SUMMARY OF CHANGES - Consent

NCI Protocol #: 10437
Local Protocol #: **75028**
Protocol Version Date: January 10, 2022

Protocol Title: A Single Arm Phase II Study of Bone-targeted Sn-117m-DTPA in Symptomatic Castration Resistant Prostate Cancer with Skeletal Metastases

Informed Consent Version Date: January 10, 2022

I. Amendments by Principal Investigator

#	Section	Comments
1.	Page 5	**PI Response:** Added (1) PSMA PET CT scan is acceptable for the baseline scans and (2) modification of urinalysis collection time points.
2.	Page 8, Page 10 and Page 20	**PI Response:** PSMA PET CT scan is added in addition to CT scan and bone scan.
3.	Page 14	**PI Response:** Modification of blood collection amount has been added.

Research Study Informed Consent Document

Study Title for Participants: Treatment of cancer-related bone pain by using bone-targeted radiation-based therapy (Sn-117m-DTPA) in patients with prostate cancer that has spread to bones

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: P10437, "A Single Arm Phase II Study of Bone-targeted Sn-117m-DTPA in Symptomatic Castration Resistant Prostate Cancer with Skeletal Metastases" (NCT # NCT04616547)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have prostate cancer that has spread (is metastatic) only to your bones, causing moderate to severe pain.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Can we lessen the severity of the pain you experience from your prostate cancer spreading to bone by adding a drug to other cancer treatments you are getting? These other treatments may be drugs to reduce bone density loss, certain hormonal therapies to treat your prostate cancer, or a combination of these drugs.

We are doing this study because we want to find out if this approach is better or worse than the usual approach for metastatic prostate cancer. The usual approach is defined as care most people get for metastatic prostate cancer.

What is the usual approach to my metastatic prostate cancer?

The usual approach for patients who are not in a study is treatment with radiation therapy (either outside the body or injected into the body) and/or drugs that improve bone density. These treatments are all approved by the Food and Drug Administration (FDA). For patients who get the usual approach for this cancer, especially internal radiation therapy, about 50 out of 100 treated patients lived at least three months longer.

The usual approach to treat cancer bone pain is with different types of opioid drugs (oxycodone, morphine, hydromorphone, oxycontin, and fentanyl) and different ways of giving them to you (short-acting and extended-release forms, skin patches, or pumps that deliver the drugs directly to the spinal cord). However, tolerance can be developed, and over time higher doses are needed to ease bone pain. There are a lot of known side effects associated with opioids from mild to moderate-severe such as nausea, vomiting, severe constipation, drowsiness, sleepiness, confusion, breathing problems, and death in extreme cases.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will get the study drug Sn-117m-DTPA through a vein in your arm twice, with 8 weeks between the two doses. Your doctor may continue with two more doses at least 8 weeks apart if your cancer-related bone pain comes back within 6 months after your second treatment. You are only allowed to get a total of 4 doses in this study. The total length of study time is up to one year (6 months for the treatment and pain assessment and 6 months for follow up).

After you finish your study treatment, your doctor will continue to follow your condition every 4 weeks for 28 weeks, and then every 12 weeks or more often if your doctor thinks they are needed, for up to 1 year after your first study treatment or until your disease gets worse. Your doctor will watch you for side effects by obtaining urine and blood, and by taking detailed pictures of areas inside your body with a computer linked to an X-ray machine. This is known as a computed tomography (CT) scan and bone scan. Scans will be performed every 8 weeks for 24 weeks, and then every 12 weeks. You will need to come to the clinic every month for up to 6 months, then every 3 months for up to 1 year after your first study treatment. This means you will keep seeing your doctor for up to 1 year from the start of the treatment.

If you decide to take part in this study, you may not be able to get the usual care for your cancer for the duration of the study. Talk with your doctor to see if this will be necessary, and to decide if this study is a good choice of treatment for you.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that the study drug may not be as good as the usual approach at reducing the pain caused by your cancer.

There is also a risk that you could have side effects from the study drug. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects that the study doctors know about are:

- Bruising, bleeding
- Infection, especially when white blood cell count is low
- Nausea

There may be some risks that the study doctors do not yet know about.

Benefits

Sn-117m-DTPA has relieved bone pain in a limited number of people with prostate cancer that had spread to bone. It is unlikely that it will work in everyone with your cancer or help you live longer. This study may help the study doctors learn things that may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (the National Cancer Institute). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to test the good and bad effects of a drug called Sn-117m-DTPA. This drug has been tested in humans in a previous study that showed the drug relieved bone pain in a limited number of people with different types of cancers, including prostate cancer that had spread to bone. This drug could reduce the bone pain caused by your cancer, but it could also cause side effects, which are described in the risks section below. The study doctors hope to learn if the study drug will reduce bone pain within 12 weeks of treatment and maintain that pain relief for at least 16 weeks.

There will be about 25 people taking part in this study.

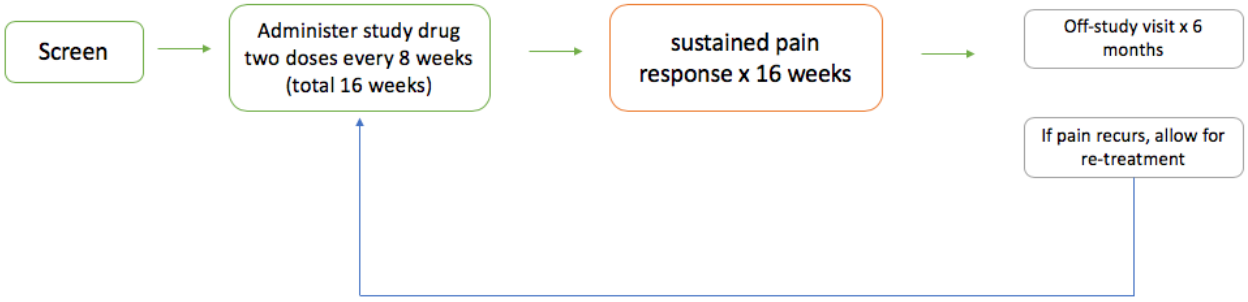
What are the study groups?

This study has a screening step. The purpose of this step is to find out if your cancer is in specific places in your body. Before beginning the study treatment, you will have a CT scan and a scan called a bone scintigraphy. If your scans do not show that your prostate cancer has spread to bone in at least two different places in your body, or if your cancer has spread to your liver, lungs, or you have any large lymph nodes, your doctor will discuss other options for your care.

In this study, you will get the study drug Sn-117m-DTPA. Your doctor will monitor your pain response, blood, and urine to monitor any side effects. All patients will receive the same dose.

About 25 patients will get the study drug.

Another way to find out what will happen to you during this study is to read the chart below.



What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- A computed tomography (CT) scan and bone scan or prostate specific membrane antigen (PSMA) CT scan before you begin treatment, every 8 weeks for 24 weeks during the study period if your doctor thinks they are necessary, and then every 12 weeks during the follow-up period for up to one year after your first dose.
- Blood counts done every 2 weeks during the first two cycles of treatment, every 4 weeks through 28 weeks, and then at routine clinic visit.
- Urine testing done at clinic visits at baseline and prior to Cycle 2.
- Physical exams done before you begin the study, every 4 weeks for 28 weeks, and then every 12 weeks or more frequently if your doctor thinks they are needed, for up to 1 year after the first study treatment.

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

If you speak English or Spanish and choose to take part in this study, you will be asked to fill out forms with questions about your pain medication use, your pain severity, and side effects from the study drug. Researchers will use this information to learn more about how well the study drug relieves your cancer-related bone pain, as well as any serious side effects the study drug causes.

You may answer the survey questions either on a paper form, your personal smart phone or tablet, or, if available, a tablet provided at your health care clinic. The use of your own electronic device on a cellular network may result in a nominal cost to your data plan. Regardless of the device you use, your answers and personal information will not be stored on the device. Your survey answers will be sent to the research database and will be kept private in the same way listed in the section about who will see your medical records. Your e-mail address will only be used for this survey study and will not be used for mail or marketing purposes.

If you need help using the survey application on your phone or tablet, ask for help at your study site. Someone may help you enter your answers in the device if you need. If using your phone or a tablet is not possible, paper-based surveys will be provided.

Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

You will be asked to fill out the questionnaires about your pain medication use, your pain severity, and side effects, before and every 2 weeks for 28 weeks after your first dose of the study drug, and when the new pain has recurred, and every 3 months starting on Week 28 for 6 months after your last dose of study treatment.

Each form will take about five to ten minutes to complete. The forms will ask about things like your pain severity, which you can rate by marking a box beside the number that best describes your pain at its worst in the last 24 hours (on a scale of 0-10). You don't have to answer any question that makes you feel uncomfortable.

A patient study calendar is attached at the end of this document. It shows how often these procedures will be done.

What risks can I expect from taking part in this study?

General Risks

If you choose to take part in this study, there is a risk that the study drug may not be as good as the usual approach at reducing the bone pain caused by your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The Sn-117m-DTPA used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about using condoms or other birth control methods to use, and about

donating sperm if you are a man, during the study and for 6 months after you have completed the study.

Blood Draw Risks

Some of the risks from drawing blood from your arm may include pain, bruising, light-headedness, and rarely, infection. For most people, needle punctures to get blood samples do not cause any serious harm. Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Side Effect Risks

The drug used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study drug.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

You should notify your doctor immediately at the first sign of poorly formed or loose stools or an increased frequency of bowel movements. Loperamide (Imodium) should be kept on hand and should be taken as recommended by your doctor.

Drug Risks

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Potential Side Effects of Sn-117m-DTPA
(Table Version Date: July 24, 2020)

POSSIBLE, SOME MAY BE SERIOUS
• Nausea • Bruising, bleeding • Infection, especially when white blood cell count is low

Additional Drug Risks

The study drug could interact with other drugs. Inform your study doctor of all prescription drugs, over-the-counter drugs, and other supplements you are taking.

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

Imaging Risks

The CT and bone scans or PSMA PET CT scan that you get in this study will expose you to low amounts of radiation. Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. This type of radiation is called "background radiation." No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The CT and bone scans or PSMA PET CT scan that you get in this study will expose you to more radiation than you get from everyday background radiation. The amount of radiation from this scan is the same as 5 years of exposure to the US national average natural background levels of radiation exposure. This amount of extra radiation has not been found harmful based on current data. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

As part of the CT scans and bone scan that you get in this study, iodine will be injected into your vein. Some people are allergic to iodine. Let your study doctor know if you have an allergy to iodine or seafood or if you have kidney problems.

Other Risks and Precautions

Sn-117m-DTPA is a radioactive therapeutic agent. Though the external radiation exposure associated with Sn-117m-DTPA is low, care must be used to keep body fluids from coming in contact with family members or caregivers. Your doctor will give you information on the good hygiene practices to follow to minimize radiation exposure from bodily fluids to household members and caregivers. Some of the precautions include using disposable gloves when wiping

up blood, urine, stools, or vomit, or when handling stained clothes. It is important to drink plenty of water (at least two to three quarts in a day) for two weeks after each Sn-117m-DTPA treatment. One quart is equal to one liter or 32 ounces. You should avoid drinking alcoholic beverages or limit the amount.

Clothing soiled with Sn-117m-DTPA or patient fecal matter or urine should be washed promptly and separately from other clothing. Use the same toilet each time you use the bathroom in your home, and if possible, use a different toilet than other members of your household. Sit down on the toilet to urinate to keep urine from splashing or spraying. Flush the toilet a few times after each use. Avoid prolonged contact with other people (for example, sleeping next to others or holding children or infants for extended periods, or taking long trips where you would have to sit near others). Please follow these guidelines after each Sn-117m-DTPA treatment for the timeframes indicated in the hygiene information your doctor gives you. Contact your health care team with questions you may have related to radiation exposure with Sn-117m-DTPA.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - if you have been or are currently in another research study.
- Complete the following forms provided to you:
    - Pain assessment forms (daily for 7 days [at least 4 out of 7 days] before your first dose of the study drug, every 2 weeks for 28 weeks after the first dose, and then at routine clinic visits or when pain recurs)
    - Analgesic Use forms (daily for 7 days [at least 4 out of 7 days] before your first dose of the study drug, every 2 weeks for 28 weeks after the first dose, and then at routine clinic visits or when pain recurs)
- **For men:** Do not father a baby or donate sperm while taking part in this study. Tell your study doctor right away if you think that your partner has become pregnant during the study or within 6 months after your last dose of study drug.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your metastatic prostate cancer. This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- your insurance co-pays and deductibles.

- the cost of any other cancer treatments (hormone therapy and drugs to improve bone density) and giving it to you.
- the CT or MRI scans and bone scans or PSMA PET CT scan before you begin treatment, every 8 weeks for 24 weeks during the study period, every 12 weeks during the follow-up period for up to one year after your first dose, or when your disease gets worse. Some of the scans will not be paid for by your insurance.
- routine blood tests to monitor your health and safety, and prostate-specific antigen (PSA) tests, every 4 weeks and at routine clinic visits.
- urinalysis at routine clinic visits during Cycles 1 and 2.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- The costs of getting the Sn-117m-DTPA ready and giving it to you.
- The blood tests to monitor your health and safety done at Week 1, Week 2, and Week 6 of each cycle during the study.

You or your insurance provider will not have to pay for the Sn-117m-DTPA while you take part in this study.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor and any company supporting the study or study agent now or in the future. This would include any organization helping the company with the study.
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.

- You will not get reports or other information about any research that is done using your information.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor (*insert name of study doctor[s]*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading these optional studies hope the results will help other people with cancer in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say "no" to any or all of these studies. There is no penalty for saying "no." You and your insurance company will not be billed for these optional studies. If you sign up for but cannot complete any of these studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

Optional bone scans during treatment

If you choose to take part in this study, you will have additional bone scans to determine how much of the study drug gets into your bones. These scans are like the bone scan you will need to have before the beginning of the study to determine if you are eligible to participate. The additional scans will be done 1 hour, 4 hours, 1 day, 2 days, 3 days, 1 week, and 4 weeks after you get the first dose of the study drug. You will also be asked for urine samples at the time of each of the additional bone scans to determine how much of the study drug has left your body. You and your insurance provider will not have to pay for these additional scans or urine tests.

Please circle your answer: I choose to take part in the additional bone scan study and will have the scans and give urine samples at the times described above:

YES NO

Optional sample collections for known laboratory studies and/or storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Known future studies

If you choose to take part in this optional study, researchers will collect your blood, as well as tumor tissue from your previous biopsy, for research on evaluating the changes in your DNA and RNA that occur during treatment. Researchers will obtain genetic material (DNA and RNA) from both your tumor cells and your blood. Your DNA and RNA will be used for genomic sequencing, which is sequencing of all or part of your DNA. All your genetic information makes up your genome. Genomic sequencing is a test that records all or part of the pieces of DNA that are in your genes, piece by piece. This is usually done to look for changes in your genome that may cause health problems. The genomic sequencing will be done by an NCI-supported laboratory in Frederick, Maryland, known as the National Clinical Laboratory Network (NCLN) Genomics Laboratory at the Frederick National Laboratory for Cancer Research. The laboratory will compare the genomic sequences from your tumor and blood cells to identify how they differ. The differences between genomic sequences of your tumor and blood cells may be important to understand why you did or did not respond to the treatment you received. Researchers hope to find potential "biomarkers" (changes present in tumor tissue that predict how patients with your type of cancer may respond to current or future treatments). This optional study may improve the ability to select future treatments or treatment combinations for others in the future. This optional study will not affect the cancer treatment or approach that you receive.

Neither you nor your study doctor will be informed when the genetic sequencing research will be done. You and your study doctor will not receive reports of these studies, as they are intended for research purposes only and cannot be used to plan treatment.

We will also perform tests to see if the radiation from the study drug changes the amounts of immune cells or markers of inflammation in your blood.

Unknown future studies

If you choose to take part in this optional study, any of your tumor tissue or blood samples left over from the genomic sequencing will be stored. Storing samples for future studies is called "biobanking." The biobank is being run by the Nationwide Children's Hospital in Columbus, Ohio, and is supported by the NCI. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

We do not know what research may be done in the future using your tumor tissue and blood samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- Future research studies may include genomic sequencing.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes.

If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

1. About 2 tablespoons of blood will be collected from a vein in your arm before you begin study treatment, at the end of the first treatment cycle, at the end of the second treatment cycle, and during Week 24 of the study, and sent to the biobank. A sample from the tissue that was collected at your previous biopsy will also be sent to the biobank. If this tissue sample is sent to the biobank, an additional 0.5 tablespoons of blood will be

collected from a vein in your arm before you begin study treatment and sent to the biobank as well.
2. Your samples will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise. Pain can be treated with regular pain medications.
- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information. Only your study doctor and a few study researchers will have access to the master list linking the code numbers to names. The biobank and the genomic sequencing laboratory will receive your samples with the following information only: your sample code number; your age, race/ethnicity, and gender; your type of cancer; any previous treatments you received for your cancer; and the treatment you will receive for this current study.
2. Researchers who study your samples and information will not know who you are. They also must agree that they will not try to find out who you are. The researchers must be trained in the handling of private information. Any researcher who wants to study your stored samples and genetic information must apply and be approved to do so.
3. Your personal information will not be given to anyone unless it is required by law.

4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

There are no costs to you or your insurance for exams, tests, and procedures done for research purposes only; these include the biopsy, blood draw, DNA/RNA sequencing, and biobanking of your specimen(s). You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, (*insert name of study doctor for main trial*), at (*insert telephone number of study doctor for main trial*), who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I need my tissue or blood samples to be returned?

Tumor tissue or blood samples that remain in the biobank can be returned if needed for medically necessary events or procedures to assure appropriate medical care, such as for DNA or RNA analysis. Specimens may also be returned if tissue is needed to determine eligibility for enrollment in a research protocol or clinical trial. Every effort will be made to facilitate medically necessary events or procedures to assure appropriate medical care for a patient with a serious or life-threatening illness.

Tumor tissue or blood samples and genetic material (DNA and RNA) that is no longer in the biobank or that has already been given to or used by researchers cannot be returned. No samples will be returned for matters related to patients needing or wanting genetic testing to determine medically important risks.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, (*insert name of study doctor for main trial*), at (*insert telephone number of study doctor for main trial*).

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for known future studies:

I agree that my samples and related health information may be used for the laboratory studies described above.

YES NO

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to learn about results from these studies.

YES NO

Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature

Date of signature

Signature of person(s) conducting the informed consent discussion

Date of signature

Patient Study Calendar

	Pre-study	Cycle 1					Cycle 2					Post-treatment						Follow-up	Off-study
		W1	W2	W4	W6	W8	W1	W2	W4	W6	W8	18 weeks	20 weeks	22 weeks	24 weeks	26 weeks	28 weeks		
Sn-117m-DTPA[a]		X					X											X[b]	
Pre-study (Before you begin study treatment) procedures including informed consent, medical history, height, and demographics	X																		
Physical Exam, vital signs, and weight	X	X		X		X			X		X		X		X		X	X[c]	X
Assessment of how you perform every day tasks and activities	X																	X	
Review of your pain medication	X	X	X	X	X	X		X	X	X	X		X		X		X	X[c]	X
Blood draws for complete blood count and general health	X	X	X	X	X	X[h]	X	X	X	X	X		X		X		X	X	X
A test to measure the amount of prostate specific antigen (PSA) in your blood	X			X		X			X		X		X		X		X	X	X
Completion of forms about your pain medication use, pain severity, and side effects	X		X	X	X	X		X	X	X	X	X	X	X	X	X	X	X[e]	X

	Pre-study	Cycle 1					Cycle 2					Post-treatment						Follow-up	Off-study
		W 1	W2	W4	W6	W8	W1	W2	W4	W6	W8	18 weeks	20 weeks	22 weeks	24 weeks	26 weeks	28 weeks		
Optional scans (dosimetry imaging) to measure how much of the study drug gets into your bones		X	X	X															
Urine collection for urine tests	X						X												
Medical Imaging scans for tumor measurements PSMA PET CT scan or CT scans and bone scans[i]	X					X					X				X			X	
Side effects evaluation		X----------X																	
Optional blood collection for research purposes	X[f]					X [d]					X [d]				X				
Optional left over tumor tissue from your previous biopsy	X[f]																		

a: You will receive Sn-117m-DTPA in vein through your arm on Day 1 of each cycle.
b: You can be retreated if you experience pain at least 6 months after your second dose of the study drug, as your doctor indicates it is necessary.
c: The assessment will occur every 3 months.
d: Your blood will be collected on the last day of each cycle.
e: Additional forms about your pain and side effects will be requested every 3 months for 6 months after your last study treatment starting at 28 weeks.
f: If you allow leftover tissue to be sent to the biobank, 0.5 tablespoons of blood will also be collected before you begin study treatment and sent to the biobank.
g: Urine collections during the first 4 weeks of Cycle 1 will be collected at each additional bone scan if you choose to take part in that optional study.
h: Will be performed 1 week before the start of Cycle 2.
i: Scans for tumor measurements will be done every 8 weeks if your doctor thinks they are needed.