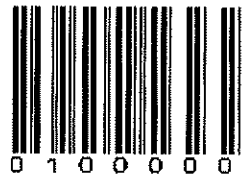


Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____**Medical Record #** _____

Principal Investigator: Craig L. Slingluff, M.D.
University of Virginia Health System
Human Immune Therapy Center
Box 801457
Charlottesville, VA 22908
Telephone: 434-924-9311

Sponsors: Human Immune Therapy Center
University of Virginia Health System

National Cancer Institute-National Institutes of Health (NCI-NIH)

Support Source: Ludwig Institute for Cancer Research

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

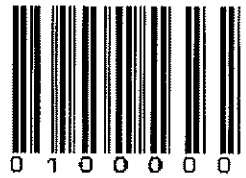
Who is funding this study?

This part of the study is being funded through a grant from the National Institutes of Health, National Cancer Institute. The study is run through the Human Immune Therapy Center, and the center provides six of the proteins used in the vaccine mix. The Ludwig Institute for Cancer Research provides one of the proteins used in the vaccine mix and may provide the polyICLC study drug.

Why is this research being done?

The purpose of this study is to learn what effects (good and bad) an experimental vaccine (LPV7) and other substances called polyICLC, resiquimod, and Montanide ISA-51 have on melanoma. The study has two parts, Part 1 and Part 2.

In Part 1 of this study, the experimental vaccine (LPV7) was tested in seven different combinations of the other study drugs, changing the location where the vaccine is given each time. The combination of the experimental vaccine (LPV7) and the substance polyICLC were determined to have the best results of the different combinations. Part 1 of the study is now complete and the experimental vaccine with the best results were chosen for continued testing in Part 2.



The purpose of Part 2 is to test the safety of the experimental vaccine with the best result in Part 1 (LPV7 and polyICLC) when it is given in the same injection location, and to study changes in your immune system.

Fifty subjects received study treatment in Part 1 of this study at all locations. Thirty-five subjects signed consent at UVA in part 1. Up to 40 more people will sign consent for this part (Part 2) of the study at UVA. A total of 75 subjects will sign consent at UVA.

How long will this study take?
Your participation in this study will require 13 study visits over 2 years. Each visit will be as an out-patient and last about 2-5 hours, and possibly more. . In addition, we will contact you about once per year for follow-up purposes to find out how you are doing.

What will happen if you are in the study?
NOTE: Throughout the study, results of tests and procedures completed as part of your clinical care will also be recorded for research purposes.

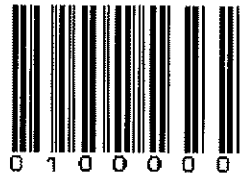
SCREENING (will take approximately 2-5 hours to complete):
This study may be introduced to you by one of the members of your clinical team, or another member of the University of Virginia, such as a member of this study's research team. Before you agree to participate in this study, you will have an opportunity to review this consent form and to have all of your questions answered.

If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate.

Further, the study team will want to have access to tests and procedures done prior to this study. The research team may ask you some questions and/or review your records for information and results, and may request copies of documents, which will become part of your study records, including the following:

- Your medical history
- Results for any test you may have completed for other reasons, including, but not limited to:
  - Physical exam and vital signs (blood pressure, heart rate, etc.)
  - Blood tests reports
  - Other testing reports
  - CT, MRI, PET scans, or other imaging reports
  - X-rays
  - pathology reports
- Notes and/or your clinicians may make about your care, and perhaps biopsies or surgeries.

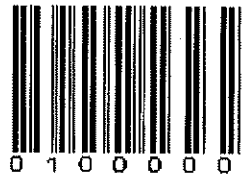
Information will be collected; such as your age, gender, and race. This will be completed as part of your clinical care and the information will also be used for research.



- Your tumor specimen may be reviewed by pathologists at UVA. This would be done to evaluate or to confirm if you are eligible for this study. However, it also may have clinical value for you, as we have in the past found that patients thought to have metastasis (spread) of melanoma did not in fact have that. This will be completed as part of your clinical care.

- You will also have a physical exam for clinical purposes to be performed by a study clinician in the Cancer Center Clinic:
    - Vital signs (blood pressure, heart rate, temperature, etc.)
    - Weight
    - Determining your ability to function and perform daily activities
    - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
    - Determining where on your body the treatment will be given
    - Medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded.
- About 1 to 2 tablespoons of blood will be drawn from a vein in your arm. You may be asked to avoid food and all liquids except water for 4 hours before the blood draw. (Abnormal tests may prompt additional clinical evaluation and management for your health.) **This blood will be completed as part of your clinical care and used to:**
    - Perform a genetic test called HLA typing. This test is like typing your blood for donating to or receiving blood from other people. If you blood cells are a certain type, you may be eligible to receive the experimental vaccine. If you already know your HLA type, this test will not be repeated.
    - Test for HIV and Hepatitis C virus, if you have not had this testing done within the past 6 months. Patients with HIV, Hepatitis C are not believed to be as likely to benefit from study treatment for their cancer, and/or may be best advised to seek treatment for those viral illnesses. Test results must be negative in order to participate in this study.
    - For women: Perform a serum pregnancy test if you can get pregnant and have not had a test done within the past two weeks. Because the safety of the study drugs to the maturing fetus has not been evaluated, this test must be negative in order to participate in this study.
    - Check your blood counts, certain levels of fats, salts, and sugars, kidney and liver function, and your immune system.
    - Check your LDH (lactic acid dehydrogenase). LDH is an enzyme in the body that helps detect tissue or cell breakdown and also can indicate the presence of cancer, meningitis (inflammation of the thin layers of tissue that cover and protect the brain and spinal cord) and other disorders.
    - Check kidney function and liver function.
- Your urine will be tested to check your kidney function. This will be completed as part of your clinical care.
- Scans will be performed if you have not completed scan(s) within 6 weeks of enrollment and randomization in this study. **All scans/imaging will be completed as part of your clinical care.**

  You will have a CT scan or PET/CT scan (special X-rays) or X-ray of your chest, a CT scan or PET/CT scan of your abdomen and pelvis, and a magnetic resonance imaging (MRI) scan or CT scan of your head. Contrast dye may be used for these scans



For the testing that is done for Clinical Care as noted above, the results of those tests will be gleaned from your medical record and used in this research.

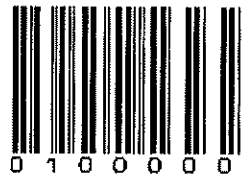
Findings of unexpected tumors/changes in disease on these scans may lead to additional tests (performed as part of your medical care) to determine if you should be treated in a manner other than enrollment in this study.

If the screening tests show you are eligible you will return again (within 14 days of randomization) to begin study treatment visits.

STUDY TREATMENT (Each study visit will take about 2-5 hours)
At each study visit you will undergo tests and/or reviews is to make sure you are healthy enough to continue to participate in the study and/or that you have not had disease progression (disease get worse) that may require a different treatment.

Day 1, Week 0

- You will have a physical exam with a licensed clinician. The physical exam will be performed for research purposes and will include:
    - Vital signs (blood pressure, heart rate, temperature, etc.)
    - Weight
    - Determining your ability to function and perform daily activities. This is sometimes called a neurological examination.
    - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
    - Looking at your skin for vitiligo (smooth white patches on your skin)
    - Determining your nerve function
    - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded.
    - Testing your vision (both visual sharpness and color vision)
    - Looking at your hair and eye color
    - Determining whether you have any symptoms that will be considered pre-existing and not related to the research
- About 1/3 tablespoon of blood will be tested for antinuclear antibody/RF (rheumatoid factor) factor, which will help identify an autoimmune disease. This will be done for research purposes.
- About 10 tablespoons of blood will be collected from a vein to test your immune response to the experimental drugs and adjuvants that you will receive. This will be done for research purposes.
- You will receive the experimental vaccine (LPV7 and polyICLC). This will be done for research purposes.
- You will be given a Symptom Diary to keep; you will log/track any symptoms you may have using this Symptom Diary, noting the time of the beginning of a symptom in the appropriate day/symptom box. Study staff will review this procedure with you. Bring this completed diary with you to your next visit, at which time the clinician will review the diary that was given to you at the last visit to see if you had any symptoms after receiving the study drug. You will also be given a new diary at each visit. The symptom review and symptom diary will be performed as part of the research study.



Day 8, Week 1

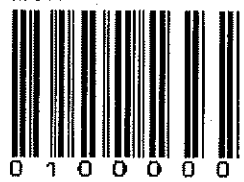
- You will have a physical exam with a licensed clinician. The physical exam will be performed for research purposes and will include:
    - Vital signs (blood pressure, heart rate, temperature, etc.)
    - Weight
    - Determining your ability to function and perform daily activities
    - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
    - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
    - Reviewing any health problems you experienced since your last visit
- You will have three 4mm biopsies of the vaccine site. This tissue will be used for research purposes to study your body's cells under a microscope.
- You will receive the experimental vaccine. This will be done for research purposes.
- About 7 tablespoons of blood will be collected from a vein to test your immune response to the experimental drugs and adjuvants that you will receive. This will be done for research purposes.
- Your symptom diary will be reviewed and you will be given a new symptom diary to keep. Please bring the completed diary with you to your next visit. The symptom review and symptom diary will be performed as part of the research study.

Day 15, Week 2

- You will have a physical exam with a licensed clinician. The physical exam will be performed for research purposes and will include:
    - Vital signs (blood pressure, heart rate, temperature, etc.)
    - Weight
    - Determining your ability to function and perform daily activities
    - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
    - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
    - Reviewing any health problems you experienced since your last visit
- You will receive the experimental vaccine. This will be done for research purposes.
- Your symptom diary will be reviewed and you will be given a new symptom diary to keep. Please bring the completed diary with you to your next visit. The symptom review and symptom diary will be performed as part of the research study.

Day 22, Week 3

- You will have a physical exam with a licensed clinician. The physical exam will be performed for research purposes and will include:
    - Vital signs (blood pressure, heart rate, temperature, etc.)
    - Weight
    - Determining your ability to function and perform daily activities
    - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
    - Looking at your skin for vitiligo (smooth white patches on your skin)
    - Determining your nerve function



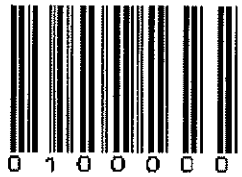
  - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
  - Reviewing any health problems you experienced since your last visit
- About 1/3 tablespoon of blood will be collected to check your blood counts, certain levels of fats, salts and sugars, kidney and liver function, and your immune system. This blood will also be used to check your LDH levels. This will be done for research purposes.
- About 1/3 tablespoon of blood will be tested for antinuclear antibody/RF (rheumatoid factor) factor, which will help identify an autoimmune disease. This will be done for research purposes.
- About 7 tablespoons of blood will be collected from a vein to test your immune response to the experimental drugs and adjuvants that you will receive. This will be done for research purposes.
- You will have three 4mm biopsies of the vaccine site. This tissue will be used for research purposes to study your body's cells under a microscope.
- Your symptom diary will be reviewed and you will be given a new symptom diary to keep. Please bring the completed diary with you to your next visit. The symptom review and symptom diary will be performed as part of the research study.

Day 36, Week 5

- You will have a physical exam with a licensed clinician. The physical exam will be performed for research purposes and will include:
  - Vital signs (blood pressure, heart rate, temperature, etc.)
  - Weight
  - Determining your ability to function and perform daily activities
  - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
  - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
  - Reviewing any health problems you experienced since your last visit
- You will receive the experimental vaccine. This will be done for research purposes.
- Your symptom diary will be reviewed and you will be given a new symptom diary to keep. Please bring the completed diary with you to your next visit. The symptom review and symptom diary will be performed as part of the research study.

Day 43, Week 6

- You will have a physical exam with a licensed clinician. The physical exam will be performed for research purposes and will include:
  - Vital signs (blood pressure, heart rate, temperature, etc.)
  - Weight
  - Determining your ability to function and perform daily activities
  - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
  - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
  - Reviewing any health problems you experienced since your last visit
- About 7 tablespoons of blood will be collected from a vein to test your immune response to the experimental drugs and adjuvants that you will receive. This will be done for research purposes.



- Your symptom diary will be reviewed and you will be given a new symptom diary to keep. Please bring the completed diary with you to your next visit. The symptom review and symptom diary will be performed as part of the research study.

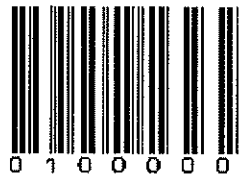
Day 57, Week 8

- You will have a physical exam with a licensed clinician. The physical exam will be performed for research purposes and will include:
    - Vital signs (blood pressure, heart rate, temperature, etc.)
    - Weight
    - Determining your ability to function and perform daily activities
    - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
    - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
    - Reviewing any health problems you experienced since your last visit
- You will receive the experimental vaccine. This will be done for research purposes.
- Your symptom diary will be reviewed and you will be given a new symptom diary to keep. Please bring the completed diary with you to your next visit. The symptom review and symptom diary will be performed as part of the research study.

Day 78, Week 11

- You will have a physical exam with a licensed clinician. The physical exam will be performed for research purposes and will include:
    - Vital signs (blood pressure, heart rate, temperature, etc.)
    - Weight
    - Determining your ability to function and perform daily activities
    - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
    - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
    - Reviewing any health problems you experienced since your last visit
- About 1/3 tablespoon of blood will be collected to check your blood counts, certain levels of fats, salts and sugars, kidney and liver function, and your immune system. This blood will also be used to check your LDH levels. This will be done for research purposes.
- About 1/3 tablespoon of blood will be tested for antinuclear antibody/RF (rheumatoid factor) factor, which will help identify an autoimmune disease. This will be done for research purposes.
- You will receive the experimental vaccine. This will be done for research purposes.
- Your symptom diary will be reviewed and you will be given a new symptom diary to keep. Please bring the completed diary with you to your next visit. The symptom review and symptom diary will be performed as part of the research study.

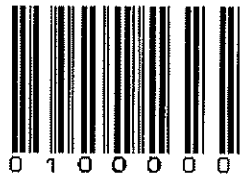
Day 85, Week 12



- You will have a physical exam with a licensed clinician. The physical exam will be performed for clinical and research purposes and will include:
    - Vital signs (blood pressure, heart rate, temperature, etc.)
    - Weight
    - Determining your ability to function and perform daily activities
    - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
    - Looking at your skin for vitiligo (smooth white patches on your skin)
    - Determining your nerve function
    - Testing your vision (both visual sharpness and color vision)
    - Looking at your hair and eye color
    - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
    - Reviewing any health problems you experienced since your last visit
- About 1/3 tablespoon of blood will be collected to check your blood counts, certain levels of fats, salts and sugars, kidney and liver function, and your immune system. This blood will also be used to check your LDH levels. This will be done for clinical care purposes.
- You will have a chest X-ray or CT scan. This will be done as part of your clinical care.
- About 7 tablespoons of blood will be collected from a vein to test your immune response to the experimental drugs and adjuvants that you will receive. This will be done for research purposes.
- Your symptom diary will be reviewed by the study clinician. This will be done for research purposes.

FOLLOW UP:
Day 183, Week 26

- You will have a physical exam with a licensed clinician. The physical exam will be performed for clinical and research purposes and will include:
    - Vital signs (blood pressure, heart rate, temperature, etc.)
    - Weight
    - Determining your ability to function and perform daily activities
    - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
    - Looking at your skin for vitiligo (smooth white patches on your skin)
    - Determining your nerve function
    - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
    - Reviewing any health problems you experienced since your last visit
- About 1/3 tablespoon of blood will be tested for antinuclear antibody/RF (rheumatoid factor) factor, which will help identify an autoimmune disease. This will be done for research purposes.
- You will have a chest X-ray or CT scan. This will be done as part of your clinical care.
- About 7 tablespoons of blood will be collected from a vein to test your immune response to the experimental drugs and adjuvants that you will receive. This will be done for research purposes.



Day 365, Week 52 and Day 730, Week 104

- You will have a physical exam with a licensed clinician. The physical exam will be performed for clinical and research purposes and will include:
  - Vital signs (blood pressure, heart rate, temperature, etc.)
  - Weight
  - Determining your ability to function and perform daily activities
  - Looking at your skin and lymph nodes for evidence of disease recurrence or spreading
  - Reviewing the medications that you are taking; including any over-the-counter, alternative medications, herbal medications, or supplements will be recorded
  - Reviewing any health problems you experienced since your last visit
- About 7 tablespoons of blood will be collected from a vein to test your immune response to the experimental drugs and adjuvants that you will receive. This will be done for research purposes.

Biopsies of Tumor

During the course of the study, you may have one or more whole tumors reduced in size or removed. This may be completed as a part of your clinical care or your physician recommends this as part of your clinical care. You will sign a separate hospital consent describing the risks of this procedure.

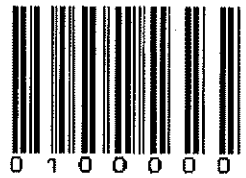
Additional Tests, Treatments, and/or Procedures

During the course of the study, you may require one or more additional tests, treatments and/or procedures. These may be performed as a part of your clinical care.

In addition, if you were to experience a skin reaction, it is possible that the digital photographs (not including your full face) might be needed to fully document the reaction.

Annual Follow Up Phone Calls

We would like to keep track of your medical condition for the rest of your life. We would like to do this by calling you on the telephone once a year to see how you are doing. Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of the study.



Study Calendar of Procedures and Tests

Study Calendars of Procedures and Tests	Screening	Day	1	8	15	22	36	43	57	78	85	183	365	730	Annual Contact
		Week	0	1	2	3	5	6	8	11	12	26	52	104	
Informed Consent	X														
Review of Pathology	X														
Medical History	X														
Urine Test	X														
Abdomen and Pelvic CT scan, head MRI or CT	X														
Chest x-ray / CT	X										X	X			
Blood draw to test to count red blood cell, white blood cells, sugars, salts and see how the liver and kidneys are working	X					X				X	X				
Blood draw for Research			X	X		X		X		X	X	X	X	X	
Physical Exam	X		X	X	X	X	X	X	X	X	X	X	X	X	
Eye Exam			X								X				
Examination of hair and eye color			X								X				
Examination of skin for vitiligo			X			X					X	X			
Toxicity diary (review/distribute)			X	X	X	X	X	X	X	X	X				
Vaccine site biopsy (all participants)				X		X									
Administration of research drugs/agents			X	X	X		X		X	X					
Follow-up Contact[1]															X

Bold "x" indicates activity performed for research purposes at that visit.
[1]Follow-up contacts- at least annually.

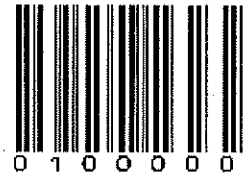
What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety.
These responsibilities are listed below:

- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Blood Testing

We will take (or "draw") up to about 11 tablespoons of blood on days when blood is to be drawn. The total amount of blood we will take will be about 64 tablespoons over 2 years.



The blood we take will be tested to measure

- measure the amount of red and white blood cells in your blood;
- check how well your kidneys/liver work;
- measure the amount of certain fats, salts, and sugar in your blood;
- check your immune system;
- test your immune response to the experimental vaccine and reagents you received

If you want to know about the results before the study is done:
During the study, your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you can ask for more information about the study results.

Collection of Samples and Health Information for Mandatory HLA typing as part of clinical care and Optional Future Genetic Research and Specimen Banking for Research

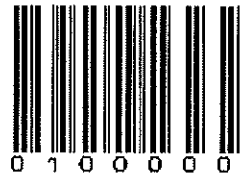
You are being asked to provide samples of your blood and tumor tissue to be used for futureresearch. Along with specimens, researchers may need to collect some health information about you. Combining information from the specimen with information from your health records may be useful for this research. For this research, the following types of information could be included:

- diagnosis
- treatment
- age
- gender
- sample type

If you agree, we plan to do future genetic research on the DNA in your specimen sample. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

In addition, if you agree, specimens collected for research will be added to a research specimen bank. The purpose of a specimen bank is to process, and store samples until researchers need them for future research. The long-term goals of the samples collected in this bank will be mainly used for research on melanoma. It is not possible, however, to list every research project that will include the samples because we cannot predict all of the research questions that will be important over the coming years. As we learn more, new research questions and new types of research may be done.

Your specimen sample may be used to create a living specimen sample (called a "cell line") that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.



What will you have to do to give samples for research?
Your doctor will obtain blood and tumor tissue for testing. These samples will be collected as part of the research study at the time points described above. If your tumor grows back and tumor tissue is removed, a portion of the tissue may be saved for research. All of these specimens may be used for genetic research and may also be banked and used in future research studies.

How Will Your Sample(s) Be Labeled?
The University of Virginia Human Immune Therapy Center will be responsible for storing your sample and for protecting your privacy.

Your sample(s) will not be labeled with your name or other information that would identify you directly. Instead, your sample will have a unique code that allows for it to be linked to some of your health information. This link means that your specimen can be identified but only indirectly. We can find out if we need to know which sample is yours in the event you wish the sample to be removed at a later date.

How Will Your Sample(s) Be Stored and Labeled for Specimen Banking
Dr. Slingluff, the Director of the University of Virginia Human Immune Therapy Center, will be responsible for storing your sample and for protecting your privacy.

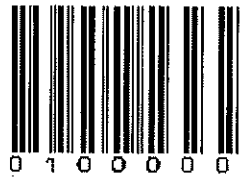
This research specimen bank is located at the University of Virginia under the leadership of Dr. Slingluff. There is no set limit to the number of people who will provide samples to this bank.

Your sample(s) will not be labeled with your name or other information that would identify you directly. Instead, it will have a unique code that allows for it to be linked to some of your health information. This link means that your specimen can be identified but only indirectly. We can find out if we need to know which sample is yours in the event you wish the sample to be removed from the bank later.

Which researchers can use your samples and what information about you can they have?
Your sample may be shared with researchers at the University of Virginia and at other institutions. Dr. Slingluff will not give your name to other researchers who want to use your sample, but will only give them information like your age and what disease/condition you have. Those who would see the information would include researchers and the others listed under "Who will see your private information?" section of this consent document.

Some of the people who receive your information may not have to follow the privacy laws and may share or release your information because they do not have to follow the privacy laws.

What Are the Benefits To Donating Your Sample(s) For Future Genetic Research and Specimen Banking?
The genetic research and/or specimen banking that is done with your sample is not meant to help you. But, doctors hope that in the future it will help people who have other diseases or conditions.



It is very unlikely that any future research (specimen banking) performed using your specimen(s) would benefit you directly, but it may provide important medical knowledge that could help other patients with your medical condition or other medical problems in the future.

What Are The Risks of Donating Your Sample(s) For This Study?

Risks to Privacy from Future Genetic Research and Specimen Banking:
The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. One of the risks to you is the release of information from your health records. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot *guarantee* it will be safe. To further safeguard your privacy, information obtained from future research will not be placed in your medical record.

There are certain risks of having health information given to other people by mistake. In the unlikely event that this happens, it could cause discrimination or mental harm to you or your family members if others were to see this information. The results could be that you may not be able to get or keep certain kinds of insurance. It could also hurt family relationships.

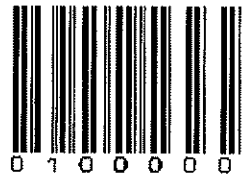
Because everyone has unique DNA, it is also possible, although very unlikely, that someone could identify you through your DNA if they have another sample of your DNA.

Different types of genetic tests carry different levels of risks. Depending upon the type of genetic testing that is completed, information about your genetic make-up could mean that you and your family members may face problems that could lead to getting or keeping some kinds of insurance or affect your ability to get or keep a job. To keep this from happening, the results of these tests will not be given to anyone outside of the study staff. There is no way to predict all the possible risks of this research.

HLA Testing for clinical care
HLA typing may be performed as part of your clinical care. However, in order to participate in this study, the results of your HLA typing is required. Therefore, in order to participate in this study, you must undergo HLA typing as part of your clinical care if you do not already have HLA testing results. If HLA typing is performed as part of your clinical care, the result will be placed in your medical record.

. HLA is a special protein commonly found in the body, especially in white blood cells. There are many different types of HLA. Because of this HLA testing is very good at figuring out things like if a person is a good match as an organ donor, how likely a person is to develop a disease or condition, or paternity testing (being able to figure out the biological parents of a person.)

Risks to Your Job, Insurance or Family Planning,
Once you have been told a test result, you may have to reveal the result when you apply for health, life, disability, or other insurance. This is true whether or not the result is entered into your medical record. Some insurance companies may consider genetic results in making insurance decisions. They may



decide not to offer coverage, to limit coverage, or to charge a higher premium for coverage. You may want to review and make any changes in your insurance coverage *before* testing. However you should know that the Genetic Information Discrimination Act of 2008, along with other Federal Laws, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. However, this law does not protect your ability to get or keep other kinds of insurance such as life insurance or long term care insurance.

You may be encouraged to share information with other family members. But some family members may not welcome the information. And you may find out some things you didn't want to know as well. For example, you may learn that a family member is adopted. This may sometimes cause relationships in families to change. Other members of your family may also learn things about your health or risk of genetic disease.

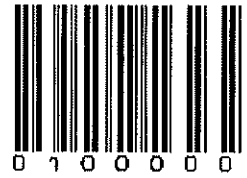
HLA Test Results
If you would like to know the results of your HLA testing, they will be may be shared with you by the researchers or your doctor. In most cases it is not risky or harmful to know your HLA type. It is important that you know that sometimes the HLA result might affect your ability to get or keep some kinds of insurance or it may affect your family relationships. This could make you feel anxious. Also, keep in mind that if you know your HLA type, you would be required, if asked, to share this information with your insurance company even if it is not in your medical record. You may wish to discuss the risks of knowing your HLA type with the researchers or your doctor.

Sometimes, a test result may show that one or both of a child's parents is not the real birth parent. If this happens, we will not share this information with anyone, including you. We, the research team, would only disclose this information if the law said we had to. Your doctor may choose to disclose this information to you.

Will You Find Out the Results of the HLA testing?
You will have the option to receive or not receive your HLA results from the UVA research team.

Will You Find Out the Results of the Future Research on Your Sample(s) for Specimen Banking?
Neither you, your health care provider, nor anyone in your family, will receive the results of any additional research done on your sample(s). The results will not be put in your health records. Therefore, results from any research done on your sample(s) will not affect your medical care. This helps protect you and other members of your family from harm that might be caused by this information.

What If You Change Your Mind About Donating Your Sample(s) for Future Genetic Research and Specimen Banking?
If you decide now that your sample(s) can be kept for future genetic research and specimen banking, and later change your mind, you can simply withdraw the sample(s) at that time. To withdraw you will



need to write to the Principal Investigator listed on the first page of this form. We will then destroy any of your tissue that has not already been used. However, if your sample has been used in genetic research, the information that we have learned will remain in the study, even if you withdraw. Unless you withdraw from the study, permission for researchers to use your tissue and to use and share your private health information for this study will never end.

Will You Be Paid For Donating Your Sample(s) for Future Genetic Research and Specimen Banking?

You will not be paid to donate your sample(s) for future genetic research and specimen banking.

Will Donating Your Sample(s) Cost You Any Money?

There is no cost to you to have your samples collected or used for future genetic research and specimen banking.

Genetic Testing and Specimen Banking Options:

- You must agree to have **HLA testing performed as part of your clinical care** (if it has not been done previously done.) in order to be in the study.
- You must agree to allow the study team to u**se the results of clinically performed HLA typing for research**
- You have the choice to find out the results of the HLA testing (see below).
- You do not have to participate and agree to **future genetic research and specimen banking** in order to be in the main part of this study.

No matter what you decide to do, your decision will not affect your medical care. You can tell us your choice by placing your initials in one of the options below:

HLA TYPING (study team disclosure of results from clinical care testing):
Please indicate your choice by placing your initials below:

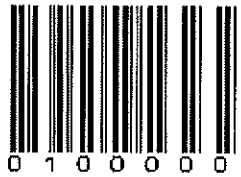
___ **YES** **I want the study team to tell me my HLA results.**
___ **NO** **I do NOT want the study team to tell me my HLA results**

SPECIMEN BANKING AND FUTURE GENETIC RESEARCH:
Please indicate your choice by placing your initials below:

___ **YES** **Your sample(s) may be saved for future research and stored in a specimen bank.**
___ **NO** **Your sample(s) may not be saved for future research and stored in a specimen bank.**

What are the risks of being in this study?

Risks and side effects which may occur with the LPV7 vaccine/Montanide include the following. These risks and side effects are based on results from prior studies conducted by the Human Immune Therapy using similar types of vaccines:

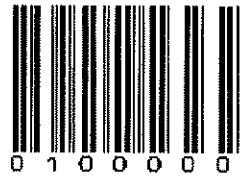


Likely

- Loss of red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath
- Fatigue (feeling tired)
- Fever
- Chills
- Sweating
- Flushing
- Local pain, bleeding, bruising at the injection site
- Redness, itching, and swelling at the injection site
- Rash
- Loss of appetite
- Diarrhea
- Nausea
- Small changes in the levels of sugar in your blood (hyperglycemia), which may make you feel thirsty or tired.
- Dizziness
- Headache
- Pain in your joints
- Pain in your muscles
- Cough

Less Likely

- Autoimmune disease (immune reactivity against your own cells). These usually are limited to loss of some pigmented skin cells, and to changes in blood tests but without symptoms. However, a severe autoimmune reaction could lead to death. Examples of autoimmune diseases in humans are lupus and rheumatoid arthritis.
- Runny nose
- Lowering of your white blood cell counts, which if serious may make you more susceptible to infection
- Loss of skin pigment (may happen anywhere on your body). This is called Vitiligo.
- Itching
- An open sore (ulceration) at the injection site
- Hives
- Constipation
- Inflammation in the mouth
- Vomiting
- Swelling in different parts of your body
- You may feel bloated, tired, weak, or thirsty
- You may feel sweaty, hungry, dizzy, weak, shaky, or have a racing and/or pounding heart beat
- You may feel anxious, agitated, or depressed
- Throat pain



- Stuffy nose/nasal congestion
- Inflammation or increased fluid in the lungs that may make you cough, have a fever, feel tired and short of breath (serious). If you have these symptoms, you may be asked to have a chest x-ray.
- Changes in your voice
- Flu-like symptoms

Rare but Serious

- Infection requiring treatment
- These are rare but serious *theoretical* risks, meaning they have not been seen in any subjects in the UVA HITC peptide vaccine studies.
    - Visual changes (blurred vision, flashing lights, floaters, or night blindness).
        - If you experience any changes in vision during or after this study, please contact a study doctor, nurse, or physician assistant immediately.
        - These symptoms could mean you are developing a condition called retinopathy or papilledema of the eye. If left untreated, these conditions can result in blindness. With proper treatment and management, the risks noted above are usually temporary conditions

Possible Side effects of study drugs/agents that have not yet been reported by study participants:

The adjuvant Montanide ISA-51 has been used in a number of human clinical trials with little or no toxicity observed. The possible side effects of receiving Montanide adjuvant include a major allergic reaction (anaphylaxis) to one of the vaccine ingredients (rare). Such a reaction might include hives, rash, generalized swelling of the body, low blood pressure, difficulty breathing, and abdominal pain, and possibly death. Anaphylaxis, if it occurs is usually treatable. Thus, we are asking you to remain in the clinic for a period of time after receiving the vaccine so that we may treat you if anaphylaxis occurs.

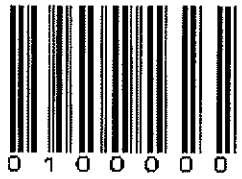
Risks and side effects related to the polyICLC

Likely

- Fatigue
- Fever
- Nausea
- Redness, itching, swelling, pain at the injection site
- Headache
- Body aches (may include muscle pain or joint pain)

Less Likely

- Chills
- Tremors
- An increase in liver proteins which may indicate that your liver cells are inflamed or damaged in some way. This may cause your skin, the white part of your eyes, and the inside of your mouth



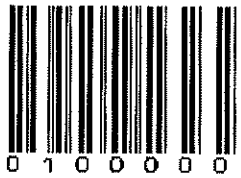
to turn yellow. You may also feel tired, your skin may itch, your legs and feet may swell and you may have some pain in your stomach.
- Rash
- Bruising at the injection site
- An open sore (ulceration) and/or hardening of the skin (induration) at the injection site
- Dry skin
- Hives
- Lowering of your white blood cell counts, which if serious may make you more susceptible to infection
- Lowering of your platelet counts, which if serious may make you more susceptible to bleeding
- Loss of red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath
- Runny nose
- Difficulty sleeping
- Vomiting
- Dizziness

Rare but Serious
- Your muscles may feel weak
- Inflammation or increased fluid in the lungs that may make you cough, have a fever, feel tired and short of breath (serious). If you have these symptoms, you may be asked to have a chest x-ray.
- The levels of oxygen in your body may be reduced. As a result, it may be difficult to breath, you may get a headache or feel nauseous, your skin may turn blue, and you may be tired. In severe cases, reduced oxygen levels may cause you to have seizures, may cause you to go into a coma and may cause death.
- Sodium-serum high. You may have excessive thirst, lethargy, weakness, irritability, and swelling due to increased sodium in your blood. This generally is easily corrected. With more severe elevations of the sodium level, seizures and coma may occur.

With proper treatment and management, the risks noted above are usually temporary conditions.

Risks and side effects related to the biopsies include:
Likely
- Discomfort from insertion of the needle for local anesthetic
- Scar at the biopsy site
- Mild discomfort at the biopsy site
- Numbness at the biopsy site
- Bleeding at the biopsy site
- Small wound which may take a few weeks to heal

Rare but serious
- Infection at the biopsy site



Risks of photograph

Photographs may be taken of your vaccine site, your biopsy sites or of any lesions that you develop on your skin. Most photographs will not include your face, unless including your face in the photograph is unavoidable (for example, you have a tumor on your head). Although it is highly unlikely that anyone could identify you from the photograph, this is still a risk should your lesion is on or near your face. To reduce this risk, only the portion of the face that has the area of interest will be photographed. If the photograph does include your face, your identifying features (eyes, nose, mouth, etc.) will be blacked out. Care will be taken to obtain the photo in such a manner that you cannot be identified. All photographs will be kept on a secure computer database and in your study chart. Further, only authorized individuals will have access to the photograph.

Blood Donation

If you participate in this study it may affect your ability to donate blood. If you have any questions call the organization where you donate blood and talk to one of their nurses.

Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

A caution about giving too much blood:

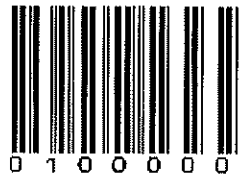
Because of the amount of blood being taken, you should not give blood for other reasons until the study is complete. For example, avoid giving blood at a blood bank or in another research study.

Risks for women:

Pregnancy and Contraception

The drug(s) used in this study can harm an unborn or nursing baby. Therefore, you cannot be in this study if you are pregnant or nursing a baby. A pregnancy blood test will be done about 2 weeks before starting this study if you are a woman able to become pregnant. You MUST NOT become pregnant while on this study or for up to 30 days after the study is over.

You and your partner must use an approved form of birth control during this study. Examples of birth control you may use are:



- Norplant
- IUD (intrauterine device)
- Depo-Provera
- Birth Control Pills
- Birth Control Patch
- Sterilization

The birth control methods listed below are less effective. They may be used if combined with other birth control methods:

- Condoms
- Jellies or foam
- Withdrawal
- Sponge
- Diaphragm
- Rhythm
- Cervical cap

Ask your doctor for more details about the proper birth control method for you. If you become pregnant during this study, you must tell your doctor right away. Your doctor will discuss your treatment and the effect on the pregnancy.

Risks for men:
We also do not know the effects of these drugs on male sperm. If you are a male, you should not father a baby while you are in this study or for 30 days after the study ends. You should also not donate to a sperm bank during this time. To do so may hurt your unborn baby. Use an effective method of birth control during this time. Effective forms of birth control are listed above.

If your partner becomes pregnant during this study, you must tell your doctor right away. The study team will ask to contact her to obtain her consent to obtain information about the baby after it is born.

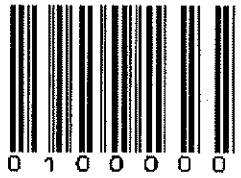
Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?
You may or may not benefit from being in this study. Possible benefits include developing an immune response against the peptides and against your tumor, which may lead to the destruction of tumor cells in your body. We do not know if you will have an immune response following vaccination with the peptides or the Montanide ISA-51, resiquimod, or polyICLC.

Further, the information obtained in this study is expected to aid us in the design of improved cancer vaccines and therefore may benefit future patients or society in general.

What are your other choices if you do not join this study?
You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment for patients who have had complete surgical removal of their melanomas may include:

- interferon alpha therapy
- Ipilimumab (Yervoy™)



- radiation therapy
- other clinical trials

However, you cannot receive these treatments while you are on this trial. This will be discussed by your physician.

The FDA has approved high-dose interferon therapy and Ipilimumab (Yervoy™) for the treatment of some melanomas. The potential benefits and side effects of interferon and Ipilimumab should have been explained to you. If this has not been explained and offered to you, please ask the study doctor.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?
You will not get any money for being in this study.

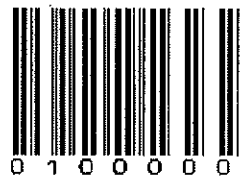
By agreeing to be in this study, you are donating your blood and tissue samples for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?
The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance:

- Vaccines and administration of the vaccines
- Physical Exams (Days 1, 8, 15, 22, 36, 57, 78)
- Research blood draws for Immunologic Analyses
- Blood draws to check your immune system (ANA and Rf)
- Blood draws to check your blood counts, certain levels of fats, salts and sugars, kidney and liver function (Days 22 and 78)
- Vaccine Site Biopsies
- Eye exams
- Examinations of skin for vitiligo
- Examinations of hair and eye color
- Toxicity diaries and review of diaries

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.



What if you are hurt in this study?
You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?
You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) Your study physician is concerned about your health
b) Your disease gets worse
c) The side effects of the treatment are too dangerous for you
d) New information shows the treatment will not work or is not safe for you
e) You do not follow your doctor's instructions
f) The study sponsor closes the study for safety, administrative or other reasons

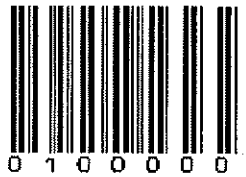
If you decide to stop being in the study, we will ask you to notify Dr. Slingluff as soon as possible.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?
The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:
- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.
- Tissue or blood samples if you agree to provide them for genetic testing for this study

Who will see your private information?
- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results



- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

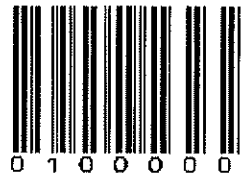
The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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.

What if you sign the form but then decide you don't want your private information shared?
You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVa will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.
- Reports to authorities if you have an infectious disease that health care providers are required to report by law.



In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

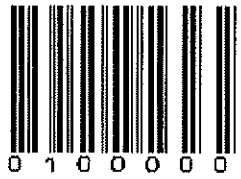
Craig L. Slingluff, M.D.
University of Virginia Health System
Human Immune Therapy Center
Box 801457
Charlottesville, VA 22908 Telephone: 434-924-9311

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.



Signatures

What does your signature mean?
Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form or full consent written in the language they can understand.

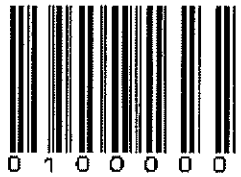
Person Obtaining Consent
By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Interpreter
By signing below you confirm that the study has been fully explained to the potential subject in a language they understand and have answered all their questions.

INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

If an interpreter was used to explain this study to a potential subject, the interpreter must sign and date the line above.



Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

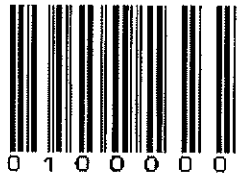
Please indicate with check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study.



Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.
The follow up information will be collected by any of the following:

- Obtaining information from my medical records
- Phone call
- In person follow up visit (please see descriptions in follow up section)

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form or full consent written in the language they can understand.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Interpreter

By signing below you confirm that the study has been fully explained to the potential subject in a language they understand and have answered all their questions.

_____	_____	_____
INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

If an interpreter was used to explain this study to a potential subject, the interpreter must sign and date the line above.