

PRINCIPAL INVESTIGATOR: Sadhana Jackson, M.D.

STUDY TITLE: Feasibility of Evaluating Abemaciclib
Neuropharmacokinetics of Diffuse Midline Glioma Using
Intratumoral Microdialysis

STUDY SITE: NIH Clinical Center

Cohort: Standard Affected Subject

Consent Version: 1/27/2026

WHO DO YOU CONTACT ABOUT THIS STUDY?

Sadhana Jackson, MD, by phone at 301-594-7037 or email sadhana.jackson@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.

This is a research study. We are asking you to take part in this study because you have a recurrent high grade glioma (including diffuse midline glioma or DMG). The main purpose of this study is to see if we can measure how much of the anti-cancer drug, abemaciclib (LY2835219) is in your brain tumor and brain fluid after you have taken this drug for a few days. The blood-brain barrier blocks some drugs and chemicals from entering the brain, which may explain why there are currently no drugs that work to shrink high grade gliomas and improve outcomes for patients with high grade gliomas.

Abemaciclib is a drug that blocks a pathway thought to be important for the development and growth of high grade gliomas. Abemaciclib has been tested in adults with cancer in several clinical trials and has been approved by the U.S. Food and Drug Administration (FDA) for use in patients with metastatic breast cancer. Studies in mice have shown that abemaciclib can cross the blood-brain barrier, and abemaciclib is currently being tested in adults and children with brain cancers in different clinical trials. Abemaciclib has not been approved for use in the treatment of high grade gliomas and, therefore its use in this study is investigational.

In this study we are evaluating whether it is safe to measure abemaciclib levels in your brain and in your blood to see if it is safe to do so. In order to measure the amount of abemaciclib in your brain, we will use small tubes called microdialysis catheters. These catheters are put in the brain temporarily at the time of tumor biopsy (a needle with a hollow middle will be inserted to remove a small piece of tissue) or surgical resection. The catheter can be removed easily without more surgery. The use of the microdialysis catheter is an FDA approved method to sample brain

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fluid, however it is not FDA approved to measure abemaciclib levels, and therefore is considered experimental in this study (Investigational Device).

Once the catheter is removed (after about 2 days), your doctor will determine if you may benefit from getting more doses of abemaciclib together with another chemotherapy drug called temozolomide (maintenance therapy). Temozolomide is approved by the FDA for the treatment of a type of high grade gliomas called glioblastoma multiforme, but the combination of abemaciclib with temozolomide has not been approved for use in the treatment of high grade gliomas and therefore the combination in this study is investigational.

Another purposes of the study is to look at your tumor tissue and see if there are mutations (or changes) in your tumor tissue that are associated with targeted therapy drugs in order to recommend other future treatment options based on these findings. The test panel that we will use to look at certain mutations in this study is not approved by the FDA and is considered experimental (Investigational Device).

You will need to enroll on another study we are conducting (*Evaluation and Treatment of Neurosurgical Disorders*). This is required for all patients needing brain surgical care at the NIH. We will also offer you the option to enroll in two additional studies while you are participating in this trial. Your enrollment on these studies is optional and you may choose not to participate in them even if you decide to participate in this study.

The standard treatment for high grade gliomas is radiation therapy. There are also other drugs that may be used to treat your disease, and these can be given by your regular cancer doctor, if you are not in this study. They all work in different ways in the body as compared to abemaciclib, and with different side effects. If you would prefer other drugs or treatments, you should consider not joining this study.

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

- Before you begin the study treatment, we will perform tests to find out whether you are eligible to participate (screening) that will include tests such as: a complete physical examination, standard blood tests, electrocardiogram and echocardiogram to check your heart, and brain imaging with MRI. Some of these may be done on a separate screening protocol before signing the informed consent document for this study.
- You will take abemaciclib by mouth, twice a day for 4 and a half days (9 doses). Your last dose of medicine should be taken the morning of surgery (less than 14 hours from your scheduled surgery). The first dose of abemaciclib will be taken at the Clinical Center at the NIH where you will be monitored for 2 hours to make sure you don't have a bad reaction to the medicine. The rest of the doses can be taken at home.
- You will come to the NIH Clinical Center operating room for surgery. You will get a tumor biopsy or surgical resection of your tumor. Then a microdialysis catheter will be placed in your brain and will remain there for 48 hours (2 days) to collect brain fluid. We will also collect several research blood samples while the microdialysis catheter is in place. You will remain in the Intensive Care Unit (ICU) during this time.
- After 2 days, the catheter will be removed at the bedside (no surgery). After the catheter is removed, you will need to stay at the Clinical Center for at least another day. If you

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are stable enough, you may be moved from the ICU and stay on an inpatient floor during this time.

- Some participants who are not predicted to benefit from continued abemaciclib therapy will work with their home oncologist to direct further care and treatment.
- Some participants will be given maintenance therapy of abemaciclib daily for 28 days and temozolomide daily on Days 1-5 of 28-day cycles. Your doctor will inform you if you will be put on maintenance therapy. You will continue to receive maintenance therapy until your disease gets worse or you have unacceptable side effects.
- Once the catheter is removed (for participants who do not go onto maintenance therapy) or you are taken off maintenance therapy, the study team will maintain contact with you or your home oncologist for long term follow-up by phone every 6 months.
- You may experience side effects from taking part in this study. Some can be mild or very serious, temporary, long-lasting, or permanent, and may include death. Examples of some of the side effects that you may have include: anemia, diarrhea, nausea, tiredness, loss of appetite. Other side effects are described further on in this consent form. It is important that you read these.

Just as we do not know what side effects you might have, we cannot know if you may benefit from taking part in this study. If you do not benefit, this study and the results from our research may 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 interventions in which they would want to participate. 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.

If the individual being asked to participate in this research study is not able to give consent for themselves, you, as the Legally Authorized Representative, will be their decision-maker and you are being asked to give permission for this person to be in this study. For the remainder of this document, the term “you” refers to you as the decision-maker and/or the individual being asked to participate in this research.

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?

We are asking you to take part in this study because you have a recurrent high grade glioma (including diffuse midline glioma or DMG). The main purpose of this study is to see if we can safely measure how much of the anti-cancer drug, abemaciclib (LY2835219) is in your brain tumor after you have taken this drug for a few days.

The blood-brain barrier blocks some drugs and chemicals from entering the brain, which may explain why there are currently no drugs that work to shrink high grade glioma and improve outcomes for patients with high grade gliomas. Radiation therapy is the only therapy that has shown some benefit in treating patients with high grade gliomas like you. Unfortunately these tumors usually return or regrow after radiation therapy.

Abemaciclib is a drug that is classified as a targeted treatment. It is a “cyclin-dependent kinase” inhibitor, which means it blocks a pathway thought to be important for the development and growth of high grade gliomas. Abemaciclib may therefore prevent high grade gliomas from growing, slow down their growth, or possibly shrink them. Abemaciclib has been tested in adults with cancer in several clinical trials and has been approved by the U.S. Food and Drug Administration (FDA) for use in patients with metastatic breast cancer. Studies in mice have shown that abemaciclib can cross the blood-brain barrier, and abemaciclib is currently being tested in adults and children with brain cancers on different clinical trials. Abemaciclib has not been approved for use in the treatment of high grade gliomas and therefore its use in this study is investigational.

A problem when treating diffuse midline glioma tumors with drugs, is that we do not know how much of the drug has gotten through the blood-brain barrier and reached the tumor in order to know if we are treating at the right dose. The amount of drug in the brain can be measured by using small tubes called microdialysis catheters to collect fluid from around the brain and measuring the level of drug in the fluid. These catheters are put in the brain temporarily at the time of tumor biopsy or surgery. They can be removed easily without more surgery. In this study we will try to measure abemaciclib levels in your brain and in your blood, and see if it is safe to do so. We will give you 9 oral (by mouth) doses of abemaciclib, to be taken twice a day (4.5 days of medicine), and then you will come in for surgery to have the catheter placed in your brain (same day as the last dose of medicine). We will use microdialysis catheters to collect brain fluid for two days. Blood samples will also be collected during this time. Please be aware that the microdialysis catheter that will be used in this study to measure abemaciclib levels is considered experimental (Investigational Device) for this type of use. Experimental means that the catheter is not approved by the U. S. Food and Drug Administration (FDA) for this use. The microdialysis catheter is however, an FDA approved method to collect brain fluid. This catheter is already being used in patients who have severe brain trauma from head injuries. The catheter is smaller in size than the standard needle that is used for brain tumor biopsies.

Once the catheter is removed, your doctor will determine if you may benefit from getting more doses of abemaciclib together with another chemotherapy drug called temozolomide (maintenance therapy). Temozolomide is approved by the FDA for the treatment of a type of high grade gliomas called glioblastoma multiforme, but the combination of abemaciclib with temozolomide has not been approved for use in the treatment of high grade gliomas and therefore the combination in this study is investigational. The FDA has given us permission to use these drugs together in this study.

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Other purposes of this study will be to look at your tumor tissue and see if there are mutations (or changes) that are associated with other targeted therapy drugs in order for your home oncologist to recommend other treatments options based on those findings. The test panel that we will use to look at certain mutations in this study is not approved by the FDA and is considered experimental (Investigational Device) and is limited by United States law to experimental use.

You will need to enroll on another study we are conducting (*Evaluation and Treatment of Neurosurgical Disorders*). This is required for all patients needing brain surgical care at the NIH. We will also offer you the option to enroll in two other studies while you are participating in this trial (*Comprehensive Omics Analysis of Pediatric Solid Tumors and Establishment of a Repository for Related Biological Studies*, and *Collection of Blood from Patients with Cancer for Analysis of Genetic Differences in Drug Disposition*). If you decide to join those studies, we will ask you to sign a separate consent for each of those studies. Your enrollment on these studies is optional and you may choose not to participate in them even if you decide to participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Summary

If you decide to take part in this study, you will be asked to:

- Take abemaciclib by mouth, twice a day for 4 and a half days (9 doses). Your last dose of medicine should be taken the morning of surgery (less than 14 hours from your scheduled surgery).
- Abemaciclib should be taken with or without food approximately every 12 hours. You should take abemaciclib at approximately the same time every day, and not more than 2 hours after your scheduled dose.
- The first dose of abemaciclib will be taken at the Clinical Center at the NIH where you will be monitored for 2 hours to make sure you don't have a reaction to the medicine. The rest of the doses can be taken at home.
- Before you start taking any new medicines, including medicines you can buy 'over-the-counter', please talk to the study doctor to make sure they are allowed on this study. You should also avoid grapefruit and grapefruit juice.
- When you come to the NIH Clinical Center, please bring all of your tablet containers (whether they are empty or not) as we will be counting the tablets.
- You will come to the NIH Clinical Center operating room for surgery. You will get a tumor biopsy (a needle with a hollow middle will be inserted to remove a small piece of tissue) or surgical resection (removing part or all of your tumor). Immediately after, the microdialysis catheter will be placed in your brain, and will remain there for 48 hours (2 days) to collect brain fluid, and we will collect several blood samples. You will remain in the Intensive Care Unit (ICU) during this time.
- After the two days, the catheter will be removed at the bedside (no surgery). After the catheter is removed, you will need to stay at the Clinical Center for at least another day. If you are stable enough, you may be moved from the ICU and stay as an inpatient during

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this time. You will be instructed not to restart any therapies until 2-4 weeks after surgical healing.

- If the study team determines that you will benefit from additional treatment with abemaciclib, you will continue to receive additional treatment as part of the study called ‘maintenance therapy’. Some participants will be given maintenance therapy of abemaciclib by mouth twice a day for 28 days, and temozolomide by mouth once a day for 5 days, on days 1-5 of the 28-day cycles.
 - Abemaciclib during maintenance should be taken with or without food approximately every 12 hours. You should take abemaciclib at approximately the same time every day, and not more than 2 hours after your scheduled dose.
 - Temozolomide should be taken with a glass of water on an empty stomach, swallowed whole, not chewed or split open and should be taken at about the same time every day (around every 24 hours).
 - When you come to the clinic at the start of every cycle, the medication bottles for temozolomide and blisterpacks for abemaciclib must be brought with you, to be collected by a staff member. A member of the team will discuss with you any issues that might be barriers to taking your medication.
 - You will continue to take these two medications for as long as your disease does not get worse and you are tolerating the medication. Your study doctor will inform you as to whether you should go on maintenance therapy or not.
- Participants on maintenance therapy will be seen at the NIH clinic as detailed below, and once their disease gets worse and they stop taking the medication, they will still be contacted by the study team for long-term follow-up.
- If the study team determines you will not benefit from additional therapy you will choose to receive additional therapy and care directed by your home oncologist, and results from the study will be shared with your home oncologist.
- Once study therapy has ended, the study team will maintain contact with you or your home oncologist for long term follow-up.

Before you Begin the Study

Before you begin the study therapy, you will have several tests performed to check whether the study is suitable for you. This is called screening. Your doctor will review your medical history and the drugs that you are currently taking as well as the previous treatments of your disease to determine whether you can participate in this study.

Some of these tests or procedures are part of regular care and may be done even if you are not being considered to join the study. If you have had some of these tests or procedures recently, they may or may not have to be repeated. Some of these may be done on a separate screening protocol before signing the informed consent document for this study. The following tests and procedures will be performed prior to starting treatment:

- Medical history: A complete review of your medical history, including obtaining information

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about your diagnosis and previous treatments, and reviewing information about your other conditions. If you have medical records from another clinic or hospital, you will be asked to get copies of these records, or your study doctor may be able to request them on your behalf.

- Physical examination: This will include height, weight, vital signs (temperature, blood pressure, oxygen level in your blood, heart rate, breathing rate), how you function in your daily activities, any current symptoms of your condition and a review of all medications that you take.
- Routine blood (about 1 $\frac{3}{5}$ tablespoons) and urine tests to check:
 - your liver, kidney, and thyroid function, red and white blood cells, platelets, electrolytes and others
 - how well your blood clots
- If you can bear children, a pregnancy test will be done (blood sample of about $\frac{3}{4}$ teaspoon). You will not be able to participate if you are pregnant.
- MRI of your brain
- An electrocardiogram (EKG), and echocardiogram (ECHO) of the heart to check the electrical activity of your heart and to check how well your heart pumps

If the screening tests show that you are not eligible, you will be removed from the study.

Study Treatment

Once the screening process showed that you are eligible to participate in the study, and if you choose to be in it, you may need to have a few additional standard tests completed if not done recently. You will also have additional samples collected for research tests. Similar to the tests done at the beginning of the study, the following study evaluations will be repeated during the study to see how you are doing:

- Your medical history, including previous cancer treatments, any current or previous medications (prescription, supplement, and over-the-counter medicines), will be reviewed- before starting treatment, while you are taking abemaciclib (Day 1-5) and when the catheter is removed (Day 7), and before the start of every cycle during maintenance therapy
- A complete physical examination will be performed that will include your vital signs (blood pressure, pulse, body temperature, and respiratory rate) and recording your height and weight and evaluation of your ability to carry out daily activities (only before starting treatment and when the catheter is removed)- before starting treatment, while you are taking abemaciclib (Day 1-5), while the catheter is in place (Day 5-6) and when the catheter is removed (Day 7). A neurologic exam will be done every few hours while you are in the ICU (Day 5 and 6 while the catheter is in place).
- Routine blood samples will be collected (about 1 $\frac{3}{5}$ tablespoons each time)- before starting treatment, while the catheter is in place (Day 5-6) and when the catheter is removed (Day 7). If you receive maintenance therapy, samples (about 2 teaspoons each time) will also be collected before the start of every cycle and on Day 22 during the first cycle (may need to be repeated weekly). These samples are collected to:

- measure your liver, kidney, and thyroid function, red and white blood cells, platelets, electrolytes and others;
 - measure how well your blood clots
- Routine urine tests will be done- before starting treatment and when the catheter is removed (Day 7).
- If you can bear children, a pregnancy test will be done before starting treatment (blood sample of about $\frac{3}{4}$ teaspoon). You will not be able to participate if you are pregnant or you are nursing because we don't know how this medicine would affect your baby or your unborn child.
- Chest X-ray and an electrocardiogram and echocardiogram (ECHO/EKG) will be done before starting treatment, and if your doctor feels it is needed when the catheter is removed (Day 7) if you have side effects involving your heart
- Brain MRI with contrast will be done to assess sites of your disease- before starting treatment, and if your doctor feels it is needed when the catheter is removed (Day 7), and every 3 cycles during maintenance therapy, if received
- Brain CT without contrast will be done on Day 5 right after the catheter is placed, and if your doctor feels it is needed when the catheter is removed (Day 7)
- Once the catheter has been removed (Day 7) you will be monitored for another day to make sure you are feeling well enough to leave the Clinical Center.

Additional research testing

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.

- Blood samples-
 - To check how much abemaciclib is in your blood (pharmacokinetics -PK studies), blood samples will be collected before your first dose of abemaciclib (about $\frac{2}{3}$ teaspoon), at the time of your last dose pre-surgery (less than 14 hours from time of surgery; about $\frac{2}{3}$ teaspoon), and then at several times while the catheter is in place (Day 5-6; about $5\frac{1}{2}$ teaspoons total). A peripheral intravenous (IV) catheter may be placed in a vein in your hand or arm for these blood draws.
 - Optional - To check how much temozolomide and abemaciclib is in your blood (pharmacokinetics -PK studies), blood samples may be collected on Day 5 of every other cycle during maintenance therapy, if you receive it and agree to this optional blood draw (about $\frac{1}{2}$ tablespoon)
 - To see if there are mutations (or changes) that are associated with other targeted therapy drugs, blood samples will be collected at the time of biopsy (about $\frac{1}{3}$ tablespoon; see details below).

- Tumor biopsy or resection will be performed on the day of surgery- Day 5 before the catheter is placed
- Brain Fluid- samples will be collected continuously while the catheter is in place (Day 5-6).

All of your samples collected for research purposes on this study may be used to look for specific changes in the DNA in tumors that could be used to develop new ways of diagnosing and treating cancer. DNA (also called deoxyribonucleic acid) in the cells carries genetic information and passes it from one generation of cells to the next – like an instruction manual. Normal tissue contains the DNA (instructions) that you were born with, DNA in tumor cells has changed – or mutated – and we think that change in the DNA is what causes tumors to form and to grow.

To look at your DNA, we will use what is called “whole genome sequencing.” This is to do special tests in the lab to look at the entire sequence, or order, of how your DNA is put together. This is what makes you unique.

To determine which parts of the DNA have mutated, we will compare the DNA in your tumor cells to DNA from your normal cells. We will then analyze the results from similar tumors to see if there are any changes in the DNA that are common to a particular type of tumor. To examine the tumor and normal tissue we may use several different techniques depending on the type of tissue we collect. These could include growing cell lines (cells which keep dividing and growing in the laboratory, sometimes for years allowing us to continually study those cells), xenograft studies (placing or growing cells in another animal, such as mice), and looking in detail at the parts of the genes that produce specific proteins.

However, you should know that 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 or testing for routine clinical care. For these reasons, we will not give you the results of the research tests done on your research samples in most cases. There may be exceptions to what we share with you and this is described later in this consent form in the section for “Return of research results.”

When you are finished with the study intervention

When you finish taking the study treatment, we will ask you to come to the clinic or arrange a telehealth call for a follow-up and assessment 30 days after stopping treatment for a safety visit. This visit may include having required blood samples collected for routine analysis (about 1½ tablespoons) and review of your medical history with a physical exam. After that, we may contact you by phone or email periodically (approximately twice a year) to see how you are doing, for the rest of your life.

For participants that do not continue on maintenance therapy, we will ask you to come to the NIH Clinical Center or go to your home cancer doctor clinic for safety follow-up visit around 30 days after the catheter is removed. At the safety visit you will have a review of your medical history, a complete physical exam with evaluation of your ability to carry out daily activities, routine blood and urine tests and a brain MRI only if your doctor feels it is clinically necessary. If you do not continue on maintenance therapy, we will contact you or your doctor for long-term follow-up about every 6 months to see how you are doing for the rest of your life.



For participants that do continue on maintenance therapy, a safety visit will instead be done about 30 days after the last dose of therapy (in-person or tele-health). Then, long-term follow-up will start once you finish maintenance therapy (when your doctor decides you should stop taking medication either because your disease got worse or you had unacceptable side effects) with the study team contacting you or your doctor about every 6 months to see how you are doing for the rest of your life.

HOW LONG WILL THE STUDY TAKE?

The length of the study intervention (treatment and surgery) is about a week long. You will come to the NIH Clinical Center for follow-up around 30 days after the catheter is removed.

If you are put on maintenance therapy after the initial study intervention, treatments cycles are 28-days long and you will continue on treatment until your disease gets worse or you have unacceptable side effects.

Long term follow-up can be done by phone as described above. The study team will continue to follow-up with you indefinitely.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Up to 7 people will receive the study drugs.

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

If you choose to take part in this study, there is a risk that the abemaciclib may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important things to know 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, and some may never go away.
- Some side effects may make it hard for you to have children.
- Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

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- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.”

Abemaciclib Risks

COMMON, SOME MAY BE SERIOUS

In 100 people receiving abemaciclib more than 20 and up to 100 may have:

- Anemia which may require blood transfusion
- Diarrhea, nausea, vomiting
- Tiredness
- Bruising, bleeding
- Loss of appetite

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving abemaciclib , from 4 to 20 may have:

- Belly pain
- Constipation
- Dry mouth
- Sores in the mouth which may cause difficulty swallowing
- Fever
- Weight Loss
- Infection, especially when white blood cell count is low
- Changes in taste
- Headache
- Cough, shortness of breath
- Hair loss

RARE, AND SERIOUS

In 100 people receiving abemaciclib, 3 or fewer may have:

- Heart attack which may cause chest pain
- Liver damage which may cause yellowing of eyes and skin, swelling
- Stroke which may cause paralysis, weakness
- Damage to the lungs which may cause shortness of breath
- Blood clot in artery which may cause swelling, pain, shortness of breath or change of color in extremity
- Blood clot which may cause swelling, pain, shortness of breath

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The following risks have been seen in other studies and may or may not be related to abemaciclib:

- Elevation in kidney function blood test levels (increased creatinine)
- Elevation in liver function blood test levels (increased AST and ALT)

Temozolomide Risks

COMMON, SOME MAY BE SERIOUS

In 100 people receiving temozolomide, more than 20 and up to 100 may have:

- Headache, seizure
- Constipation, nausea, vomiting, diarrhea
- Trouble with memory
- Difficulty sleeping
- Muscle weakness, paralysis, difficulty walking
- Dizziness
- Tiredness
- Hair loss

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving temozolomide, from 4 to 20 may have:

- Infection, especially when white blood cell count is low
- Bruising, bleeding
- Anemia which may cause tiredness, or may require transfusions
- Severe skin rash with blisters and can involve inside of mouth and other parts of the body
- Rash

RARE, AND SERIOUS

In 100 people receiving temozolomide, 3 or fewer may have:

- Cough, damage to the lungs which may cause shortness of breath
- Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require blood transfusions
- Liver damage which may cause yellowing of eyes and skin, swelling
- A new cancer including leukemia resulting from treatment of a prior cancer

Fever has also been seen in other studies and may or may not be related to temozolomide.

Other Study Risks

- Anesthesia: The most common side effects are temporary drowsiness, nausea, and vomiting after recovery from anesthesia. Rare side effects include fluid entering the lungs, extreme changes in body temperature, blood pressure that is too high or too low, changes in heart rate or rhythm, reduced oxygen to the tissues, and allergic reaction. Some of these side effects may be life threatening or lead to life-threatening conditions such as heart attack or stroke. To reduce the risk of fluid entering the lungs, you will not be allowed to

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eat or drink for 8 hours before the procedure, and until you have had enough time to recover after the procedure. Some people may also have a tube inserted into their nose or mouth that connects with the windpipe (trachea) to reduce this risk and to make it easier for a machine. This procedure is associated with a small risk of vocal cord and airway spasms, high blood pressure, damage to teeth and lips, swelling and irritation of the “voice box” (larynx), sore throat, and hoarseness.

- Blood draws: We will collect up to 5 tablespoons of blood on any single timepoint and up to 18 tablespoons of blood throughout any 8-week period of the study. The possible side effects of drawing blood include pain, bleeding, bruising, dizziness, light-headedness, fainting and, on rare occasions, local blood clot formation or infection with redness and irritation of the vein.
- Peripheral IV Catheter: A catheter may be placed in a vein in your hand or arm for blood draws for the 2 days that the catheter is in place. The risks of IV insertion include temporary pain and bleeding or bruising at the site where the IV enters the skin. In placing the IV, there is a small chance of fluid leaking into the tissue surrounding the IV and infection, which may cause some swelling and discomfort. Rarely, the IV site may become infected, which might require treatment with antibiotics.
- ECHO/EKG: These tests involve placing electrodes (small stickers that are attached to wires that go to the machine) on the chest and arms/legs and recording the electrical activity of your heart. If you have a lot of hair on your chest, it may hurt a little bit when they remove these stickers. Other than possibly experiencing some minor skin irritation from the electrodes there are no anticipated risks related to complete the electrocardiogram and/or the echocardiogram.
- Urine collection: There are no risks associated with urine collection
- Microdialysis Catheter: Side effects related to placement of catheter into the tumor include bleeding, seizure, or tissue scarring or infection, which could be severe or even fatal. Side effects related to the sampling while the catheter is in place could include infection, although in other trials infection risk was not increased due to microdialysis sampling.
- Imaging as follows:
 - Brain CT: The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures showing the inside of your body. During the procedure, you will need to lie still on a table inside the CT machine. The table will move you in and out of the machine during the scan and you will be instructed to hold your breath. The scan itself will only take a few minutes to complete, the entire visit will take about 30 minutes. CT scans expose you to radiation; the amount depends on the number of body areas scanned, and is described below.
 - Brain MRI: Magnetic resonance imaging (MRI) uses a strong magnetic field and radio waves to take pictures of the body. We will obtain pictures of your brain this study. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you will lie on a table that can slide in and out of the cylinder. We

will place soft padding or a coil around your head. You will be in the scanner about 45 minutes. You may be asked to lie still for up to 15 minutes at a time. While in the scanner you will hear loud knocking noises, and you will be fitted with earplugs or earmuffs to muffle the sound. You will be able to communicate with the MRI staff at all times during your scan, and you may ask to be moved out of the machine at anytime.

It is very important that you do not move your head or body inside the scanner. We will use padding around your head to help keep it in place. We may place a bar in your mouth to help keep your head still. 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.

○ Gadolinium enhanced MRI scans:

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.

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.

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.

- **Biopsy:** We will obtain a piece of your tumor (biopsy) using a needle. You will be given local anesthesia (numbing medicine) and a sedative prior to the biopsy. The biopsy will be taken through a needle put through the skin into your tumor. The likely side effects include discomfort or pain, redness, swelling, and/or bruising at the site of the needle insertion. Bleeding from the site of the needle insertion is a less likely risk. Rare side effects include brain swelling, seizures, stroke, blood clots, significant infection or bleeding, allergic reaction, or formation of a scar at the site of needle entry. If you will have sedation with the procedure, these risks will be discussed with you prior to the procedure. You will be asked to sign a separate consent form prior to any biopsy procedure. We will take the biopsy right before the catheter is placed, while you are in the OR.
- **Surgical Resection:** If you are eligible and will proceed with surgical resection, a separate consent for this procedure will be done prior to surgery.

What are the risks related to pregnancy?

If you are able to become pregnant, we will ask you to have a pregnancy test before starting this study. You will need to practice an effective form of birth control before starting study treatment, during study treatment, and for and for 3 weeks after the last dose of abemaciclib and 6 months after the last dose of temozolomide. If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to a fetus. You must tell the study doctor if your birth control method fails during the restricted period. If you think or know you have become pregnant during the restricted period, please contact the study team as soon as possible. If you plan to become pregnant in the future, please discuss with the study team how long you need to wait before becoming pregnant after completing the study.

If you are a sexually active person with a partner able to become pregnant, it is important that your partner not become pregnant before starting study treatment, during study treatment, and for and for 3 weeks after the last dose of abemaciclib and 6 months after the last dose of temozolomide. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your partner has become



pregnant during the restricted period, please contact the study team as soon as possible. If you and your partner plan for your partner to become pregnant after the restricted period, please discuss this with the study team.

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

During your participation in this research study, you may be exposed to radiation from 1 chest X-ray and 1 brain CT each year. This is considered a low exposure. The risk of this exposure is too low to be reliably measured.

Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. This type of radiation is called “background radiation”. No one knows for sure whether exposure to these low amounts of radiation is harmful to your body. The radiation you will get by participating in this study is less than the average yearly background radiation in the United States.

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.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study.

We do not know if you will receive personal, medical benefit from taking part in this study. The potential benefits could include shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the cancer.

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

In the future, other people might benefit from this study because the knowledge gained from this study may help others in the future who have cancer

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

- choose to be treated with surgery, radiation therapy, or with drugs already approved by the FDA for your disease
- choose to take part in a different study, if one is available
- choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

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

We will share the results of some of our research with your home oncologist about 4 weeks after your biopsy is taken. This includes genomic testing of tumor tissue and drug studies of brain fluid.

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

These include:

- Changes in genes that are related to diseases other than cancer.
- Changes in genes that are not known to cause any disease. These are known as normal variations.
- Changes in genes that are new and of uncertain clinical importance. This means that we do not know if they could cause or contribute to a disease or if they are normal variations.

Since some of the analyses that we perform in our laboratory are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing, the genetic changes that we find may or may not be valid. Therefore, we do not plan to inform you of all of the genetic 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 believed to be clinically important based on medical standards at the time 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.

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EARLY WITHDRAWAL FROM THE STUDY

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

- if he/she believes that it is in your best interest to stop
- if your disease worsens or comes back during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if you become pregnant
- if the study drugs become unavailable
- if new information shows that another treatment would be better for you
- if you do not follow the study rules
- if the study is stopped for any reason

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

After therapy is stopped, we may see you for a safety visit 30 days after your last dose.

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 Division of Cancer Treatment and Diagnosis (DCTD), Eli Lilly or designated representatives.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA**Will your specimens or data be saved for use in other research studies?**

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding 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 coded specimens and data to be stored and used for future research as described above.

_____ Yes _____ No

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Initials

Initials

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

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials

Initials

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. 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 has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

Will your genomic data be shared outside of this study?

As part of this research study, we will put your genomic information 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.



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

Your specimens and data may be stored by the NIH as long as the study is open. When this study is closed, we may keep the data and any samples that are leftover for future research 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.

PAYMENT**Will you receive any type of payment for taking part in this study?**

You will not receive any payment for taking part in this study.

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

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.

COSTS**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.

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.

The NIH and the research team for this study are using abemaciclib developed by Eli Lilly through a collaboration between your study team and the company. The company also provides financial support for this study.



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

Some of your health information and/or information about your specimen from this study will be kept in a central database for research. Your name or contact information will not be put in the database. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you.

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 National Cancer Institute, Division of Cancer Treatment and Diagnosis (DCTD) or their agent(s)
- Qualified representatives from Eli Lilly, the pharmaceutical company who produces abemaciclib or any drug company supporting the study now or in the future

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 Privacy Act helps keep your NIH medical information confidential. In some cases, it is different from the Certificate. Under 42 U.S.C. § 282, NIH is authorized to collect the data for this study. This data is covered by an NIH Privacy Act System of Records Notices: [09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of Health](#) and [09-25-0099, Clinical Research: Patient Medical Records](#). Sometimes the Privacy Act allows sharing your information without your permission. An example is if Congress requests it.

Information may also be shared for some research. It can be given to some federal and state agencies. It can be used for HIV partner notification, or for infectious disease, abuse, or neglect reports. It may be shared with tumor registries, for quality and medical reviews. It may also be shared if NIH is involved in a lawsuit or event of a suspected or confirmed breach. However, NIH will only release medical record information if allowed by both the Certificate and the Privacy Act.

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, Sadhana Jackson, MD, PhD, sadhana.jackson@nih.gov, 301-594-7037. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.



CONSENT DOCUMENT

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

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

Signature of Research Participant

Print Name of Research Participant

Date

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

Signature of LAR

Print Name of LAR

Date

Investigator:

Signature of Investigator

Print Name of Investigator

Date

Witness should sign below if either:

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

Signature of Witness

Print Name of Witness

Date

NOTE: The witness must be fluent in both the language of the participant and the language of the investigator. The interpreter may also serve as the witness, however the investigator obtaining consent may not serve as the witness. Document the use of an interpreter in the medical or research record. Refer to [Policy 301](#) for details.