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Consent to Participate in Research

Study Title: A Single Arm Phase 2 Study of talimogene laherparepvec (T-VEC) in patients with cutaneous squamous cell cancer

Principal Investigator & Sponsor: Clara Curiel, MD
Financial Support: Amgen

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate. If you have any questions, please discuss this with your study provider.

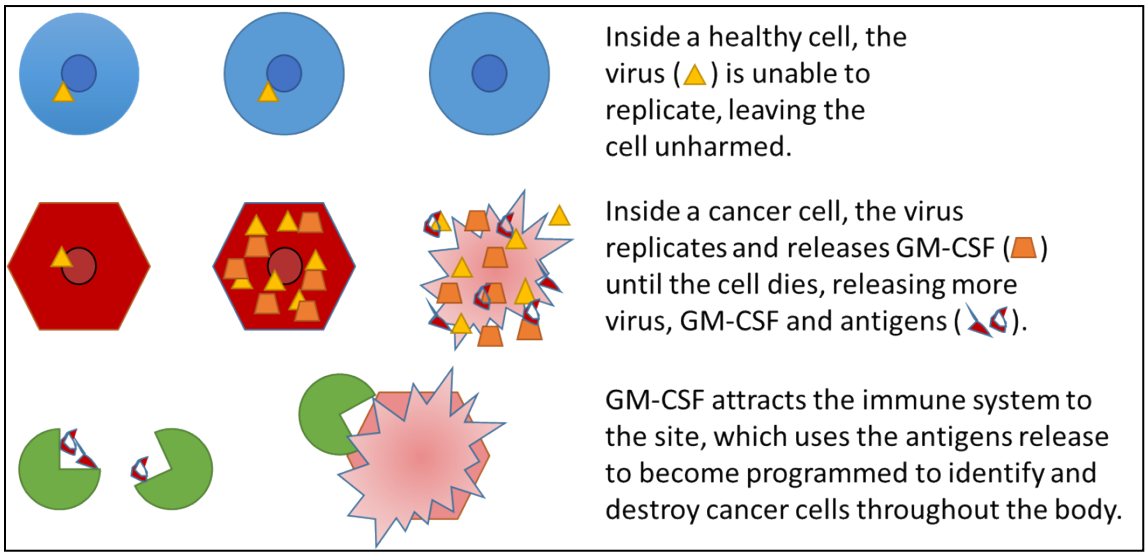
Summary of the research

You are being asked to participate in a study about talimogene laherparepvec (also known as OncoVEXGM-CSF or IMLYGIC®) in people with a healthy immune system with confirmed low-risk squamous cell carcinoma (see the "Why is this study being done" section). The study will take approximately 48 weeks. This will include a screening visit, 4 injection visits and 5 follow up visits, which are defined in greater depth under "What will happen if I participate in this study?" There is some risk of an allergic reaction, an autoimmune reaction or a reaction at the injection site. There is no direct benefit to you in participating in this study.

Why is this study being done?

The purpose of this study is to find out more about talimogene laherparepvec (also known as OncoVEXGM-CSF or IMLYGIC®) in people with a healthy immune system with confirmed low-risk squamous cell carcinoma. Skin cancer is the uncontrolled growth of cells in the skin. Squamous cell carcinoma (SCC) is a type of skin cancer that is classified into low-risk and high-risk disease. Usually, low-risk SCC is treated with a surgical procedure, but surgery can be challenging when patients have: multiple SCCs on their body, when the SCC is on a challenging place on the body to remove or when patients are older or have diseases that place them at risk for surgery related complications. Immune therapy is a treatment that uses certain parts of a person's immune system to fight disease. Immune therapy is a proven therapeutic approach in many cancers, including melanoma, another type of skin cancer. Talimogene laherparepvec (TVEC) is made from a modified herpes simplex virus type 1 (HSV-1, the "cold sore" virus). The virus' genes were modified in a laboratory so that it produces a protein called human granulocyte macrophage colony-stimulating factor (GM-CSF), which multiplies and grows in tumor cells. Human GM-CSF is normally produced by various cells within the body and is used as a medicine to treat patients with white blood cell counts that are too low. This modified HSV-1 is not designed to change any of your genes, but instead produces a protein that acts on tumor cells and stimulates your immune system. TVEC is administered by injection with a needle directly

into one or more tumors and works by directly destroying cancer cells and enhancing immune response to destroy cancer cells.



What will happen if I take part in this study?

All subjects will receive TVEC. This study will not use placebo treatments.

This study will measure the tumor's response over the course of four injections (given 2 weeks apart) of TVEC. Participation in the study involves 8 visits to the clinic and 1 phone call follow up. TVEC injections will be done at visits 1-4 (2-3 weeks apart). Tumor measurements will be done at each visit using photographs. High-frequency ultrasounds will be performed to assess lesions at the screening visit and second follow up visit (12-13 weeks from the screening visit). Skin biopsy tests will be done on each tumor to make sure that each tumor is a skin cancer. This procedure will be performed in the following manner: a small volume of local anesthetic (painkiller) will be injected into the skin at each test area to numb the area. A small piece of skin will be removed and will be covered with a small bandage. You will need to keep the sites clean, dry and covered until the area heals. After you have completed your study treatment, the study team will review your patient chart to assess the number of nonmelanoma skin cancers before and after your study treatment.

Please see below for the schedule you will follow if you participate in this study:

<u>Screening Visit:</u>

During the screening visit (visit 0), the provider will examine your suspected low-risk SCC lesions and perform partial skin biopsies to confirm the diagnosis. You will also have a blood test done to determine your overall health. For women of childbearing potential (or able to become pregnancy), you will be required to do a urine test to determine if you are pregnant. If the urine test comes back inconclusive, then a pregnancy blood test will be ordered. The provider will choose up to five lesions for treatment, with no more than three lesions in one anatomical

area. A high-frequency ultrasound will be performed on the lesions so researchers can have a better sense of the size and depth without the need of removing it before treatment with TVEC.

Your study provider and his/her staff will take photographs of areas of your body where your squamous cell cancer lesion is present to document how your tumor responds to study treatment. Your face and any tattoos or other marks on your body that might identify you may be temporarily covered up. The photographs will be taken during your regular study visits.

Visit 1: First Injection Visit:
One to two weeks after your screening visit, you will come in for your first injection with TVEC. Your lesions will be measured and photographed. Then you will receive 0.1–4 ml of TVEC (depending on lesion size) in each lesion the provider selects.

Visit 2: Second Injection Visit:
Three weeks after Visit 1, your lesions will be measured and photographed. Then, you will receive 0.1-4 ml of TVEC (depending on lesion size) in each lesion the provider selects.

Visit 3: Third Injection Visit:
Two weeks after Visit 2, your lesions will be measured and photographed. Then, you will receive 0.1-4 ml of TVEC (depending on lesion size) in each lesion the provider selects.

Visit 4: Fourth Injection Visit:
Two weeks after Visit 3, your lesions will be measured and photographed. Then, you will receive 0.1-4 ml of TVEC (depending on lesion size) in each lesion the provider selects.

Visit 5: First Follow-Up Visit:
Four weeks after Visit 4, your lesions will be measured and photographed.

Visit 6: Second Follow-Up Visit:
Four weeks after Visit 5, your lesions will be measured and photographed. A repeat high-frequency ultrasound of target lesions will be performed, and compared to the ultrasound taken at your screening visit to evaluate your response.

Visit 7: Third Follow-Up Visit:
Six weeks after Visit 6, your lesions will be measured and photographed.

Visit 8: Fourth Follow-Up Visit:
Fourteen weeks after Visit 7, your lesions will be measured and photographed.

Visit 9: Telephone Follow-Up:
One year after Visit 1, you will receive a phone call from the study coordinator asking you about your lesions.

Post-Treatment Chart Review:
One year after Visit 4, the study team will review your patient chart in your medical record to assess the number of nonmelanoma skin cancers during the following timepoints:

- Before your study treatment: 12 months before Visit 0.
- After your study treatment: 12 months after Visit 4, and again at 24 months after Visit 4 if available.

This review would allow the study team to assess the rate of skin cancer development before and after your treatment with TVEC. The study team will not contact you during this review.

How long will I be in this study?
Participation in the study involves 8 visits to the clinic over the course of 48 weeks and 1 phone call follow up 1 year after Visit 1.

How many people will take part in this study?
Approximately 20 patients will be enrolled in this study at the University of Arizona Cancer Center.

What benefits can I expect from being in this study?
If you agree to participate in the study, you may have a direct medical benefit depending on your response to the study drug. We hope the information learned from this study will benefit other patients with cancer in the future.

What risks, side effects or discomforts can I expect from being in the study?
As with any experimental drug it is impossible to foresee all potential risks. Adverse drug reactions, or side effects, observed in patients given TVEC in clinical trials for metastatic (spreading) melanoma are listed below.

Very common (occurring in 1 or more out of 10 patients given TVEC):

- Chills
- Fever
- Influenza-like illness: Symptoms can include fever, chills, cough, sore throat, runny or stuffy nose, muscle or body aches, headaches, or fatigue (tiredness)
- Injection site reactions: Symptoms can include pain, redness, swelling, inflammation, or warmth at the injection site; or the release of blood or other fluid from the injection site
- Upset stomach (nausea)
- Vomiting

- Loose or watery stools (diarrhea)
- Infrequent or difficult bowel movements (constipation)
- Muscle or body aches
- Joint pain
- Pain in extremity
- Headache
- Tiredness (fatigue)

Common (occurring in at least 1, but fewer than 10, of 100 patients given TVEC):

- General discomfort, illness, or feeling unwell (malaise)
- Pain in the armpits
- Pain or discomfort in the belly (abdomen)
- Groin pain
- Loss of skin color in blotches (vitiligo)
- Rash
- Inflammation of the skin (dermatitis)
- Cellulitis: Skin infection caused by bacteria at the site of injection, which may cause fever, chills, or redness or swelling at the injection site or site of the tumor, and may require hospitalization for antibiotic treatment.
- Cold sore or blister in mouth (oral herpes)
- Dizziness
- Pain in the throat
- Dehydration
- Bruising
- Procedural pain
- Wound complication at the injection site (secretion or discharge)
- Tumor pain
- Infection in a new, abnormal tissue growth
- Weight loss
- Deep vein thrombosis (blood clot)
- Skin or face becomes warm and reddened (flushing)
- Anemia (low red blood cell count), which can increase infection risk
- Inflammation of the lungs (pneumonitis)
- Inflammation of the tiny filters in the kidneys (glomerulonephritis)
- Inflammation of the blood vessels (vasculitis)
- Vitiligo

Uncommon (occurring in fewer than 1 out of 100 patients given TVEC):

- Incision site infection
- Herpetic keratitis, a type of eye infection caused by herpes virus

- Obstructive airway disorder, which causes difficulty breathing: If you have a tumor in your neck, your provider may warn you that you might experience compression of your airways during treatment with TVEC. This complication might require a surgical procedure on the neck to open a direct airway. A tube, which may be connected to a machine to help you breathe, might need to be inserted into the opening in your throat.
- Plasmacytoma (a collection of abnormal antibody-producing white blood cells) in the area where TVEC was injected. Plasmacytoma may be associated with multiple myeloma (a cancer of white blood cells affecting the bone marrow).
- Worsening psoriasis, a condition in which skin cells build up on the skin surface, forming scales and itchy, dry patches.
- Symptoms of delayed wound healing at or around the injection site such as injection site discharge, foul odor, or dead tissue at the injection site. If you notice symptoms of delayed wound healing at the injection site(s), especially if you have risk factors such as diabetes, poor blood circulation, have had radiation to the site, you should contact the study provider or his/her study staff immediately.

Allergic Reaction

You may have an allergic reaction to TVEC. Symptoms of an allergic reaction in general may include headache, rash, itching, flushing, swelling, shortness of breath, nausea and sometimes vomiting. Severe allergic reactions can cause dizziness, severe skin reactions, difficulty breathing or swallowing, a decrease in blood pressure, and could be life threatening. If you have symptoms of an allergic reaction, you should contact the study provider or the study staff immediately. If you have had an allergic reaction to TVEC or any of its ingredients, you should inform your provider.

Autoimmune Reactions

Autoimmune reactions to the body's own tissues have been reported in some subjects administered TVEC. It is possible that these reactions could occur in any part of the body. Examples of autoimmune reactions that have been reported in subjects receiving TVEC include **inflammation of the kidneys (nephritis), blood vessels (vasculitis), or lungs (pneumonitis) and worsening psoriasis**. It is possible that an autoimmune reaction could occur in any part of the body. Please tell your provider if you have had any type of autoimmune disease before treatment with TVEC, and all treatments you are receiving for the disease.

Other potential side effects: Transmission of TVEC

Can TVEC be spread to my family members or other close contacts and how long after treatment is this possible?

There have been no reported cases of spreading of TVEC to close contacts or family members in clinical trials to date. However, TVEC could potentially be spread to your family members or other close contacts (household members, care-givers, sex partners, or someone you share a bed with) at any time after your tumor(s) are injected with TVEC. This may occur if your family member or other close contact touches the injection site or has contact with your body fluids or with the inside of the dressing(s) covering your injection site(s).

Spreading TVEC may be more likely if your close contact has a break in the skin or mucous membranes that comes into contact with your injection site or your body fluids. In patients treated with TVEC in clinical trials, TVEC has been found on the surface of the injected tumors, into the second week after the injection, and on the outside of the dressings that covered these injection sites. Talimogene laherparepvec have also been detected in patient's blood and urine, and in the patient's mucous membranes of the mouth and genitals no samples had detectable talimogene laherparepvec 30 days after the end of treatment. For patients who had talimogene laherparepvec presence in the surface of injected tumors, no sample had detectable talimogene laherparepvec 60 days after end of treatment.

Are there any precautions I should take to prevent spread of talimogene laherparepvec to others?

- Avoid touching or scratching the injection site.
- Avoid direct contact with your injection sites and body fluids.
- Injection sites should be covered for at least 7 days after the injection with watertight dressings which allow for air exchange. If the dressing comes loose or falls off prior to 7 days after the injection, it should be replaced right away with a clean dressing. However, you may need to keep the dressing on longer if the lesions at the injection sites or the injection sites are weeping or oozing.
- You should always observe proper hygiene (wash your hands with warm water and soap before and after touching your injected lesions or handling the dressings) to avoid potentially spreading TVEC to other persons.
- Wear gloves while changing your dressings that cover your injection site.Place all used dressings and cleaning materials in a sealed plastic bag, and throw them away as household waste or return to the study site for disposal as you are instructed by the site staff.
- Close contacts who are pregnant or who have a weakened immune system should not touch injection sites, change your dressings or clean your injection sites.
- If you participate in this study, your provider and/or his staff will provide you with additional instructions for injection site care.

Is there any risk to my family members or other close contacts if they are exposed to TVEC?

If a close contact has been exposed to TVEC, it is possible that they could develop symptoms of a herpes type infection (see below). However, the chance of this happening is low due to the changes in TVEC that make it different from the naturally occurring herpes simplex virus, but you should know how to recognize these symptoms.

What to do if you or a close contact develop any of the above symptoms:

- If your close contacts are accidentally exposed to TVEC, they should clean the affected area on their body with soap and water and/or a disinfectant. If they develop signs or symptoms of herpes infection, ask them to call their provider, and you should report this to your study provider.
- You should report any signs or symptoms to your study provider right away and you should ask your close contact to call their provider for evaluation and appropriate treatment.
- You or your close contact may be asked to come to a clinic for a test that may be able to determine if these symptoms may be due to TVEC.
- Your close contact should report suspected herpetic lesions to Amgen (the manufacturer of TVEC) at 1-855-465-9442 and they will have the option to receive follow-up testing for further characterization of the infection.
- This test is likely to be most reliable if it can be performed in the first 3 days after symptoms develop.

Symptoms that may be related to the naturally occurring herpes simplex virus (HSV-1) or TVEC:

Most adults in the population have been exposed to the naturally occurring herpes simplex (also known as “cold sore”) virus (HSV-1) (the “cold sore” virus). Common signs and symptoms of the naturally occurring herpes simplex virus include:

- Sores around the mouth (“cold sore”, “fever blister”) or the genitals (“genital sore”).
- Blisters may develop on the fingers, ears, or face.
- Eye infection (herpetic keratitis) with eye pain, light sensitivity, discharge from the eyes, or blurry vision.
- Abdominal pain and infections and inflammation inside the abdomen (infrequently).
- Rarely, serious infections of the brain (encephalitis) or spinal cord, causing paralysis (unable to move) have been reported. Signs may include fever, confusion or other behavior changes, headache, numbness and pain in the legs, constipation, or difficulty with urination.
- Life-threatening infections (disseminated herpes) can develop in people with a weakened immune system.

After infection, the naturally occurring herpes virus may travel to spinal nerve roots. The virus can reactivate from the nerve roots and cause recurrent cold sores or other signs of infection as described above. Stress, other illness, or menstruation are common triggers for reactivation of the naturally occurring virus. Signs and symptoms of infection with TVEC could be similar to those described above, although TVEC has been changed to reduce the chance of this happening.

Can talimogene laherparepvec be transmitted through sexual contact?
The naturally occurring herpes simplex virus (HSV-1) can be transmitted through sexual contact. It is not known if talimogene laherparepvec will behave the same way, thus you or your partner should use a latex condom during treatment and for up to 30 days after your last dose when engaging in sexual activity to prevent possible transmission of talmogene laherparepvec. For those with latex allergies, polyurethane condoms may be used.

Who should not have contact with TVEC?
Persons with severely weakened immune systems should not be treated with TVEC, as they may be at increased risk for serious, life-threatening herpetic infections after receiving TVEC. Tell your provider if you have a weakened immune system.

If your close contact or family member is pregnant or has a weakened immune system, they should not touch injection sites, change your dressings, or clean your injection sites. Keep used dressings and cleaning materials away from pregnant women, newborns, and those with weakened immune systems.

Pregnant or breastfeeding women, and women planning to become pregnant, should not participate in this study**.** If you are unable to become pregnant for one of the following reasons, the use of birth control methods is not required during this study:

- Your healthcare provider has confirmed that you are postmenopausal.
- You have had your uterus, or both ovaries, or both fallopian tubes removed.
  If you could become pregnant, you:
- Should let your sexual partner know you are in this study.
- Must agree to practice true sexual abstinence (not have sex) or use an acceptable method(s) of effective birth control during treatment and for an additional 3 months after the last dose of TVEC.
- Must discuss your pregnancy prevention method with the study provider to ensure it is acceptable. You should be aware that true sexual abstinence is the only 100% effective method of birth control.

What if you become pregnant or breastfeed during the study?

If you decide to participate in this study, you must agree to not become pregnant or to breastfeed. If you think you are pregnant or inadvertently become pregnant or breastfeed during treatment and for an additional 3 months after stopping TVEC you must tell the study provider or study staff right away. Treatment with TVEC may be stopped. The study provider will notify Amgen of the pregnancy or that you are breastfeeding. You will be asked to provide information on the pregnancy or breastfeeding outcome for you and the baby. There is a risk of transmitting herpes virus to the baby when passing through the birth canal of a mother with a genital herpes infection. You should tell your provider if you have had a genital herpes infection or think you may have one while on this study. Your provider may recommend a Caesarean Section if you have signs of a genital herpes infection around the time you will give birth.

What if your partner is pregnant when you begin this study or becomes pregnant during the study?
If your partner is pregnant when you begin this study or becomes pregnant during treatment and for an additional 3 months after stopping TVEC you must tell the study provider or the study staff right away. The study provider will notify Amgen of the pregnancy and ask to obtain information on the pregnancy outcome for both the mother and baby.

What are other risks associated with procedures done in this study?

Ultrasound scan:
High frequency sound waves are used to create an image of part of the inside of the body, such as the heart (for example, echocardiogram) using a small handheld sensor. There are no known harmful effects from having an ultrasound scan.

Biopsy Skin Test
Brief discomfort may be felt when the local painkiller (lidocaine) is injected prior to skin biopsies; however, it is usually minimal. Some people experience discomfort from the biopsies despite the use of the painkiller, and there is a slight risk of an allergic reaction to the painkiller. There is a slight chance of infection following the biopsies. It is expected that you will have a small (1/4 – 1/2 inch) scar at the biopsy site(s), which may be permanent or may fade over time. In addition, rare complications associated with skin biopsies include moderate temporary bleeding, as well as a numbing sensation of the skin around the biopsy sites, which might or might not be reversible.

What other choices do I have if I do not take part in this study?
You can choose not to participate in this study. If you do not participate, there are other medical choices that do not include surgery to treat your SCCs, such as radiation therapy. Radiation therapy and intraregional chemotherapy are alternative treatments for SCCs that cannot have surgery done. The study provider can discuss other health care choices with you. You will not experience penalty or loss of benefits to which you are otherwise entitled.

When will my participation in the study be stopped?

The study provider may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the investigator, IRB, or FDA.

Can I stop being in this study?

If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits.

Your participation is voluntary. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with the University of Arizona or Banner Health. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

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

Side effects (injury) can happen in any research study. These effects may not be your fault or the fault of the researcher involved. Known side effects have been described in this consent form. However, side effects that are not currently known may happen and require care. It is important that you tell your study provider if you feel that you have been injured because of taking part in this study. You can tell the provider in person or call him/her at 520-626-6024 during office hours. During the evening and on weekends, call 520-694-6000 (after hours MD paging) and ask for the Medical Oncology physician on duty.

The study provider or study staff will help you get medical care for your injury or illness. You and/or your health insurance plan will be charged for this treatment. The study will not pay for medical treatment. This, however, does not waive your rights in the event of negligence. If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

What are the costs of taking part in this study?

TVEC will be provided by Amgen at no charge to you, the patient. There are no charges for the additional visits, tests or procedures that are required solely for this study. Therefore, you will not have any additional costs beyond those related to the standard treatment of your disease. You may be responsible for payment of any bills that your insurance may refuse to pay due to your standard care while participating in this research study.

Will I be paid for taking part in this study?

You will not be compensated for your participation in this study.

Will my data or specimens be stored for future research?

You will be assigned a unique subject identification number to de-identify your research data and specimens. This number will be used to identify you throughout the clinical study and will be used on all applicable study documentation related to you. The subject identification number will remain constant throughout the study. Your data and biospecimens may be used or distributed for future research. The investigators might request your skin biopsies or excisions to perform additional testing to understand the reason why you responded or did not respond to the study drug.

Will my specimens be sold for commercial profits?

Your data and specimens used in this research will not be sold for commercial profits.

Will I hear back on any results that directly impact me?

You will receive information regarding how you are doing with respect to your cancer. Results from the study will be posted on clinicaltrials.gov when available.

Will Whole Genome Sequencing be done with my specimen?

No Whole Genome Sequencing will be done with your specimen.

Will my study-related information be shared, disclosed, and kept confidential?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Medical records of research study subjects are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study.

It is anticipated that there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups may include:

- Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies
- Banner University Medical Group and Banner Health
- The University of Arizona (UA) and the UA Institutional Review Board
- Your primary care physician or a specialist taking care of your health.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- Name
- Address
- Contact details
- Date of birth
- Medical records
- Past medical history
- Family history
- Race
- Ethnic origin

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and investigator's monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

When will my authorization expire?

There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

Do I have to sign this authorization form?

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

What do I need to know if I decide to cancel my authorization?

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under "Who can answer my questions about the study" at the end of this document.

Will access be limited to your research study record during this study?

You may not have access to the research information developed as part of this study until it is completed.

Who can answer my questions about this study?

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact Clara Curiel, MD, at 520-694-6024.
For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or online at https://research.arizona.edu/compliance/human-subjects-protection-program.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Clara Curiel, MD, at 520-694-6024.

If you have questions, concerns, or complaints about the use or sharing of your health information or would like a copy of the Banner Notice of Privacy Practices, you may contact the Banner Research HIPAA Liaison at BannerResearchCompliance@bannerhealth.com.

To cancel your authorization for access to PHI you must notify the Principal Investigator in writing at the following address

Clara Curiel, MD
University of Arizona Cancer Center
3838 N. Campbell Ave.
Tucson, AZ 85719

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable

state and federal regulations and University policies designed to protect the rights and welfare of participants in research.
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.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

Printed name of subject	**Signature of subject**	**Date**

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**	**Date**