleted if the active participation has ended (i.e. identified data analysis is the only remaining activity).*

*This consent/assent template can be used for both consent of parent(s) and assent of minors. Generally this template is acceptable to assent minors ages 14-17 years old. For minors younger than 14, a separate assent form is typically used.*

*According to Wisconsin State Law, minors are persons under the age of eighteen. Investigators overseeing research outside of the State of Wisconsin should be aware that age of majority varies according to State Law.*

*Additional modules for special cases can be found on the IRB website.   
These modules can be inserted into the appropriate project-specific text boxes.*

**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.

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 study-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>**

**INTRODUCTION TO THE INFORMED CONSENT**

Name of Subject: ­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<Title>

<Principal Investigator>

<Department>

<Telephone Number>

Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee WI 53226



Children’s Wisconsin

8915 W Connell Ct

Milwaukee, WI 53226

**Definitions**

[*Include a brief list of definitions in this text box that will assist in subject understanding. This should include some of the most common words that subjects will hear or read throughout their participation in the project.*]

**SGN-CD123A** – SGN‑CD123A is a type of drug called an antibody-drug conjugate or ADC. ADCs usually have 2 parts; a part that targets leukemia cells (the antibody) and a cell-killing part (the chemotherapy).

**Word** – definition

**Word** – definition, etc.

**Procedures/Activities**

[You may insert a brief introduction. E.g. There are two groups in this project. You will be enrolled in one of the two groups based on…]

**List of visits:**

*[Option 1 formatting]*

* [Screening Visit]
  + Total Number: \_\_\_\_
  + Total Time: \_\_\_\_
* [Baseline Visit]
  + Total Number: \_\_\_\_
  + Total Time: \_\_\_\_
* [Etc. (Duplicate based on visit type)]
  + Total Number: \_\_\_\_
  + Total Time: \_\_\_\_

*[Option 2 formatting]*

* <You will have/this project involves> x number of visits.
* Depending on the type, each visit may last anywhere from x to x hours.

**Procedures/Activities that will occur at various visits:**

**Invasive Procedures/Activities**

* [Briefly list most invasive and intensive procedures. E.g. drug administration, blood sample collection, bone marrow collection]

**Non-invasive Procedures/Activities**

* [Briefly list less invasive procedures. E.g. Full medical history exam, urine sample collection, physical exam, and questionnaires]

**Risks**

This is a brief list of the most commonly seen side effects/risks. The ***full consent form*** after this introduction contains a more complete list of potential research risks.

**[Drug/Device/Intervention] risks:**

* [Insert list of most common risks related to the research]

**Length**

* You will be in this research project for about…[estimated length of time of subject’s involvement]. / Research activities will occur for…[estimated length of time].
* We would also like to follow you for [estimated length of time of follow-up].

**Purpose**

This project is being done to…[insert brief purpose]

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 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 Office at 414-337-7133.

**My Other Options**

You do not have to join this project. You are free to say yes or no.

* Whether or not you join this project, you are free to seek services from this or other agencies.
* Whether or not you join this project, your usual medical services will not change.

**Benefits**

This project [will not/may or may not] help you, but we hope the information from this project will [help us develop a better treatment for x… or help us provide better health services for x….]

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

***Describe reason(s) for subject participation, such as diagnosis and eligibility.***

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.

***The number of subjects can be any or all of the following depending upon the specific project: local enrollment, total enrollment, or enrollment by arm.***

A total of about xx people are expected to participate in this research [nationally / world-wide / all at / including about xx at] the Medical College of Wisconsin/Froedtert Hospital/Versiti, Inc./Children’s Wisconsin.

The Director of the project is <Principal Investigator> in the <Department of XYZ>. A research team works with <Principal Investigator>. You can ask who these people are.

***List any funding source for the project, including departmental or internal funding:***

The <research doctor and/or [*Institution*]> will be paid by the Sponsor, [*insert Sponsor name*] for carrying out this project.

***If a financial conflict of interest needs to be explained, state it here.***

***For example:*** <Funding source> is funding this research. <PI name> receives financial support from <funding source.>

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. [If you do not agree to join, or if you leave, you will not be penalized or lose any benefits that you had before starting the research project.] Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A3. WHY IS THIS PROJECT BEING DONE?

***Describe the purpose of the research. While you may phrase the purpose in a way lay people may understand, do not be evasive about the real purpose.***

The purpose of this project is [to test whether a nutrition program we have developed leads people to eat healthier.]

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

***Insert this section if the only remaining activity is identified data analysis:***

You completed all research activities when your parent(s)/guardian gave permission for you to join the project. The only activity is reviewing information collected during the project.

***Describe the project procedures clearly and simply. This description should be separated into an abbreviated list of activities that have already occurred (if applicable) and a description of the activities that will occur after the subject reaches the age of majority.***

* ***Begin with screening procedures, if any.***
* ***Describe the groups and randomization, if it applies.***
* ***Include the duration of each visit or procedure***
* ***Specify what is for research purposes versus clinical purposes***

***State if video or audio recording is involved, and how recordings will be used.***

***Insert this section if you wish to provide subjects with information about key-coding:***

For this project, the research team will assign you a unique code, such as a series of numbers and/or letters. When sending your project data to [the Sponsor], the research doctor will use your unique code instead of other information that could easily identify you.

The data that is recorded with your unique code rather than your name is called “key-coded data”. The research doctor will keep a confidential list linking your name to your code and only the research doctor and authorized research team members will have access to this list.

Some study data will identify you (such as medical records), and the ways this data may be used and shared is described later in this form.

***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 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.

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 others. 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 |

***Insert the below language or equivalent if subjects are given the option of notifying a primary care physician or specialist. Please note, this information may be required by a Sponsor if a project follows ICH-GCP guidelines.***

**PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OPTION**

|  |  |
| --- | --- |
| Please indicate below whether you want us to notify your primary care physician or your specialist or your participation in this project. | |
| **INITIAL** | Yes, I want the <<research doctor/researcher/research director>> to inform my primary care physician / specialist of my participation in this project. |
| **INITIAL** | No, I do not want the <<research doctor/researcher/research director>> to inform my primary care physician / specialist of my participation in this project. Please note, this may not be possible depending upon the information placed in your electronic medical record as part of the project. |
| **INITIAL** | I do not have a primary care physician / specialist. |

***Insert the below language or equivalent if applicable.***

We are requesting your email address so we can stay in touch with you throughout the project. This may include setting up clinic visits, sending project-related reminders, or answering any general questions you may have. Email is generally not a secure way to communicate about your health because there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact <Principal Investigator> at <Telephone number>. You do not have to provide your email address to participate in this project.

B2. HOW LONG WILL I BE IN THE PROJECT?

***Modify as needed regarding subject’s involvement.***

* You will be in this research project for about [estimated length of time of subject’s involvement].
* After your visit(s) to the health facility is finished, we want to keep in touch with you to follow your health over time. We will telephone you / ask you to come in to the health facility [once a month, once a year] [for the next year] and ask about ….
* Since it is possible that you will become a legal adult while enrolled in this project, we will ask for your permission to continue participating in the project once you turn 18.

B3. CAN I STOP BEING IN THE PROJECT?

***Modify as needed for the project.***

You may stop at any time. If you decide to leave the project, please let the research team know.

The research doctor may stop your participation in the study at any time for any reason without your consent. He / She will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

***The following paragraphs may be deleted if the only remaining activity is identified data analysis:***We watch everyone in the project for unexpected problems [side effects]. **You need to tell the research [director/doctor] or a member of the research team immediately if you experience any problems [or become too upset].**

***Describe the risks of any project procedures. Some examples are listed below:***

* **Questionnaires:** You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. [If you become upset, please let us know and we can…provide names of counselors…**OR** give you information about individuals who may be able to help you…]
* **Blood Draw:** The side effects that you might experience as a consequence of donating a blood sample for this project include possible discomfort and bruising at the needle entry site. Rare complications of any venipuncture (drawing blood from a vein) include fainting, arterial puncture, peripheral nerve injury, local infection, and local blood clot. There may be other unanticipated risks, but every precaution will be taken to assure your personal safety and to minimize discomfort. The person drawing your blood will observe you for side effects, but please inform him or her if you experience any discomfort or feel faint.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. If you have questions, you can talk to the project director about whether this could apply to you.

***The following paragraph is the only one that should remain if the only remaining activity is identified data analysis:***

The only remaining risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. If you have questions, you can talk to the project director about whether this could apply to you.

***Include section only if reproductive risks remain following a subject’s completion of research-related procedures.***

C2. REPRODUCTIVE RISKS

**Risks to subjects who could become pregnant**

***Include section only if applicable to the project.***

We do not know if the [drug(s) / intervention] cause(s) harm to a baby, so we do not want anyone who might be pregnant to enter the project. // We know the [drug(s) / intervention] in this project affect(s) babies, so we do not want anyone who might be pregnant to enter the project.

You should not become pregnant or nurse a baby while in this project. You must tell the research doctor right away if you think you are pregnant. You will be asked to have a pregnancy test to be sure you are not pregnant at the start of the project /and during the project / and at the end of the project.

***Include section only if applicable to the project.***

[Results from animal studies may be inserted here]

***Include section only if applicable to the project.***

<Some medications may be present in human milk; therefore, if you are breastfeeding you cannot take part in this project.>//<It is unknown if the research drug can harm a nursing baby.>

***Include section only if applicable to the project.***

You may not donate eggs during your participation in the project or for XX days/months after stopping the [drug/intervention].

***Include section only if applicable to the project.***

If you become pregnant during the project, <you will be withdrawn from participation for safety reasons/the research drug will be stopped for safety reasons>. If you become pregnant while you are taking this experimental drug [or within xx days after you have stopped taking it,] we ask that you inform the research doctor immediately. The research doctor will ask you for written permission to obtain information from you or your obstetrician on your pregnancy and the health of the baby.

***Include section only if applicable to the project.***

You should discuss future fertility planning with the research doctor.

**Risks to a** **subject who could father a child and the subject’s partner(s)**

***This risk does not need to be included unless there is evidence or concern that the drug causes paternity-related birth defects, or unless required by a Sponsor. Modify as needed.***

If you and your partner(s) are able to become pregnant, one or both of you must use some form of effective birth control, because [it is unknown if [drug/intervention] could affect a baby // we know that the [drug/intervention] affects babies.] You must tell the research doctor right away if you think your partner is pregnant.

***Include section only if applicable to the project.***

[Results from animal studies may be inserted here]

***Include section only if applicable to the project.***

You may not donate sperm during your participation in the project or for XX days/months after stopping [drug/intervention].

***Include section only if applicable to the project.***

If you think you have gotten your partner pregnant while you are taking this experimental drug [or within xx days after you have stopped taking it], we ask that you inform the research doctor immediately. At that time, the research doctor will ask permission of your partner for the use and disclosure of health information regarding the pregnancy. Your partner will be asked to sign a separate consent form and can choose to do this or not. Your partner will be asked to sign this form to allow your research doctor to contact your partner’s obstetrician to collect information on the progress of the pregnancy and its outcome. The research doctor will make this information available to the sponsor for safety monitoring.

***Include section only if applicable to the project.***

You should discuss future fertility planning with the research doctor.

**Birth control methods for all subjects**

***Insert this section if needed and modify list as needed. The list of birth control methods may be separated into methods required for subjects who could become pregnant and subjects whose partner could become pregnant.***

Check with the research doctor about the birth control methods needed for this project and how long to use them. Some methods might not be good enough for this project. If you are having sex that could lead to pregnancy, you should use [one form/two forms/one form of highly effective/ two forms of highly effective/etc.] birth control while you are in this project.

This may include:

* Not having vaginal sex (abstinence)
* Taking birth control pills orally
* Having birth control shots or patches such as Depo-Provera
* Surgical sterilization (hysterectomy/tubal ligation or vasectomy)
* Limiting sexual activity to a partner who has undergone surgical sterilization
* Use of an intrauterine device (IUD)
* Use of diaphragm with contraceptive jelly
* Use of condoms with contraceptive foam
* Use of diaphragm with condoms (“double barrier”)

You should continue using birth control for xx months after stopping the TEST DRUG.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

***Choose one of these options and modify.***

* This project will not help you, but we hope the information from this project will help us develop a better treatment for x… or help us provide better health services for x….
* This project may or may not help you, but we hope the information from this project will help us develop a better treatment for x… or help us provide better health services for x….

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

***Outline clearly*** ***the activities/costs to be billed to subject / subject’s insurance company, and those to be paid by sponsor /Investigator. Froedtert Hospital cannot be identified as a funding source unless approved through the Office of Clinical Research and Innovative Care Compliance. Choose one of these options and modify:***

* There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact Dr. \_\_\_\_\_.
* The costs to you of being in this project are \_\_\_ [list as applicable]. If you have questions regarding costs, please contact Dr. \_\_\_\_.
* *Include only if D5 is applicable, otherwise delete:* If you participate in this research, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

***Describe amount to be paid and payment schedule, or state if none. Choose one of these options and modify:***

* You will be paid $xx after each visit for your time in completing the survey and the cost of parking or traveling by public transportation.
* To pay you, we need your social security number. **[if paid through MCW/FH]** Any payment may be reportable as income on your taxes.
* You will not be paid for participating in this project.

***Include this language if subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit***

* The research sponsor, other researchers, or research companies may patent or sell products, discoveries and data or information that result from this research. Neither the research sponsor nor <PI> will 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 biospecimens>.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

***Include only if applicable, otherwise delete.***

You do not have to join this project. You are free to say yes or no.

* Whether or not you join this project, you are free to seek services from this or other agencies.
* Whether or not you join this project, your usual medical services will not change

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

***Include only if new information (ex. risks, study results/outcomes, etc.) will be given to subjects, otherwise delete. Examples are listed below:***

* If we learn any important new information [about the intervention] that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.
* After the project has been completed, we will notify you of the results.

***If the results of any procedure or test performed as part of this research may yield clinically relevant results and will be shared with the subject, the following must be inserted:***

When research [data/biospecimens/images/etc.] is/are collected and analyzed , there is the chance of finding something clinically relevant. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

In this study, you will be informed of any findings of possible clinical significance that may be discovered during review of results from your research [data/biospecimens/images]. The results of your research [data/biospecimens/images] will/will not be placed in your medical record.

The results from the [data/biospecimens/images] we collect in this research study are/are not the same quality as what you would receive as part of your health care. The [data/biospecimens/images] will/will not be reviewed by a physician who normally reads such results. We will provide you with this information so that you may discuss it with your primary care physician.

[*Please include any additional conditions for disclosure.*]

***If the results of some procedures or tests performed as part of this research may yield clinically relevant results and will be shared with the subject, the following must be inserted:***

When research [data/biospecimens/images/etc.] is/are collected and analyzed, there is the chance of finding something clinically relevant. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

In this study, you will be informed of any findings of possible clinical significance that may be discovered during review of results from your research [data/biospecimens/images], but you will not be informed of the results from your research [data/biospecimens/images]. The results of your research [data/biospecimens/images] will/will not be placed in your medical record, [but the results of your [data/biospecimens/images] will not be placed in your medical record.

The results from the [data/biospecimens/images] we collect in this research study are/are not the same quality as what you would receive as part of your health care. The [data/biospecimens/images] will/will not be reviewed by a physician who normally reads such results. We will provide you with this information so that you may discuss it with your primary care physician.

[*Please include any additional conditions for disclosure.*]

***If the results of any procedure or test performed as part of this research may yield clinically relevant results and will NOT be shared with the subject, the following must be inserted:***

When research [data/biospecimens/images] is/are collected and analyzed, there is the chance of finding something clinically relevant. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

The results from the [data/biospecimens/images] we collect in this research study are not the same quality as what you would receive as part of your health care, so you will not be informed of any clinically relevant research findings. The results of your research [data/biospecimens/images] will not be placed in your medical record.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

***This section is only required for projects involving greater than minimal risk. However, if the project involves a medical intervention, it is recommended that this section be included.***

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 research doctors 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.**

**If the project is occurring at CW, insert the following language instead of the above*:***

Emergency medical treatment for injuries caused by your participation in this research project will be arranged for you. You or your health insurance may be billed for the costs of this emergency treatment. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer may 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 research doctors 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.

D6. 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.

***Delete section E if no identified health information will be collected about the subject.***

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. 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>]

E2. 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.

E3. 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.

E4. 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.

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

**E6. 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.>>

***Insert this section if applicable***

F1. FOR MORE INFORMATION ABOUT THE PROJECT

***If an FDA-regulated drug or device study, insert this section regarding required registration on ClinicalTrials.gov***

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can look up this project by referring to the ClinicalTrials.gov number (insert trial number) or by asking the research team for a printed copy.

***If the Sponsor plans to provide results on a website in addition to ClinicalTrials.gov, insert additional information about the other site(s).***

The project may also be registered on national registries, and a summary of results may be posted on publicly available databases (such as [insert website(s)]), if required by local laws or regulations.

**CONSENT/ASSENT 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.***

|  |  |  |
| --- | --- | --- |
| **Consent of Adult Subject (18 years or older)** | | |
|  |  |  |
| **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** |