RESEARCH SUBJECT INFORMED CONSENT FORM

TITLE: A phase 1/2 single center investigation of safety/efficacy of nivolumab (Opdivo®) and ABI-009 (*nab*-rapamycin) in patients with advanced Ewing's sarcoma, PEComa, epithelioid sarcoma, desmoid tumor, chordoma, non-small cell lung cancer, small cell lung cancer, urethelial carcinoma, melanoma, renal cell carcinoma, squamous cell carcinoma of head and neck, hepatocellular carcinoma, classical Hodgkin's lymphoma, MSI-H/dMMR metastatic colorectal cancer, and tumors with genetic mutations sensitive to mTOR inhibitors.

PROTOCOL NO.: SOC-1701

PROTOCOL DATE: September 26, 2019

SPONSOR: Sarcoma Oncology Research Center

INVESTIGATOR: Erlinda M. Gordon, MD
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Santa Monica, CA 90403
USA

STUDY-RELATED PHONE NUMBER(S): Erlinda M. Gordon, MD
310-825-6301 ID#11737 (24 hours)
310-552-9999

INFORMED CONSENT VERSION: 6.0

1. BACKGROUND AND PURPOSE

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject. If you are a legally authorized representative, please remember that "you" means the research (study) subject.

You are being asked to take part in this study because you have been diagnosed with advanced Ewing's sarcoma, PEComa, epithelioid sarcoma, desmoid tumor, chordoma, non-small cell lung cancer, small cell lung cancer, urethelial carcinoma, melanoma,

renal cell carcinoma, squamous cell carcinoma of head and neck, hepatocellular carcinoma, classical Hodgkin's lymphoma, MSI-H/dMMR metastatic colorectal cancer, and tumors with genetic mutations sensitive to mTOR inhibitors.

The purpose of this study is to determine whether ABI-009 (study drug) in combination with nivolumab will make your cancer smaller and slow the spread of your cancer. About 40 patients will take part in this study.

ABI-009, human albumin-bound rapamycin, is an experimental drug used to treat patients with five types of sarcoma in this study. Rapamycin, the active part of the drug, prevents a biological pathway out of control in sarcoma cancer cells. Rapamycin and similar types of drugs have been used in many other tumors, including advanced renal cell carcinoma. The human albumin component of ABI-009 may allow rapamycin to reach cancer cells more effectively.

ABI-009 has not been approved for the treatment of advanced Ewing's sarcoma, PEComa, epithelioid sarcoma, desmoid tumor, chordoma, non-small cell lung cancer, small cell lung cancer, urethelial carcinoma, melanoma, renal cell carcinoma, squamous cell carcinoma of head and neck, hepatocellular carcinoma, classical Hodgkin's lymphoma, MSI-H/dMMR metastatic colorectal cancer, and tumors with genetic mutations sensitive to mTOR inhibitors. The information from this study might help us identify if ABI-009 plus nivolumab treatment is safe and effective in these diseases.

This consent form gives you detailed information about this research study. If you wish to participate in the study, you will be asked to sign and date the informed consent form and you will be given a complete copy of this informed consent form to keep.

2. WHAT DOES THE STUDY ENTAIL?

This research study will be conducted at the Sarcoma Oncology Research Center by Dr. Erlinda M. Gordon, the Principal Investigator (person in charge of the study in this Cancer Center) and her study staff. About 40 patients will be entered in this study at this single site in the United States.

Before you can receive study treatment, the doctor will perform tests to find out whether you can participate in the study.

In this study, you will receive **nivolumab** (Opdivo, an FDA approved vaccine for lung cancer and a certain type of skin cancer, melanoma) given through a vein (intravenous) on Day 1, and **ABI-009** also given through a vein once weekly on days 8 and 15 of a 21-day cycle. ABI-009 will not be given in Cycle 1, and only nivolumab will be given. ABI-009 begin on day 8 of the second 3-week cycle.

If you are found to be eligible by your study doctor, you will receive therapy within 14 days. Treatment will last until your disease progresses or depending on how well you tolerate the therapy. After your study treatment has been completed, you will be

checked upon by phone calls every 3 months or more frequently if needed to see how you are doing and to collect information on any new anti-cancer treatment you may be taking. Altogether the total time you spend on study may be up to 1 year. Your study doctor or staff will tell you when and where you will go for treatment, tests, exams, and procedures.

The study doctor or his/her staff will perform the following procedures during the study:

- At screening, a copy of your pathology report from your tumor sample will be collected.
- At screening, your archived tumor will be tested for a genetic mutation known as PTEN
- At screening, your demographic information (date of birth, sex, race, and ethnicity) will be collected.
- At screening, you will be asked questions about past and present diseases, surgeries, allergies, medicines you are taking, other studies you were in, and any method of birth control, if appropriate.
- At the beginning of every cycle and End of Treatment (EOT) visit, you will have a physical examination including medical/cancer history and measurement of vital signs (blood pressure, temperature, heart rate).
- At screening, your height will be measured.
- At screening, day 1 and day 8 and day 15 of every cycle, your weight will be measured.
- At screening, an electrocardiogram (or ECG) will be performed. This is a simple, painless test that records the heart electrical activity.
- At screening, at day 1 of every cycle, and at the End of Treatment visit, your performance status will be assessed, which is your ability to carry out normal activities and take care of yourself. This will involve asking you questions about your daily life.
- At screening, a urine sample will be collected for routine analysis.
- At any time after signing the informed consent and up until 28 days after your last study treatment dose, you will be asked questions about any medical conditions or side effects which you may experience during the study
- At screening and throughout the course of the study, you will be asked about additional medicines that you have taken (this includes medicines that you do not need a prescription for such as: aspirin, ibuprofen, vitamins, and herbal medicines) as well as additional procedures you underwent. This includes medications taken less than or equal to28 days prior to screening. You should check with your study doctor before starting any new medicines.
- If you are eligible to take part in the study, you will be asked to return to the clinic to receive your study treatments. If you are not eligible, the study staff will discuss other treatment options with you.
- Blood samples will be taken:
    - If you are female and able to become pregnant, 5 mL (1 teaspoon) of blood will be drawn at screening and End of Treatment (EOT) visit for a serum pregnancy test to prove that you are not pregnant before your treatment begins and once treatment is completed.
    - At screening, the beginning of every cycle, and End of Treatment (EOT) visit, 5-10 mL (1-2 teaspoons) of blood will be collected to test for levels of certain common substances such as sodium, calcium, sugar, and others
    - At screening and at every study visit, 5 mL (1 teaspoon) will be collected to test for blood cell counts

  - At screening, about 5 mL (1 teaspoon) will be collected to test how well your blood clots
  - At screening and every 3 months, about 5 mL (1 teaspoon) will be collected to test your thyroid function
  - At screening, about 10 mL (2 teaspoons) will be collected to test for HIV, Hep B/C, and your liver functions. State/Provincial law requires positive test results for certain communicable diseases, including HIV, hepatitis, sexually transmitted infections, and tuberculosis, to be reported to a local health agency. Some of the tests for this study must be reported when positive. The study doctor can discuss this with you.
  - At screening and every 3 months, about 5-10 mL (1-2 teaspoons) will be collected to test your fasting lipid (cholesterol test). You may be asked not to eat anything and only drink 9-12 hours before having your blood cholesterol tested
  - On the fifteenth day of the second and third cycles of ABI-009, 5 ml (1 teaspoon) will be collected immediately before ABI-009 infusion, to determine the trough (lowest level) of rapamycin in your blood
  - After 3 courses of treatment, your study doctor may recommend that your tumor is removed and examined for the effects of the treatment on your tumor.
- Your study doctor will determine your response to treatment. This will be based on the information gathered from a CT scan or MRI scan of your chest, abdomen and pelvis within 14 days prior to first treatment, then every 6 weeks for the first year, and at the End of Treatment (EOT) visit only for those patients that discontinue treatment for a reason other than disease progression. Together, the total time you would have these scans during the study can be up to one year. NOTE: an unscheduled scan for suspected disease progression may occur at any time. If your disease recurs, no more CT or MRI scans will be done. CT scan uses a series of x-rays which create a three-dimensional picture of the inside of your body, while an MRI uses magnetic fields to create a picture. These scans allow the study doctor to measure if your cancer is progressing.
- After your End of Treatment visit, you will be contacted every 3 months or more frequently if needed (can be by telephone) to see how you are doing and to collect information on any new treatments you may be taking.

3. POTENTIAL BENEFITS OF THE STUDY

There is no promise that the study treatment you receive in this study will help you. It is hoped that potential benefits may include improvement of some disease related symptoms and a decrease in the size of your tumor. You should be aware that the treatment you receive may be harmful. Information obtained from your participation may help other people in the future.

4. POTENTIAL RISKS OF THE STUDY

Sometimes during a research study, new significant information becomes available about the treatment that is being studied. If this happens, your doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your doctor will make arrangements for your care to continue outside of the study. If you decide to continue with the study, you will be asked to sign an updated consent form that contains this new information.

(a) Risks from the Study Procedures

***Risk with Intravenous (IV) Drug Administration*:** Temporary irritation and bruising may occur at the infusion site. There may also be discomfort, pain, or bruising from the needle puncture. In rare cases, an infection may also occur at the site of the needle stick.

***Blood drawing* -** Needle sticks carry some risks such as fainting, bleeding, bruising, discomfort, dizziness, infection and/or pain at the puncture site.

ECG: There are no serious risks with an ECG, it is a harmless and painless test that detects the heart's electrical activity. They do not give off electrical charges, such as shocks. However, you may develop a mild rash where the electrodes (soft patches) were attached. These rashes often go away without treatment.

***CT and MRI Scans*:**

As part of this study, you will have CT and MRI scans. CT scans involve exposure to radiation. Some people may be worried about the amount of radiation they receive during a CT scan. The amount of radiation from this entire study is well below the levels that are thought to result in a significant risk of harmful effects. Radiation exposure from a CT scan can be higher than from a regular x-ray. However, not having the procedure can be more risky than having it, especially if cancer is suspected. People considering having a CT scan must think about the risks and benefits. The amount of radiation exposure from having CT scans, in this study is about the same as the amount of radiation a person would get from natural surroundings in 3 years.

You may get contrast (dye) for imaging. Some people experience mild itching or hives. Signs of a more serious allergic reaction include shortness of breath and swelling of the throat or other parts of the body, abdominal pain, or vomiting. You should tell the technologist immediately if you experience any of these symptoms, so you can be treated immediately. You may experience discomfort related to lying still in an enclosed space for a prolonged period of time while the CT scan or MRI is being taken.

(b) Risks from the Study Treatment

ABI-009 Risks

You may have side effects while you are in the study, but you will be carefully checked by the study doctor for any problems. There may be risks or side effects of the study drug that are unknown at this time. You should tell the study doctor/staff about anything that is bothering you or any side effect you have, even if you do not think they are related to the study drug.

The following is a list of the most medically significant or most common side effects reported in previous studies and considered to be related to ABI-009. In some cases, side effects can be serious or long-lasting. Some side effects go away soon after you stop the study drug/therapy and some may take time to resolve. The study doctor may alter the dosage regimen of ABI-009 or give you medicines to help lessen the side effects. This is not a complete list of all side effects that may occur. For more information about risks and side effects, please ask the study doctor.

Very common (10% or more chance that this will happen, based on a previous study with ABI-009):

- low blood platelets (thrombocytopenia)
- low blood hemoglobin (anemia)
- low white blood cell count (neutropenia)
- low potassium levels (hypokalemia)
- low blood phosphate levels (hypophosphatemia)
- diarrhea
- nausea
- constipation
- inflammation of the mucus membrane (mucosal inflammation)
- fatigue
- decreased liver function (elevated AST)
- weight decrease
- rash
- infection (candidiasis)
- labored breathing (dyspnea)
- lung inflammation (pneumonitis)

Common (between a 4% to less than 10% chance that this will happen):

- elevated potassium levels (hyperkalemia)
- elevated lipid levels (hypertriglyceridemia)
- irritations in the mouth (stomatitis)
- vomiting
- edema
- cough
- insomnia
- weakness, numbness in hand and feet (neuropathy)

Uncommon (between a 0.1 to less than 4% chance that this will happen):

- decreased appetite

- anorexia
- alkalosis
- dehydration
- elevated cholesterol (hypercholesterolemia)
- elevated blood glucose (hyperglycemia)
- elevated creatinine levels
- low sodium levels (hyponatremia)
- lip blister
- oral pain
- infusion site pain
- fever
- thirst
- decreased liver function (elevated ALT)
- low blood albumin levels
- dermatitis
- infections
- vertigo
- suicidal ideas
- disorientations
- fast heart rate (tachycardia)
- hypertension
- muscle pain (myalgia)
- transient chest pain (acute coronary syndrome)

ABI-009 contains human serum albumin. Human serum albumin presents a small risk of allergic or anaphylactic type reactions. Tell your doctor if you have ever had a reaction to human serum albumin.

Human serum albumin is a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin.

Nivolumab Risks

The following is a list of the most medically significant or most common side effects reported in previous studies and considered to be related to nivolumab. In some cases, side effects can be serious or long-lasting. Some side effects go away soon after you stop the study drug/therapy and some may take time to resolve. The study doctor may delay or permanently discontinue nivolumab or give you medicines to help lessen the side effects. This is not a complete list of all side effects that may occur. For more information about risks and side effects, please ask the study doctor.

Very common (10% or more chance that this will happen, based on previous studies with nivolumab):

- Rash
- Itchiness
- Cough and congested throat
- Edema or swelling of legs and feet
- Decreased liver function (Increased AST, ALT, alkaline phosphatase
- Decreased blood electrolytes (decreased sodium, potassium)

Special immune side effects:

- lung inflammation (pneumonitis) 3.4%
- diarrhea (colitis) 21%
- liver disease (hepatitis) 9-28%
- kidney disease (nephritis) 13%
- thyroid disorders (hypo- or hyperthyroidism) 2-8%

Uncommon (2% or less that this will happen, based on previous studies with nivolumab

- Pancreatitis
- Increased amylase
- Increased lipase
- Eye disorders (uveitis, iridocyclitis)
- Facial weakness
- Dizziness
- Irregular heart rate (ventricular arrhythmia)
- Disorders of the nervous system (demyelination, neuropathy, hypophysitis; Guillain-Barre syndrome; muscle weakness)
- Disorders of Adrenal gland (adrenal insufficiency)

- Diabetic ketoacidosis

General Disorders and Administration Site Conditions: infusion-related reactions can happen. Dexamethasone is given to prevent allergic reactions. Dexamethasone may cause irritability, increased appetite, stomach bleeding, stomach ache, and rarely, confusion. You will receive an antacid to prevent stomach ache and stomach bleeding as a result of dexamethasone treatment.

Pregnancy Risk with ABI-009

No studies of ABI-009 have been conducted in pregnancy. It is not known if ABI-009 passes into milk during breast feeding

Females: If you decide to take part in this study, and are able to have children, you must agree to use medical doctor-approved contraception throughout the study, and for 3 months after your last dose of study treatment. In addition, if you have had your tubes tied (tubal ligation) you must also agree to use a second form of birth control. If you become pregnant while receiving study treatment you must tell the study doctor right away. If this happens, your participation in this study treatment will be discontinued. If you become pregnant within 3 months after taking your last dose of study drug you must tell the study doctor right away. The study doctor will follow you and your pregnancy to birth.

Males: If you are a man, you will not be able to donate sperm for the length of the trial and for 3 months following treatment. If you have a partner able to have children, you must agree to use a medical doctor-approved form of contraception throughout the study, and should avoid fathering a child for 3 months after your last dose of study treatment. In addition, if you have had a vasectomy you must also agree to use a second form of birth control. If your partner becomes pregnant during the study or within 3 months after you took your last dose of study treatment, you must tell the study doctor right away. Your study doctor and the sponsor will ask your partner to allow them to collect information about her pregnancy and the health of the baby in a separate consent form.

5. OTHER CHOICES

You do not have to take part in this study in order to receive treatment for your cancer. Although you have failed standard treatment, there may be other drugs which your doctor can prescribe without being on the study. Your doctor will inform you of these other options.

6. VOLUNTARY PARTICIPATION IN THE STUDY

Your participation in this study is voluntary. You can decide not to take part, or leave the study at any time for any reason without penalty or loss of medical care or benefits to which you are entitled.

If you wish to stop the study treatment, please tell the study doctor or his/her staff and return to the study center for a final visit. If you want to stop the study treatment because of a side effect, it is important that you tell the study doctor about the side effect. The study doctor will help you stop safely and make arrangements for further medical care and follow-up.

7. WHAT ARE MY RESPONSIBILITIES WHILE PARTICIPATING IN THE STUDY?

- Follow the instructions of the study doctor or the study staff.
- Tell the study doctor or his/her staff about any injuries or illness (including side effects, discomfort, or declining health) you may experience in the course of the study.
- If you visit or receive medical care from another doctor, tell him/her that you are in a research study.
- Talk to the study doctor before you take any new medicines, even if another doctor prescribed the medicines. If there is an emergency, you may take the medicines and then tell the study doctor as soon as possible.
- Do not participate in any other medical research study while you are on this study, until you have discussed it with the study doctor.
- Do not miss your appointments with the study doctor or his/her staff.

8. YOUR PARTICIPATION IN THE STUDY MAY BE STOPPED

The study doctor may stop your participation if you do not follow the instructions in Section 7. He/she may also stop your participation, if you have side effects, if your condition worsens, if you or your partner become pregnant, or you no longer meet the requirements of the study.

The Sarcoma Oncology Research Center or the drug manufacturer, AADi, may also stop your participation or the study at any time (for example, for safety reasons). If that happens, the reason will be explained to you.

If the study doctor or AADi stops your study participation, the study doctor will make arrangements for further medical care and follow-up.

9. NEW INFORMATION ABOUT THE STUDY TREATMENT

During the course of a study, new information may become available that may influence your willingness to participate in the study. If that happens, the study doctor will tell you about it.

10. PRIVACY AND CONFIDENTIALITY

10.1. Data privacy

The study doctor will collect information from you.

All the information will be processed without your name, ID number or any other information which allows your identification. The information will be labeled with a code. A confidential list of names will link the code to your name. Only authorized people (for example, the study doctor) will have access to the list of names and be able to identify you.

The study doctor will keep your medical records and any other record identifying you confidential. To the extent permitted by law, monitors, auditors, the Food and Drug Administration and other competent authorities will have access to your medical records in order to verify the study data and compliance with the study procedures. Those persons will have the obligation to keep your records and the information contained in them confidential.

The study results may be mentioned in medical books or journals or used for teaching purposes. Your identity will not be mentioned. The Sarcoma Oncology Center and AADi may also share information collected during the study with scientists outside Sarcoma Oncology Center and AADi for further scientific research in the interest of public health. The Sarcoma Oncology Center and AADi will, however, not provide information about your identity to these scientists.

If you leave the study or after your participation has been stopped for any other reason (see Section 8 above) any information collected while you were in the study will be kept and may be included in the final results of the study.

You have the right to access and verify your personal information held by the Sarcoma Research Oncology Center and AADi and to obtain its deletion or the correction if it is inaccurate. If you wish to exercise that right please tell the study doctor (see contact details above).

11. WILL YOU BE PAID FOR YOUR PARTICIPATION IN THE STUDY?

You will not receive payment for being in the study. Please discuss with the research staff what will be reimbursed and what information you should provide.

Taking part in this study does not make you an employee of the sponsor or the study site.

12. COSTS FOR BEING IN THE STUDY

The collaborating company of this study, AADi, will provide the AABI-009 study drugs to you free of charge. The nivolumab drug is FDA-approved and will be charged to your insurance company or provided free of charge by the drug manufacturer, Bristol Myers Squibb. Costs related to your routine medical care will be billed to you or your insurance company. This is because they are the same standard of care you would receive if you were not on study. Your health insurance company may or may not pay for these charges.

13. STUDY RELATED INJURIES

You should notify the study doctor as soon as you believe you have had a study-related illness or injury, so that proper medical care can be provided. You will receive proper medical care if you are injured or become ill in connection with the study. If the injury or illness is directly related to the proper management of the study drug or proper performance of research procedures, AADi will pay the reasonable costs of that treatment to the extent those costs were necessary, directly related to the Study and are not covered by your health insurance. If your insurance does not cover an expense and AADi does not pay for the medical expense, you may be responsible for payment.

However, AADi will not pay for expenses that are (in any way) related to your failure to follow instructions, the progression of any illness or disease you may currently have or the wrongdoing on the part of the study site, study doctor, or study staff. Further, AADi will not routinely pay for lost wages or other damages.

14. WAIVER OF RIGHTS TO DISCOVERIES

You agree that you will not receive any rights to or compensation for any discovery, development, invention, or patent that may result from your participation in this study.

15. IF YOU NEED MORE INFORMATION

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.

ClinicalTrials.gov is a registry in English of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and contact information for more details.

When the results of the study are available, you will be given an opportunity to receive them.

Please do not hesitate to contact the study doctor if you have any questions, concerns, or complaints about the study, the procedures, the treatment, or your rights, if you need help because you suffered an injury or illness in the course of the study, or if you want to review your personal data held by the study doctor. The contact details of the study doctor are mentioned at the top of this document.

If you have questions about your rights while you are in this study or if you have concerns, or complaints about the research, you can contact the IRB. Western Institutional Review Board® (WIRB®) 1019 39th Avenue SE Suite 120, Puyallup Washington 98374-2115, Telephone: 1-800-562-4789 or 360-252-2500, E-mail: Help@wirb.com. The IRB/IEC is a self-governing group of people who review research studies to make sure the safety and rights of the people taking part in the study are protected. The IRB/IEC for this study is Western IRB and they have given their approval or favorable opinion for this study to begin. They will continue to review the study while it is going on.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

INFORMED CONSENT

Feel free to discuss the information in this document with your family, doctor(s) or friends. Do not sign this document until you have had a chance to ask the study doctor or his/her staff all of your questions and all questions have been answered to your satisfaction.

- I agree to participate in the study.
- I understand that I can leave the study at any time.
- I understand and agree that study monitors, auditors, the ethics committee, the Food and Drug Administration, and other competent authorities will have direct access to my medical records in order to verify the study data and compliance with the study procedures.
- I agree that my personal data are collected for the purposes of the study and the follow-up of the safety of the study medication. If my participation stops, my personal data may be further processed and the samples which I provided during the study will be analyzed for the purposes of the study and to follow-up the safety and the effect of the study drug. AADi may share information collected during the study with scientists outside AADi for further scientific research in the interest of public health. AADi shall however not share information about my identity with these scientists.
- I agree /I do not agree (circle one) that my family doctor can be informed that I am taking part in the study.
- If I pass away after I leave the study, I authorize/I do not authorize (circle one):
  (a) the study doctor or the doctor in charge of my treatment to inform AADi about the date and the cause of my death; and
  (b) AADi to process this information for the purposes of the study or the follow-up of the safety and the effect of the study drug.

I understand that all medical information, specimens, imaging studies and samples obtained from me during this study will be used and kept by Sarcoma Oncology Research Center/AADi for the purposes described in this Informed Consent Form. I also understand that all data and materials created from this study shall become the property of Sarcoma Oncology Research Center and AADi. I further understand that Sarcoma Oncology Center and AADi have no plans to compensate (pay) me or to share in any possible profits that Sarcoma Oncology Research Center and AADi may derive (collect) from such specimens, samples, data, or materials.

I have read this Informed Consent Form, which is written in a language I understand, and I understand it. I understand the procedures and what I will be asked to do. All my questions about the study, possible risks, side effects and study drug have been answered. I understand that I can choose not to take part in this study without penalty or loss of rights to which I am entitled. I have been told that I can change my mind about being in the study at any time and that by signing this consent form, I am not giving up any of my legal rights. I have told the person obtaining this consent if I am involved in

other medical research studies. I have been given a copy of this Informed Consent Form and a copy of the California Research Participant's Bill of Rights.

Signature

By signing this information and consent form, you have not given up any legal rights which you otherwise would have as a research participant.

_____
Research Subject's Name (Print)

_____ _____
Research Subject's Signature Date of signature

I have explained the purpose of this study, the study procedures, the possible risks, discomforts and benefits. I have answered all questions regarding the study to the best of my ability.

CONFIDENTIALITY

Records identifying your medical information will be kept confidential to the extent permitted by applicable laws and/or regulations, and will not be made publicly available. If the results of the study are published, your identity will remain confidential. Your name will not be used in any study reports, blood samples, or scans, and all study reports will be used for research purposes only. The Sarcoma Oncology Research Center and AADi, its designee(s), ethics committees, independent review boards, personnel at the study site, and various government health agencies (such as the Food and Drug Administration) may inspect and review your medical records of this study for the purpose of checking data collected for the study. By signing this consent, you are authorizing access to your medical records for the purpose of checking data collected from your participation in this study.

You also provide consent for the release of copies of your CT/MRI scans, laboratory test results, and all medical reports for review as part of this research study. To protect your privacy, your blood and tissue samples and scans will be labeled with only your subject ID as an identifier. There will be no personal identifiers to link these samples to you. Samples and scans may be transferred to companies working with the Sponsor for testing or review for this study. Although efforts will be made to protect your privacy, absolute confidentiality of your records cannot be guaranteed.

You are also giving your permission to have your Protected Health Information (PHI) collected, used and disclosed for the purposes of this clinical trial. PHI is protected by federal privacy laws, but once the study doctor discloses it to others, it could be redisclosed and will no longer be protected by the federal privacy laws.

You may decide not to give permission for the use or disclosure of your PHI for this study; however, you will not be able to participate in the study. This is because the study doctor and site staff would not be able to collect all the information that is needed. You may also cancel your permission to use or disclose PHI after you have started the study; however, you will not be able to continue participating in the study or receive study drug. This is because the study doctor and site staff would not be able to continue collecting all the information that is needed for the study.

If you choose to withdraw your authorization to use and disclose your personal health information, please notify the study doctor in writing.

Signing this informed consent also allows the study doctor to release study results to the Sponsor and its designees. The study results will not contain information that identifies you (such as your name).

This permission will be good until December 31, 2060.

Your study doctor will keep your personal medical records and a list that links each patient's name to his or her study subject number for at least 15 years.

After your PHI is disclosed to the study sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The study collaborator (AADi, LLC) and people who work with the study sponsor may use your coded study information, samples and scans for this study and for other research purposes in the future, including:

- Reviewing the safety and effectiveness of ABI-009/nivolumab
- Conducting performance reviews of the study
- Improving the design of future studies
- Studying UPS, LPS other solid tumors associated with this study, as well as any related diseases

You have the right to request access to, and to correct any inaccuracies in your recorded PHI collected as part of this study. However, due to the nature of the study it may only be possible to access this information after the study is completed. This is done to maintain the scientific integrity of the study. After the study is concluded you can obtain access to your information through your study doctor.

As your primary doctor may not be the doctor you will be seeing for this study, you should inform him/her of your participation in this study. The study doctor may contact your primary doctor to obtain medical records.

_____
Research Subject's Name (Print)

_____ _____
Research Subject's Signature Date of signature

_____
Name of Person Obtaining Consent (print)

_____ _____
Signature of Person Obtaining Consent Date of signature

ASSENT SIGNATURES, For Subjects Ages 12 through 17 years:

Assent:
This research study has been explained to me and I agree to be in this study.

_____ _____
Subject's Signature for Assent Date Age (years)

I confirm that I have explained the study to the extent compatible with the subject's understanding, and that the subject has agreed to be in the study.

_____ _____
Signature of Person Conducting Assent Discussion Date

---------- Use the following only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

_____ _____
Impartial Witnesses Signature Date

_____
PRINT Name of Impartial Witness

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.