UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

If you are the legally authorized representative for the subject, as you read the information in this Consent Form, you should put yourself in the subject's place to decide whether or not to allow us to collect research information about the subject and to allow the subject to take part in this study. Therefore, for the rest of this form, the word "you" refers to the subject (adult participant).

If you are an adult participant reading this form, the word "you" refers to you.

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

A Phase 2, Historically Controlled Study Testing the Efficacy of TTFields (Optune®) with Adjuvant Temozolomide in High-risk WHO Grade II and III Astrocytomas (FORWARD)

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Ashley Ghiaseddin, MD at (352) 273-9000.

Other research staff: Dr. Ghiaseddin's Research Coordinator at (352) 273-9000.

For emergencies after hours or on weekends or holidays: Call (352) 273-9000 and ask to speak with the Neurosurgery Resident on call.

4. Who is paying for this Research Study?

The funding sponsor of this study is Novocure Ltd.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research study is to determine if treatment with Optune during maintenance cycles of Temozolomide is effective in the treatment of Grade II or III astrocytoma brain tumor(s). Some molecular types of Grade II and III astrocytomas can behave like a more aggressive glioblastoma (GBM), and current treatment is suspected to be less effective on these tumors than other Grade II and III astrocytomas.

Optune is a portable battery operated electronic device that is attached to the head and delivers continuous electrical stimulation to try to stop or slow the growth of tumor cells. Optune is approved by the Food and Drug Administration (FDA) for the treatment of glioblastoma (GBM) brain tumors, but it is not approved by the FDA for the treatment of Grade II and III astrocytoma brain tumors, which means its use in this study is investigational.

Temozolomide is a chemotherapy drug that is used in the treatment of patients with astrocytoma during and after radiation. Temozolomide is approved by the FDA for the treatment of refractory anaplastic astrocytoma (Grade III). Temozolomide is not approved by the FDA for the treatment of newly diagnosed Grade III or any Grade II astrocytomas, which means its use in this study is investigational.

You are being asked to be in this research study because you have been newly-diagnosed with astrocytoma, have undergone surgery to remove as much of your tumor as possible and will receive standard treatment for your tumor.

Study treatment may continue for up to 2 years. After that, we would like to collect information on how you are doing indefinitely, or as long as you allow us to do so.

b) What is involved with your participation, and what are the procedures to be followed in the research?

If you meet the qualifications to be included and decide to take part in this study, you will be treated with Temozolomide and Optune. A detailed description of the screening, treatment and follow-up procedures is outlined in Question 7 of this form.

c) What are the likely risks or discomforts to you?

The most common side effects of temozolomide are loss of appetite, nausea, constipation and decrease in blood cell counts. Optune treatment may cause local

skin irritation, skin breakdown, or infection at the sites of electrode contact to your skin. Common side effects when Optune and temozolomide are used together previous were low platelet count, nausea, constipation, vomiting, fatigue, medical device site reaction, headache, seizures, and depression. Detailed risks, including rare but serious side effects, are outlined in Question 12.

d) What are the likely benefits to you or to others from the research?

Since the effectiveness of temozolomide and Optune in your type of brain tumor is unknown, you may or may not benefit from taking part in this study.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

Normal clinical care for patients with astrocytoma would include surgery to remove as much of their brain tumor as possible and then radiation therapy with temozolomide (chemoradiation) followed by monthly cycles of temozolomide. Participation in a different clinical trial may be possible if one is available and you qualify. You can also choose to have no treatment.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

If you choose not to participate in this research study, normal clinical care for patients with astrocytoma would include surgery to remove as much of their brain tumor as possible and then radiation therapy with temozolomide (chemoradiation) followed by monthly cycles of temozolomide. Participation in a different clinical trial may be possible if one is available and you qualify. You can also choose to have no treatment.

Radiation Therapy with Temozolomide (chemoradiation)

Following surgery to remove as much tumor as possible, you will undergo radiation therapy 5 days a week for six weeks and be treated with temozolomide once daily for the duration of radiation treatment. About four weeks after you finish chemoradiation, you will have a brain MRI to assess your tumor.

Maintenance Temozolomide

Four to six weeks after radiation therapy with temozolomide, you will start monthly maintenance cycles of Temozolomide. You will take temozolomide once each day for 5 straight days every 28 days; this 28-day period is called a cycle. Treatment with temozolomide is expected to continue for 6-12 cycles. If your doctor determines that your tumor has grown or if you experience serious side effects, your treatment with temozolomide will stop. Throughout your treatment, you will be regularly evaluated by your physician, have routine laboratory blood tests, and have a brain MRI (or CT scan if you cannot have an MRI) every 2-3 months to see if the tumor has returned or grown.

The number of days you receive temozolomide and the dose you receive may be changed by your doctor if you experience side effects or have problems with your laboratory blood test results.

Follow-up Care

After completing treatment, you will be regularly evaluated by your physician and have brain MRI scans every two months for two years then every 3 months thereafter.

7. What will be done only because you are in this Research Study?

Your doctor will discuss the option of participating in this study. You may be eligible to participate if you have undergone surgery to remove as much of your tumor as possible and been treated with chemoradiation and you are a candidate for Optune therapy and maintenance temozolomide as described above. If you are a female of childbearing age, you must not be pregnant, to participate. If you decide to participate in this research study and you are otherwise eligible, you will have many different tests and procedures that you would have as part of your regular cancer treatment even if you did not participate in this study to determine if it is safe for you to take part in this study. If you meet the qualifications to be included and decide to take part in this study, you will be treated with Temozolomide and Optune. If you cannot safely be included in this study, your cancer doctor or neurosurgeon will discuss other treatment options, as outlined in Section 6 that might be of value to you.

<u>Treatment with Optune</u>

Treatment with Optune will start at about the same time as the first cycle of maintenance TMZ. Prior to beginning treatment with Optune, you will be instructed on how to operate the device, replace batteries, recharge batteries, and connect to an external battery pack overnight by specialists employed by Novocure, the maker of the device. Treatment consists of wearing four insulated electrodes on your head for the entire length of treatment. This requires that you shave your head before beginning treatment and every 2-3 days when the electrodes are replaced. You must wear the electrodes around the clock, but may remove them for up to an hour twice a day for personal needs (such as bathing). You may require assistance from a family member or other caregiver in order to properly place the electrodes on your scalp. Your treatment with Optune may continue for up to 2 years depending on how your tumor is responding and if you are not having any

intolerable side effects. Compliance reports to evaluate treatment time with the device will be collected monthly from Novocure.

We will ask you to complete questionnaires during appointments to help us understand your memory, your health and your symptoms. These questionnaires will be completed at screening, approximately every 2 months while you are wearing the Optune device, and then approximately every 3 months after that. You do not have to answer any questions that you do not wish to.

In the remainder of the description of what will be done, both temozolomide and Optune will be described as "study treatment."

Your MRI images will be submitted to Beth Israel Deaconess Medical Center for electric field mapping. The results will not be available to you during treatment. Because the analysis will be performed after completion of this trial, you may not benefit from this electric field analysis. However, knowledge that is gained from this part of the study may help others.

Throughout your treatment you will be regularly evaluated by your physician, and have laboratory blood tests, which may occur more frequently than if you did not take part in this study, specifically if you continue on Optune treatment after completing or stopping temozolomide.

We will ask you if you donated tumor tissue for future research to the Florida Center for Brain Tumor Research (FCBTR) brain tumor bank at the University of Florida and/or other facilities that performed surgery on your brain tumor. If you have tissue available and you give permission below, we will confirm with the FCBTR or outside facility that a sample was collected and can be used in this study.

Please indicate your wishes by signing your initials next to the choices below:

_____ You may contact the FCBTR to find out if my tumor tissue was collected.

_____ If collected, you may use tissue I donated to the FCBTR for use in this study.

_____ You may contact other facilities to find out if tumor tissue is available for use in this study and if available collect and use the specimen in this study.

Follow-up

Treatment with Optune may continue up to 2 years if your tumor has not returned or grown. After completing treatment, we would like to follow you for as long as you will allow us to see how you are doing and if your tumor has returned or grown. This information will be collected from your medical records and by contacting you by telephone every three months until the end of the study (up to 5 years).

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect

- Information that identifies or could be used to identify you such as name, date of birth, address, telephone and fax numbers, medical record number, health plan numbers or account numbers, and exact dates collected from your past, current or future health records
- Complete past and current medical history
- Records of physical and neurological exams and functional status
- Laboratory, pathology, radiology, and other test results
- Records about medications or drugs: prescription, over the counter, or study medications
- Records about Optune use and compliance
- Ability or potential ability to conceive a child
- Records about side affects you may experience
- Information collected during follow-up telephone calls

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

9. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in Question 4 of this form);
- Novocure's device support specialists (DSS);
- Investigators at Beth Israel Deaconess Medical Center for electrical field modeling of MRI images;
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- Your primary care physician if he or she needs this information to treat a medical condition;
- A Data Safety Monitoring Committee;
- Your insurance company for purposes of obtaining payment;
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

Study treatment may continue for up to 2 years. After that, we would like to collect information on how you are doing indefinitely, or as long as you allow us to do so.
This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

Up to 16 people are expected to take part in this study at the University of Florida: 8 control patients and 8 patients receiving study treatment.

This study will recruit up to 200 total participants across all study sites: 100 control patients and 100 patients receiving study treatment.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

Cancer treatments often cause side effects. You may have none, some, or all of the side effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your doctor. Your doctor will also be looking out for side effects. There may also be other side effects that you experience that were not predicted. Many side effects go away shortly after the study treatment is stopped, but in some cases, side effects may be serious, long lasting, and/or permanent and may even cause death.

The risks described below can vary in severity from person to person; therefore, you must inform your healthcare team of all side affects you experience so that they can evaluate each of them.

Risks of Temozolomide:

The most common side effects of temozolomide are loss of appetite, nausea, constipation and decrease in blood cell counts. A decrease in the number of white blood cells may increase your risk of infections. A reduction in the number of platelets may increase the risk of bleeding and a reduced number of red blood cells may increase fatigue or shortness of breath. Some people who have taken temozolomide also had the following side effects:

- nausea and vomiting, especially on the first day of each cycle
- back, abdominal and/or stomach pain, breast pain
- diarrhea
- hair loss
- dry skin, skin redness, itching and/or rash
- swelling of extremities (your arms, legs, fingers, or toes)
- inflammation or swelling of the mouth, throat and/or sinuses
- headache, confusion, loss of memory, dizziness, fatigue, fever, and/or weakness
- anxiety, depression
- joint and muscle pain
- abnormal coordination when using your arms or legs (such as walking or feeding yourself) and/or abnormal feelings in your extremities
- trouble sleeping or sleepiness
- changes in your sense of taste
- changes in your vision such as double or blurred vision
- coughing or shortness of breath, respiratory tract infection
- urinary incontinence/frequency, urinary tract infection
- weight increase
- seizures, hemiparesis (weakness on one side of the body)
- adrenal hypercorticisim (elevated hormone levels)

- allergic reactions, sometimes severe
- hepatotoxicity (abnormal liver function tests); sometimes these may be severe, which is why liver function tests may be performed throughout temozolomide treatment cycles
- Low blood counts, specifically white blood cells, red blood cells, and platelets may temporarily decrease; safety blood tests will be performed periodically to monitor these levels

Rarely, unusual ("opportunistic") infections have occurred. Rare cases of erythema multiforme (a skin condition that is similar to a bad rash) have been reported which got better after temozolomide was stopped and, in some cases, recurred upon restarting treatment with temozolomide.

Very rare side effects have included secondary cancers including leukemia and myelodysplastic syndrome (MDS). MDS is a disorder of the bone marrow in which blood cells that do not function normally are produced.

Reproductive studies have not been done with people who are taking temozolomide. Immature sperm and testicular atrophy occurred in studies with rats and dogs, using doses of temozolomide 1/4 and 5/8 of the recommended human doses. In animal studies, temozolomide caused death and multiple malformations in fetal rats and rabbits.

Risks of Optune:

Treatment with Optune is not expected to cause any serious side effects. It is possible that the treatment may cause local skin irritation, skin breakdown, or infection at the sites of electrode contact to your skin. If any of these conditions occur, they will be evaluated and treated by the physician and should heal completely after treatment is stopped. You may also experience headaches and fatigue. It is possible you will have an allergic reaction to the adhesive gel used to stick the electrodes to your scalp. Because Optune is an electronic device, potential risks associated with its use include the risk of electrical or mechanical failure, electrical shock, and electromagnetic interference. Electromagnetic interference can occur when the Optune system is in the vicinity of another electronic device, and Optune may not work properly. You may experience a warm or tingling electric sensation below the device on your scalp. If the Optune device overheats, you may feel it begin to overheat leading to pain and/or localized burns on your skin. However, the company that makes Optune has taken appropriate action to minimize the likelihood of these risks. It is also possible that the treatment may not delay the growth of the tumor.

Additional potential Risks of Optune with temozolomide:

Common side effects where Optune and temozolomide were used together previous were low platelet count, nausea, constipation, vomiting, fatigue, medical device site reaction, headache, seizures, and depression.

In earlier clinical trials where Optune and temozolomide were used together, some severe side effects were seen: seizure and consecutive seizures, decrease or loss of ability to carry out daily activities, neurological decline or death.

MRI/MRS Imaging:

Magnetic resonance imaging (MRI) is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This procedure is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur. The risks of MRI are:

The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. Someone will ask you questions about this before you have the MRI.

There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in close spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system, and, in the event of an emergency, you can tell them to stop the scan. If have claustrophobia, you may require medication to help you relax ("sedation"). If you do require medication to relax, you should not drive a car, take part in activities like riding a bike, or perform other similar tasks until the next morning because the medication(s) can affect your thinking for several hours and can slow down your reflexes.

The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

If you are a woman of childbearing potential, there may be unknown risks to the fetus. Therefore, before you can have the MRI, you must have a pregnancy test.

For the MRI, you will be given gadolinium to enhance the image of your brain tumor. Gadolinium may cause nephrogenic systemic fibrosis (NSF), which is a skin disease that primarily affects people with kidney problems. You may also experience mild symptoms such as sweating, headaches, skin rashes, itching, hives, or throat tightening. More serious symptoms, although rare, might include blood clots, irritation to blood vessels, and anaphylactic shock (or severe allergic reaction). Recent information shows that when you receive gadolinium repeatedly, it may collect in the brain. This would apply whether you receive the gadolinium as part of a research study or as part of your healthcare. The importance of this information and how it impacts your health are not known.

Reproductive Risks:

Because the treatment in this study might affect an unborn baby, you should not become pregnant while on this study. Since this treatment will not be given to any patients who are pregnant, all women and adolescents of childbearing potential must take a pregnancy test prior to starting any treatment on this study. We encourage all

women and men enrolled on this study to use one of the highly effective birth control methods during treatment and for six months after treatment is stopped. These methods include total abstinence (no sexual intercourse), Levonorgestrel (LNG), Copper T IUDs, or an intrauterine device (IUD). If preferable, two of the following methods of birth control may be used in combination: an etonogestrel implant (Implanon), oral contraceptives ("the pill"), hormone patch, Vaginal ring, or medroxyprogesterone acetate injections (Depo-Provera shots). You must notify the doctor if you become pregnant during the course of this study. Surgical sterilization for at least 6 months before study treatment administration will also be considered highly effective birth control.

We do not know whether using this treatment will affect sperm. As a result, men and adolescents who have not had a vasectomy are advised to either (a) abstain from reproductive sexual intercourse or (b) use a condom and contraceptive foam during intercourse. These precautions should be taken while on therapy and for at least one month after completing therapy.

You should not nurse a baby while receiving treatment on this study or for six months after completing treatment.

These precautions should be taken while on therapy and for at least six month after completing therapy.

Blood Draws:

The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure.

You may feel uncomfortable about answering some of the questions on the questionnaires. You may skip any questions that you would prefer not to answer.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 8 and 9 in this form discuss what information about you will be collected, used, protected, and shared.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

Since the effectiveness of temozolomide and Optune in your type of brain tumor is unknown, you may or may not benefit from taking part in this study.

13b. How could others possibly benefit from this Research Study?

We hope that, in the future, other people with brain tumors might benefit from this study because researchers may learn if treatment of with temozolomide and Optune helps in the treatment of brain tumors, specifically astrocytoma.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

Dr. David Tran, the Protocol Chairman and Sub-Investigator at the University of Florida, is a paid member of the medical advisory board of Novocure which sponsors the study. Novocure provides other research funding to Dr. Tran outside of this study. Also, Novocure makes the device used in the study which prevents cancer cells from dividing in the brain. Please feel free to ask any questions you may have about this matter.

13d. Will you be allowed to see the research information collected about you for this Research Study?

You may not be allowed to see the research information collected about you for this Research Study, including the research information in your medical record, until after the study is completed. When this Research Study is over, you will be allowed to see any research information collected and placed in your medical record.

14. What other choices do you have if you do not want to be in this study?

If you do not want to be in this study, treatment would include surgery, radiation therapy with temozolomide, and monthly cycles of temozolomide. You may also choose to

participate in another research study, if one is available and you qualify, or you can choose to have no treatment.

Your participation in this study is voluntary and any decision to take part or not to participate in the study will in no way affect the quality of your care.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- You do not follow the instructions given to you by the research staff
- You did not comply with Optune treatment
- The study is stopped
- You are pregnant or become pregnant
- The Principal Investigator determines it is in your best interest to be withdrawn from the study

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

Study Drugs

The cost of the Temozolomide will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, or co-payments for these services, and for any non-covered or out-of-network services.

Study Devices

Novocure, the company that makes the study device, will provide the Optune system to you and will bill you or your insurance for the cost of the device. Novocure will need to obtain your insurance information. You will be responsible for paying any deductible, co-insurance, or co-payments, and for any non-covered or out-of-network services. You may also qualify for assistance with these costs through Novocure's financial assistance programs.

Study Services

The Sponsor will pay for or provide the following study-required services/activities at no cost to you:

1. Research-only data collection, questionnaires, or surveys.
2. Collection and processing of any donated tumor tissue.

If you receive a bill for these services, please contact Dr. Ghiaseddin or his study coordinator at (352) 273-9000.

Items/Services Not Paid for by the Sponsor

All other medical services you receive would have been provided to you even if you were not in this study. These services will be billed to you or your insurance company in the usual manner. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services.

Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.

17. Will you be paid for taking part in this Research Study?

You will not be paid for being in this research study.

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Ghiaseddin at (352) 273-9000 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____
Signature of Person Obtaining Consent & Authorization Date

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

_____ _____
Signature of Adult Consenting & Authorizing for Self Date

Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____ _____
Consent & Authorization Signature Date
of Legal Representative

_____ _____
Print: Name of Legal Representative Print: Relationship to Participant:

_____
Print: Name of Subject:

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your legal representative above means he or she gives permission (consent) for you to take part.

_____ _____
Assent Signature of Participant Date

UF UNIVERSITY of FLORIDA

ADDENDUM TO INFORMED CONSENT FOR AUTHORIZED REPRESENTATIVE

Study Title: A Phase 2, Historically Controlled Study Testing the Efficacy of TTFields (Optune®) with Adjuvant Temozolomide in High-risk WHO Grade II and III Astrocytomas (FORWARD)	Study Number:IRB201806600

In the event that I _____, should become incapacitated (no longer able to make decisions for myself) during the course of this study, the person named below will act as my authorized representative to make decisions on my behalf, regarding continued participation in this research study.

Please list an authorized representative, if you were unable to make decisions for yourself.

Contact Name:		Relationship:	
Address:	City:	State:	ZIP:
Home Phone:	Alt. Phone:	Email:	

In an effort to help your authorized representative comply with your wishes, we are requesting your views about continued participation in this study should you become incapacitated (no longer able to make decisions for yourself). Please select one:

	1. I would like to fulfil my study participation as indicated in the informed consent.
	2. I would like my authorized representative as identified above to withdraw me from this study.
	3. I will let my authorized representative make this decision in my best interest.

Participants Signature:	Date:
Witness Signature:	Date:
Witness Printed Name:	