THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

A Phase I study of intraperitoneal paclitaxel in patients with gastric adenocarcinoma and carcinomatosis or positive cytology
2019-0784

Subtitle: Phase I IP PTX

Study Chair: Brian D. Badgwell

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB – a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical research study is to find the highest tolerable dose of paclitaxel that can be given as intraperitoneal chemotherapy to patients with gastric or gastroesophageal cancer. Intraperitoneal chemotherapy is a system in which chemotherapy is delivered directly inside the abdomen.

This is an investigational study. Paclitaxel is FDA approved and commercially available for the treatment of gastric and gastroesophageal cancer. It is considered investigational to give this drug as an intraperitoneal chemotherapy.

The study doctor can explain how the study drug is designed to work.

The study drug may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side

effects, potential expenses, hospitalization, and time commitment. If you are not from the Houston area, travel to the clinic may be a burden.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You will receive paclitaxel for up to 2 months. You will be on the study for about 5 years after your last dose of paclitaxel.

You and/or your insurance provider will be responsible for the cost of the study drug and the intraperitoneal port placement. In order to take part in this study, the financial clearance center will need to confirm that you and/or your insurance provider can pay for the cost of participation.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive chemotherapy (including paclitaxel) by vein outside of this study. You may choose to receive other investigational therapy, if available. The doctor will discuss these options with you, including their risks and benefits. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will be performed within 30 days before your first dose of study drug to help the doctor decide if you are eligible:

- You will have a physical exam.
- Blood (about 2-3 tablespoons) will be drawn for routine tests.
- You will have a CT scan, MRI, or PET/CT scan to check the status of the disease. If you have had scans within the past 6 weeks, these scans will not need to be performed.
- If you can become pregnant, blood (about 2 teaspoons) or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Study Groups

If you are found eligible to take part in this study, you will be assigned to a dose level of paclitaxel based on when you join this study. Up to 3 dose levels of paclitaxel will be tested. At least 3 participants will be enrolled at each dose level. The first group of participants will receive the lowest dose level. Each new group will receive a higher dose than the group before it, if no intolerable side effects were seen. This will continue until the highest tolerable dose of paclitaxel is found.

Up to 30 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

Before receiving your first dose of study drug, you will have a laparoscopy to check the status of the disease. During a laparoscopy, you will be given a general anesthetic, and a thin camera (called a laparoscope) will be inserted into your abdominal cavity through a small incision. During the laparoscopy, you will also have an intraperitoneal port (the device used for administering paclitaxel) placed in your abdomen. You will sign a separate consent describing the laparoscopy and intraperitoneal port placement procedures and their risks.

You will receive 6 doses of paclitaxel over 2 months (8 weeks). You will receive paclitaxel as a liquid that is injected through the port in your abdomen over about 30 minutes, 1 time a week during Weeks 1-3 and 5-7. Paclitaxel will be delivered through plastic tubing that is connected to a pump into the abdominal cavity.

You will not receive paclitaxel during Week 4 or 8.

You will be given standard drugs to help decrease the risk of side effects. You may ask the study staff for information about how the drugs are given and their risks.

You will no longer be able to receive the study drug if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Your participation on this study will be over after the follow-up visits.

Study Visits

Within 3 days before your 2nd-6th doses of study drug:

- Blood (about 2-3 tablespoons) will be drawn for routine tests.
- The study staff will ask you about any side effects you are having. This may be done in clinic, by phone, or by email. The phone call should take about 5-10 minutes.

Within 30 days after your last dose of study drug:

- Blood (about 2-3 tablespoons) will be drawn for routine tests. This may be performed at an outside clinic closer to your home.
- The study staff will ask you about any side effects you may be having. This may be done in clinic, by phone, or by email. The phone call should take about 5-10 minutes.

Follow-Up Visits

Every 6 months for up to 5 years after your last dose of study drug:

- The study staff will ask you how you are doing and about any other cancer treatments you are receiving. This can be done at a routine clinic visit or over the phone. If you are called, the phone call should last about 5-10 minutes.
- You will have a CT scan, PET scan, or MRI to check the status of the disease. These can be performed at a clinic closer to your home. If you left

the study early and the doctor thinks it is needed, you may have CT scans, PET scans, or MRIs more frequently.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after the drugs are stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs and procedures.

Paclitaxel Side Effects

Common (occurring in more than 20% of patients)

• abnormal EKG • swelling • flushing • hair loss (partial or total) • mouth blisters/sores (possible difficulty swallowing)	• nausea/vomiting • diarrhea • low blood cell counts (red/platelets/white) • abnormal liver tests (possible liver damage) • pain (muscle/joint)	• nerve damage (possible numbness, pain, and/or loss of motor function) • abnormal kidney test (possible kidney damage) • allergic reaction • infection

Paclitaxel may commonly cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Occasional (occurring in 3-20% of patients)

• low blood pressure (possible dizziness/ fainting) • slow heartbeat	• skin rash • abdominal pain • abnormal liver tests (possible yellowing of the skin and/or eyes)	• weakness • injection site reaction (possible redness, swelling, skin discoloration)

Rare but serious (occurring in fewer than 3% of patients)

• fast/irregular heartbeat • blood clots in a vein (possible pain, swelling, and/or redness) • heart failure • heart attack • decreased blood supply to the heart • high blood pressure • fainting • decreased brain function (possible paralysis and/or coma) • decreased brain function due to liver damage • seizure • severe sunburn-like rash at site of previous radiation (called radiation recall) • death of skin • worsening of existing scleroderma (severe hardened skin, which can cause difficult movement)	• inflammation at the site of previous tissue death • very severe blistering skin disease (with ulcers of the skin and digestive tract) • very severe blistering skin disease (loss of large portion of skin) • inflammation of the pancreas (possible abdominal pain) • inflammation of the intestines • dehydration • hole in the intestines (possible leaking contents into the abdomen) • decreased blood flow to part of the bowel (possibly causing death of tissue) • paralysis of the intestines	• intestinal blockage • difficulty walking • liver damage and/or failure • hearing loss • decreased kidney function • blockage in the lung (possible pain and/or shortness of breath) • lung inflammation and/or damage (possible difficulty breathing) • blood clots in the lung (possible failure to breathe) • difficulty breathing • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) • tissue death at the injection site caused by drug leakage

Giving the study drug by the intraperitoneal route may cause side effects not seen when given by vein.

Receiving drugs through an intraperitoneal port may cause the following side effects:

• abdominal pain • slow emptying of food from the stomach into the intestines	• paralysis of the intestines • inflammation of the pancreas (possible abdominal pain)	• difficulty breathing • build-up of fluid around the lungs • wound healing problems

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

A PET scan may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort, or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

Although every effort will be made to keep **study data** safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study. Physical

copies of data will be stored in an MD Anderson-approved long-term off-site storage center, and electronic data will be kept indefinitely on MD Anderson services behind an institutional firewall. Your study data and paper records will not be destroyed; they will be kept permanently.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: If you can become pregnant or father a child, you must use acceptable methods of birth control while taking the study drug. Acceptable methods of birth control include birth control pills, implants or injections or a double barrier method (diaphragm plus condom, for example). Talk to the study doctor for more details or if you have any questions about acceptable methods of birth control.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell the study doctor right away.

Getting pregnant will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Brian D. Badgwell, at 713-792-6940) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. You may be removed from this study if you are unable to follow study directions or the study is closed or if the study doctor thinks the study cannot help your disease.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Samples
Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research
Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurers or health plan administrators from requesting or requiring genetic information of you or your family members or using such information for decisions regarding your eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments. Please contact the study doctor if you would like more information about GINA and how it protects you from genetic discrimination.

Outside Care

Part of your care may be provided outside of MD Anderson by your home doctor(s).

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

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

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2019-0784**.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION