Kiromic, Inc.

**Protocol KiroVax 003**

Phase I/II Study of Low Dose Cyclophosphamide, Tumor Associated Peptide Antigen-Pulsed Dendritic Cell Therapy and Imiquimod, in patients with Progressive and/or Refractory Solid Malignancies.

Informed Consent Template 20181008

***Concise Summary***: We are asking you to consent to participation in a research study. Your participation is voluntary. This is a Phase I/II trial to test a study cancer vaccine. The goal of this research study is to check the following: a) Test the safety of a cancer vaccine developed based on the characteristics of the subjects' own tumor cells, and b) To find out if the immune system will be stimulated against the patient's cancer. This vaccine is made from your own blood cells, so it is unique to you.

First, a course of the study cancer vaccine will be given to 6 study subjects. If the study vaccine does not cause serious side effects, it will be given to up to 11 more study subjects at the same dose. Each subject will get the study vaccine every 7 days for up to 3 doses, and the response to the study vaccine will be evaluated per study guidelines.

There have been few side effects observed in Vaccine studies like the one used in this study. Generally, side effects are well tolerated and mild. Common side effects include fever, chills, fatigue, back and joint pain, nausea, and headache. Local irritation at the site of injection may also occur and may include reddening of skin or irritation, swelling, tissue thickening, ulceration, and itching. It is possible that you may have some benefit from the study vaccine although this is unknown. If you are interested in learning more about this study, please continue reading below.

## *Informed Consent for Participation in Research*

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**Participant's Name: _____Subject ID Number:_____**

**Official Study Title:** Protocol KiroVax 003; Phase I/II Study of Low-Dose Cyclophosphamide, Tumor Associated Peptide Antigen-Pulsed Dendritic Cell Therapy and Imiquimod, in Patients with Progressive and/or Refractory Solid Malignancies

**Principal Investigator:**

**Sponsor:** Kiromic, Inc

Before consenting to participate in this research study, you should have enough time to read the information in this form, or have it read to you. A member of the research team will discuss it with you. Be sure to ask questions about anything that is not clear before giving consent.

You can choose not to participate at any time, even after starting the study, without any penalty or loss of benefits to which you are entitled.

You will have procedures done that are considered research and may or may not be a part of the usual care for you condition. If you decide to participate, your private health information will be collected; however, the researchers in this study will take appropriate measures to ensure

confidentiality of your information. In the case you are injured in result of the study, medical treatment is available.

If you go to [Site Name] or another healthcare facility or provider for any reason while participating in this study, you should inform them that you are involved in this research study, as it may impact the type(s) of care provided and protect your safety.

**Why me:** You are being asked to take part in this research study because you have been diagnosed with a cancer that is not responding at this time to standard anti-cancer therapy. The cancer vaccine will be administered to see if it is safe and has any effect on your cancer.

**Study Summary:** This study is a Phase I/II trial to test an investigational treatment cancer vaccine (study vaccine/drug). "Investigational" means that the treatment cancer vaccine being tested has not been approved by the United States Food and Drug Administration (FDA).

Phase I trials are the first stage of testing a potential treatment in human subjects. This means that the study drug has not been tested or tested very little in humans before. However, similar vaccines have been tested in animals and people.

This research study is a combined Phase I/II trial. The first part (Phase I) will treat 6 patients to determine the safety of the investigational cancer vaccine and how well the patient may tolerate it (Phase I). Immune responses (if any) to the cancer vaccine will be evaluated in these cancer patients as well. During the second part (Phase II) up to 11 additional patients will be treated to determine how your body's immune system responds to the drug, and how it affects the cancer (stops the tumor from spreading, or results in any destruction of cancer cells). Patients will be under close supervision of the study doctor for the duration of the study.

This vaccine is made from your own blood cells and is unique to you. Therefore, you will be the first and only person to receive this vaccine.

The purpose of this study is to:

a. Test the safety of a cancer vaccine developed based on the characteristics of the subject's own tumor cells

b. The study will also measure any anti-cancer effects associated with the cancer vaccine.

Furthermore, the Sponsor's scientists will perform research by analyzing your tumor and blood, and the way your immune system responds to the therapies. These research efforts will not affect your therapy but may lead to important discoveries and potential commercialization that may further improve the treatment for your and other cancer types, and may allow the Sponsor's scientists to develop new effective products. In the latter case, you understand that all the information related to said new products will remain strictly the confidential property of the

Sponsor, and as such cannot be disclosed to you or anyone involved in this study.

We hope to enroll at least 6 subjects with solid cancers at our site, [Site Name], for Phase 1 portion of the study and may enroll up to 11 additional cancer subjects in the Phase 2 portion of the study depending on how the first 6 subjects do on the Phase 1 study respond. The study will last about 6 months, including screening. A maximum of 17 subjects, male and female, may be enrolled and receive the study drug.

**What other choices do I have?**

If you decide not to be in this study, you have other choices, such as:

- You may choose to have the standard treatment for your cancer.
- You may choose to be in a different research study if one is available.
- You may choose not to be treated (with care to make you feel more comfortable). If you choose not to get treatment, you can get comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

You can get treatment for your cancer whether you are in this study, or not. You should talk to your own doctor about each of these choices before you decide if you will take part in this study.

**What extra test and procedures will I have if I take part in the study?**

Many of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra tests and/or procedures that you will need to have if you take part in this study.

Before you begin the study:

- You will have a test that will look at your tumor cells to see if they have at least one of several substances that may cause your body to make a specific immune response related to the cancer vaccine. To perform such a test, your doctor might require taking a small sample of your tumor from an easy to reach site, using minimally-invasive procedures. While this procedure, called a biopsy, only carries minimal risk, it may be needed to prove if the vaccine is effective.

Before you receive the vaccine you will need to have the following extra tests and procedures:

- About a pint of blood will be drawn from a vein in your arm via phlebotomy. However, if for some reason, you are ineligible for phlebotomy, you may undergo an FDA-approved procedure called a leukapheresis. This procedure is used to remove the blood from your body to collect specific blood cells. Then the remaining blood is returned to the body. You will be asked to sign a separate consent that will explain the procedure in more detail. The

cells removed from your body by either process will be used to make the study vaccine for you.
- A skin test will be done to check you for immune reactions as well.

During the study:

- Patients will take a low dose of a FDA approved chemotherapy drug called cyclophosphamide by mouth for 5 days before receiving the study vaccine. Studies in animals and other cancer vaccine trials suggest that cyclophosphamide may make tumor vaccines more potent. It is expected that this drug will increase the chances of having a response to the study cancer vaccine.
- The study vaccine will be given in 4 small injections under the skin. The study vaccine will be repeated every 7 days for up to 3 doses.
- After the vaccine, you will receive topical Imiquimod cream, a drug to help boost your immune system.
- A skin test will be done to check for immune reaction to study vaccine components before and after the study vaccine as specified in the study.
- Blood tests will be done that can provide information to the study doctor about your immune system. For these tests, up to 7 – 14 tablespoons of blood will be taken as directed by the study calendar.

When you are finished taking the vaccine:

- Blood tests will be done that can provide information to the study doctors about your immune system. For these tests, up to 7 tablespoons of blood will be taken as directed by the study calendar.
- A skin test will be done to check for immune reaction to the vaccine at as directed by the study calendar.

A study calendar will be provided to you, showing how often these procedures will be done.

If you decide to be in this study, you will be asked to read and sign this consent form and that will take about 30-60 minutes. This is an average time. It may take longer depending on how many questions you have about this research study. You may take this consent form home with you if you would like more time to read it and think about your decision.

If you need to have leukapheresis to collect your blood cells, that procedure may take up to 8 hours.

You will receive the study vaccine once every week. After you finish the study vaccine, you will return to the clinic as per the study calendar, so the study doctor can watch you for side effects and follow your condition. At that time, you will have some of the tests and procedures described above to check your health.

**What risks will I face by taking part in the study and how will Researchers protect me from these risks?**

If you choose to take part in this study, there is a risk that you may:

- Lose time at work or home and spend more time in the hospital or doctor's office than usual
- Be asked sensitive or private questions which you normally do not discuss

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

There is also a risk that you could have side effects. Vaccines like the one used in this study have been used in other research studies. There have been few side effects observed and vaccines are generally well tolerated and mild.

Here are important points about side effects:

- The study doctor does not know who will or who will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are some important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

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

The tables below show the most common side effects that researchers know about. Because this study vaccine is investigational, there might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

## Possible Side Effects of Dendritic Therapy/Vaccine

| COMMON, SOME MAY BE SERIOUS |
| --- |
| Flu-like symptoms that include:<br>• Fever<br>• Chills<br>• Fatigue<br>• Back and joint pain<br>• Nausea<br>• Headache<br><br>Local reaction at the site of the injection that may include:<br>• Reddening of the skin or irritation<br>• Swelling<br>• Area of hardened/thickened tissue<br>• Ulceration/necrosis<br>• Itching |

| OCCASIONAL, SOME MAY BE SERIOUS |
| --- |
| • Slight enlargement in the lymph node(s) in the injected area after the vaccine injection |

| RARE, AND SERIOUS |
| --- |
| • Vitiligo, a skin condition that causes the patchy loss of skin color has been seen in patients who had melanoma.<br>• Normal function of the testicles may be affected in men.<br>• The vaccine may cause the development of a condition in which the body recognizes its own tissues as foreign and directs an immune response against them.<br>• It is possible that the vaccine may stimulate the growth of your tumors thus making your cancer worse. |

## Possible Side Effects of Imiquimod

| COMMON, SOME MAY BE SERIOUS<br>In 100 people receiving Imiquimod, more than 20 may have: |
| --- |
| • Itching<br>• swelling<br>• burning<br>• skin that becomes hard or thickened<br>• redness<br>• flaking and scaling |

- sores, blisters, or ulcers
- dryness
- changes in skin color that do not always go away
- scabbing and crusting

**OCCASIONAL, SOME MAY BE SERIOUS**

In 100 people receiving Imiquimod, from 4 to 20 may have:

- Flu-like symptoms: tiredness, fever, nausea, muscle pain and chills.

**RARE, AND SERIOUS**

In 100 people receiving Imiquimod, 1 or fewer may have:

- No serious events reported.

The above side effects were recorded in patients undergoing a standard Aldara therapy, which in most cases consists of 5 applications per week, for a total of 6 weeks. Instead, in this study you will be given Aldara cream only once after each vaccine injection, for a total of three (3) applications, one (1) week apart. Since you will receive only 10% of the standard dose, the probability of any side effect from Aldara is very low, but still possible.

**Possible Side Effects of Cyclophosphamide**

**COMMON, SOME MAY BE SERIOUS**

- Nausea, vomiting
- Diarrhea
- Feeling weak
- Confusion
- Shortness of breath
- Rash or dry, itchy skin
- Low urine output
- Abnormal blood tests which suggest that the drug is affecting the liver or kidneys

**OCCASIONAL, SOME MAY BE SERIOUS**

- Feeling dizzy
- Feeling drowsy
- Sores in the mouth or on the lips
- Loss of appetite
- Abdominal (stomach area) pain
- Increased heart rate or change in heart rhythm
- Swelling in the face, hands, or feet
- Trouble sleeping
- Trouble concentrating
- Runny nose
- Low platelet count with increased risk of bleeding
- Low red blood cell count (anemia) with symptoms like tiredness, weakness, shortness of breath

| |
|---|
| • Low white blood cell count with increased risk of infection |
| **RARE AND SERIOUS** |
| • Allergic reaction<br>• Cough<br>• Confusion<br>• Damage to bowel, ruptured or bleeding bowel<br>• Serious infection<br>• Kidney failure |

It is possible that the combination of the drugs will increase the number or severity of side effects or cause different side effects than the ones mentioned for either drug alone.

**General**

- Risk/side-effects of intravenous (in the vein) injection/infusion:
  There may be swelling or soreness at the area of the injection. It is possible that local bruising may develop at the place where the study drug is given, and there is a rare risk of infection at that location.
- Venipuncture (blood draw):
  The risks and discomforts associated with having your blood drawn are pain at the site, bleeding, infection, bruising, possible fainting and a drop in blood pressure.
- Injection: Risks from an injection include pain at the site of the injection; bleeding; bruising; soreness; swelling; redness around the Central Line or Catheter (if used to collect blood cells to prepare vaccine).
- Catheter placement if needed for leukapheresis: One risk of the catheter (small tube) being placed in a vein in your chest is the collapse of the lung. If this should happen, another special tube would have to be placed into the chest for several days to re-expand the lung. There is also a chance that infection will develop at this site, which would require the tube be removed and replaced and possible treatment with antibiotics. Such an infection can cause other side effects leading to longer hospitalization; however, with the use of oral antibiotics, used to prevent these kinds of problems, the chance of infection is uncommon. There is a risk of air in your chest due to a punctured lung. Bleeding in the chest and into and under the skin is possible. It is possible you will have some pain or discomfort when the central line is placed.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

As with any research study, there may be additional risks that are unknown or unexpected. If these become known, the study team will notify you in a timely manner of any changes that may change your willingness to participate. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

Please tell the researchers in the contact section about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

**Unforeseeable Risks**

Because this vaccine is investigational, all its side effects may not be known. There may be rare or unknown side effects that could possibly occur, including life-threatening reactions.

**Pregnancy/Birth Control**

Because the drugs in this study can affect an unborn baby, you should not become pregnant or father a baby while on this study. Women should not breastfeed a baby while on this study.

Either a female or a male wishing to be in this study must be using one or more types of birth control during the entire study and for 6 months after completing the study. Birth control methods may include condoms, diaphragm, birth control pills, spermicidal gels or foams, injections, intrauterine devices (IUD), surgical sterilization, or subcutaneous implants. Another choice is for your sexual partner to use one of these birth control methods.

If you feel you have experienced a side effect or an unusual symptom to the study drug or any procedures during this study, you should call the study doctor and the research staff at the phone numbers listed on page one of this consent form.

**Will there be any added risks from this study if you are a female?**

If you are a woman who can become pregnant, you must have a negative pregnancy test before you start the study. If you are a nursing mother and wish to be in this study, you must stop breastfeeding. You cannot be in the study if you are pregnant or breastfeeding. Even if you use a medically acceptable birth control method, you could still become pregnant. Not having sex (abstinence) is the only certain way to prevent pregnancy. If you become pregnant during the study, stop taking the study drugs and call the study doctor.

If you are pregnant or become pregnant during the study, the study drug or procedures may involve risks to the unborn baby, which are currently unforeseeable. The effects of the study drug on an unborn baby or breastfed baby are unknown. If you become pregnant while on this study, you will no longer be eligible to be in the study and your study drugs will be stopped.

**New Findings**

If new findings develop during the study that might affect your agreement to continue in this study, you will be notified as soon as possible.

**How could I and others benefit if I take part in this study?**

This study may or may not help you. This study may help us learn things that may help people in the future.

**What is the cost of participating in this study?**

Kiromic, Inc, a bio-pharmaceutical company, is providing the supplies and funding for this study. No one on the research staff will receive anything of value from other agencies, organizations, or companies to carry out this research.

The vaccine will be prepared, supplied and administered at no charge to you, or your insurance company, while you take part in this study. Cyclophosphamide, a chemotherapy drug known to decrease resistance to vaccines will be given by mouth for 5 days before study vaccine administration. Imiquimod, a medication to "boost" your immune response to the study vaccine, will be applied topically following each vaccine administration. Your insurance company may be billed for the cost of these drugs since they are commercially available and approved for stimulation of the immune system in diseases, such as melanomas and kidney cancers. If your insurance company denies payment, the cost may be covered by the study.

You and/or your health plan/insurance company will need to pay for all the other costs of treating and/or evaluating your cancer while in this study, including the cost of managing any side effects. Please be aware that some insurance plans may not pay for research-related injuries. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

The study team will review a list of procedures with you that show which are standard of care and which are research only. Unless a procedure is listed as 'research' you should expect that you and/or your insurance company will be responsible for payment of items and services. You will be responsible for your normal co-payments and co-insurance/deductibles.

If you have questions about the cost of participation, ask for more information before deciding to participate in the study.

**Will I be paid for participating in this study?**

There will be no compensation payments provided to patients for study participation.

**Who could profit or financially benefit from the study results?**

This study is paid for by Kiromic, Inc which owns the drug being tested and thus has a financial interest in the outcome of the study. Payments are made to [Site Name] and the funds are used to cover the expenses of the study and related academic and research activities of the institution.

The investigator and [Site Name] do not have any financial interest in the outcome of the study.

If commercial products or other valuable discoveries result from this research project, these products and discoveries could be patented, licensed, or otherwise developed for commercial sale by [Site Name] or the study Sponsor or their respective designees. If this should occur, there are no plans to provide financial compensation to you. There are no plans for you to share in the patent rights, other ownership rights, or rights to control the commercial products and discoveries that may result from this research project.

**If I take part in this study, can I also participate in other studies?**

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

**If I want to stop participating in the study, what should I do?**

If you wish to stop your participation in this research study for any reason you should let the principal investigator/study coordinator know as soon as possible so that you can stop safely. You may be asked why you are leaving the study and your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in "Contact Information".

If you stop your participation in this study, you can decide whether to let the study doctor continue to provide your medical information to the organization running the study.

It is important for you to tell the study doctor if you are thinking about stopping so he/she can evaluate any risks from the study drug. Another reason to tell your own doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

If you leave the study, your right to standard medical care will continue.

If you leave the study, we cannot remove any information we have collected to that point.

**Could the researchers take me out of the study even if I want to continue to participate?**

Under certain circumstances, your study doctor may decide to take you out of the study. This might happen because:

- Your health changes and the study are no longer in your best interest.
- Your disease gets worse despite the cancer vaccine;
- The side effects of the cancer vaccine are too dangerous for you;
- New information about the cancer vaccine becomes available and this information suggests the cancer vaccine will be ineffective or unsafe for you;
- It is unlikely, but the study may be stopped early due to lack of vaccine supply or

lack of funding. Should the study be stopped early for any reason, you will continue to be treated for your cancer. Your own doctor will discuss all treatment options with you at that time.

Your part in this study may be stopped at any time without your permission. The following people can stop your participation and/or the study itself:

- Study Doctor
- Sponsor Company
- IRB
- The United States Food and Drug Administration (FDA)
- Other State and Federal Regulatory Agencies

If you withdraw from the study, no new data about you will be collected for study purposes. All data that have already been collected for study purposes will be shared with the study sponsor.

**What happens if I get hurt, my condition worsens, or have other problems because of this research?**

If you are injured as a direct result of this study, medical care is available. In general, no long-term medical care or financial compensation for research-related injuries will be provided by [Site Name]. You do not waive (give up) any legal rights by signing this informed consent form.

Kiromic, Inc and its affiliates do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness unless specifically stated.

If you have a research related illness or injury, care will be available to you as usual, but you and/or your medical or hospital insurance company will be billed for the cost of treatment. Your insurance company may not be willing to pay for study-related injury. If you have no insurance coverage, you would be billed for any costs. Before entering this study, you should check whether your insurance company might limit your insurance coverage if you take part in a research study.

**What information about me could be seen by the researchers or by other people? Why? Who might see it? How will it be protected?**

Release of Health Information – If you decide to participate in this study, information about your health may be used or disclosed (shared outside of the Hospital) for the purposes of conducting this study. This information may include information from your medical record that is relevant to this study, such as your medical history, medications, test results, diagnoses, treatments, operative reports (reports from operations that you have undergone), and discharge summaries. It may also include information *relating to: Human Immunodeficiency Virus ("HIV") infection or Acquired Immunodeficiency Syndrome ("AIDS"); treatment for or history of drug or alcohol abuse;*

*or mental or behavioral health or psychiatric care.* Information collected by the study doctor and/or research staff specifically for this study, such as test results, blood samples, physical examinations, information about possible side effects, and surveys you might be asked to complete could also be used or disclosed.

Individuals that may use or release this information include: physicians, physicians' office staff, hospital staff, the study doctor, and authorized members of the study doctor's research staff. These individuals may release this information to the study doctor, authorized members of the study doctor's staff, the funding agency of the study Kiromic, Inc as well as its agents or contractors, other researchers, the Institutional Review Board (IRB), the United States Food and Drug Administration (FDA) and its representatives, and other government agencies.

In most cases, the information released to the above listed individuals or entities will not contain your name, social security number, or any other personal information. However, authorized representatives of your study doctor, IRB, FDA, or other government agencies may review records containing personal information to make sure that the study information is correct. Because of the need to provide information to these parties, absolute confidentiality cannot be guaranteed.

Use of Information – This information may be used to determine whether you meet all requirements for participation in the study, to monitor your healthcare during the study, to enable the sponsor to answer the scientific questions for which the study was designed, and to ensure that the study has been done properly. Examples of the use of this information are as follows: the sponsor may use the information in submissions to government agencies throughout the world, to request approval of the study drug or device; the sponsor may use the information for reporting adverse events to government agencies, such as the FDA; the sponsor may also transfer the information to business partners or companies it hires to provide study-related services; the sponsor may also provide overall study results, including your information, to other study doctors; and the sponsor may reanalyze the data from this study in the future or combine it with data from other studies for analysis. In addition, both the sponsor and the study doctor may use the information to prepare reports or publications of the study results. However, when results of the research study are reported in medical journals or at scientific meetings, the people who were in the study are not named and identified. Therefore, your names would not be disclosed in any presentation or publication.

You need to understand that once your information has been released, it may no longer be protected by US federal regulations relating to data privacy and could be used or re-disclosed in ways other than those listed in this section of the consent form.

You have the right to see and copy your medical records but information relating to this study may be withheld until the end of this study.

**What happens to information about me after the study is over or if I cancel my permission?**

If you stop participating in this study, you also have the right to revoke (withdraw) your authorization to disclose and use your information. Revoking your authorization means taking back the permission you gave the study doctor to send information about you to the sponsor or other people and entities. If you revoke your authorization, your doctor will not use or release any more information about you after receiving your request, except to tell the sponsor that you have stopped early and have revoked your authorization. However, the sponsor and the study doctor can keep and use any information that it has already received to the extent necessary to preserve the integrity of the research study. To revoke this authorization, contact the research team. The research team will accept either a written or verbal request.

Your blood/tissue samples and/or clinical data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them. The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form. ***(may be removed if no specimens are collected)***

**When does my permission expire?**

Because this information is being disclosed for research use, there is no expiration date for the authorization to disclose and use this information. The sponsor may keep and continue to use your study information for many years. Your study doctor may need to add to or correct information about you even after your study participation is over; including providing updates of your health status if that is important to the purpose of the study. The review of your medical records may also take place after the study is over. This authorization will remain in effect unless you revoke it.

Authorization– By signing this consent form, you authorize use and disclosure of personal information to, and review of your medical records by, the people and entities described above. You do not have to authorize this disclosure of information. However, if you do not, you will not be able to participate in this study.

**What are my rights in this study?**

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights as a research participant, or if you have complaints, concerns, or questions about the research, please contact [IRB Contact Information]. You may also contact the [Additional Site Contact Information, if applicable].

The research team will take proper precautions to ensure that any information regarding your identity obtained in connection with this research will remain confidential; **however, confidentiality cannot be guaranteed.**

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. (21CFR50.25(c))

**Where can I get more information?**

You may contact the study doctor or study staff at the phone number listed below

- for answers to questions, concerns, or complaints about this research study,
- to report a research related injury, or
- for information about study procedures.

If you have any questions regarding your participation in this study, please ask us. If you have any additional questions later, please contact the researchers listed below to:

Principal Investigator:

Mailing Address:

Telephone:

Study Coordinator:

Telephone:

**NOT RECONTACTING PARTICIPANTS**

It is possible that, in studying tissue samples and data from you and others, researchers may discover information that would be potentially relevant to your future health. If this occurs, there are no plans to make this information available to you. This is because the tissue samples may have been coded or de-identified in a way that makes it difficult to trace the result back to a specific person, and because the results of research often are too uncertain to be used as specific medical information. Your signature below indicates that you understand this to be true.

**Please √ check one:** [ ] Yes [ ] No

**Future Contact**

Please indicate whether you would or would not be willing to let our researchers get in touch with you in the future, to ask whether you would be willing to contribute more tissue samples or data or participate in another study at that time:

**Please √ check one:** [ ] Yes [ ] No

**Signatures**

**Study Participant or Legally Authorized Representative (LAR)**

I have read this consent form, or had it read to me. I have discussed it with the study team and my questions have been answered. I will be given a signed copy of this form. I agree to take part in this study *including any options where I checked 'yes'.*

**Signature**: _____ **Date**: _____ **Time**:_____

**Name (Print Legal Name):** _____

Legal Representative Information (If Applicable) Phone: _____

Relationship to Subject: ☐Parent ☐ Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

Reason subject is unable to consent for self:_____

**Person Obtaining Consent:**

**I have given this research subject (or his/her LAR) information about this study that I believe is accurate and complete. The subject (or LAR) has indicated that he or she understands the nature of the study and the risks and benefits of participating.**

Name: _____ Title: _____

Signature: _____ Date: _____Time:_____

**Translation Service:** I verbally translated the informed consent process and the conversation between the person obtaining consent and the study participant.

Name: _____ Organization: _____

Signature: _____ Date: _____Time:_____

**Witness** ***(required if 'short form' used for translation, or when participant physically unable to read, write, talk or see):*** I was present as an impartial witness (not a member of the research team or family) for the informed consent process. I observed the above subject (or his/her legally authorized representative, if applicable) indicate consent.

**If applicable participant has capacity to consent but is unable to sign, how did he or she indicate consent:** _____

Witness Name: _____

Signature: _____ Date: _____Time:_____