Official Title: A Combined Phase i/II Efficacy Study of a Carbohydrate Mimotope-based Vaccine With MONTANIDE™ ISA 51 VG STERILE Combined With Neoadjuvant Chemotherapy in Triple Negative Breast Cancer

"Vaccination of Triple Negative Breast Cancer Patients"

IRB Number: 206010
NCT Number: NCT02938442

to be conducted at
University of Arkansas for Medical Sciences
Highlands Oncology Group

Sponsor: University of Arkansas for Medical Sciences

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Main Consent Form
Version 10
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CONSENT FORM
AND INFORMATION ABOUT

"Vaccination of Triple Negative Breast Cancer Patients"

A Combined Phase I/II Efficacy Study of a Carbohydrate Mimotope-Based Vaccine with MONTANIDE™ ISA 51 VG STERILE Combined with Neoadjuvant Chemotherapy in Triple Negative Breast Cancer

TO BE CONDUCTED AT
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

(Study Doctor: Sindhu Malapati, MD)

SUBJECT NAME _____ HOSPITAL ID NUMBER _____

INTRODUCTION

This is a clinical trial, a type of research study being conducted at the University of Arkansas for Medical Sciences (UAMS) and Highlands Oncology Group (HOG). This research is being sponsored by UAMS. Your research doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your research doctor for more information. The vaccine that will be used in this study is not approved by the Food and Drug Administration (FDA) for general public use; however, the FDA has allowed it to be used in this research study.

You are being asked to take part in this research study because you have triple negative breast cancer (breast cancer that is not very responsive to hormonal treatment or treatment targeting the HER2/neu protein).

Why is this research being done?

The purpose of this research is to compare the effect on your cancer of using a new experimental breast cancer vaccine (used to stimulate immune cell production) with chemotherapy and surgery versus the usual treatment of chemotherapy and surgery. This study will help us learn if the vaccine is safe and whether your body responds to the vaccine. We will also see if the vaccine helps to improve the effectiveness of the chemotherapy for treating your cancer. There are no commercially available breast cancer vaccines at this time. There are other breast cancer vaccine trials at other institutions but no other breast cancer vaccine trials are now available in Arkansas.

If you are eligible to participate, you will be randomized, like flipping a coin, into one of the two treatment groups in this study. Neither you nor your doctor can choose the group you will be assigned. The two treatment groups are described below:

- Group 1: subjects will receive the standard of care treatment for triple negative breast cancer consisting of chemotherapy and surgery.
- Group 2: subjects will receive the experimental vaccine in addition to the standard of care treatment for triple negative breast cancer consisting of chemotherapy and surgery.

Mimotope P10s-PADRE Vaccine:

The experimental vaccine is a small protein that is similar to proteins on breast cancer cells. Because the vaccine has a different chemical make-up, if the vaccine is successful, it will increase your body's immune response against breast cancer.

MONTANIDE™ ISA 51 VG STERILE:

MONTANIDE™ ISA 51 VG is an investigational agent (not commercially available to the general public) that is mixed with the vaccine to make it stronger. Adding MONTANIDE™ ISA 51 VG to the experimental vaccine may stimulate your immune system even more than if the vaccine was given by itself.

Throughout the remainder of this document, the combined P10s-PADRE/MONTANIDE™ ISA 51 VG mixture is referred to simply as "the vaccine."

How many people will take part in research?

We will screen up to 120 women in order to enroll up to 102 women, ages 18 and older with clinical stage I, II or III triple negative breast cancer from two sites in Arkansas: the University of Arkansas for Medical Sciences (UAMS) and Highlands Oncology Group (HOG). It is possible that up to 102 women are enrolled at either site but the total combined enrollment for both sites combined will not be more than 102. A total of 34 subjects will be enrolled into Group 1 (standard of care only) and a total of 68 subjects will be enrolled into Group 2 (standard of care plus experimental vaccine). This means you have a one in three chance of being assigned to the usual care group, and a two in three chance of being assigned to the usual care plus vaccine group.

What is involved in this research?

Your participation in this research is voluntary. If you refuse to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are otherwise entitled. If you choose to participate in this research, but then change your mind, you can stop participating in the research and you will not be penalized or lose any benefits.

Before you begin the research:

You will need to have the following exams, tests or procedures to find out if you can participate in the research study. Most of these exams, tests or procedures are part of regular cancer care and will be done even if you do not join the research. If you have had some of them recently, they may not need to be repeated. This will be up to your research doctor.

Summary of tests to be done prior to the study:

Standard medical care for cancer treatments:

- Medical history and physical exam
- Blood work for blood counts, liver and kidney function and calcium level
- Urine pregnancy test if you are able to have children

The total amount of blood that will be taken for standard medical care is one and a half teaspoons.

Summary of tests to be done during the clinical trial:

If the exams, tests and procedures show that you can be in the research, and you choose to take part, then you will need the following tests and procedures at different times throughout the study.

These are standard for patients undergoing cancer treatments:

- Blood work for blood counts, liver and kidney function and calcium level
- Medical history and physical exams
- Notations of side effects
- Chemotherapy

You will need the following tests and procedures that are either being tested in this research or are being done to see how the research is affecting your body:

- Blood work for research
- Investigational vaccine (for subjects assigned to Group 2 only)

During this study, you will be asked to provide blood samples for research. For subjects in Group 1, you will have three blood samples for research. For subjects in Group 2, you will have eight blood samples for research. Up to 100mL (approximately seven tablespoons) of blood will be collected each time “Blood work for research” is listed in the breakdown of study visits below. These samples will be used to determine the effect of the vaccine on your immune system. Any leftover samples will be discarded, unless you give us permission to save them for future research.

We would like to collect leftover archival breast tissue samples from tissue collected as part of standard biopsy and/or surgery. Your doctor will not take any more tissue during biopsy and/or surgery than is needed for your care. These samples will be used to look at and examine the tissue and the effect of the vaccine on the tissue.

To examine the effect of the vaccine on your immune system and tissue, we may test your blood and tumor samples for immune and tumor cell gene expression (genetic information about how cells behave) or methylation (epigenetic information about changes in genes that turn them “on” or “off”).

What happens when I am finished taking the vaccine?

The research lasts for approximately 70 weeks (about one year and three months). You will continue your standard treatments and follow-ups for breast cancer after completing the study.

You should avoid becoming pregnant for at least 18 months after participation in the study (see additional information about pregnancy risks in the “Reproductive Risks” section). To avoid becoming pregnant, you should either abstain from sexual activity or practice a method of birth control. Except for surgical removal of the uterus, tubal ligation, and abstinence, birth control

methods such as oral contraceptives (birth control pills), barrier method, and IUDs (implanted device) are not totally effective in preventing pregnancy.

Breakdown of study visits:

Group 1 (standard chemotherapy and surgery only)

The visit breakdowns below will give you a detailed description of everything that will happen while participating in this study.

This breakdown includes standard chemotherapy and surgery, which are part of standard care. The chemotherapy and surgery are not being tested as part of this study. Your research visits will be combined with your regularly scheduled clinic visits. Research blood samples will be collected two times during the study.

Screening visit prior to starting chemotherapy

- Sign informed consent
- Clinic visit for history and physical exam
- Body Mass Index (BMI) and the evaluation of weight change before the study
- Review of medications you are taking
- Routine blood work
- Urine pregnancy test for women who are able to have children
- Skin test

48-72 hours after Screening visit

- Skin test reading

Week 1

- Clinic visit for history and physical exam
- Administer routine chemotherapy - cyclophosphamide and doxorubicin with pegfilgrastim on day two of each AC cycle
- Review of side effects
- Review of medications you are taking
- Routine blood work (not repeated if screening blood work is done within 7 days of Week 1)
- Blood work for research

Weeks 3 & 5

- Clinic visit for history and physical exam
- Administer routine chemotherapy - cyclophosphamide and doxorubicin with pegfilgrastim on day two of each AC cycle
- Review of side effects
- Review of medications you are taking
- Routine blood work

Week 7

- Clinic visit for history and physical exam
- Administer routine chemotherapy - cyclophosphamide and doxorubicin with pegfilgrastim on day two of each AC cycle
- Review of side effects
- Review of medications you are taking

- Routine blood work
- Blood work for research

Weeks 9-20 (weekly)
- Clinic visit for history and physical exam (week 9, 12, 15, 18 and 20 only)
- Administer routine chemotherapy - paclitaxel (may be replaced with docetaxel)
- Review of side effects
- Review of medications you are taking
- Routine blood work

Breast cancer surgery
It is standard practice for surgery to be performed within 4-8 weeks after completion of chemotherapy.

Week 46 & Week 70
- Clinic visit for history and physical exam
- Review of side effects
- Review of medications you are taking
- Routine blood work
- Blood work for research (Week 46 only)

Group 2 (standard chemotherapy and surgery plus experimental vaccine)

You will receive subcutaneous (SC) injections, or a shot given under the skin, of the vaccine at Weeks 1, 2, and 3 for a total of 3 doses. The shots will be given to you at different places on your abdomen. The visit breakdown below will give you a detailed description of everything that will happen while participating in this study.

This breakdown includes standard chemotherapy and surgery, which are part of standard care. The chemotherapy and surgery are not being tested as part of this study, just your response to the vaccine.

Your research visits will be combined with your regularly scheduled clinic visits, with the exception of the visits for weeks 2 and 3. These visits are just for research. Research blood samples will be collected eight times during the study.

Screening visit prior to starting chemotherapy
- Sign informed consent
- Clinic visit for history and physical exam
- Body Mass Index (BMI) and the evaluation of weight change before the study
- Review of medications you are taking
- Routine blood work
- Urine pregnancy test for women who are able to have children
- Skin test

48-72 hours after Screening visit
- Skin test reading

Week 1
- Clinic visit for history and physical exam
- Urine pregnancy test for women who are able to have children
- Administer vaccine
- Review of side effects
- Review of medications you are taking
- Blood work for research

Weeks 2 & 3
- Administer vaccine
- Review of side effects
- Review of medications you are taking

Weeks 4 & 6
- Clinic visit for history and physical exam
- Administer routine chemotherapy - cyclophosphamide and doxorubicin with pegfilgrastim on day two of each AC cycle
- Review of side effects
- Review of medications you are taking
- Routine blood work

Week 7
- Review of side effects
- Review of medications you are taking
- Blood work for research

Week 8
- Clinic visit for history and physical exam
- Administer routine chemotherapy - cyclophosphamide and doxorubicin with pegfilgrastim on day two of each AC cycle
- Review of side effects
- Review of medications you are taking
- Routine blood work

Week 10
- Clinic visit for history and physical exam
- Administer routine chemotherapy - cyclophosphamide and doxorubicin with pegfilgrastim on day two of each AC cycle
- Review of side effects
- Review of medications you are taking
- Routine blood work
- Blood work for research
- Skin test

48-72 hours after Week 7
- Skin test reading

Weeks 12-23

- Clinic visit for history and physical exam (week 12, 15, 18, 21 and 23 only)
- Administer routine chemotherapy - paclitaxel (may be replaced with docetaxel)
- Review of side effects
- Review of medications you are taking
- Routine blood work
- Blood work for research (week 15, 18 and 23 only)

Breast cancer surgery

It is standard practice for surgery to be performed within 4-8 weeks after completion of chemotherapy.

Week 46 & Week 70

- Clinic visit for history and physical exam
- Review of side effects
- Review of medications you are taking
- Routine blood work
- Blood work for research

How long will I be in the research?

The approximate length of complete study participation will be around 18 months.

If you are in Group 2, you will be treated with the vaccine for 3 doses within 3 weeks. If you have significant side effects or problems related to the vaccine, the remaining doses will not be given. If you discontinue the vaccine early, your visits will remain the same as listed above including collection of blood work for research.

Can I stop being in the research?

Yes. You can decide to stop at any time. Contact the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely. It is important to tell the research doctor if you are thinking about stopping so any risks from the vaccine can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow up care and testing could be most helpful for you.

The research doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped. This may happen without your consent.

If there is new information from the research concerning side effects or new information about alternate treatments, which may benefit you, you will be informed by your research doctor.

If you withdraw from the study, any information collected before you withdraw will be retained in the study. If blood samples are collected and you withdraw from the research, we will discard your samples.

What side effects or risks can I expect from being in the research?

You may have side effects while on the research. Everyone taking part in the study will be watched carefully for any side effects. However, doctors do not know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away once you stop taking the vaccine. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your research doctor about any side effects that you have while taking part in the research. In general, the risks and side effects are lower than standard chemotherapy treatments and blood draws are similar in the quantity of blood taken and frequency of the tests.

Risks and side effects related to the vaccine:

Likely

- Localized itching, redness, stinging at the site of the injection of the vaccine
- A decrease in energy
- Temporary swelling, tenderness of the glands (lymph nodes)
- Discomfort from needles used for blood work

Less Likely

- Flu-like symptoms including muscle ache, joint aches, fever, chills, nausea and diarrhea

Rare but serious

- Severe allergic reactions (anaphylaxis) can result in shock and even death
- Over activation of your immune system
- Guillain-Barre Syndrome: a condition resulting in severe weakness to the point of not being able to walk or breathe. In extreme cases, it can require a breathing machine. It can be treated and most people recover.

Risks and side effects related to MONTANIDE™ ISA 51 VG:

- Redness of the skin, rash, itching
- Diarrhea, loss of appetite, nausea, vomiting, abnormal taste
- Confusion
- Tingling or burning sensation
- Shortness of breath, chest pain
- High blood pressure, irregular heartbeat, chest pain
- Headache, joint pain, bone pain, abdominal pain, muscle pain
- Fever
- Flu-like syndrome (chills, achiness)
- Fatigue

Risks and side effects related to blood collection:

- Pain or bruising at the injection site
- Rarely – infection

Reproductive Risks

You should not become pregnant or have a baby while on this study and for 18 months after the last dose of the vaccine because the vaccine in this study may affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. It is not known how the vaccine would affect an unborn baby. If you or your partner should become pregnant while participating in the study or within 18 months of study participation, notify your physician.

Other Risks

- Identification of previously unknown conditions during collection of medical history, physical exam assessment, or blood draw laboratory results.
- Possible breach of privacy and confidentiality. Participants will be identified by study numbers only on all research documents to minimalize the risk of a privacy and/or confidentiality breach. Research records will be stored in a locked area with access to study personnel only.

Genetic Testing Risks

With genetic testing of your tissue, there is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed. The genetic information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location in the Breast Cancer Vaccine Research Laboratory, accessible only by authorized members of the study team, and will not be disclosed to third parties except as described in this consent form, with your permission, or as may be required by law.

Genetic testing involves unique risks such as psychological and social risks and the risk of re-identification. Social risks include being stigmatized, discriminated against, labeled, or having difficulty obtaining employment or insurance. Some of your genetic information may be sent to other scientific or commercial databases, such as one maintained by the National Institutes of Health, for other researchers to use. This information would include a code number instead of your name. There is a risk that someone could trace the information back to you. Even without your name or other identifiers, your genetic information is unique to you. We believe the chance that someone will identify you is very small, because your samples will be coded (without your name or identifying information), but the risk may change in the future as people come up with new ways of tracing information. The genetic testing will be done for research purposes only, and we do not plan to return any results to you or your doctor.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

- GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Are there benefits to taking part in the research?

Taking part in this research may or may not directly benefit your health. While doctors hope a breast cancer vaccine will be more useful against breast cancer as compared to the usual treatment, there is no proof of this yet. We do know that the information from this research will help doctors learn more about breast cancer treatment. This information could help future breast cancer patients.

UAMS cannot and does not guarantee you will benefit if you take part in this study. The research drug you receive may even be harmful. You have the right to refuse to participate in this study.

Will I be compensated (paid) to take part in this research?

You will not receive any form of compensation or payment for your participation in this research study.

What if I am injured while participating in this research?

In the event you are hurt by being in this research, treatment will be available. This treatment may include: first aid, emergency treatment, and/or follow-up care. This treatment may be billed to you or your insurance company in the normal manner. There is no guarantee that your insurance company will agree to cover those charges. Normally, no other form of compensation is available.

If you think you have been hurt by this research or if you have any questions about this medical care, let the study investigator know right away by calling Dr. Sindhu Malapati at (501) 686-8530. After hours, you may reach Dr. Malapati by digital pager at (501) 405-9707 or the medical oncology physician on call at UAMS at (501) 686-8530.

Any suspected side effects must be brought to the attention of your physician immediately.

What other choices do I have if I do not take part in this research?

Your other choices may include:

- Chemotherapy or hormonal therapy as standard treatment or care for your cancer without the vaccine.
- Taking part in another study.
- No treatment

Talk to your doctor about your choices before you decide if you will take part in this research.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. We may share your de-identified study information with other researchers outside of UAMS, and we may publish our findings or present them at scientific meetings. However, if information from this study is published, presented at scientific meetings, or shared for reanalysis with other researchers, your name and other personal information will not be used. Participants will be identified by study numbers only on all research documents. The connection with the participants name will be kept by research personnel in a locked facility. The study sites shall retain the records and reports for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified. After such time all study records will be destroyed as well as the links between identifiers of the research participants and their research study numbers, unless you give us permission to store your study information for future research.

Authorized representatives from many organizations are eligible to review your medical records, including information that identifies you, as part of their responsibilities to protect human participants in research, and to conduct quality assurance, safety and data analysis. These organizations include:

- Winthrop P. Rockefeller Cancer Institute (WPRCI)
- Food and Drug Administration (FDA)
- National Cancer Institute (NCI)
- Office for Human Research Protections (OHRP)
- UAMS Institutional Review Board (IRB)
- UAMS Office of Research Compliance (ORC)
- UAMS Office of Research Regulatory Affairs (ORRA)
- Other institutional oversight offices

Authorized representatives from these agencies may need to review your records and may see your name. They are bound by rules of confidentiality not to reveal your identity to others.

In the future, it is possible that we may share your coded (de-identified) genetic testing results with other researchers in an public-access national database, so that other investigators can use them for research. We would use a code number instead of your name, address, or identifying information. This is done to confirm results from studies like ours and to allow for more rapid discoveries. There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is small, because your samples will be coded (without your name or identifying information), but the risk may change in the future as people come up with new ways of tracing information.

By law, the study team must release certain information to the appropriate authorities if at any time during the study there is concern that abuse has possibly occurred or you disclose a desire to harm yourself or others.

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.

Are there other things I should know about this trial?

Dr. Kieber-Emmons, Dr. Karbassi and UAMS have a financial interest in the investigational vaccine used in this clinical trial. These financial interests have been reviewed by the UAMS Conflicts of Interest Committee. The study will be conducted in accordance with the UAMS conflict of interest policies.

What are the costs of taking part in this research?

The vaccine will be provided free of charge. The research will include tests and procedures that are conducted solely for the research study and not as part of routine care for your condition. You will not be charged for tests and procedures that are done only for research. You and/or your insurance will be billed for your routine care in the usual manner. Your insurance will usually only pay for the routine care and they may deny payment making you responsible for payment.

In addition, your physician will discuss with you any additional tests and procedures that may be required due to changes of your condition during your research participation, which may or may not be routine care. Therefore, there may be additional charges billed to you if these tests are not considered as routine care. You have the right to refuse to have any additional tests or procedures done. If you feel that you have been billed in error, please contact Dr. Sindhu Malapati, who is responsible for conducting this study, at (501) 686-8530.

What are my rights if I take part in this research?

Taking part in this research is your choice. You may choose either to take part or not to take part in the research. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Your relationship with your doctor or with UAMS will not be affected by not participating or leaving the research. Leaving the research will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. We will tell you of any new findings (good or bad) in the research or new alternatives to participation that may cause you to change your mind about continuing in the research. If new information is provided to you, your consent may be re-obtained. You may also request the results of the research from your research doctor after all the analyses are completed.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the research?

If you have questions during the study about the research, you should contact Dr. Sindhu Malapati at (501) 686-8530. For questions about your rights while taking part in this research, or to talk to someone independent of the research team, call the UAMS Institutional Review Board (a group of people who review the research to protect your rights) at (501) 686-5667.

Genetic Studies

As described above, as part of this study, your blood and tumor samples may be tested for genetic and epigenetic information to examine the effect of the vaccine on your immune system and tissue. The samples will be assigned a number instead of your name. The number will be linked to your name but the code will be kept by research personnel in a locked facility. Samples will either be used immediately or frozen and stored until needed for these tests. You can withdraw your cell sample at any time. If at any time you would like to withdraw your stored sample, please write to:

Sindhu Malapati, MD
University of Arkansas for Medical Sciences
4301 West Markham Street, Slot 508
Little Rock, AR 72205

You may agree to participate in this research study, but refuse to allow your samples to be tested for the genetic studies mentioned above. Please initial and date below.

_____ _____ **I AGREE** to have my samples tested for genetic studies.
Initials *Date*

_____ _____ **I DO NOT AGREE** to have my samples tested for genetic studies.
Initials *Date*

Breast Tissue Samples

We would like to save any leftover breast tissue collected as part of standard biopsy and/or surgery to study the effect of this cancer vaccine on the tissue. Your breast tissue samples will be frozen and stored with a number assigned to them instead of your name. The breast tissue samples may be stored indefinitely until needed for this cancer vaccine research. The number will be linked to your name, which means you can withdraw your tissue samples at any time. If at any time you would like to withdraw your stored sample, please write to:

Sindhu Malapati, MD
University of Arkansas for Medical Sciences
4301 West Markham Street, Slot 508
Little Rock, AR 72205

You may agree to participate in this research study, but refuse to allow your tissue samples to be stored for this cancer vaccine research. Please **initial and date** the appropriate line below.

_____ _____ **I AGREE** to have my leftover tissue samples saved for this research.
Initials *Date*

_____ _____ **I DO NOT AGREE** to have my leftover tissue samples saved for this research.
Initials *Date*

Future Use – Blood Samples

We would like to save any leftover blood samples for future research studies on cancer vaccines. Your blood samples will be frozen and stored with a number assigned to them instead of your name. The blood samples may be stored indefinitely until needed for a future research study. The number will be linked to your name, which means you can withdraw your blood sample at any time. If at any time you would like to withdraw your stored sample, please write to:

Sindhu Malapati, MD
University of Arkansas for Medical Sciences
4301 West Markham Street, Slot 508
Little Rock, AR 72205

You may agree to participate in this research study, but refuse to allow your blood samples to be stored for future research. Please **initial and date** the appropriate line below.

_____ _____ **I AGREE** to have my leftover blood samples stored for future research.
Initials *Date*

_____ _____ **I DO NOT AGREE** to have my leftover blood samples stored for future research.
Initials *Date*

Future Contact

You may agree to participate in this research study, but refuse to be contacted for future research. Please **initial and date** the appropriate line below.

_____ _____ **Yes, I agree** to be contacted for future research related to this study.
Initials *Date*

_____ _____ **No, I do not agree** to be contacted for future research related to this study.
Initials *Date*

Signature

I have been told that I will be given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I understand my participation in this study is voluntary. I agree to take part in this study.

I should avoid becoming pregnant for at least **18 months** after participation in the study. To avoid becoming pregnant, I should either abstain from sexual relations or practice a method of birth control. Except for surgical removal of the uterus, birth control methods such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy.

Participant Signature	*Date*	*Time*
Person Obtaining Consent Signature	*Date*	*Time*