

Kansas City Clinical Oncology Program

N0577, Phase III Intergroup Study of Radiotherapy versus Temozolomide alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Co-deleted Anaplastic Glioma

This is an important form. Please read it carefully. It tells you what you need to know about this research study. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about the study and what the risks are. Your signature on this form also means that you want to take part in this study.

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in a research study because you have a newly diagnosed Grade 3 anaplastic oligodendroglioma or anaplastic mixed glioma.

Why is this research study being done?

The research in this study is investigational. This study is being carried out under the sponsorship of the North Central Treatment Group (NCCTG).

This research study is being done in people like you who have a certain type of brain tumor, called "anaplastic glioma." In addition, some of your tumor cells must also be missing parts of chromosomes 1 and 19. These chromosomes are missing parts only in the tumor cells, and are not typically missing in your normal body cells. This type of anaplastic glioma has a more favorable outcome than other types of anaplastic glioma. Standard therapy at this point in time is surgery followed by radiation therapy.

The two main reasons this research study is being done are to see if:

- people have longer survival if they get treatment with the combination of both radiation therapy temozolomide chemotherapy as compared to people who receive treatment with radiation therapy alone.
- people treated with temozolomide therapy alone (no radiation therapy) have a better or worse quality of life and mental function than those patients who are treated with either the combination of radiation therapy and temozolomide or radiation therapy alone. Survival will also be monitored in the people getting temozolomide alone.

There are three possible treatments that you might get while on this study. You will be "randomized" into one of the study groups (radiation therapy alone [Arm A], radiation therapy alone with temozolomide given during and after radiation therapy [Arm B], and temozolomide alone [Arm C]). Randomization means that you are put into a group by chance (as in a roll of the dice). A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. If you are put on this study during the first portion of the trial, you will have a one in three chance of getting any one of these three treatments. Late in the trial, only the first two treatments will be included in the study. If you are put on this study in the later portions of the trial, you will have a 50/50 chance of getting either

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radiation therapy alone or radiation therapy along with temozolomide given during and after the radiation therapy.

How many people will take part in the research study?

About 488 people will take part in this study.

What will happen if I take part in this research study?

Before you begin the study ...

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Medical history
- Complete physical exam
- Neurological history and exam
- Routine blood tests (including pregnancy tests, if necessary)
- Scans of the head with contrast (for tumor measurement)

A portion of your tumor tissue taken at the time of your surgery will be sent to laboratories associated with the North Central Cancer Treatment Group (NCCTG) to be tested for deletion (absence) of portions of chromosome 1p and 19q. You would not be eligible for this particular trial if the portions of both of these chromosomes are not missing.

During the study

You will need these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body.

- Medical history
- Complete physical exam
- Neurological history and exam
- Routine blood tests
- Scans of the head with contrast (for tumor measurement)

If you are in group 1 (Arm A), you will get radiation therapy Monday through Friday for about 6-7 weeks.

If you are in group 2 (Arm B), you will get radiation therapy Monday through Friday as well as daily (7 days a week) temozolomide by mouth for about 6-7 weeks. You will then have a 4-week treatment break. You will then get temozolomide alone week 1 (days 1 through 5) every 28 days for up to one year.

If you are in group 3 (Arm C), you will get temozolomide week 1 (days 1 through 5) every 28 days for up to one year.

The chart below shows what will happen to you. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

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Group 1 (Arm A) - Cycle 1 (no future cycles)

Day(s)	What you do
Within 21 days of starting the study	<ul style="list-style-type: none"> • Medical history • Complete physical exam • Neurological history and exam • Routine blood tests (including pregnancy tests, if necessary and additional blood [about 3 tablespoons] for research purposes if agreed to) • Scans of the head with contrast (for tumor measurement) • Complete patient questionnaires • Brief memory and thinking tests
Monday through Friday for up to 7 weeks	<ul style="list-style-type: none"> • Radiation therapy
Every other week until radiation therapy is completed	<ul style="list-style-type: none"> • Get routine blood tests (can be done weekly if study doctor feels it is needed).
4-6 weeks after radiation therapy is completed	<ul style="list-style-type: none"> • Medical history • Complete physical exam • Neurological physical exam • Routine blood tests • Scans of the head with contrast (for tumor measurement) • Complete patient questionnaires • Brief memory and thinking tests
Observation: After you are done with radiation therapy, the items listed will be done every 12 weeks for up to 2 years from starting the study, then every 6 months thereafter unless your disease gets worse	<ul style="list-style-type: none"> • Medical history • Complete physical exam • Neurological physical exam • Scans of the head with contrast (for tumor measurement) • Routine blood tests if your study doctor thinks they are needed
About every 6 months during the time of observation unless your disease gets worse and at the time your disease gets worse	<ul style="list-style-type: none"> • Complete patient questionnaires • Brief memory and thinking tests

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Group 2 (Arm B) - Cycle 1

Day(s)	What you do
Within 21 days of starting the study	<ul style="list-style-type: none"> • Medical history • Complete physical exam • Neurological history and exam • Routine blood tests (including pregnancy tests, if necessary and additional blood [about 3 tablespoons] for research purposes if agreed to) • Scans of the head with contrast (for tumor measurement) • Complete patient questionnaires • Brief memory and thinking tests
During radiation therapy	<ul style="list-style-type: none"> • Begin radiation therapy on a weekly basis, Monday through Friday, for up to 7 weeks • Begin temozolomide by mouth and continue taking on a daily basis (7 days a week) for up to 7 weeks. Take in the morning with a full glass of water (1 cup) on an empty stomach or one to two hours after food. Because temozolomide can sometimes cause an upset stomach, your study doctors will give you an anti-nausea pill to take before you take your temozolomide. A diary that keeps track of when you take your temozolomide will need to be filled out every day as you take a capsule. Give to the doctor when you see him/her the next time. Temozolomide treatment has been associated with an increased risk of infection, and these types of infections can be prevented with antibiotics (either Bactrim or pentamidine or dapsone). Your doctor will decide with you which medication you will need to take to protect you from these infections.
Every other week until radiation therapy is completed	<ul style="list-style-type: none"> • Get routine blood tests (can be done weekly if study doctor feels it is needed).
4 week rest period	<p>Nothing will need to be done during this time period, however, at the end of the rest period you will do the following:</p> <ul style="list-style-type: none"> • Scans of the head with contrast (for tumor measurement) • Complete patient questionnaires • Brief memory and thinking tests

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Group 2 (Arm B) - All future cycles

Day(s)	What you do
Before each cycle of treatment (Cycles 2-7)	<ul style="list-style-type: none"> • Medical history • Complete physical exam • Neurological history and exam • Routine blood tests
Days 1 through 5 every 28 days for 6 cycles (cycle = 28 days)*	<ul style="list-style-type: none"> • Temozolomide by mouth. Take in the morning with a full glass of water (1 cup) on an empty stomach or one to two hours after food. Because temozolomide can sometimes cause an upset stomach, your study doctors will give you an anti-nausea pill to take before you take your temozolomide. A diary that keeps track of when you take your temozolomide will need to be filled out every day as you take a capsule. Give to the doctor when you see him/her the next time. Temozolomide treatment has been associated with an increased risk of infection, and these types of infections can be prevented with antibiotics (either Bactrim or pentamidine or dapsone). Your doctor will decide with you which medication you will need to take to protect you from these infections.
Every third cycle	<ul style="list-style-type: none"> • Scans of the head with contrast (for tumor measurement)
When all temozolomide treatment has ended, the items listed will be done every 12 weeks for up to 2 years from starting the study, then every 6 months thereafter unless your disease gets worse	<ul style="list-style-type: none"> • Medical history • Complete physical exam • Neurological history and exam • Routine blood tests if your study doctor thinks they are needed • Scans of the head with contrast (for tumor measurement)
About every 6 months following the 10-week time point noted above unless your disease gets worse	<ul style="list-style-type: none"> • Complete patient questionnaires • Brief memory and thinking tests

*Your study doctor might have you keep taking temozolomide for an additional 6 cycles, depending on how well you are doing.

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Group 3 (Arm C) - Cycles 1 -12

Day(s)	What you do
Within 21 days of starting the study	<ul style="list-style-type: none"> • Medical history • Complete physical exam • Neurological history and exam • Routine blood tests (including pregnancy tests, if necessary and additional blood [about 3 tablespoons] for research purposes if agreed to) • Scans of the head with contrast (for tumor measurement) • Complete patient questionnaires
Days 1 through 5 every 28 days for 12 cycles (cycle = 28 days)	<ul style="list-style-type: none"> • Temozolomide by mouth. Take in the morning with a full glass of water (1 cup) on an empty stomach or one to two hours after food. Because temozolomide can sometimes cause an upset stomach, your study doctors will give you an anti-nausea pill to take before you take your temozolomide. A diary that keeps track of when you take your temozolomide will need to be filled out every day as you take a capsule. If you should make a mistake on the diary, draw through the mistake with one line and then sign off with your initials by the correction. Give to the doctor when you see him/her the next time. Temozolomide treatment has been associated with an increased risk of infection, and these types of infections can be prevented with antibiotics (either Bactrim or pentamidine or dapsone). Your doctor will decide with you which medication you will need to take to protect you from these infections.
Every cycle	<ul style="list-style-type: none"> • Medical history • Complete physical exam • Neurological history and exam • Routine blood tests
Every third cycle (before starting Cycles 4, 7 & 10)	<ul style="list-style-type: none"> • Scans of the head with contrast (for tumor measurement)
Before starting Cycle 4, then every 6 months thereafter unless your disease gets worse.	<ul style="list-style-type: none"> • Complete patient questionnaires • Brief memory and thinking tests
When all treatment has ended, the items listed will be done every 12 weeks for up to 2 years from starting the study, then they will be done every 6 months unless your disease gets worse	<ul style="list-style-type: none"> • Medical history • Complete physical exam • Neurological history and exam • Routine blood tests (including pregnancy tests, if necessary and additional blood for research purposes if agreed to) • Scans of the head with contrast (for tumor measurement)

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This study also has laboratory tests that will be done to study small samples of tissue. No additional biopsies will be done to get this tissue.

The tissue will be sent to laboratories associated with NCCTG, where the tests will be done. These tests will be done in order to understand how your cancer responds to treatment. It is hoped that this will help investigators better understand your type of cancer. The results of these tests will not be sent to you or your study doctor and will not be used in planning your care. These tests are for research purposes only and you will not have to pay for them.

Neurocognitive/Quality of Life Study

We want to know your view of how your life has been affected by cancer and its treatment. This “neurocognitive/quality of life function” study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities. You will be asked to participate by having your symptoms, quality of life, and neurocognitive function evaluated.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

You will be asked to complete a brief cognitive evaluation (paper and pencil tasks administered by an examiner) and 1 questionnaire booklet. It takes about 20 minutes to complete the cognitive evaluation and 15 minutes to complete the questionnaire booklet.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

How long will I be in the research study?

You will be in the treatment part of the study for up to 1 to 1½ years, depending on which treatment group you are randomized to. After you are done with your treatment, the study doctor will ask you to visit the office for follow-up exams unless your disease gets worse. We would also like to keep track of your medical condition. Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of the study.

Can I stop being in the research study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the treatment can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the research study?

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You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop treatment. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death. You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to the temozolomide include:

Likely (*events occurring greater than 20% of the time*)

- Nausea (feeling sick to your stomach)
- Vomiting (throwing up)
- Decreased appetite
- Constipation
- Headache
- Fatigue
- Fever
- Hair loss

Less Likely (*events occurring less than or equal to 20% of the time*)

- Fall in the white blood cell counts that leads to a higher risk of infection
- Low number of a particular white blood cell, which is important to the immune system (lymphopenia)
- Fall in the platelet count leading to a higher risk of bleeding
- Fall in the red blood cell count leading to anemia (feeling tired and low energy).
- Sores in the mouth
- Diarrhea
- Pain in the abdomen
- Change in liver function tests (tests that show how the liver is working)
- Rash
- Itchiness
- Lack of interest in or ability to carry out daily activities
- Weakness
- Dizziness
- Confusion
- Blurred vision
- Anxiety
- Depression
- Memory loss
- Muscle or joint pain
- Tingling or burning in your arms or legs
- Shortness of breath
- Cough
- Swelling in your arms or legs
- Increased need to pass urine
- Red scaly patches that affect the skin and joints (psoriasis)

Rare but serious (*events occurring less than 2-3% of the time*)

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- Myelodysplastic syndrome (problem with the bone marrow that causes decreased production of red cells, white cells, or platelets that can sometimes turn into blood cancer)
- Convulsions
- Weakness on one side of your body
- Abnormal coordination
- Paralysis
- Severe skin reaction (rash/flaking or shedding of outer layer of skin)
- Allergic reaction that can include chest pain and tightness, difficulty breathing, feeling hot, flushed and anxious, swelling around the eyes, dizziness, feeling sick to the stomach, a fall in blood pressure, back pain, and numbness and tingling
- Re-activation of hepatitis infection (if you have previously been diagnosed with Hepatitis – a type of infection in the liver)
- A blood disorder in which the body's bone marrow does not make enough new blood cells (aplastic anemia)
- Inflammation of the lungs (pneumonitis)
- Change in kidney function tests (tests that show the kidneys are working)
- Later development of secondary leukemia, lymphoma or other cancers

Risks and side effects related to the radiation therapy include:

Likely (*events occurring greater than 20% of the time*)

- Short-term reddening and drying of the skin, fatigue, and hair loss within treated area

Less Likely (*events occurring less than or equal to 20% of the time*)

- Nausea (feeling sick to your stomach)
- Vomiting (throwing up)
- Headache

Rare but serious

- Seizures
- Coma
- Lower white blood cell and platelet counts raising the risk of infection and bleeding
- Radiation therapy at these dose levels also may cause damage to normal brain, but this is rare.
- Specific effects depend upon the location of the area(s) of damage but may be a decrease in judgment, memory, emotions, vision, hearing, sensation, or ability to control movement.

Reproductive risks: You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breast feed a baby while on this study. It is important you understand that you need to use birth control while on this study and for up to 6 months after you quit taking the study drugs. Check with your health care provider about what kind of birth control methods to use. Some methods might not be approved for use in this study.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the research study?

Taking part in this study may or may not make your health better. We do know that the information from this study will help doctors learn if there is any advantage to give temozolomide with the radiation therapy as compared to just giving the radiation therapy alone. For patients treated on Arm C

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(temozolomide alone), it is possible (although unproven) that there might be benefit from the delay in getting radiation therapy-induced side effects. If you are in Group 3, you will not receive radiation therapy while on this protocol. If your illness worsens while on temozolomide alone, your doctor might determine that you need radiation therapy. If so, you would be taken off of this clinical trial. This information from this study could help future brain tumor patients.

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

You do not have to be in this study to receive treatment for your cancer.

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Getting radiation and temozolomide off study
- Taking part in another study
- Getting no treatment
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Talk to your doctor about your choices before you decide if you will take part in this study.

Will my 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. 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 personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- NCCTG
- EORTC (European Organisation for Research and Treatment of Cancer)
- The Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- Merck, manufacturer of temozolomide
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

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.

What are the costs of taking part in this research study?

You and/or your health plan/ insurance company will need to pay for all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check

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with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

NCCTG will supply the temozolomide at no charge while you are taking part in this study. NCCTG does not cover the cost of getting the temozolomide ready and giving it to you, so you or your insurance company may have to pay for this.

Even though it probably won't happen, it is possible that the manufacturer may not continue to provide the temozolomide to NCCTG for some reason. If this would occur, other possible options are:

- You might be able to get the temozolomide from the manufacturer or your pharmacy but you or your insurance company may have to pay for it.
- If there is no temozolomide available at all, no one will be able to get more and the study would close.

If a problem with getting temozolomide occurs, your study doctor will talk to you about these options.

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

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this website. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What happens if I am injured because I took part in this research study?

It is important that you tell your study doctor, _____ [investigator's name(s)], if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ [telephone number].

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this research study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

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In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the research study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ [name(s)] at _____ [telephone number].

For questions about your rights while taking part in this study, call the Kansas City Clinical Oncology Program Institutional Review Board (a group of people who review the research to protect your rights) at 913-948-5588.

About Using Biological Samples for Research

Additional blood (about 3 tablespoons) will be taken at the time of your routine blood tests. This additional blood will be stored for future research purposes only. The research that may be done with your blood is not designed specifically to help you. It might help people who have cancer and other diseases in the future. Reports about research done with your blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

You can take part in the treatment portion of this study without taking part in this request for additional blood.

Please read the following statements and mark your choice:

I agree that additional blood can be taken at the time of routine blood tests for use in future research.

Yes No Please initial here: _____ Date: _____

We would also like to keep some of the tissue that is left over for future research. If you agree, this left over tissue will be kept and may be used in research to learn more about cancer and other diseases.

The research that may be done with your left over tissue is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your left over tissue will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the left over tissue and blood sample for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your left over tissue and blood can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your left over tissue and/or blood. Then any left over tissue or blood that remains will no longer be used for research.

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In the future, people who do research may need to know more about your health. While NCCTG may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes left over tissue and blood is used for genetic research (about diseases that are passed on in families). Even if your left over tissue and/or blood sample is used for this kind of research, the results will not be put in your health records.

Your left over tissue and blood will be used only for research and will not be sold. The research done with your left over tissue and blood may help to develop new products in the future.

Benefits

The benefits of research using left over tissue and blood include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, check "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at the IRB's phone number.

No matter what you decide to do, it will not affect your care.

1. My left over tissue sample(s) may be kept for use in research to learn about, prevent, or treat cancer.

Yes No Please initial here: _____ Date: _____

2. My blood sample may be kept for use in research to learn about, prevent, or treat cancer.

Yes No Please initial here: _____ Date: _____

3. My left over tissue sample(s) may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes No Please initial here: _____ Date: _____

4. My blood sample may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes No Please initial here: _____ Date: _____

5. My tissue sample(s) may be kept for use in future genetic research.

Yes No Please initial here: _____ Date: _____

6. My blood sample may be kept for use in future genetic research.

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Yes No Please initial here: _____ Date: _____

If you want your sample(s) destroyed at any time, write to the Secretary of the Kansas City Clinical Oncology Program Institutional Review Board at 4121 W 83rd St, Ste 259, Prairie Village, KS 66208. NCCTG has the right to end storage of the sample(s) without telling you.

Outside researchers may one day ask for a part of your sample(s) for studies now or future studies.

How do outside researchers get the sample?

Researchers from universities, hospitals, and other health organizations do research using blood and tissue. They may call NCCTG and ask for samples for their studies. NCCTG looks at the way that these studies will be done, and decides if any of the samples can be used. NCCTG sends the samples and some information about you to the researcher. NCCTG will not send your name, address, phone number, social security number, or any other identifying information to the researcher. If you allow your sample(s) to be given to outside researchers, it will be given to them with a code number. If researchers outside NCCTG use the sample(s) for future research, they will decide if you will be contacted and, if so, they would have to contact the researchers at NCCTG. Then NCCTG will contact the clinic where you registered for this study, who will contact you.

Please read the following statements and mark your choice:

1. I permit NCCTG to give my left over tissue sample(s) to outside researchers:

Yes No Please initial here: _____ Date: _____

2. I permit NCCTG to give my blood sample to outside researcher

Yes No Please initial here: _____ Date: _____

3. I permit NCCTG to contact me in the future to take part in more research

Yes No Please initial here: _____ Date: _____

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:
1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at <http://cancer.gov/>

- For NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials/>
- For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo/>

You will get a copy of this form. If you want more information about this study, ask your study doctor.

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Release

By signing this form you authorize KCCOP to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

You will get a copy of this form. If you want more information about this study, ask your study doctor

Signature

I have been given a copy of all 15 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Printed Participant Name: _____

Participant Signature: _____

Date: _____

Printed name of person obtaining informed consent:

Signature of person obtaining informed consent:

Date _____

Approval Date: 12/15/11 to 9/14/12
Assurance #: FWA00003582