NCT02816736

HFN-LIFE Informed Consent Document v2019-02-20

Consent to Participate in a Research Study

Title of Study: Entresto™ (**L**CZ696) **I**n Advanced Heart **F**ailur**e (LIFE Study)**

Investigator *[**add name of site PI, contact information for PI and study team**:]*

You are being asked to participate in this research study because you have an advanced stage of heart failure (a condition in which the heart has difficulty pumping blood to the rest of the body).

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully. A member of our research team will talk with you about this consent form. Please ask him/her to explain any words or information that you do not clearly understand. We also encourage you to talk with your family and friends before you decide to take part in this research study. If you decide to take part in this research study, you must sign this consent form to show that you want to take part. The nature of the study, potential risks, inconveniences, discomforts and potential benefits as well other important information about the study are listed below. Please tell the study doctor or research team if you are taking part in another research study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to test whether LCZ696 (sacubitril/valsartan, commercially available as Entresto™), a newly approved drug for heart failure that combines sacubitril and valsartan, improves symptoms and outcomes in persons with advanced heart failure in comparison to treatment with valsartan alone over 24 weeks. Sacubitril/valsartan has been studied in only a very small number of patients with advanced heart failure, like you. This study is being done to obtain more information on the benefits and risks of sacubitril/valsartan in patients with advanced heart failure. Sacubitril/valsartan and valsartan are already approved by the U.S. Food and Drug Administration (FDA) for patients with heart failure. You do not have to take part in this study in order to receive sacubitril/valsartan.

WHO WILL PROVIDE FUNDING?
This study is being funded by a grant from the National Heart, Lung, and Blood Institute (NHLBI) to Duke University. Portions of Dr. [insert PI name]'s salary and the research staffs salaries are being paid by this grant to conduct this study.

WHO WILL BE MY STUDY DOCTOR?
If you decide to take part in the study, [add the name of the PI] will be your study doctor. The study doctor will be in contact with your regular doctor while you are in the study to discuss the study and procedures and afterwards if needed.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
A total of approximately 400 people at 40 institutions in the United States will take part in this study, including approximately *[insert number]* people from this institution.

WHAT IS INVOLVED IN THE STUDY?
PROCEDURES
If you agree to be in this study, you will be asked to sign and date this consent form. You will then

undergo the following procedures:

Screening/Enrollment Visit Assessments:

- A complete physical exam, including vital signs (temperature, blood pressure, heart rate and breathing rate), height and weight
- A medical history, including information about your heart failure
- A review of the medication(s) you are taking
- Review of echocardiogram, angiogram, or other tests performed during the past 3 months to find out how well your heart is pumping blood
- A blood sample for chemistry evaluation. Approximately 1 teaspoon or 5mLs of blood
- KCCQ- a questionnaire about how heart failure affects the quality of your life
- A blood pregnancy test (approximately 1 teaspoon of blood) will be done only for women who could become pregnant

After completion of the enrollment visit, you will return to the study site to start the test dose phase to see if you are able to tolerate sacubitril/valsartan.

Study Visit 1 Assessments:

- A complete physical exam, including vital signs (temperature, blood pressure, heart rate and breathing rate) and weight
- An interim medical history
- A review of the medication(s) you are taking
- A blood sample for chemistry evaluation. Approximately 1 teaspoon or 5mLs of blood
- Assessment of adverse events

Test Dose Administration:

Before starting the study, a test of sacubitril/valsartan will be administered to see if you will tolerate the study drug. You will take sacubitril/valsartan 1 tablet twice per day for up to 7 days or until your next study clinic visit. If you are taking an ACE inhibitor (such as enalapril, lisinopril, benazepril, ramipril, moexipril, perindopril, quinapril or trandolapril), your first dose of sacubitril/valsartan would not start until 36 hours after your last dose of ACE inhibitor. If you are taking an ARB (such as candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan or valsartan), you will need to stop taking your medication prior to the first test dose.

After completion of this visit and the test dose phase, you will return to the study site for the study doctor to determine if you were able to tolerate sacubitril/valsartan. There will need to be a 36 hour washout period before resuming an ACE Inhibitor after stopping sacubitril/valsartan.

Study Visit 2 (Randomization) Assessments:

- A complete physical exam, including vital signs (temperature, blood pressure, heart rate and breathing rate) and weight

- An interim medical history
- A review of the medication(s) you are taking
- A blood sample for chemistry evaluation. Approximately 1 teaspoon or 5mLs of blood
- A blood sample for biomarkers (test that gives information about the status of your heart failure). Approximately 2 teaspoon or 10mLs of blood
- Assessment of adverse events
- Study drug administration

Randomization:

You will be randomly assigned (a process like a flip of a coin) to decide your study group. You will have an equal chance (50%) of being enrolled in the sacubitril/valsartan group or the valsartan group. The study is blinded which means neither you nor the study doctor will know which drug you will be assigned, but in case of an emergency, this information is available to your study doctor.

You will take both active study drug and placebo pills. A placebo is an inactive substance given in the same form as the study drug.. It is sometimes called a "sugar pill".

sacubitril/valsartan group: About 200 subjects will receive sacubitril/valsartan and placebo pills
Valsartan group: About 200 subjects will receive valsartan and placebo pills

Taking Study Drug:

You will take the study drug by mouth twice daily for 24 weeks. If you are taking an ACE Inhibitor, it will need to be stopped. Your first dose of study drug will be ≥36 hours after your last ACE Inhibitor dose. You will start out at a twice daily dose of 1 placebo tablet and 1 active tablet (low dose tablet or high dose tablet, depending on your previous ACE inhibitor or ARB medication dosage or lab tests results) and, if tolerated, the study drug dose will be increased (doubled) at your next study visits (approximately 2 weeks and 4 weeks later) until you reach the maximum dose (2 high-dose tablets plus 2 placebo tablets twice a day). Once increased, if you are not able to tolerate the increased dose, you should contact your study doctor, and the study drug dose will be decreased to your previous tolerated dose. Talk to your study doctor about all of your medications.

You may not take other ARBs (such as candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan), ACE inhibitors (such as enalapril, lisinopril, benazepril, ramipril, moexipril, perindopril, quinapril or trandolapril), or direct renin inhibitors (aliskiren brand name Tekturna) while you are being treated with the study drug.

Follow up Clinic Visits: At approximately 2, 4, 8, 12 and 24 weeks after randomization, the following assessments will occur:

- A complete physical exam, including vital signs (temperature, blood pressure, heart rate and breathing rate) and weight (except at week 8)
- An interim medical history
- A review of the medication(s) you are taking

- A blood sample for chemistry evaluation. Approximately 1 teaspoon or 5mLs of blood
- A blood sample for biomarkers (test that gives information about the status of your heart failure). Approximately 2 teaspoon or 10mLs of blood
- Assessment of adverse events
- Assessment for tolerance of study drug and adherence to the dosing schedule

At approximately 4, 12 and 24 weeks after randomization, in addition to the above, KCCQ, a brief questionnaire about how heart failure affects the quality of your life, will be completed.

Follow up Telephone Call Evaluations:

At various times throughout the trial and approximately 2 weeks after your last clinic visit, study staff will call you to speak with you about how you are feeling, what medications you are taking, if you have had any problems since your last visit, and if you are tolerating the study drug.

HOW LONG WILL I BE IN THE STUDY?

You will be in this study for approximately 27 weeks, including the test-dose phase. If you stop taking the study drug for any reason during the study, you will still complete all of the scheduled study visits. You can choose to stop participating in the study at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk with your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

This study will involve the use of sacubitril/valsartan and valsartan; both of which are currently approved by the U.S. Food and Drug Administration (FDA) and have been used for the treatment of patients with heart failure. As a result of your participation in this study, you may be at risk for the side effects listed below. You should discuss these with the study doctor, and you may choose to talk with your regular health care provider too.

sacubitril/valsartan may cause some, all, or none of the side-effects listed below.

Common (5% or more)

- hypotension (low blood pressure)
- hyperkalemia (high levels of potassium in the blood)
- cough
- dizziness (light-headedness)
- kidney failure
- decreases in hemoglobin and hematocrit

Less Common (1-5%)

- Black patients: Serious allergic reactions causing swelling of your face, lips, tongue, and throat (angioedema) that may cause trouble breathing and death
- decreases in hemoglobin/hematocrit (anemia)

Rare (less than 1%)

- Non-Black patients: Serious allergic reactions causing swelling of your face, lips, tongue, and throat (angioedema) that may cause trouble breathing and death

The following additional adverse reactions have been reported in postmarketing experience (people taking sacubitril/valsartan in a clinical trial conducted after drug approval or as a prescription not part of a clinical trial):

- Allergic reactions in which symptoms may vary from mild to severe: rash, itching, shortness of breath; wheezing; trouble breathing; sudden drop in blood pressure; swelling around the mouth, throat, or eye; fast pulse; and sweating. You should get immediate medical help and contact the study doctor if you have any of these or any other side effects during the study.

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or to know whether the events were caused by the drug.

Valsartan may cause some, all, or none of the side-effects listed below.

Common (5% or more)

- dizziness (light-headedness)
- hypotension (low blood pressure)
- diarrhea

Less Common (1-5%)

- arthralgia (joint pain)
- back pain
- fatigue (tired)
- hyperkalemia (high levels of potassium in the blood)
- headache
- nausea
- abdominal pain
- fainting
- blurred vision
- vertigo
- dizziness (light-headedness) when standing
- kidney insufficiency/kidney failure
- upper abdominal pain

Rare (less than 1%)

- decreases in hemoglobin/hematocrit (anemia)
- rash/dermatitis (inflammation of the skin)

The following additional adverse reactions have been reported in postmarketing experience (people taking valsartan in a clinical trial conducted after drug approval or as a prescription not part of a clinical trial):

- rare reports of angioedema (swelling that affects deeper layers of the skin)
- abnormal elevated liver enzymes and very rare reports of hepatitis
- very rare reports of thrombocytopenia (low platelet count in the blood that can lead to bruising or bleeding)

- alopecia (hair loss)
- vasculitis (inflammation of the blood vessels)

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or to know whether the events were caused by the drug.

In addition, you may experience unforeseeable risks and inconveniences associated with the use of the study drug.

Other Study Procedure Risks:

Risks Associated with Drawing Blood: The risks of blood drawing include bleeding at the puncture site, bruising and pain. These risks occur in a very small portion of the population.

Should any of these occur, your doctor may treat you. You should report any problems you have to the study team. If this happens, the sponsor of the study may need to review your entire medical record.

Reproductive Risks: Being a part of this study while pregnant may expose a fetus to significant risks. There are no adequate well controlled studies in pregnant women. Some of the risks may not be known at this time. Therefore, pregnant women cannot participate in this study. If you are a woman who is able to get pregnant, a blood pregnancy test will be done using 1 teaspoon of blood drawn from a vein by needle-stick. The blood pregnancy test must be negative for you to continue in this study. If you are sexually active, you must agree to use appropriate contraception for as long as you are taking the study drug. Medically acceptable contraceptives include:

- surgical sterilization (such as a tubal ligation or hysterectomy)
- approved hormonal contraceptives (such as birth control pills, patches, implants or injections)
- barrier methods (such as a condom or diaphragm) used with a spermicide, or
- Intrauterine device (IUD)

Contraceptive measures such as Plan B™, sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately. Pregnancies occurring in female study participants will be followed for safety until final outcome. Pregnancies occurring in partners of male participants will not be followed.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Both medications are proven effective in reducing the symptoms of heart failure. If you receive sacubitril/valsartan and it is effective, it may control your symptoms of heart failure better than valsartan. There is no guarantee that you will receive any direct medical benefit from participation in this study. We hope that in the future the information learned from this study will benefit other people with your condition.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Participation in this study is voluntary. You do not have to participate in this study. Both of the drugs in this study are commercially available. You can get treatment or care for your illness even if you are not in a research study. Your doctor will treat your condition according to usual medical care. Please talk to your doctor about these options before you decide to take part in this study.

WHAT PERSONAL HEALTH INFORMATION ARE YOU ASKING PERMISSION TO GET FROM MY MEDICAL RECORD?
If you sign this consent form, you are giving your permission for the following people or groups to give the researchers certain information about you:

- Any health care providers, professionals or agencies who have provided your health services or treatment, such as physicians, clinics, hospitals, home health agencies, diagnostic centers, laboratories, treatment or surgical centers, or government health agencies
- Any agencies that provide payment for health care, such as insurers, or government agencies

If you sign this form, this is the health information about you that the people or groups listed above may give to the researchers to use in this research study**:**

- Review of medical records to include:
    - Medical History and current medications
    - Blood pressure
    - Pulse rate
    - Height and weight
    - Number of hospitalizations, clinic visits, emergency department visits
    - Laboratory results
    - Types, dates, and results of various tests and procedures
    - Name
    - Initials
    - Date of birth

If needed to oversee the research study, this information may be shared with, used by, or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, institutional review boards, Novartis Pharmaceutical Corporation and its authorized agents, and government agencies (like the FDA or the National Institutes of Health). Anybody who receives your information from us could share it with others without your permission, and such sharing would not be protected by the federal privacy regulations. We can use or share your information if we do so in a way that nobody can tell it is your information.

By signing this consent, you are agreeing to allow the use of your medical records, disclosure of your test results and shipment of blood to the HFN Core laboratory at the University of Vermont to be analyzed for the study. All information collected by the sponsor or its agents will be coded and will not identify you.

If you choose to not sign it, you are still able to receive your medical treatment not related to the study. If you do sign it, you can change your mind later by writing a letter that states you are

taking back your permission. Mail the letter to ***[add Address]*** or you can send us an email at ***[List email address].*** Stopping your authorization will prevent sharing of information in the future, but will not affect any information that has already been shared.

Research information collected about you might be put in your medical record. It's possible that you may not be able to see the research study information that has become part of your medical record until the entire research study is over.

The permission you give us to access your medical record will last until the end of the study. You will be given a copy of this authorization.

When the results of this study are made public, it will be combined patient data, and none of the information will identify you.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Except when required by law, you will not be identified by name, Social Security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of your hospital. For records disclosed or samples shipped outside of your hospital, an assigned a unique code number will be included. Labels on study data or samples being sent outside of your hospital will contain your unique study code. The key to the code will be kept at the hospital where you took part in the study. As part of the study, results of your study-related tests will be reported to the data coordinating center, Duke Clinical Research Institute (DCRI).

A Certificate of Confidentiality has been obtained from the National Institutes of Health to cover this study. With this Certificate, the investigators cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself, or your involvement in this study.

If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Disclosure will be necessary, however, upon request of Department of Health and Human Services (DHHS) for the purpose of audit or evaluation, and is limited only to DHHS employees involved in the review.

You should understand that we will in all cases, take the necessary action, including reporting to authorities, to prevent serious harm to yourself, children, or others. For example, in the case of child abuse or neglect.

A copy of this consent form will go into your medical record. This will allow the doctors caring for

you to know what study medications or tests you may be receiving as a part of the study, and to know how to take care of you if you have other health problems or needs during the study.

Dr. [***add PI name***] and his staff may send copies of parts of your record to DCRI to monitor the study. Monitoring means that DCRI staff will review study records to ensure that your information was entered correctly. A copy of this signed consent document, along with copies of your laboratory reports and records of important medical events that occur while you are in the study will be sent to DCRI via a secured electronic system. The study staff will ensure that your name is removed from all medical record documents (except the signed consent form) before they are sent and that you are identified only by your unique study code number on all the documents that are sent. These documents will remain secured through DCRI's password protected electronic file system.

This consent form will be retained for at least six years from the date it was signed. Study records will be retained for at least six years after the study has ended. Any research information that is part of your medical record will be in your record indefinitely.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

WHAT ARE THE COSTS TO ME IF I PARTICIPATE IN THIS STUDY?
All tests and procedures that are required for this study but are not considered to be part of your routine medical care will be paid for by the study. You and/or your insurance provider will be responsible for all costs related to your routine medical care, which is care you would have received whether or not you were part of this study. You may wish to contact your insurance representative to discuss costs further before making your decision about participating in the study.

The study drug will be provided to you free of charge for your use in this study.

WHAT ABOUT COMPENSATION?
You will not be paid for participation in this study.

WHAT IF I AM INJURED?
Immediate necessary medical care is available at ***[add your 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 NHLBI, Duke University, Novartis Pharmaceuticals, DCRI or your study doctor to provide monetary compensation or free medical care to you in the event of a study-related injury. You do not give up any of your legal rights when you sign this consent document.

For questions about the study or research-related injury, contact Dr. ***[add PI name]*** at **[*add phone number here with area code*]** during regular business hours or at **[*add PI's 24-hour number with area code*]** after hours and on weekends and holidays.

WHAT IF I WANT TO STOP BEFORE MY PART IN THE STUDY IS COMPLETE?
You can withdraw from this study at any time without penalty or loss of benefits to which you are

entitled, and withdrawal will not affect your medical treatment. If you withdraw, no new information will be collected, but we will use data that has already been collected.

If you do decide to withdraw, we ask that you contact Dr. [***add PI name]***, and let the doctor know that you are withdrawing from the study. When withdrawing from the study, you must return all unused study drug to Dr. [***add PI name]*** or the doctor's staff.

The investigators have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If your regular doctor feels that your medical condition requires a different treatment than what you are receiving as part of the study, your study drug might be stopped and your doctor will determine the type of care that is best for you. Should this happen, the study team will continue to follow your progress as before.

NEW FINDINGS
If important new findings come up that might change your decision to be in this study, you will be given information about those findings as soon as possible. If you choose to stay in the study, you may be asked to sign a new version of the consent form.

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 or suggestions about the research, contact Dr. *[PI]* at *[PI's Number with Area Code]* during regular business hours and at *[PI's 24-hour Number with Area Code]* after hours or on a weekend or holiday.

For questions about your rights as a research participant, contact *[the IRB name and contact number]*

Optional Biorepository Study

As an optional part of this study, we are asking for your permission to store your samples and research data for possible use in other research studies on heart failure and related diseases. You do not need to participate in this optional study to participate in the main research study. Participation is voluntary. Each research study that may use your sample or data would be submitted to the Heart Failure Network and reviewed by appropriate committees for scientific and ethical value. Each sub-study would also need approval by the National Institutes of Health. No other research can be performed without such approval.

Biorepository

Biorepository is a place where researchers can deposit and store blood that will be used in research. This Biorepository will allow us to store your blood plasma (the liquid remaining after removal of blood cells). These samples may be used in future research to develop diagnostic

and/or prognostic tests to improve our understanding of what causes heart failure and other cardiovascular diseases and assist in developing new therapies. Plasma and serum from blood contain many substances. New substances are being discovered and methods for measuring these substances are being developed all the time.

If you agree to participate in this optional Biorepository study, we will collect an additional 10 ml (approximately 2 teaspoons of blood) at each study clinic visit starting at Visit 2 through Visit 10. You will not be required to make an extra visit or have an additional blood draw in order to provide this sample. The samples will be stored at the University of Vermont College of Medicine, and used to develop and evaluate future blood tests for heart failure. Your Biorepository sample will be assigned a unique code number. The key to the code (or the 'link' to your identity) will be kept in a secure, password protected computer file with access limited to key clinical personnel involved with your samples. At no time will investigators who use the samples be able to identify you or connect you to the samples.

The samples and research data will be kept until all samples have been used for analyses, unless you decide to withdraw your permission for us to use your samples.

Taking part in this Biorepository will not provide you with a direct benefit. However, your participation may contribute to:

a) our understanding of the response of patients receiving treatment for heart disease,
b) the possibility of developing new treatments related to heart failure, and
c) increasing our understanding of why and how heart failure occurs.

You will not be compensated for your participation in the Biorepository.

The Biorepository Study described above is for research purposes only. Therefore, you will not receive results from this study. The studies that may be done with your sample will not identify information that could be used to modify your medical care, diagnose diseases, or provide any specific data on your risk for certain diseases. It is not the purpose of these studies to look for or provide you with any medical information related to your present condition or any other disease or illness. Your participation in these studies is not a substitute for your regular medical care or check-ups.

What will happen to my specimen(s)?

The samples you give will be securely stored and labeled with a unique code number. The samples will be kept indefinitely (banked) and will only be identified by a number or code to protect your privacy.

Confidentiality: There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed. To help us protect your privacy in the Biorepository study, we have obtained a Certificate of Confidentiality from the

National Institutes of Health. With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

If you agree to participate in these optional study, you may withdraw at any time. If you decide to withdraw, we ask that you notify [INSERT YOUR PI and PI address] in writing. You do not have to indicate the reasons for your decision to withdraw. If you decide not to take part in this optional study or to later withdraw, there will be no change in your medical treatment or your participation in the main study. You will still receive medical care for your condition. Your decision regarding participation will not influence the quality of care that you are entitled to receive.

If you withdraw**,** the researchers will take the necessary steps to have your samples destroyed. However, if biomarker testing has already been done on your samples, the researchers will not destroy any results obtained before your withdrawal, but all identification linked to your sample will be permanently removed.

Any information derived from the Biorepository research, as well as any patents, diagnostic tests, drugs, or biological products developed as a result of this research, are the sole property of the Heart Failure Network participating institutions and might be used for commercial purposes. You will not have access to this property nor share the profits that may be earned directly or indirectly as a result of this research.

Please initial your choice as to whether you agree to have your blood samples stored for possible future research.
_____ I agree to allow my blood samples to be stored for possible future research of heart failure related conditions as described above.
_____ I DO NOT agree to allow my blood samples to be stored for possible future research as described above.

STATEMENT OF CONSENT FOR THE LIFE STUDY

The purpose of this study, the procedures to be followed, the study's 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 talk about problems, concerns or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form (or it has been read to me), and I 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 copy of this consent form and that a copy of this form will become part of my medical record.

_____ _____

Signature of Research Subject Date Time

_____

Printed Name of Research Subject

_____ _____

Signature of Research Team Member Who Obtained Consent Date Time

_____

Printed Name of Research Team Member Who Obtained Consent