BAYLOR SCOTT & WHITE RESEARCH INSTITUTE
Baylor Scott & White Healthcare, 2401 S. 31st Street, Temple, TX 76508

CONSENT FORM AND PRIVACY AUTHORIZATION

PROJECT TITLE: Prognosis and therapeutic biomarkers for glioblastoma patients

PRINCIPAL INVESTIGATOR: Ekokobe Fonkem

TELEPHONE NUMBER: 254-724-7600

Introduction:
Before you say that you will be in this clinical trial (a kind of research study) you need to read this form. It is important for you to understand all the information in this form. This form will tell you what the clinical trial is about and how it will be done. It will tell you about some problems that might happen during the clinical trial. It will also tell you about the good things that might happen for you during the clinical trial. When you read a paper like this to learn about a clinical trial it is called "informed consent." The people who are doing this clinical trial are giving you very important information about the clinical trial. When you give your consent for something, it is the same as giving your permission. This consent form may contain words that you do not understand. Please talk with one of the doctors or their staff if you have questions. Do not sign this consent form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the form to keep.

You are being asked to take part in this study because you have been diagnosed with glioblastoma (GBM).

Why Is This Study Being Done?
This study is looking for markers in body fluids that might be used to diagnose and monitor brain tumors in the future. Having these markers, called "biomarkers," might someday mean that people could have tests of cerebrospinal fluid, blood, or saliva to find out about the disease instead of bigger procedures like surgery. This study will compare levels of biomarkers in the body fluids of people who have a type of brain tumor called glioblastomas with people who do not have brain tumors.

How Many People Will Take Part In The Study?
Thirty people including 20 patients with GBM will take part in this study at Baylor Scott & White Health and 10 people will be used as controls who do not have GBM.

The reason to be selected for this study:
You are over 22 years old without pregnancy, or an infectious disease (cold, flu, HIV, etc.) or a blood disorder (e.g., lack of platelets, anemia, and thrombosis) and diagnosed with GBM.

What Is Involved In The Study?
You will be asked to allow us to use your leftover tumor tissues from surgery for genetic testing (this is optional and you will be asked to allow permission at the end of this consent). You will also be asked for cerebrospinal fluid (CSF), blood, and saliva draws at one week after surgery, 6 weeks after your standard of care combination therapy, and 8 months after Optune or Optune plus TMZ treatments for genetic testing.

CSF is standard of care and a routine test for all GBM patients and we will ask to store the leftover CSF for research. The doctor will discuss with you the choice of treatment options as part of your standard care, as all the treatments are FDA approved standard of care for GBM patients, and you will receive the best option that you and your doctor decide upon. This research study only involves getting your leftover tumor and CSF samples, and then taking saliva (spit) samples and blood samples.

For the saliva and blood collection, you will be asked to come back to the clinic at a later date with nothing to eat or drink except for water for at least 8 hours prior to the visit. The researcher will then collect a blood sample (2 ml of blood or less than half a teaspoon) and a saliva sample (5ml of saliva or a teaspoon) from you. Blood and saliva samples taken from you in this study will be used for analysis of biomarkers at gene or protein levels.

Information will also be collected out of your medical record for this study.

Your Responsibilities as a Research Subject:

Commitment: While you always have the right to change your mind and leave the study, you should enter this study only if you think you will want to be in it until it ends.

Visits: You agree to come for all study visits and to follow the instructions of the research doctor/staff, even if you stop the study medicine. In case it is not possible for you to attend a visit, we will contact you by phone or mail.

Problems: You will let the research doctor/staff know immediately if any problems occur while you are involved in this study. You will also let the research doctor/staff know if you have to go to an emergency room, doctor's office, or a hospital.

Medicines: You will let the research doctor/staff know about any changes in your prescription medicines, over-the-counter medicines, and all vitamins or supplements that you take, and will keep all study medicine and/or supplies out of the reach of others.

Women of child-bearing potential: You will let the research doctor/staff know immediately if you miss a period or think you may be pregnant.

Other studies*:* You will not take part in any other study at the same time you are in this study (unless you are given permission by the PI).

How Long Will I Be In The Study?
You will be in this study for approximately 10 months (over three visits: the first visit is before your standard combination therapy; the second visit will be after 6 weeks of standard treatment; and the third visit will be 8 months after treatment using Optune or Optune plus TMZ as decided by you and your doctor).

The researchers may decide to take you off the study if any of the following occur:

- S/he feels that it is in your medical best interest.
- Your condition worsens.
- You have an infectious disease (flu, HIV, etc.).
- New information becomes available.
- The study is stopped by the sponsor.
- You ask to be withdrawn from the study for any reason.

You can stop taking part in this study at any time. However, if you decide to stop taking part in the study, we encourage you to talk to the researcher and your regular doctor first.

What Are The Risks of The Study?
While on the study, you are at risk for these reactions, sometimes bad, which are listed below. You should discuss these with the researcher and/or your regular doctor. There also may be other reactions that we cannot predict. These unknown reactions could also be a risk to your unborn child if you are become pregnant while on the study. Other medicines may be given to make them less serious and uncomfortable.

Risks of genetic testing: The purpose of having this genetic test is to evaluate some biomarkers in the tumor and cerebrospinal fluid, blood, and saliva from patients, which may help doctor decide which therapy option is best for the future patients with GBM. In this study, only a few genes will be tested and this test will only help your doctor understand certain therapies are better for the patients like you. The results will **NOT** show whether your disease is caused by genetic abnormalities. Thus, you and your family members will not any face problems in obtaining insurance coverage. However, in case there is possible any kind of risk to you or your family members, in order to do everything possible to keep this from happening, the results of this test will **NOT** be given to anyone outside the study staff. This means that these results will not be made available to you, your family members, your private physician, your employer, your insurance company or any other party unless required by law.

Use of Genomic Testing Information: In this study, your samples will only be used for the specific regions related potential biomarkers for glioblastoma; the results from this test will not include the full genomic information about you. This information from this test should **NOT** affect your insurance coverage. Insurance companies in Texas may not use the results of genetic testing to deny anyone insurance coverage, cancel their coverage, or increase their premiums. Even so, to avoid any potential risk, we will do everything possible to make sure that the results of your genomic testing are not given to anyone except the study staff. The results of the testing will not be given to you or your family, will not be placed in your medical record, and will not be given to your private physician, your employer, your insurance company or any other party unless required by law. To further protect against the misuse of this information, your name will be removed from the results before the results are shared with the sponsor of the study.

Risks of genomic testing: If the genomic tests being done in this study show that your disease is caused by genetic abnormalities, your family members could face problems in obtaining

insurance coverage for this disease, even if they have no symptoms. However, in order to do everything possible to keep this from happening, the results of this test will **NOT** be given to anyone outside the study staff. This means that these results will not be made available to you, your family members, your private physician, your employer, your insurance company or any other party unless required by law. If you have additional questions about these risks, ask the researcher.

If you have any questions about these or other risks, please ask the researcher.

Conflict of Interest
Your doctor may be an investigator in this research study. If so, s/he is interested both in your medical care and in the conduct of this research. Before you sign up for this study or at any time during the research, you may discuss your care with another doctor who is not associated with this research project. You are not under any obligation to take part in any research study offered by your doctor.

Are There Benefits to Taking Part in the Study?
If you agree to take part in this study, there will be no direct medical benefit to you. We hope that the information learned from this study will benefit other patients with this disease in the future.

What Other Options Are There?
Instead of being in this study, you have the following options:

- You may choose not to take part in the study.
- You may choose to receive treatments for you GBM without taking part in the study
- You may choose to receive no therapy at this time and receive only care to help you feel more comfortable.

Please talk to your regular doctor about these and other options.

What About Confidentiality?
You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on the study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Scott & White Health (BSWH) and Baylor Scott & White Research Institute (BSWRI) get your permission before giving any of your health information to other people. There are people who need to review your information to make sure the study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to BSWRI to give other people information about your health as needed for the research project. These groups include people who work for BSWRI (including the Institutional Review Board), Baylor Scott and White Health, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. In addition, the

information may be given to the other members at Baylor Scott & White Healthcare who are involved in this study.

Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also be notes written by your doctor from your medical record or notes written by your doctor asking for tests to be done on you. By agreeing to participate in this study, the participants are giving authorization for the research team to use and report the results of treatments, tests and examinations conducted for the purposes of this research and for matters related to study oversight and data analysis.

You do not have to give this permission and it is alright to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for us to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in the research study.

If you give permission to Baylor Scott & White Research Institute to give other people information about your health and the other people are not part of the group that must obey this law, your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 3310 Live Oak, Suite 501, Dallas, TX 75204. Please be sure to tell us the name of the study and Principal Investigator for the study for which you are withdrawing your permission. You should also talk to your PI and make sure they are aware you are withdrawing your permission. If you decide to do this, it will not apply to information that was given before you withdrew your permission and you will no longer be able to take part in the study.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after the study is completed.

Unless permission is withdrawn, this permission will not expire at the end of the study.

What Are the Costs?

Taking part in the study will not lead to added costs to you or your insurance company. Both Optune (the device) and TMZ (the drug) are standard treatment options for patients with GBM and their cost will be covered through your insurance company. Your insurance company may ask us to provide a copy of this consent form. If you have any question about the cost for the trial, please contact Dr. Fonkem.

- The study sponsor will provide the investigational device at no charge. However, you or your insurance company will be required to pay for all expenses related to the implantation procedure and your other hospital care.
- The study sponsor will pay for all costs related to your taking part in this study.

Will I Be Paid For Taking part in This Study?
Your payment will be made by from Baylor Scott & White Research Institute and is considered taxable income. You must be eligible to be paid in the United States and willing to complete all the necessary tax/legal paperwork to receive this payment. You will be paid $25 for each visit for a total of $75.

Tissue, bodily fluids, or blood samples taken from you in this study may be used to establish a cell line that could be patented and licensed. There are no plans to pay you for this or other products should this occur.

What If I am Injured While Taking Part in This Study?
The people doing this research project will do everything they can to make sure you do not get hurt during the project. If you do get hurt, you should tell the researcher or his/her staff and they will help you to get necessary medical care. You or your insurance company may need to pay for the medical care. Baylor Scott and White Health, Baylor Scott and White Research Institute and Scott and White Memorial Hospital have not set funds aside to pay you money if you are hurt. You have not given up any of your legal rights by signing this form.

What are My Rights As a Participant?
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. At certain times during the treatment, it may be unsafe for you to suddenly withdraw, so please be sure to discuss leaving the study with the principal investigator or your regular physician. Deciding not to be in the study, or leaving the study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

All of the people working on the project must be careful not to carelessly harm you. If you are hurt during this project, you have the right to seek legal counsel. Nothing in this consent form takes away that right if you are hurt during this research.

Whom Do I Call If I have Questions or Problems?
If you have concerns, complaints or questions about the study or have a research-related injury, contact the Principal Investigator, Dr. Ekokobe Fonkem, at 254-724-7600, 24 hours a day, seven days a week.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact the IRB Office at 254-771-4854.

Optional Tissue Storage
The investigators for this study would like to use any tumor tissue that may be left over for future research. This tissue will be kept for 10 years for testing and will be labeled with your subject ID when sent over to the lab personnel.

Please indicate your preference regarding the participation in future tissue storage and research by initial one of the boxes below:

☐ I agree that my samples may be stored and used for future research described above.

☐ I do not agree that my samples may be stored and used for future research described above.

Statement of Person Obtaining Consent:

I have explained to _____(printed name of subject) the purpose of the research project, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part.

_____ _____ _____
Signature of Person Obtaining Consent Date Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this research study. You will be asked to give your written consent if you want to be in the study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all the pages in this form. If you cannot read, then someone can read the form to you. Make sure that all your questions about this research project have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ (printed name of person obtaining informed consent) has explained to me the purpose of the research project, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about the research study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I agree to give my consent to take part as a subject in this research project.

_____ _____ _____
Signature of Subject Date Time