Concise and Focused Presentation

This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care. This first section gives you an overview of the key information you should know about the research study. More detailed information about these topics can be found in the pages that follow. Please read this consent form carefully and take your time making a decision. Do not join this study unless all of your questions have been answered.

You are being asked to volunteer for a research study. This study is being sponsored by Merck, Baylor College of Medicine, and Baylor St. Luke's Medical Center (BSLMC).

Being in this research study is voluntary; it is your choice. If you join this study, you can still stop at any time. Once your eligibility has been confirmed and you have been registered in the study, you will begin a chemotherapy (chemotherapy is the use of drugs to kill cancer cells) treatment called modified FOLFIRINOX (mFOLFIRINOX), which is a combination of 4 cancer-treating medications. Chemotherapy will be given to you every 2 weeks; this 14-day period is called a Cycle. A total of six cycles will be given and must be completed within 15 weeks in order for you to stay in the study. You will receive growth factor support, a medication indicated to prevent some of chemotherapy's side effects like a lower-than-normal amount of red blood cells in your blood or susceptibility to infections, at the treating physician's discretion.

The purpose of this study is to better understand how Neoadjuvant (medical treatment of cancer prior to having surgery) FOLFIRINOX combined with Pembrolizumab, a medication that will help your immune system attack tumor cells, will react in patients with pancreatic cancer. If you agree to participate in this study, you will receive 6 doses (one every 2 weeks) of FOLFIRINOX with 2 doses (one every 6 weeks) of Pembrolizumab before surgery. Following surgery, you will receive 5-Fluorouracil-based chemotherapy for up to 6 doses (one every 2 weeks) with 7 more doses of Pembrolizumab (one every 6 weeks). You may receive a total of 9 doses of Pembrolizumab during the course of this study.

Potential risks and discomforts of participating in this clinical trial include itching and paleness of your skin, diarrhea cough, joint and back pain, fever, skin rashes, hypothyroidism (not enough thyroid hormone), hyponatremia (low levels of salt in the blood); you could also experience inflammation of your lungs, hyperthyroidism (too much thyroid hormone), inflammation and/or malfunction of your nerves, kidneys, heart, muscles, pancreas, liver, brains, spinal cord or blood vessels; hair loss, difficulty swallowing, heartburn, infections or anemia (low red blood cells).

Overall, approximately 30 subjects (patients participating in a research study are called subjects) will participate in this site. Your participation in this trial is about 16 months and up to 2 years of long-term follow-up contacts. This trial will be open for approximately 3.5 years.

This study is designed to benefit you directly. You may, also, derive benefit from knowing that you are

contributing to medical science and that your experiences may help other people like you in the future.

The alternative is to not participate in this study. You do not have to take part in this clinical study to have treatment at this hospital. Your study doctor will discuss these options with you before you decide whether or not to take part in this clinical study. Please see below for additional details about the study. A member of the study team will review the full.

Background

Before you decide if you want to continue taking part in this study, it is important for you to understand why the research is being done, how your information will be used, what the study will involve, and the possible benefits, risks, and discomforts. Please take time to read this Informed Consent Form (ICF) carefully and discuss it with your doctor and anyone you want in order to better understand this study and your options.

After you read this Informed Consent Form you should ask any questions you might have about the study. You should not sign and date the consent form until all your questions are answered. If you have any questions or do not understand anything in this form, please ask the Study Doctor or study staff.

It is up to you to decide whether or not to take part in the study. If you decide not to take part in the study, your decision will not affect the medical care you are entitled to receive. If you decide to take part in the study you are still free to withdraw from the study at any time without any penalty or loss of benefits to which you are otherwise entitled. This is described in more detail in a later section of this document entitled "Can I stop being in this study?"

This is a Phase II study trial of Neoadjuvant FOLFIRINOX Chemotherapy with Pembrolizumab followed by Surgery and Adjuvant (medical treatment after surgery) Pembrolizumab for Patients with Localized (a cancer that is limited to a certain part of the body), resectable (that can be removed with surgery) pancreatic cancer. A phase II clinical research is a type of study where researchers administer an investigational treatment to a group of patients with a specific condition or disease. This type of study tells doctors more about how safe the treatment is and how well it works. We think that appropriately timed neoadjuvant FOLFIRINOX with Pembrolizumab can be administered safely and feasibly and that this combination will lead to improved outcomes associated with increased numbers of cancer-attacking cells in surgically removed pancreatic tumors.

If you decide to take part in the study, you will be asked to sign and date this Informed Consent Form. You must sign and date this Informed Consent Form before any study procedures are performed. If you do not sign and date this Informed Consent Form, you cannot take part in the study.

You should understand the information listed below before deciding to take part in the research study:
- The goal of regular medical care is to help individual patients.
- The main goal of a research study is to learn things to help patients in the future.

- Joining the research study will not cause you to lose any medical benefits to which you would otherwise be entitled.
- If you decide not to join the study, or if you decide to stop, there is no penalty and you will not lose any benefits to which you are otherwise entitled.

Your Study Doctor is a researcher for this study. As a researcher, he is interested both in your health and how this study is carried out.

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

This research study is funded by Merck

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Purpose
The goal of the project is to better understand how Neoadjuvant FOLFIRINOX combined with Pembrolizumab will react in patients with resectable pancreatic cancer after surgery and investigate whether Pembrolizumab can can improve cancer's response to chemotherapy. If you agree to participate in this study, you will receive 6 doses (one every 2 weeks)s of FOLFIRINOX with 2 doses(one every 6 weeks) of Pembrolizumab before surgical resection (the process of cutting out tissue or part of an organ). Following surgery, you will receive 5-Fluorouracil (5-FU), an anticancer medication, based chemotherapy for up to 6 doses (one dose every 2 weeks) with 7 more doses (one every 6 weeks) of Pembrolizumab. You will receive a total of 9 doses of Pembrolizumab throughout the study.

Procedures
A total of 30 subjects at 1 institutions will be asked to participate in this study.
You will be one of approximately 30 subjects to be asked to participate at this location.

Once you have agreed to participate in the study and have signed this informed consent document, your participation in the study will involve the following stages.

The research will be conducted at the following location(s):
Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC).

Once your eligibility has been confirmed and you have been registered in the study, you will begin chemotherapy treatment with FOLFIRINOX. Each cycle is 14 days; a total of six cycles will be

administered and must be completed within 15 weeks. You will receive growth factor support at the treating physician's discretion.

Pembrolizumab will be administered every 6 weeks.

Patients will receive 6 doses (one every 2 weeks) of FOLFIRINOX with 2 doses (one every 6 weeks) of Pembrolizumab before surgical removal of tumor. Following surgery, patients will receive chemotherapy consisting of 5-Fluorouracil alone for up to 6 doses (one every 2 weeks) with 7 more doses (one every 6 weeks) of Pembrolizumab. Patients will receive a total of 9 doses of Pembrolizumab. Toxicities (undesirable effects of medications) for Pembrolizumab and FOLFIRINOX will be continuously monitored to make sure their side effects are in line with prior experience of their use, individually or combined.

Pembrolizumab will be initiated starting with Cycle 2 Day 1 (during your second chemotherapy session). Trial intervention(s) should begin on the day of enrollment (the process of registering or entering a patient into a clinical trial) or as close as possible to the date on which intervention is allocated/assigned.

Re-Staging
Staging is a way to describe a cancer. The cancer's stage tells you where a cancer is located and its size, how far it has grown into nearby tissues, and if it has spread to nearby lymph nodes (a small bean-shaped structure that is part of the body's immune system) or other parts of the body.
For this study, your doctor will order for you to have a Computerized Tomography (CT), a series of X-ray images taken from different angles, or a Magnetic Resonance Imaging (MRI), a medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed images of the organs and tissues in your body, done before any intervention, with the purpose of staging the cancer, determining if it is removable by surgery.
Restaging with the same method of imaging used to meet initial eligibility requirements, including either contrast-enhanced pancreatic CT or MRI (for patients with an intravenous contrast allergy) must be performed 4-8 weeks following completion of chemotherapy. All re-staging imaging will be centrally reviewed for assessment of resectability (to determine if the cancer can be removed).

Surgery
After eligible patients have recovered sufficiently from any adverse effects of neoadjuvant chemotherapy and still have removable cancer on re-staging, they should proceed to surgery at the participating site within 8 weeks following completion of chemotherapy.

ADJUVANT CHEMOTHERAPY
When patients have recovered from surgery, they will be offered adjuvant therapy, which will consist of up to 6 doses of biweekly (every 2 weeks) 5-Fluorouracil-based chemotherapy (physician's choice), and 7 doses of Pembrolizumab (every 6 weeks) for a total of 9 doses, including the doses given prior to surgery.

Repeat imaging will be performed according to the Schedule of activities (Section 2.3)

The investigator is responsible for ensuring that procedures are conducted by appropriately qualified (by education, training, and experience) staff.

All screening evaluations must be completed and reviewed to confirm that potential participants meet all eligibility criteria.

Additional evaluations/testing may be deemed necessary by the investigator, the Sponsor, and/or Merck for reasons related to participant safety. In some cases, such evaluation/testing may be potentially sensitive in nature (eg, HIV, Hepatitis C), and thus local regulations may require that additional informed consent be obtained from the participant. In these cases, such evaluations/testing will be performed in accordance with those regulations.

Procedures conducted as part of the participant's routine clinical management (eg, blood count) andobtained before signing of ICF may be utilized for screening or baseline purposes provided the procedure met the protocol-specified criteria.

The investigator will maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure (if a patient does not qualify to participate in the study), as applicable. Only authorized study personnel will have access to participants' medical records. There is a small risk for the loss of confidentiality of patients' personal and health data. However, study personnel will make every effort to minimize this risk. No health information identifiers will be retained for screened subjects who do not qualify. All research data will be stored on a password-protected electronic database. Only the Principal Investigators (PIs) and research coordinators will have access to the clinical stored database.

Blood, Urine and Tissue Collection
A series of six blood draws will be collected during the study to analyze how your immune system works and how its activity changes in response to cancer. During each of these visits, approximately 40 mL (around 4 tablespoons) of blood will be drawn. Added to this, during each visit the hospital staff will also collect blood (the total amount of blood per visit may vary from 12 to approximately 25 mL.) and/or urine to assess how your organs are working, see if there is any infection and/or monitor the cancer. The total amount of blood collected for research purposes during the course of the study will be approximately 240 mL (around 24 tablespoons). The total amount of blood collected for safety purposes during the course of the study will be approximately 465 mL (around 32 tablespoons). The total amount of blood collected over any 6-week period will not exceed 550 mL.

Fertile participants must agree to use contraception during the length of the study and up to 220 days after the last dose of study treatment. Female participants must also agree to have one or more pregnancy tests before the start of treatment. By signing this consent form you agree to these requirements.

After your surgery part of the tumor will be stored and analyzed to see the characteristics of cancer cells and its surrounding tissue, as well as to determine the effects of chemotherapy on the tumor.

Clinically Relevant Research Results

There is a possibility that clinically relevant research results will be discovered during the study. Primarily, this will be involved with the response to the treatment determined by the pathologist who will evaluate the tumor once it is removed. Information regarding response to treatment will be shared with the patient during the clinic visits after surgery.

Sharing and Future Research Studies with Identifiable Private Information

Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Sharing and Future Research Studies with Identifiable Biospecimens

Information that identifies you may be removed from your identifiable biospecimens collected as part of this research, and after such removal, your biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Genome Sequencing Potential

Your identifiable biospecimens(s) will be or may be sequenced in whole or in part so that your genetic information can be compared to others' genetic information.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Identifiable biospecimens

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), and MERCK SHARPE & DOHME CORP. (US)

and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

The data coordinating center will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC).

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, MERCK SHARPE & DOHME CORP. (US) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, data coordinating center, and Baylor St. Luke's Medical Center (BSLMC) may still use or

disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. E. Ramsay Camp
One Baylor Plaza, MS: BCM 390
Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

Potential Risks and Discomforts
Pembrolizumab, which is approved in the USA and some other countries, is available by prescription to treat several different cancers but may not be approved to treat your type of cancer.

Pembrolizumab works by helping your immune system to fight your cancer. However, Pembrolizumab can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (i.e., causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking Pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

What side effects could Pembrolizumab cause?
VERY COMMON:
- Itching of the skin
- Loose or watery stools
- Cough

COMMON:
- Joint pain
- Rash
- Fever
- Back pain
- Pain in your belly
- Loss of skin color
- Not enough thyroid hormone (hypothyroidism)

- Low levels of salt in the blood (hyponatremia)

UNCOMMON:
- Inflammation of the lungs (pneumonitis)
- Too much thyroid hormone (hyperthyroidism)
- Infusion (slow injection of a substance into the body, usually into the blood) reaction, where you may feel dizzy or faint, feel flushed, get a rash, have a fever, feel short of breath, experience a decrease in your blood pressure or have pain at the site of infusion
- Inflammation of the bowels/gut (colitis)
- Peeling of the skin, itchiness, and/or skin redness. This could also be widespread throughout your body. - More severe skin reactions may involve the inside of your mouth, the surface of your eye and genital areas, and/or may cause the top layer of your skin to peel from all over your body (Stevens-Johnson syndrome or toxic epidermal necrolysis)

RARE:
- Inflammation of the nerves that may cause pain, tingling or severe muscle weakness and possible temporary paralysis (Guillain-Barré syndrome)
- Inflammation of the muscles (myositis)
- Inflammation of the pancreas, a gland in your abdomen that controls sugar levels (pancreatitis)
- Eye redness, blurred vision, sensitivity to light, eye pain, see floaters, or have headaches (uveitis)
- Inflammation of the liver (hepatitis)
- Inflammation of the pituitary gland, a gland in the head (hypophysitis)
- Adrenal glands, glands on top of the kidneys, that may not make enough hormone (adrenal insufficiency)
- Type 1 diabetes, a condition that can cause too much sugar in your blood
- Inflammation of the kidney (nephritis)
- Inflammation of your heart, which can cause chest pain, shortness of breath, swelling of the legs, fast or irregular heartbeat that may cause dizziness or fainting (myocarditis)
- Inflammation of the thyroid gland, an organ that makes and stores thyroid hormones (thyroiditis)
- A condition that may make you feel weak and tired and may cause drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing (myasthenic syndrome/myasthenia)
- The formation of small clusters of white blood cells, called granulomas, in parts of your body such as your lymph nodes, eyes, skin, or lungs (sarcoidosis)
- Inflammation of the brain (encephalitis)
- Inflammation of the spinal cord, a column of nerve tissue that runs from the base of the skull down the center of the back (myelitis)
- Inflammation of the blood vessels (vasculitis)

Additionally, since Pembrolizumab was approved in September 2014, the following side effects have been reported by people receiving Pembrolizumab.
These side effects were voluntarily reported from a group of people of unknown size. It is not possible to

estimate the frequency of these side effects:
- Inflammation of the joints (arthritis)
- Severe responses of the immune system that cause the body to attack its own organs
- The nervous system may also be affected and cause confusion, seizures, and even coma (hemophagocytic lymphohistiocytosis)
- Changes in eyesight, eye pain, whitish patches on the skin, and hearing loss (Vogt-Koyanagi-Harada syndrome)
- Inflammation and scarring of the bile ducts, tubes that carry digestive fluid that is made in the liver (sclerosing cholangitis).

What side effects could FOLFIRINOX (Leucovorin, 5-Fluorouracil, Irinotecan, and Oxaliplatin) cause?
COMMON:
- Hair loss
- Redness, pain, or peeling of palms and soles
- Rash, increased risk of sunburn, itching
- Severe diarrhea, nausea, vomiting, constipation, loss of appetite, weight loss
- Difficulty swallowing
- Sores in the mouth
- Heartburn
- Infections
- Anemia
- Bruising, bleeding
- Headache
- Tiredness, weakness, dizziness
- Numbness, tingling or pain, "pins and needles" of the hands, feet, arms and legs
- Tingling or a loss of feeling in your hands, feet, nose, or tightness in throat or jaw
- Cough, shortness of breath
- Fever, pain

OCCASIONAL:
- Chest pain
- Abnormal heartbeat which may cause fainting
- Swelling and redness at the site of the medication injection
- Hives
- Skin changes
- Weight gain
- Belly pain
- Internal bleeding, which may cause black tarry stool, blood in vomit or urine, or coughing up blood
- Changes in taste
- Blood clot which may cause swelling, pain, shortness of breath
- Bleeding from multiple sites including vaginal bleeding, bleeding of the testis, or bleeding of the brain
- Liver damage, which may cause yellowing of eyes and skin

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of
- the face or throat
- Change in voice
- Confusion
- Inability to move your shoulders or turn your head
- Blurred vision, watering eyes, discomfort from light
- Abnormal body movement including the eye and eyelid
- Difficulty walking, using your hands, opening mouth, talking, with balance and hearing, smelling, eating, sleeping, urinating
- Hearing loss
- Swelling of the body
- Kidney damage which may require dialysis
- Scarring of the lungs
- Blockage of the airway which may cause shortness of breath, cough, wheezing
- Dehydration

RARE:
- Damage to the heart which may cause shortness of breath
- A new cancer resulting from the treatment of a prior cancer

Loss of Confidentiality:
There is a small risk of loss of confidentiality. Every attempt will be made to minimize this risk. These concerns are minimized because there are safeguards in place and any research-related information that leaves the study site is not linked to your identity. If you have any questions or concerns, please discuss these with the study doctor or study staff.

Risks from taking a blood sample

You will have routine blood samples taken from a vein in your arm by a needle stick. Risks associated with drawing blood from your arm include slight discomfort and/or bruising. Infection, bleeding, clotting, or fainting also are possible, although unlikely.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits
The benefits of participating in this study may be: The benefits of participating in this study may be:
1. Possible improved response and increased chance of survival with the additional immunotherapy added to standard of care chemotherapy;
2. Increased long-term anti-tumor immune defenses.. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: You may receive treatment with FOLFIRINOX therapy alone; receive a course of FOLFIRINOX with consecutive surgery, or choose to have FOLFIRINOX chemotherapy before and after surgical removal of the cancer. You can also choose not to receive any treatment. You are free to choose not to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Your doctor's attitude towards you will not change if you choose not to participate in this study.
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Subject Withdrawal from a Study

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Ernest Camp at 713-798-4321 during the day and at 713-798-4321 after hours.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study.

Research Related Injury

BCM will provide necessary medical treatment to a research subject injured by participating in a Research project. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. BCM will not cover the costs of this treatment.

If you sustain an injury as a direct result of your study participation, medical care will be provided by Baylor College of Medicine and/or Baylor St. Luke's Medical Center. You will receive medical care that you or your insurance will have to pay.

Financial compensation is not available for such things a lost wages, disability, or discomfort due to an injury.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Women of Childbearing Potential

It is possible that the medicines used in this study could injure a fetus if you or your partner becomes pregnant while taking them. Because of the potential risks involved, you or your partner should not become pregnant while you are participating in this study.

If you are sexually active or become sexually active and can get pregnant or can get your partner pregnant, you must agree to use one of the following forms of birth control every time you have sex and for (8) months afterwards:

* oral contraceptives ("the pill"),
* intrauterine devices (IUDs),
* contraceptive implants under the skin, or contraceptive injections,
* condoms with foam.

Should you become pregnant while on this study, you must immediately notify the study personnel.

The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can choose not to provide this information.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact

the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, ERNEST CAMP, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: ERNEST CAMP at 713-798-4321 during the day after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date