

PRINCIPAL INVESTIGATOR: Mark Gilbert, M.D.
STUDY TITLE: Phase II Clinical Trial of Marizomib for Recurrent Low-Grade and Anaplastic Supratentorial, Infratentorial and Spinal Cord Ependymoma
STUDY SITE: NIH Clinical Center

Cohort: Affected Patient
Consent Version: 11/02/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Mark Gilbert, M.D.
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Email: mark.gilbert@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?

In this study we will investigate if marizomib can increase the time it takes for your disease to get worse.

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Marizomib is in a class of medications call ‘proteasome inhibitors’ and works by slowing the spread of cancer cells. The proteasome is a part of the cell that is responsible for using proteins. In cancer cells proteasomes destroys “good proteins” responsible for killing cancer cells. Marizomib interacts with proteasomes and prevents them from eliminating proteins that are blocking or inhibiting cancer growth. Marizomib is not approved by the U.S. Food and Drug Administration (FDA) and is experimental.

Ependymomas are classified by location, grade, clinical and molecular features. One of the molecular features is RELA-fusion status of the tumor. It can be positive or negative. We believe that marizomib can be more effective in patients with RELA-fusion positive ependymomas, but we do not know for sure. Considering this, we first will enroll people with RELA-fusion positive ependymomas. If we see that marizomib treatment is effective, we will continue enrollment of people with RELA-fusion negative ependymomas.

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 ependymoma already treated with standard therapies.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up 70 patients will be enrolled on the study, but because not everyone will be eligible, it is expected that 18 with RELA-fusion positive ependymoma will be treated in the first part and approximately 32 participants with RELA-fusion negative ependymoma will be treated in the second part.

DESCRIPTION OF RESEARCH STUDY

Before you begin the study

Before you begin this study, you will need to have the following exams and tests to make sure you are eligible for this study. The exams and tests are part of regular cancer care. If you recently had some of the tests, they may not need to be repeated. You will be removed from the study if you are not eligible.

- A review of any past or current medical conditions, medicines you are taking and cancer history.
- Physical examination, including height, weight, neurologic assessment and vital signs.
- Electrocardiogram (EKG – a record of your heartbeat) to evaluate your heart.
- Review of your symptoms and your ability to perform your normal activities.
- Imaging Assessments – magnetic resonance imaging (MRI) that uses a magnetic field to produce an image of your body.
- Routine blood tests to find out if you are anemic, have low blood counts, and if your liver, kidneys, and other organs are working well;
- Routine urine tests
- Pregnancy test if you are a woman who can have children

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- You will be asked to provide samples of your tumor to confirm your diagnosis. If a tumor sample from a previous surgery/biopsy is not available, we will perform a biopsy (collect a sample of your tumor) to confirm your diagnosis and *RELA* fusion status.
- If you have had prior placement of radioactive seeds or non-surgical radiation therapy, we might need to do a fresh biopsy to confirm that your disease has gotten worse even if you have sample from prior surgery/biopsy.

During the study

Marizomib will be administered to you IV (through an intravenous catheter, a small plastic tube that is put into a vein, usually in your arm) on days 1, 8 and 15 of each cycle (1 Cycle = 4 weeks).

You will continue treatment with marizomib until your disease gets worse, you have unacceptable side effects or you have completed 24 months of study therapy, whichever comes first.

Ongoing Procedures before treatment on the days 1, 8 and 15 of each cycle

- Review of your medications, your symptoms and vital signs
- Routine blood tests to find out if you are anemic, have low blood counts, and if your liver, kidneys, and other organs are working well
- Weight always will be measured on Day 1 and might be measured on Days 8 and 15 if loss or gain is observed during a cycle.

Ongoing Procedures after treatment on the days 1, 8 and 15 of each cycle

- Electrocardiogram (EKG – a record of your heartbeat) to evaluate your heart after drug infusion.

Additional Procedures before treatment on first day of cycles:

- Physical exam and neurologic assessment
- Review of your ability to perform your normal activities
- Blood tests to evaluate if your muscles are damaged
- Pregnancy test if you are a woman who can have children
- Imaging Assessments – MRI of brain or spine– every 8 weeks. If a scan identifies objective response, a confirmatory clinical MRI will be obtained 4-8 weeks following initial documentation of objective response.

Research tests

In addition to the tests that we will conduct to determine whether you are having side effects or if you are responding to the study therapy, we will also collect samples from you for purposes of research only. These studies include:

- Blood samples before initiation of treatment to study if specific markers in your blood can be connected with the outcome of treatment and side effects caused by treatment.

- Collecting of tumor samples from prior surgery/biopsy to study genetic markers of your tumor.
- You will be asked to complete questionnaires to determine your general well-being and function - before start of the treatment and approximately every 8 weeks after that (before imaging studies). It will take you about 5 minutes and will only be done if you can complete the surveys in English.
- Genetic testing – Your tissue samples contain genes, which are made up of DNA (**deoxyribonucleic acid**) which serves as the "instruction book" for the cells that make up our bodies. We will use the tissue samples and blood you provided to learn about how the genes in your tumor compare to genes in normal tissue. Your tissue will help us study how genes might play a role in pancreatic cancer and other diseases. We will not share the results of these research tests with you.

When we are conducting the above genetic tests, it is possible that we could identify changes in other parts of your DNA that are not related to this research. These are known as “incidental medical findings”.

However, the analyses that we perform in our laboratory are for research purposes only; they are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing. Changes that we observe unrelated to our research may or may not be valid. Therefore, we do not plan to inform you of the results of testing on your tissue and blood that is performed in our research lab. However, in the unlikely event that we discover a finding that is believed to be clinically important based on medical standards at the time that we first analyze your results, we will contact you. This could be many years in the future. We will ask you to have an additional tube of blood drawn to verify the findings we have seen in our lab. If the results are verified, you will be re-contacted and offered a referral to a genetic healthcare provider to discuss the results.

When you are finished taking the drugs

About 4 – 5 weeks after you have finished taking the study drugs, you will be asked to return for a safety follow up visit. At this visit, you will be asked questions about your health, get a physical and neurological exam, undergo blood tests and might have an MRI.

If you still have unresolved health issues, caused by study drug, you will be invited to NIH for additional tests and treatment.

If your disease got worse, after the safety visit, we will call or e-mail you approximately once every 6 months to ask about your health and about any other medications you may have taken for your cancer.

If your disease did not get worse, but you finished taking marizomib, we will invite you for imaging studies every 2 months for 1 year; then, every 3 months for 1 year; then, every 4 months for 1 year; then, every 6 months. During these visits you will be asked questions about your health, get a physical and neurological exam and asked to complete questionnaires to determine your general well-being and function. If your disease gets worse, these visits will be canceled. If you are unable to return for these visits, we will obtain the information from you by telephone or e-mail.



BIRTH CONTROL

If you are a woman who is breast feeding or pregnant, you will not take part in the study because we don't know how this medicine would affect your baby or 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 an effective form of birth control before starting study treatment, during study treatment, and for 1 month after the last drug infusion. 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

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss

Marizomib used in this study may affect how different parts of your body work such as your liver, kidneys, heart, blood and brain. The study doctor will be testing your blood and perform neurological exam and will let you know if changes occur that may affect your health.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having any symptoms.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

Late side effects of the investigational agents may affect your ability to tolerate subsequent regimens of standard of care chemotherapy.

Below we show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Risks from study therapy

Marizomib

Common (occurring in more than 10 % of patients)

- Constipation
- Peripheral edema (swelling)
- Muscular Weakness
- Dizziness
- Headache
- Hallucinations
- Difficulty sleeping
- Change of taste
- Fatigue (tiredness)
- Nausea
- Diarrhea
- Vomiting
- Decreased appetite
- Infusion-related pain
- Hypertension (high blood pressure)
- Memory impairment

Occasional, but serious (occurring in less than 10% of patients)

- Confusion
- Seizure
- Difficulty to speak or understand speaking
- Loss of consciousness
- Feeling drunk
- Elevated mood

- Gait imbalance and incoordination
- Difficulty breathing
- Lung infection
- Low blood counts
- Double Vision

Allergic reactions or reactions in the context with the infusions might occur during treatment. In general, these reactions are mild and can be handled with appropriate drugs.

For the prevention of nausea or vomiting you will receive a premedication of ondansetron or prochlorperazine 30-90 minutes before the infusion.

If any of these side effects occur, you must inform your study doctor immediately.

Marizomib may cause psychiatric symptoms in some participants, please call your study doctor if you experience any worrisome change in mood, behavior or thoughts.

Poor fluid intake with vomiting and/or diarrhea may hurt your kidneys, contact your study doctors immediately if this is occurring.

Very important: please, do not drive or operate machinery if you develop central nervous system side effects while receiving marizomib.

Risk from Biopsy

If a tumor sample from a previous surgery/biopsy is not available, we will perform a biopsy (collect a sample of your tumor) to confirm your diagnosis and RELA fusion status.

The biopsy procedure usually causes only brief discomfort at the site from which the biopsy is taken. Rarely, infection or bleeding may occur at the needle site.

Risks for MRI:

People are at risk for injury from the MRI magnet if they have some kinds of metal in their body. It may be unsafe for you to have an MRI scan if you have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metal prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, tattoos, an implanted delivery pump, or shrapnel fragments. Welders and metal workers may have small metal fragments in the eye. You will be screened for these conditions before having any MRI scan. If you have a question about metal in your body, you should inform the staff. You will be asked to complete an MRI screening form before each MRI scan you have.

In addition, all magnetic objects (like watches, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the scanner



is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you should let us know right away.

There are no known long-term risks of MRI scans.

Additional risk for gadolinium enhanced MRI:

Procedure

During part of the MRI you may receive gadolinium, a contrast agent, through an intravenous (iv) catheter. It will be done for medical purposes.

It is not known if MRI with contrast is completely safe for a developing fetus. Therefore, all women of childbearing potential will have a pregnancy test performed no more than 24 hours before each MRI scan with contrast. The scan will not be done if the pregnancy test is positive.

Risks

The risks of an IV catheter include bleeding, infection, or inflammation of the skin and vein with pain and swelling.

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.

Please tell your research team if you have had any MRI scans in the past 12 months. 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.

Risks from Blood Collection

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



Risks from Questionnaires

Questionnaires contain questions that can be sensitive for you to answer.

Privacy Risks:

The following general points are indirectly related to your participation in the research study.

Privacy Risks Associated with Genetic Testing

It may be possible that genetic information from you could be used by law enforcement agencies or other entities to identify you or your blood relatives

Psychological or Social Risks Associated with Return of Incidental or Secondary Findings

As part of the research study, it is possible that you could learn that you have genetic risks for another disease or disability. This may be upsetting and, depending on what you learn, might create a need to make challenging decisions about how to respond.

Although your genomic information is unique to you, you share some genomic similarities with your children, parents, brothers, sisters, and other blood relatives. Therefore, learning your research results could mean something about your family members and might cause you or your family distress. Before joining the study, it may be beneficial to talk with your family members about whether and how they want you to share your results with them.

Protections against misuse of genetic information

This study involves genetic testing on samples. Some genetic information can help predict future health problems of you and your family and this information might be of interest to your employers or insurers. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

POTENTIAL BENEFITS OF PARTICIPATION

Are there benefits to taking part in this study?

The aim of this study is to find out whether the experimental treatment can increase the time it takes for your disease to get worse. We do not know if you will receive personal, medical benefit from taking part in this study. 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 drug'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

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

- Getting standard FDA approved treatment or care for your cancer without being in a study
- Taking part in another study

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- 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 comes back during treatment
- if you need to take medication that is not allowed on the study
- if you become pregnant
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you
- if the investigator decides to end the study

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. However, according to FDA guidelines, information collected on you up to that point may still be provided to Celgene or designated representatives. 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 cannot 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 Protocol Review Guide. You may ask your research team for a copy of the Protocol Review 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.

Members of the research team working on this study may have up to \$15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

The National Institutes of Health and the research team for this study are using therapies developed by Celgene through a joint study with your researchers and the companies. The company also provide financial support for this study.



USE OF SPECIMENS AND DATA FOR FUTURE RESEARCH

To advance science, it is helpful for researchers to share information they get from studying human samples. 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 specimens and data stored in scientific databases to advance science and learn about health and disease.

These specimens and data will be used for future research and shared with other researchers. We will not contact you to ask about each of these future uses. These specimens and 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 specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used. Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

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

Genomic Data Sharing

As part of this research study, we will put your genomic data 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 and ethnicity, and sex. If your individual data are placed in one of these repositories, they will be labeled with a code and not with your name or other information that could be used to easily identify you, and only qualified researchers will be able to access them. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access the data.

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.

NIH policies require that genomic data be placed in a repository for sharing. Therefore, we cannot offer you a choice of whether your data will be shared. If you do not wish to have your data placed in a repository, you should not enroll in this study.



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.

The NCI generally does not cover expenses during screening. If you are scheduled for and begin treatment, 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
- The study Sponsor, Center for Cancer Research, NCI, or their agents
- Qualified representatives from Celgene, the pharmaceutical company who produces marizomib.



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, Mark Gilbert, MD, Telephone: 240-760-6023, Email: mark.gilbert@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

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 to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

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: _____.

