

Consent and Authorization Document

Study Drug A plus Study Drug B as first-line therapy for cisplatin-ineligible advanced urothelial carcinoma

You are being asked to take part in a research study. Once you learn more about the study, you will make a decision about whether to take part. Before you decide, it is important for you to understand why the research is being done and what it will involve. If you decide to take part, you'll be asked to sign this form.

First, the most important points about this study are going to be summarized. Some of the information will be explained in greater detail after this summary.

Your decision to take part in this study is voluntary which means you are free to decide to join this study or not to join this study. You are being asked to take part in this study because you have been diagnosed with advanced urothelial carcinoma. In this study you will be given a combination of two drugs, Study Drug A and Study Drug B. The combination of the drugs used in the study is investigational. It has not been approved by the U.S. Food and Drug Administration (FDA).

The main reason for you to take part in this study is to help in answering the following research questions:

1. How safe is Study Drug A in combination with Study Drug B? What, if any, side effects that you might have when you receive the combination treatment.
2. What effect the study treatment combination may have on your disease.

The study drugs, Study Drug A and Study Drug B will be given to you in segments of time called "cycles". For this study, a cycle will be 21 days. Study Drug A will be given to you as a pill that you will take daily at home. The study treatment may last for up to 1 year. Once you complete your end of treatment visit, you will continue to be followed for up to 6 months. A detailed description of the study procedures is explained later in this document.

There are side effects that may occur from taking Study Drug A and Study Drug B. The side effects range from very common to rare. The side effects vary in seriousness. Study Drug B can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (i.e. causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking Study Drug B. A detailed list of possible side effects is provided later in this document.

There may not be any benefit to you from your being in the study. The information gained in this study will aid in the understanding of cancer and help in the development of new approaches to its treatment in the future.

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You do not have to be in this study to get help for the type of cancer you have. The study doctor will talk to you about other things you can do for this type of cancer, including the important risks and benefits. Some other things you might do are:

- Use other approved cancer treatments.
- Use other investigational treatments.
- Get supportive care.
- Choose to have no further treatment.

This document may contain words and information that you do not understand. Please ask your study doctor or study staff to explain anything that is not clear to you. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

Why is this study being done?

The combination of Study Drug A and Study Drug B has not been approved by the U.S Food and Drug Administration (FDA) for advanced urothelial carcinoma so this combination is being considered “investigational” for use in this study. An investigational drug is a drug that is being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA).

Study Drug A is an anti-cancer agent which is approved in the United States (US) to treat patients with progressive metastatic medullary thyroid cancer, and patients with advanced renal cell carcinoma. However, it has not been FDA approved to treat patients with advanced urothelial carcinoma.

Study Drug B is approved by the FDA for the treatment of your type of cancer, advanced urothelial carcinoma, and is available to be prescribed for patients with that disease. Study Drug B works by helping your immune system to fight your cancer.

The study is being conducted by <<PI name>> at Huntsman Cancer Institute of the University of Utah.

NUMBER OF PARTICIPANTS

Approximately 39 patients are expected to be enrolled in this study from the Huntsman Cancer Institute/University of Utah.

STUDY PROCEDURES

If you decide you will take part in the study and you sign this informed consent form, you will have some screening tests and procedures done to make sure you are eligible to enroll.

Screening Period

- Medical history will be collected, including smoking history, as well as details about what medications and vitamins you are currently taking.
- You will have a physical exam and a measure of your vital signs, including weight and height.
- An evaluation of your ability to perform everyday activities (performance status) will be done.

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- You will have an electrocardiogram (ECG) done. An ECG measures the electrical activity of your heart, including the rate and rhythm of your heartbeat.
- You will have a CT (Computerized Tomography) scan. This is considered standard of care and would be done even if you were not participating in this study.
- If required by your doctor, you will have a bone scan. A bone scan involves injecting a radioactive material (radiotracer) into a vein. The radiotracer travels through the bloodstream. As it wears away, it gives off radiation. This radiation is detected by a camera that slowly scans your body. The camera takes pictures of how much radiotracer collects in the bones. This is considered standard of care and would be done even if you were not participating in this study.
- If you are female with the potential of becoming pregnant, you will have a pregnancy test.
- You will have your blood drawn and a urine sample taken for standard lab testing to ensure you are healthy enough to take part, this may include hepatitis testing. Positive viral hepatitis test results may be reportable to local health authorities according to local laws. Your blood test results should be negative for hepatitis B and C for study participation.

Treatment Period

Once it is decided that you are able to enroll into this study, you will begin study treatment. The study drugs, Study Drug A and Study Drug B will be given to you in segments of time called “cycles”. For this study, a cycle will be 21 days. Study Drug A will be given to you as a pill that you will take daily at home. You will be given a “dosing diary” to track when you take your Study Drug A dose at home. Study Drug B will be given to you as an intravenous (IV) infusion on Day 1 of every cycle. Your doctor will give you more information about your treatment plan.

You will come to the clinic on Day 1 of each cycle for various procedures. Some of the procedures are being done as part of your routine cancer care. Some are being done because you are participating in this study. You will continue on the study treatment for up to 1 year unless your disease gets worse, you have intolerable side effects, you decide to stop, or if your doctor decides it would be in your best interest to stop or the study ends. If your disease responds well to the drug, your treatment may be extended, you will discuss this with your doctor.

Study Procedures during the Treatment Period:

- You will have physical exams and measures of your vital signs, including weight, during your clinic visits. You will also be asked about any changes in medications that you are taking and changes in how you are feeling to check for potential side effects.
- Evaluations of your ability to perform everyday activities (performance status).
- You will have CT scans to check how your disease is responding to treatment. This will be done every 12 weeks (4 cycles). This is considered standard of care and would be done even if you were not participating in this study.
- You will have ECGs done. This will be done every 12 weeks (4 cycles).
- If required by your doctor, you will have bone scans. This is considered standard of care and would be done even if you were not participating in this study.
- You will have blood draws for standard lab testing for safety at each cycle.
- Additional blood draws and urine samples will be collected to see how your cancer is responding to the treatment. There may be one or more blood draw during a clinic visit.

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- If you are female with the potential of becoming pregnant, you will have a pregnancy test every other month while on treatment (even cycles).
- Review of dosing diary for Study Drug A taken at home, return of empty Study Drug A containers or any unused supplies.

In addition, because you have consented to the Total Cancer Care protocol (IRB #89989) stool and blood will be collected prior to treatment at Cycles 1, 2, 4, 7, 13 and your end of treatment visit. You may also have a tissue biopsy collected prior to beginning treatment and again prior to treatment at cycle 4. When possible, these will be done at the same time as a blood draw or biopsy for clinical care. These are taken to look at the immune system components of your blood as well as genetic components and how they have changed since starting treatment. If you have any questions, ask your study team for more information about these samples.

End of Treatment

- You will have a physical exam and measure of your vital signs, including weight. You will also be asked about any changes in medications that you are taking and changes in how you are feeling to check for potential side effects.
- Evaluation of your ability to perform everyday activities (performance status).
- You will have your blood drawn and a urine sample taken for standard lab testing for safety.
- You will have a CT scan. This is considered standard of care and would be done even if you were not participating in this study.
- If required by your doctor, you will have a bone scan. This is considered standard of care and would be done even if you were not participating in this study.

Follow-up

Once you complete your end of treatment visit, you will continue to be followed for up to 6 months. If you stop coming in to see your doctor for any reason, phone calls and/or medical chart reviews will occur to continue to check on your health. At different time points in this follow up, you will have the following procedures done:

- You will have physical exams and measures of your vital signs during your clinic visits. You will also be asked about any changes in medications that you are taking and changes in how you are feeling to check for potential side effects. You will be asked for potential side effects for 90 days after you stop taking the study drugs.
- You will have a CT scan to check the status of your disease. These will be done every 12 weeks. The CT scan is considered standard of care and would be done even if you were not participating in this study.

RISKS

Study Drug A

Study Drug A may cause one or more of the side effects listed below. This information is based on data from cancer patients in other clinical trials with Study Drug A. In addition, there may be side effects that are not yet known that may occur. You should tell your doctor or nurse right away about any possible side effects that you experience.

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VERY COMMON

In 100 people receiving Study Drug A, as many as 10 and up to 100 may have:

- Abdominal pain
- Alteration of thyroid function tests
- Blisters, rash, or pain in hands or feet
- Changes in blood tests used to monitor the liver, which may indicate liver damage
- Change in voice
- Changes to the way things taste
- Constipation
- Diarrhea
- Fatigue
- Hair color changes or hair loss
- High blood pressure
- Inflammation of mucus membranes
- Loss of appetite
- Mouth and throat sores or swelling
- Nausea
- Rash
- Vomiting
- Weakness
- Weight loss

COMMON

In 100 people receiving Study Drug A, as many as 1 and up to 10 may have:

- Abnormal thickening of the outer layer of the skin
- Change in the feeling of touch
- Bleeding from stomach or intestines, which may look like coffee grounds or black sticky bowel movements and bleeding from the brain
- Blood clot in a large vein, usually in the leg
- Blood clot that travels from a vein to the lung
- Confusion and disorientation
- Decreased amounts of red blood cells (anemia), which may cause feelings of tiredness or shortness of breath
- Decreased amounts of calcium or sodium in the blood
- Decreased or increased amounts of potassium in the blood
- Decreased amounts of magnesium or phosphorus in the blood
- Decreased level of albumin in the blood
- Decreased platelet counts, which increases the risk of bleeding or make bleeding more difficult to stop
- Decreased white blood cell counts, which may increase chances of infection
- Dermatitis acneiform, a type of acne
- Dehydration

- Difficulty swallowing
- Dizziness
- Dry mouth
- Dry skin
- Fever
- Fungal infections including mouth, lung, and other locations
- Hemorrhoids and bleeding hemorrhoids
- Headache
- Increased amounts of pancreas enzymes in the blood, which may indicate damage to the pancreas
- Increased levels of bilirubin in the blood, which may indicate complications with the liver
- Increased levels of creatinine in the blood, which may indicate complications with the kidneys
- Mouth or throat pain
- Muscle spasm
- Muscle weakness
- Pain in a joint or muscle
- Pain in extremities
- Protein in the urine, which may indicate kidney damage
- Shortness of breath
- Stomach acid coming up from the stomach into the esophagus
- Swelling of the limb(s)
- Ulcer
- Upset stomach or indigestion

Uncommon

In 100 people receiving Study Drug A, 1 or fewer may have:

- Abnormal electrical activity in the heart that could cause a potentially serious change in heart rhythm.
- Abnormal opening between two organs or from an organ to the outside of the body
- Abscesses (infected cavities filled with pus)
- Blood clot in an artery
- Chest discomfort originating from the heart
- Clouding of the lens in the eye that affects vision
- Damage to skeletal muscle tissue
- Decreased brain function or decreased alertness and ability to think
- Decrease in all blood counts (red blood cells, white blood cells and platelets)
- Destruction of bone tissue, in particular, bone in the jaw
- Feelings of unease or fear
- Gallstones
- Heart attack
- Heart failure
- Holes in the stomach or intestines

- Infections
- Inflammation of the intestine, appendix, gall bladder or thin tissue lining the inner wall of the abdomen and most of the abdominal organs
- Reduced kidney function
- Liver failure
- Loss of consciousness, fainting episode
- Pneumonia and inflammation of the lungs
- Rapid heart rhythm
- Re-opening of wounds after surgery
- Respiratory failure
- Seizure
- Stroke / mini-stroke
- Tear or inflammation in skin that lines the anus
- Temporary paralysis of the intestines
- Throat swelling
- Uncoordinated movements

Side effects that occurred in less than 0.1% of patients but were considered medically important or severe or life-threatening and rarely fatal are listed in the tables below. These events occurred in studies of Study Drug A given alone. If you are at the clinical site and notice any signs or symptoms of the side effects listed below, check with the staff in the clinic immediately; if you are no longer at the clinical site, call your doctor or go immediately to the nearest hospital.

RARE

In 100 people receiving Study Drug A, less than 1 may have:

- Air in the chest between lungs and chest wall
- Allergic reaction
- Anemia caused by destruction of red blood cells
- Blocked intestines
- Brain dysfunction caused by brain swelling
- Cancer of the mouth or skin
- Damage to the outermost surface of the eye
- Inflammation and blockage of channels that carry bile from the liver
- Severe swelling of the mouth, lips, tongue, eyes and throat, or difficulty swallowing or breathing
- Very high blood pressure that comes on suddenly and quickly and which can lead to serious injury to the heart and brain

There may be additional unforeseen risks associated with the use of Study Drug A in combination with Study Drug B treatment. You should tell your study doctor or study staff immediately about any side effects that you have or about any change in how you feel while on this study.

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Study Drug B

Study Drug B, which is approved in the USA and some other countries, is available by prescription to treat several different cancers, but may not be approved to treat your type of cancer.

Overall, as of 03-Mar-2018, approximately 25,519 patients have been treated with Study Drug B in clinical studies.

Study Drug B works by helping your immune system to fight your cancer.

However, Study Drug B can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (i.e. causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking Study Drug B.

Very Common

Out of 100 people who receive Study Drug B, 20 or more people may have the following:

- Itching of the skin
- Loose or watery stools
- Cough

Common

Out of 100 people who receive Study Drug B, at least 5 but less than 20 people may have the following:

- Joint pain
- Rash
- Fever
- Back pain
- Pain in your belly
- Loss of skin color
- Not enough thyroid hormone so you may feel tired, gain weight, feel cold, have infrequent or hard stools
- Low levels of salt in the blood that may cause you to feel tired, confused, have a headache, muscle cramps and/or feel sick to your stomach

Uncommon

Out of 100 people who receive Study Drug B, at least 1 but less than 5 people may have the following:

- Inflammation of the lungs so you may feel short of breath and cough
- Too much thyroid hormone so you may feel anxious, angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools
- Infusion reaction, where you may feel dizzy or faint, flushed, get a rash, have a fever, feel short of breath at the time of receiving your infusion (IV) or just after, or pain at the site of infusion
- Inflammation of the bowels/gut which may cause severe pain in your belly with loose or watery stools, and black, tarry, sticky stools or stools with blood or mucus
- Inflammation of the skin so you may have peeling of the skin, itchiness, and/or skin redness. The skin inflammation (i.e. peeling, itching and redness) could also be widespread throughout your body. More severe skin reactions may involve the inside of your mouth, the surface of your eye

and genital areas, and/or may cause the top layer of your skin to peel from all over your body which can cause severe infection.

Rare

Out of 100 people who receive Study Drug B, less than 1 person may have the following:

- Inflammation of the nerves that may cause pain, weakness or tingling in your hands and feet, and may spread to your legs, arms and upper body leading to severe muscle weakness and possible temporary paralysis
- Inflammation of the muscles so you may feel weak or have pain in your muscles
- Inflammation of the pancreas (a gland in your abdomen that controls sugar levels) so you may have severe pain in the top part of your belly that may move to your back, feel sick to your stomach, and have vomiting that gets worse when you eat
- Inflammation of the eye so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters or have headaches
- Inflammation of the liver that may make you feel sick to your stomach and vomit, feel like not eating, feel tired, have a mild fever, have a pain in the right side of your belly, yellow eyes and skin, and dark urine
- Inflammation of the pituitary gland (a gland in the head), which may cause you to feel sick to your stomach or have headaches, changes in your behavior, double vision, few to no menstrual cycles, weakness, vomiting and dizziness or fainting
- Adrenal glands (glands on top of the kidneys) that may not make enough hormone, which could cause tiredness, weight loss, muscle weakness, feeling faint, joint, muscle and belly aches, nausea, vomiting, loose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan
- Type 1 Diabetes, a condition that can cause too much sugar in your blood, feeling thirstier than usual, frequent urination and weight loss. You are likely to need regular insulin shots.
- Inflammation of the kidney so you may pass less urine or have cloudy or bloody urine, swelling and low back pain
- Inflammation of the middle layer of your heart wall that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting.
- Inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. This condition may lead to change in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy.
- A condition that may make you feel weak and tired and might have drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing
- The formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs
- Inflammation of the brain with confusion and fever. This may also include: disorientation, memory problems, seizures (fits), changes in personality and behavior, difficulty speaking, weakness or loss of movement in some parts of your body, and loss of consciousness.

Additionally, since Study Drug B was approved in September 2014, the following side effects have been reported by people receiving Study Drug B. These side effects were voluntarily reported from a group of people of unknown size. It is not possible to estimate the frequency of this side effect:

- Inflammation of the joints which may include joint pain, stiffness and/or swelling

In addition to the above, **if you have had an allogeneic stem cell transplant** (a procedure in which a person receives blood-forming stem cells from a donor), you may experience graft versus host disease (GvHD), which may include diarrhea, skin rashes, and liver damage, after receiving Study Drug B. Sometimes this condition can lead to death.

If you have had a solid organ transplant (for example, if you have received a kidney or heart transplant), you may experience rejection of the transplanted organ. Your doctor will monitor you and should tell you what signs and symptoms you should report depending on the type of organ transplant that you have had.

REPRODUCTIVE RISKS

It is possible that if these treatments are given to a pregnant woman it will harm the unborn child. Women of childbearing potential must have a negative pregnancy test before beginning treatment. Pregnant women must not take part in this study, nor should women who plan to become pregnant during the study. Women should not breastfeed a baby while on the study and for at least 4 months after you have stopped taking the study drugs. Women of childbearing potential must use an effective contraceptive while on the study and for 4 months after the last dose. Examples of medically acceptable birth control include medically prescribed IUDs, a contraceptive rod implanted into the skin and double barrier methods, e.g., condom in combination with spermicide or oral birth control pills and a condom. Check with your study doctor about what kind of birth control methods to use. Some methods might not be approved for use in this study.

If you become pregnant while taking part in the study, you must immediately tell your research doctor. If you become pregnant, you will be withdrawn from the study and we will follow the outcome of your pregnancy.

Male Reproductive Risks

Because the study drugs may affect an unborn baby, you should not father a baby while taking part in this study. You and your sexual partner should use an effective method of birth control as described above, while taking these investigational treatments. You should continue using birth control for 4 months after receiving the last dose of study drugs. If you think that you have fathered a baby while receiving treatments in this study, you should inform your doctor immediately.

Other Risks and Inconveniences including Genetic Risks

There are also non-physical risks associated with taking part in this study, such as the risks associated with a breach of privacy or confidentiality. For example, if your identity as a participant in genetic research or your identifiable genetic or health information were disclosed to unauthorized persons, there is the possible risk of discrimination by employers or insurance providers. The risks of such improper disclosure

are very small because Huntsman Cancer Institute has adopted strict privacy and confidentiality procedures for this research.

Blood draws or IV: Risks associated with drawing blood or putting a needle in your vein might include pain from the puncture, bruising, bleeding, infection, or fainting. Every effort will be made to minimize discomfort.

UNFORESEEABLE RISKS

Problems or side effects that are not known could also occur. Most side effects are expected to go away after treatment is stopped or interrupted; however, in some cases the side effects may be serious, long-lasting, permanent or lead eventually to death. You will be given any new information when it becomes available that may affect your willingness to start or continue in the study.

What are the Uses for my Samples Collected During the Study

Your participation in genetic testing is a mandatory part of this study. It will be performed in order to learn more about factors which may predict response to the study treatments.

Segments of the DNA called genes are responsible for passing particular traits such as eye color from parents to children.

We may perform a whole genome or whole exome analysis on your blood sample. In whole genome or whole exome analysis, all or most of your genes are studied and used by researchers to find causes of diseases, such as cancer. It is also possible that this type of testing will discover a gene that you do not know about that may indicate you or a relative is at risk for a genetic disorder in the future.

You will not receive any of your genetic information that comes from the testing in this study, nor will it become a part of your medical record. The results will be kept on password-protected computers and results will be accessible only to the investigator and other authorized people.

In the United States, the **Genetic Information Nondiscrimination Act of 2008 (GINA)** prohibits discrimination in health coverage and employment based on genetic information. GINA, together with the Health Insurance Portability and Accountability Act (HIPAA), generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. Utah State Law also offers protection against discrimination in health coverage and employment.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact <<PI Name>> at <<phone number>>. If you think you may have been injured from being in this study, please call <<PI Name>> at <<phone number>>. The University Hospital Operator can be reached at this number: 801-581-2121 available 24-hours a day. Please ask for the oncologist on call.

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Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah, as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

Taking part in this research study is voluntary. You may decide not to take part or you may leave the study at any time. Refusal to take part or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled.

Tell the study doctor if you are thinking about stopping or decide to stop, as it may be necessary to do certain tests in order to ensure your safety. If you choose not to return for an assessment, we may ask for medical records from your current general practitioner in order to continue to monitor your health.

If you decide not to continue in the study at any time, your study doctor will arrange for you to receive alternative treatment and any necessary assessments or procedures according to standard of care.

RIGHT OF INVESTIGATOR TO WITHDRAW

Your study doctor may decide to take you off this study at any time without your consent for any of the following reasons:

- if your disease becomes worse and is not responding to the study drug,
- if he or she believes it is in your best interest,
- if you do not follow the study rules,
- if you miss study visits and/or procedures,

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- if you have serious side effects,
- or if you become pregnant.

There is also the possibility that the investigator, may close the study before your participation is complete and without prior warning. If any of these events were to happen, your study doctor would assist with arrangements for your continued care as appropriate.

COSTS AND COMPENSATION TO PARTICIPANTS

Some of the procedures and treatments you'll have while you are on the study are considered "standard of care" for your type of illness. Even though you will be a part of the study, these types of procedures and treatments will be billed to you and/or your insurance company just like regular medical care. Some procedures and treatments you'll have while you are on the study are considered "study related" and are not billed to you and your insurance company. You should ask your study coordinator and treating physician for details about the specific procedures you or your insurance company will be financially responsible for.

You may be eligible for assistance with costs associated with travel for purposes of research participation. Please speak with your study coordinator or physician for details. If eligible, you may be asked to provide receipts in order to receive reimbursement. It will be necessary for us to collect your Social Security Number for your reimbursement. You will need to provide this information on a Federal W-9 Form that is filed with our accounts payable department. No other information (e.g. the name of this study) will be provided to that office. This amount will not be reported to the Internal Revenue Service (IRS).

Exelixis, the manufacturer of Study Drug A, will be supplying Study Drug A to you free of charge in this study.

Tissue or blood samples obtained from you in this research may help in the development of a commercial product by the University of Utah or its research partners. There are no plans to provide financial compensation to you should this occur.

NEW INFORMATION

You will be given any new information about the study drugs that may affect your willingness to start or continue in the study as it becomes available. You will not receive any results from the genetic testing performed in this study. The results will also not be included as part of your medical records.

During the study, we may learn something about your health that could help you and your doctors make decisions about your healthcare. If this happens, we will tell you about these results. We will contact you and make arrangements to discuss this with you.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and other working with us to use some information about your health for this research study.

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This is the information we will use and include in our research records:

- Demographic and identifying information like your name, address, telephone number, and email address.
- Related medical information about you like family medical history, allergies, current and past medications or therapies, information from physical examinations such as blood pressure readings, heart rate, temperature, and lab results.
- All tests and procedures that will be done in the study

How we will protect and share your information:

We will do everything we can to keep your information private, but we cannot guarantee this. The research records will be kept in a secured manner and computer records will be password protected. We may need to disclose information about you as required by law.

Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital.

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.

In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:

- Members of the research team and University of Utah Health
- The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
- Exelixis, the manufacturer of Study Drug A, and their affiliates
- Government agencies responsible to confirm research accuracy such as the United States Food and Drug Administration (FDA), and the National Cancer Institute (NCI) which is a part of the National Institute of Health (NIH)
- Governmental agencies in other countries where the study drug may be considered for approval.

All positive contagious diseases, such as hepatitis B, and hepatitis C tests must be reported to the Utah State Health Department. The State and Local Health Departments have established procedures for contacting individuals who have had contact with persons testing positive for communicable diseases. Your partner(s) will be notified. If your test is positive, you will not be eligible for this study. The follow-up to a positive test will be done according to standard procedures. The results will be securely stored in a locked filed cabinet, accessible only to the investigator and other authorized people.

If we share your identifying information with groups outside of the University of Utah Health, the groups may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

UNIVERSITY OF UTAH IRB CONSENT DOCUMENT SAMPLE

Greater than minimal risk research; Concise Summary; HIPAA Authorization; Investigational Drug; FDA-regulated; Reproductive Risks; Biospecimens; Genetic Research; Possible Whole Genome Sequencing; Reportable Diseases, Language Interpreter Statement

If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health.

What if I Decide Not to Take Part After I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

Participant's Name

Participant's Signature

Date

Time

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent

Date

Time

LANGUAGE INTERPRETER STATEMENT (if applicable):

UNIVERSITY OF UTAH IRB CONSENT DOCUMENT SAMPLE
Greater than minimal risk research; Concise Summary; HIPAA Authorization; Investigational Drug; FDA-regulated; Reproductive Risks; Biospecimens; Genetic Research; Possible Whole Genome Sequencing; Reportable Diseases, Language Interpreter Statement

