PRINCIPAL INVESTIGATOR:	Jeremy L. Davis, MD.
STUDY TITLE:	Phase II Randomized Trial of Bethesda Protocol Compared to Cambridge Method for Detection of Early Stage Gastric Cancer in *CDH1* mutation carriers.
STUDY SITE:	NIH Clinical Center
Cohort:	Affected patient
Consent Version:	03/12/2024

WHO DO YOU CONTACT ABOUT THIS STUDY?

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

KEY INFORMATION ABOUT THIS RESEARCH

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). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.

You are being asked to take part in this study because you have a mutation in the *CDH1* gene that is known to lead to gastric (stomach) cancer.

Current guidelines recommend that people with these mutations have regular upper gastrointestinal endoscopies (a procedure using a small tube with a camera at the end that is passed through the throat and into the stomach) with biopsies (approximately 30 small samples of tissue taken from 6 areas of stomach) even if their stomachs appear normal. This approach is called the "Cambridge Method" and is currently the minimum recommended by the International Gastric Linkage Consortium (IGCLC) for patients with this CDH1 mutation to catch early signs of cancer, such as the appearance of tiny cancer cells that signal cancer development. The Cambridge Method detection of signet ring cancer cells ranges from 15-60%, with false negative rates of 37%-84.6%.

In order to improve the ability to catch these early signs of cancer we have developed an investigational method in which 88 small samples of tissue (biopsies) are taken from 22 distinct areas of stomach. We refer to this new, more extensive evaluation of the entire stomach based on stomach anatomy as the "Bethesda Protocol". We believe that using this systematic approach to determine where and how many biopsies to collect during a regular, clinically-necessary endoscopy will be more efficient in catching early signs of cancer than the Cambridge Method. This investigational method will change the number and locations in the stomach that biopsy

tissue samples will be taken compared to current guidelines. No investigational devices or drugs will be used for either method.

The purpose of this study is to compare Cambridge Method and Bethesda Protocol and find out which method is more efficient in catching early signs of cancer. This study will also look at whether the extensive evaluation used in the Bethesda Protocol is more accurate in catching early signs of cancer, and if it will do so more consistently than current guidelines.

If you decide to join this study, here are some of the most important things that you should know that will happen:

- First, we will ask you questions over the telephone or in person about your medical history and review your medical records. If you sign the consent and do not end up meeting the criteria for participation in the study, it may be possible for you to be re-screened.
- If you fit the study requirements and decide to take part, you will be assigned to Group 1 (Bethesda Protocol) or Group 2 (Cambridge Method). You cannot choose the group, because decision will be done randomly (by chance) like flipping a coin.
- In this study we also will use an FDA approved small microscope attached to the endoscope to inspect the stomach lining. This special microscopic endoscopy will be performed in addition to the standard endoscopy in about the first 50 enrolled participants immediately after Bethesda or Cambridge procedure. You cannot choose if this special microscopic endoscopy will be done.
- The entire endoscopy procedure (Bethesda Protocol or Cambridge Method with or without additional microscopic endoscopy) will take an about an hour to an hour and 20 minutes, and will be done under general anesthesia.
- After the procedure, we will keep you for observation in the hospital for a few hours. If you live nearby and have someone to accompany you, you can go home on the same day. Otherwise you may spend the night in the hospital prior to going home.
- As described later in more detail in this consent form, you may have side effects if you take part in this study. Some can be mild or very serious, temporary, long-lasting, or permanent, and may include death. These risks are no different from undergoing standard endoscopies outside of the study. You will be observed to see how you tolerate the procedure. We also may collect samples from you (such as blood, throat swab, saliva, stool samples, stomach tissue and fluid) for clinical and research purposes. Some of the samples are required and some are optional.
- After the study procedure we would like to see you in the NIH Clinical Center 2 weeks later to discuss results of these imaging procedures and check if you had any side effects from the procedure. If you are not able to come, we can do this over the phone. We may also invite you to the Clinical Center about 3 to 6-month intervals over a 12-month period after endoscopy to collect stool samples for research purposes.
- If it is clinically necessary, we may repeat endoscopy at least 6 months, but no greater than 18 months from the date of initial endoscopy. For second endoscopy you will be re-

assigned to Group 1 (Bethesda Protocol) or Group 2 (Cambridge Method) again. You cannot choose the group, because decision will be done randomly (by chance) like flipping a coin.

- Prophylactic gastrectomy (removal of the stomach to prevent development of disease) is not a part of this protocol, but if you choose to have it on another NIH protocol or at your home institution, we would like to see you at the Clinical Center before and about 3, 6 and 12 months after the gastrectomy to undergo additional tests done for research purposes.

This study may benefit you by detection of stomach cancer at its earliest stage so that it can be cured. Even if you do not benefit from this study, the results from our research will help others in the future.

You are free to stop taking part in the trial at any time. If you decide to stop, the study doctor may ask you to agree to certain tests to make sure it is safe for you to stop.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information 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 you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

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?

This is a research study. The purpose of this study is to compare Cambridge Method and Bethesda Protocol and find out which method is more efficient in catching early signs of cancer. This study will also look at whether the extensive evaluation used in the Bethesda Protocol is more accurate in catching early signs of cancer, and if it will do so more consistently than current guidelines.

We are asking you to join this research study because you have a mutation in *CDH1* gene that is known to lead to gastric (stomach) cancer.

Current guidelines recommend that people with these mutations have regular upper gastrointestinal endoscopies (a procedure using a small tube with a camera at the end that is passed through the throat and into the stomach) with biopsies (approximately 30 small samples of tissue taken from 6 areas of stomach) even if their stomachs appear normal. This approach is called the "Cambridge Method" and is currently the minimum recommended by the International Gastric Linkage Consortium (IGCLC) for patients with this CDH1 mutation to catch early signs of cancer, such as the appearance of tiny cancer cells that signal cancer development. The Cambridge Method

detection of signet ring cancer cells ranges from 15-60%, with false negative rates of 37%-84.6%. This is likely due to the limited number and 6-area sampling approach of these gastric biopsies.

In order to improve the ability to catch these early signs of cancer we have developed an investigational method in which 88 small samples of tissue (biopsies) are taken from 22 distinct areas of stomach. We refer to this new, more extensive evaluation of the entire stomach based on stomach anatomy as the "Bethesda Protocol". We believe that using this systematic approach to determine where and how many biopsies to collect during a regular, clinically-necessary endoscopy will be more efficient in catching early signs of cancer than the Cambridge Method. This investigational method will change the number and locations in the stomach that biopsy tissue samples will be taken compared to current guidelines. No investigational devices or drugs will be used for the Bethesda protocol.

WHAT WILL HAPPEN DURING THE STUDY?

Before you begin the study

You will need to have certain tests done in order to determine whether you meet the criteria to participate in this study including confirmation of your gene mutation. We will ask you questions over the telephone or in person about your medical history, current physical status and review your medical records.

During the study

You will be assigned to Group 1 (Bethesda Protocol) or Group 2 (Cambridge Method). You cannot choose the group, because decision will be done randomly (by chance) as flipping a coin.

Endoscopy, a procedure to examine your stomach, will be done under general anesthesia (so that you sleep through the procedure). General anesthesia may be given through an IV (intravenous catheter, a small plastic tube that is put into a vein, usually in your arm), a face mask, or through a tube in your nose or throat. The general anesthesia may make it difficult to think once you wake up after your surgery, but this is temporary. However, because a side effect of general anesthesia is that it may take longer to fully recover then it will feel like at the time, you should plan ahead of time not to make any important decisions for 24 hours after the operation has been completed.

Before imaging, we will do a physical examination, including weight and vital signs. We also will put compression devices to help prevent blood clots in the deep veins of the legs. The devices use cuffs around the legs that fill with air and squeeze your legs.

During endoscopy a lighted tube will be inserted into your mouth and go down to the stomach.

If you are in Group 1, we will look at your stomach with regular device and collect 88 small pieces of tissue (biopsy) from 22 areas of your stomach.

If you are in Group 2, we will look at your stomach with regular device and collect about 30 small samples (biopsy) from 6 areas of your stomach to compare the performance of the microscope in detecting gastric cancer to the technique that biopsies 30 small samples from 6 areas of your stomach.

In addition, about the first 50 enrolled participants immediately after the Bethesda or Cambridge procedure are required to have microscope insertion and collect more small samples. You cannot choose if the microscope insertion will be done during your procedure. Before adding the

microscope, we will inject you intravenously with a contrast agent called fluorescein. We will not use this agent if you are allergic to it.

The entire procedure in Group 1 or 2 will take about an hour to an hour and 20 minutes.

After the procedure, we will keep you for observation in the hospital for a few hours. If you live nearby and have someone to accompany you, you can go home on the same day. Otherwise, you may spend the night in the hospital prior to going home.

If it is clinically necessary, we may repeat endoscopy at least 6 months, but no greater than 18 months from the date of initial endoscopy. For the second endoscopy you will be re-assigned to Group 1 (Bethesda Protocol) or Group 2 (Cambridge Method) and have pre- and post- evaluations exactly as with first procedure.

When you are finished with study intervention

Approximately 14 days after the endoscopy we would like to invite you to the Clinical Center to discuss results of these imaging procedures and check if you had any side effects from the procedure. If you are not able to come, we can do this over the phone. We may also invite you to Clinical Center about 3 to 6-month intervals over a 12-month period after endoscopy to collect stool samples for research purposes.

If you undergo subsequent gastrectomy (removal of the stomach), performed on another protocol or at your home institution, we would like to see you at Clinical Center before and about 3, 6 and 12 months after gastrectomy to undergo additional tests done for research purposes.

Additional research testing

In addition to the procedures described above, we may also collect samples from you and perform tests for purposes of research only.

Gut microbiota

We will analyze genetic profile of gut microbiota (the bacteria that live in your gut) and try to find out how these profiles might be connected to the development of gastric cancer.

To study gut microbiota, we may:

- Review nutritional or dietary supplements, antimicrobial medications, pro- or prebiotics, and laxative agents you have been taken,
- Collect stool samples before your endoscopy and every about 3 to 6 months for up to 12 months after your endoscopy,
- Collect stomach fluid and stomach tissue during endoscopy.

If you decide to have total gastrectomy, we may collect additional stool samples, throat swabs or saliva, and samples of blood (about 1 teaspoon collected each time) before and about 3, 6 and 12 months after gastrectomy.

If you have a second endoscopy, stool samples, stomach fluid and stomach tissue will be collected again.

Questionnaires

We may ask you to complete questionnaires about your diet and the foods you recently ate and drank.

- A questionnaire about what you ate and drank within a 24-hour period – to be done on or about the day after your scheduled stool sample collection, and on the day prior to or about the day after your endoscopy. It will take about 30 minutes to complete each time.
- A questionnaire about what you ate and drank over the past month – to be done prior to or about the day after your scheduled stool sample collection, and within 4 weeks of your endoscopy as instructed by the study team. It will take about 45-60 minutes to complete each time. You may save your answers and then return later to finish this questionnaire if needed.

In some cases, the study team may ask you to complete a questionnaire again during the study visit. This will only be done in cases in which the 24-hour questionnaire was completed on a different day then when the stool sample was able to be collected.

Esophageal motility (Optional)

Esophageal motility refers to contractions occurring in the esophagus, which propel the food you have swallowed forward toward the stomach.

We noticed that sometimes after total gastrectomy some people have problems with the normal function of esophagus. To understand the effects of total gastrectomy on the esophagus, we want to do an esophageal manometry test before endoscopy and approximately 3 and 12 months after gastrectomy if you ever have gastrectomy.

Esophageal manometry is a test to determine how well the muscles of your esophagus work and can help in the evaluation of acid reflux, problems with swallowing, and chest pain that may be coming from the esophagus. This test typically takes 15 to 20 minutes to complete. You will be asked to stop eating or drinking after midnight on the day of the test. Prior to the test, one nostril is numbed using a lubricant. A small, flexible plastic tube, which is connected to a computer, is then passed through the nostril down the back of the throat, and into the esophagus. The esophageal manometry probe contains sensors which will measure muscle contractions of the esophagus and how liquid or viscous materials are propelled through the esophagus during swallowing. You will be asked to swallow small sips of water during the test. Afterwards the flexible tube is removed. No activity restriction or dietary restriction is necessary following this test.

You can participate in this study even if you decide not to undergo this test.

Machine learning

We plan to use images collected during microscope endoscopy performed in the first 50 people for application of artificial intelligence. We would like to essentially teach the computer how to reliably detect gastric cancer through an iterative process. Information from our machine learning research will not be used to diagnose or treat patients on this study.

HOW LONG WILL THE STUDY TAKE?

This study will take approximately 12 months starting from endoscopy procedure.

If you have second endoscopy, we will follow you additionally for about 12 months after second endoscopy.

If you undergo subsequent removal of your stomach, we will follow you for about 12 months after gastrectomy.

Visits will range from 4-8 hours in length.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have up to 350 people take part in this study.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

Risks associated with endoscopy and biopsy:

- discomfort in your throat,
- bleeding,
- perforation,
- infection.

Risks associated with general anesthesia:

- temporary confusion and memory loss,
- dizziness,
- difficulty passing urine,
- bruising or soreness from the IV drip,
- nausea,
- vomiting,
- shivering and feeling cold,
- sore throat,
- heart attack,
- pneumonia,
- stroke

Risks associated with fluorescein (first 50 study participants that have microscope insertion only):

- nausea,
- vomiting,
- headache,
- dizziness,
- fainting,

- low blood pressure

You should tell the doctors or nurses about any discomfort you may have. Care will be taken to avoid any complications

Risks from Blood Collection (only if you have gastrectomy on another protocol)

Side effects of blood draws include pain and bruising in the area where the needle was placed, lightheadedness, and rarely, fainting and infection. When large amounts of blood are collected, low red blood cell count (anemia) can develop.

Risks of Throat Swabs

Throat swab may cause momentary gagging because the back of the throat is a sensitive area, but it shouldn't be painful.

Risks of Saliva Collection

There is no physical risk involved with saliva collection.

Risks from Questionnaires

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

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study.

However, the potential benefit to you could include detection of gastric cancer at its earliest stage so that it can be cured.

Are there any potential benefits to others that might result from the study?

In the future, other people might benefit from this study because what we learn in this study may eventually be used to treat others with your disease.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could get regular endoscopy.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

Results of esophageal motility will be shared with you.

EARLY WITHDRAWAL FROM THE STUDY

Your doctor may decide to interrupt study intervention if you have side effects from the intervention that your doctor thinks are too severe.

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.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved by the study team for use in other studies?

As part of this study, we are obtaining specimens and data from you. We plan to store and use these specimens and data for studies other than the one described in this consent form that are going on right now, as well as studies that may be conducted in the future. The specimens and data will be kept in a way that we will still know that they came from you (i.e., they will be identifiable to us). If we use your identifiable specimens or data for future research, our study will be reviewed and approved by an Institutional Review Board who will make sure that we are protecting your confidentiality. These future studies might help us better understand cancer or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my identifiable specimens and data to be stored and used by the study team for future studies as described above.

Will your specimens or data be shared with other researchers for use in other studies?

We may share your specimens and data with other researchers. The other researchers may be doing studies in similar areas to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or at commercial entities.

If we do share your specimens or data, we will know that the specimens and data came from you. However, the other researchers will not know that they came from you (i.e., they will be de-identified).

I give permission for my **de-identified** specimens and data to be shared with and used by other researchers for future studies.

In some cases, it may help other researchers to know that the specimens or data were collected from you (i.e., they will have your identifiers). If we share your identity with other researchers, their study will be reviewed and approved by an Institutional Review Board who will make sure that the study team is protecting your confidentiality.

I give permission for my **identifiable** specimens and data to be shared with and used by other researchers for future studies.

In addition to the planned use and sharing described above, we might remove any labels from your specimens and data that might identify you (i.e., anonymize them), and use them or share them with other researchers for future studies at the NIH or other places. When we or the other researchers use your anonymized specimens and data for these projects, there will be no way to know that they came from you. We want to make sure that you understand that this is a possibility if you participate in this study. Once we do this, we would not be able to remove your specimens or data from these studies or prevent their use in future studies because we would not be able to tell which specimens or data belong to you.

Can you change your mind about use and sharing for future research?

If you change your mind and do not want us to store and use your specimens and data for future studies, you should contact the study team. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data is already complete, the information from that research may still be used. Also, if the specimens and data have been shared already, it might not be possible to withdraw them.

Will your genomic data be shared outside of this study?

As part of this research study, we will put genomic information of your gut microbiota (the bacteria that live in your gut) in a large database for broad sharing with the research community. These databases are commonly called data repositories. The information in this database will include but is not limited to genetic information, race, ethnicity, and sex. If your information is placed in one of these repositories, it will be labeled with a code (not with your name or other information that could be used to easily identify you), and only qualified researchers will be able to access it. These researchers must receive permission from individuals or committees with the authority to determine whether these researchers can access the data. Before receiving the data, the researchers must promise that they will not attempt to re-identify the subjects whose data they will receive.

Summary information about all of the participants included in this study (including you) is being placed in a database and will be available through open access. That means that researchers and non-researchers will be able to access summary information about all the participants included in the study, or summary information combined from multiple studies, without applying for permission. The risk of anyone identifying you with this information is very low.

How long will your specimens and data be stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely.

Risks of storage and sharing of specimens and data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

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. The amount and form of these payments are determined by the NCI Travel and Lodging Reimbursement Policy. You will be given a summary of the policy which provides 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 intervention will not generally 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.

CONFLICT OF INTEREST(COI)

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 or the guidelines of their home institution, 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.

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

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

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

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: _____.