Official Title: Assessing the Immunogenicity of pING-hHER3FL in Patients With Resected Malignancies

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DUKE UNIVERSITY HEALTH SYSTEM

PI: Michael Morse
Consent to participate in a research study:
Assessing the Immunogenicity of pING-hHER3FL Vaccine in Patients with Resected Malignancies

CONCISE SUMMARY

The purpose of this study is to study the effects that an investigational cancer vaccine has on you, your immune system, and your cancer. The cancer vaccine is called pING-hHER3FL (referred to as pING-HER3). Once it is taken up by your cells, it will make extra copies of the HER3 protein. The immune cells in your body will then attack cancer cells that express HER3.

If you agree to be in this study, you will receive the study vaccine three times over 8 weeks and provide blood samples for research at regular intervals up to 10 years, in combination with your clinical care visits. You may also have a clinical biopsy taken to collect tumor tissue if your cancer returns.

This is the first time pING-HER3 vaccine will be given to humans. Injections of the vaccine could cause fever, chills, headache, joint pain and reactions at the site. Allergic reactions may occur and serious side effects could include autoimmunity (low white blood cell count that could lead to infections) and liver toxicity. There may be other side effects that the researchers cannot predict.

If you are interested in learning more about this research study, please continue reading the consent form and discuss this with a member of the study team.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

Please tell the study doctor or study staff if you are taking part in another research study.

This study is being conducted by Dr. Michael Morse. Dr. H. Kim Lyerly is providing funding to conduct the study at Duke.

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Who will be my doctor on this study?

If you decide to participate, Dr. Michael Morse will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

Why is this study being done?

The purpose of this study is to study the effects that a cancer vaccine has on you, your immune system, and your cancer. The cancer vaccine is called pING-hHER3FL (referred to as pING-HER3). HER3 is a protein. Proteins, which are made from a gene or gene product, are the building blocks of your body, cells, and organs. A gene contains information that determines in part the traits, such as eye color, height, or disease risk, that may be passed on from parent to child. The vaccine in this study is made from a circular strand of DNA called a plasmid that contains the HER3 gene. The HER3 protein is found on some cancer cells. When this plasmid is given to you as a vaccine, it can enter some cells in your body. Once it is taken up by your cells, the plasmid will cause cells to make extra copies of the HER3 protein. The cells will then chop up the HER3 protein into small pieces that can be displayed on the cell surface. By doing this, the cell is showing pieces of HER3 to the immune cells in your body to tell them to attack cancer cells that express HER3.

The pING-HER3 vaccine is an investigational drug. The word "investigational" means pING-HER3 is still being tested in research studies and has not been approved by the U.S. Food and Drug Administration (FDA).

This study will be the first time that the pING-HER3 vaccine is used in humans. The goal of the study is to determine whether pING-HER3 triggers your immune system to fight the cancer, to see if it is safe, and to see what side effects it may cause.

Up to 18 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. If you do not sign the consent, you may still receive care at Duke, but not as part of this study. Once the consent form is signed, screening tests and procedures will begin to see if you qualify for the study.

You will receive the study vaccine every 4 weeks for a total of 3 vaccinations and will return 4 weeks after the third vaccination and then every 3 months for up to one year for follow-up. At each vaccination visit, you will receive 4 injections of the pING-HER3 vaccine into muscle of your thigh or shoulder area. You will also be followed for up to 10 years after the immunizations for evidence of recurrence of disease. If you have recurrence of your cancer, you will have a tumor tissue biopsy as part of your clinical care, and we will take a sample for research.

Screening

The screening tests and procedures will be performed prior to the first drug regimen visit and may take place over multiple visits from 1-28 days prior to receiving the vaccine. Some of these tests and procedures are part of routine cancer care and may be done even if you do not join the study. After your screening tests are completed, your study doctor will check the results of your screening tests to see if you can be enrolled in the study. If you are qualified and choose to participate, you will need to return to Duke within 28 days to receive the study vaccine.

- You will be asked about your medical history
- You will have a blood pregnancy test (only for women who could possibly become pregnant). The test must be done within 7 days of the first vaccine administration, and must be negative in order for you to participate in the study.
- You will have a physical exam
- Your vital signs will be measured
- You will be asked questions about how you are feeling and how well you are doing
- You will have a blood sample collected for routine health monitoring
- You will have a blood sample collected for immunological research blood tests
- Tumor Tissue will be obtained from your clinical biopsy

Week 0, 4 and 8 Visit

- You will have the pING-HER3 vaccine administered
- Your vital signs will be measured before injection, and at 15 minutes after injection
- You will be asked questions about how you are feeling and how well you are doing

- You will be asked about what medications you are taking
- You will be asked if you are having any side effects
- You may have a blood sample collected for routine health monitoring if the doctor thinks it is necessary
- You will have a blood sample collected for immunological research blood tests at week 0 and 8 (if the doctor thinks it is necessary, it may also be collected at week 4)

12 Week Follow-up Visit

- You will have a physical exam
- Your vital signs will be measured
- You will be asked questions about how you are feeling and how well you are doing
- You will be asked about what medications you are taking
- You will be asked if you are having any side effects
- You will have a blood sample collected for routine health monitoring
- You will have a blood sample collected for immunological research blood tests

6, 9 and 12 month Follow-up Visit

- You will be asked questions about how you are feeling and how well you are doing
- You may have a blood sample collected for immunological research blood tests

Yearly Follow-up Visit

- You will be asked questions about how you are feeling and how well you are doing
- You may have a blood sample collected for immunological research blood tests

If you have a Recurrence

- We will ask you to return to Duke.
- You will have a physical exam
- You will be asked questions about how you are feeling and how well you are doing
- You will have a blood sample collected for immunological research blood tests
- Tumor Tissue will be obtained from your clinical biopsy

End of Study Visit

- You will have a physical exam
- You will be asked questions about how you are feeling and how well you are doing
- You will have a blood sample collected for immunological research blood tests

Research Tests for this Study

You will also undergo tests and procedures that are only being done because you are in this study. These tests are for research only and the results will not be part of your medical record. All of the research tests are being done to help find out which people are most likely to benefit and/or have side effects from this study drug. These additional tests are described below.

1. **Blood Tests for Immunological Research**
   Immunogenicity tests show whether a drug can cause an immune response in the body. One way we can tell if the body is producing an immune response is by testing blood samples. This information will not change how you are treated, but it is hoped that this will provide information that may benefit future people with cancer. Between 3-6 tablespoons of blood (40- 90 mL) will be taken.

2. **Tumor Tissue Samples**
   If you have a tissue sample taken as part of your clinical care, cells from your tissue sample may be requested from pathology. These samples may be useful in looking for changes in your tissue in response to the antibodies activated by the pING-HER3 vaccine. Your doctor will discuss with you the specific risks of the procedures based on how the biopsy will be done and the location of the tissue sample as part of your clinical care. No biopsies will be done for research purposes.

3. **Genetic Testing**

a. Participation in genetic studies: The genetic studies described are for research purposes only. Therefore, you will receive no results from this study (except as described below). It is not the purpose of this study to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. The research tests are not being used as diagnostic tests for any disease or illness.

Your participation in this study is not a substitute for your regular medical care or check-ups.

b. Research Results: Through this research, we may find that you have an abnormal gene or gene product (RNA or protein) which indicates a risk for developing a disease at some time in the future. It is also possible that the research results may indirectly provide unexpected personal information about you or your family (such as ethnic/racial background or an unknown genetic relationship between family members). Please talk with the study doctor if you have any questions or concerns about the genetic testing being done in this research study. He may also refer you to a genetic counselor for further information.

c. Incidental Findings: It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician unless the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable. In that case, we will attempt to notify you using the contact information you have provided, so that you can speak with Dr. Michael Morse at Duke University Health System (DUHS). DUHS staff will not provide this information in a voice mail, email, or otherwise prior to contacting you. Please notify us of any change in your contact information by contacting the study team at 919-681-3480 to update it. Please initial your choice below.

Subject Initials _____	Please **do not** notify me of any incidental findings obtained from this research.
Subject Initials _____	Please **do** notify me of any incidental findings obtained from this research.

If you prefer, we can ask you at the time of notification whether or not you want to receive incidental findings information. In this case, please initial below.

Subject Initials _____	Please ask me at the time of notification whether or not I want to receive incidental findings information.

If at any time during or after the study you change your mind about whether or not you would like to be notified, you can contact the study doctor at 919-681-3480.

After providing the information to you, Dr. Michael Morse may arrange for you to meet with him/her and/or a genetic counselor or refer you to another appropriate health care provider to review the incidental findings with you or your physician.

d. Use and ownership of samples: By agreeing to participate in this research, you authorize DUHS and members of its staff to use your tissue, blood or other samples for the purposes described in this consent form. DUHS will maintain these samples indefinitely or until they are exhausted. These samples will not be available to you for diagnostic or therapeutic purposes. Therefore, for any future diagnostic testing or treatments, a new sample will be obtained from you. Tissue, cells, or blood collected as part of this study may be valuable for scientific, research, or teaching purposes or for the development of a new medical or commercial product. DUHS and/or the developers will assert all rights of ownership in the samples and all rights arising from use of the samples. There is no plan to compensate you for any use of the samples.

e. Availability/withdrawal of samples: You will not have access to the sample once it is obtained. Samples may be stored indefinitely. If you decide to withdraw your permission to use your samples in this research project, please contact the study doctor, Michael Morse, in writing and let him know you are withdrawing your permission for your samples to be stored and used for this study or future research. His mailing address is DUMC 3233, Durham, NC 27710. Data collected using your sample before your withdrawal will continue to be used as part of the study.

If you withdraw your consent to use the sample(s) before your blood is sent to the laboratory for processing and analysis, your study doctor and the laboratory responsible for processing the sample(s) will make every effort to ensure your sample(s) are destroyed. If your sample(s) has already been sent to be processed and analyzed, the study doctor and the responsible laboratory will make every effort to destroy your sample(s) after it has been processed and analyzed, and to ensure that no further testing is performed on your sample(s).

However, it is important that you understand that if your sample(s) has already been processed and analyzed, the results including information obtained regarding gene patterns and genetic variations cannot be destroyed and will continue to be available to the researchers even if you decide to withdraw your sample(s) from this optional genetic study.

Will I be given research results that may affect my medical care?
Clinically relevant results of this research will be communicated with you by phone or at study visits if it affects your health care or when the results are published.

How long will I be in this study?
Your direct participation in this study will last about one and a half years. We may contact you by phone, email or in person (if you come for a clinic visit) up to ten years after your last dose of the study vaccine, in order to obtain information about the long-term safety.

You can choose to stop participating at any time without penalty. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

What are the risks of the study?
This is the first time the pING-HER3 vaccine will be given to humans. While participating in this study, you are at risk for side effects from the investigational vaccine. You should discuss these with your doctor. In addition to the side effects listed below, there may be other side effects that the researchers cannot predict. Other drugs may be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the medications are discontinued but, in some cases, it is possible that side effects may be serious, long-lasting and permanent or may result in death.

The pING-HER3 vaccine is designed so that it does not make any long-lasting changes to your cells or your DNA, and should only be in your cells for a short time. Although a plasmid containing a gene may in rare cases cause a disease or a new cancer, this possibility is very small.

The known side effects and possible risks of this research study are discussed below:

Study Vaccine

Minor side effects of pING-HER3 could include:

- Fever
- Chills
- Headache
- Injection site reactions

Major side effects of pING-HER3 could include:

- Allergic reactions with swelling in such places as your throat or lungs which could lead to shortness of breath, breathing failure or death.
- Your immune system may be stimulated to attack your own body (called autoimmunity) leading to a low white blood cell count that result in an infection, skin rash, joint swelling, intestinal inflammation (chronic colitis), or fluid around the heart and lungs.
- Liver toxicity

Side effects from the Injection could include:

- Pain
- Bruising
- Redness

There may also be risks, discomforts, drug interactions or side effects that are not yet known. Some side effects may occur that do not require medical attention and may go away while you are receiving the study drug as your body adjusts. Others may be severe and need immediate attention or lead to hospitalization. Seek emergency care and contact your doctor immediately if severe side effects occur.

Risks for women of childbearing potential

The effects of the pING-HER3 vaccine on a developing pregnancy or breastfeeding infant are unknown. To reduce the risk of any harmful effects, women who are pregnant, planning a pregnancy, or breastfeeding are not allowed to participate in studies using the pING-HER3 vaccine.
If you are a woman who could possibly become pregnant (you have not completed menopause, had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, a blood pregnancy test will be performed, and it must be negative in order to continue in the study.

You and your partner must agree to either abstain completely from vaginal intercourse for the duration of the study and for 90 days after your last dose of study drug, or use a highly effective method of contraception for the same length of time. These methods include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), (d) hormonal implants (such as Implanon), or (e) other hormonal methods (birth control pills, injections, patches, vaginal rings). If you and your partner are not currently using one of these methods your study doctor will discuss options with you, given your medical condition, your personal preferences, and the level of effectiveness required for this study. Because no birth control method is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant.

If you do become pregnant during the study, your study doctor will stop the vaccine and withdraw you from the study. You will be followed for the duration of the pregnancy to better understand the potential effects of the vaccine on pregnancy outcomes. You will be asked to sign a separate medical release form to allow the study team to follow the pregnancy.

Contraceptive measures for men

It is unknown whether pregnancies from a father taking the pING-HER3 vaccine are at increased risk for birth defects, miscarriages, or other bad outcomes. To reduce the risk of any harmful effects, men who are trying to become fathers are not allowed to participate in studies of this vaccine. You should notify your partner about your participation in this study, and the potential risks to pregnancies that begin while you are receiving the vaccine. If she does become pregnant during the study, you should notify your study doctor, and she should notify her doctor. She will be asked for permission to

collect information about the pregnancy to better understand the potential effects of the study drug on pregnancy outcomes. She will be asked to sign a separate medical release form to allow the study team to follow the pregnancy.

If you are able to father children and your partner is a woman who could possibly become pregnant (she has not completed menopause, or has not had a hysterectomy and/or both tubes and/or both ovaries removed), you must agree to either abstain completely from vaginal intercourse for the duration of the study and for one month after your last dose of study drug, or use a condom every time you have vaginal intercourse, even if you have had a vasectomy (because vasectomy does not prevent transmission of drug in semen). If your partner is currently pregnant, breastfeeding, or becomes pregnant during the study, you must use a condom for all types of intercourse to prevent transmission.

For all study participants
You should not donate blood while you are in this study and for possibly longer. If you are male, you should also not donate any sperm while you are in this study. Please discuss with your study doctor how long you should wait before donating any blood or, if applicable, sperm.

Risks of drawing blood:
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Drug and food interactions:
For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies and alcohol that you are taking before you start the study and before taking any of these products while you are on the study.

The study vaccine may interact with certain other drugs. This could make those drugs less effective or increase the risk of side effects from those drugs. The study doctor will check the medications that you are taking to ensure that you are not on any medications that have a potential interaction with the study vaccine. To participate in this study, you may need to stop or change some of your current medications because they may affect how well the study drugs

work. You will be notified if any of your current medications need to be stopped or changed to allow you to participate in this study. If there are any changes, your doctor will let you know of any risks that may be associated with changes in your current medications. If you are on study, there may also be limitations to the other medications and supplements or foods that you can take while you are receiving the study vaccine. Changing or limiting the medications you take for other conditions may be associated with additional inconvenience, costs, and/or side effects.

Potential risks and the Genetic Information Non-Discrimination Act (GINA)

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 at DUHS, 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.

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.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

Are there benefits to taking part in the study?
If you agree to take part in this study, there may be direct medical benefit to you. If the study drug works for you, you may live longer or have better control of your cancer, but this cannot be guaranteed. We hope that in the future the information learned from this study will benefit other people with your condition.

What other choices are there to being in this study?
Instead of being in this study, you have the following alternatives:

- Getting treatment or care for your cancer without being in a study.
- Taking part in another study of an investigational drug
- Getting no treatment
- Getting comfort care, also known as palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by cancer. It does not treat the cancer directly but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

The risks and benefits of alternative treatments will depend on your type of cancer, disease status and alternative treatment chosen. If you have any questions concerning alternative treatments, please ask your study doctor. You and your doctor can decide what is best for you.

Will my information be kept confidential?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration (FDA), representatives of the National Cancer Institute, Duke Cancer Institute, Duke Office of Audit, Risk and Compliance, and the Duke University Health System Institutional Review Board. If any of these groups review your research record, they may also need to review your entire medical record.

Because this study involves a DNA plasmid containing a gene fragment, safety information must be reported to the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health. This information is available to the public. However, no information by which you can be identified will be reported with the safety information.

As part of this study, you will be asked to have certain tests and/or procedures. Some of tests and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record. The results of the immune monitoring tests will be performed only for research and the results of the immune monitoring will not be placed in your medical chart, only that blood was drawn.

The study results will be retained in your research record for 15 years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Will it cost me anything to be in the study?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine

medical care services are those that you would have received for your condition if you were not participating in this research study.

Taking part in this study may cost you and/or your insurance company more than the cost of getting regular medical treatment due to certain research blood tests which are not part of your clinical care. Duke will bill them to your insurance, however, if you have no insurance, or have a high deductible insurance plan, or if the company refuses to pay for them, then you may be responsible for these charges.

The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan.

The study sponsor, Duke, has agreed to pay for the cost of the vaccine and vaccine administration. Please talk with the PI/study team about the specific services and procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

Your study doctor may request that you return for a checkup before you stop the vaccine if he/she thinks that stopping it suddenly may harm you and may ask you to complete the tests that would ordinarily occur when a person completes the study.

Will I be paid to be in the study?
You will not be paid for your participation in this study.

What about research related injuries?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke

University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or a research related injury, contact Michael Morse, M.D. at 919-681-3480 during regular business hours and at 919-970-5626 after hours and on weekends and holidays.

What if I want to withdraw from the study?
If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Morse in writing and let him know that you are withdrawing from the study. His mailing address is DUMC 3233, Durham, NC 27710. You will be asked to complete an end of study visit including physical, routine blood collection, and research blood collection for immunological response evaluation.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include if study results indicate that the vaccine is not effective, or if funding ends. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your samples and/or data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

Future Research
There may be blood samples left over from this study. If you are willing to allow these samples to be used for research purposes that are not specifically related to this study, please initial below.

Subject Initials _____	"I **do** consent to allow my blood and/or tumor samples to be used for future research.
Subject Initials _____ _____	"I **do not** consent to allow my blood and/or tumor samples to be used for future research.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS or PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Michael Morse at (919) 681-3480 during regular business hours and at (919) 970-5626 after hours and on weekends and holidays.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have questions about your rights as a research participant,
- You wish to discuss problems,
- You have any concerns or suggestions related to the research,
- You want to obtain information or offer input about the research

DUKE UNIVERSITY HEALTH SYSTEM

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Witness (if applicable)

_____ _____ _____
Signature of Witness (if applicable) Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time