*This template* ***(EFIC) is for projects involving planned emergency research.***

*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 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**

**INTRODUCTION TO THE INFORMED CONSENT**

<Title>

<Principal Investigator>

<Department>

<Telephone Number>

Medical College of Wisconsin

8701 Watertown Plank Road

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, urine sample collection, bone marrow collection]

**Non-invasive Procedures**

* [Briefly list less invasive procedures. E.g. Full medical history exam, 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 study risks.

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

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

**Length**

* If you do not agree to continue in the project, your participation is over.
* If you agree to continue, you will remain in the project until [you are discharged OR you have completed your participation OR you decide to withdraw].

**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

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

***Describe reason(s) for subject participation, such as diagnosis and eligibility, and a brief description of the key intervention.***

You are being invited to participate in this research because [you had a life-threatening stroke/cardiac arrest/had a seizure] and received an investigational <drug/device/biologic>.

This project is different from other research projects because you were enrolled without your consent. This type of research is called Planned Emergency research. Planned Emergency research is for life-threatening conditions when it is impossible to get consent from the patient. Also, because these patients require immediate treatment, there is no time to obtain consent from a legally authorized representative before starting treatment. Planned emergency research is only approved by <the US Department of Health and Human Services (HHS), the Food and Drug Administration (FDA)> and the local Institutional Review Board (IRB) when the standard treatments for the life-threatening disease have not been proven to work or are not good enough. Before a planned emergency research project can be started in any community, researchers must seek feedback about the project from the community and notify the community that this type of research will be done. This research must then have final approval from <HHS, the FDA> and IRB before beginning. As another requirement for planned emergency research, we must notify you that you were enrolled in this project and ask you if you want to continue taking part in it. You do not have to continue in this project. If you say no, your regular medical care will not change.

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

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.

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 <[researcher/ research doctor/ research director] 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?

Because of the seriousness of your condition and your immediate need for treatment, we were unable to ask for your permission to participate in the project. However, you now have the option to continue to take part in this project or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you decide to continue in this project, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS PROJECT BEING DONE?

***Describe the purpose of the project.***

***- For drug studies, select the Phase example for your study. For a study of mixed phases, choose the lowest phase to describe your study.***

***- For device or other studies, see the instruction section below.***

***For Phase 1 drug studies:***

In this study, we want to find out more about the side effects (problems and symptoms) of a new drug for [X condition], [drug name] and what doses of [drug name] are safe for people to take. Everyone in this study will receive [drug name] which is still experimental and is not approved by the U.S. Food and Drug Administration. We do not know all the ways that this drug may affect people. This study is not likely to help you, but we hope the information from this study will help us develop a better treatment for [X condition] in the future.

***For Phase 2 drug studies:***

In this study we want to find out more about a new drug, [drug name], in people with [X condition]. We want to find out whether the new drug [drug name] reduces the symptoms of [X condition], and whether it causes any problems (side effects). Everyone in this study will receive [drug name], which is still experimental and is not approved by the U.S. Food and Drug Administration / is approved by the U.S. Food and Drug Administration for use in patients but not with your condition. We are testing [drug name] to see what effect it has on people with [X condition]. 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. We hope the information from this study will help us develop a better treatment for [X condition] in the future.

***For Phase 3 drug studies, or studies with comparator:***

In this study we want to find out whether a new drug for [X condition], [drug name], is <better than/similar to> [old drug name], a routine treatment for [X condition]. To do this, we will compare the two drugs in people with [X condition] and see which one reduces pain faster or better, and which one is safer (causes fewer problems).[Drug name] is still experimental and is not approved by the U.S. Food and Drug Administration / is approved by the U.S. Food and Drug Administration for use in patients but not with [X condition]. [Drug name] may have advantages over Old-drug, but we won’t know until we do more research studies.

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. We hope the information from this study will help us develop a better treatment for [X condition] in the future.

***For Phase 4 drug studies, describe the post marketing study:***

This drug has been approved by the U.S. Food and Drug Administration, and in this study we want to learn more about …

This research drug may be available by prescription for [*indication*].

***For device studies, describe the FDA status of the device in a way the subject is likely to understand, so that the subject knows the FDA’s ruling on the safety and effectiveness of the device and the FDA indication(s) for the device.***

***For market-approved or cleared (e.g., 510(k)) devices when the device will be used ON indication:***

The medical device that we are studying, \_\_\_ [name device], has been approved by the U.S. Food and Drug Administration for patients with \_\_\_\_\_[condition]. We want to collect more information about the safety/effectiveness of the device / - OR - / we want to compare how patients treated with this device do when compared to \_\_\_\_\_.

***For market-approved or cleared (e.g., 510(k)) devices when the device will be used OFF indication:***

While the medical device that we are studying, \_\_\_\_ [name device], has been approved by the U.S. Food and Drug Administration for patients with \_\_\_\_\_\_ [approved indication], we will be using the same device for a different purpose. For this reason this use must be considered experimental. We want to collect information about the safety/effectiveness of the device when used in this way / - OR - / we want to compare how patients treated with this device do when compared to \_\_\_\_\_\_\_.

***For devices the FDA considers Investigational Device Exemptions (IDEs), OR when the device is considered to be Non-Significant Risk (NSR)*:**

The U.S. Food and Drug Administration considers the device we are studying, \_\_\_\_\_ [name device], to be experimental while researchers study how safe it is and how well it works. We do not know all the ways that \_\_\_\_\_ [device] may affect people.

***For Humanitarian Use Devices (HUDs) with Humanitarian Device Exemption (HDE) status, when the device will be used ON-indication*:**

The U.S. Food and Drug Administration has given the device we are studying, \_\_\_\_\_\_ [name device], a special status because while there is some information that the device is safe and possibly effective, there are simply not enough patients with \_\_\_\_\_\_ [indicated condition] to test its safety and effectiveness in the usual ways.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

***Provide a concise overall summary of the procedures.***

* ***Begin with screening procedures, if applicable.***
* ***Describe the groups and explain randomization, placebo, blinding if applicable.***
* ***Use lay language and explain the purpose of the procedure if it is unfamiliar.***
* ***Include the duration of each visit or procedure.***
* ***Emphasize drugs/procedures specifically for the research, compared to routine care.***
* ***State if any procedure is experimental.***
* ***An attachment may be added [Attachment #1, optional] with details of the project schedule and procedures.***

**Research groups**

***If the research has interventional groups, describe the groups and how they are defined.***

[Describe the groups, for example… to find out if an investigational drug for headaches, [drug name], is better than [old drug name], the routine treatment for headaches, one group of people in the research will be given new-drug and a second group of people will be given [old drug name]. We will check how many headaches people have after one month, and compare the results in the two groups.]

***If the research has a placebo, insert the following in description of groups above:***

You should know that the placebo is a pill [or infusion, etc.] that contains no real medicine and we do not expect it will do anything for your health.

***If the research is randomized, insert the following:***

Because no one knows which of the [drugs/devices/interventions] is best, you will be “randomized” into one of the [two / three / etc.] groups. [One group will receive [investigational drug name] and one group will receive [old drug]]. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have a(n) [equal / one in three /explain weighting, etc.] chance of being placed in [either / any] group. Neither you nor the <research doctor/ research director> can choose what group you will be in.

***If the research is double-blinded, insert the following, or modify for single-blind:***

Neither you nor your <researcher/ research doctor/ research director> can know which drug you will get until the research is over. A computer program chooses which group you are in, and the pills (infusion, etc) in each group will look the same. In an emergency, your <researcher/ research doctor/ research director> can find out which drug you are taking.

***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 <researcher/ research doctor/ research director>.

* 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.]

***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 <researcher/ research doctor/ research director> 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 <researcher/ research doctor/ research director> will keep a confidential list linking your name to your code and only the <researcher/ research doctor/ research director> 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.

**Summary of Procedures:**

***Provide a summary of procedures***

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

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

***Include the following 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**

v

|  |  |
| --- | --- |
| 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 to be specific regarding the subject’s involvement:***

* If you do not agree to continue in the project, your participation is over.
* If you agree to continue, you will remain in the project until [you are discharged OR you have completed your participation OR you decide to withdraw].

Even if you do not agree to continue, the FDA requires that we will still collect outcome data from your medical record.

B3. CAN I STOP BEING IN THE PROJECT?

***Choose one or more of these options and modify:***

You are free to withdraw from the project at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the <researcher/ research doctor/ research director>.

* The <researcher/ research doctor/ research director> can tell you about the effects of stopping, and you and the <researcher/ research doctor/ research director> can talk about what follow-up care would help you the most.
* You might be asked to come back for one more visit or be contacted in the future to check your health.
* If you withdraw from the project, the research team may search public records to get information about your survival status.
* [Information relating to locator agencies may be inserted here]

The <researcher/ research doctor/ research director> [or the sponsor] may take you out of this project at any time for any reason, including if:

* They think it is in your best interest.
* You do not follow the project rules.
* The whole project is stopped.

If this happens, the <researcher/ research doctor/ research director> will tell you.

If you withdraw from the project early or decide that you do not want to continue in the project, any data already collected about you will be kept. This is a requirement of the FDA for planned emergency research.

B4. ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM IN THE PROJECT?

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

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

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

There are risks to taking part in any research project. There is a risk that you may get [a drug/drug combination/device/intervention/dose of a drug] that does not help your condition or may make it worse. There also may be problems (side effects) we do not know about yet, from [drug] itself, or how it combines with other drugs you are taking. If we learn about new important side effects, we will tell you.

We watch everyone in the project for problems (side effects). **You need to tell the <researcher/ research doctor/ research director> or a member of the research team immediately if you experience any problems, side effects, or changes in your health.** If you have \_\_\_\_ [severe bleeding], call Dr. \_\_\_ immediately at \_\_\_\_\_. In an emergency, call \_\_\_\_.

**C2. RISKS OF \_\_\_\_\_\_\_ [THE INTERVENTION FOR GROUP A, GROUP B, ETC.]**

The research [drug/device/intervention] itself may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away.

Many go away soon after you stop taking the [drug/device /intervention]. Drugs can affect individuals in different ways. . Complications of some of the side effects below may lead to life-threatening events such as …. (infections, kidney failure, bleeding, and possibly death).

The side effects that other people have experienced so far with the [drug/device /intervention] are:

***State here the risks related to the research intervention(s) itself.***

* ***Include the research intervention(s) both investigational and comparator***
* ***Risks can be described as a bulleted list or table, using lay language.***
* ***Begin with the most common, and include the probabilities or commonality of each side effect.***

***Device risks:*** *In addition to risks of the device itself, including possible malfunction and its consequences, also address the following long-term risks, such as: risks of removal, consequences of removal, device maintenance, and who will bear the cost of maintenance and/or removal.*

C3. OTHER RISKS OF THIS RESEARCH PROJECT

***Here list other project procedures and their risks, such as***

* ***to assess eligibility,***
* ***more frequent assessments for safety or for disease progression,***
* ***other required medications, etc.***

Other procedures [and medications] that are part of the research also involve some risks:

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

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, it may be embarrassing if your research information were accidentally seen.If you have questions, you can talk to the project director about whether this could apply to you.

C4. 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 <researcher/ research doctor/ research director> 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 <researcher/ research doctor/ research director> immediately. The <researcher/ research doctor/ research director> 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 <researcher/ research doctor/ research director>.

**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 <researcher/research doctor/research director> 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 <researcher/ research doctor/ research director> immediately. At that time, the <researcher/ research doctor/ research director> 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 <researcher/ research doctor/ research director> to contact your partner’s obstetrician to collect information on the progress of the pregnancy and its outcome. The <researcher/ research doctor/ research director> 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 <researcher/ research doctor/ research director>.

**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 <researcher/ research doctor/ research director> 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.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

***Describe medical benefits to subject if any, and add a phrase related to the purpose of your study on how / whom the project might help.***

* ***Do not list compensation in this section. Payment is a recruitment incentive, not a benefit.***
* ***Do not feature “extra medical supervision” as a benefit.***
* ***If the drug is investigational, do not suggest that the drug is beneficial.***

***Choose one of these options and modify. If not a drug study, choose an appropriate option and modify.***

***For Phase 1 drug studies:***

This study is not likely to help you, but we hope the information from this study will help us develop better treatments for X condition.

***For Phase 2 or 3 drug studies:***

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. We hope the information from this study will help us develop better treatments for X condition.

***For Phase 4 drug studies:***

This study may or may not help you, but we hope the information from this study will help us develop better treatments for X condition.

D1. ARE THERE ANY COSTS TO BEING IN THE 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 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 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 you or your health insurance.

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

***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.

***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 healthcare choices listed below if applicable***

You do not have to continue participating in this project. You are free to say yes or no. If you do not continue in this project, your <researcher/ research doctor/ research director> can discuss other healthcare choices with you.

Your other choices may include:

* [List/describe the different kinds of routine care for this condition or symptoms.]
* Joining a different research project
* The procedure or drug offered to you may be available to you without being in any research project.

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

If we learn any important new information [about the drug/device/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.

***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?

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

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

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

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

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

* 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.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

The research team needs your permission to continue to access, collect and use some of your health information. If you say no, you cannot continue in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); Versiti, Inc.; Children’s Wisconsin (CW); any Froedtert Health Affiliate- Froedtert Hospital (FH), Inc.; Froedtert Menomonee Falls Hospital;  Froedtert West Bend Hospital;  Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

**The health information to be collected and used for this project is:**

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

* [Medical records of the care you receive for this project]
* [Medical records dating from when you join this project until you die]
* [CT scan taken when you were first diagnosed with <specific disease/condition>]

E2. Who will see the health information collected for this project?

The only MCW/Froedtert Hospital/Versiti, Inc. employees allowed to handle your health information are those on the research team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital’s rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

***Delete this section if no one outside MCW/FH will access identified data***

The research team may share your information with people who don’t work at MCW/Froedtert Hospital/Versiti, Inc. because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital/Versiti, Inc. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

***Here list*** (***name), institution, city and state for each sponsor or collaborator needing access to identified data or source records. It is NOT necessary to list Sponsors who do not need access to data or source records.***

***The information in this section should be specific, but the following inclusive phrases (or equivalent) may be used:***

- “Sponsor” includes any persons or companies that are working for or with the sponsor or are owned by the sponsor

- Government agencies in other countries that monitor [research, research drugs, etc.] for those countries

[Industry Sponsor, City, State]***(Delete if not applicable)***

[CRO, City, State]***(Delete if not applicable)***

[Multisite Coordinating Center, City, State]***(Delete if not applicable)***

[NCI Cooperative Group, City, State]***(Delete if not applicable)***

[Dr. X, Y University, City, State*]* ***(Delete if not applicable)***

***If the study 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.

***The following two paragraphs are required if data and/or biospecimens are being collected as part of the research.***

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record or BloodCenter blood donor record.  As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information and/or biospecimens, the information and/or biospecimens may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

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 <researcher/ research doctor/ research director>.

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 study 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, we may/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 for reasons other than blinding***

You may not be able to see, or copy, your project-related health information until after the project has been completed; otherwise, it could affect the study. *[The following text may be deleted, but it cannot be edited.]* <<You may ask the <researcher/ research doctor/ research director> for updated information on what data he/she has recorded for you, and you can request corrections of any errors in the recorded data.>>

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 TO PARTICIPATE**

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

* I have read (or had read to me) this entire consent document, including Attachment 1.   
  All of my questions have been answered to my satisfaction.
* The project’s purpose, procedures, risks and possible benefits have been explained to me.
* I agree to let the research team use and share the health information and other information gathered for this project.
* I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

**IMPORTANT:** You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

***Signature line instructions:***

*Generally, the subject's signature is sufficient. Thus, the following signature lines are* ***optional*** *to include: Legally Authorized Representative, Witness, Principal Investigator or designated representative. These should only be included when the Investigator chooses to include them, or when required by the Sponsor.*

***Date or Date & Time: Time is optional to include; if included, must be completed by each signer.***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Subject's Name** *please print* | **Subject's Signature** | **Date** OR **Date**/**Time** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Legally Authorized Representative, if applicable**  *please print* | **Signature of Legally Authorized Representative** | **Date** |
|  |  | |
| ***Name of Subject*** *please print* | ***Relationship to Subject*** *(e.g. Court-appointed guardian, healthcare power of attorney, next of kin, etc.)* | |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Witness, if applicable** *please print* | **Signature of Witness** | **Date** |
| **Rationale for Use of Witness**  Subject has limited/no literacy  Subject has limited English proficiency  Subject has limited/no vision | Sponsor requirement  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **\* Name of person discussing/ obtaining consent** *please print* | **Signature of person discussing/obtaining consent** | **Date** |

*\* A member of* *the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol.* *The Principal Investigator is responsible and accountable for the research project.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Principal Investigator** *please print*  \_\_ I participated in consent process  \_\_ I acknowledge enrollment of this subject into the project | **Signature of Principal Investigator** | **Date** |

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

Attachment 1 – Details of project schedule and procedures