CEDARS-SINAI MEDICAL CENTER

CONSENT FORM FOR RESEARCH

Title: IIT2020-09-YU-BBIST001: PHASE 2 STUDY OF FLUORESCENCE DETECTION OF ADULT PRIMARY CENTRAL NERVOUS SYSTEM TUMORS IN SUBJECTS RECEIVING TOZULERISTIDE AND IMAGED WITH THE CANVAS SYSTEM

STUDY SUPPORT PROVIDED BY: CEDARS-SINAI MEDICAL CENTER, BLAZE BIOSCIENCE, INC. & SYNAPTIVE MEDICAL

PRINCIPAL INVESTIGATOR: JOHN YU, MD

STUDY CONTACT PHONE NUMBER AT CSMC: 310-248-6693

AFTER HOURS CONTACT (24 HOURS): 310-423-7900

This research study is sponsored by Cedars-Sinai Medical Center. Additional study support is provided by Blaze Bioscience, Inc. Blaze Bioscience, Inc. only reimburses Cedars-Sinai Medical Center for the costs associated with running the study; Blaze Bioscience, Inc. is not providing additional compensation to Cedars Sinai Medical Center or the Principal Investigator for their participation in the study.

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1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are doing this study to examine the use of the drug tozuleristide and the Canvas imaging system device during surgical resection of primary central nervous system tumors. We want to know if the use of tozuleristide and the Canvas imaging system may be useful to assist clinical decision-making during surgery. Another purpose of this study is to examine the use of the Modus IR device to detect the drug tozuleristide during and after surgical resection of primary central nervous system tumors.

You are being asked to take part in this research study because you have a primary central nervous system tumor and are planning to undergo surgery to remove the tumor.

The study will enroll up to 55-60 people in total.

This research study is designed to test the investigational use of tozuleristide and the Canvas imaging system. This drug and device have not been approved by the U.S. Food and Drug Administration (FDA).

The U.S. Food and Drug Administration (FDA) cleared the Modus IR device under K231986 to be used with a Synaptive surgical exoscope (Modus X, a high-definition digital imaging system that enables surgeons to see a magnified, three-dimensional (3D) image of the surgical field) with a medical dye to visualize vessels and blood flow before, during, and after neurosurgery, plastic, and

reconstructive surgeries. However, in this study, we are using it differently from what was cleared by the FDA. The Modus IR will be used with the investigational drug, tozuleristide, and this has not been approved by the FDA.

In this study, we want to learn what effects, good or bad, tozuleristide has on people with your condition. We will give tozuleristide to research participants and watch carefully for any side effects. We want to learn whether use of tozuleristide with the Canvas imaging system may be useful to assist clinical decision-making during surgical resection of primary central nervous system tumors. We also want to learn whether the Modus IR device can detect the drug tozuleristide during and after surgical resection.

2. WHAT WILL HAPPEN DURING THE STUDY?

This section provides a general overview of what will happen during your participation in this study. Information included below should be considered along with the flowchart of procedures attached as an Appendix.

The flowchart shows a timeline for research-related or standard of care procedures that are involved in your participation in this study. **Research-related procedures** are those performed solely for the research. They would not be performed if you did not take part in the study. **Standard of care (routine)** procedures would be performed both as part of this study and if you do not participate in this study.

A table describing common medical procedures done solely for the purposes of monitoring and assessing your condition during this study is attached as an Appendix to the end of this consent form. Standard of care procedures that will be repeated or done at greater frequency are listed in the flow chart Appendix.

Overview of study:

If you choose to participate in this study, you will receive one dose of tozuleristide administered through a vein between 1 and 24 hours prior to your planned surgery. Your doctor will use the Canvas imaging system during the surgery and the Modus IR during and after surgery. The Canvas imaging system is a device that attaches to a surgical microscope and is used to detect fluorescence (shining) of the study drug, which helps identify central nervous system (CNS) tumors. Your doctor will obtain 5-6 tissue biopsies during your surgery and up to 5 additional tissue biopsies after surgery when feasible, for research purposes to evaluate the usefulness of tozuleristide and the Canvas imaging system on clinical decision-making during surgery. The Modus IR is a device that attaches to a surgical exoscope and is used to detect fluorescence (shining) of the study drug during and after your surgery (of the biopsied samples), if feasible. Only participants with certain tumor types will receive Modus IR imaging. The Modus IR imaging will add about 5-10 minutes to your surgery.

In order to properly follow the study's protocol (research plan), all participants will receive treatments and procedures that have been pre-determined by the protocol. In effect, the protocol describes which medications or procedures you will receive, rather than those decisions being made by your personal doctor or based on your preference. There may be options available outside of this study that you will not be able to receive while participating in this study. We do not believe you should be at any increased risk due to this limitation.

How long will you be in the study?
We think you will be in this study for about 60 days. The total time includes up to 30 days for screening, 1 day for surgery, and 30 days for follow-up after surgery.

3. WHAT ARE THE POSSIBLE RISKS?

Risks of common medical procedures performed solely for research purposes are described in a table attached to the end of this consent form as an Appendix. Side effects and risks of standard of care procedures are not described in this consent form.

This section describes the possible risks and/or discomforts we anticipate you could experience that are related to the study procedures.

Unknown Risks
There may be other side effects or risks that we cannot predict. Many side effects may go away shortly after the study medication or procedure is stopped. However, in some cases they can be serious, long-lasting, permanent, and/or fatal.

Risks of tozuleristide

As of October 31, 2024, safety data are available for 251 subjects who received tozuleristide in clinical trials. To date, no subject deaths or serious adverse events due to tozuleristide have occurred.

> In the list below, "**Serious**," refers to those side effects that may require hospitalization, may be irreversible, long-term, life-threatening or fatal.

Less Likely, Some May Be Serious (*Occurs in >3% - 20 % of people)*
- Nausea
- Abdominal distension (bloating)
- Abdominal (belly) pain
- Upper abdominal (belly) pain
- Diarrhea or constipation
- Increased frequency of bowel movements
- Vomiting
- Anemia, which may cause tiredness
- Decreased lymphocyte count, which may increase your risk for infections

Rare, Some May Be Serious (*Occurs in 3% or less of people; may require hospitalization or may be irreversible, long-term, life-threatening or fatal***)**
- Headache
- Dysgeusia (change in taste)
- Elevated liver enzymes (an increase in the enzymes alanine aminotransferase (ALT), aspartate aminotransferase (AST), and/or alkaline phosphatase, which may indicate a problem with your liver)
- Hypertension (elevated blood pressure)

- Hypoalbuminemia (low levels of the protein albumin in your blood; symptoms include swelling of the feet or hands, yellowing of the skin or eyes, feelings of weakness or exhaustion, fast heartbeat, vomiting, diarrhea, nausea, or appetite changes)
- Chromaturia (a change in the color of your urine)
- Pruritis (itching)
- Proteinuria (excess protein in your urine, which may cause fluid retention)
- Rash maculo-papular (skin rash)
- Injection site joint pain
- Rash acneiform (acne skin rash)

Risks of Canvas Imaging System Device
To date, there have been no reported adverse device effects or serious adverse device effects related to the Canvas Imaging System used in tozuleristide clinical studies.

Risks of Modus IR Device
To date, there have been no reported adverse device effects or serious adverse device effects related to the use of Modus X or Modus IR in clinical procedures (with over 30,000 total procedures completed to date).

Risks of Biopsy
The type of biopsy you will receive will depend on the type of tumor you have. Please see the separate and attached Appendix detailing the possible risks associated with the biopsy to be performed. Possible side effects from the collection of any tumor biopsies include:

- Pain
- Inflammation
- Bleeding
- Swelling
- Infection
- There is a rare possibility of tumor cells spreading from the tumor into the nearby area

Reproductive and Lactation Risks
Taking part in this research study can affect an unborn baby. Therefore, you should not become pregnant or father a baby while on this study. If you or your partner is capable of becoming pregnant you will need to use birth control for 30 days after surgery. Check with the researcher about approved birth control methods to use while participating in this study.

Women should not breastfeed a baby while on this study.

Unknown Risks to the Developing Embryo or Fetus (an unborn baby)
If you are pregnant, or become pregnant during participation in this research, the study drug and procedures might involve risks to an embryo or fetus, which are currently unknown. It is important that you contact the researcher immediately if you believe you might be pregnant.

Collection of Pregnancy Outcomes
If you become pregnant during the study, we will collect information on the outcome of your pregnancy including spontaneous or voluntary termination, details of the birth, and the presence or absence of any birth defects, abnormalities, or complications, and the health status of your child. By signing this consent, you are agreeing to have this information about you and your child collected

from your medical records in the rare case that you become pregnant during your participation in this research study, however, you are always free to withdraw your consent to participate in any research procedure.

If you are a male participant and your female partner becomes pregnant during the study, we will ask your female partner for consent and authorization to collect information on the outcome of her pregnancy and the status of your child, including spontaneous or voluntary termination, details of the birth, and the presence or absence of any birth defects, abnormalities, or complications. Your partner is free to decline to consent to provide this information. This information will be collected from your female partner's medical records with her permission.

Follow-up Visit for Discontinuing Participants
While you are free to discontinue your participation at any time, we encourage you to complete a Final Study Visit. During this visit, we will conduct tests to collect safety data, and discuss any information that may be important to share with your treating physician.

4. ARE THERE BENEFITS IN TAKING PART IN THE STUDY?

You should not expect to benefit from taking part in this research study.

We hope the information learned from this research study will benefit other individuals with primary central nervous system tumors in the future by helping us to learn whether tozuleristide and the Canvas Imaging System may improve clinical decision-making during surgical resection and whether the Modus IR can detect tozuleristide during and after surgical resection.

5. WILL I BE INFORMED OF RESEARCH RESULTS?

All the research tests done in this study follow standard clinical procedures and are performed in certified clinical labs. These test results may be shared with you and may be placed in your Cedars-Sinai medical record.

Unanticipated Incidental Findings
If, unexpectedly, we find that results of your research procedures could suggest important medical information and we determine there is something you or your doctors can do in response to this finding, we will contact you using the last contact information provided by you. If necessary, we may recommend additional clinical testing to confirm the research finding. The cost of any additional testing and any related treatment will be your responsibility.

6. WHY WOULD MY PARTICIPATION BE STOPPED?

Your participation in this study may be stopped at any time by the researcher or the sponsor without your consent for any reason, including:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- If it is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- You do not follow the study procedures.

You may choose (or you may be required) to withdraw from certain parts of the study, but invited to continue with other parts. For example, you might stop taking a study drug, but continue with follow-up visits or allow us to continue to collect data from your medical records. Separate written consent will be requested if your continued participation will involve procedures not described in this consent form.

7. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary, so you have the right to decline to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing not to participate will not affect the care you receive at Cedars-Sinai Health System.

If you decide not to take part in this study, you have other choices. For example:

- you may choose to be treated following the usual clinical approach (surgical resection without the use of the study drug and device)
- you may choose to take part in a different study at CSMC or elsewhere, if one is available
- you could decide not to be treated.
- you may choose to pursue supportive or palliative care for your condition. Such care is focused on reducing suffering and improving the quality of life of individuals with chronic or life-threatening illnesses. The primary intent of palliative care is not to cure a disease or to prolong life. Palliative therapy is focused primarily on managing symptoms.

The researcher will discuss these options and their risks and benefits with you.

8. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable personal information will not be used. Organizations that may look at and/or copy your medical records for research oversight, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

Attached to this consent form is an “Authorization Form” that outlines with whom your information may be shared for the purposes of this research and under what circumstances.

We might share your information and/or research samples collected in this study with other researchers at Cedars-Sinai, other academic institutions, or third party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

9. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research-related illness or injury?
A research-related injury or illness is a direct result of either the study drug or device. Injury or illness related to your underlying medical condition or activities (such as any treatments provided during this study whether considered standard of care or not) would not be considered research-related. If you are being treated for a research-related injury or illness that is a direct result of either the study drug or device, you will not pay for the costs of your appropriate medical or emergency room care. Cedars-Sinai and company have no plans to pay for losses such as lost wages or pain and suffering. You do not waive any of your legal rights by signing this form.

Cedars-Sinai has no plans to pay for costs associated with the treatment of a injury or illness that is a direct result of a procedure performed only as a part of this study and that is not part of your standard clinical medical treatment. We will make every effort to seek reimbursement from your health plan. However, you will be responsible for any deductibles and copayments required under your health plan and for any claims ultimately denied by your health plan. Financial assistance may be available under Cedars-Sinai's Financial Assistance Program. If you feel that you have had a research-related injury and need financial assistance, please contact the IRB Office at 310-423-3783. You do not waive any of your legal rights by signing this form.

10. FINANCIAL CONSIDERATIONS

Costs of Participation
Please review the attached Appendix flowchart for a listing of items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the study sponsor.

Only items, drugs and services that are reasonable and necessary for your medical care throughout the study will be billed to your insurance. You remain responsible for all deductibles, co-pays, and balances under your health benefit plan. If your insurance company does not pay, you will be billed for those charges. You should check with your health benefit plan if you have questions or concerns about your insurance coverage.

Compensation for Participating
You will not be paid for taking part in this research study.

Financial Interest in the Research
The PI and institution have no potential financial conflict of interest with respect to this study.

11. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

Please contact the investigator listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

12. CONSENT PROVISIONS

If you sign this form below, it means that:

(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received and understand all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights;
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study; and
(8) You have been provided with a copy of the "Experimental Subject's Bill of Rights", if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form and the Experimental Subject's Bill of Rights.

SIGNATURE PAGE

Consent Form for Research and
Authorization for Use and Disclosure of Identifiable Health Information (Research)

SIGNATURE BY THE PARTICIPANT

I hereby agree to participate in the research study described to me during the informed consent process and described in this informed consent form. ***You will be given a signed copy of this form.***

Name of Participant (Print)	Signature	Date Signed

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with this "Authorization for Use and Disclosure of Identifiable Health Information (Research)" form attached as Appendix to this form.*

Name of Participant (Print)	Signature	Date Signed

SIGNATURE BY THE INVESTIGATOR: *I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.*

Name of Investigator (Print)	Signature	Date Signed

SIGNATURE BY THE INTERPRETER/WITNESS

(Signature of an interpreter is only required when a non-English speaking subject is consented with the assistance of an interpreter and an IRB-approved 'short form.' The witness may be any person who is conversant in both English and the language of the Non-English speaking subject, such as the interpreter (the certified hospital interpreter), study staff, a family member, or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.)

Name of Witness (Print)	Signature	Date Signed

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APPENDIX: EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

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AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

- **USE AND DISCLOSURE OF HEALTH INFORMATION**

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "IIT2020-09-YU-BBIST001: PHASE 2 STUDY OF FLUORESCENCE DETECTION OF ADULT PRIMARY CENTRAL NERVOUS SYSTEM TUMORS IN SUBJECTS RECEIVING TOZULERISTIDE AND IMAGED WITH THE CANVAS SYSTEM" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

- ☒ Laboratory tests
- ☒ Pathology reports
- ☒ Imaging reports (e.g., x-rays or scans)
- ☒ Photographs or videos of your image
- ☒ Doctor/clinic records
- ☒ Hospital/medical records
- ☐ Mental health records
- ☐ Billing records
- ☐ Other tests or other types of medical information: N/A

- **WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?**

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, data analysis and use of research results in product development, and payment or reimbursement.

- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai is required by law to protect your private information. However, the recipients described above may re-disclose (or share) your information with other parties unless such sharing is prohibited by law.

- **WHEN WILL MY AUTHORIZATION EXPIRE?**

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

- **REVOKING AUTHORIZATION**

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

- **NOTICE OF RIGHTS AND OTHER INFORMATION**

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. The Research Team may not condition (withhold or refuse) treating you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

APPENDIX: Detailed Description of Common Medical Procedures Performed for Research Purposes and Associated Risks

The procedures listed below are often performed as part of routine care for a person with your condition. They are being repeated or performed more frequently as part of this research. However, the risks associated with each procedure should be comparable to what you would experience even if you were undergoing the procedure outside this research study.

Study Procedure	Related Risks
Blood draw: A needle is placed in the vein in your arm to draw blood	Blood drawing may cause some pain and has a small risk of bleeding, bruising, or infection at the puncture site. There is also a small risk of fainting.
Intravenous (IV) lines: You will receive the study drug or other medications or contrast agent through an intravenous (IV) line. An IV line is a small tube that is attached to a catheter and inserted by needle into a vein usually in your hand or arm. Qualified medical professionals will place IV lines for use in this study.	IV lines are usually safe and well tolerated and complications are rare, but can include phlebitis (swelling of the vein) and infection. The IV may come out accidentally or blood may leak around the line. If the IV is not in the vein, medication or fluid can enter the surrounding soft tissues, and can be associated with swelling, discomfort, bruising and irritation. Rarely, a clot can develop in the IV line itself. If this happens, the staff may remove the old IV line and start a new IV line. There is also a small risk of feeling lightheaded and fainting.
Magnetic Resonance Imaging (MRI): A MRI is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. During the procedure you will lie down in a large donut-like looking magnet and we will ask you to lie still on a table for the duration of the procedure (about 2 hours). You will be able to communicate with researchers all the time and you will have a panic button to use if you want to stop the procedure at any time.	You may feel slightly anxious inside the scanner due to a fear of small, enclosed spaces (claustrophobia). Also, at times, you may hear very loud noises as the MRI machine is taking pictures of your body. You may be given headphones and may request ear plugs if you feel the noise is too loud. At any time, you may ask the technician to stop the exam if you are unable to complete the exam.
Biopsy: A biopsy is the removal of a sample of body tissue for examination under a microscope, by the doctor or scientist, to determine the state of health or disease in the tissue. The type of biopsy you will require is dependent upon the disease/condition for which you are being treated.	There are some risks associated with biopsies. A small amount of bleeding, pain and skin bruising may occur. There is a potential for injury to internal organs from this procedure. These risks will be discussed with you further by the physician doing the biopsy. A separate summary of the risks associated with the type of biopsy you will require is included as an appendix to this consent form. The appendix describes the biopsy procedure and its risks in more detail, specific to the type of biopsy you will have.

	If you have a bleeding tendency, you need to disclose this to the investigator and his or her staff. If you are taking aspirin, you will be advised to temporarily discontinue it. Infection is also a risk. Any additional specific risks will be disclosed prior to any procedure.
Physical Exam: Includes height, weight, and vital signs (heart rate and blood pressure).	There are no physical risks associated with these procedures.
Concomitant Medications: You will be asked about your previous and current medications that you take.	There are no physical risks associated with these procedures.
Medical History Review: You will be asked about your medical and surgical history with attention to your cancer history and underlying conditions.	There are no physical risks associated with this procedure.
Pregnancy Test: If you are a woman who is able to become pregnant, blood/urine samples will also be used to do a pregnancy test	If your test is positive, you will be told and at that point you should discuss options available with your primary physician.
Demographic Information: You will be asked about your age, gender, race, and ethnicity.	There are no physical risks associated with these procedures.

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APPENDIX: CENTRAL NERVOUS SYSTEM TUMOR BIOPSY

INTRODUCTION

This information sheet is provided to you as a supplement to the consent form for a research biopsy presented to you today. This document is intended to summarize the known risks specific to the type of biopsy you will have. This appendix will always be provided together with a consent form, which you will be asked to sign if you agree to undergo a research biopsy. This is meant to describe the biopsy procedure and its risks in more detail, specific to the type of biopsy you will have.

It is important that you understand that the research biopsies are NOT required for your ongoing care.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

The level of risk will depend upon where in your body the biopsy is taken. Central nervous system tumor biopsies are safe procedures. Serious problems from a central nervous system tumor biopsy are not common. Complications are rare but can include:

- Bleeding from the biopsy site. People with bleeding problems or low platelet counts have a higher chance for this.
- Infection at the biopsy site. This is more of a risk in people with weakened immune systems.
- Long-lasting discomfort/bone pain at the biopsy site
- Bruising at the biopsy site
- Complications related to sedation, such as an allergic reaction, nausea or irregular heartbeats.

The specific risks associated with the procedure will be further discussed with the physician who will perform the procedure. Your doctor will provide you with a separate surgical consent form for this hospital procedure. In addition to the risks described above, there may be other discomforts or risks to you which are presently not foreseeable. You should discuss possible risks with your doctor before making a decision to take part in this optional procedure.