Official Title: ETAPA I: Evaluation of Tumor Associated P30-Peptide Antigen I; A Pilot Trial of Peptide-based Tumor Associated Antigen Vaccines in Newly Diagnosed, Unmethylated, and Untreated Glioblastoma (GBM)

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CONCISE SUMMARY

The purpose of this study is to learn whether the study vaccine is safe and whether the study vaccine can activate your immune system to fight off tumor cells in patients who are newly diagnosed with high-grade malignant glioma or glioblastoma (brain cancer). The study vaccine is comprised of three different peptides (small proteins) mixed with Hiltonol® (also known as poly-ICLC). Hiltonol® is a drug given to further stimulate your immune system against the cancer. Each peptide (protein) is designed to be an "antigen," which is a molecule capable of being detected and causing a response by your immune system.

If you decide to participate in this study, you will first receive a tetanus booster shot (Td vaccine) in your arm after you have had surgery for your tumor and have completed standard radiation therapy [with or without chemotherapy (temozolomide)]. This will be followed by a series of seven injections of the study vaccine. The study vaccine is given by injection (shot) in the muscle in the area of your thigh. The first five vaccines are intended to build the immune reaction or "prime" your immune system (Priming Phase), while the second two vaccines are considered strengthening or "booster" injections (Booster Phase). During the Booster Phase, you will also give yourself injections at home of Hiltonol® every 2 weeks. The study team will train you on how to do this and provide instructions and support.

This specific combination of peptides and Hiltonol® have not been given together in a vaccine before now. However, our center has conducted studies with other peptide vaccines. The most common side effects of peptide vaccines are redness or swelling at the injection site, local changes to the texture of your skin (hardening) at the injection site, itching, allergic reactions, and a potentially serious side effect called cytokine release syndrome. Cytokines are chemicals that help direct the body's immune response. In cytokine release syndrome (CRS), a dramatic increase in the number of these type of immune cells could result in symptoms like fever, chills, flu-like symptoms, and low blood pressure or could result in swelling of the brain. If you show any signs of CRS, you will be treated immediately to lessen these symptoms. The most common side effects of Hiltonol® are reactions at the injection site and flu-like symptoms.

Please read this consent form for additional information on this study.

You are being asked to take part in this research study because you have been diagnosed with a malignant glioma (brain tumor). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form

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with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Mustafa Khasraw and his study team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Mustafa Khasraw will either be your doctor for the study, or he will work closely with your doctor here at Duke. Dr. Khasraw and the study team will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to learn whether the study vaccine is safe and whether the study vaccine can activate your immune (protection) system to fight off the tumor cells in your brain. The dose of the study vaccine that you receive will depend upon when you start the study. People who enroll earlier in the study will receive a lower dose of study vaccine than those who enroll later. This study vaccine is investigational, which means that it is not approved by the US Food and Drug Administration (FDA) and is still being tested in research studies.

The study vaccine is comprised of three different peptides (small proteins) mixed with Hiltonol®. Each peptide is designed to be an "antigen," which is a molecule capable of being detected and causing a response by your immune system. The three peptides that make up the study vaccine are called pp65, EphA2, and survivin. The immune system can recognize certain peptides on the surface of tumors as a signal to attack and fight the cancer. The peptides in the study vaccine are designed to be tumor-specific antigens, which means antigens that are present only on tumor cells and not on other cells in the body.

The peptides in the vaccines are mixed with Hiltonol® (also called Poly-ICLC). Hiltonol® is made up of synthetic (manmade) RNA (ribonucleic acid) and is used as an adjuvant to the vaccine, meaning it is used with the vaccine to stimulate or enhance the activation of your immune system. Hiltonol® has been given to people in prior research studies, including people with high-grade malignant glioma. Combining Hiltonol® and the study vaccine is

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investigational.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 36 people will take part in this study Duke, although up to 40 people may consent to participate to reach this goal.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following screening tests and procedures to make sure that you are eligible:

- Physical exam, neurologic exam, and medical history
- Magnetic Resonance Imaging (MRI) of the brain with and without contrast
- Blood tests-
  - Complete blood count (CBC) with differential (about 1 teaspoon of blood)
  - Complete metabolic panel (CMP), which tests your liver and kidney function (about 1 teaspoon of blood)
  - For people who could possibly become pregnant, a blood pregnancy test (about 1 teaspoon of blood)
- Review of your medical records and your pathology report from your brain surgery (results of your tissue sample test that confirmed your diagnosis), including your HLA results on the CARIS pathology report. HLAs (human leukocyte antigens) are specialized proteins on the surface of most cells in your body.
- You previously had your blood tested for CMV (cytomegalovirus) as part of pre-screening (separate consent form). Patients whose blood is either positive or negative for CMV may participate in the study.

During the process where your eligibility for the study is being determined, the study team will confirm that tissue from your surgery was tested for O6-methylguanine-DNA methyltransferase (MGMT) and Isocitrate Dehydrogenase (IDH). MGMT is a gene that has been shown to be important in predicting the response to the chemotherapy drug temozolomide (TMZ). Tumors without methylated MGMT do not respond as well to TMZ chemotherapy as tumors with methylated MGMT. The ETAPA I study is for patients whose tumors are without methylation of MGMT. Mutations of IDH genes also affect how cells develop. The ETAPA I study is for patients without IDH mutation. For patients who had surgery for their tumor outside of Duke, the study team will request a sample of your tumor from the outside hospital to complete testing for MGMT and IDH mutation.

The study team will also request an archival sample of your tumor, from the hospital where biopsy or resection (removal) of your tumor was performed, as well as from any future surgeries you may undergo for tumor resection or biopsy while participating in this

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study. This tumor sample will be used for further research purposes, that are not related to testing for MGMT and IDH mutation. Genetic testing may also be done on your tumor tissue sample.

If you are eligible and decide to participate in the ETAPA I study, you will first be given a tetanus booster shot (Td vaccine) in your arm.

Treatment Period
The treatment period is divided into two parts, the Priming Phase and the Booster Phase. Before beginning the **Priming Phase** and receiving your first study vaccine (Day 1), you will have the following tests and procedures:

- Physical exam, neurologic exam, and medical history
- Vital signs (blood pressure, heart rate, breathing rate, and temperature)
- Mini-mental state exam, which is a quick test of your thinking ability
- Blood tests-
  - Complete blood count (CBC) with differential (about 1 teaspoon of blood)
  - Complete metabolic panel (CMP), which tests your liver and kidney function (about 1 teaspoon of blood)
  - For people who could possibly become pregnant, you may have another blood pregnancy test (about 1 teaspoon of blood) if the one during screening is more than 48 hours before your first study vaccine.
  - Research blood to look at several immune system markers (about 6 and a half tablespoons of blood)

After these tests and procedures are complete, you will be given an anti-nausea medication, like Zofran, and the fever reducer Tylenol before receiving your first study vaccine. Study vaccines are given as an injection (shot) in your thigh. We will alternate the leg you receive the study vaccine in each time you receive it. We hope this will lessen reactions at the site of the injection. At the first vaccine, you will also have an intravenous (IV) catheter (small tube placed in a vein) to provide fluids. These fluids can help to minimize reactions to the vaccine. The IV catheter will remain in place while you are receiving the vaccine and during the monitoring period afterwards, in case additional medications are needed to reduce reactions. Additional medications given through the IV catheter could include more fluids, Benadryl (an antihistamine), or a type of steroid called Solu-medrol. If, at any point, you experience a reaction after receiving a study vaccine, you will have these same precautionary measures and medications with all of your later vaccines. If these additional medications do not adequately minimize your reactions to the study vaccine, you may also be offered a corticosteroid called prednisone before receiving

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the study vaccine. Prednisone suppresses your immune response and may affect how well the study vaccine works.

You will remain in clinic after the study vaccine for observation and to have your vital signs (blood pressure, heart rate, breathing rate, and temperature) taken about every 30 minutes. The observation period will be 2 hours for all study vaccines unless the time needs to be extended depending on how you react to the study vaccine. About 2 hours after you receive the study vaccine on Day 1, you will have additional blood drawn to check for cytokine release syndrome (CRS) (about 4 teaspoons of blood).

You will return to clinic for study vaccines on Day 4 (plus or minus one day), Day 8 (plus or minus one day, Day 15 (plus or minus 2 days), and Day 22 (plus or minus 2 days). At each of these study vaccine visits, you will have the following tests or procedures before receiving the study vaccine:

- Physical exam, neurologic exam, and medical history
- Vital signs (blood pressure, heart rate, breathing rate, and temperature)
- CBC with differential and CMP (about 2 teaspoons of blood)

Before your vaccine on Day 22, you will also have a research blood draw to look at several immune system markers (about 6 and a half tablespoons of blood) and you will undergo an MRI of the brain.

Approximately 9 weeks later, you will begin the **Booster Phase** of the study. On Day 84 (plus or minus 7 days) and on Day 140 (plus or minus 7 days), you will have the following tests or procedures before receiving the study vaccine:

- Physical exam, neurologic exam, and medical history
- Vital signs (blood pressure, heart rate, breathing rate, and temperature)
- Blood tests-
  - CBC with differential (about 1 teaspoon of blood)
  - CMP(about 1 teaspoon of blood)
  - Research blood to look at several immune system markers (about 6 and a half tablespoons of blood)
  - Blood to check for CRS (about 4 teaspoons of blood) about 2 hours after receiving vaccine

During the Booster Phase, you will also give yourself injections at home of Hiltonol® every 2 weeks. The study team will train you on how to do this and provide instructions and support. We will provide you a guide to you to take home, as well as a diary to record the dates, times, and locations on your body of your injections. You can also record any

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comments like side effects or reasons for late injections. In addition, a member of the study team will contact you prior to each of your home injections to make sure you know when it is due and to see if you have any questions.

If You Experience Brain Swelling:
In the event that you experience brain swelling after you receive the study vaccine due to an inflammatory response, your physician may treat you with a reduced dose of bevacizumab (also known by the brand name Avastin). Bevacizumab for the purpose of reducing brain swelling is prescribed at a dose that is lower than what is approved for the treatment of brain tumors (7.5 mg/kg every three weeks).

Bevacizumab is given intravenously (through a vein), and the need for it will be reassessed by your study doctor after every MRI scan you receive.

If your study doctor does not feel it is safe for you to receive bevacizumab, he/she may discuss other interventions, including steroids or surgery, with you to treat the inflammatory response (swelling of the brain) to the study vaccine.

Magnetic Resonance Imaging (MRI) Scans:
You will have several MRIs during the course of the study. MRIs use a magnet and radio waves to make diagnostic medical images of the body. The MRI involves entering a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the study. During the study, you can have voice contact and physical contact with someone in attendance if you desire. You may be given a dye intravenously (through a vein) in order to enhance the MRI image. Let the study doctor know if you have a fear of enclosed spaces.

HOW LONG WILL I BE IN THIS STUDY?
You will remain in this study for about 6 months, unless your tumor gets larger (progresses), the side effects become too severe, or you or the study team feels it is in your best interest to stop participating. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

All tissue samples will be kept and stored indefinitely since the understanding of biological markers and testing is constantly evolving.

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

ADDITIONAL TISSUE SAMPLE(S) FROM FUTURE TUMOR BIOPSY OR RESECTION
If, at a future date, you have a biopsy or resection, we would like to request a sample of that tissue. This sample would be analyzed for the presence of biological or genetic markers related to your immune response to the study vaccine. If you agree to allow these tumor samples to be requested and analyzed by initialing below, the study team will contact you at that time to make certain that you still agree. If you agree to allow us to request future tissue samples and your surgery is not at Duke, we may need to provide details about your participation in this study and a copy of your consent form to the outside hospital. If you choose not to allow these tumor samples to be taken, you can still be part of this study. No matter what you choose, it will not affect the care you receive as part of this study or at DUMC.

Please indicate your choice by placing your **initials** below on the appropriate line:

_____ "**YES**, I agree to allow the study team to request leftover tissue from future biopsies or resections from DUMC or the facility where my biopsy or resection is performed."

_____ Subject Initials _____Date

_____"**NO**, **I DO NOT** agree to allow the study team to request leftover tissue from future biopsies or resections from DUMC or the facility where my biopsy or resection is performed."

_____ Subject Initials _____Date

ADDITIONAL USE OF YOUR SAMPLE(S)
In addition to the research tests described previously, we would like to request to store any remaining samples for future research tests. We are always learning, and new tests can help us better understand your disease and the study drug. Any leftover blood or tissue used for this research study may be stored at Duke for future research with your permission.

Please indicate your choice by placing your **initials** below on the appropriate line:

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_____"**YES**, I agree to allow my leftover tissue and blood sample(s) to be stored for use in additional research related to my disease/condition as part of this study."

_____ Subject Initials _____Date

_____"**NO**, **I DO NOT** agree to allow my leftover tissue and blood sample(s) to be stored for use in additional research related to my disease/condition as part of this study."

_____ Subject Initials _____Date

If you agree to allow your tissue and blood to be stored for future research, you are free to change your mind at any time. We ask that you contact Dr. Khasraw in writing or by email and let him know you are withdrawing your permission for your tissue and blood to be used for future research. His mailing address is Room 047 Baker House Duke Hospital South, Durham, NC 27710 and his email is mustafa.khasraw@duke.edu.

WHAT ARE THE RISKS OF THE STUDY?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Peptide Vaccines:
The injections may cause an allergic reaction that can include:

Most Likely
- Redness or swelling at the injection site, which may persist for an extended period of time
- Local changes to the texture of your skin (hardening) at the injection site
- Itching

Less Likely
- Hives
- Low-blood pressure
- Difficulty breathing
- In rare occasions, death

The peptide vaccines may cause an increase in the number of immune cells in the brain. This may cause swelling (edema) of the brain. Symptoms of swelling of the brain include:
- Severe headaches

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- Confusion
- Lack of energy
- Unconsciousness
- Coma
- Losses of movement, sensation
- Loss of function in certain areas of the body

The peptide vaccines may activate the immune system to such a high degree that the immune system may start to attack normal brain tissue or other tissues in the body. Although this is very unlikely, this type of severe reaction can cause serious injury or death.

There may be a small risk of infection due to potential contamination of the injection during the manufacturing or mixing process. This may result in redness, swelling, and/or irritation at the injection site. In the most extreme situations, this may lead to systemic bacterial/fungal infections and possible death.

Hiltonol®:
- Discomfort at the injection site
- Flu-like symptoms, which can include muscle pain, joint pain, nausea, and general discomfort
- Temporary decrease in the white blood cells, which may result in increased risk of infection
- Mild and temporary increase in liver enzymes (Abnormal results in a blood test measuring your liver function)
- A possible worsening of tuberculosis (TB) in individuals who are already infected with TB
- When combined with a vaccine, Hiltonol may cause a temporary, but serious, allergic reaction.

Zofran (ondansetron):
The most common side effects of Zofran are headache and fatigue. Less likely side effects include constipation, diarrhea, and dizziness.

Tylenol (acetaminophen):
The most common side effects of Tylenol seen in adults are nausea, vomiting, headache, and insomnia (unable to sleep).

Benadryl (diphenhydramine):

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The most common side effects of Benadryl injection are drowsiness, dizziness, headache, irritability, stomach upset, blurred vision, decreased coordination, constipation, and dry mouth, nose, or throat.

Solu-medrol (methylprednisolone):
The most common side effects of Solu-medrol are increased appetite, irritability, difficulty sleeping, swelling in the ankles or feet, nausea, heartburn, muscle weakness, problems with wound-healing, and increased blood sugar levels.

Prednisone:
The most common side effects of oral (by mouth) prednisone are increased appetite, irritability, difficulty sleeping, swelling in your ankles and feet, nausea, heartburn, muscle weakness, difficulty healing from wounds, and increased blood sugar. Less common side effects include headaches, and dizziness.

Bevacizumab:
The risks below are for a standard dose of bevacizumab used for treating recurrent malignant glioma. The dose used to treat brain swelling in this study is lower.

More Likely (greater than or equal to 1 out of 5 or 20% of patients)
- High blood pressure (hypertension) which may cause headache or blurred vision
- Abdominal Pain

Less Likely (about 4 – 20% of patients)
- Numbness, tingling or pain in the fingers or toes (peripheral sensory neuropathy)
- Low numbers of white blood cells (neutropenia, leucopenia and lymphopenia) potentially associated with fever. Low white cell count may increase the risk of infection.
- Low numbers of platelets (thrombocytopenia)
- Shortness of breath (dyspnea)
- Diarrhea
- Bleeding from the rectum (rectal hemorrhage)
- Nausea and vomiting
- Pain, including headache and joints pain (arthralgia)
- Alteration in speech (dysarthria)
- Constipation
- Mucosal inflammation or inflammation of the mouth (stomatitis)
- Protein in the urine

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- Nose bleed (epistaxis)
- Lack of energy, weakness (asthenia, fatigue), or dizziness
- Loss of appetite (anorexia), or heartburn
- Body water loss (dehydration)
- Fever (pyrexia)
- Runny nose (rhinitis), stuffy nose, hoarseness, or cough
- Dry skin, flaking and inflammation of the skin (exfoliative dermatitis), change in skin color (skin discoloration)
- Change in the sense of taste (dysgeusia)
- Problems with the eyes (eye disorder), tearing (lacrimation increased)
- Low numbers of red blood cells (anemia) which may require blood transfusion
- Abnormal heartbeat which may cause palpitations or fainting
- Internal bleeding which may cause black tarry stool, vomit in blood, coughing up blood, or blood in urine
- Delay in healing of wounds or spontaneous opening of wounds. Fatal outcomes have been reported.
- Damage to jaw bone which may cause loss of teeth
- Allergic reaction during or after infusion of bevacizumab which may cause fever, chills, rash, itching, hives, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Blood clot in limbs or lungs which may cause swelling, pain or shortness of breath
- Infection, presence of bacteria in the blood (sepsis), collection of pus in tissue or organs (abscess)

Occasional (3% or less of patients)

- A tear or a hole in the gut (perforation of the gastrointestinal tract)
- Abnormal tube-like connection (fistula) between internal organs such as the nose, throat, lungs, esophagus, rectum or vagina that are not normally connected. These conditions may cause serious infections or bleeding and require surgery to repair.
- Bleeding (hemorrhage), including bleeding associated with the tumor
- Clogging of a vessel in the lung (pulmonary embolism)
- Blocking of the arteries by a blood clot, including stroke (cerebral vascular accident) or heart attack. This risk is significantly increased in patients who are elderly or with a history of diabetes.
- Heart failure (cardiac failure congestive), especially in patients who have taken certain chemotherapy treatments in the past (doxorubicin or mitoxantrone) and rapid beating of the heart (supraventricular tachycardia)

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- Rapid beating of the heart (supraventricular tachycardia)
- Blood clots in the veins (deep vein thrombosis)
- Abdominal pain
- Blockage in the intestine (ileus, intestinal obstruction)
- Pain, tenderness, or blistering on the fingers or feet (hand-foot syndrome, palmar-plantar erythrodysesthesia syndrome)
- Reduced consciousness, sleepiness, feeling tired (somnolence, lethargy)
- Low levels of oxygen in the blood (hypoxia)
- Fainting (syncope)
- Gastrointestinal disorder
- Voice changes, hoarseness (dysphonia)
- Muscular pain (myalgia) and muscular weakness
- Flesh-eating bacteria syndrome, an infection in the deep layers of the skin
- Kidney damage which may require dialysis

Uncommon (0.1% to Less than 1% of patients)
- Abnormal connection between the windpipe (trachea) and the esophagus (the tube that connects the mouth to the stomach) (tracheo-esophageal fistula)
- A hole in the gut lining of the stomach or duodenum (gastro-intestinal ulcer)

Rare (0.01% to Less than 0.1% of patients)
- Reversible posterior leukoencephalopathy syndrome: this may include symptoms of impaired brain function (headaches, vision changes, confusion, or seizures), and often, high blood pressure

Very Rare (Less than 0.01% of patients)
- Hypertensive encephalopathy: this may include symptoms of impaired brain function (headaches, vision changes, confusion, or seizures), and often, high blood pressure

Frequency Unknown
- Lesion in the gums with an exposed jawbone that does not heal and may be associated with pain and inflammation of the surrounding tissue (osteonecrosis of the jaw) in particular when treated with "bisphosphonate drugs" in this trial or in the recent past.
- A hole in the gallbladder (gallbladder perforation)
- A hole in the nasal passage (nasal septum perforation)
- Abnormalities to the fetus/unborn child when bevacizumab is given during pregnancy

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In trials for colorectal cancer using bevacizumab and chemotherapy, female subjects had a 32% higher incidence of ovarian failure with early menopause (loss of menstrual cycle) and sterility (inability to have children) than subjects using chemotherapy alone.

Reproductive Risks:
This information is for people who have at least one sexual partner and engage in activity that could possibly result in a pregnancy. This means that:

One partner was born potentially able to become pregnant AND

- Has not completed menopause, OR
- Has not had a hysterectomy and/or both tubes and/or both ovaries totally removed

AND the other partner was born potentially able to produce sperm AND

- Has not had surgery that removes both testes, OR
- Is not undergoing treatment that prevents the production of sperm

Although it's not likely, there is still a chance of a pregnancy occurring after a tubal ligation/occlusion ("tubes tied") or vasectomy, so you should still read this section if you or your partner have had one of those procedures.

If you do not currently have a partner, or there is no possibility of a pregnancy occurring with your current partner, you do not have to have pregnancy tests or follow any of the birth control requirements for this study. However, if your partnership situation changes during the study in a way that could result in a pregnancy, you should notify your study doctor right away so that pregnancy testing can begin, and your study doctor can advise you about the steps you and your partner should take to avoid an unplanned pregnancy during the study.

<u>If YOU Could Possibly Become Pregnant:</u>

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Pregnancy in people with cancer is associated with an increased risk of complications for both the pregnant individual and the developing pregnancy , and pregnancy may affect the risk of disease progression. The effects of the study drug on a developing pregnancy or breastfeeding/chestfeeding infants are unknown. To reduce the risk of any harmful effects, people who are pregnant, planning a pregnancy, or breastfeeding/chestfeeding are not allowed to participate in studies using study vaccine. We do not know how the long-term effects of the study vaccine will impact your ability to become pregnant, or whether the study vaccine will increase or decrease the risk of pregnancy complications. The study vaccine may affect your ability to become pregnant in the future.

If you are a person who was born potentially able to become pregnant (you have not completed menopause, had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who was born potentially able to produce sperm AND has not had surgery that removes both testes OR is not undergoing treatment that prevents the production of sperm, a blood pregnancy test will be performed, and it must be negative in order to continue in the study. Although it's not likely, there is still a chance of a pregnancy occurring after a tubal ligation/occlusion ("tubes tied") or vasectomy, so you should still read this section if you or your partner have had one of those procedures. In people 40 years old and older, blood pregnancy tests may sometimes give a false positive or "indeterminate" result and additional testing may be required to confirm your eligibility for the study.

You and your partner must agree to either abstain completely from vaginal intercourse for the duration of the study and for 6 months after your last dose of study drug, or use a highly effective method of contraception for the same length of time These methods include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), (d) hormonal implants (such as Implanon), or (e) other hormonal methods (birth control pills, injections, patches, vaginal rings). If you and your partner are not currently using one of these methods your study doctor will discuss options with you, given your medical condition, your personal preferences, and the level of effectiveness required for this study.

<u>If You Think You May Be Pregnant</u>
Because no birth control method is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant, even if you have had a recent negative pregnancy test. Home pregnancy tests are less accurate than tests performed by a lab or your study team, so you should call the study team immediately if you have any questions about your home test results. If you are not sure if you are able to perform the home tests, talk to your study doctor about alternatives. If pregnancy is confirmed, the study vaccine will be stopped, and your study doctor can help you find a

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ETAPA I: Evaluation of Tumor Associated P30-Peptide Antigen I; A Pilot Trial of Peptide-based Tumor Associated Antigen Vaccines in Newly Diagnosed, Unmethylated, and Untreated Glioblastoma (GBM)

specialist in high-risk pregnancy. Your study doctor will continue to follow you to collect information on your health during pregnancy and, if appropriate, the health of the baby, in order to better understand the possible effects of the study vaccine on pregnancy.

The risk of miscarriage, birth defects, and other pregnancy complications increases with age. These risks are higher in people with conditions like yours. Because of these risks, and the health risks to you of pregnancy given your condition, some people decide that pregnancy termination is the best choice for them. If you become pregnant, information on the outcome of the pregnancy, which might be a miscarriage or abortion, will be collected. Although health information collected as part of a study is usually protected, in some cases information can be obtained by law enforcement under applicable law.

If YOUR PARTNER Could Possibly Become Pregnant
The effects of the study vaccine on sperm and the potential impact on a developing pregnancy are not known (in addition, the vaccine may be present in semen and transmitted to a partner during sexual activity). The study vaccine may affect your future fertility. If you and your partner are planning a pregnancy, you should not participate in this study. If your partner is a person who could possibly become pregnant (they have not completed menopause, or have not had a hysterectomy and/or both tubes and/or both ovaries removed), you must agree to either abstain completely from vaginal intercourse for the duration of the study and 6 months after your last dose of study drug, and use a highly effective method of contraception for the same length of time. Highly effective methods include (a) vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), or (d) hormonal methods (birth control pills, implants, injections, patches, vaginal rings). If you and your partner are not using one of these methods, you should use a condom with spermicide every time you have intercourse, and your partner should discuss options with their doctor.

You should not donate sperm for the duration of the study and for 2 months after your last dose of study drug.

You should inform your partner about your participation in this study and the potential risks to a pregnancy. If your partner does become pregnant during the study or within six months of your last dose of study drug, you should tell your study doctor immediately. Your partner may be asked for their permission to collect information on their health during the pregnancy and, if appropriate, on the health of the baby, in order to better understand the possible effects of the study drug on pregnancy. If your partner becomes pregnant, information on the outcome of the pregnancy, which might be a miscarriage or abortion, will be collected. Although health information collected as part of a study is

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usually protected, in some cases information can be obtained by law enforcement under applicable law.

MRIs:
You will have MRIs study as part of this research. MRI uses a magnet and radio waves to make diagnostic medical images of the body. There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. However, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body, including medical implants, devices such as pacemakers and internal defibrillators, or certain dyes found in in tattoos. We will also keep the MRI room locked so that no one carrying metal objects enters the room while you are in the scanner.

If there is any question about potentially hazardous metal within the body, you will not undergo the MRI. This may exclude you from participation in this research study. The MRI involves entering a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the MRI. During the MRI, you can have voice contact and physical contact with someone in attendance if you desire. Let the study doctor know if you have a fear of enclosed spaces.

You may have a number of MRI scans that are part of the regular care for your condition, and you would have them whether or not you participate in this research. These studies will not add to the risk of the research. However, if you have concerns about the MRI safety issues, you should discuss them with your physician.

The most common side effects of the MRI contrast agents are local warmth/pain at the injection site, nausea and/or vomiting. Serious allergic reactions are very rare, may occur and may be life-threatening.

A rare but potentially serious drug reaction called nephrogenic systemic fibrosis (NSF) has been observed in patients who received a gadolinium-based contrast agent (GBCA) during MRI examinations. Patients with severe kidney disease are at increased risk of developing NSF. NSF may cause skin thickening, joint pain and/or swelling. In rare cases, NSF can lead to lung and heart problems and cause death. To minimize the likelihood that you will be affected, you will have a blood test to measure your kidney function. If your blood test is abnormal, you will not be permitted to receive a GBCA.

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Additionally, it has been shown that patients who receive multiple doses of GBCAs may have gadolinium remain in some tissues. Some individuals who received GBCAs have reported general symptoms such as skin burning, confusion, bone pain, and others, which has been termed "Gadolinium Deposition Disease" by some. However, it is not clear that there is a link between GBCAs and these symptoms, and no authoritative group has determined that this is a disease.

Risks of Drawing Blood:
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Drug and Food Interactions:
For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

Risks of Genetic Testing:
It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician, unless the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable. In that case, we will attempt to notify you using the contact information you have provided, so that you can speak with your study doctor. The study team will not provide this information in a voice mail, email, or otherwise prior to contacting you. Please notify us of any change in your contact information.

If you do not want to be notified of any incidental findings, please initial and date below.

_____ Please do not notify me of any incidental findings obtained from this research.

Initial: _____ Date: _____

If you prefer, we can ask you at the time of notification whether or not you want to receive incidental findings information. In this case, please initial and date below.

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_____ Please ask me at the time of notification whether or not I want to receive incidental findings information.

Initial: _____ Date: _____

If at any time during or after the study you change your mind about whether or not you would like to be notified, you can contact us at 919-684-5301.

After providing the information to you, your study doctor may arrange for you to meet with them and possibly a genetic counselor or refer you to another appropriate health care provider to review the incidental findings information with you or your physician.

Potential Risks and the Genetic Information Non-Discrimination Act (GINA)
There is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed. The genetic information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location at DUHS, accessible only by authorized members of the study team, and will not be disclosed to third parties except as described in this consent form, with your permission, or as may be required by law.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you.

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Possible benefits of your participation include improvement in the symptoms of your disease and/or delayed growth of your tumor and/or lengthening the time of your survival, but this cannot be guaranteed. Your disease may worsen while on this study. However, by participating in this study, you will help doctors better understand the side effects caused by the study drug and whether or not there are potential benefits of the study drug. We hope that in the future the information learned from this study will benefit other people with your condition.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Instead of being in this study, you have the following alternatives:

- Refusing all further therapy
- Receiving comfort care with or without other treatments
- Receiving combinations of drugs and/or radiation therapy and/or surgery, if medically indicated, to reduce your tumor size or treat symptoms related to your tumor
- Participating in another study

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

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, scans, and procedures may be reported to the National Institute of Health (NIH) who is funding this study and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration (FDA), representatives and affiliates of NIH, the Duke University Health System Institutional Review Board (IRB), the National Cancer Institute (NCI), and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain tests, scans, and/or procedures performed. Some of these tests, scans and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to

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complete this research. These test results will be recorded in your medical record and will be reported to representatives and affiliates of NIH. Results of tests and studies done solely for this research study and not as part of your regular care will also be included in your medical record.

As part of the study, the study team will request a sample of tissue from your tumor biopsy or resection from the hospital where it was performed, and may request samples of tissue from any future surgeries that you undergo while you are on this study. In doing so, the study team may provide a copy of your signed consent form to the hospital, which shows both your name and Duke medical record number. This is necessary in order to request your tissue sample for this research study.

Some of the tissue may be sent to a company outside of Duke for genetic testing.

Your tumor and blood samples will be kept and stored at a Duke Lab dedicated to sample analysis. Maintaining confidentiality is important to Duke. All samples will be kept and stored in a secure place. Your sample will be identified by a unique barcode, which means that your name will not be on the sample. However, this barcode can be linked to your unique study identification number, age, gender, ethnic background. Besides protecting your confidentiality, this barcode system will allow the sponsor to destroy your sample in case you change your mind. Your sample will be kept for the duration of the study. After that time, the sample will be destroyed by methods in accordance with laboratory or institution procedures.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

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You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record forever. Any research information in your medical record will also be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket

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expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Khasraw**.** At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

The grant funding this study will pay for services and procedures that are done solely for research purposes, such as the CMV blood test and research blood tests for immune system markers. Please talk with the Dr. Khasraw and the study team about the specific services and procedures that the study will pay for, and the ones for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

The grant funding this study will provide the study vaccine and Hiltonol® free of charge to you, including all costs associated with injections of the study vaccine and Hiltonol® in Duke Clinic. At the end of the study, or if you decide to withdraw from the study before it ends, your study doctor may request that you return for a checkup before you stop your study drug(s) if he/she thinks that stopping them suddenly may harm you and may ask you to complete the tests that would ordinarily occur when a person completes the study.

WHAT ABOUT COMPENSATION?
You will not be compensated for participating in this study. There are also no plans to provide any compensation to you for any new products or discoveries that may result from your participation in this research or from the use of your blood or tumor samples.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Mustafa Khasraw at (919) 684-5301 during regular business hours and at (919) 206-0493 after hours and on weekends and holidays.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Mustafa Khasraw in writing and let him know that you are withdrawing from the study. His mailing address is: Dr. Mustafa Khasraw, The Preston Robert Tisch Brain Tumor Center, DUMC 3624, Durham, N.C. 27710. Dr. Khasraw may ask you to return for a check-up before you stop your study vaccinations if he thinks that stopping the vaccination suddenly may harm you. He may also ask you to complete the tests that would ordinarily occur when a person completes the study.

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

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include if you need additional medication, don't follow the study plan, experience a study-related injury, or for administrative reasons. If this occurs, you will be notified and your study doctor will discuss other options with you.

If you agree to allow your tissue, blood, cells to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact Dr. Khasraw in writing and let him know you are withdrawing your permission for your identifiable tissue, blood, or cells to be used for future research. His mailing address is above. At that time we will ask you to indicate in writing if you want the unused identifiable tissue, blood, or cells destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

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Your samples and/or data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Mustafa Khasraw at (919) 684-5301 during regular business hours and at (919) 206-0493 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time