

# STANFORD UNIVERSITY Research Consent Form

Protocol Director: Susan J Knox, MD

*IRB Use Only*

Approval Date: April 17, 2018

Expiration Date: April 17, 2019

Protocol Title: A Phase 1 Study Evaluating the Efficacy and Safety of Sodium Selenite in Combination with Palliative Radiation Therapy in Patients with Metastatic Cancer

Are you participating in any other research studies?  Yes  No

## PURPOSE OF RESEARCH

You are invited to voluntarily participate in a research study of the investigational drug sodium selenite. This document is to be used as a guide for a discussion between you and your Study Doctor and the study team. This form, called an informed consent document, was designed to help you understand why this study is being done; what part of the study is “research” or “experimental;” what will be asked of you if you choose to participate; possible risks; any inconveniences or discomforts you may experience; and other important information. This form may also be helpful as a reference if you choose to participate, as a reminder of what your role in the study is, and who to contact if you have questions at any time during your participation. You are urged to discuss any and all questions you have about this study with members of the study team. If you wish, you can also discuss this study and your role with your family doctor or medical provider. The study team hopes to learn if adding sodium selenite to radiation therapy improves the overall anti-cancer effect, and is safe to use. You were selected as a possible participant in this study because you are an adult with actively growing cancer (metastatic cancer).

The parts of this study that are research are treatment with sodium selenite; an extra electrocardiogram (ECG) procedure (discussed below), and collection of certain blood samples. Your radiation treatment and treatment monitoring will be according to standard medical practice, also known as standard-of-care (SOC).

The use of sodium selenite in this research study is investigational. The word “investigational” means that sodium selenite is not approved by the Food and Drug Administration (FDA) to sell in the United States for the use in this study. However, FDA is allowing the use of sodium selenite as part of this research study.

If you decide to terminate your participation in this study, you should notify Susan J Knox, MD at [REDACTED] or [REDACTED] (administrator).

This research study is looking for about 35 patients with metastatic cancer. All participants will be enrolled at Stanford University.

This study is being paid for by Stanford Cancer Center.

## VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate

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now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

### DURATION OF STUDY INVOLVEMENT

Treatment for this research study will start within 28 days of your initial Screening Visit. The duration of your participation in this research study is based on the details of your SOC radiotherapy treatment plan.

You will be scheduled for your first Follow-up Visit about 2 to 3 months after your last treatment with sodium selenite, or you otherwise stop being in this study. You may be asked to return for additional visits to see how you are doing.

### PROCEDURES

It may be harmful to enter this study while receiving some medications, therefore, you may need to stop taking certain medications. Your Study Doctor will review your medications and provide you with specific instructions.

Before you begin the study, you will need to have certain medical examinations, tests, or procedures to find out if you can be in the study. Some of these examinations, tests, or procedures may be part of your regular medical care, and/or and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated.

Before you join this study, the Protocol Director Susan J Knox, MD, and/or the research study staff will review this document with you, and ask you to sign this informed consent document. After you have signed this document, and received a signed copy, the study will begin with a screening visit.

#### Screening Visit

If you choose to participate, the first activity will be screening. During the Screening Visit, you will be asked to have the following tests and activities or assessments.

**General information:** Information about you, such as date of birth; gender (sex); and ethnic origin (“demographic information”)

**Medical history:** Your complete medical history will be reviewed

**Physical examination:** A complete physical exam will be performed, including:

- Your vital signs (blood pressure, heart rate, temperature, breathing rate); weight; and other measurements

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- General examination of your heart and lungs; skin; muscles and joints; stomach and gastrointestinal tract; and nervous system
- Ear, nose, and throat examination
- You will be asked how well you are able to perform normal daily living activities. This is called a performance evaluation or a performance status assessment.

**Electrocardiogram (ECG):** This non-radiation test measures and records the electrical activity of your heart. The procedure is called a 12-lead ECG because 12 wires will be attached to your chest near your heart, and at your wrists/arms and ankles/legs with adhesive pads. You will be asked to lie still during the procedure. A computer will make a recording of your heart's electrical activity, which will tell doctors information about how well your heart is working. This test may be used in combination with other imaging procedures described below.

**Blood collection:** Blood collection will typically be from a vein in your arm, using a blood collection needle. This is called venipuncture. About 2 tablespoons (30 mL) of blood will be collected for:

- **Complete blood count (CBC) with differential and hematology**, including red blood cells (RBC, oxygen-carrying cells); white blood cells (WBC, infection-fighting cells); platelets; and other blood components.
- **Serum chemistry**, consisting of tests for blood chemicals, including lactate dehydrogenase (LDH), that indicate how well your body and organs are working, and if you have any significant diseases.
- **Prostate-specific antigen (PSA) testing (for prostate cancer only)**. PSA is a tumor marker. The levels of tumor markers indicate how active a person's cancer is.

**Tumor assessment:** The extent of your cancer will be determined by a radiology scan(s) such as a magnetic resonance imaging (MRI); bone scan; computed tomography (CT); positron emission tomography/CT (PET/CT); of your cancer. These procedures are reviewed below.

### **Magnetic Resonance Imaging (MRI) with or without the use of a contrast agent:**

An MRI, which does not require a radiation exposure, may be used in place of the computed tomography (CT, described below) or other radiological X-ray scan. The scan will take about 30 to 60 minutes. The MRI scan evaluates blood flow and the extent of the cancer. The MRI will be performed according to standard practice. MRI machines use a powerful magnet and radiofrequency fields to make images of the body interior. An MRI scanner is large, tunnel-shaped machine, and uses a strong magnet and radiofrequency magnetic fields to make images of the body interior. This magnet is very strong, and will attract or pull on some metals and affect some electronic devices, including magnetic access cards, and the magnetic strip on credit / debit / ID cards. Do not bring any metal objects into the magnet room. Any metal objects that you are

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carrying or have in your body could be a hazard to you or others. Watches; hearing aids or other removable medical devices; jewelry/rings; credit/debit /ID cards; access cards; should be removed. You will be provided a way to secure these items. Because the magnetic field is so strong, tell the study team now, and also tell the MRI operator before entering the MRI room, if any of the following apply to you.

- **IT IS VERY IMPORTANT THAT YOU IMMEDIATELY TELL THE INVESTIGATOR AND THE MRI OPERATOR** if you have a cardiac pacemaker or any other biomedical device in or on your body.
- You have any other metal objects in or on your body, such as:
  - Metal plates; pins; screws; surgical clips
  - Medical devices, including hearing aids
  - Other implants
  - Metal fragments in your body, such as bullet fragments or shrapnel fragments
- You have ever had a head or eye injury involving metal fragments;
- You have ever worked in a metal or fabrication shop;
- You have a history of severe allergies, or have previously had a reaction to a Gadolinium-based contrast agents.
- You have, or previously had, kidney problems, or
- In some cases, these could mean you should not have an MRI scan performed.

The scanning procedure is very much like an X-ray, but uses a strong magnetic field instead of X-rays. You will not be able to feel the magnetic field. You will be asked to lie on a long narrow bench for up to 45 minutes while the machine performs the scan. You will be asked not to move during the scan and to relax and breathe normally. During this time you will not be exposed to X-rays, but rather the magnetic field. During the scan, the bench you are lying on will move into a narrow space in the scanner.

Many steps have been taken to make the procedure comfortable, but you may still may experience some discomfort or anxiety ("claustrophobia") from being in this confined space. If this bothers you too much, the study team may provide you with a medication to help you stay calm. The scanner will make repetitive tapping noises, which can seem very loud inside the scanner. You may be provided with earplugs or headphones to wear.

A **bone scan** may be performed according to standard practice to detect, monitor, or rule out malignant bone lesions. If you have had an X-ray using a barium contrast material (such as a barium enema) or have taken a medicine that contains bismuth (such as Pepto-Bismol) within the past 4 days, tell the Study Doctor or study team as barium or bismuth can interfere with the scan results (ask if you need more information about this). It is not necessary to fast before the bone scan, but it is best to avoid eating a meal or drinking large amounts of fluids before the test. A tourniquet will be applied to

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your arm to help find a vein, and a radioactive tracer [(technetium-99m-methyl diphosphonate (“99mTc-MDP”)) will then be injected into a vein.

A radioactive tracer is a combination agent that has a radioactive element attached. 99mTc is the radioactive part of the tracer, and is widely used for this procedure and the most commonly-used medical radioisotope. The tracer circulates through the body part of interest, and the pattern of the signal from the radioactive element tells the doctor information about that body part. You will have to wait 2 to 3 hours after the injection before the scan can be performed. You will lie on your back on a bench for up to about an hour within the scanner and must be as still as possible during the scan. You may be asked to assume various positions on the table in order for all of the necessary images to be taken. The scanner will move back and forth slowly, recording images for about 1 hour. After the scan, you should drink plenty of fluids.

**A computed tomography (CT) scan (an “X-ray”)** may be performed according to standard practice, and is a computerized imaging procedure that makes many cross-sectional images (often called slices), both horizontally and vertically, of the body. For this study, the CT scan will be used to look at blood flow and the extent and activity of the cancer in your entire body. The scan will take about 30 to 60 minutes. You must not drink or eat anything for 4 hours before the test. You will need to remove all jewelry, piercings, and other metal items. Unless there is medical reason not to (a “contraindication”), a contrast agent called Omnipaque 350 (Iohexol); or Isovue (iopamidol) 300 or 370 will be used for the scan to improve the quality of the image. **IT IS VERY IMPORTANT THAT YOU IMMEDIATELY TELL THE INVESTIGATOR AND THE CT TECHNICIAN** if any of the following apply to you:

- You have, or previously had, kidney problems.
- You are taking Glucophage (metformin).
- You have any allergies to medications, contrast agents, iodine, or shellfish, or have a history or severe allergies.
- You have recently taken or received barium (“barium study”) or bismuth, or have recently taken Pepto-Bismol; Kaopectate; Maalox; Bismatrol; or other digestive aids.
- You have a cardiac pacemaker or any other biomedical device, such as surgical clips, pins; screws; or metal plates in or on your body.
- You have any body piercings near your cancer
- You have ever had a head or eye injury involving metal fragments;
- You have ever worked in a metal or fabrication shop;
- In some cases, these could mean you should not have a CT scan performed.

A tourniquet will be applied to your arm or leg to help find a vein, and a contrast agent will be injected into a vein, or possibly given by mouth. The contrast agent does not contain any radioactivity, but instead, reacts with the X-rays to release a signal that is detected by the scanner. The pattern of the signal will provide the doctors with

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information about your cancer. You will be asked to lie still on a long narrow bench, or scanner bed, for up to 45 minutes. A strap and/or pillows may be placed around you to prevent movement so that the X-ray picture will be clear. The scanner bed you are on will then slide into a large, tunnel-shaped machine. You will be able to see the CT technician during the entire procedure, and there are microphones and speakers so you can communicate with the CT technician. You will have a call button. You will be asked not to move during the scan and to relax and breathe normally. You may experience some discomfort or anxiety from being in the confined space. If this bothers you too much, the study team may provide you with a medication to help you stay calm. During the CT scan procedure, the scanner will rotate around you, and make clicking sounds, which is normal. Tell the CT technician if you start to feel unusual, especially if you have a flushing sensation; a salty or metallic taste; a headache; and/or nausea/vomiting. These effects usually last for a few moments. Tell the CT technician immediately if you have any breathing difficulties; sweating; numbness; or heart palpitations. When the CT scan procedure and follow-up is finished, you may immediately resume your usual activities and diet.

A **positron emission tomography (PET) scan** may be performed according to standard practice. A PET scan is a computerized image that looks at blood flow and the extent and activity of the cancer in your entire body. You will be asked to not eat or drink anything but water (ie, "fast") for about 4 to 6 hours before the scan. The scan will take about 30 to 60 minutes. A tourniquet will be applied to your arm or leg to help find a vein, and a small amount of a radioactive tracer called  $^{18}\text{F}$ -FDG ( $^{18}\text{F}$ -fluorodeoxyglucose) will be injected into a vein about 1 hour before the scan. You will be asked to lie on a long narrow bench for up to 45 minutes while the machine performs the scan. You may experience discomfort related to lying still in an enclosed space for a long period. The camera will record the tracer's signal as it travels through your body.

A **PET / CT scan** may be performed according to standard practice. A PET / CT scan combines PET and CT scans, as described above, in a single imaging session, to accurately diagnose and locate cancers.

**Study Treatment**

All participants who are enrolled to this study will receive SOC cytotoxic (cell-killing) radiation therapy (RT) to relieve their cancer symptoms. The RT will be produced by linear accelerators that deliver high energy photon irradiation. This radiation treatment will be directed to (localized) to the site of the tumor, which may have associated symptoms. The radiation treatment will take place in either the Stanford Cancer Center Palo Alto or Stanford Cancer Center South Bay.

You will continue on any hormone or other systemic cancer therapy that you are currently taking, except for any chemotherapy drug (e.g. cisplatin, taxol). This exclusion

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does not apply to immunotherapy or other targeted therapies. In addition, all participants will also receive sodium selenite, which may improve your body's response to radiation, or cause side effects, or both.

Sodium selenite is not approved by FDA for the treatment of cancer. Sodium selenite is manufactured by biosyn Arzneimittel GmbH in Fellbach, Germany, and the tablets are manufactured by Rottendorf Pharma GmbH in Ennigerloh, Germany.

This is a phase 1 study, meaning that there will be several groups of participants, with each group receiving a higher dose of sodium selenite to determine if that dose is safe and/or has a treatment effect. Sodium selenite is provided in tablet form. Each treatment with sodium selenite will be 2 hours before that day's radiation therapy. The 1<sup>st</sup> dose to be assessed in the study is 5.5 mg per day sodium selenite. The following doses, also to be taken for the duration of the radiation therapy, may be assessed in this study.

- 11 mg per day
- 16.5 mg per day
- 33 mg per day
- 49.5 mg per day
- 66 mg per day
- 99 mg per day
- 121 mg per day

Your treatment with sodium selenite will be for the duration of your radiation therapy. You will be provided with sodium selenite in tablet forms. You will need to take your sodium selenite by mouth. As food intake may reduce the rate of absorption, you will take your sodium selenite on an empty stomach (e.g., at least 2 hours before or 2 hours after eating.)

**Radiation therapy:** Radiation treatment will be designed to delivery cytotoxic levels of radiation to your cancer at 1 or 2 locations. Your radiation treatment will be designed to specifically treat your cancer.

Radiation primarily acts on genetic material (the "DNA") during active growth phases, and therefore preferentially affects the tumor, which is growing faster than the tissues around it. However, some of your other organs, located very close to the tumor that will be irradiated will, by necessity, receive the full dose of radiation. While special care will be taken to position the equipment and radiation exposure to minimize exposure of other tissues to the radiation, you may experience some side effects from the irradiation of normal tissues nearby. The total dose and fractionation regimen (number of sessions) of radiation will be at the discretion of the attending physician, and will be determined by such factors as the location and size of the tumor lesion that requires radiation and your overall clinical status. For the radiation therapy procedure, you will

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need to sit in the same position for the radiation therapy that you sat in for the planning CT scan. The radiation therapy procedure will take about 30 minutes at each session.

**Study Treatment Period Evaluations**

You will be examined for how the radiation treatments and the sodium selenite are affecting your cancer on a weekly basis. On the day of the evaluation, the following will be performed.

**Physical examination:** A complete physical exam as described above will be performed at your 1<sup>st</sup> Treatment Visit, and about every 2 months after that. At other weekly Treatment Visits, a brief physical examination will be conducted.

**Blood collection:** Blood collection, as described above. Less than 3 tablespoons (about 45 mL) of blood will be collected at each visit for:

- **Complete blood count (CBC)**, as described above.
- **Serum chemistry**, including LDH, as described above.
- **Zinc and copper levels** (optional), at your 1<sup>st</sup> Treatment Visit and on the last day of radiation therapy.
- **Prostate-specific antigen (PSA) testing (for prostate cancer only)**, as described above, at your 1<sup>st</sup> Treatment Visit.
- **Laboratory correlative study (optional):** For your 1<sup>st</sup> Treatment Visit, a research blood sample will be collected before your 1<sup>st</sup> dose and at 2-4 hours after your 1<sup>st</sup> dose of sodium selenite to see if there is any effect on certain proteins in the blood.
- **Blood levels of sodium selenite [pharmacokinetics (PK)]** (Note: PK is only required for patients receiving their radiation therapy at the Stanford Cancer Center Palo Alto. Patients treated at the Stanford Cancer Center South Bay radiation therapy facility are not required to have PK blood draws.): These samples collected at specific times after you take the tablets help determine how quickly your body uses and gets rid of the sodium selenite.
  - For your 1<sup>st</sup> Treatment Visit, PK samples [each about 1/3 teaspoons (1.5 mL)] will be collected before your 1<sup>st</sup> dose, and about 15 minutes; 1 hour; 2 hours; and 4 hours after treatment. The doctors may ask you to provide 2 additional blood samples as described up to 24 hours after your 1<sup>st</sup> dose. You will also need to come back to the clinic about 24 hours after your 1<sup>st</sup> dose to provide a PK sample as described.
  - If your treatment is longer than 1 week, we may ask for additional PK blood samples before and after treatment on Day 1 of Week 2 and Day 1 of the last week of treatment.
  - Additionally, we may request PK samples before your final dose on the last day of treatment, as well as 1, 2, 3 days or later after last day of treatment.

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**Electrocardiogram (ECG)**, as described above, at your 1<sup>st</sup> Treatment Visit, and at later Treatment Visits or after completion of radiation if your Study Doctor determines it is needed.

**Brief Pain Inventory:** This is 2-page questionnaire about your cancer symptoms. You will be asked to fill this out at your 1<sup>st</sup> Treatment Visit and on the last day of radiation therapy.

**Tumor assessment:** Repeat medical scans as described above will be performed at the Treatment Visits, if your Study Doctor determines it is needed to assess the status of your cancer. These scans will be performed if your cancer gets worse. You will have the same scan or scans that you had at Screening.

**Side effects:** During your treatment, you will be examined for any possible side effects of the sodium selenite on a weekly basis. After the last dose of sodium selenite, the study team will call you weekly for 4 weeks to see how you are doing and to ask about any possible side effects of the treatment.

### End-of-Treatment

Your active treatment in the study will end when your cancer gets significantly worse (disease progression); if you need a change in therapy; if you experience a severe reaction that justifies stopping treatment; you decide to discontinue; or your doctor decides to discontinue treatment.

### Study Follow-Up Procedures

After the last dose of sodium selenite, the study team will call you weekly for 4 weeks to see how you are doing and to ask about any possible side effects of the treatment. We may request PK samples 1, 2, 3 days or later after completion of treatment. You might be asked to perform ECG at any time after your treatment course if your Study Doctor determines it is needed.

You will have the first Follow-up Visit about 2 to 3 months after your last treatment with sodium selenite, unless your disease has progressed since completion of radiation therapy and you have been started on another new cytotoxic or hormonal therapy. You may be asked to have additional Follow-up Visits until your cancer gets worse at the site of your radiation treatment (disease progression). At each Follow-up Visits, the following procedures will be performed.

**Physical examination:** A complete physical exam as described above.

**Blood collection:** About 2 tablespoons (30 mL) of blood will be collected for:

- **Complete blood count (CBC)**, as described above.
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- **Zinc and copper levels** (optional).
- **PSA (for prostate cancer only)**

**Brief Pain Inventory:** As described.

**Tumor assessment:** Repeat medical scans as described above will be performed at the Follow-up Visits, if the investigator determines it is needed to assess the tumor status. These scans will be performed if your cancer gets worse. You will have the same scan or scans that you had at Screening.

If, at any time, you have any symptom, side effect, or injury affecting you physically or mentally during the study, **you should tell the Study Doctors or nurses right away**, even if you do not think it was caused by the study medication.

Any remaining blood or other samples collected for this study will be destroyed when the study is complete.

### **PARTICIPANT RESPONSIBILITIES**

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Maintain control of the Study Drugs, and keep them in a safe place where children cannot access them. Follow any additional storage instructions that you are provided with.
- Ask questions as you think of them.
- Take the Study Drug as instructed. Do not eat for at least 2 hours before you are expected to take the study drug, and for 2 hours after taking the study drug.
- Do not take or use black cohosh and kava at any time while you are receiving sodium selenite and radiation therapy, as there are potential interactions, but these are not known.
  - Black cohosh (scientific name *Actaea racemosa* or *Cimicifuga racemosa*) is a member of the buttercup family native to North America, and is also known as black snakeroot; bugbane; bugwort; rattleroot; rattletop; rattleweed; and macrotys.
  - Kava is a member of the pepper family, and is also known as awa, kava pepper, and kava kava.
- Tell your Study Doctor before using use of any drugs, herbal supplements, or compounds while participating in this study
- Tell the Study Doctor or study staff about all of your present and past diseases and allergies
- Drugs such as cyclosporine; terfenadine; ketoconazole; erythromycin; or troleandomycine may also lead to an interaction. Tell the Study Doctor or

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study staff about all any drugs or medications you are taking. This is for your safety. Other drugs or medications includes all prescription drugs; over-the-counter (OTC) drugs; herbal preparations; and nutritional supplements. If any other medical provider prescribes new medications for you while you are on this study, please contact the study staff before taking the new medicine, or have that medical provider contact the study staff before prescribing it to you. You should not take any new non-prescription medicine while you are on this study unless you first check with the study staff.

- Tell the Protocol Director or study team if you change your mind about staying in the study.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Complete your questionnaires (the Brief Pain Inventory) as instructed.
- **Women capable of having children:** You must:
  - You must always use a type of birth control (such as “the pill”) that your doctor thinks is reliable. You should tell your doctor if you are taking any hormonal contraception (oral contraceptives, implantable or injectable agents) not prescribed by him or her.
  - Inform your Study Doctor immediately if you become pregnant.
- **Men:** You must:
  - Prevent pregnancy in your female partners for at least 3 months after your last dose of Study Drug
  - You should inform your female partners of the potential for harm to a fetus “(unborn child). They should know that if pregnancy occurs, they should promptly notify their doctors
  - Inform your Study Doctor if a partner becomes pregnant
  - Your doctor will discuss with you whether your preference for birth control is considered adequate.

### WITHDRAWAL FROM THE STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Susan J Knox, MD at [REDACTED] or [REDACTED] (administrator). To help you safely finish your participation in the study, the Study Doctors may ask you to have

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more tests and you will be asked to come into the clinic for an End-of-Treatment Visit after stopping the Study Drug. The Study Doctor will discuss your treatment options and follow-up assessments with you at this time. If your participation in the study is ended, you must return all study-related supplies, including unused Study Drug. If you withdraw from the study, or the study medication is stopped for any reason,

- If you withdraw from the study, or the radiation therapy and/or sodium selenite treatment is stopped for any reason, your cancer may get worse.
- To help you leave the study safely, the Study Doctors may ask you to have more tests.
- The Study Doctors may also ask if you wish to take part in the follow-up portion of the study. If you agree to continue with the follow-up portion of the study, information about your health will continue to be collected as described above in the Follow-up Procedures section.
- The Study Doctor will discuss with you the different withdrawal decisions. If your participation in the study is ended, you must return all study-related supplies, including unused Study Drug.
- Data and information from your participation may not be removed from the research study database and may continue to be used to complete the research analysis. This is discussed in more detail under the heading "Authorization To Use Your Health Information For Research Purposes" on the following pages.

The Protocol Director may also withdraw you from the study and the study medication may be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- If your cancer worsens.
- You get sick with another condition that might interfere with study treatment, or if study treatment might interfere with treatment for the new condition
- If you have serious side effects from the Study Drug.
- You need treatment not allowed in the study.
- The study is stopped by the study sponsor; the Stanford Institutional Review Board (the IRB, a group of people who review the research to protect your rights), or by a regulatory agency such as the US Food and Drug Administration (FDA).
- Other administrative reasons.
- Unanticipated circumstances.

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If your study treatment with radiation therapy and sodium selenite treatment has to be stopped, the Study Doctors will discuss your treatment options with you.

### **POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES**

There are risks, discomforts, and inconveniences associated with any research study. This section describes the reasonably foreseeable risks; discomforts; and inconveniences that you may experience. In addition, because this is a research study, there may be risks that are not yet known (“unforeseeable”), including a risk of death due to unknown risks. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

You must tell the Study Doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

Your Study Doctor may give you medications to try to help lessen some of the side effects. All patients in the study will be monitored for side effects.

Risks associated with sodium selenite include, but are not limited to:

- Death
- Coma
- Impairment of the flow of blood in the body, resulting in a shock-like condition, known medically as:
  - Fulminating peripheral vascular collapse
  - Internal vascular congestion
  - Edematous lungs
- Brick red gastric mucosa
- Hair loss
- Weakened nails
- Dermatitis
- Dental defects
- Gastrointestinal (GI) disorders
- Nervousness
- Mental depression
- Metallic taste in the mouth
- Vomiting
- Garlic odor of breath
- Sweating
- Cardiac arrest

Notify the Protocol Director immediately if you experience any of the following symptoms:

- Garlic-like odor of the breath

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- Fatigue
- Nausea
- Diarrhea
- Abdominal pain

In addition, there are other risks and possible discomforts you might experience from the study procedures, including:

- **Blood draws:** A blood draw may cause inflammation of the vein; stinging, discomfort, or pain; bruising; discomfort; redness; burning; or bleeding at the site where the needle is placed to draw the blood. You may feel dizzy or you may faint. There is a slight chance of infection.
- **Questionnaires:** A questionnaire may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaire, you should contact the Study Doctors.
- **ECG:** Risks from an ECG can include skin irritation and/or a rash from the gel, or from wearing or removing the patches.
- **MRI:** The very strong magnetic fields of the MRI machine do not cause generally cause harmful effects at the levels used in the machine. However, there are some important considerations. The magnet that will attract or even move some metals and affect or damage some electronic devices. This can be a hazard to you and others. If you are aware of any of the following, you need to **tell the study team or the MRI technician before entering the magnet room.**
  - *If you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member.*
  - *There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs.*
  - If you have an artificial heart valve; a pacemaker; or any other biomedical device in or on your body. These devices could malfunction when exposed to the very strong magnetic field.
  - If you have a metal plate; pin; screws; surgical clips; or any other metallic implant in your body. These pieces of metal could move while in your body, causing possible serious injury or death.
  - If you have any history of head or eye injury involving metal fragments, or if you have any other foreign metal fragments in your body, such as bullet fragments or shrapnel, or if you have ever worked in a metal shop. Any small fragments that are still embedded could cause injury.
  - If you have previously been anxious or concerned about being in tight spaces, or from loud noises. You may receive a medication to calm you if you need help with this.

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- You have a history of severe allergies (eg, bee-sting reaction, food, shellfish, or nut reactions)
- If you have had a previous reaction to medications or contrast agents, in particular Gadolinium-based contrast agents.
  - If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator. If you have kidney problems, please tell the operator.
  - It has been observed that deposits of Gadolinium-based contrast agent (GBCA) remain in the brains of some people who undergo four or more contrast enhanced MRI scans, long after the last administration. It is not yet known whether these Gadolinium deposits are harmful or can lead to adverse health effects. You should talk to the study doctor if you have any questions about the use of GBCAs with MRIs
- In some cases, these could mean you should not have an MRI scan performed.

When you are in the MRI scanner, you may experience discomfort or anxiety due to be in the small inside the machine, or from the loud noises the MRI scanner makes.

### **IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.**

- **Bone scan:** A bone scan exposes you to a small dose of radiation. Although all radiation you receive builds up over your lifetime, the small doses from the bone scans for this study should not create a significant risk to your health.
- **X-ray / CT scans:** A contrast agent or dye is usually injected when you get a CT scan. The risks associated with contrast agents are:
  - Risk of allergic reaction, which can be severe and/or life-threatening. If you have **ever** had a history of severe allergies / allergic reactions, including anaphylaxis (eg, bee-sting reaction, food, shellfish, or nut reactions), or any previous reactions to medications; iodine; or contrast agents, tell the study team or technician. If you experience any breathing difficulties; sweating; numbness; or heart palpitations after the injection, tell the study team or technician **immediately**.
  - Risk of kidney problems or kidney failure, especially if you are taking Glucophage (metformin, a common medicine for diabetes). Patients with kidney failure or other kidney problems should notify their physician **before the scan**.
  - After the injection, there is a risk of pain, discomfort, or a burning sensation at the injection site; a flushing sensation; a salty or metallic taste in the mouth; a brief headache; or nausea/vomiting. These effects usually last for a few moments.

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In addition, if you become anxious or concerned in tight spaces, or from loud noises, tell the study team or technician **before the scan**. When you are in the CT scanner, you may experience discomfort or anxiety due to be in the small space inside the machine, or from the loud noises the CT scanner makes. You may receive a medication to calm you if you need help with this

- **PET scans:** You may have some soreness or swelling where the tracer was injected. These symptoms can usually be relieved by applying moist, warm compresses to the injection site. Rarely, allergic reactions, which can be serious, occur. When you are in the PET scanner, you may experience discomfort or anxiety due to be in the small inside the machine.
- **Radiation from X-ray / CT / PET / MUGA scans:** CT; PET; and MUGA scans expose you to radiation. These scans are part of your regular evaluations (Standard-of-Care, SOC) in preparation for your radiation therapy, and so do not present additional risk beyond your SOC treatment.
- **Radiation from radiation therapy:** The details of your radiation therapy has been designed by your doctor specifically for your cancer therapy, and are not directly a part of this study. The risks of radiation therapy will be explained to you in a separate clinical consent.
- **Allergic reactions:** All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. You should get medical help and contact the Study Doctors right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue or neck. Other allergic reactions may include rash, hives, or blisters.
- **Pregnancy:** There may be known or unknown risks to a fetus or the pregnant woman, from a man participating in this study. There is a risk that pregnancy could still result despite the responsible use of reliable method of birth control. Detailed information about preventing pregnancy are given elsewhere in this document.
- **Other risks:** Since sodium selenite is investigational (experimental) as used in this study, there may be other risks that are unknown (“unforeseeable”) at this time.
- You may experience some inconvenience due to the schedule and length of Study Visits. Your doctor may require that you remain in the clinic until very late in the day or that you even stay overnight in order to comply with the requested blood sampling schedule on some of the pharmacokinetic (PK) days if applicable.

**It is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the Study Drug. Contact the Study Team at [REDACTED]. If you are unable to reach anyone at the number(s) listed above, and you feel you may need medical attention, call or go to the nearest emergency room.**

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### POTENTIAL BENEFITS

Being in this study may or may not help your cancer. Results from your participation in this study may benefit other patients in the future.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

### ALTERNATIVES

You do not have to be in this study to receive treatment for your cancer. Instead of taking part in this study, you may choose:

- Receive treatment without sodium selenite. This might include chemotherapy such as docetaxel or mitoxantrone, and/or standard radiation therapy, and/or hormonal suppression or antiandrogen therapy (prostate cancer).
- Participate in another clinical trial (research study) with a different Study Drug
- Receive best supportive care
- While your type of cancer is treatable with currently approved and available medications and treatments, another alternative is to receive only comfort care, also called "palliative care," like painkillers. These types of treatments do not treat your cancer (i.e., "are not curative"), and only make you comfortable.

Possible alternative treatments and side effects of these treatments depend on the characteristics and stage of your cancer. The effectiveness and side effects of other treatments may be different for different people. The Study Doctors will discuss with you the risks and benefits of these alternatives, including which other treatments might be suitable for you.

If you decide that you do not wish to take part in this study and wish to pursue any of these, or other alternatives, this will not change your regular medical care or the other treatment choices in any way.

### PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director. You can also tell any other member of the study staff.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study. After you hear about this information, you have the right to withdraw from the program.

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**ClinicalTrials.gov**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US 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.

**CONFIDENTIALITY**

Your identity will be kept as confidential as possible as required by law. However, there is always some risk that even de-identified information might be re-identified. Your personal health information related to this study may be disclosed as authorized by you. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of sodium selenite. The results will be provided to the Food and Drug Administration (FDA); and other federal and regulatory agencies as required.

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## Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

### What is the purpose of this research study and how will my health information be utilized in the study?

This study aims to test whether sodium selenite is safe and effective when used with radiation therapy. Information from this study may be submitted to international regulatory agencies including the FDA. The results from this research study are expected to be presented at scientific or medical meetings or published in scientific journals. You will not be personally identified in the publications, although representatives of the FDA and other international regulatory agencies may need to know who you are.

### Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment.

Signing the form is not a condition for receiving any medical care outside the study.

### If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (eg, necessary to maintain integrity of research). If you wish to

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revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Susan J Knox, MD, MC [REDACTED]

[REDACTED]

[REDACTED]

**What Personal Information Will Be Obtained, Used or Disclosed?**

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to identifiers such as your name and initials; address including ZIP code; phone numbers; dates including date of birth; age; sex; race; ethnicity; and medical record number (MRN). During the study, researchers will also obtain information about your medical history and medical diagnoses, including family medical history and allergies; your current and past medications or therapies; your physical examination results including weight, blood pressure readings, heart rate, breathing rate and temperature; your laboratory test results; results of procedures, such as eye exams, tumor measurements, scans such as ECG, CT, MRI, and PET scans; and medical reports, such as pathology reports. The researchers will also get information from your medical record (includes hospital record from the Stanford Cancer Institute and your referring physician’s records).

**Who May Use or Disclose the Information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Susan J Knox, MD
- Research Staff
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary

**Who May Receive or Use the Information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the US Department of Health and Human Services (DHHS)

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- The Food and Drug Administration (FDA) and/or other state or international regulatory authorities

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**

Your authorization for the use and/or disclosure of your health information will end on 31 December 2064 or when the research project ends, whichever is earlier.

**Will access to my medical record be limited during the study?**

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (eg, if included in your official medical record).

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

Participant ID:

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### FINANCIAL CONSIDERATIONS

#### Payments

You will not be paid to participate in this research study. There is no reimbursement offered for any expenses related to your participation in this study.

#### Costs

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the Study Visits.

The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. **You will be responsible for any payments, co-payments, and/or deductibles as required by your insurance.** Some insurance companies or other 3<sup>rd</sup>-party payers may not pay for standard-of-care procedures or laboratory tests, including hospitalization, when they are done as part of a research study. You should consult with your health benefit plan to determine whether your medical costs associated with your care during this study are covered.

#### Sponsor

Stanford University is providing financial support and/or material for this study. The National Institutes of Health (NIH) are providing some financial support for the facility and staff where part or all of the study is taking place.

### COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

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If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

**CONTACT INFORMATION**

**Questions, Concerns, or Complaints or to Report an Injury or Side Effect:** If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Susan J Knox, MD. Ask her in-person or call [REDACTED] or [REDACTED] (administrator). You should also contact her at any time if you feel you have been hurt by being a part of this study.

If you are unable to reach anyone at the number(s) listed above, and you feel you may need medical attention, call or go to the nearest emergency room.

**Independent Contact:** If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at [REDACTED] or toll-free at [REDACTED]. You can also write to the Stanford IRB, Stanford University, [REDACTED].

**Appointment or Alternate Contact:** If you need to change your appointment, or if you cannot reach the Study Doctor, please contact the study staff at [REDACTED].

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**EXPERIMENTAL SUBJECT'S BILL OF RIGHTS**

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- Be informed of the nature and purpose of the experiment;
- Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- Be given a description of any attendant discomforts and risks reasonably expected;
- Be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- Be given an opportunity to ask questions concerning the experiment or the procedures involved;
- Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- Be given a copy of the signed and dated consent form; and
- Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

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May we contact you about future studies that may be of interest to you? \_\_\_ **Yes** \_\_\_ **No**

Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short-form foreign language informed consent document.

\_\_\_\_\_  
Signature of witness

\_\_\_\_\_  
Date

(eg, staff, translator/interpreter, family member, or other person who speaks both English and the participant's language)

- Translated short form must be signed and dated by **BOTH** the participant (or their LAR) **AND** the witness.
- The English consent form ("referred to as the "Summary Form" in the regulations"):
- Must be signed by **BOTH** the witness **AND** the Person Obtaining Consent (POC).
- The non-English speaking participant / LAR does not sign the English consent.
- The non-English speaking participant / LAR should not sign the HIPAA participant line.
- If the participant / LAR is non-English speaking, the POC must ensure that:
  - 1) The LAR's Description of Authority is completed, and
  - 2) Any questions or options presented by the consent form are documented and initialed by the
- POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.

Participant ID: \_\_\_\_\_