CONSENT TO PARTICIPATE IN RESEARCH

CASCARA: A Phase II Study of Carboplatin, Cabazitaxel and Abiraterone in High Volume Metastatic Castration Sensitive Prostate Cancer

Investigator Team Contact Information: For questions about research appointments, the research study, research results, or other concerns, contact the study team at:

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Supported By: This study is being conducted by the Prostate Cancer Clinical Trials Consortium (PCCTC) with the Masonic Cancer Center at the University of Minnesota as the lead site. For the purposes of this study, Sanofi-Genzyme is providing cabazitaxel and some funds to cover research related costs.

What is research:
Doctors and researchers are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to answer one or more questions about a new treatment approach to learn if it is safe and effective. Researchers learn things by following the same treatment plan with a number of participants. You, as an individual, may or may not be helped by volunteering for a research study; however, your participation helps answer the research question(s). Often one or more of the drugs offered on a research study are only available on a research study.
- The goal of routine (standard) treatment is to help you get better or to improve your quality of life using drugs and other methods that have been proven (often through previous research studies). Standard treatments are available from any cancer doctor.

If your doctor is also the person responsible for this research study, please note that he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

Why you are being asked to take part in this research study:
You are invited to take part in this research study because your prostate cancer has spread beyond the prostate but you still are responding to hormone therapy (androgen deprivation therapy or ADT). This is called metastatic castration-sensitive prostate cancer (mCSPC). This study is done to see if giving a course of anti-cancer drugs (6 treatments over about 18 weeks) followed by a once a day oral drug improves cancer control as measured by prostate-specific antigen (PSA) level (may indicate the presence of prostate cancer) and imaging studies (e.g. CT scan, bone scan).

This study consists of two parts:
1) Treatment with two anti-cancer drugs (carboplatin and cabazitaxel) given as an intravenous (into a vein) infusion once every 3 weeks for six treatment cycles over approximately 18 weeks (4 ½ months).

Followed by:

2) Treatment with abiraterone, taken once a day by mouth and continued until your disease worsens (progresses), you decide you want to stop, or it is felt to no longer be of benefit. As part of the study, you will only be followed for up to two years from the start of carboplatin and cabazitaxel.

You will continue to receive standard ADT throughout the study.

What you should know about a research study:
- The research study will be explained to you.
- You will receive a copy of this consent form to review.
- You can ask all the questions you want before you decide.
- It is up to you whether or not you take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.

Why this research is being done:
Once the cancer has spread beyond the prostate, it may become difficult to treat. The drugs used in this study are approved by the United States Food and Drug Administration (FDA) for the treatment of cancer; however, the combination is not standard and cabazitaxel is approved only for advanced prostate cancer. Carboplatin is an older drug and often used for the treatment of prostate cancer, although it is only FDA approved for

ovarian cancer. For this reason, cabazitaxel and its use with carboplatin is considered investigational.

The purpose of this study is to determine if giving carboplatin and cabazitaxel, followed by abiraterone, improves cancer control as measured by PSA level and disease assessment scans.

Duration of study participation:
Involvement in this study is approximately 2 years from the start of the chemotherapy drugs, cabazitaxel and carboplatin. If your disease progresses or you or your doctor decide to stop treatment, direct participation in this study will end, but disease related information will be collected from your medical record or other sources for 2 years.

What you need to do to participate:
If you are eligible based on the screening evaluations and agree to take part in the study, the following treatment is given. All treatment, tests and procedures are standard of care for the treatment of prostate cancer unless otherwise noted. You will continue on your current androgen deprivation therapy (ADT) through-out the study.

1) **Cabazitaxel and Carboplatin** (once every 3 weeks for 6 treatment cycles):
   Cabazitaxel and carboplatin are given once every 3 weeks as intravenous (into a vein) infusions in the outpatient clinic. You will also take prednisone twice a day. Six treatment cycles are planned over approximately 4 ½ months; however, if you end treatment before 6 cycles for a reason other than progression of your disease, you may be able to continue onto abiraterone.

Three weeks after your last dose of chemotherapy, you should have a standard of care **End of Study Treatment/Start of Abiraterone Visit**. This is to ensure you have no ongoing side effects, obtain a PSA level before start of abiraterone, and to receive a supply of abiraterone acetate.

2) **Abiraterone Acetate** begins about 3 weeks after the last dose of chemotherapy**:**
   You will start once a day abiraterone with daily prednisone. Both of these drugs are taken orally (by mouth).

   While receiving abiraterone, you will have a standard of care disease reassessment (bone scan and CT of chest, abdomen and pelvis), blood work and clinic visit once every 12 weeks (3 months). The PSA and scan results are collected from your medical record. Abiraterone continues until disease progression, you decide to stop, or it is felt to no longer be of benefit.

3) **At 1 Year and 2 Years** from the start of the cabazitaxel/carboplatin, you will have a visit directly related to this study, but at the time of a routine standard of care visit.

More detailed information about the study procedures can be found under **"What is involved in this study**".

Is there any way that being in this study could be bad for you:
You will have side effects from the treatment. This may include low blood counts which would increase the risk of infection, bleeding/bruising and anemia which could result in feeling tired or week. Other side effects may include diarrhea. You will receive medications before, during, and after the cabazitaxel and carboplatin infusion to prevent or lessen the expected side effects. The dose of one or more drugs may be reduced or treatment delayed if needed.

More detailed information about the risks of this study can be found under ***"*Risks of being in this study*".***

Will being in this study help you:
Each of the drugs given in this study are used to treat prostate cancer; however, in this study the combination and ordering of the treatment is investigational. It is not known if this will produce a better and longer disease control than standard therapy. This is why the study is being done.

More detailed information about the benefits of this study can be found under **"Benefits of taking part in this research".**

Alternatives to being in this research:
You do not have to be in this study. The study doctor will talk to you about other things you can do for your disease, including the important risks and benefits.

Your regular medical care at this study center will not change if you decide not to be in the study. Some other things you may be able to do include:

- Standard of care for your cancer without being in a study, which may include:
    - Androgen deprivation therapy (ADT)
    - ADT + abiraterone
    - ADT + docetaxel
    - Radiation therapy
- Taking part in another research study at this institution or another research center
- No treatment at this time with comfort care for your symptoms

Your doctors can provide you with additional information regarding your options.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be enrolled in this study:

Up to 61 persons with metastatic castration-sensitive prostate cancer (mCSPC) will take part in this study through Prostate Cancer Clinical Trials Consortium (PCCTC). It is expected that 30 patients will be enrolled at this site.

What is involved in this study:

Before you begin the study….

You will need to have the following exams, tests or procedures to find out if you can be in the study. These are part of regular cancer care and may be done even if you decide not to join the study. If you had some of them recently, they may not need to be repeated. This will be up to your study doctor:

- Medical history
- Physical examination with vital signs and height/weight
- Review of current medications
- Document your current androgen deprivation therapy (ADT) which you will continue for the duration of treatment. If you are not receiving ADT, your doctor will get you started on it per standard of care.
- Routine blood tests including blood counts (white blood cell, hemoglobin and platelet counts) check of liver and kidney function, and testosterone and PSA levels
- Assessment of symptoms from your disease and/or side effects from your current therapy
- Bone scan
- Computerized tomography (CT) scan and/or MRI of your chest, abdomen and pelvis
- An electrocardiogram (ECG) will be done to measure heart activity

It is important that you tell the study staff all of the medications you are taking. This includes both prescriptions and non-prescriptions (herbal products and over-the-counter medications). There are some medications that you are not allowed while on the study drugs. You should ask your study doctors any questions about the other medications you want to take during the study.

During cabazitaxel and carboplatin chemotherapy
If the exams, tests and procedures show that you can be in the study, and you chose to take part, then the following events will occur in the clinic once every 3 weeks.

- Physical examination with vital signs and weight
- Review of current medications
- Review of any side effects you may have experienced
- Routine blood tests as done at the start of the study
- Receive cabazitaxel and carboplatin intravenously (through a vein, or IV) over about 60 minutes

You will take prednisone by mouth two times a day every day during chemotherapy and continue with your current ADT medications.

3 weeks after the last dose of cabazitaxel and carboplatin:

- You will have a standard of care **End of Study Treatment/Start of Abiraterone Visit** to make sure you are not having ongoing side effects and to obtain a PSA level. At this appointment you will receive a prescription for abiraterone and prednisone with instructions to begin daily dosing.

You may continue on abiraterone for as long as you want to and it is considered to be of benefit.

Every 12 weeks you will have a repeat CT scan of the chest, abdomen and pelvis, a bone scan and blood collected for a PSA level. This is standard of care. The results of the PSA and scans are recorded in the study record. You may be scheduled for additional bloodwork and/or a clinic visit.

At 1 Year and 2 Years after the start of the cabazitaxel and carboplatin or at Progression/Change in Therapy:
At the time of a routine standard of care visit the following will take place:

- Physical examination with vital signs and weight
- Review of current medications
- Routine blood tests including a complete blood count and chemistries as well as PSA levels

If you discontinue abiraterone, your disease worsens, or you decided you want to stop at any time before the 2 Year visit, you will instead have a **Progression/Change in Therapy** visit. If the **Progression/Change in Therapy** visit occurs prior to the visit at 1 year, you will not be required to have the 1 Year and 2 Year visits. If the **Progression/Change in Therapy** visit occurs after the 1 Year visit, you will not be required to have a 2 Year visit. Instead your medical record will be reviewed for your PSA and scan results.

Research Related Sample Collection:
As this is a clinical research study, research related testing will be done on blood and tumor samples.

Additional blood (approximately 1 tablespoon) to look at circulating tumor cells (CTC) and cell free DNA (cfDNA) is collected at 3 timepoints at the time blood is collected for routine medical care:

- Before the 1st dose of cabazitaxel and carboplatin,
- Before the 2nd treatment of cabazitaxel and carboplatin,
- At the **2 Year visit** or, if you have disease progression or discontinue abiraterone before the 2 Year visit, this sample is collected at the **Progression/Change in Therapy** visit.

Circulating tumor cells are cells from your tumor that may be found in your bloodstream. Cell-free DNA may contain DNA shed by cancer cells into the bloodstream. Analyzing cfDNA may lead to a less invasive way to screen for changes in the cancer.

If you do not want genetic testing to be done on your samples, you cannot participate in this study.

If you have stored “archival” tissue from a previous biopsy it may be used; a sample of this tissue will be obtained prior to treatment start.

Genetic testing may include looking at mutations in both your tumor DNA and your normal DNA. Additional research tests may be done on the “archival” tissue sample to see if clues can be found as why some people respond to the study treatment better than others.

In addition, if you had any genetic testing done on a previous tumor sample, signing this consent form gives us permission to obtain those results.

At the time of study enrollment you are assigned a unique participant code that will be used instead of your name or other identifying information. The research samples are labelled with your unique code making it difficult for anyone looking at the sample to know it belongs to you.

None of the research related testing results will affect your care or your participation in this study. Neither you nor your health insurance provider will be charged for the cost of research sample processing, storage and/or testing. No research results will be placed in your medical record.

Storage of leftover blood and tumor samples for future research:

Your tumor sample and research blood samples that were taken for research related testing may be stored indefinitely for future research related to this study.

The results of the future testing will be used for research purposes only and you will not be told the results, nor will the results be put in your health record. The results of the future testing will not have an effect on your care. You will not receive any benefit from this future testing.

If you do not want your samples to be stored for future research related to this study, you cannot participate in this study.

Leaving this research:
You may leave the research at any time. Leaving will not be held against you.

If you decide to leave the research, contact the investigator or study staff. A member of the study team may ask you some questions about being in the study. If you decide to leave the study, let your study doctor know so you can receive the proper supportive care.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Meaning, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop being in the research, already collected information about you may not be removed from the study database. You will be asked whether the investigator can collect information from your routine medical care, such as your medical records. If you agree, this information will be handled the same as the information obtained for the research study.

Risks of Being in This Study:

Risks of Study Treatment:
While receiving treatment on this study you may experience side effects. You may experience all, some, or none of the side effects listed below, and the side effects may vary in severity. The severity may be mild, moderate or severe, up to and including death. Also, there is always the risk of a rare or previously unknown side effect occurring.

Other drugs will be given to make side effects less serious and uncomfortable, or your doctor may decrease or withhold a dose of one or more of the drugs. Many side effects go away shortly after the drugs are stopped, but in some cases side effects can be serious, long-lasting or permanent, even fatal.

You should tell your study doctor immediately if you think you are developing any unusual side effects even if they are not listed here. Any delay in treating these side effects may prolong their course, make them more difficult to treat and in rare occasions may even be fatal.

The tables below show the most common and the most serious side effects. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

Possible risks of **Cabazitaxel and Prednisone** include:		
Common, Some May Be Serious (more than 20% of patients)	**Occasional, Some May Be Serious (5 to 20% of patients)**	**Rare but serious (less than 5% of patients)**
• Decrease in your red blood cells (anemia) which can cause tiredness and/or shortness of breath and may require transfusions • Decrease in your white blood cells which could lead to infection • Decrease in your platelets (cells responsible for clotting) which may lead to an increased risk for bleeding and may require transfusions • Diarrhea which can be severe • Fatigue • Nausea • Vomiting	• Constipation • Generalized weakness • Abdominal pain • Blood in your urine • Loss of appetite • Back pain • Tingling or numbness in your hands and feet • Fever • Shortness of breath • Joint pain • Changes in taste • Cough • Indigestion/reflux • Hair loss • Water retention with swelling and weight gain mainly in your legs • Weight loss • Infection or fever with a low neutrophil count which may require hospitalization • Urinary tract infection • Dizziness • Headache • Muscle spasms • Painful urination • Sores in your mouth or throat • Changes in heart rate and rhythm (arrhythmias) • General pain • Dehydration • Low blood pressure which may cause you to pass out	• Life-threatening (fatal) infection can occur when your white blood cell count is low • Diarrhea with imbalance of your fluids and electrolytes (sodium, magnesium, potassium) can be severe, require hospitalization and, rarely, has been fatal • Vomiting which may be severe enough to cause dehydration, low blood pressure and/or abnormal kidney function, requiring treatment in the hospital • Allergic reaction while the drug is being given (fall in blood pressure, dizziness, flushing, fever, rash, shortness of breath, and/or wheezing) which can be fatal. This reaction usually occurs with the first few doses, is usually temporary and resolves after slowing the rate or stopping the infusion of cabazitaxel. • Decrease in platelets (cells responsible for clotting) which may lead to an increased risk for bleeding and may require transfusions • Decrease in kidney function which in rare cases has been fatal

Persons over 65 years of age were more likely to experience fatal outcomes and certain side effects, including a decrease in white blood cells, fatigue, generalize weakness, fever, dizziness, urinary tract infections and dehydration.

Possible risks of **Carboplatin** include:	
Common, Some May Be Serious (more than 10% of patients)	**Occasional, Some May Be Serious (10% or less of patients)**
• Decrease in your white blood cells which could lead to infection • Decrease in your red blood cells (anemia) which can cause tiredness and/or shortness of breath and may require transfusion • Decrease in your platelets (cells responsible for clotting) which may lead to an increased risk for bleeding and may require transfusions • Nausea and/or vomiting • Tiredness • Changes in the minerals in the blood such as sodium, calcium, magnesium and potassium as detected by routine blood tests • Skin rash	• Changes in the nerves that can cause numbness, tingling, or pain in the hands and feet • Mild to severe allergic reaction which may be life-threatening with hives, wheezing and low blood pressure • Hair loss • Ringing in the ears and hearing loss • Other sensory side effects (for example: visual disturbance or changes in taste) • Abdominal pain, diarrhea, or constipation • Decrease in kidney or liver function as detected by routine blood tests

Possible Risks of **Abiraterone and Prednisone** include**:**		
Common, Some May Be Serious (20% or more of patients)	**Occasional, Some May Be Serious (1 to 19% of patients)**	**Rare but serious (less than 1% of patients)**
• Peripheral edema (swelling of the legs as a result of body keeping too much fluid) • Low blood potassium (a mineral that helps regulate heart rate/function, fluid balance in the body and is needed for adequate body function) • High blood pressure	• Increase in enzymes that measure function of the liver • Urinary tract infection • High blood levels of triglycerides (a fatty molecule) • Cardiac failure (heart failure, the heart is unable to supply enough blood flow to meet the body's needs) • Chest pain • Changes in heart rhythm • A fast and irregular heart beat • Rapid heartbeats • Fractures (break in bones) • Indigestion, uncomfortable feeling in upper belly • Blood in urine • Fluid retention • Stomach bleeding • Seizures • Swelling of the brain • Emotional changes • Mood swings or severe depression • Eye problems such as cataracts or glaucoma	• Adrenal insufficiency (disorder that occurs when the adrenal glands don't make enough of certain hormone and don't produce adequate amount of steroid hormones) • Rhabdomyolysis (breakdown of muscle tissue) and myopathy (muscle weakness and/or muscle pain). • Allergic alveolitis (swelling and irritation of the lung) • Failure of the liver to function (called acute liver failure)

Possible Risks of **Abiraterone and Prednisone** include:		
Common, Some May Be Serious (20% or more of patients)	**Occasional, Some May Be Serious (1 to 19% of patients)**	**Rare but serious (less than 1% of patients)**
	• Insomnia (sleeplessness, wakefulness) • Elevated blood sugar (for diabetics, this can make your glucose level more difficult to control) • Increased risk of bone loss • Cushing's Syndrome: taking corticosteroids over a long period of time can cause a condition called Cushing's syndrome. Symptoms of Cushing's syndrome include: o Weight gain o Muscle weakness o A moon faced appearance o Thin, fragile skin o Brittle bones • Purplish stripe marks on the skin	

Reproductive Risks:
The drugs in this study may damage sperm or be present in seminal fluid. You should not father a child or donate sperm while on this study and for at least 30 days after stopping study treatment. You must use a condom during sexual intercourse for at least 30 days after stopping study treatment. If you are sexually active and could cause a pregnancy, you must use a condom with spermicide, or you must not have sex.

Risks of Blood Collection:
You will have blood drawn for research purposes at the same time blood is collected for your medical care. The risks of drawing additional blood will not change the usual risks which include:

- pain at the site of the needle stick
- tenderness and/or bruising at the site of blood collection
- dizziness or light-headedness
- very rarely, infection at the site of the needle stick

Risks of Genetic Research:
The risks to you and your family from genetic research on the tumor and blood samples are very low. The unique participant code assigned at study enrollment will be used instead of your name or other identifying information making it difficult for anyone looking at the sample to know it belongs to you. Testing will be done in batches (more than 1 participant at a time) and no research results will be placed in your medical record.

Risks of Radiation Exposure:
The CT scans and bone scan will expose you to radiation. These scans are standard of care for patients with your cancer and the risks are no different than any routine scan. The effects of radiation exposure add up over a lifetime. It is possible that having several of these tests may add to your lifetime risk of injury or disease such as cancer.

Benefits of Taking Part in This Research:

There may be no benefits to you from your taking part in this research. Your disease may not get better or may even get worse while you are in this study. Information from this study may help researchers develop better treatment options for others with prostate cancer in the future.

Discontinuation of Study Treatment:
You may be discontinued from abiraterone before the planned 2 years if any of the following occurs:

- you experience unacceptable side effects
- you are unable to comply with the study requirements
- your disease worsens or you require other anti-cancer treatment
- if the study doctor believes, for any reason, continuing on treatment is not in your best interest
- you decide you do not want to continue the treatment as planned

If you stop abiraterone you will have a **Progression/Change in Therapy Visit**. In this case your medical record may be reviewed for results of PSA testing and CT and bone scan results for up to two years from the start of chemotherapy.

Notification of Significant New Findings:
You will be told about any new information that may affect your health, welfare, or choice to stay in the research. You may be discontinued from treatment without your approval. Even if you want to continue treatment, there may be reasons the study doctor or study staff will need to take you off it.

Costs:
Cabazitaxel will be supplied at no cost by Sanofi-Genzyme for the purposes of this study. Carboplatin and the cost of the collecting, storing, and analyzing the research samples will be paid for by study research funds.

You and/or your insurance company will be responsible for all costs related to this treatment including, but not limited to, cost of preparing and giving the cabazitaxel and carboplatin, the costs of abiraterone and prednisone; the androgen depravation therapy (ADT), clinic visits, routine lab work, scans or imaging for disease assessment, any

medications given to prevent or treat side effects. You will be responsible for any costs your insurance does not cover, such as deductibles and co-payments. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. If your insurance does not pay, you will be responsible for the charges of your conventional medical care.

Compensation for Participation:
You will not be paid for participating in this study.

Research Related Injury:
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Confidentiality and Privacy:
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy.

Organizations that may inspect and copy your information including those that have responsibilities for monitoring or ensuring compliance include:

- Research personnel and/or their designee involved with carrying out this study,
- The Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution,
- The Prostate Cancer Clinical Trials Consortium (PCCTC), the group coordinating this study
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA), the U.S. Department of Health & Human Services (DHHS), and the Office for Human Research Protections (OHRP)).

The monitors, auditors, the IRB at your study site, PCCTC, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access.

The University of Minnesota (the lead institution) and Sanofi-Genzyme, the company providing cabazitaxel will receive patient data with indirect identifiers including reports of serious adverse events, information on treatment, disease response and side effects.

The results of this study will be used for teaching, publications, or for presentation at scientific meetings. The results also may be summarized in the background section of future research studies and publications. Results will never include information to allow an individual patient to be identified.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. The web site will include a summary of the results after the study is completed. You may search this web site at any time.

Research Samples:
Research samples will be sent to central research laboratories for study directed testing. No identifying information will be provided on these samples. In addition, Sanofi-Genzyme, who is providing some funding for the research related testing, will receive compiled (from the whole study) results with no patient directly identified.

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 or when setting the terms of your employment.

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.

Use of Identifiable Health Information
Your personal health information (PHI) created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the separate HIPAA authorization for details concerning the use of this information.

Contacts and Questions

You can call the investigator team at any time if you have any questions, concerns or complaints about the study procedures, study costs, study payment, or if you get hurt or sick during the study. Information for contacting the investigator team is provided on the 1st page of this document.

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

STATEMENT OF CONSENT
Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date
or Legally Authorized Representative

_____
Printed Name of Participant
or Legally Authorized Representative

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Use the signature block only if a witness to the consent process is required:

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:
☐ The participant is illiterate.
☐ The participant is visually impaired.
☐ The participant is non-English speaking.
☐ The participant is physically unable to sign the consent form. Please describe:_____
☐ Other *(please specify)*:_____

For the Consent of Non-English Speaking Participants when an Interpreter is Used:
A**s** someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Interpreter Date

_____
Printed Name of Interpreter

OR:

Statement from a Non-Interpreter:
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____
Printed Name of Individual