Ascension Wisconsin IRB

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

***Minimal Risk Studies***

Template v.10/03/17

This template is for minimal risk studies, such as surveys, interviews, focus groups or observation, and minimal risk interventions/interactions, like blood draws, MRI, community or educational interventions.

**INSTRUCTIONS**

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

**Modify the content languages 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:**

**D**elete 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**

* 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.

**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 and use lay terms.

For example:

“This study is being done to learn how we can better prepare people being discharged from the hospital”

[Explain purpose of the 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 had X treatment and are being discharged from the X unit.”

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:

“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.”

"You will talk with the study team and complete one survey before you leave today. After that we will call to check on you two times over the next three months. You will also be asked to complete another survey when you come in for your follow up visit for your normal care. Each call should take about 10 minutes and each survey should take about 20 minutes to complete. In addition to the time you are active in the study, we will collect information from your medical records for another year after your participation. You will be considered part of the study for a total of about 1 year and 3 months.”

[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.

Identify ALL research-specific 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

[Describe and screening process or procedures required]

During the study

You will be asked to [complete a survey, participate in a focus group, etc.].

Describe the activity, including any exams, test, procedures, and interaction with subjects and their identifiable data. Remember to present clear, key information for someone to use to decide if they should participate. This can be sentence or bullet format.]

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

After you are finished [with the survey today, the intervention], you will be asked to have follow-up including:

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

A [study chart/study plan] is another way to describe what will happen if you are part of the study. The [study chart/study plan] is included [later in 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.

Depending on the study, this section may or may not be all-inclusive. If the study is straightforward, all information may be presented here and does not need to be repeated later.

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 common are listed below.

**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. This is described in more detail later in this form.

**Other 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].

**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

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

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

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

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 template language below that is most applicable to the study, delete the others.

[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 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 the proposed language that is consistent with the contract, along with justification for the change.

Choose the template language below that is most applicable to the study, delete the others.

There are no additional costs to you if you participate in this study.

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]

If you have questions about study costs, you can talk to the Investigator or study team.

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

This section must be included for all studies that are greater than minimal risk. However, it is recommended to be included if there is any medical intervention.

If there is no medical intervention, this entire section can be deleted.

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 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?**

If we learn new things during the study that may affect you 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.

If new information, such as risks, outcomes or study results will be shared with subjects, describe it in this section.

Describe if/how clinically relevant research results, including general or aggregate research findings and individual research results, will be shared with subjects. For example, research-specific genetic testing or MRI results.

This section may be deleted if not applicable or modified as applicable to the specific study plan; preferred template language is provided.

[Required if the study is posted on ClinicalTrials.gov]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.

# 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]

[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?**

Describe if there are any alternatives available.

This section can be deleted if the only alternative is to not participate.

You do not have to be in this study. If you choose not to be in this study, you can [Describe. e.g. still receive services for X]

**Is there anything else I should know?**

Include if the PI or research staff have a financial COI: [Name] [is/are] [a 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.

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.

**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 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](mailto: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.

**Statement of Consent**

The signature lines can be removed ONLY if you are requesting to waive the requirement to obtain the subjects signature as documentation of informed consent (this is requested in the IRB application)

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 

Legally Authorized Representative (LAR) 



Signature of LAR Date

*Staff- Describe use/ authority of LAR:*



**Person Obtaining Informed Consent**

Print name and title of person obtaining consent

Signature of person obtaining consent Date