PRINCIPAL INVESTIGATOR: Jeremy L. Davis, MD

STUDY TITLE: Phase II Trial of Heated Intraperitoneal Chemotherapy and Gastrectomy for Gastric Cancer with Positive Peritoneal Cytology

STUDY SITE: NIH Clinical Center

Cohort: Standard

Consent Version: 01/12/2022

WHO DO YOU CONTACT ABOUT THIS STUDY?

Jeremy L. Davis, MD, by phone at 240-858-3731 or email at jeremy.davis@nih.gov

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

Gastric cancer is the third most common type of cancer; few patients diagnosed with this disease live beyond 5 years after being diagnosed. The standard treatment for gastric cancer is a combination of chemotherapy drugs. At the NIH Clinical Center, we have treated patients with other types of cancer including gastric cancer, cancer of the appendix, and other gastrointestinal cancers whose tumors have spread throughout their abdomen with aggressive surgical removal of their tumors followed by heated chemotherapy called HIPEC (heated intraperitoneal peritoneal

chemotherapy) with good results. Cisplatin and mitomycin-C, the chemotherapy drugs used on this study are approved by the FDA for cancers other than gastric cancers; however, there is strong evidence that they are effective in the treatment of gastric cancers. We think that this type of treatment may help patients with gastric cancers. In this study, we would like to determine if surgical removal of the gastric cancer plus heated chemotherapy can improve survival in patients with gastric cancers.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this study because you have been diagnosed with gastric cancer and although your tumor has spread throughout your abdomen, we think that we will be able to remove some or potentially most of the tumors with an operation. Standard chemotherapy usually does not prevent tumors like yours from growing following surgery, but we think that giving heated chemotherapy directly into your abdomen may prevent or increase the length of time that it takes for the tumors to grow back.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 40 people will take part in this study.

DESCRIPTION OF RESEARCH STUDY

Stage	Timeframe	Location	Events
Evaluations before you receive any study therapy	1-8 weeks	Inpatient and out patient	Evaluation of your medical records, scans, and/or tissue from previous surgeries you may have had to determine if you are eligible for this study, other medically indicated tests as needed, CT or PET/CT, and completion of Quality of Life research questionnaire
Surgery, HIPEC and recovery	4-12 weeks	In-patient, ICU and out-patient	Number of days in the hospital and length of recovery will depend on the size and location of your tumors. During this time routine post-op care such will be done if your doctor thinks you need them
Follow up	At 1 and 3 months after your surgery, then every 3 months until 2 years after your surgery, then every 6 months for 3 years, then every year thereafter	NIH Clinical Center as possible	Physician visits for medical follow up examinations, to include medically indicated tests as needed, CT or PET/CT (starting at 3 months post-surgery), and completion of Quality of Life research questionnaire (for the first 2 years only)

WHAT WILL HAPPEN IF YOU TAKE PART IN THIS RESEARCH STUDY?

Before you begin the study

You will have several tests performed in order to determine whether you meet the criteria to participate in this study and to be certain it is safe for you to have the operation and the HIPEC. We will ask you questions about your medical history and may ask about the medical history of your family members. We will ask to review your medical records, and will perform a physical exam, EKG, routine blood tests (a few tablespoons), and a CT or PET/CT scan to examine your chest, abdomen, pelvis. (Your study doctor will let you know if you need MRI scans instead.) We will also request a tissue sample from your tumor if it is available from a previous surgery to confirm your diagnosis.

A pregnancy test (urine or blood sample) will also be performed if you are a female who is capable of having children.

You will also be asked to co-enroll on the Surgical Oncology Program's tissue collection protocol 13C0176 ("Tumor, Normal Tissue and Specimens from Patients Undergoing Evaluation or Surgical Resection of Solid Tumors") so that any remaining tumor samples from your surgery and the blood or urine collected as a part of this study can be used for future research purposes. Usually, when cancer tissue is removed, very small amounts of nearby normal tissue are also removed. If there is normal tissue left over from the removal of your cancer during surgery, we would also like to receive some of this tissue for research. The surgical removal of your visible cancer tumors is not part of this research study and will only be done to treat your disease.

During this study we may collect information from your medical records including your age, diagnosis, disease history, clinical lab and imaging results, medical treatments, and response to treatments for research purposes.

You will be removed from the study if you are found to be not eligible.

During the study

If you are eligible for the study and agree to participate, you will be asked for a CT or PET/CT scan to measure your disease pre-treatment for our research. You will be asked to complete a Quality of Life questionnaire assessing your general well-being and function for research purposes during your pre-treatment evaluation. It will take about 30 minutes to complete and will only be done if you can complete the survey in English.

If you are a female who is capable of having children, a pregnancy test (blood sample) will be performed prior to your surgery.

Surgery

Once you have completed all the testing and your physician has reviewed the results to determine that this procedure is safe for you, you will be admitted to the hospital. Most patients are admitted 1-2 days before their operation. Your physician will explain the surgical procedure and HIPEC and will answer any questions you may have. You will be asked to sign a separate consent for the operation.

You will undergo a major surgical operation to remove as many of your visible cancer tumors as possible. At the end of the surgical procedure, while still in the OR (and under general anesthesia) you will receive HIPEC cisplatin and mitomycin C. Following the procedure, you will likely remain in the hospital for 7-21 days and will then be seen in clinic at one month and then at 3-months post-surgery until fully recovered.

If your surgeon cannot remove the majority of your tumors or if the surgeon considers it unsafe, you will not receive the HIPEC.

HIPEC

Two catheters (or thin tubes) will be put in your abdomen. The cisplatin and mitomycin C will be given to you through one catheter in your abdomen and drained out through another, bathing the inside of your abdomen with cisplatin. This chemotherapy solution will be washed through your abdomen over 60 minutes at a temperature a few degrees above your normal body temperature. After your abdomen has been bathed for 60 minutes, the chemotherapy will be rinsed out and the catheters will be removed. During this procedure, we will carefully monitor your temperature. If your body temperature goes up during the procedure, we will use cooling blankets and ice packs to keep your body temperature normal.

In order to reduce the risk of side effects (especially kidney damage), from any of the cisplatin that may leak into your bloodstream while it is in your abdomen, a third medicine called sodium thiosulfate will be given to you through your vein during the HIPEC treatment. Sodium thiosulfate binds to cisplatin in the blood and makes it less harmful.

Recovery

After the operation, you will be admitted to the Intensive Care Unit (ICU) where you will be monitored closely for 1-4 days. As with any major operation, you may have a breathing tube and be connected to a breathing machine for 1-2 days following the operation. You will have a tube in your stomach, a catheter (tube) in your bladder and several IVs during this period. As soon as you are able, you will be helped to get out of bed, to cough and take deep breaths and to walk. Once your bowel function has returned to normal, you will be allowed to eat – this usually takes 5-7 days.

When your condition is stable, you will be transferred to the regular patient care unit until you are ready to be discharged to home, usually 7-21 days following the operation. Throughout your hospitalization, you will receive pain medications, IV fluids, antibiotics, and blood transfusions as necessary.

Follow Up

You will be asked to return to the NIH Clinical Center for follow up examinations after a month and then examinations and CT or PET/CT scan about every 3 months for the first 2 years, every 6 months for the next 3 years, and then every year after that.

If you are not able to come to the NIH Clinical Center for your follow up visit, we will contact you by phone, videocall or other NIH approved remote platforms, or e-mail and may ask that you send copies of your scans, lab works and physician notes to us.

In certain cases, such as if your disease worsens after this therapy, we may ask that your follow up examinations start being every year (1 visit each year) earlier than indicated above.

We will also ask you to complete the Quality of Life questionnaire during your follow up examinations, about every 3 months for the first 2 years. It will take about 30 minutes to complete and will only be done if you can complete the survey in English.

BIRTH CONTROL

If you are a woman who is breast feeding or pregnant, you may not take part in the study because some of the medications used in this study may harm your unborn child. If you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you will need to practice two effective forms of birth control before starting study treatment, during study treatment (HIPEC and gastrectomy). If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Effective forms of birth control include:

- abstinence
- intrauterine device (IUD)
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

RISKS OR DISCOMFORTS OF PARTICIPATION

Surgery Risks

The operation to remove the tumors throughout your abdomen is likely to be quite extensive and will include HIPEC as well. The risks from these operations, HIPEC and general anesthesia include:

Likely side effects:

- Pain
- Temporary slowing or stopping of bowel function, known as an ileus. This could take several days to resolve and may require that the tube in your nose that drains your stomach stay in place longer.
- This surgery may also cause changes in your bowel pattern, either constipation or diarrhea. Fluid may develop in your abdomen, known as ascites. This may go away on its own, or may need to be drained if it becomes too uncomfortable.

Less likely side effects:

- Leakage of bowel contents may occur from an area where the bowel was sewn together or from any area of your bowel due to the effects of the chemotherapy, the increased temperature during HIPEC, or from the surgery itself. This may cause an infection in your abdomen that may be life threatening and may require an additional operation to repair the leak. Rarely this will cause openings to form from the bowel through the skin or into the abdomen (fistulas) that may require you to stay in the hospital longer, may require antibiotics, or require a second operation to repair.

- The chemotherapy in your abdomen may also cause irritation to structures surrounding the abdomen, particularly the lining of your lungs. This irritation may result in a condition called "pleural effusion" which means that the lung lining is irritated. This may cause pain and some fluid may collect between the lining and the lung. The fluid usually resolves by itself, but on occasion it may need to be drained with a needle and syringe, if it is causing difficulty breathing.
- Bleeding which might require transfusions or a second operation to correct.
- Blood clots that have the risk of moving to the lungs causing difficulty breathing.
- Infection in the abdomen, where the incision was made, or in the lungs (pneumonia). All types of infections would be treated with antibiotics.
- Breathing problems which may require oxygen or rarely reinsertion of the breathing tube and breathing machine for a few days.
- Slow and complicated wound healing which may require additional procedures and hospitalization.

Rare but Serious side effects:

- Heart failure, lung failure, kidney failure, liver failure, blood clots in your extremities or lungs and stroke. This may require treatment in the ICU including need for a breathing machine, dialysis, and blood pressure medications.
- Damage to the various organs of your body which may cause your death.

Medication Risks

Cisplatin

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, more than 20 and up to 100 may have:
• Nausea, vomiting, • Infection, especially when white blood cell count is low • Anemia which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Kidney damage which may cause swelling, may require dialysis • Hearing loss including ringing in ears

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, from 4 to 20 may have:
• Hair loss • Change in taste • Diarrhea • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, from 4 to 20 may have:
• Confusion • Difficulty with balance • Numbness and tingling of the arms and legs • Blurred vision or changes in ability to see colors (especially blue or yellow)

RARE, AND SERIOUS In 100 people receiving Cisplatin, 3 or fewer may have:
• Cancer of bone marrow caused by chemotherapy later in life • Seizure

Mitomycin

COMMON, SOME MAY BE SERIOUS In 100 people receiving Mitomycin, more than 20 and up to 100 may have:
• Infection, particularly when white blood cell counts are low • Anemia which might require blood transfusion • Bruising, bleeding • Tiredness • Swelling of the body • Difficult, painful or frequent urination (when the drug is administered into the bladder) • Blood clot

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Mitomycin, from 4 to 20 may have:
• Loss of appetite • Nausea, vomiting • Sores in the mouth • Rash • Hair loss • Loss of fertility • Swelling and redness at the site of the medication injection • Fever • Anemia, kidney problems which may cause tiredness, bruising, swelling, or may require dialysis

RARE, AND SERIOUS In 100 people receiving Mitomycin, 3 or fewer may have:
• Shortness of breath, cough, scarring of the lungs • Kidney failure that could require treatment with dialysis

Sodium thiosulfate

The medical literature has reported the following adverse events in association with sodium thiosulfate administration.

- **Cardiovascular system**: hypotension
- **Central nervous system**: headache, disorientation
- **Gastrointestinal system**: nausea, vomiting
- **Hematological**: prolonged bleeding time
- **Body as a Whole**: salty taste in mouth, warm sensation over body

Research Procedure Risks

Blood Draw

There is the risk of slight pain, bruising or infection when your blood is drawn. Drawing blood may *cause* some people to faint.

Urine Collection

There are no physical risks associated with urine collection.

Questionnaire

The questionnaire may contain questions that are sensitive in nature. You are asked to only answer questions that you are comfortable with.

Electrocardiogram (EKG)

Some skin irritation can occur where the ECG electrodes are placed. Once the electrodes are placed and the test has begun, it is completely painless, and generally takes less than a minute to perform. After the test, the electrodes are removed.

Tumor Biopsy

The likely side effects include discomfort or pain, redness, swelling, and/or bruising at the site of the needle insertion. Bleeding from the site of the needle insertion is a less likely risk. Rarely, significant infection or bleeding from this procedure, allergic reaction to the anesthetic, or formation of a scar at the site of needle entry occurs. If you will have sedation with the procedure, these risks will be discussed with you prior to the procedure. You will be asked to sign a separate consent form prior to any biopsy procedure.

Scans and Contrast

CT, PET/CT and MRI scans are common standard imaging tests used in the diagnosis of cancer. The most common discomfort is the length of time a patient must lay still during a scan. Occasionally, a patient may become uncomfortable with the closed space of the machines, particularly the MRI. If this occurs, your doctor can order a medicine to help you relax during this scan. If a contrast agent (the special dye) is given with the scan there is a small risk of having a reaction to the contrast. In that small group of patients who have a reaction, the most common symptoms are nausea, pain in the vein where the contrast was given, a metallic or bitter taste in the mouth, and a warm or flushing feeling that lasts from 1-3 minutes. Rarely do these symptoms require any treatment. In very rare cases, people have had severe reactions that affect their breathing and heart rhythm. If you have had a reaction in the past, be sure to tell you doctor or nurse about it.

An IV line may need to be inserted for administration of the contrast agent or anesthetic. This can cause pain at the site where the IV is placed and carries a small risk of bruising or infection.

Patients with a cardiac pacemaker, neural pacemaker, some types of surgical clips, cochlear implants, foreign metal objects, permanent retainers, or any iron-containing material within the body should not undergo MRI, because of the effect of the strong magnet on these objects.

Risks of gadolinium during MRI:

Mild symptoms from gadolinium infusion occur in fewer than 1% of those who receive it and usually go away quickly. Mild symptoms may include coldness in the arm during the injection, a metallic taste, headache, and nausea. In an extremely small number, fewer than one in 300,000 people, more severe symptoms have been reported including shortness of breath, wheezing, hives, and lowering of blood pressure. You should not receive gadolinium if you previously had an allergic reaction to it. You will be asked about such allergic reactions before gadolinium is given.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis" which has resulted in a very small number of deaths. A blood test of your kidney function may be done within the month before an MRI scan with gadolinium contrast. You will not receive gadolinium for a research MRI scan if your kidney function is not normal or if you received gadolinium within the previous month.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA recently issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The effects of the retained gadolinium are not clear. At this time, retained gadolinium has not been linked to health risks in people whose kidneys work well. Some types of gadolinium contrast drugs are less likely to remain than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain, whenever possible. We will also give you additional information called a "Medication Guide." Upon request, we will give you individual information about retained gadolinium we see on your studies.

What are the risks of radiation from being in the study?

During your participation in this research study, you may be exposed to radiation from up to 6 CT or PET/CT scans, as well as a potential CT-guided biopsy, during your first year on study. The

amount of radiation exposure from these procedures is equal to approximately 8.0 rem. A rem is a unit of absorbed radiation.

Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. The average person in the United States receives a radiation exposure of 0.3 rem per year from these sources. This type of radiation is called "background radiation." This study will expose you to more radiation than you get from everyday background radiation. No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The CT or PET/CT scans that you get in this study will expose you to roughly the same amount of radiation as 26.7 years' worth of background radiation. Being exposed to too much radiation can cause harmful side effects such as an increase in the risk of cancer. The risk depends on how much radiation you are exposed to. Please be aware that about 40 out of 100 people (40%) will get cancer during their lifetime, and 20 out of 100 (20%) will die from cancer. The risk of getting cancer from the radiation exposure in this study is 0.8 out of 100 (0.8%) and of getting a fatal cancer is 0.4 out of 100 (0.4%).

You may not participate in this study if you are pregnant. If you are able to become pregnant, we will perform a pregnancy test before exposing you to radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

POTENTIAL BENEFITS OF PARTICIPATION

Are there benefits to taking part in this study?

The aim of this study is to see if this experimental treatment will make persons with your disease live longer. We do not know if you will receive personal, medical benefit from taking part in this study. These potential benefits could include shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the cancer. Because there is not much information about the treatment's effect on your cancer, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have cancer.

ALTERNATIVE APPROACHES OR TREATMENTS

What other choices do I have if I do not take part in this study?

Instead of being in this study, you have these options**:**

- Getting treatment or care for your cancer without being in a study.
- Taking part in another study.
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly. Instead, it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

STOPPING THERAPY

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease gets worse during treatment
- if new information shows that another treatment would be better for you

In this case, you will be informed of the reason therapy is being stopped.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. If you withdraw your consent and leave the trial, any samples of yours that have been obtained for the study and stored at the NCI can be destroyed upon request. However, any samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases can**not** be recalled and destroyed.

CONFLICT OF INTEREST

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines but they do not need to report their personal finances to the NIH.

No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.

USE OF SPECIMENS AND DATA FOR FUTURE RESEARCH

Your samples will be stored for future use under the separate specimen collection protocol (13C0176) in which you have agreed to be co-enrolled.

However, to advance science, it is helpful for researchers to share information they get from studying human data. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your data that we collect on this study and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These data will be stripped of identifiers such as name, address or account number, so that they may be used for future research on any topic and shared broadly for research purposes. Your data will be used for research purposes only and will not benefit you. It is also possible that the stored data may never be used. Results of research done on your data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

In addition to the use and sharing of your data described above, we might remove any information from your data that can identify you such as name, address, or medical record number, and then use the data for additional research studies at the NIH or other places. If we do this, we might not contact you to ask your permission or otherwise inform you.

If you do not want your stored data used for future research, please contact us in writing and let us know that you do not want us to use your data. Then your data will not be used for future research. However, it may not be possible to withdraw or delete data once they have been shared with other researchers.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

On this study, the NCI will cover the cost for some of your expenses. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. Someone will work with you to provide more information.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

- If some tests and procedures are performed outside the NIH Clinical Center, you may have to pay for these costs if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the NIH Clinical Center.
- Once you have completed taking part in the study, medical care will no longer be provided by the NIH Clinical Center.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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 PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act

allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Dr. Jeremy Davis, MD, jeremy.davis@nih.gov, 240-858-3731. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.