**Instructions for Completing the Informed Consent Form**

Please follow these formatting guidelines when creating your Informed Consent Document. Additionally, review the Guidelines to Ensure Health Literacy in the Consent Process when creating the content of your consent form. *Informed Consent Documents that are submitted outside of these and the literacy guidelines will be sent back for correction before review.*

* Follow the information outlined in the Guidelines to Ensure Health Literacy in the Consent Process which can be found in the Forms and Templates library within IRBNet.
* Consent forms should be typed in one font. We recommend not changing the font/size that is used in this template, but rather utilize bolding and italics to emphasize different sections of consent forms. It is strongly recommended that you use no smaller than 12-point font.
* Use black font.
* Write the consent form in the 2nd person (i.e., “you are being asked to participate in a research study…”) and keep the pronoun usage consistent throughout.
* Add the protocol #, version #, and version date to the top left corner of the header. **Do not remove the Template Effective Date.**
* Any portion of this template that is highlighted is instruction to the principal investigator and research team. **Highlighted text** **must be removed, and/or correct information must be entered** **prior to submitting the informed consent for review**.
* Do not change the size of the header and footers.
* Do not adjust the footer of this document. It is set at a size that accommodates our IRB stamp. An area approximately 1 inch by 2 inches on the bottom of each page is required for the IRB approval stamp. If you receive a consent document from a sponsor, you will need to copy and paste that document onto our template.
* If applicable, list the name of the study sponsor on the first page of the informed consent document where indicated. All other references to the sponsor document should be “sponsor” or “study sponsor.”
* **Make sure to use spell check and proof the document for grammar before submission.**
* If a section includes options for text to include, choose the option that is most appropriate for your study.
* If your study will require you to send patient specimens and/or identifiable patient data to a foreign country, contact Legal Affairs at (864) 797-7985.
* **Consent forms should be written at a 6th to 8th grade reading level.** Similarly, if you cut and paste language from another document into the consent form, please review the language to be sure that it is understandable at a 6th to 8th grade level.
* Avoid exculpatory statements such as “you understand.” Exculpatory statements are statements that appear to have the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.
* Readability statistics can be displayed in Microsoft Word. Search Microsoft Office Help for “readability statistics” for further instructions.

DELETE THIS PAGE OF INFORMATION IF YOU ARE USING THIS DOCUMENT TO CREATE YOUR CONSENT FORM.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

# *LIST COMPLETE TITLE HERE*

*Reminder: Highlighted sections are instructions to the investigator and* ***should be removed*** *from the final version of the consent form. Text in [square brackets] should be replaced with information that is specific to your study.*

## Study to be Conducted at: *List each facility name*

 *Address*

 *City, State Zip*

**Sponsor Name:** *List sponsor name here (if applicable)*

**Principal Investigator:** *List PI name and telephone number*

If your study includes children, use the following statement:

For legal guardians of minors, please note that any words referring to “you” (such as I, me, myself, you, your, yourself) also refer to “your child” throughout this consent form. Permission from you is required for your child to participate in this study.

**KEY INFORMATION**

You are being asked to participate in a research study. Participation in a research study is voluntary. The information in this consent form is meant to better inform you so you may decide whether or not to participate in this research study. Please ask the study doctor to explain anything you do not understand.

*Insert a concise summary of the study. Focus on key information that is most likely to assist a person in understanding the study and deciding why they might or might not want to participate. This includes, but is not limited to, the study purpose, the main risks and benefits, a description of how participation in the study would differ from routine care, and alternatives to the study.*

The Institutional Review Board of Prisma Health has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations.

Insert if applicable:

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

Insert if applicable:

#### This is a Phase I research study, which means that it is designed to test the safety of an investigational drug. “Investigational drug” means the drug is still being tested to see if it is safe and effective. It has not been approved for sale by the United States Food and Drug Administration. Phase I studies are done to find out the proper dosage levels and side effects of drugs that have never been given to humans, or that have been approved but have not been used, for example, in a specific drug combination or for a specific kind of cancer,(choose the appropriate reason).We do not know and we are not studying whether the study drug will help you or your disease.

#### *Insert if the study protocol includes data from animals:*

#### Animal studies with this drug have shown that *(take from study-specific protocol).*

#### PURPOSE

You are being asked to participate in this study because you have *[insert type of disease/condition, specific circumstance, certain credentials, etc.].*

##### The purpose of this study is …

*Include the following; can be in paragraph or bullet format:*

* *Background information on the condition being studied;*
* *Purpose(s) of the study;*
* *Information about whether or not the drug/device is approved by the Food and Drug Administration (FDA), and whether the drug/device is or isn’t approved for this specific disease/condition, etc.;*
* *Clear identification of what is investigational about the study and how it differs from routine care*
* *Approximate number of participants involved nationally and/or internationally;*

*Include the following if this is a Phase I trial:*

[Study drug] is an investigational drug and is not approved by the Food and Drug Administration (FDA). [Study drug] has never been given to humans. Therefore, specific side effects related to [study drug] in humans are not yet known. This study is a dose escalation study. Over the course of the study, the doses will be increased to determine the highest amount of the drug that can be given before the side effects make you too sick to continue. You may experience severe side effects, including death.

This study is not intended to evaluate whetherthe study drug is effective in the treatment of [study-specific disease]. Your participation will last for [months/weeks/until a certain event]*.*

*Include the following statement if this is a Phase II trial:*

The purpose of this study is to find out what effects (good and bad) [drug/intervention] has on your [condition].

*Include the following statement if this is a Phase III trial:*

The purpose of this study is to compare the effects (good and bad) of the [new drug/intervention] with [commonly used drug/intervention] on your [condition] to see which is better.

This research study is being done because… *choose an appropriate example, such as “currently, there is no effective treatment for this type of cancer,” or “it is not known which of these commonly used treatments is better.”*

# Your participation will last for *[months/weeks/until a certain event]*. *Where appropriate, state that the study will involve long-term / life-long follow-up (i.e., the study will continue to collect information until the death of the participant).*

*If the study is part of a student’s thesis, dissertation or class project, insert this text:*

The study is being conducted as part of the [thesis, class project] requirements of [university, school of nursing, etc.].

#### HOW THE STUDY WORKS

Include the following:

* *Clearly identify what is investigational about the study; describe all procedures to be followed and identify which procedures are experimental/investigational. Include the standard of care for this disease, if applicable (i.e., what the participant would receive if s/he were not enrolled in this study).*
* *Specific identification of any research or experimental procedures, drugs, devices, etc. and whether they are approved or not approved by the FDA;*
* *A complete description of the procedures to be followed; organize this section in chronological order with a list of study visits and requirements.*
* *How the participant will be placed into study groups (i.e., randomized);*

*If your study involves randomization, please insert this language:*

You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin (use if only 2 choices) or drawing straws (use if more than 2 choices). Neither you nor your doctor will choose what group you will be in. You will have an (equal, one in three, etc.) chance of being placed in any group.

* *If study is double/triple-blinded, explain steps to break the code in an emergency;*
* *If the study involves collection of body fluids such as blood, peritoneal fluid, urine, etc., include the amount of fluid taken in teaspoons or tablespoons.*
* *If your study involves a collaboration, indicate which other institutions are involved, to what extent they are involved, what information/specimens they will receive, and any other information relative to the collaboration that would be important to the patient.*

The section below is required only if the study collects any biospecimens (blood, urine, saliva, tissue, etc.). If this section is not applicable to your study, remove the header and text.

**RESEARCH USE OF BIOSPECIMENS**

This study involves the collection of biospecimens (bodily substances). Identify the biospecimens that will be collected and describe how they will be used in this study. You must specify whether or not research on the biospecimens may include whole-genome sequencing.

MUST include one of these four options:

OPTION 1

After use in this specific study, your identifiable private information will be removed from the biospecimens. These specimens and/or the information (other than identifiable information) may be used for future research or shared with another researcher without your consent. On the last page of this consent form, you can note whether you want your leftover specimen, if any, to be used for future research studies.

OPTION 2

The biospecimens collected for this study will not be used or distributed for future research studies.

OPTION 3

The biospecimens collected in this study will be stored for future research. The biospecimens may be labeled with your identifiable private information and also linked with your health information. If you do not agree to this storage/future use of your biospecimens, you cannot participate in the main study.

If using Option 3, include the following (can be explained in paragraph format):

* Purpose of the future research, if known, or explain possible ways the specimen could be used for any type of research
* Explain where the specimen will be sent/stored and who is responsible for maintaining the specimen(s)
* The length of time the specimens will be stored (e.g., 5 years, indefinitely, etc.)
* Explain the risks/benefits of specimen storage. Example language: There are no direct benefits to you for participating in the specimen storage part of this research study. The information gained form your specimen may possibly benefit others for the early detection, diagnosis, treatment, or cure of various diseases. The greatest risk is the release of information from your health records. The records about your specimen are considered confidential (private), but this confidentiality cannot be guaranteed.
* Describe if any information will be given back to the participant or their doctor.
* Include the following language as the HIPAA authorization for future use: Your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information for future research use.
* Explain how the participant can withdraw. Describe if their specimen and information will be destroyed and/or if the information already collected could still be used. Example language: You may ask to withdraw from this part of the study at any time, but there is no guarantee that your specimen can be returned. If you withdraw from using your specimen for future research, you are unable to continue in this study.

OPTION 4

With your permission, the biospecimens collected in this study will be stored for future research. The biospecimens may be labeled with your identifiable private information and also linked with your health information. You can participate in the main study even if you choose not to allow your biospecimens to be stored. You will be asked to review and sign a separate consent form for this future research use.

**Include one of the following for all research involving specimens:**

Your biospecimen may be used to develop new technologies, treatments or medications for different diseases. There may be financial gain by individuals or places using the information gathered from research on your biospecimen. You [will/ may/ will not/ may not] receive any financial compensation or share in any commercial profit that results from this research.

**OR**

Your biospecimen will be destroyed upon completion of this research project and will not be used or distributed for future research.

**POSSIBLE RISKS**

OPTION 1: For studies that involve no medical treatment or clinical procedures:

There are no known medical risks related to participation in this study. The greatest risk is the possible release of your personal health information. Your study records are considered confidential, but absolute confidentiality cannot be guaranteed. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

OPTION 2: For studies that involve medical treatment / clinical procedures:

Any treatment has possible side effects. The treatments and procedures used in this study may cause all, some, or none of the side effects listed. There is always the risk of very uncommon or previously unknown side effects.

Include the following:

*List side effects related to each drug/device/procedure involved in the study; consider presenting in table format or bulleted list. Describe any known risks associated with study-related procedure. Do not list risks for treatments that the patient would receive even if not participating in the study. Instead, include this statement:*

This study includes a [surgery/procedure] that is associated with certain risks. These risks are described in the separate treatment consent form.

*Use the following statement if applicable:*

These complications can sometimes lead to serious illness requiring hospitalization or lead to death.

**Include the statements below only if applicable to your study:**

If your study involves the use of a medical device, include the following:

A problem or malfunction of the device may increase your time in surgery under anesthesia.

If the study involves the possibility of an allergic reaction, include the following:

As with all medications, side effects may include allergic reactions. Allergic reactions may range from minor itching or rash to major reactions, which can lead to death.

*If the study involves inserting an IV or drawing blood*: Inserting a needle into a vein in the arm to receive fluids and study treatment and/or to collect blood samples may cause pain, redness, bleeding, bruising, fainting, a clot in the accessed vein and infection at the location where the needle is placed.

*If the study involves surveys, questionnaires, or diaries*: Some of the questions in the *choose one*: [survey/questionnaire/diary] are personal and may be upsetting to some participants. The study doctor or staff will be available to discuss these questions should you have a concern or problem. You do not have to answer any questions that you do not want to answer.

*For studies that involve questionnaires or surveys asking about depression/suicide/other mental health issues* ***OR***

*For studies that involve medications that may cause depression/suicidal thoughts/other mental health issues, please insert the below language:*

If you are depressed or become depressed as a result of this study, steps will be taken to ensure that you are put into contact with someone who can help you. If you have any suicidal thoughts or tendencies, please contact the Suicide Hotline at 1-273-TALK (1-800-273-8255) or 1-800-SUICIDE (1-800-784-2433). If you feel in crisis, you can also call 911 or go to the nearest Emergency Room.

If the study involves reproductive risks:

If the sponsor has more specific language regarding reproductive risks, please alter the language below as necessary.

You should practice an adequate method of birth control while taking part in this study. If you think that you have become pregnant or caused a pregnancy during this study, you must tell the study doctor immediately. This study may involve unknown risks to an unborn or nursing child. Women who are pregnant or nursing a child may not be able to participate in this study. You should tell the study doctor if you intend to become pregnant during this study. You may be required to take a pregnancy test before you participate or during the course of this study.

If the study involves the use of drug(s):

It is possible that receiving the study drug with your regular medications, supplements, or some food (for example, grapefruit juice) may change how the study drug, your regular medications, or your regular supplements work. It is very important that you tell the study doctor about all medications or supplements you are taking during the study. Tell the study doctor if you are taking any drugs, or non-prescription medications or supplements, including vitamins or herbs, other than those being used in this research study because of the risk of possible and/or serious drug interactions. Tell anyone who gives you medical care that you are participating in a research study.

*If this is an NCI-funded study, or any other study requiring physical and non-physical risk disclosure, please follow these instructions:*

List by regimen the physical and nonphysical risks of participating in the study in categories of “most common” and “less common” and “rare but serious.” Nonphysical risks may include such things as the inability to work. Do not describe risks in a narrative fashion. They should be in bullet format. Highlight or otherwise identify side effects that may be irreversible or long-term or life threatening.

If this is a Phase I trial, include the following statements:

While on the research study, you are at risk for side effects. Because (study drug) has never been given to humans, specific side effects are not yet known. In some cases, side effects can be serious, long-lasting or permanent, and could lead to death.

A significant risk to taking part in this research study is the likelihood of receiving a drug or dose of a drug that is not effective in helping your disease. This means that you may spend time and experience side effects of taking a drug that does not provide you with any health-related benefits.

Your study doctor will be following you closely to see if any side effects occur. Your doctor will discuss these with you. It is important that you promptly report any side effects that you experience to your study doctor or study nurse. Other drugs may be given to make side effects less serious and uncomfortable. If you or your study doctor feels that the side effects are too severe, the (study drug) may be stopped and you will be removed from the study.

(Study drug) has never been given to humans. In non-human testing, the following side effects have happened:

* list study-specific side effects in non-humans and add any study-specific language. Bulleted list preferred.

If there is a risk of secondary cancer, include the following statement:

Several chemotherapy drugs are known to increase the risk of developing a second cancer and/or leukemia (cancer of the blood). However, drugs in use today that are not currently known to cause this risk may be shown at a later time to cause the development of a secondary cancer and/or leukemia.

**The following language must be inserted for studies with genetic research:**

**GENETIC RISKS**

[Specify the genetic test(s) to be performed.]

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you.

Be aware that this Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

### POSSIBLE BENEFITS

It is not possible to know whether or not you may benefit from participating in this study. The treatment or procedures you receive may even be harmful. The information gained from this study may be useful and may help others.

Include any benefits to the participant or others that may reasonably be expected.

### ALTERNATIVE (OTHER) TREATMENTS

OPTION 1 (use when there is a medical intervention):

You can still receive evaluation and treatment for your condition if you do not participate in this study. Discuss any alternative treatments with your regular doctor and/or the study doctor before you decide to participate. The decision is entirely up to you. If you decide not to participate in the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

Describe appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant or routine care available outside the study. Describe Standard of Care (SOC) for this disease, if applicable; state what this is in lay language. Include “no further treatment” and/or “comfort care only”, if applicable.

List all that apply:

* You may choose to have the standard of care treatment, which is [Explain the standard of care].
* You may choose to take part in a different research study if one is available.
* You may choose not to be treated.
* You may choose to receive only comfort care to help relieve your symptoms, without receiving any treatment.
* List any other treatment options.

Please discuss these choices with your doctor.

*OPTION 2 (use when the study does not involve a medical intervention):*

The decision to participate in this study is entirely up to you. The alternative to participating in this study is simply not to participate. If you decide not to participate in the study, you will not be penalized in any way.

**NEW INFORMATION**

Your doctor will tell you about new information that may affect your willingness to participate in this research study. Alternatives, or other choices, concerning your care will be discussed at that time.

There are no plans to share individual research results with you. (Alternately, explain the circumstances under which clinically relevant or individual research results will be disclosed to study participants. This may also be covered under the “Procedures” section of this consent form).

*If the study utilizes a DSMB, insert the following statement:*

A Data Safety Monitoring Board will be reviewing the data from this research from time to time throughout the study. It will notify the study doctor of any new information that should be shared with you.

**COST TO YOU FOR PARTICIPATING IN THIS STUDY**

*OPTION 1. If the study is covering all study-related costs, include this text:*

Study funds will pay for all study-related items and services required by the research. We will bill you or your health insurer for items and services that are not part of the research and are part of your routine care. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. You will be responsible for the cost of any care not covered by insurance or study funds.

If you have any questions or are unsure about costs from taking part in the research, please speak with the study doctor or staff.

*OPTION 2. If the study is covering some but not all costs, include this text:*

Study funds will pay for the following items/services required by the research:

* *Include bulleted list*

Although study funds will pay for the study-related items and services specified above, there may be study-related services not paid for by the sponsor. We will bill you or your health insurer for routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. You will be responsible for the cost of any care not covered by insurance or study funds.

If you have any questions or are unsure about costs from taking part in the research, please speak with the study doctor or staff.

*OPTION 3. If the study is NOT covering any costs, include this text:*

All of the tests and procedures in this study are considered part of your routine care and will not be paid for by the study. We will bill you or your health insurer for these routine items and services, which you would have received even if you did not take part in the research. You will be responsible for payment of any deductible and copayments required by your insurer.

If you have any question about costs to you that may result from taking part in the research, please speak with the study doctor or staff.

*OPTION 4 If the study does not involve clinical care/any billable service (i.e., focus groups/surveys), include this text:*

There are no anticipated costs to you for participating in the study.

*If applicable (e.g., for expanded access studies), include the following paragraph:*

The following drug(s) are supplied free of charge: \_\_\_\_\_\_\_\_\_\_\_\_\_. If, during the study, this drug becomes commercially available, you may be asked to pay for the amount of drug needed to complete the study.

### PAYMENT FOR PARTICIPATION

**To You:**

*OPTION 1. If the participant will not be paid for participating, include this text:*

*You will not be paid for participating in this study.*

*OPTION 2. If the participant will be paid or reimbursed for any expenses,**describe the payment schedule, method of payment, total anticipated amount, and any situations in which the subject would not be paid. If the patient will be reimbursed, specify for what expenses the participant will be reimbursed (e.g., hotel, travel expenses, etc.).*

You will be paid [*fill in details requested above*]…

*This statement must be included if funds to pay participants will flow through Prisma Health:*

To process your study payment, you will be asked to complete a W-9 form with your name, address, date of birth, and Social Security number. If you receive $600 or more for study participation in this research study, or a combination of studies at Prisma Health in one tax year, Prisma Health will send you an IRS Form 1099 for tax purposes.

*Insert this language if using the Greenphire ClinCard for payment method:*

You will be paid via ClinCard, a reloadable debit card. The ClinCard program is owned by a company called Greenphire. The study team will give Greenphire your name, address, date of birth and Social Security number as part of the payment system. Greenphire will only use this information to make sure you get paid. Greenphire will not use your information for any other purposes, and they will not give or sell your information to any other company. The study team will provide you more information about the ClinCard program following study enrollment.

**To Institution:** *(remove statement if no sponsor/no funding)*

The Prisma Health (or appropriate institution) is being funded by the sponsor for staff and administrative costs associated with conducting this study.

*If any investigator on the study has a real or perceived conflict of interest with the study’s sponsor, refer to the Informed Consent Form Guidance Document for sample statements to use here. If there are no conflicts of interest that need to be disclosed to the participant, delete this section heading and content.*

**Conflict of Interest Disclosure**

*Insert required disclosure language from the conflict of interest management plan, when a study investigator has a conflict with the study sponsor. If this section is not applicable to your study, delete it.*

###### Compensation for Injury as a Result of Study Participation

###### We will provide you the care needed to treat any injury, or illness, that directly results from taking part in this research study. We reserve the right to bill your insurance company, the sponsor or other third parties for the care you get for the injury. You may be billed for these costs. For example, if the care is billed to your insurer, you will be responsible for the payment of any deductibles and co-payments required by your insurer.

The study sponsor, Prisma Health, or the investigators as part of this study have no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form

*Regarding financial responsibility for injury treatment, insert language that matches the Clinical Trial Agreement negotiated with sponsor. Prisma Health generally expects sponsors to pay for the costs associated with treatment of true research-related injuries.*

### VOLUNTARY PARTICIPATION

If applicable, include a statement that the study doctor and/or sponsor may withdraw the participant from the study at any time without the participant’s or their legally authorized representative’s permission, including a description of circumstances in which this may happen (e.g., if the participant did not follow study instructions).

Participation in this research study is voluntary. You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

However, if you decide to stop study participation, you are encouraged to talk with your doctor regarding safe removal from the study. Further treatment would be discussed at that time.

If your participation in this research study is stopped, your study doctor will discuss any tests or procedures that might be needed for your health and safety, but you may refuse any or all of these tests or procedures. Following this discussion with your study doctor, you still have the right to refuse any or all of these tests or procedures.

*[Describe any serious consequences of sudden withdrawal from the study.]*

# *Include the authorization below only if a HIPAA authorization is applicable to your study (i.e., the study involves the collection of medical data/PHI, the use of medical records, etc.) If your study does not use PHI, delete the section heading and content.*

*[For research involving Prisma Health employees, please include the following statement:]*

You are not required to participate in this study as a condition of your employment. Your participation is voluntary and should you choose to participate you may withdraw at any time. Any information that is shared as part of this research will not impact your continued employment at Prisma Health or impact any assessment or evaluation of your performance as an employee of Prisma Health.

# AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, the study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical records that is related to the research study. The study doctor and his/her research team will use and disclose (release) your health information to conduct this study. This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

Some of the organizations/entities that may receive your information are:

* The study sponsor and any company supporting the study (the sponsor’s authorized representatives)
* The Institutional Review Board, which is a group of people who review research with the goal of protecting the people who take part in the study
* Include this bullet only if the study involves a drug or device: The Food and Drug Administration (FDA) and the groups it works with to review research. Add similar regulatory agencies if other countries are involved in the study in the last bullet of this section. Remove this bullet for studies, such as NCORP cancer care delivery research studies, where the FDA will not see study data.
* List any other relevant trial organizations that could receive identifiable study data.

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information. If you do not agree to this use, you will not be able to participate in this study. Once your health information has been released, federal privacy laws may no longer protect it from further release and use.

The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written notice to the study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

If you have any questions about the privacy of your health information, please ask the study doctor.

Include the Confidentiality paragraph below only if the above HIPAA Authorization is not applicable to your study (i.e., study does not involve collection of medical data/PHI). If not applicable, delete the section heading and text:

**CONFIDENTIALITY**

Your study records are considered confidential (private), but absolute confidentiality cannot be guaranteed. Information may be kept on a computer. All records may be examined and copied by the Prisma Health Institutional Review Board, and other regulatory agencies. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

Certificate of Confidentiality language is required for any study that has been issued a Certificate of Confidentiality. This includes all studies funded by NIH after December 2017. If this is not applicable to your study, delete the section heading and content. If you have any questions, please contact Legal Affairs at 864-797-7985 or the Office of Human Research Protection at IRB@prismahealth.org.

**CERTIFICATE OF CONFIDENTIALITY**

The investigators of this study have been given a privacy permit, also called a certificate of confidentiality. This permit adds special protections for information and specimens that may identify you. Researchers are not allowed to share your identifiable information or identifiable specimens for any reason, including for a court order or subpoena.

Certain information from the research may be put into your medical record and will not be covered by the privacy permit. This includes records relating to medical tests, procedures, and other care your receive during the course of the study, as well as other information that Prisma Health and your providers may need to care for you and secure payment for your care.

Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy permit. The privacy permit does not stop you from voluntarily releasing information about yourself or your participation in this study.

**CONTACT FOR QUESTIONS**

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, whose information is included below.

You may also contact a representative of the Prisma Health Office of Human Research Protection for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997.

Principal Investigator Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# CONSENT TO PARTICIPATE

The study doctor, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given the opportunity to review my study doctor’s Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date Time

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date Time

Principal Investigator: Phone:

Sub-investigators: Phone:

If your study includes children, also include the following:

**PARENTAL PERMISSION**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Parent/Guardian Date Time

**FOR CHILDREN WHO BECOME ADULTS**

My parents/legal guardian agreed for me to participate in this treatment plan as a minor. I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to continue to participate in this treatment plan until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed and dated consent document.

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

If the study includes the option for any leftover specimen collected as part of this study to be de-identified and stored for use in future research studies, include the following; otherwise, delete the heading and text:

**CONSENT FOR ANY REMAINING SPECIMEN TO BE STORED FOR FUTURE RESEARCH**

I understand that I will have a specimen collected as part of this study. If any of my specimen is left over after use in this study, I understand that my study doctors would like to remove my identifiable information from the specimen and store it for use a future research study.

I [ ]  DO or [ ]  DO NOT agree to have any leftover specimen stored for future research, with the understanding that the specimen will not be labeled with any information that could be used to identify me.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_

Initials Date

If your study will not utilize a legally authorized representative for obtaining consent for a research subject, delete these pages.

**Legally Authorized Representative (LAR)**

You are being asked to enroll an individual in a research study because you are their Legally Authorized Representative (LAR). Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you. Please ask him/her to explain any words or information you do not clearly understand. We encourage you to talk with your family and friends before you decide to enroll your loved one in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are contained in this document. Please tell the study doctor or study staff if your loved one is taking part in another research study.

**Consent of Legally Authorized Representative (LAR) and Authorization for the Collection, Use and Disclosure of Health Information**

# I give consent to have \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ take part in this study [*and authorize that his/her health information be disclosed/collected as outlined above*]. I have received a signed copy of this form to take with me.

I understand that I am being asked to serve as the LAR and give permission for the individual outlined above to participate in this IRB reviewed and approved research study. My decision is based on what I believe this individual would choose for him/herself and what I believe is now best for him/her, based on the information I have been provided. I do not have any financial conflict of interest nor am I receiving payment for this individual’s participation in the research study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative Date Time

Printed Name Legally Authorized Representative

**Statement of Person Obtaining Informed Consent / Research Authorization**

I have carefully explained to the LAR of the person taking part in the study what he or she can expect from participation, the nature of the study, and the purpose of the study. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. The participant signing this consent form has (1) been given the time and place to read and review this consent form; (2) been given an opportunity to ask questions regarding the nature, risks and benefits of participation in this research study; and (3) appears to understand the nature and purpose of the study and the demands required of participation. This research subject has provided legally effective informed consent.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date Time

Principal Investigator: List PI name and telephone number

Co-Investigators: List all Co-Investigator names and telephone numbers