Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are invited to participate in a research study on the safety and efficacy of a chemotherapy regimen known as Modified FOLFIRINOX (mFFX) alone or with the addition of Stereotactic Body Radiotherapy (SBRT). We hope to learn if this new treatment combination helps to control the disease and improve survival for patients with pancreatic cancer. You were selected as a possible participant in this study because you were diagnosed with locally advanced pancreatic cancer.

This informed consent document tells you about the study. It tells you about the purpose of the study and describes what is expected of you during the study. It also explains the possible risks and discomforts of taking part in this study and how being in the study may help you or others. This document also provides information about your rights while you are taking part in this study.

It is important that you read and understand the information in this document. Please ask the study doctor or the study clinic staff to explain anything that you do not understand. Please make sure the study doctor or the study clinic staff answers questions that you have about this study before you sign this document.

This research study is looking to enroll a total of 172 people with pancreatic cancer among different academic centers in the U.S. Stanford University expects to enroll between 20 and 50 study participants total over the duration of the study.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. If you decide that you want to terminate your participation in this study, you should notify Dr. Daniel Chang at 650- 724-3547.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 72 months including follow-up. The time of study participation varies but we estimate that most patients will remain a subject in this study for approximately one year.

PROCEDURES

Before you begin the study

For this study you may already be receiving the chemotherapy regimen mFFX, or may soon start it. In addition, you will need to sign this form and have the following exams, tests or procedures to find out if you are eligible to be in the study. These exams, tests, or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated:

- Complete a clinic visit with physical examination: To review and evaluate your weight, vital signs, current symptoms, and medical history.
- Provide a biopsy: This procedure involves the removal of a small amount of tumor tissue through a needle, and confirms your diagnosis.
- Provide blood samples: A small needle will be placed into a vein in your arm to draw blood for clinical testing and/or research purposes. Up to 60 mL (4 tablespoons) of blood may be taken at this visit. The blood may be used for the following tests:
  - Testing for pregnancy if you are a woman who can have a child
  - Looking at tumor markers to help better understand your disease
  - Testing your liver and kidney function, your blood's clotting function, and the numbers and types of cells in your blood
- Get a computed tomography (CT) or magnetic resonance imaging (MRI) of your abdomen (and if needed of your chest and pelvis), to examine the location and size of tumors in your body.

If the exams, tests, and procedures show that you are eligible for the study, you will likely have another clinic visit to further discuss the study and answer any questions you may have. If you choose to take part in the study, you will be asked to complete a questionnaire about your well-being and symptoms before any study treatment. You will also be enrolled and registered for the study, and then "randomized" into one of the 2 different study groups described below.

Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups and neither you nor your study doctor can choose the group you will be in. You will have a 50% chance of being placed in either group.

Treatment Groups

If you are in Group 1 (A), you will receive mFFX chemotherapy only, according to your Medical Oncologist's guidelines.

If you are in Group 2 (B), you will receive SBRT and then chemotherapy with mFFX. If you are assigned to receive SBRT, you will have the following procedures prior to SBRT:

- Placement of 'seeds' or fiducial markers. These are small (1-5mm length) gold seeds that will be placed directly into and/or around the tumor for radiation targeting purposes. The

seeds are usually placed as an outpatient procedure in endoscopy using an ultrasound device to visualize the tumor. If the markers cannot be placed endoscopically, then they will be placed percutaneously (through the skin), or by minimally invasive surgery (laparoscopic) or open surgery (laparotomy). This may have already been done prior to you signing this consent form (for instance at the time of an attempted surgical resection), which is an accepted standard of care procedure.

- Radiotherapy treatment planning or 'simulation'. At least 5 days after seed placement, you will have an appointment in Radiation Therapy which will be in 2 parts: 1) getting a plastic mold made to immobilize your body during your radiation treatments, and 2) having a PET and/or CT scan focusing on the area of your cancer. Prior to the scan you will be administered a contrast agent either intravenously (through an IV) and/or orally. During the scan, you may be asked to hold your breath for short periods of time. The Radiation Oncologists use the scan images to plan the radiation delivery.
- SBRT treatment. About 1-2 weeks after the simulation, you will receive SBRT in 5 sessions (also called fractions) over a five-day period, or over 2 weeks as long as you receive at least 2 fractions a week. During the SBRT you will be positioned on a treatment bed and immobilized, and you may be asked to hold your breath for short periods of time. The machine will move the radiation aperture around you delivering the planned dose of radiation. The radiation itself is painless. Your only job is to lie as still as possible. Each radiation treatment will last up to about 1 hour.
- Medications. You will be asked to take a medication before each radiation treatment to help prevent or relieve nausea and vomiting symptoms that may occur. You will also be asked to take a proton-pump inhibitor (PPI) from the start of radiation and continue for at least 6 months after it ends. PPIs decrease the acid in your esophagus and stomach and help prevent ulcers forming in the area where you receive radiation. Your physician or study coordinator can give you more information about these medicines.

Following your treatment with SBRT, you will receive mFFX chemotherapy within 8 weeks.

Tests and Procedures

During the time that you are receiving study treatment, you may have the following tests and procedures that are part of regular cancer care.

- A clinic visit: To review your condition and evaluate physical changes or effects due to treatment.
- Blood samples:
  - To test your liver and kidney function, your blood's clotting function, and the numbers and types of cells in your blood
  - To look at tumor markers to help better understand your disease

Follow-up procedures

After the treatment period, you will be monitored with your chemotherapy (mFFX) infusions. You will also have evaluations every 3 months during the first year of the study. You will then have follow-up every 6 months. You may have visits or evaluations more frequently if your doctor thinks it is needed. You will be followed on this study until disease progression, death, study withdrawal, or study termination.

Follow-up visits will include:

- Clinic visit with physical examinations
- Blood tests to look at the side effects of chemotherapy and other measures to evaluate your health
- Scan (CT, MRI, or PET/CT) to monitor your tumor and/or disease spread
- Questionnaire about your well-being and symptoms
- Other tests as appropriate

The scans, labs, visits and other procedures will be used to monitor you for treatment response and recurrence of your cancer. The frequency of these is about the same as you would receive as standard care.

Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use adequate contraception while you are participating in the study and for at least 3 months following the last treatment. Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant.

Tissue and Blood Sampling for Research

Research using tissues is an important way to try to understand human disease. The investigators of this study want to include your tissue and/or blood in an optional research project and want to save these samples for future research. There are several things you should know before allowing your tissues to be studied.

Blood samples of up to 20ml (4 teaspoons) will be drawn when you enroll into the study, then at each follow up visit, along with your normally scheduled blood tests. Tissue may be obtained at seed placement or another procedure. Your blood and/or tissue (if obtained) will be stored under a specific confidential identification number at Stanford University. The information about the link between your name and the study number will be stored in a password-protected computer file. Only research personnel will have access to this information. The samples will be stored until the end of the optional research.

You have the right to refuse to allow your blood and tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests.

_____ I consent to my blood samples being saved for future research.

_____ I consent to my tissue samples being saved for future research.

_____ I do not consent to my samples being saved for future research.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study drug as instructed.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep the study drug in a safe place, away from children and for your use only.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Daniel Chang at 650- 724-3547.

The Protocol Director may also withdraw you from the study and the study medication may be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. Cancer treatments often have side effects. The treatment used in this program may cause all, some or none of the side effects listed. In addition, there is always the risk of very uncommon or previously unknown side effects occurring.

CT Scan

CT scans are special X-ray tests used to study the internal organs and bones of your body, and are necessary for measuring your response to treatment. You would undergo these scans even if you were not participating in this research study because your doctor would need to monitor your disease. As part of the CT scan, a contrast agent may need to be taken by mouth and/or injected into your vein to make certain organs and disease sites visible on the scan. Oral contrast may cause side effects such as nausea, constipation, diarrhea, and abdominal bloating. Pain, bruising, redness, swelling, or infection may occur at the site where a needle is inserted to administer the contrast material into your vein. It is normal to experience a warm, flushing feeling when the contrast material is given. You may have an allergic reaction to the contrast material that may cause rash, hives, shortness of breath, wheezing, and itching, and rarely may cause your heart to stop beating (“cardiac arrest”). The use of contrast material during these tests would be a normal part of measuring your response to therapy, even if you were not participating in this research study.

If you have had a previous reaction to contrast agents or a history of severe allergies, please notify the operator/investigator.

MRI Scan
MRI scans are specialized imaging procedures that may be needed for measuring your response to this treatment (especially if you cannot get a CT scan). For most patients, the risks or side effects associated with undergoing MRI are minimal. An MRI scan does not involve ionizing radiation like conventional X-rays. Instead, images are generated using a magnetic field and radio signals. Because an MRI scanner uses strong magnets, you cannot have any metal implants in your body to have an MRI scan. People with an artificial heart valve, metal plate, pin, or other metallic objects in their body (including gun shot or shrapnel) may not be able to get this scan. Study personnel will ask you questions to make sure you can safely have an MRI scan.

There may be some anxiety and claustrophobia (fear of being in small places) associated with the scanner. Staff at the imaging center use techniques to help reduce these feelings in patients. Your study doctor may also prescribe mild sedatives or anti-anxiety drugs to help manage your symptoms. As part of the standard MRI scan, a contrast agent containing gadolinium is injected into your vein to enhance visibility. The risks associated with the contrast agent include mild nausea, headache, hives, temporary low blood pressure, chest pain, back pain, fever, weakness, and seizures. There have been reports of a severe and potentially fatal condition known as nephrogenic systemic fibrosis (a scarring condition that can lead to kidney failure) that has occurred in some patients who received gadolinium-based contrast agents. This has not been seen in patients with normal working kidneys or mild problems in kidney function. Prior to study entry, your study doctor will run tests to determine if your kidneys are working properly to make sure that the contrast agent is safe for you.

If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator.

PET/CT
There is exposure to ionizing radiation from the FDG administered for PET imaging. If there is any risk from this exposure, it is too small to be measured. The risk is low compared to other everyday risks.

Biopsies
Risks associated with biopsies include pain, excessive bleeding, bruising, or draining at the needle site, abnormal wound healing, fever, or infection at the biopsy site.

Modified FOLFIRINOX (mFFX)

Risks associated with Fluorouracil (5-FU)

Likely:
- Transient hair loss
- Inflammation of the mucosa in your mouth, throat and esophagus
- Diarrhea
- Nausea
- Vomiting

- Anorexia
- Transient decrease in white blood cell count (leucopenia) which can lead to increased risk of infections
- Skin irritation like red rash, bumps, itching, and blisters

Less likely:
- Transient deficiency in all types of blood cells (pancytopenia) with symptoms such as bleeding, easy bruising, fatigue, shortness of breath, and weakness
- Chest pressure or pain and shortness of breath
- Stomach ulcers or bleeding
- Various allergic reactions
- Sudden loss of balance, nystagmus, headache
- Dry skin, increased skin photosensitivity, increased skin and vein pigmentation
- Tingling in the hands and feet followed by pain
- Vision disturbances such as increased sensitivity to light
- Increased tearing, recurrent red eye or eye irritation
- Disorientation, confusion, euphoria
- Blood clots
- Nose bleeds
- Nail changes (including loss of nails)

Very rarely:
- Severe hematological toxicity and gastrointestinal hemorrhage leading to death

Risks associated with Leucovorin

Likely:
- Diarrhea, vomiting and upset stomach

Very rarely:
- Seizures and loss of consciousness

Risks associated with Irinotecan

Likely:
- Diarrhea shortly after the infusion accompanied by symptoms of stuffy nose, increased salivation, abnormal pupil constrictions, flushing, and intestinal discomfort
- Other gastrointestinal complications such as nausea, vomiting, abdominal cramping, loose stools, and infection
- Hypersensitivity reaction including hives, tongue swelling, vomiting, and in rare instances shock

Less likely:
- Transient weakening of your immune system caused by abnormally low number of neutrophils in your blood (neutropenia) which can lead to increased risk of infections

- Renal impairment
- Blood clots

Very rarely:
- Delayed diarrhea (more than 24 hours after the injection) which can be life threatening
- Blood infection (sepsis) caused by severe neutropenia which can lead to death

Risks associated with Oxaliplatin

Likely:
- Low blood cell counts (anemia)
- Transient neurological symptoms such as:
  - Sensation of tickling, tingling, burning, pricking, or numbness of the skin
  - Partial loss of sensation in the hands, feet, mouth area, or throat
  - Jaw spasms and abnormal tongue sensation
  - Speech disorders
  - Eye pain
  - All of the above symptoms may be precipitated and exacerbated by exposure to cold or cold objects

Less likely:
- Persistent neurological symptoms as described above lasting for more than 2 weeks
- Allergic reactions such as rash, hives, redness of the skin, and itching

Very rarely:
- Severe allergic reactions such as breathing spasms (bronchospasm) and sudden drop of blood pressure (hypotension) that can result in death
- Severe respiratory symptoms such as non-productive cough and shortness of breath which in some cases may be fatal

SBRT

There are risks associated with the endoscopic placement of 'seeds' or markers in the pancreas. These include infection, perforation (extremely rare), bleeding, pain, and pancreatitis. The gastroenterologist will discuss with you in more detail these risks. We estimate the risk of any significant complication to be less than 5%.

If the seeds cannot be placed endoscopically, then they will be placed either percutaneously (through the skin), by minimally invasive surgery (laparoscopic), or open surgery (laparotomy). The surgeon and anesthesiologist will discuss the risks associated with these prior to your procedure.

Toxicity commonly associated with radiation includes 1) nausea, vomiting, and loss of appetite, which often go away after a few days; and 2) fatigue which is temporary and resolves a few weeks after treatment. Severe side effects such as gastrointestinal (GI)

obstruction, fistula, perforation, or hemorrhage are uncommon. It is important to note that vomiting, GI obstruction, GI hemorrhage, anorexia and weight loss are also commonly associated with pancreatic cancer progression.

In the long term, over many years, there is a very low risk of developing a new cancer as a result of the radiological evaluations and radiation treatment for your cancer.

Assessments with labs and scans will be performed in an effort to identify these effects, determine their etiology and provide appropriate symptom relief or palliative measures. Hepatic (liver) and renal (kidney) toxicity is not anticipated given the expectation of limited incidental radiation of these organs.

POTENTIAL BENEFITS

There is no guarantee that you will receive any benefits from this study, and taking part in this study may or may not cause your health to improve. Information from this study may help doctors learn more about mFFX and SBRT. This information may benefit other patients with pancreas cancer or a similar condition in the future.

ALTERNATIVES

Alternative therapies include chemotherapy alone, standard chemoradiation, or no further treatment. Additionally, patients may choose to receive treatment to improve quality of life but which may have no effect on the growth of their cancer. The risk of pursuing no further treatment is tumor progression or spread. You should feel free to discuss your disease, prognosis, and treatment options with your doctor. You may withdraw from the study at any time to pursue other treatment options or for any other reason.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director or research staff member. You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

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.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Your personal health information related to this study may be disclosed as authorized by you. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of SBRT in the treatment of pancreatic cancer; the results will be provided to the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to determine if combining Stereotactic Body Radiation Therapy treatment with chemotherapy regimen known as modified FOLFIRINOX will help in controlling the advancement of pancreatic cancer. Your health information will allow the researchers to compare the two arms of the study (one with and the other without the SBRT) and determine if one of the treatment regimens included in this study is preferable to the other.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to Dr. Daniel Chang at

Daniel T. Chang, MD
Associate Professor
Department of Radiation Oncology
Stanford University
875 Blake Wilbur Drive
Stanford, CA 94305

What Personal Information Will Be Obtained, Used or Disclosed?
Protected Health Information which may be used or disclosed in connection with this research study includes but is not limited to: name, certain demographics (age and other dates of clinical significance, gender, ethnicity), medical record number, clinic visit or consultation notes (including history and physical examination report and findings), chemotherapy reports and/or administration records, lab results, pathology results, pregnancy test results (when applicable), blood serum samples, questionnaire/survey responses, and scan images and reports.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Daniel Chang
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Food and Drug Administration
- Johns Hopkins University
- Memorial Sloan Kettering Cancer Center
- BC Cancer Agency

- Loyola University
- UCLA

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2025 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative Date

_____
Print Name of Legally Authorized Representative

_____
Description of Representative's Authority to Act for Subject

FINANCIAL CONSIDERATIONS

Payment
You will not be paid to participate in this research study.

Costs
If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.

This study does not involve services, supplies, procedures and care that are not part of your routine medical care. You and your health insurance carrier will be responsible for all costs during this study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. You will be responsible for any co-payments and/or deductibles as required by your insurance.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director Dr. Daniel Chang at 650- 724-3547. You should also contact him at any time if you feel you have been hurt by being a part of this study.
Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone

independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you were given a copy of this consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of LAR (Parent, Guardian or Conservator) Date

_____ _____
Print Name of LAR Authority to act for participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed **only** if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness* Date

_____
Print Name of Witness

*(e.g., staff, translator/interpreter, family member, or other person who speaks both English and the participant's language)

- Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.
- The English consent form (referred to as the "Summary Form" in the regulations):
  - Must be signed by the witness AND the Person Obtaining Consent (POC).
  - The non-English speaking participant/LAR does not sign the English consent.
  - The non-English speaking participant/LAR should not sign the HIPAA participant line
  - If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.