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

Consent Form

Study Title for Study Participants: **A study looking at targeted therapy for people with papillary craniopharyngiomas**

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: **Phase II trial of BRAF/MEK inhibitors in papillary craniopharyngiomas**

This study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute. The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

What is the usual approach to my craniopharyngioma?

You are being asked to take part in this study because you have a craniopharyngioma which has recurred (came back), gotten bigger or has residual tumor after surgery. People who are not in a study are usually treated with either surgery or radiation. Sometimes combinations of these are used and your doctor can explain which may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for several months or more.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for craniopharyngioma but you may want to receive comfort care to relieve symptoms.

Why is this study being done?

The purpose of this study is to test any good and bad effects of the study drugs called vemurafenib and cobimetinib. Researchers have looked at the genes that can be affected in craniopharyngiomas and have found mutations or changes in the gene called BRAF. When BRAF is altered, it can cause a tumor to grow.

Vemurafenib and cobimetinib have already been FDA-approved to treat advanced melanoma. Unlike craniopharyngioma, melanoma is a malignant tumor, however, both melanoma and craniopharyngiomas may have mutations in the gene called BRAF. Both drugs have not been tested in craniopharyngiomas. Because craniopharyngiomas have the same change in the BRAF gene as has been found in melanoma, the purpose of the study is to see if these drugs can shrink craniopharyngiomas. When needed, researchers will also look at a gene called beta-catenin for further confirmations in some cases.

Vemurafenib and cobimetinib could shrink your tumor but they could also cause side effects. Researchers hope to learn if the study drugs will shrink the tumor by at least one-quarter compared to its present size. There will be about 36 people taking part in this study.

What are the study groups?

This study has two groups. All study participants in each group will get vemurafenib and cobimetinib.

- **Group 1:** Patients who have a new diagnosis (i.e. surgery may have been performed, but no other therapy has been given) will be assigned to Group 1. Patients in Group 1 will receive 4-5 cycles of the study drugs and then go on to have radiation therapy and/or surgery depending on how their tumor responded to the treatment. If the tumor responded very well to the study drugs (also known as complete response), then the patient will go on to receive radiation therapy. If the tumor did not respond as well (i.e. did not show a complete response), then the patient and doctor will decide whether continue on to radiation, surgery or both. In special cases (for example, if you are not able to have surgery or radiation because of the location or other issues with your tumor) then you may be able to continue treatment beyond 5 cycles. However, your doctor must get approval from the researcher who is overseeing this study, and their approval will only be given in special cases. If approval is granted, then you can stay on study drugs until your tumor gets worse or comes back.

- **Group 2:** Patients who have a previous diagnosis and received prior treatment (i.e. surgery, radiation, chemotherapy, etc.) will receive 4 cycles of study drugs. After four cycles of treatment, the patient and doctor will decide what further treatment the patient will receive. The patient may choose to continue to receive more study drugs until their tumor gets worse or comes back.

A "cycle" is 28 days of treatment.

You will take vemurafenib two times a day for 28 days. If a dose of vemurafenib is missed, it can be taken up to 4 hours prior to the next scheduled dose. If vomiting occurs after the tablets are taken, do not take more tablets. Swallow tablets whole with a glass of water, do not crush or chew.

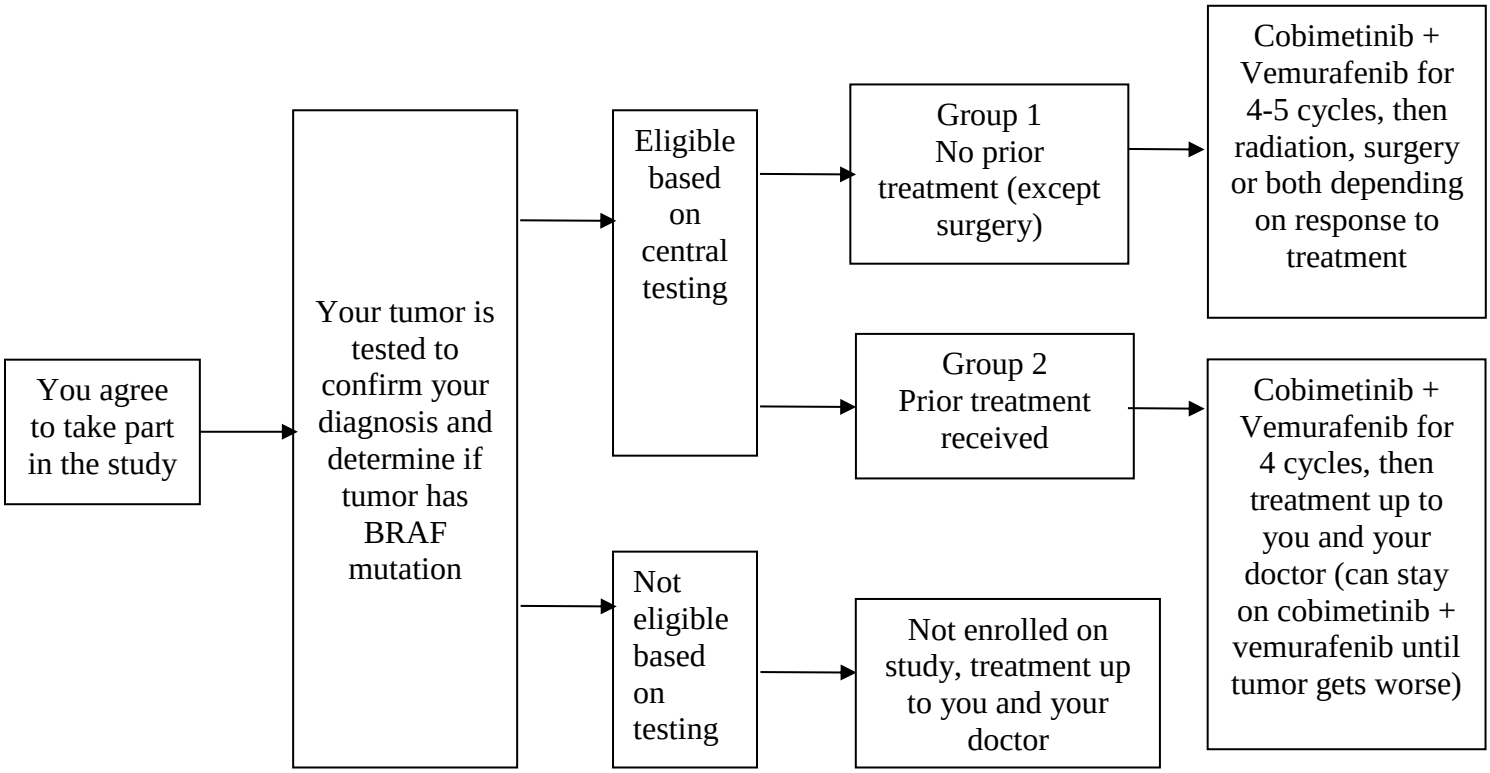
Due to the potential interactions of caffeine and vemurafenib, you must limit your caffeine intake to less than 200 milligrams (mg) per day while you are taking vemurafenib. Caffeine is found in a number of food and beverages, such as tea, coffee (even decaffeinated), chocolate, energy drinks, soft drinks, and fancy water beverages like Vitamin Water. It is important that you track the total milligrams (mg) of caffeine you have each day so that you do not go over 200 mg. You and your doctor should discuss your typical daily caffeine intake and strategies for limiting caffeine to less than 200 mg while on this study.

You will take cobimetinib for 21 days, then you will not take it for 7 days. If a dose of cobimetinib is missed by more than 6 hours, do not make up that dose; resume dosing with the next scheduled dose. Swallow tablets whole with a glass of water, do not crush or chew.

You will be given two medication diaries to record when you take vemurafenib and cobimetinib at home.

Since the study medications have the potential to interact with other medications, you may be given a drug interaction handout and wallet card as a resource for yourself, caregivers and other health care providers.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How long will I be in this study?

If you are in Group 1 (no prior treatment, except surgery), you will receive the study drugs (vemurafenib and cobimetinib) for a total of 4 to 5 cycles. Each cycle is 28 days long.

If you are in Group 2 (you have had previous treatment), you will receive the study drugs (vemurafenib and cobimetinib) for at least 4 to 5 cycles, then it is up to you-and your doctor whether you would like to continue to receive the study drugs. You can receive the study drugs as long as you do not have severe side effects or until your tumor grows.

After you finish (or discontinue) taking the medication, your doctor will continue to watch you for side effects and follow your condition for 5 years from the date you enrolled on the study.

What extra exams, tests and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests and procedures to make sure it is safe for you to take part. If you join the study, there will be exams, tests, and procedures that will be

done to closely monitor your safety and health. Most of these are included in the usual care you would receive even if you were not in a study.

Listed below are those exams, tests, and procedures that may not be needed with the usual approach, but are needed more frequently if you are in the study. The purpose of these procedures is to ensure your safety while you are taking the study treatment. We will use them to carefully monitor the effects of the study treatment, including preventing and managing side effects.

The insurance coverage information for the tests and other parts of the study is listed in a later section, "What are the Costs."

Before you begin the study:
You will need to have the following tests and exams to find out if you can be in the study. These tests and exams are part of routine clinical care for papillary craniopharyngiomas.

- Physical exam, including neurologic exam
- Blood tests
- Pregnancy test, if you are a woman of childbearing potential
- Brain MRI. As part of your participation in this study, your scans will be submitted to a central image library. These scans will be saved, and then sent to researchers so that they can analyze them.
- An eye exam is needed to make sure you do not have any eye disorders you may not be aware of that it would make it unsafe to start the study drug

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are those procedures that will be done for research purposes only.

- This study has a screening step. The purpose of this step is to confirm your diagnosis and find out if your tumor has a specific gene change or mutation called "BRAF." Your study doctor will need to obtain some of the tissue left-over from when you were diagnosed. This sample is a required part of the study. We will look for these changes by testing your tumor. If your tumor has this specific mutation, we think the drugs used in this study are more likely to work. If we find that your tumor does not have the genetic changes that are needed for this study, you will not be able to take part in this study, and your doctor will discuss other options for your care. Your tissue will be sent to Dana-Farber Cancer Institute/Brigham and Women's Hospital. Your initials and the date the tissue was collected will be included with the tissue. Your privacy is very important and the researchers will make every effort to protect it. The test results will be shared with your treating physician.
- The study researchers also would like to learn more about fatigue and quality of life. All study participants will be asked to complete a questionnaire with 2 questions. It will take less than one minute to complete the questions.

Before you begin treatment:
You will need to have the following tests and exams before you begin treatment to make sure that it would not be unsafe to start the study drugs. These tests are part of routine clinical care for papillary craniopharyngioma:

- Physical exam, including neurologic exam
- Blood tests

You will need to have the following tests and exams before you begin treatment to make sure that it would not be unsafe to start the study drugs. You will not be able to continue on the study or receive study drugs if any of the tests or exams show that it would be unsafe. These studies are NOT part of routine clinical care for papillary craniopharyngiomas.

- O2 saturation

- Electrocardiograms (EKG) of the heart
- Echocardiograms (Echo) of the heart (or MUGA)
- A skin exam is needed to make sure that you do not have any skin cancers you may not be aware of

During the study:
You will need to have the following tests and exams that are part of routine clinical care for papillary craniopharyngiomas:

- Physical exam, including neurologic exam, at the beginning of each cycle during treatment, and 4 weeks after the end of treatment with study drugs
- Blood tests at the beginning of each cycle during treatment, and 4 weeks after the end of treatment with study drugs
- Brain MRI every 8 weeks during study treatment, then every 16 weeks after completion of study treatment. As part of your participation in this study, your scans will be submitted to a central image library. These scans will be saved, and then sent to researchers so that they can analyze them.
- An eye exam is needed every 2 months for one year, then every 6 months while on study drugs, and at the end of treatment with study drugs, to make sure you do not have any eye disorders and to monitor effects of your tumor and potential side effects of the study drugs

You will need to have the following tests and exams to monitor side effects and make sure it is safe for you to continue taking study drugs. These studies are NOT part of routine clinical care for papillary craniopharyngiomas.

- O2 saturation will be performed at the beginning of each cycle during study treatment
- Electrocardiograms (EKG) will be performed every month for 3 months, then every 3 months while receiving vemurafenib
- Echocardiograms (Echo) of the heart (or MUGA) will be performed after 1 month of treatment and every 3 months while on cobimetinib
- A skin exam is needed about every 6 months while receiving study treatment to make sure that you do not have any skin cancers. When you stop taking the study drugs, your doctor will determine how often the skin exams should be performed.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- Because of the screening step, this study will use a sample of your tissue. Generally, your hospital will keep some of your tissue. This tissue may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. (For non-U.S. participants, please verify the existence of such laws before including the following sentence.) There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.
- There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study.

The drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drugs, radiation therapy or surgery.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.
- The study doctor will provide you with information about other drugs you may need to avoid while receiving the study drugs.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Risks of Vemurafenib

COMMON, SOME MAY BE SERIOUS In 100 people receiving vemurafenib, more than 20 and up to 100 may have:
• Nausea • Tiredness • Pain • Hair loss, rash, skin changes • Increased risk of sunburn

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving vemurafenib, from 4 to 20 may have:
• Constipation, diarrhea, vomiting • Swelling of arms, legs • Fever • Allergic Reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Swelling and redness of the throat and sinuses (might not be caused by infection) which may cause difficulty breathing and swallowing • Change in the heart rhythm • Weight loss, loss of appetite • Scarring in the tissues of the hands and feet which may cause fingers and toes to be stuck in the bent position

- Wart
- A new skin cancer resulting from treatment of earlier cancer
- Dizziness, headache
- Changes in taste
- Muscle weakness
- Numbness, tingling or pain of the arms and legs
- Kidney damage which may require dialysis
- Cough
- Dry skin
- Redness, pain or peeling of palms and soles
- Itching, hives
- Sores on the skin which may become cancer
- Swelling and redness of the skin

RARE, AND SERIOUS
In 100 people receiving vemurafenib, 3 or fewer may have:

- Swelling and redness of the eye
- Liver damage which may cause yellowing of eyes and skin, swelling
- Swelling and redness of the area of radiation
- A new cancer resulting from treatment of earlier cancer
- Abnormal movement of the facial muscles
- Skin rash developing 1-8 weeks after a drug is given which may be accompanied by fever, lymph node swelling and organ failure
- Severe skin rash with blisters and peeling which can involve mouth and other parts of the body

Because many subjects experienced photosensitivity while taking vemurafenib and more frequently when given with cobimetinib, you should avoid prolonged sun exposure while on study treatment and for at least 5 days after study drug discontinuation. You should also use a broad-spectrum sunscreen and lip balm of at least 30 SPF to help protect your skin against sunburn or sun damage and wear protective clothing.

Risks of Cobimetinib

COMMON, SOME MAY BE SERIOUS
In 100 people receiving cobimetinib, more than 20 and up to 100 may have:

- Diarrhea, nausea, vomiting
- Dehydration
- Rash and acne

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving cobimetinib, from 4 to 20 may have:
• Anemia which may require blood transfusion • Changes in the eyes (retinal detachment) which may cause blurred vision, visual disturbances, or visual loss • Chills, tiredness, fever • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath swelling of the face or throat • Decrease in heart function • Increased risk of sunburn • High blood pressure which may cause headaches, dizziness • Bleeding

RARE, AND SERIOUS In 100 people receiving cobimetinib, 3 or fewer may have:
• Heart failure which may cause shortness of breath, swelling of ankles, and tiredness • Blood clot in the eyes which may cause blindness • Muscle pain and/or weakness with dark red urine • Damage to the lungs which may cause shortness of breath

You should tell your doctor if you have any medical conditions that increase the risk of bleeding or if you are taking any medications that increase the risk of bleeding. You should tell your doctor right away if you experience:
• Headaches
• Dizziness
• Feeling weak
• Abdominal pain
• Vomiting blood
• Blood in your stools
• Black stools that look like tar
• Blood in your urine or unusual vaginal bleeding

<u>Vision disturbances in patients receiving vemurafenib and cobimetinib:</u>
Vision changes or disturbances can occur in patients treated with cobimetinib and other MEK inhibitors. The visual changes may be due to a temporary buildup of fluid within the layers that make up the retina (the light-sensing cells) of the eye, which is called "serous retinopathy." Other visual changes may be due to a separation of the retina (layers of tissue on the back of the eye that are responsible for sight). Symptoms may include blurred vision, seeing halos, distorted vision, partly missing vision, or other visual changes. Most patients with this side effect had this side effect improve or go away after temporarily stopping cobimetinib.

You will be monitored for these potential side effects during the study. <u>You should tell your doctor right away if you have any changes in your eyesight as you will need to undergo a medical evaluation as soon as possible.</u>
You should not drive a car or operate heavy equipment if you are having any changes in your vision.

Possible Side Effects of Research Radiation Therapy

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, more than 20 and up to 100 may have:
• Reddening, tanning, itching or peeling of the skin • Hair loss, which may be temporary or permanent • Tiredness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, from 4 to 20 may have:
• Temporary increase of brain tumor symptoms, such as headaches, seizures, or weakness • Changes in thinking patterns, decreased ability to concentrate, behavior changes, difficulty walking, difficulty talking • Temporary hearing decrease or loss, which may be permanent • Cataracts • Nausea, vomiting • Loss of appetite • Abnormal hormone levels related to changes to the pituitary gland may cause symptoms such as low blood sugar, low blood pressure, and fatigue which may require hormone replacement • Dry mouth, changes in taste

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Damage to the brain • Swelling of the brain • Blurred vision with chance of blindness • A cancer resulting from treatment of your craniopharyngioma

The combination of vemurafenib and cobimetinib may enhance the toxicity of radiation therapy. This means that you may experience more or worse side effects.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study and for 6 months after you discontinue study drug. The drugs used in this study could be very damaging to an unborn baby. As there is evidence that vemurafenib and cobimetinib may decrease the concentration of hormonal contraceptives (such as birth control pills), you must agree to use two acceptable methods of birth control while in this study and for 6 months after your last dose of vemurafenib or cobimetinib (whichever is later) to prevent exposing an unborn baby to a potentially dangerous unknown risk. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

What possible benefits can I expect from taking part in this study?

This study has only a small chance of helping you because we do not know if the study drug/study approach is effective. This study may help researchers learn things that may help other people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ *(insert name of center)* Institutional Review Board at _____ *(insert telephone number). (Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)*

What are the costs of taking part in this study?

The vemurafenib and cobimetinib will be supplied at no charge while you take part in this study. It is possible that the study drugs may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company

may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

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

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

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

Some of these organizations are:

- The Alliance and other organizations from the National Clinical Trials Network that take part in this study (such as SWOG, ECOG-ACRIN and NRG)
- The drug companies supporting the study
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.
- The laboratory/pathology office at Dana-Farber Cancer Institute/Brigham Women's Hospital that perform the BRAF testing and central review for study eligibility

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

ADDITIONAL STUDIES SECTION:

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say "no" to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part in this optional study, the study doctor for the main study would like to collect tissue and blood to study changes in genes that could help us understand why the therapy in this study works better in some patients than others. These studies could provide information that might help treat papillary craniopharyngiomas in the future.

The researchers will also ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by the Alliance and supported by the National Cancer Institute.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) If you agree to take part in the optional research study, about 2 tablespoons of blood will be collected from a vein in your arm before you start treatment, and about 1.5 tablespoons of blood will be collected from a vein in your arm after ~2 months of study treatment, at the end of treatment, and if your cancer comes back or gets worse. These samples will be sent to the Alliance Biobank. A sample from the tissue that was collected at the time of your surgery at diagnosis and at time of surgery if your cancer comes back will also be sent to the Biobank. A new biopsy or surgery will not be required. These samples and some related health information will be sent from the Biobank to researchers for use in the study described above.

2) If you agree to having your samples used for future research, any leftover blood and tissue samples and some related health information will be stored in the Biobank. The samples will be kept until they are used up or destroyed.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2) If your cancer comes back, then this study will use a sample of your tissue. Generally, your hospital will keep some of your tissue. This tissue may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.
3) Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
~~4)~~ In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your tissue samples are sent to the researchers, your initials and the date of the samples were collected will be sent along with the tissue. The blood samples will also be identified by a unique code.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and Alliance staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom Alliance sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part.

Your samples may be helpful to research whether you do or do not have cancer. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial),* at _____ *(insert telephone number of study doctor for main trial).*

Please circle your answer to show whether or not you would like to take part in each option:

SAMPLES FOR THE LABORATORY STUDIES:

I agree to have my blood collected and tissue submitted, and I agree that my specimen sample(s) and related information may be used for the laboratory study described above.

YES NO

SAMPLES FOR FUTURE RESEARCH STUDIES:

My samples and related information may be kept in a Biobank for use in future health research.

YES NO

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

:

This is the end of the section about optional studies.

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. this may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

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

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study *and any additional studies where I circled 'yes'.*

Participant _____

Participant's signature_____

Date of signature_____

Person obtaining consent_____

Signature of person obtaining consent_____

Date of signature_____