*This is a template for banking: the collection of health information and/or biospecimens for future unspecified research, i.e., any purpose other than those specified in the study for which it was obtained.*

*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.*

**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 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>**

**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

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

Children’s Wisconsin

8915 W Connell Ct

Milwaukee, WI 53226

**Subject:** We are asking your permission to save some of your <health information/specify biospecimens> for research projects in the future. This form tells you what we would like to do and possible risks. If there is anything that you do not understand, please ask questions. Then you can decide if you want to join this project or not. If you are under the age of 18, your parent or guardian also needs to give their permission for you to join this project.

**Parent/Guardian**: We are asking your permission to save some <health information/specify biospecimen> from your child for research studies in the future. This form tells you what we would like to do and possible risks. If there is anything you do not understand, please ask questions. Then you can decide if you want to give permission for your child or not. The word “you” in this form refers to your child.

***Insert the sentence below IF the research has the possibility of uncovering child abuse or neglect, otherwise delete.***

The researcher is required by law to report child abuse or neglect (or suspicion of abuse or neglect) if you mention it to the researcher or if it is suspected.

**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 *or* 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/Your data and/or biospecimens will be in this bank for about…[estimated length of time of subject’s involvement].
* We would also like to follow you for [estimated length of time of follow-up].

**Purpose**

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

**My Other Options**

You do not have to join this bank. Your other options may include:

* Joining a different bank
* Not joining any bank

**Benefits**

There is no benefit to you for participating in this bank.

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.

CONSENT TO PARTICIPATE IN RESEARCH

A1. WHAT IS BANKING AND WHAT IS A BANK?

“Banking” is storing health information and/or blood or tissue for future research. A “bank” is the place where it is stored.

A2. WHY IS THIS BANKING BEING DONE?

[PI]/[Sponsor] wants your permission to bank your <health information/<specify biospecimen(s)>> for future research.

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>. In the future, other doctors and scientists at this and other medical and research centers may use your <health information/specify biospecimen> to learn about many different diseases and conditions. Their goal is to improve health and develop new treatments.

***If banking biospecimen(s), insert this paragraph; otherwise delete:***

If you agree to allow your <specify biospecimen> 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 studies 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.

A3. DO I HAVE TO BANK MY <HEALTH INFORMATION/SPECIFY BIOSPECIMEN(S)>?

You are free to say yes or no. Your decision will not change your current or future health care.

***Insert appropriate statement if there is a “main project”; otherwise delete.***

* [No matter what you decide, you can still take part in the main project, <Original Project Title>].
* [If you decide not to bank your <health information/specify biospecimen(s)> you cannot take part in the main project, <Original Project Title>].

***Delete this entire section and header if no biospecimens are being banked. Insert appropriate statement(s) as applicable.***

B1. WHAT SAMPLES WILL BE BANKED?

* <PI> will bank your leftover <specify biospecimen(s)> from [specify procedure… [This procedure was recommended by your doctor as part of your routine care for your condition and is not part of the research]. There is no extra physical risk to you as part of the bank.
* <PI> will take [an / \_\_ (number) additional sample(s) of your <specify biospecimen(s)> during [specify procedure] [from the main project] and bank [it/them]. [This procedure is part of your routine care and not part of the research]. [Describe extra physical risks incurred for biospecimen to be banked, if any.] [The amount of blood taken will still be within safety limits for you.]
* <PI> will bank your <specify biospecimen> which will require [insert procedure] only for the purpose of this bank.

***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.

***Delete this entire section and header if no health information will be collected or used.***

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

B2. WHAT HEALTH INFORMATION WILL BE BANKED?

To be in this bank, 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 bank. This information may come from questions we ask, forms we ask you to fill out, or from your medical record, as described below. We will only collect and use information needed for the bank.

***If any of the health information to be banked 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 bank is:**

* [Medical records of the care you receive during the main 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>]

B3. WHERE WILL MY <HEALTH INFORMATION/SPECIFY BIOSPECIMEN> BE BANKED?

<PI> will bank your <health information/specify biospecimen> at [MCW/Froedtert Hospital / Children’s Wisconsin/ Zablocki Veteran’s Hospital / Blood Research Institute / <other outside institution or laboratory>] along with samples of many other people.

B4. ARE THERE ANY SPECIAL INSTRUCTIONS?

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

[You should not take aspirin while taking this drug.]

C1. WHAT RISKS OR PROBLEMS CAN I EXPECT?

***If biospecimen will be collected only for banking******, describe the amount, procedures, and physical risks in obtaining the biospecimen:***

[Describe amount and collection procedure]. [This 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.

***If banked health information/biospecimen(s) is/are IDENTIFIED or CODED, describe the risks to confidentiality:***

Your <health information/specify biospecimen(s)> will be banked 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/study 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. 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. If some records include genetic information, it is against federal law (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.

***If banked information/biospecimen(s) is/are ANONYMOUS, describe the risks to confidentiality:***

Your <health information/specify biospecimen(s)> will be banked with no personal identifiers so that no one will know that it came from you.

C2. ARE THERE BENEFITS OF BANKING MY <HEALTH INFORMATION/SPECIFY BIOSPECIMEN(S)>?

There is no direct benefit to you. Other people might benefit if researchers learn more by using your banked <health information/specify biospecimen(s)>.

D1. WHAT ARE THE COSTS OF BANKING MY <HEALTH INFORMATION/SPECIFY BIOSPECIMEN(S)>?

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

***This sample can be modified:***

There are no costs to you or your insurance company for any of the procedures in this banking project, which are \_\_\_\_\_[list procedures such as blood draw, … ]. If you have questions regarding costs, please contact Dr. \_\_\_\_\_.

*Include only if D3 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 BANKING MY <HEALTH INFORMATION/SPECIFY BIOSPECIMEN(S)>?

***Describe amount to be paid and payment schedule, such as, if payment is pro-rated. Examples to be modified:***

* There is no payment for being in this project [but we will give you a parking voucher for free parking every visit, and a gift certificate for ….]
* You will receive [$] for each visit. [Describe payment schedule and total possible payment]. To pay you, we need your social security number. **[if paid through MCW/FH]** Any payment may be reportable as income on your taxes.

Your <health information/specify biospecimen(s)> will be used only for research. <PI> and <name of bank/laboratory/repository> will not sell any of it. <The research 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 research sponsor nor <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 biospecimens>.

***This section is required for projects involving greater than minimal risk or invasive procedures/interventions (such as a blood draw).***

D3. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE BANK?

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 <researchers/ research doctors/ 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.**

**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 <researchers/ research doctors/ 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.

D4. WHO CAN ANSWER MY QUESTIONS ABOUT THE BANK?

* If you have more questions about this bank 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.

E1. WHO WILL SEE MY HEALTH INFORMATION?

The only MCW/Froedtert Hospital/Versiti, Inc./CW 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.

***Delete this paragraph if Section D3 is not applicable and has been deleted.***

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/Versiti, Inc./CW will access identified data***

The research team may share your information with people who don’t work at MCW/Froedtert Hospital/Versiti, Inc./CW 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 records.

***Insert the following paragraph if applicable:***

If we share your <health information/specify biospecimen> with other research groups outside of <MCW/Froedtert Hospital/Versiti, Inc./CW>, your personal identifiers will be removed so that no one will know that it came from you.

***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 bank.***

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, the information might 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.

E2. HOW LONG WILL MY <HEALTH INFORMATION/SPECIFY BIOSPECIMEN(S)> BE BANKED?

***Insert appropriate statement and delete the other.***

Your <health information/specify biospecimen> will be banked for \_\_\_ [insert number] years [after the project is over, which we expect will be \_\_\_ [insert year]. // The purpose of the bank is to answer questions in the future, so we expect to keep your <health information/specify biospecimen> for a long time, maybe forever.

Since it is possible that you will become a legal adult while enrolled in this bank, we will ask for your permission to continue banking your <health information/specify biospecimen(s)> once you turn 18.

E3. CAN I REMOVE MY <HEALTH INFORMATION/SPECIFY BIOSPECIMEN(S)> ONCE IT IS/THEY ARE BANKED?

***Insert if health information/biospecimen(s) is/are identified:***

If your <health information/specify biospecimen(s)> is/are still identified as yours, you can have it/them removed or destroyed by contacting <PI> in writing at specify address.

***Insert if health information/biospecimen(s) is/are identified (by identifiers, codes or double-coding):***

You can contact <PI> in writing at specify address and ask to have your <health information/specify biospecimen> removed from the bank or destroyed. [Because your sample is identified by a code / double-code, it can be destroyed even though the bank does not know your identity.] Since your <health information/specify biospecimen> is at <name of bank/laboratory/repository> we cannot guarantee that this will happen.

***Insert if health information/biospecimen is not identified:***

No. Your banked <health information/specify biospecimen> *is/are* no longer identified as yours, so it is not possible to remove it/them from the bank.

**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.   
  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.
* At any time, I can ask the bank to stop collecting <health information/specify biospecimen(s)>, and ask the bank to delete/destroy all my <health information/specify biospecimen(s)>, if it is still identified as mine.

**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** |

|  |  |  |
| --- | --- | --- |
| **Assent of Minor Subject (17 years old or younger)** | | |
|  |  |  |
| **Name of Minor Subject** *please print* | **Signature of Minor Subject** | **Date or Date/Time** |
| **If child’s assent is not obtained above, please indicate reason below (check one):**  Assent is documented on a separate IRB-approved assent form  Child is under the IRB-approved age range for assent  The IRB granted a waiver of assent, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **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.)* | |
| ***\*This signature line should be utilized for adult subjects who lack decisional ability and require a legally authorized representative to consent on their behalf. The signature line should not be used for parental permission*** | | |

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