Official Title: LCI-LUN-ABR-001: A Pilot Study of Carboplatin With Nab-Paclitaxel in Patients With Advanced Non-Small Cell Lung Cancer of Squamous Histology
IRB-Approved Date: 2/2/2017
NCT02328105

CAROLINAS HEALTHCARE SYSTEM
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title: **Levine Cancer Institute, A Pilot Study of Carboplatin with Nab-Paclitaxel in Patients with Advanced Non-Small Cell Lung Cancer of Squamous Histology**

Protocol Number: **LCI-LUN-ABR-001**

Principal Investigator: **Kathryn Mileham, M.D.**

Telephone: [redacted] **(24 Hours)**

Address: **Levine Cancer Institute**
[redacted]

INTRODUCTION

The study doctor and study associates (the investigators) are asking you to participate in a research study at Levine Cancer Institute (LCI) and Carolinas HealthCare System (CHS) of a study with carboplatin and nab-paclitaxel in patients with advanced non-small cell lung cancer of squamous histology. The purpose of this study is to see how well patients respond to this study drug combination. You are being asked to take part in this study because you are a patient with advanced non-small cell squamous lung cancer.

This is a clinical trial, a type of research study. Your study 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 have also been told that you have the option not to participate. You may discuss your decision with your friends and family. You can also discuss it with your healthcare team. If you have any questions, you can ask your study doctor for more explanation.

This study is being carried out under the sponsorship of Levine Cancer Institute (LCI). Celgene Corporation is the company that makes nab-paclitaxel that will be used in this study but is not providing the drug for this study.

WHY IS THIS STUDY BEING DONE?

Lung cancer is the leading cause of cancer death in the United States and worldwide. Squamous cell carcinoma (SCC) accounts for about 30% of new cases of lung cancer in the United States. Recent studies have shown improved outcomes for SCC potentially due to new treatment options for

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cancer. Nab-paclitaxel (commercially known as Abraxane) was recently approved by the Food and Drug Administration (FDA) for the treatment of lung cancer in combination with carboplatin for newly diagnosed patients with lung cancer who are not eligible for curative surgery or radiotherapy. Nab-paclitaxel is thought to work by increasing the amount of paclitaxel (the active ingredient in nab-paclitaxel) in the tumor and also reducing the toxic effects in normal tissue.

The primary purpose of this study is to explore this study drug combination in patients with advanced SCC and compare to best responses in prior studies involving patients with SCC, as well as determine whether there are any biomarkers (biologic characteristics) which can predict response to treatment.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

You will be 1 of approximately 50 subjects enrolled on this study at Levine Cancer Institute and your participation will last for 6 cycles of study treatment followed by follow-up data collection for 3 years after completion of follow-up from your enrollment date, or until you no longer wish to participate.

HOW THE STUDY WORKS

Before you begin study treatment (Baseline):
In order to participate in this study, you will need to review, sign, and date this informed consent document. Following this, information about you will be obtained from your medical record to determine your eligibility to enroll on the study. We will collect demographic information (i.e. your age, race), review your medical history, perform a physical exam, and collect blood for laboratory tests. We will also keep a record of any medications you are taking and any existing side effects.

An EKG to assess your heart function and a CT scan will also be required if you haven't had one within the last 30 days. These tests are often routinely obtained before standard chemotherapy.

Additionally, if you are a woman of child-bearing potential, you will have a urine or blood pregnancy test.

Specimen Collection for the Purposes of Research Before you Begin Study Treatment:

If you agree to participate in this study and have had a tumor biopsy within the past 60 days, we would like to analyze a portion of your previously collected biopsy specimen for tissue biomarkers.

If the previously collected tumor tissue is unavailable or insufficient, we would like to obtain a new biopsy tumor sample for tissue biomarker analysis instead. You will be required to sign a separate procedure consent to have the biopsy procedure, which will be done before you begin treatment on this study. **If you do not have sufficient tumor tissue from a previous biopsy or surgery, and you do not wish to have a new biopsy, you will not be eligible to participate in this study.** Recent archived (previously collected tissue within the last 60 days) or fresh tissue tumor specimen is REQUIRED.

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In addition to tumor biomarker analysis, we will also collect an additional tube of blood (about 1-2 tablespoons) for blood-based biomarker analysis within 30 days of the start of study treatment and before your first dose of study treatment. This additional tube of blood will be drawn during a time when you are already having blood drawn for clinical laboratory tests. Your blood will be used to examine biological molecules found in blood that may signify normal or abnormal processes related to your cancer. **If you do not wish to have this additional tube of blood drawn for blood-based biomarker research, you will not be eligible to participate in this study.**

All samples collected for research purposes will be labeled with a unique number instead of your name. If you decide later that you do not want Levine Cancer Institute to use these samples for research, you may request that unprocessed samples be destroyed by writing to your study doctor at the address listed on the first page of this consent form.

During Study Treatment (Intervention; 6 cycles):

During the treatment period, you will receive a chemotherapy infusion of carboplatin and nab-paclitaxel for 6 cycles. Each cycle is 21 days long. You will have physical exams, lab work, and medications and side effects assessments during each cycle according to the study calendar.

Every 6 weeks you will also have a CT scan. An additional tube of blood (about 1-2 tablespoons) will be collected for blood-based biomarker analysis before you receive your study treatment on cycles 3 and 5. The additional tube of blood will be drawn during a time when you are already having blood drawn for clinical laboratory tests. This additional tube of blood will be labeled with a unique number instead of your name. If you decide later that you do not want Levine Cancer Institute to use these blood samples for research, you may request that any unprocessed samples be destroyed by writing to your study doctor at the address listed on the first page of this form. Samples already processed will not be able to be destroyed and will remain part of the study data.

After You Complete Study Treatment (Post-intervention; one visit):

Within 30 days of your last chemotherapy infusion, you will have a physical exam, lab work, CT scan, and medications and side effects assessments. A tube of blood (about 2 tablespoons) will also be collected for blood-based biomarker analysis.

Follow-Up:

After you have completed the treatment period of this study, you will have doctor's visits and CT scans according to routine care. We will collect information from your medical record for the purposes of this study to document your disease status every 6 months until you complete 3 years of follow-up from your enrollment date.

RISKS

You may have side effects while you are on this study. Everyone taking part in the study will be carefully watched for side effects. However, doctors don't know all the side effects that may happen. Side effects can be mild or very serious. Your healthcare team may give you medicines to lessen side

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effects. Many side effects go away after you stop taking carboplatin and nab-paclitaxel. In some cases, side effects can be serious in that they can be long lasting, may never go away, may result in hospitalization, or may result in death.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Carboplatin:

Likely:

- Low white blood cell counts- this may make you more open to infection
- Low platelet count- this may make you bruise more easily and bleed longer if injured
- Low red blood cell count (anemia) which may cause tiredness, shortness of breath
- Fatigue (feeling tired)
- Loss of appetite and weight loss
- Diarrhea
- Constipation
- Nausea
- Vomiting
- Abdominal (belly) pain
- Skin rash
- Changes in taste
- Changes in electrolytes in the blood such as magnesium and potassium
- Decrease in kidney or liver function
- Hair loss

Less Likely, but Serious:

- Numbness or tingling in fingers or toes
- Ringing in the ears and hearing loss
- Allergic reactions (Some symptoms of allergic reactions are rash, wheezing and difficulty breathing, dizziness and fainting, swelling around the mouth, throat or eyes, a fast pulse or sweating. Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.)
- Chills and fever with aches and pains
- Sores in the mouth and throat [that can lead to difficulty swallowing and dehydration (lack of fluids)]
- Altered (changed) vision

Rare, but Serious:

- Seizures
- Secondary cancers such as acute leukemia (cancer of the blood) which may cause death
- Kidney failure requiring dialysis (the blood is circulated outside of the body to be filtered)
- Deafness

- Death

Nab-Paclitaxel (Abraxane):

Likely:

- Anemia
- Low number of white blood cells with or without fever (that may make it easier to get infections)
- A decrease in the number platelets, the cells that help your blood to clot (which may lead to unusual bleeding or bruising under the skin)
- Constipation
- Diarrhea
- Nausea
- Vomiting
- Stomach pain
- Pain, swelling or sores on the inside of the mouth
- Neuropathy, a disorder of the nerves which can cause tingling or numbness, weakness, or decreased sensation or movement
- Dizziness
- Headache
- Feeling tired or weak
- Pain (including muscle, joint, bone, and chest pain)
- Swelling caused by fluid held in the tissues, especially of the ankles, feet or fingers
- Fever
- Chills
- Decreased appetite
- Change in taste
- Weight loss
- Difficulty sleeping
- Depression
- Cough
- Shortness of breath
- Hair loss
- Rash, possibly red, bumpy or generalized
- Itchiness
- Changes in nails, including discoloration or separation from nail bed
- Abnormal liver function test results
- Dehydration (loss of water and minerals in the body)
- Nose bleed

Less Likely:

- Bone marrow depression which is a severe reduction of red or white blood cells and platelets (at nearly the same time) which can cause weakness, bruising, or make infections more likely
- Infections, including pneumonia or of the lung, mouth, gallbladder, urinary tract, nail, or hair follicle, (which may be bacterial, fungal or viral)
- A very severe infection of the blood which may include a decrease in blood pressure to dangerous or even fatal levels
- Inflammation of the lung passages
- Thickening, inflammation or scarring in the lungs which may cause breathlessness, cough
- Inflammation of the bowel causing abdominal pain or diarrhea
- Blockage of the intestine
- Trouble swallowing
- Indigestion or upset stomach
- Abnormal chemistry or electrolyte blood test results
- Acute kidney failure (Inability to eliminate fluids or waste products from digestion)
- Blood in the urine
- Lack of muscle coordination
- Muscle weakness
- Anxiety
- Nasal congestion
- Mouth or throat pain
- Dry mouth, nose and throat
- Coughing up blood or bloody sputum
- Blood clot in the lungs or in deep vein
- Fluid in the chest cavity
- Red or flushed skin
- Dry skin
- Hand-foot syndrome, involving reddening, swelling, numbness and peeling of palms and soles of feet
- High blood pressure
- Low blood pressure
- Faster heart beat
- Watery eyes
- Changes in vision or blurry vision
- Infusion site reactions (described as discomfort, bleeding or bruising/swelling at the needle site, and in some instances infection or leaking of fluid outside of blood vessel)
- Localized swelling due to build-up of lymph fluid
- Acute renal failure (when your kidneys suddenly lose the ability to function)
- Hemolytic-uremic syndrome (HUS) (the abnormal early destruction of red blood cells which can lead to kidney failure)

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Unlikely:

- Stevens-Johnson Syndrome (SJS), a serious, potentially life threatening, skin reaction often with painful blistering of the skin and mucous membranes
- Toxic epidermal necrolysis (TEN), a serious, potentially life threatening, skin reaction often with painful blistering of the skin and mucous membranes
- A decrease in the heart's ability to pump blood to all parts of the body and possibly heart failure (back-up of fluid in the lungs and accumulation of excess fluid in body tissues, such as legs and abdomen.)
- Irregular or slow heart beat
- Cardiac arrest (stopping of the heart)
- Allergic reaction (may include skin inflammation, rash, trouble breathing, trouble speaking, fever), sometimes fatal
- Syndrome involving abnormal blood clotting, with decreased platelets, bruising (including tiny red or purple spots under the skin) and possibly leading to blood clots
- Edema/swelling and cyst formation of the macular area of the retina (the most sensitive and centrally-located part of the back of the inside of the eye responsible for the most detailed vision)
- Irritation and redness of the thin membrane covering the eye
- Inflammation of the cornea
- Too much fluid in the body
- Feeling unwell
- Sleepiness
- Scaly or peeling skin
- Hives
- A loss of nerve function in the muscles of the face

Other Risks:

Blood Sampling: Taking blood from a vein in your body may cause some pain, redness, or bruising at the injection site. In addition, lightheadedness, fainting, or an infection (rare) at the blood draw site is possible. If you feel faint, you should immediately lie down to avoid falling.

Radiological exams (CT scans): Computed tomography scans use X-ray radiation. Radiation has the potential to cause cancer or harm an unborn child. The amount of radiation you will receive during a CT scan is very low and most doctors agree that the benefits outweigh the risks. Some CT scans will require you take a "contrast solution" either by mouth, through the rectum or by injection into a vein. You may experience discomfort from lying still in an enclosed space for a prolonged period of time.

Although rare, the contrast solution used in CT scans may cause an allergic reaction such as nausea, vomiting, itching, skin rash, or in very rare instances swelling of the throat and difficulty breathing. **If you feel any of these symptoms of an allergic reaction you must tell the clinical staff immediately so that you can be treated quickly.**

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Tumor Biopsy: The risks of a biopsy can include bleeding, pain, and infection. To reduce these risks, the site of the biopsy will be numbed and sterile techniques will be used. You will sign a separate consent for this procedure.

ECG (Electrocardiogram) Risks: An ECG traces the electrical activity of the heart. You may have mild irritation, slight redness, or itching at the sites on your skin where the recording patches are placed.

Reproductive Risks: If you are a woman who can get pregnant, or if you think you might be pregnant or might get pregnant during the study, you should not take part in this study. Nab-paclitaxel can cause harm to an unborn child if given to a pregnant woman. You cannot take part in this study if you are pregnant or breast-feeding. Because of the possible risks to an unborn child, if you are a female who can become pregnant, you will be asked to take a pregnancy test within 72 hours prior to starting study drug treatment. Women who may become pregnant should use effective birth control (contraception) throughout the study and for 3 months after your last dose of study drug. Talk to your study doctor about the best way to prevent pregnancy while receiving nab-paclitaxel.

If you become pregnant during the study you must tell the study doctor right away. If this happens, your participation in this study will be discontinued. If you become pregnant within 3 months after taking your last dose of study drug you must tell the study doctor right away. The study doctor will follow you and your pregnancy to birth.

If you are a man with a partner of childbearing age, you must agree to use a medical doctor-approved form of contraception throughout the study, and should avoid fathering a child for 6 months after your last dose of study drug. If your partner becomes pregnant during the study or within 6 months after you took your last dose of study drug, you must tell the study doctor right away. Nab-paclitaxel can harm the unborn baby of your partner. Talk to your study doctor if this is a concern to you.

EXCLUSION CRITERIA

You may not participate in this study if any of the following are true:

- You decline this consent.
- You have received prior treatment for metastatic disease.
- You are receiving drugs as part of another clinical trial.
- You have a hypersensitivity to either carboplatin or nab-paclitaxel.
- You have an uncontrolled and current illness such as an active infection, heart problems, or psychiatric/social issues that would limit your compliance with study requirements.
- You are pregnant or breast feeding.
- You have another active malignancy.
- You have significant neuropathy (weakness, numbness, or tingling of the hands or feet).

Please inform your study doctor if any of the above are true.

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BENEFITS OF STUDY TREATMENT

The benefits of nab-paclitaxel in combination with carboplatin are not fully known and it might be that you do not gain any benefit from the study treatment. Information from this study may help you and/or other people with your disease in the future.

ALTERNATIVE TO BEING IN THE STUDY

You may choose not to participate in this study and receive routine care treatment as recommended by your study doctor, such as other chemotherapy or targeted therapies. Your study doctor can discuss the alternatives and the risks and benefits of these alternatives with you. Please ask any questions you may have and take as much time as you need to make your decision.

COSTS AND COMPENSATION FOR PARTICIPATION IN THIS STUDY

You and/or your health plan/insurance will need to pay for chemotherapy and all routine care procedures. There is no additional cost to you to take part in this study. LCI will pay the costs of the additional tissue and blood collection for biomarker analysis.

You will not receive payment for taking part in this study. For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this web site. Another way to get the information is to call [redacted] and ask them to send you a free copy.

You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

None of the doctors asking you to participate in this study has received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the doctor or study staff is associated.

COMPENSATION FOR INJURY RESULTING FROM THE STUDY

If you become ill or are hurt while you are in the study, get the medical care that you need right away.
In the event that you are harmed as a result of your participation in this study, inform your study doctor immediately so you can access medical treatment. You and/or your health plan will be charged for this treatment in the usual manner. The study will not pay for standard medical treatment.

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You still have the right to make a claim through the legal system even if you sign this form, accept medical care, or accept payment for medical expenses.

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WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, your decision will not in any way harm your relationship with your doctors or with CHS or LCI and there is no penalty or loss of benefits to you. You are free to stop being in the study if you change your mind after entering it. This would not harm your relationship with your doctors or CHS and there is no penalty or loss of benefits to you. Information contributed to the study will remain in the study even if you choose to withdraw. If you choose to withdraw from the study, please notify the study doctor in writing at the address listed on the first page of this form.

Your study doctor, Levine Cancer Institute, or the FDA can remove you at any time, from this study without your consent for any reason, including but not limited to, the judgement that any condition or circumstance may jeopardize your welfare or the integrity of the study, your failure to follow instructions of the study doctor, or the study is stopped by Levine Cancer Institute. Your study doctor will explain the reasons for doing so and will help arrange for your continued care, if needed.

If you leave the study for any reason you will be asked to have the procedures completed for the final visit. If you decide to no longer participate in the study for any reason, you have the option not to allow Levine Cancer Institute to use your blood and tissue samples for testing by contacting the study doctor at the telephone number or address listed on the first page of this form. Blood and tissue samples will be destroyed only if they have not already been tested.

NEW INFORMATION

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE, AND DISCLOSE PERSONAL MEDICAL INFORMATION

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by the sponsor, by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

We will do our best to make sure that the personal information in your medical records will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal identifying information will not be used.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location that is only accessible by the study doctor and research staff.

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Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Carolinas HealthCare System (CHS)
- Government agencies, like the Food and Drug Administration (FDA) that are involved in keeping research safe for people
- Levine Cancer Institute
- Chesapeake Institutional Review Board (The Institutional Review Board is a committee of individuals who review research studies to make sure subjects rights and safety are adequately considered in the way the study is designed and carried out.)

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied, by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

Information about genetic testing

A Federal law called the Genetic Information Nondiscrimination Act (GINA) of 2008 generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we may get from this research.
- Health insurance companies and group health 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 that we may get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law. All employers with 15 or more employees must follow this law. Be aware that this Federal law does **not** protect you against discrimination by companies that sell life insurance, disability insurance, or long term care insurance.

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor (LCI) and study investigators to collect, process and pass on any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will

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be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the clinical study sponsor-investigator, investigators and research staff
- the study sponsor and/or its associated companies, Levine Cancer Institute
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study sponsor,
- Celgene Corporation,
- Carolinas HealthCare System employees, and/or
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- monitor your study treatment with carboplatin and nab-paclitaxel,
- compare results with those of other subjects in the study, and
- support the development of the other study protocols.

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed, it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study sponsor-investigator will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain until the study is terminated. If you wish to revoke authorization to use your personal information,

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you will notify the study doctor in writing at the address and telephone number listed on the first page of this form.

Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

QUESTIONS

You can ask questions about this consent form or the study (before you decide to start the study or at any time during the study). Questions may include:

- Who to contact in the case of a research-related injury or illness.
- Any payment for being in the study.
- Your rights and your responsibilities as a study subject.
- Other questions.

Contact the study doctor or study staff at Carolinas HealthCare System with any questions or concerns. Their telephone number is printed on the first page of this form. If you have any questions or complaints about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  [redacted]
- or call toll free: [redacted]
- or by email: [redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00010224.

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 study results. You can search this Web site at any time.

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CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form. I will receive a copy of this signed and dated form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

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