*This template (NCI Local Review) is for NCI-cooperative group sponsored projects being reviewed by the MCW IRB.*

**Instructions**

The NCI-approved consent form should be used for these projects. The MCW/FH IRB-required language that must be included is below in black type. Language in blue is not required as long as equivalent language is present in the NCI-approved consent template for this project.

* The black language should not be changed.
* The MCW/FH IRB header and footer should be added to the NCI consent.
* Section header names in the NCI consent should not be changed.
* The order of the NCI consent should be followed.

**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 Menomonee Falls Hospital

Froedtert West Bend Hospital

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

Froedtert Hospital

Medical College of Wisconsin

<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 project 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.

**My Other Options**

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

* Joining a different project
* 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 project will help you. Your condition may get better but it could stay the same or even get worse.

CONSENT TO PARTICIPATE IN RESEARCH

Why is this project being done?

There will be <number> subjects enrolled at this site.

How long will I be in this project?

***Choose one or more options and modify regarding the subject’s involvement:***

* You will be in this research project for about [estimated length of time of subject’s involvement].
* You will take the [drug/intervention] for \_\_\_\_ months/ weeks.
* After the [drug/intervention] 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 clinic [once a month, once a year] [for the next year / for the rest of your life] and ask about ….

What will happen if I take part in this project?

***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.

***Insert this section if access to records will be prohibited due to blinding of project***

If you join this project, you will be given one of two [or three, etc.] [drugs / interventions] without knowing exactly which one (a “blinded” project). If you ask to see your health records during this “blinded” project, the research team cannot tell you which [drug / intervention] you are being given. This is because the research team also remains “blinded” about which [drug / intervention] the sponsor has randomly assigned to you. You would have to wait until the time given below. We cannot do the project unless you agree. However, if the blinded information is needed to treat you, it will be provided to the research doctor.

* What are the blinded options? You will get one of these drugs/interventions: \_\_\_\_
* When can you find out which [drug / intervention] you were given? [You can find out in [state in weeks / months from the start of the project, or as a date.]

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

GENETIC TESTING

Genetic testing is done on blood and other specimens. In this project, we will do genetic testing on your <blood or specimen>. 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.

***Will the item for genetic testing will be identified or de-identified? Choose one statement and delete the other.***

Information that can identify you [will / will not] be attached to your <blood or specimen>. The reearch 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 questions 1, 2, and 3:***

Initial next to the appropriate statement(s) to indicate your decision:

1.\_\_\_\_I do NOT want genetic testing done on my <blood or specimen> in this project. This means that I can still participate in the project.

2.\_\_\_\_I agree to have genetic testing done on my <blood or specimen> in this project.

3.\_\_\_\_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 questions 1, 2, and 3:***

1.\_\_\_\_I do NOT want genetic testing done on my <blood or specimen> in this project. This means that I cannot participate in the project.

**Stop here** and speak to Dr. \_\_\_\_. Do not sign this form.

2.\_\_\_\_I agree to have genetic testing done on my <blood or specimen> in this project.

3.\_\_\_\_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:

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

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’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.

What are my rights in this study?

You can decide whether to take part in this study 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 study, 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.

A research study is different from routine medical care in three ways: 1) there areextra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the study procedures, tests and visits follow a set plan that must be kept.

If you have questions about your rights as a study participant, want to report any problems or complaints, obtain information about the study, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

***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>.

***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.

What are the costs of taking part in this project?

***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 project and to be paid by sponsor/MCW/FH***
* ***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 project. All costs will be paid by the project. If you have questions regarding costs, please contact Dr. \_\_\_\_\_.
* Some of / Most of the medical care that you will receive in this project is considered routine care for your condition and would be recommended whether or not you join the project. 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 project 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 project. 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 your or your health insurance.

What happens if I am injured or hurt because I took part in this 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 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 NCI cooperative group requires its specific injury language be included in the local consent form, insert the applicable group’s language after the MCW-required injury language.***

***[ECOG]***

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

***[NRG]***

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

***[NSABP]***

It is important that you tell your study doctor, <PI>, if you feel that you have been injured because of taking part in this study.  You can tell the study doctor in person or call him/her at <telephone number>.

You will get medical treatment if you are injured as a result of taking part in this study.  You and/or your health plan will be charged for this treatment.  The study will not pay for medical treatment.

***[SWOG]***

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Where can I get more information?

***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> 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 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 project 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.

***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