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

CONSENT FORM ADDENDUM

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

You are currently participating in the research study called N0577. The study has undergone some changes to help the researchers learn more from this study. Because you are a participant in this research study, it is very important that you read this.

What has happened?

On December 8, 2017, the study was changed so that new patients who joined the study would be required to submit MRI images as part of their participation on the study. The model consent document was changed to reflect this new approach.

The study researchers would like to collect MRI images from patients who were enrolled on this study before December 8, 2017. Researchers would like to use these scans for a related research study to see whether they can predict how well a patient will do following treatment.

What is involved?

If you decide to take part, your MRI scans will be sent to the central image library, and then sent on to the University of Heidelberg. Any scans that were taken in the past as part of your participation on this study would be sent to the image library. Any scans that you may get in the future as part of your participation on this study would also be sent to the central image library. The scans will be sent to the University of Heidelberg and will be saved so that researchers can look back at these scans after the study is over.

What are benefits to taking part?

You will not benefit from submitting your images to a central image library. The researchers, using images from you and others, might make discoveries that could help people in the future.

What are the possible risks?

There is no radiation associated with an MRI scan which is the standard scanning method for this study. However, if you have a metal device (such as a pacemaker), are not comfortable with close spaces or are unable to lie still comfortably, you may not be able to have an MRI and must have a CT scan instead. Most MRI scanners make loud knocking noises during use; you will be asked to wear earplugs to minimize any discomfort from noise. If you have to have CT scans, you will be exposed to a small amount of radiation. The amount of radiation you will receive has a low risk of harmful effects.

What are the costs?

You and/or your insurance plan will continue to pay for the costs of the MRIs you get as part of the study, just as you would if you were getting the MRI scans as part of your usual care for your glioblastoma.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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
- When your scan or blood samples are sent to the researchers, no information identifying you (such as your name) will be sent. Images and samples will be identified by a unique code only.
- The list that links the unique code to your name will be kept separate from your image, sample and health information. Any Biobank and Imaging Core Laboratory staff with access to the list must sign an agreement to keep your identity confidential.
- Researchers to whom the Imaging Core Laboratory sends your images and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- Information that identifies you will not be given to anyone, unless required by law.
- If research results are published, your name and other personal information will not be used.

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

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 3 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 have my MRI scans sent to an image library and analyzed as part of my participation on this study.

Participant _____

Participant's signature_____

Date of signature_____

Person obtaining consent_____

Signature of person obtaining consent_____

Date of signature_____