NCI Community Oncology Research Program – Kansas City (NCORP-KC)

N0577 (CODEL): Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade 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 study 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 this research study because you have been newly diagnosed with an anaplastic glioma or low grade glioma, a type of brain tumor. Your tumor has already been tested by your doctors, and has specific changes in the tumor cell DNA. These changes include deletions (missing parts) of chromosomes 1 and 19, also known as '1p/19q codeletion, and mutation (an altered form) of a gene called IDH, which is known as "IDH mutation". Only people specifically with your type of tumor are eligible to take part in this research study.

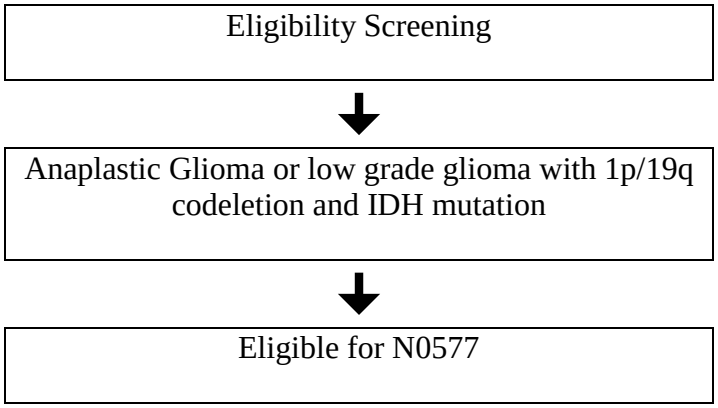
At this time, you are only being asked if you will allow a small piece of tumor tissue that was already obtained during your prior surgery to be tested to confirm diagnosis. If you are interested in taking part in this treatment research study and you are eligible, your study doctor will discuss with you the treatment research study in more detail. You will be given and asked to read a different consent form for further information about the research study at that time.

This consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of the research study, alternatives to participation, and your rights as a research subject. The decision to take part is yours. If you decide to take part, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study.

This consent form provides permission for eligibility testing of your tumor tissue **ONLY**.

Why is this research study being done?

The purpose of this part of the research study is to determine your eligibility for this study, which involves treatment for people with newly diagnosed anaplastic or low grade glioma and codeletions of chromosomes 1p and 19q and IDH mutation.



This study is being conducted by the, ALLIANCE / Alliance for Clinical Trials in Oncology, a national collaboration of researchers and physicians with different types of backgrounds and training who work together to plan and conduct clinical trials in cancer. Members of these organizations come from major academic medical centers, community hospitals and community practice.

How many people will take part in the research study?
About 396 people will take part in N0577.

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

A small piece of tumor tissue that was already obtained during your prior surgery will be examined by an Alliance neuropathologist to confirm the results of your local review and diagnosis of either anaplastic glioma or low grade glioma, and also to review the prior testing reports from the local laboratories showing that the tumor contains 1p/19q codeletion and IDH mutation. This review is mandatory. These slides will be kept by Alliance. No further testing will be done on these slides used for eligibility.

How long will I be in the research study?
You will be in this eligibility study only for the time required to confirm the results of your local laboratory review and diagnosis.

If you are interested in taking part in the treatment research study, your study doctor will discuss with you the treatment research study in more detail. You will be given and asked to read a different consent form for further information about the research study at that time, including information about how long you will be in the research 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 you can discuss what follow-up care and testing could be most beneficial 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?

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.

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 these eligibility studies will help doctors learn more about the radiotherapy and chemotherapy regimens as treatments for cancer.

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
- 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?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- Alliance for Clinical Trials in Oncology (Alliance)
- European Organisation for Research and Treatment of Cancer (EORTC)
- Other organizations from the National Clinical Trials Network that take part in this study
- The Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- 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 not need to pay for any of the testing to confirm the diagnosis for eligibility testing that will be performed for this research study.

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://www.cancer.gov/clinicaltrials/learningabout/payingfor/insurance-coverage. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237).

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.

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 _____ *name of center* Institutional Review Board (a group of people who review the research to protect your rights) at _____ *(telephone number).*

*You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).

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 website 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/
- For NCI's general information about cancer in Spanish, go to http://www.cancer.gov/espanol

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

Release

By signing this form you authorize NCORP-KC 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 5 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 _____