Ascension Wisconsin IRB

**INFORMED CONSENT FORM GUIDE: INSTRUCTIONS FOR USE**

***Greater than Minimal Risk Studies***

Template v.5/19/2022

This template is for studies that involve an interaction or intervention that poses more than minimal risk to subjects, such as an investigational drug or device trial.

**INSTRUCTIONS**

Read through this form taking note of the instructions and guidance for each section.

* **Modify the content language as applicable:**
  + **RED**= this language is required to be used as is, do not change or delete this language.
  + **YELLOW**= this language is required, if it is applicable to the study. If it is applicable, it must be used as is. If it is not applicable, delete the language.
  + **GREEN**= this is suggested language or instructions, you can freely change or delete this language.
  + **[brackets]**=text of ANY color inside brackets must be modified to be specific to the study or deleted.
* **DO NOT:**
  + Change the color of any text.
  + Change the order of the sections.
  + Modify the margins, header or footer of document, except to add or delete a version date.
* **Before you submit your final version to the IRB be sure to:**
* Delete the outlined instruction text boxes.
* Update the footer version date, or delete if you are not using.
* Make sure that all text, of any color, inside [brackets] is either updated for the study or deleted.

**Other Tips to help get the Consent Form Approved Quickly**

* Read the instruction boxes on this form.
* **Do not change the required (red) language; use required (yellow) language with no changes when it is applicable.**
* **Use the suggested (green) language whenever possible to speed up IRB consent form review and acceptance**.
* Replace the [brackets] and text inside them with your study specific language (i.e. delete the actual brackets).
* Proofread the document for spelling, grammar and formatting errors.
* Use language that is understandable to subjects and is presented in a way that is clear.
* Use of scientific or legal jargon is not appropriate without also include a lay explanation
* Try to write the document at an 8th grade reading level.
* Write in second person (e.g., “You are being asked to be in a research study because…”); it is more open and conversational. Also, use active voice, simple declarative sentences and personal pronouns.
* For studies involving minor subjects, modify the consent form from “you” to “your child”, as appropriate (in this case, template language of any color can be changed throughout the form to accomplish this).
* Use clear page layout, white space and large fonts make documents easier to read and understand.
* Remember that informed consent is a process, not a form; accurately describe the process in the IRB application.

**Documentation of Informed Consent**

* A copy of the signed consent form must be added to the medical record if the study involves a drug, device or other intervention that would be important for caregivers to know about. (use standard process at local ministry)
* Signatures must include a time for all consents that will become part of the medical record.
* In addition to the consent form, the person obtaining consent should complete a consent note to document the process. A consent note template is available on the Research Education and Quality Management [website](http://www.wfhealthcare.org/wfhealthcare/irb/research-quality-improvement-unit/).
* Keep the original signed consent form in the research file; provide a signed copy to the subject.

**Translation of Consent Forms for Safe Harbor languages**

* Ascension Wisconsin Institutional policy requires consent forms for studies that include information important for treatment/care (more than minimal risk studies) have the full consent form translated into the safe harbor language(s) of the location of the research prior to approaching subjects who speak that language. The short form consent process cannot be used for these languages. See the Policy or Language Services for more information.

# RESEARCH INFORMED CONSENT INFORMATION

# Agreement to be Part of a Research Study

Study Title:[Study title]

Principal Investigator: [Name]

[Phone]

[Hospital or Clinic Name of main local study site]

[Address of main local study site]

Study Sponsor: [Name]

## What should I know about a research study?

* This is a consent form for participation in a human research study.
* Taking part in this study is voluntary. You decide if you want to be in the study.
* You can choose to not be in the study. If you choose to be in the study, you may stop at any time. If you stop the study before it is finished, there will be no penalty to you and you will not lose any benefits that you could normally receive.
* No one can promise you that this study will help you.
* If you decide to be in the study, there may be extra risks or side effects.
* Someone will explain this research study to you. Make sure all of your questions are answered before you decide if you want to be in the study.
* If you join the study, you will be asked to sign this form and you will get a signed and dated copy of this form for your records.

## Why is this study being done?

Include a brief explanation of the reason for doing the study or research question. This should be limited to a few sentences. Use lay terms and identify anything that is experimental.

For example, if the study includes a drug:

“Drug X is an experimental drug that is not approved to treat Y condition. This study is being done to see if Drug X is safe to use in patients with Y condition and to find out if it helps to reduce Z symptoms.”

“Drug X is already approved by the FDA to treat Y condition. This study is being done to see how well people with Y condition do over time when they are taking Drug X, compared to people with Y condition that don’t take the drug.”

[Identify the study drug/device]

[Explain purpose of the study]

[Describe if experimental or approved for how it is being used in this study]

## Why am I being told about this study?

Explain the circumstance or condition that makes subjects eligible for the research.

Include the number of subjects to take part in the study.

For example:

“…you have had X condition for more than 6 months.”

“…you may be eligible for a device that senses changes in blood pressure to be implanted in your chest.”

You have the option to be in this study because [explain].

About [insert number] people will take part in this research study at this location. About [insert number] people are expected to participate [nationally/world-wide/etc.].

## How long will I be in the study?

Describe how long the subject will be part of the study. This section may be modified based on the study, but may include the time in hours, number of visits, amount of time each visit will entail, etc. Include expectations for long-term follow-up visits, if applicable. Be liberal in your estimations of time.

For example:

"You will receive Drug X for 6 months. After that you will have at least 3 follow-up visits to the researcher over the next year. Each visit is expected to last about 1 hour. In addition to the time you are active in the study, we will collect information from your medical records for another 3 years after your participation. The entire study should last for about 5 years.”

“If you decide to participate, you will be asked to complete one survey today. Your participation in the study is done after you finish that survey.”

[Describe duration of active participation]

In addition to the time you are active in the study, we will collect information from your medical records for another [insert number of months/years, etc.] after your participation. You will be considered part of the study for a total of about [insert number of months/years, etc.].

## What will happen if I take part in this study?

Explain in lay terms what will happen to subjects during the study. **This section should be a concise and focused presentation of the key information about participation.**

Depending on the study, *this section may or may not be all-inclusive.* If the study has multiple visits or varied procedures, it may be appropriate to include a detailed description later in the consent form. This may be in the format of a calendar or schedule, or, you may list procedure organized as a visit-by-visit breakdown of what happens in the study. If the study is fairly straightforward, all information may be presented here and does not need to be repeated later.

For example, for a study that includes investigational drug, many study visits with different procedures at each and years of follow up, you would not list all procedures here. Rather, this section should present a clear summary of key information, and additional details could be presented later in the form.

This section should identify ALL research-specific or experimental procedures and distinguish these procedures from routine or regular care.

This section should be organized in a way that is clear and easy for subjects to understand; the best organization format may vary depending on the study. The preferred language/format is listed below, modify as appropriate for the specific study.

If you agree to be in this study, we will ask you to do the following:

Before you start the study

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are [part of your normal care and may be done even if you do not join the study/ are not part of your normal care and are will be done only if you agree to be part of this study]. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

[List tests and procedures as appropriate. Depending on the study, you might not list each test. Remember to present clear, key information for someone to use to decide if they should participate. This can be sentence or bullet format.]

This study requires an HIV test. Before any testing can take place, you will be asked to review and sign a separate consent form.

If the researchers confirm that you can be in the study and you choose to take part, then you can continue to be part of the study.

Before you begin, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. [A computer program/ or other description] will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an [equal/one in three/etc.] chance of being placed in any group.

If you are in group 1 ([also called]):[Explain what will happen for this group with clear indication of which interventions depart from routine care.]

If you are in group 2 ([also called]): [Explain what will happen for this group with clear indication of which interventions depart from routine care.]

This study compares an active [drug, device, or explain] to a placebo. A placebo looks like the [study drug, device, or explain] but it includes no active ingredients. If you are assigned to this group, you will not get any [drug, device, or explain].

[For studies with more than two groups, repeat explanation for each group]

This study is “blinded”. That means that you will not be told which group you are in, however the Investigator and research team will know.

This study is “double-blinded”. That means that you will not be told which group you are in, even after you have stopped taking the study drug or placebo. The Investigator and research team will not know what group you are in either, but can find out in an emergency situation.

During the study

You will [be asked to take drug/ undergo intervention/ other description] [describe time frame- for months, weeks/until a certain event/ etc.]. You will also complete the exams, tests and procedures below.

These exams, tests and procedures are part of your regular care but information about them will be used for this study: [List tests and procedures as appropriate. Depending on the study, you probably will not list each test. Remember to present clear, key information for someone to use to decide if they should participate.]

These tests and procedures that are part of regular care but they are being done more often because you are in this study: [List tests and procedures as appropriate. Depending on the study, you probably will not list each test. Remember to present clear, key information for someone to use to decide if they should participate. This can be sentence or bullet format.]

These tests and procedures will be done only if you are part of this study. The test or procedures are either being tested in this study or being done to see how the study is affecting your body: [List tests and procedures as appropriate. Depending on the study, you probably will not list each test. Remember to present clear, key information for someone to use to decide if they should participate.]

When you are done [with the study/ the study intervention/ taking the drug]

After you are finished [taking the drug/ having the intervention], [you will be finished with the study/ you will be asked to have follow-up including:]

* [visit the office for follow-up exams] for [indicate time frame and follow-up requirements]
* [complete surveys] for [indicate time frame and follow-up requirements] [etc.]

A [study chart/study plan/list of visits] is another way to describe what will happen if you are part of the study. The [study chart/study plan] is included [ at the end of this form], the study team will review it with you.

Any [data and/or biospecimens] collected as part of this study [may/will/will not] be used for future research studies. We will describe the future use in more detail later in this form.

We [will/may] complete whole genome sequencing using the biospecimens that were collected as part of this study.

## What risks, side effects or discomforts can I expect from being in the study?

**This section should be a concise and focused description of reasonably foreseeable risks related to participation in the study.** **This section should not outline risks of standard of care drugs or interventions.**

Depending on the study, *this section may or may not be all-inclusive.* If the study has multiple risks or side effects, they should be included in greater detail later in the consent. If the study is fairly straightforward, all information may be presented here and does not need to be repeated later.

For example, for a study that includes investigational drug, this section should list the most important risks, similar to the information that a doctor might deliver in the clinical context in telling a patient how sick the drug will make them, but with a particular emphasis on how those risks are changed by participating in the study.

This section should be organized in a way that is clear and easy for subjects to understand; the best organization format may vary depending on the study. The preferred language/format is listed below.

You might have risks, side effects or discomforts if you take part in this study that you may not have if you are not in the study. The most likely and most serious are listed below. More details and other research related risks and discomforts will be listed for you at the end of this form. The researchers will discuss the risks with you and make sure that you have time to ask questions.

The study [drug, device, etc.] can cause side effects. Everyone taking part in the study will be watched carefully for any side effects. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the [drug(s) or intervention]. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

Most Common Side Effects or Discomforts are:

[List the most common side effects here. Depending on the study, you probably will not list each side effect. Remember to present clear, key information for someone to use to decide if they should participate. This can be sentence or bullet format.]

Rare but more serious side effects are:

[List the most common side effects here. Depending on the study, you probably will not list each side effect. Remember to present clear, key information for someone to use to decide if they should participate. This can be sentence or bullet format.]

Because this research study involves an experimental [drug, device, etc.], we do not know all of the possible harms or risks. There may be other risks related to your participation in this study such as [risks related to Genetic testing, social or legal risks or breach of confidentiality].

Talk to your study doctor about any side effects that you have while taking part in the study.

## What benefits can I expect from being in the study?

Describe any direct benefits to subjects, or possible benefits to others or society in general. Monetary reimbursement for participation is not a benefit and should not be included in this section.

If there are multiple study groups, modify the text to list the potential benefits for each study group.

Choose the statement(s) that apply to this study, delete the others.

[Option] We do not expect this study to benefit you.

[Option] Being in this study may or may not benefit you. [Describe]

[Option] Being in this study might benefit you by [Describe]

We hope to use information we get from this study to [describe expected benefit others i.e. help develop treatments for people with X disease/better understand how X works/ etc.].

## Will my study-related information be kept private?

If you sign this consent form, you are giving permission to let the Investigator and study staff use and share your information for the purpose of this study.

In general, the records of the study will be kept private. There are some cases where we may share your information. For example, your records may be reviewed by Ascension Wisconsin employees or agents, study sponsors or monitors, or government agencies (U.S. or foreign) that conduct the study or have to make sure that the study is being done safely and correctly. You will not be identified in any articles or presentations about this study.

There may be certain times when the study doctor and research team may have to share or report information learned during this study, these include the following:

* If the sponsor pays any of your medical expenses, we may be required to give them your name, date of birth, and Medicare ID or social security number.
* If the study staff finds evidence of abuse or neglect, researchers may be required by law to report this to local law authorities.
* As part of this study you will be tested for [identify the disease being tested for in this study (i.e. HIV or other communicable disease)]. Wisconsin state law requires the study doctor or study staff to report positive test results, including to the local health department. These reports are required to identify you by name.

Video and/or audio recording

This study involves [video and/or audio recording]. [Describe what will be done with recording. Include plans for storage during use and what will be done after transcription, e.g., how long the tapes will be kept.]

Interview or focus group

As part of this study, you will be involved in [interview, a focus group, etc.]. [Advise participants that they do not need to reveal their name, or that they may use a fictitious name and that they must agree not to reveal anything they learn from group discussions or other activities.]

Certificate of Confidentiality

This study has a Certificate of Confidentiality from the National Institutes of Health. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. The Certificate means that researchers will refuse to give out study information that identifies you.

For example, if Ascension Wisconsin received a subpoena for study records, it would not give out information that identifies you. The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. The Certificate does not stop Ascension Wisconsin from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,

- Giving law officials information about abuse of a child, elderly person or disabled person.

- Giving out information to prevent harm to you or others.

- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

For more information about Certificates of Confidentiality see http://grants.nih.gov/grants/policy/coc/faqs.htm%20

Medical Records and Health Information

If you agree to be in this study, this consent form will be included in your medical record. This is done so that other people involved in your normal care know about the study when they are making decisions about your care or treatment. Because of this, anyone with access to your medical record could learn that you are in the study.

Federal law provides additional protections of your medical records and related health information. These are described in a different form.

## Will it cost anything to be in the study?

Describe the cost, if any, to the subject for participation. Explicitly describe what the subject (and/or the subject’s health care insurer) will have to pay for.

If there is a contract/research agreement, the content of this section must be consistent with the agreement, as well as the description in the IRB application. **The study cannot be submitted to the IRB until this language in the contract/research agreement is finalized.**

If the contract is not consistent with the template language below, provide the IRB with other language to use for this section and provide justification for the change.

There are no additional costs to you if you participate in this study. [Describe if the study Sponsor will pay for items, such as the study drug/device, extra scans or tests, etc.]

You or your insurance company may be billed for:

* Usual medical care (care you would need if you were not in this study).
* [list other costs as appropriate]

You have the right to ask what it may cost you to take part in this study. Talk with the study doctor about costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. Also, if you are a Medicare beneficiary and have opted for a Medicare Advantage plan to manage your health care needs, your out-of-pocket expenses may increase while you are on this study. It is important that you talk with your health benefit plan to find out if the costs of care from being in this study are covered. If your insurance company does not pay, you may be billed for those charges.

If you have concerns or questions about what you will be asked to pay for or what your insurance company will pay for, financial counselors are available at phone number [123-123-1234].

## What happens if I am injured because I took part in this study?

Include this section for studies that are no Greater than Minimal Risk, and do not include medical intervention this section can be deleted.

Except for choosing an appropriate option below and inserting the Sponsor and study doctor information, **THIS LANGUAGE CANNOT BE REVISED** for any consent form created after 6/1/2022.

In rare cases, Ascension Legal may require or allow changes to this section; if this occurs, include the changes and a comment to the IRB with the rationale/reason and legal staff who approved.

If there is an emergency, call 911 right away or go to the emergency room and contact your study doctor as soon as you can. If you are hurt or get sick while you are in this research study, you must tell your study doctor right away. Treatment will be available.

Treatment may be billed to you or your insurer. If your insurance is billed, you may be required to pay deductibles and copayments that apply. You should check with your insurance company about any such payments. Ascension does not offer financial compensation or payment if you are hurt or get sick as a result of participating in this research.

[Option: Greater than Minimal Risk- Industry Sponsored or Funds available]

If you are hurt or get sick because of a research procedure or the experimental [drug/ device/ intervention], [SPONSOR] may pay for reasonable medical expenses required to treat the injury or illness. This does not mean that a mistake happened.

[OPTION: Greater than Minimal Risk- No Industry Sponsor (i.e. NIH) or No Funds available]

Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. No money or funds are set aside to pay for these types of injuries.

If you think you have been hurt or got sick from taking part in this study, call [Dr. XXXX at (xxx)-xxx-xxxx]. They can go over things with you, let you know of resources that may be available and give you information on what you need to do.

You are not giving up any of your legal rights by signing this consent form.

## Will I be paid for taking part in this study?

Describe the compensation, if any, to the subject for participation. Describe the amount, method and frequency of payment.

If there is a contract/research agreement, the content of this section must be consistent with the agreement, as well as the description in the IRB application. **The study cannot be submitted to the IRB until this language is in the contract/research agreement is finalized**.

[Option] You will not be paid for being in this research study.

[Option] You will receive [$ amount] [indicate frequency-per visit, day, etc.] as reimbursement for your travel, time and effort. That means, for the whole study, you could receive up to [$ amount].You will receive the payment by [list method- check, gift card, etc.] [Describe when and how- in the mail about 3 weeks after each visit, at the end of your visit, etc.].

Because you will be paid, we will collect your name, address, telephone number, and social security number and you will be asked to complete an IRS Form W-9. We will give this information to the Ascension Wisconsin office that processes the payments. The payments you receive may be reportable as income on your taxes. If you are paid $600 or more in a calendar year by any Ascension Wisconsin owned location, you will be sent a Form 1099 to use when preparing your tax forms.

If you do not provide your social security number and complete an IRS Form W-9, you can still be in the study but you will not receive any payments for your participation.

[If the above aren’t applicable, include other description]

(required if biospecimens are collected) Any biospecimens collected as part of this study may be used by the [Investigator and/or Sponsor] to develop new information or products. They will own the use of the results, treatments, or inventions that can be made from this research. You will not be entitled to receive compensation from any commercial profit.

## Will I be told about the results of this research?

This section must include details about what information is shared with the subject.

You must describe if/how clinically relevant research results, including general or aggregate research findings and individual research results, will be shared with subjects.

If the research may reveal incidental or secondary findings, describe whether or not the results will be read for incidental findings; suggested language is provided in the template language document. For example, this may apply if the study includes research-specific imaging or genetic testing. Optional template language for different circumstances is provided.

If we learn new things during the study that may affect your health or your willingness to continue in the study we will tell you as soon as possible. After the study has been completed, we will notify you of the results.

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

[Option] The [scans, images, tests, etc.] that you will have in this study are being done [for research purposes only/ as part of your clinical care and for research purposes]. [They are not/ Not all of the tests are] intended for diagnostic or therapeutic purposes. However, it is possible that doctors may notice something that could be important to your health. This is expected to be very rare. If this happens, we will contact you to let you know. If you want us to, we can explain what was noticed and can also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

[Option] You will have [scans, images, tests, etc.] in this study are being done for research purposes only. They are not intended for diagnostic or therapeutic purposes. The investigator or other staff is not able to make any medical comments about your results.

If you want your [scan, test results, etc.] to be reviewed by a physician so that the physician can look for medical issues, you can request a copy of your [scan, test results, etc.]. We will provide a copy at no charge.

[Option] You will have [scans, images, tests, etc.] in this study are being done for research purposes only. They are not intended for diagnostic or therapeutic purposes. The investigator or other staff is not able to make any medical comments about your results. You will not be notified of the results of these [scans, images, tests, etc.].

[If the options above to not describe how incidental findings are handled, you are required to include an accurate description of the plan]

## Can I stop being in this study? What are my rights?

You don’t have to be in this study. If you do choose to be in the study, you are free to partially or completely end your participation in the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your relationship with Ascension Wisconsin or any location owned or operated by Ascension Wisconsin. If you are an employee, your decision will not affect your employment status.

[Describe circumstances of withdrawal][An example of partially ending your participation would be to keep doing the follow-up visits/phone calls with the study doctor, but you will not be given any study drug. This way the study doctor can ask about your health and any changes in your health. The follow-up visits/phone calls will occur every other month until the study ends.]

If you decide to leave the study, talk with the study doctor first. The study doctor will help you withdraw in the safest way. [Describe any study specific details, if available].

[OPTION. Required if the study is FDA regulated]After you leave the study, no new information will be collected from you. Information that has already been collected will remain in the study database and be used to determine the results of the study.

[OPTION] After you leave the study, no new information will be collected from you. Information that has already been collected [can be withdrawn from the database if you choose/ will remain in the study database and be used to determine the results of the study/ other description].

In addition, the study doctor could end your participation in this study if they don’t feel that it is in your best interest, or if the study is stopped early. [Explain any other reasons or other circumstances where the PI may terminate the subject’s participation]

## What other choices do I have if I do not take part in the study?

If you choose not to be in this study, other options include the following:

* [List alternatives. Include major care options, such as drugs /devices/ procedures / supportive. This can be bullet or sentence format, depending on the information.]

The study doctor will discuss these with you. You do not have to be in this study to be treated for [disease, condition, symptoms].

## Is there anything else I should know?

Template language is provided for certain common cases, additional information can be provided here as needed for the study.

This section can be deleted if not applicable.

[Name] [is/are] [consultant/consultants] for [Sponsor]. In the past, they have been paid to [give lectures, to train other staff, and to provide consultation services]. They currently have an agreement to provide similar services for payment. We want you to be fully informed of this financial relationship with [Sponsor] as you consider your decision to participate in this study. Please let the study team know if you have any questions about this financial interest before deciding to participate in this study.

[Describe information. Examples might be information specific to Sponsor of funding (e.g. DoD) or population (e.g. prisoners)]

## Who can answer my questions?

You should contact the research team if you have any questions about the study, concerns, complaints, or if you think you have been hurt by the study.

You can contact them at:

[Name, title]; phone number: [###-###-####]; email: [include email if desired]

[If the researcher is a student, include the advisor’s name and telephone number]

[Repeat this information for all possible PI/contacts as needed]

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You can contact them at: at 414-465-3134 or IRB@ascension.org. You can contact them if:

* You have questions about your rights as a research subject.
* Your study questions, concerns or complaints are not being answered by the research team.
* You can’t get a hold of the research team or if you want to talk to someone else.

## ADDITIONAL INFORMATION

## about what will happen during this study

If only a summary of procedures was included earlier in the consent form, this section should be used to provide the details about study procedures.

Procedures listed earlier do not need to be repeated, but may be elaborated upon as appropriate.

This section should be customized to best explain the specific study.

Examples of formats include the following:

Study Calendar

Study Chart/Table

Study Plan/Schema (the schema from the protocol should not be used as it is usually too complex)

Visit List

Examples of these can be found in the document: INFORMED CONSENT FORM GUIDE: EXAMPLES “ADDITIONAL INFORMATION about what will happen during this study”

## ADDITIONAL INFORMATION

## About possible risks and side effects from being in this study

If only a summary of procedures was included earlier in the consent form, this section should be used to provide the details about possible risks, side effects and discomforts.

Risks listed earlier do not need to be repeated, but may be elaborated upon as appropriate.

Tips:

List risks and side effects related to the investigational aspects of the trial.

Side effects of supportive medications should not be listed unless they are mandated by the study.

If risks related to standard of care drug/procedure must be listed, it must be clear that the risks are the same whether or not they are in the study.

Physical and nonphysical risks and side effects should be listed, including such things as the inability to work.

* The terms should be written in lay language that is understandable to possible subjects; you can include technical language following each term if desired. Whenever possible, describe side effects by how they make a patient feel.

For example, "Loss of red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath.”

If frequency data is available, use the categories of “likely,” less likely,” and “rare but serious” as applicable for the specific study. If this format is not used, provide justification for why the format was changed.

“Serious” is defined as side effects that may require hospitalization or may be irreversible, long-term, life threatening or fatal.

Use numbers, not percentages, as a quantitative way for the reader to understand the category (i.e. 10 out of 100, not 10%).

Only side effects that are reasonably foreseeable should be included here. Side effects that occur in less than 1-2% of patients do not have to be listed unless they are serious, and should then appear in the "rare but serious" category with adequate, clear explanation that is helpful for subjects.

* Side effects that have been noted during treatment where not enough data is available to determine if the side effect is related to the drug/intervention/device are not required to be included in the consent form. However, if included, these side effects should be listed under a separate category.

Risks of the Investigational [Drug, Device, Biologic, Intervention, etc.]

The study [drug, device, intervention, etc.] can cause side effects. Everyone taking part in the study will be watched carefully for any side effects. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the [drug(s) or intervention]. In some cases, side effects can be serious, long lasting, or may never go away*.* There also is a risk of death.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Potential risks or side effects from the [drug, device, etc.] are:

Likely: Likely to happen to more than [20 out of every 100] people

* [Potential harm]

Less Likely: Likely to happen to [6-20 out of every 100] people

* [Potential harm]

Rare but Serious**:** Likely to happen to less than [5 out of every 100] people

* [Potential harm]

Side effects reported by patients, but not proven to be caused by [drug, device, etc.]

* [Potential harm]

Unknown Risks

Because this research study involves an experimental [drug, device, etc.], we do not know all of the possible harms or risks. Please tell the study doctor if you have any unusual side effects, even if you don’t think those side effects are a result of being in the study.

Risks from [Drug, Device, Biologic, Intervention, etc.] that are part of normal care

There are certain risks or discomforts from drugs or procedures that are done as part of your normal care. These risks would be the same if you are in this study or not.

They include the following:

[Describe]

Pregnancy During the Study

[This is the preferred template language; see additional optional language in the related IRB guidance]

The study drug or procedures performed during this study may include unknown risks to an unborn child if a woman is already pregnant or becomes pregnant during the study. Since the effects of the investigational drug on the female [and male] reproductive systems are still unknown, you and your partner MUST take appropriate precautions to avoid becoming pregnant [or fathering a child] throughout the study until your follow-up visit.

If you are pregnant or currently breast feeding, you cannot be in this in this study. Women are able to be part of the study if they are:

- post-menopausal for at least 1 year, or

- surgically sterile (had a hysterectomy or bilateral oophorectomy (removal of ovaries)) for at least 3 months, or

- able to have children and agree to take actions to avoid becoming pregnant

To check that you are not pregnant, you will need to agree to have a pregnancy test done [within the screening period and before you start the first dose of the drug. You will also have a blood or urine pregnancy test before each dose of study drug is given. If the urine test is positive, you will have a blood test done. If the blood test is positive, you will not receive any more doses of study drug.]

If you are able to become pregnant [or father a child] you must agree to take precautions that are at least 99% effective in preventing pregnancy while you are in this study [and for 3 months after your last dose of study drug]. The following methods have been identified in the medical literature as being at least 99% effective in preventing pregnancy:

1) Complete abstinence from sexual intercourse

2) Use of two of the following methods in combination (a+b or b+c or a+c)

a. Condom or occlusive cap (diaphragm or occlusive/vault caps) with spermicide

b. Oral, injectable, or implanted hormonal contraceptives

c. Tubal ligation or vasectomy (surgical sterilization) or intrauterine device or intrauterine system

You should discuss this matter thoroughly with your physician so that you are able to make an informed decision, and so you and your physician agree that you are taking appropriate precautions.

Other Potential Risks or Discomforts

Placebo

If you are randomized to the group who gets placebo, there is the risk that you will not get [the study drug/device or your normal medicine/treatment/ etc.] which means [condition/ specific symptoms] [may get worse/ explain effect].

Contrast Agent Used in Research Images

You will receive a contrast agent, called [name of agent], as part of your [name of procedure] done because you are part of this study. Contrast agents can cause allergic reactions and kidney damage. Allergic reactions can include mild itching associated with hives and can be as serious life-threatening emergency from difficulties breathing. If this occurs, it is treatable.

Exposure to Radiation from Scans or Images

This research study involves exposure to a small dose of radiation from a [procedure name]. This radiation dose is not necessary for your medical care and will occur only be done if you are part of this study. The cumulative radiation exposure from these tests is considered small and is not likely to adversely affect you or your disease. However, the effects of radiation add up over a lifetime. When deciding to enter this study, think about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason or radiation therapy for cancer treatment.

Genetic Tests

The risks to you and your family from genetic research are low. Your samples will be [Describe identification e.g. identified only with your study code number]

Also, a federal law (Genetic Information Non-Discrimination Act, GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you in this study. This law applies to all health insurance companies, group health plans, and employers with 15 or more employees. This law does not apply to companies that sell life insurance, disability insurance, or long-term care insurance. If you have questions about GINA or the risks of research on genetic information, please ask study staff.

We may wish to share your data or DNA samples with other investigators or national databases (e.g. the NIH database for Genome-Wide Association Studies (GWAS)) for future research. The shared information [will not include information that can identify you]. This information will include information about your diagnosis and genes. If you withdraw consent for sharing your information or samples, it will be removed and will no longer be used for future research. However, data and samples that have already been shared with other researchers cannot be taken back.

Illegal Behavior

If the study staff finds evidence that suggests that you have been physically or sexually abused, they are required by law to report this to local law authorities.

[We will not ask you about child abuse, but/ the study will ask about child abuse,] if the study staff finds evidence of child abuse or neglect, they are required by law to report this to local law authorities.

In this study, you will be asked about [illegal activities, sensitive information; specify]. We will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, courts have subpoenaed (required release) research records. The principal investigator has a Certificate of Confidentiality from the federal government. Your study records cannot be subpoenaed (released to courts at their request), and we will only release your study records if you ask us in writing.

Social and/or legal risks

There could be a risk of discomfort and harm [to psyche, reputation, employability, insurability, social status, criminal or civil liability] that may occur as a result of participation.

Questionnaires/ Surveys

There are no physical risks but some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question. If you become angry, emotionally upset or stressed out now or at a later time you can contact the following person for help [insert appropriate person’s name and contact information].

**[HIV Testing/ or other** Communicable Disease Testing**]**

There is the risk that you may find out that you are [HIV positive/ or explain]. These results may be emotionally upsetting and may cause you psychological distress. If you become angry, emotionally upset or stressed out now or at a later time you can contact the following person for help [insert appropriate person’s name and contact information].

Breach of Privacy and Confidentiality

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure your personal information to ensure confidentiality.

[Other Type of Risk]

[Describe]

Talk to your study doctor about any side effects that you have while taking part in the study.

## Statement of Consent

I have read the information above. I have asked questions and received answers. I consent to be in the study.

Print name of subject

Signature of subject Date Time

Legally Authorized Representative (LAR)

Signature of LAR Date Time

*Staff- Describe use/ authority of LAR:*

**Person Obtaining Informed Consent**

Print name and title of person obtaining consent

Signature of person obtaining consent Date Time

**Documentation of Risk, Benefit and Alternatives Discussion by Physician Investigator**

This is to verify that the physician investigator/ co-investigator below has explained to and discussed with the subject or the subject’s Legally Authorized Representative, the availability of all alternate, viable modes of treatment and the benefits and risks of such treatments before the initiation of the research-related intervention.

Include this section for any research study that involves a medical treatment or intervention in which consent is normally obtained in the clinical setting, and the medical records will be maintained at an Ascension Wisconsin facility, state law requires documentation that a physician who is the principal investigator or a physician sub-investigator on the study has informed the patient (subject) about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. It is the IRB’s position such discussion should take place prior to the initiation of any research related activity, and any attempt to delegate this responsibility to another individual (e.g., a non-physician study coordinator) would constitute a breach of the physician’s duty to provide informed consent under state law. However it is ultimately the principal investigator’s decision.

Print name of physician Investigator/Co-Investigator

Signature of physician Investigator/Co-Investigator Date Time

*The physician investigator completed this discussion prior to subject agreeing to participate. However, the physician investigator was not available to sign the form at the time the subject’s signature was obtained, so his/her signature was obtained at a later time.*

*Subject is signing this consent due to updates that do not involve risks, benefits or alternatives to participation. Therefore, physician investigator discussion/signature is not required at this time.*

## OPTIONAL RESEARCH ACTIVITY

## Agreement to allow the

## sharing, storage and use of [samples and/or health information] for future research

Include this section if the subject’s data and/or biospecimens will be shared with the sponsor, and the sponsor plans to use the specimens for future unspecified scientific research. Otherwise delete this section.

What is the purpose of this part of the study?

The purpose of this part of the study is to describe a research [samples and/ or data bank]. A research bank is a collection of health information or biospecimens (like blood, urine or tissue from a biopsy). The purpose of this bank is to collect, process and store [samples and/ or health information] until researchers need them to do research.

[Describe any specific purpose of this bank]

**Why am I being told about this bank?**

Because you have agreed to be part of the main study, we would like to ask you to allow your [samples and/ or health information] to be added to this bank.

[Briefly describe if the samples/health information will be collected specifically for the bank or if there will need to be extra collection for banking (e.g. We would like to take any leftover blood that we get as part of the main study and add it to this bank, along with some information about your health.)].

There is no set limit to the number of individuals who provide samples to this bank. The more [samples and/ or health information] we collect, the more useful the bank will be for research

You [have/ do not have] to be part of this bank if you agree to be part of the main study. So, if you don’t want to be part of this bank, you [will still/ will not] be able to be part of the main study.

**What will the [tissue and/ or health information] be used for?**

Your [samples and/or information] will be used to [describe the purpose of this collection and type of research which will be performed]. The long-term goals of the research are to learn how to better understand, prevent, diagnose or treat [insert condition]*.*

It is not possible to list every research project that might be done. Also, we cannot predict all of the researchquestions that will be important over the next years. As we learn more, there are new research questions and new types of research may be done.

Your samples and information may also be used for research on other conditions, including purposes that you might not have chosen to allow. This could include a wide variety of conditions such as mental illness, HIV/AIDS, cancer and others.

Any future research that is done [will/may/will not] include whole genome sequencing or other genetic testing.

**What happens to the biospecimen [samples and/ or health information] collected from me?**

Any [samples and/ or health information] that we collect will be sent to the research bank for storage. This research tissue bank managed by [name], the [Sponsor of the main study, or describe]*.* The [samples and/ or health information] will be stored and maintained in the bank to be used for research studies for [up to timeframe/ until they are used up/etc.]

Your samples may be used by [Sponsor], and [may also/ will not] be shared with research partners for scientific research purposes. Research partners working with the sponsor are not allowed to share samples with anyone who is not authorized by the sponsor. The [Sponsor, or describe] will control what is done with your samples.

What will I be asked to do for this banking study?

State explicitly that the procedures/excisions are being done as part of routine medical care and would be done whether or not they give their permission for their samples to be stored in the tissue bank.

If “extra” material will be taken for research, state this, and include the amount of extra material and, when applicable, any increase in procedure time.

If research specific procedures are being done for this bank, description of study visits and procedures the research participants will undergo, any surveys/questionnaires that will be administered, expected time commitment for the visit(s), etc.

Optional template language for each circumstance is included below.

[OPTION. If using left over research samples] If you agree to agree for you samples to be part of the bank, there is nothing else you need to do. As part of your participation in the main study, the study doctor will obtain [specify samples to be collected, e.g., tumor, blood, urine etc.] from you. After the tests for the main study are done, some of your samples might be left over. Normally these leftover samples would be thrown away. Instead, we will send your samples to the bank for storage and to be used later in research.

[OPTION. If collecting extra samples for banking] In addition to the samples that are being collected for the main study, we will ask you [Describe (e.g., to have an extra tube of blood drawn when they take the other samples/ to allow us to take an extra biopsy during your biopsy procedure] to be sent to the bank.

[OPTION. If collecting samples for specifically for banking] In addition to the samples that are being collected for the main study, we will ask you [to come in for an extra visit] to collect samples. [Describe the samples collected, how long it will take]. We may ask you to return [Describe (e.g. up to 3 more times)] to [Describe (e.g., provide the same or a smaller amount of blood)].

[OPTION. If collecting data with banked samples] We will collect some information from you or from your medical record. We want to understand how your blood sample tests relate to your other health information. We will [ask you a few questions about your medical history/ ask you to complete a short questionnaire about your health/take your temperature and pulse (heart rate)/etc.]. We plan to continue to review your medical record for up to [timeframe] to update your health information in the tissue bank computer database.

[OPTION. If collecting only data (no samples)] We will collect some information from you or from your medical record to add to the bank. We will [ask you a few questions about your medical history/ ask you to complete a short questionnaire about your health/take your temperature and pulse (heart rate)/etc.]. We plan to continue to review your medical record for up to [timeframe] to update your health information in the tissue bank computer database.

What are the possible risks or discomforts?

The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of confidentiality. We will protect your confidentiality by [Describe how (e.g. labeling your samples and information only with a code, and keeping the key to the code in a password protected database/ removing all identifying information from your information and/or samples before sending them to the bank/ etc.)].

Information that could be used to identify you will [only/not] be shared with [researchers working on this study/ researchers who have approval of an IRB/ or describe].

There is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record. Genetic information that results from this study does not have medical or treatment importance at this time. [**Your samples will be identified only with your study code number/ or describe].**

**Also, a federal law (Genetic Information Non-Discrimination Act, GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you in this study. If you have questions about GINA or the risks of research on genetic information, please ask study staff.**

**[Describe any other risks]**

There is no benefit to you for participating in this banking study. We hope that by using the specimens and data in this bank, researchers can find new information that might help breast cancer patients in the future.

What about results or new information?

Results of research done using your banked [samples and/or health information] will not be returned to you or your doctor and will not be used to make a diagnosis about your health. This kind of research can take a long time and has to include many people before results are known. Results may not be ready for many years and will not be relevant to your clinical care.

[If there are will be clinically relevant results, modify the above section and describe how they will be shared]

Any biospecimens collected as part of this study may be used by the [Investigator and/or Sponsor] (or research partner) to develop new information or products. They will own the use of the results, treatments, or inventions that can be made from this research. You will not be entitled to receive compensation from any commercial profit. [Or, describe if they would receive compensation]

**Can I stop being part of the bank?**

[OPTION. If NOT able to be withdrawn] You are not able to withdraw your [samples and/ or health information] once they are sent to the bank. This is because [Describe. e.g. the samples do not contain any identifying information about you so they cannot be found to be removed].

[OPTION. If able to be withdrawn]You can withdraw your consent for your samples to be sent to the bank and used for future research. This can be done at any time, for any reason. This will not affect your access to the medical care you would otherwise be getting.

If you do this, your samples will be destroyed after they are no longer needed for the main study. You would need to tell your study doctor that you are withdrawing your consent for your samples to be used for future research. If any samples and/ or health information] were already used for future research they cannot be taken back, but the sponsor will destroy any samples [samples and/ or health information] that they have left in the bank.

**Who can answer my questions?**

If you have any questions about the research or your rights as a research participant, use the contact information in the main consent form to contact the study doctor or the Institutional Review Board.

**Statement of Consent for Banking and Future Research**

**Mark your choice with your initials:**

\_\_\_\_\_\_\_ **I agree** to allow my samples to be kept and used for future research, as described in

this form.

\_\_\_\_\_\_\_ **I do not agree** to allow my samples to be kept and used for future research.

Print name of subject

Signature of subject (or LAR) Date Time

**Person Obtaining Informed Consent**

Print name and title of person obtaining consent

Signature of person obtaining consent Date Time