***This template is for BMT CTN studies that are deferred to the NMDP IRB for review.***

***Instructions:***

The NMDP approved consent form for BMT CTN studies should be used. The MCW/FH IRB required template language that must be included in that consent form is below.

1) The language has been pre-approved by NMDP and may not be changed.

2) Section header names in the NMDP consent cannot be changed.

3) The order of the NMDP consent cannot be changed.

4) Use track changes when adding the boilerplate language listed below into the NMDP approved consent form for BMT CTN studies. Add the following comment “MCW required language is replacing NMDP language.”

5) When MCW required language replaces language in the NMDP template, use track changes and add the following comment “MCW required language is replacing NMDP language”.

6) Insert local information as requested in the NMDP consent form for each study.

7) Extra tests/procedures section: When some tests/procedures are extra and some are not: Do not delete the word “extra” in relation to tests. Anything identified as “extra” is considered to be performed solely for research purposes. Using track changes delete any test in the “extra” test section that is considered routine care in a qualifying clinical trial and add the following comment “Per MCW/FH, this test is considered routine care.”

8) Create a separate HIPAA Authorization using the “Standalone HIPPA Authorization - Deferred Projects” Template

**Medical College of Wisconsin**

**INTRODUCTION TO THE INFORMED CONSENT**

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

Froedtert West Bend Hospital

Froedtert Menomonee Falls Hospital

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

Froedtert Hospital

Medical College of Wisconsin

<Study Title>

<Principal Investigator>

<Department>

<Telephone Number>

* Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee WI 53226

OR

* Froedtert Hospital

9200 W. Wisconsin Avenue

Milwaukee, WI 53226

**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**

[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 that will occur at various visits:**

**Invasive Procedures**

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

**Non-invasive Procedures**

* [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. 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 study 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 study is being done to…[insert brief purpose]

If you have more questions about this study 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.

**My Other Options**

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

* Joining a different study
* Routine care for this condition [*This option may be removed if not applicable, but it cannot be edited.*]
* Getting no treatment for this condition

**Benefits**

We don’t know if this study will help you. Your condition may get better but it could stay the same or even get worse.

**CONSENT TO PARTICIPATE IN RESEARCH**

**5. Study Activities**

***Include the following if research involves infectious disease testing (if the project involves both infectious disease testing and applicable research activities at Versiti, Inc., the latter paragraph regarding infectious disease notification should be used).***

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, we will/may inform you and will 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 <<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 research involves 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 research involves genetic testing or whole genome sequencing of biospecimens.***

Whole genome sequencing will be included as part of the genetic testing for this research.

**8. New Information Available During the Study**

***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.

**11. Physical Injury as a Result of Participation**

***Language below should replace language provided in the NMDP consent form.***

Emergency medical treatment for injuries directly related to your participation in this research study 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 study, 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.**

**12. Payment**

***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>.

**13. Costs**

***Outline clearly:***

* ***Activities/financial costs that are part of routine care and to be billed to subject/ subject’s insurance company***
* ***Activities/costs that are part of the research and 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***
* There are no costs to you for any of the visits, drugs or services you receive in this study. All costs will be paid by the study. If you have questions regarding costs, please contact Dr. \_\_\_\_\_.
* Some of / Most of the medical care that you will receive in this study is considered routine care for your condition and would be recommended whether or not you join the study. Costs for routine care will be billed to you or your insurance carrier. For routine clinical care, you will be responsible for paying any copayment, coinsurance, or deductible that is required by your insurance carrier. Activities / costs that are part of the study will not be billed to you or your insurance company. These are \_\_\_ [list as applicable]. Some insurers will not pay for drugs, tests or hospitalization that are part of research, so check with your insurer before you join this study. If you have questions regarding costs, please contact Dr. \_\_\_\_.

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.

**16. Contact Someone about Your Rights**

*Insert the following:*

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.

***As of 1/1/2024, the NMDP IRB no longer accepts embedded HIPAA authorization language. Please utilize a separate HIPAA Authorization using the “Standalone HIPPA Authorization - Deferred Projects” Template***

***Language below should replace language provided in CIRB template.***

**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 study’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 study.
* I voluntarily agree to participate in this research study. 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** |

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

Attachment 1 – Details of project schedule and procedures