COMBINED CONSENT AND AUTHORIZATION TO PARTICIPATE IN A RESEARCH STUDY

UNIVERSITY OF KENTUCKY
CHANDLER MEDICAL CENTER
MARKEY CANCER CENTER

Study Title: 14-Multi-14-MCC: A Pilot Study to Determine the Biological Effects of Hydroxychloroquine on PAR-4 Levels in Patients with Resectable Solid Tumors

INVESTIGATOR INFORMATION: Peng Wang, MD
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University of Kentucky Markey Cancer Center
(859) 323-6522 (Days)
(859) 323-5321 (Evenings and Weekends)

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about a drug called Hydroxychloroquine (HCQ) and the effects it has on a tumor suppression protein called Prostate apoptosis response-4 (PAR-4). You are being invited to take part in this research study because you have a solid tumor that may be surgically removed. If you volunteer to take part in this study, you will be one of about 18 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Peng Wang, MD of the University of Kentucky, Department of Internal Medicine. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

Prostate apoptosis response-4 (PAR-4) is a tumor suppressor protein that induces apoptosis (cell death) in cancer cells but not in normal cells. PAR-4 is widely found in normal cells and tissues, but is often inactivated, decreased or changed in cancer cells. Usually the amount of PAR-4 secreted by normal cells is not enough to cause massive cell death in cancer cells. The drug used in this study, Hydroxychloroquine (HCQ), has been approved by the FDA for the treatment of Malaria, lupus erythematosus and rheumatoid arthritis. Prior studies suggest that HCQ can increase serum (blood) PAR-4 levels so that PAR-4 can induce death of cancer cells and may be able to prevent recurrence after surgical resection of the primary tumor. By doing this study, we hope to learn about the effects of HCQ on the levels of PAR-4 in patients with resectable (removable) solid tumors at the time of and after resection and to compare them to pre-treatment levels. We also hope to learn more about side effects related to the use of HCQ. The results of this study will be shared with the company providing financial support for the study, the Food and Drug Administration and other federal agencies, if required.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not take part in the study if:

- You are under the age of 18
- You are pregnant or nursing a child
- You are currently taking any other investigational agents
- You are unable to ingest oral medications
- You currently have illnesses that would keep you from being in this study and following the study requirements such as: an active infection, symptomatic congestive heart failure, unstable angina, cardiac arrhythmia, or psychiatric illness/social situations
- You are HIV-positive and receiving combination antiretroviral therapy
- You have Porphyria

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of Kentucky's Markey Cancer Center. You will need to come to the cancer center four times during the study. Each of those visits will take about between 30 minutes and 2 hours. The total amount of time you will be asked to volunteer for this study is 8 hours over the next 10 weeks.

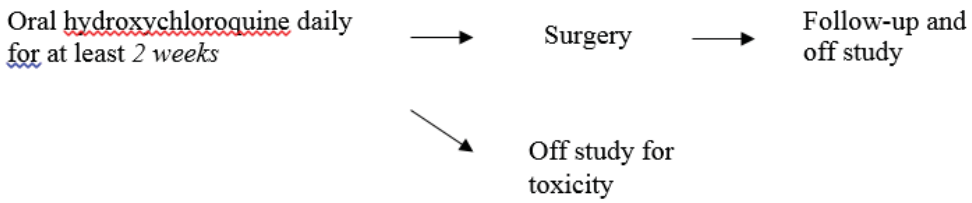
WHAT WILL YOU BE ASKED TO DO?

Before you begin treatment (Pre-study visit)…

If not already completed within 2-4 weeks of starting the study:

- You will be asked questions about your medical history.
- You will have a physical examination including vital signs, height/weight and performance status.
- Tumor collection for correlative studies (Previous biopsy of primary tumor if available)
- Blood collection for correlative studies
- If you are a female, you will have a serum (blood) pregnancy test performed if necessary.

All laboratory (blood) tests and radiological scans should be completed within 4 weeks prior to receiving study treatment.



If the exams, tests and procedures above show that you are able to participate in the study, and you choose to take part, then you will be asked to do the following:

You will receive HCQ every day for 14 days, starting at least 14 days before planned surgery. HCQ can be taken at any time of the day with meals. HCQ will be administered in divided doses (twice a day) for doses above 200 mg/day to minimize nausea. The divided doses should be taken in the AM and at night with meals. You will also be required to keep a medication diary and to present this at the end of the treatment. Should a subject regurgitate (vomit) within 30 minutes of taking the medication, the dose may be repeated once, but if vomiting occurs longer than 30 minutes after ingestion, the dose should not be repeated. If you are taking antacids, proton-pump inhibitors or H2-blockers should not take hydroxychloroquine within 4 hours of these medicines.

The starting HCQ dose will be 400 mg/day. If three subjects tolerate a dose level, the dosage will be increased to the next dose level. Once the maximum number of subjects (18) has been reached, the lowest dose that has shown the greatest biological effect based on Par-4 levels will be used. If you experience severe side effects, your dose level will be reduced by one level.

Dose Schedule	
Dose Level	**Dose**
	Hydroxychloroquine (mg/day)
Level -1	200 mg/day
STARTING DOSE: Level 1	400 mg/day
Level 2	800 mg/day
Level 3	1200 mg/day

Week 1 on day 7

- You will be asked questions about your medical history.
- You will have a physical examination including vital signs.
- You will have a blood sample drawn for routine laboratory tests including complete blood count and blood chemistries.
- Blood collection for correlative studies

Week 2 on day 14

- You will be asked questions about your medical history.
- You will have a physical examination including vital signs.
- Blood and Tumor collection for Correlative Studies (if available)
- You will have a blood sample drawn for routine laboratory tests including complete blood count and blood chemistries.
- Blood collection for correlative studies

Post-operative (inpatient)

- Tumor collection for correlative studies (Resected primary tumor if available)
- Blood collection for correlative studies

Post-operative visit

- You will be asked questions about your medical history.
- You will have a physical examination including vital signs.
- You will have a blood sample drawn for routine laboratory tests including complete blood count and blood chemistries.
- Blood collection for correlative studies

Off study

- You will be asked questions about your medical history.

Studies to be obtained	Pre-Study	Week 1 (Day7)	Week 2 (Day 14)	Day of Surgery	Post-operative visit	Off study
History	X	X	X		X	X
Physical Exam with vital signs	X	X	X		X	
Height, Weight	X					
Performance Status	X					
Blood collection for complete blood count and blood chemistry	X	X	X		X	
Pregnancy test (only females of childbearing potential)	X					
Tumor collection for Correlative Studies (if available)	X			X		
Correlative Blood work	X	X	X		X	

You will be followed for 30 days after your surgery or 30 days after completion of the last dose of hydroxychloroquine if no surgery is completed. If you are removed from study for unacceptable adverse event(s) you will be followed until the event has resolved.

The following procedures will be done as per standard of care and would be performed even if you are not in this study:

- Medical history **(Pre-study, Post-Operative and Off study visit)**
- Physical examination including vital signs and height/weight **(Pre-study and Post-Operative visit)**
- Performance status **(Pre-study visit)**
- Blood tests including complete blood count and blood chemistries **(Pre-study and Post-Operative visit)**.
- Serum (blood) pregnancy test performed **(Pre-study visit)**

All other procedures will be performed for the purposes of research.

The effects of hydroxychloroquine on the developing human fetus are unknown. For this reason, women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation. If you become pregnant or suspect that your partner has become pregnant, you should inform your or your partner's treating physician immediately. Men treated or enrolled on this protocol must also agree to use adequate contraception prior to the study, for the duration of study participation, and 4 months after completion of hydroxychloroquine administration.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

Risks and side effects related to <u>hydroxychloroquine</u> include those which are "Very common", "Common", "Uncommon", "rare", "Very rare" and "not known". The percentages associated with these labels are listed below:

- Very common ≥ 10 %
- Common ≥ 1 and <10 %
- Uncommon ≥ 0.1 and < 1 %
- Rare ≥ 0.01 and <0.1 %
- Very rare < 0.01 %
- Not known (frequency cannot be estimated from available data)

Blood and lymphatic system disorders
Not known: Bone marrow depression, anemia (your body makes too few red blood cells), aplastic anemia (your body makes too few red blood cells, white blood cells, and platelets), agranulocytosis (a condition involving a severe lowered white blood cell count), leucopenia (decreased white blood cells) and thrombocytopenia (decreased platelets in the blood).

Cardiac disorders
Not known: Cardiomyopathy, which may result in cardiac failure and in some cases a fatal outcome. Chronic toxicity should be considered when conduction disorders (bundle branch block/ atrioventricular heart block) as well as biventricular hypertrophy are found. Drug discontinuation may lead to recovery.

Ear and labyrinth disorders
Uncommon: Vertigo (a sensation of rotation or movement of one's self or of one's surroundings), tinnitus (a buzzing or ringing in the ears)

Not known: Hearing loss including cases of irreversible hearing loss.

Eye disorders
Common: Blurring of vision due to a disturbance of accommodation which is dose dependent and reversible.

Uncommon: Maculopathies (a disease of the macula retinae-an area at the center of the retina) which may be irreversible.

Retinopathy (disease of the retina) with changes in pigmentation and visual field defects. In its early form it appears reversible upon discontinuation of the drug. If allowed to develop however, there may be a risk of progression even after treatment withdrawal. Patients with retinal changes may be not notice symptoms at first, or may have scotomatous vision (blind spots), abnormal color visions, reduction in visual acuity (clarity of vision), night blindness, difficulty reading and skipping words. Corneal changes including edema (swelling) and opacities (clouding). They are either symptomless or may cause disturbances such as halos around lights especially at night, blurring of vision or photophobia (sensitivity to light). They may be transient or are reversible upon discontinuation of therapy.

Not known: Macular degeneration (deterioration of a critical region of the retina called the macula) which may be irreversible.

Gastrointestinal disorders
Very common: Abdominal pain, nausea

Common: Diarrhea, vomiting
These symptoms usually resolve immediately upon reducing the dose or upon stopping the treatment.

Hepatobiliary disorders
Uncommon: Abnormal liver function tests

Not known: Fulminant hepatic failure (acute liver injury)

Immune system disorders
Not known: Urticaria (Hives), angioedema (swelling under the skin), bronchospasm (tightening of the airways going into the lungs).

Metabolism and nutrition disorders
Common: Anorexia (Lack or loss of appetite). This symptom usually resolves immediately upon reducing the dose or upon stopping the treatment).

Not known: hypoglycemia
HYDROXYCHLOROQUINE may exacerbate porphyria (a disorder characterizes by decreased heme production).

Musculoskeletal and connective tissue disorders
Uncommon: Sensory motor disorders

Not known: Skeletal muscle palsies (paralysis) or skeletal muscle myopathy (weakness) or neuromyopathy leading to progressive weakness and atrophy of proximal muscle groups. Depression of tendon reflexes, abnormal results of nerve conduction tests. Myopathy may be reversible after drug discontinuation, but recovery may take many months.

Nervous system disorders
Common: Headache

Uncommon: Dizziness

Not known: Convulsions

Psychiatric disorders
Common: Affect lability (rapidly changing mood)

Uncommon: Nervousness

Not known: Psychosis, suicidal behaviour

Skin and subcutaneous tissue disorders
Common: Skin rash, pruritus

Uncommon: Pigmentary changes in skin and mucous membranes, bleaching of hair, alopecia. These usually resolve readily upon cessation of therapy.

Not known: Bullous eruptions (blisters) toxic epidermal necrolysis (a condition where the top layer of skin separates from the lower layers), erythema multiforme/Stevens-Johnson syndrome (drug induced hypersensitive reaction that results in sores on the skin), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS syndrome), photosensitivity (light sensitivity), exfoliative dermatitis (scaling of the skin), acute generalized exanthematous pustulosis (AGEP). AGEP has to be distinguished from psoriasis, although HYDROXYCHLOROQUINE may precipitate attacks of psoriasis. It may be associated with fever and hyperleukocytosis (elevated white blood count). Outcome is usually favorable after discontinuation of drug.

Blood Draw: soreness, bruising, pain, infection, possible fainting, bleeding.

Reproductive risks:
You should not become pregnant or father a baby while on this study because the treatment used in this study may involve a risks to you (or your embryo or fetus if you become pregnant) which are currently unforeseeable. Women should not breastfeed a baby while on this study. It is important that you understand that you need to use birth control while on this study and for 4 months after your last treatment. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. Some of the drugs used in the study may make you unable to have children in the future.

If you or your partner becomes pregnant anytime during the study or within 4 months after stopping the study drug, you MUST immediately tell your study doctor. The study doctor must then report the outcome of the pregnancy to the Sponsor (and/or the FDA).

For more information about risks and side effects, ask your study doctor.

There is always a chance that any medical treatment can harm you, and the investigational treatment in this study is no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There may be no direct benefit to you for participating in this study. The growth of your cancer may be slowed as a result of your participation in this study; however, that result cannot be guaranteed. Your participation in this study could help advance medical research and the information from this research may help other people with cancer.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, you will proceed with surgery as planned. You do not need to participate in this study to receive treatment for your cancer.

You may talk with your study doctor about these and other options before you agree to enter the study, and about other options that may become available during the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive for your condition. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

Medicare, or Medicaid will pay medically necessary costs (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid at 1-800-635-2570. **A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs.** Some health plans will not pay for some costs of people taking part in clinical trials. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

The University of Kentucky may not be allowed to bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research. You will not be billed for the costs associated with the week 1 and week 2 visits or for the blood and tumor correlative collections or for the study drug (Hydroxychloroquine). These costs will be paid by the sponsor.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. At the University of Kentucky, data is stored at the Markey Cancer Center in locked facilities, and with limited access to records by designated research staff.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.

Organizations that may look at and/or copy your medical records for research, quality assurance and data analysis include:

- The University of Kentucky Institutional Review Board
- Representatives of the U.S. Food and Drug Administration as required by law
- Representatives of the National Cancer Institute (NCI)
- Representatives of the Kentucky Cancer Registry
- Authorized representatives of the University of Kentucky, UK Hospital, and the Markey Cancer Center

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

If you choose to withdraw from the study early, the data collected until that point will remain in the study database and may not be removed.

The individuals conducting the study may need to withdraw you from the study, and the study medication will no longer be provided by the investigator. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

Certain drugs may harm you if you stop taking them suddenly. To make sure this doesn't happen, the doctor may ask you to gradually reduce the amount of medication you are taking, if you want to stop

taking part in the study. If you are a female of childbearing potential, your participation in this study may be discontinued if you become pregnant or suspect you may have become pregnant.

If you decide to leave the study, please contact **Peng Wang, MD** or one of the study associates who will tell you what you should do before leaving. You may be asked to return to the clinic for follow-up care, if necessary. You may be asked to have any laboratory tests, or physical examinations that the study doctor feels are necessary. Until your permission is withdrawn, additional information may continue to be taken from your medical records for study follow-up purposes.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may **not** take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call **Peng Wang, M.D. at (859) 323-6522** immediately. If you should have an emergency after 5pm during the week or on the weekend, please contact the **UK Paging Operator at (859) 323-5321** and ask to page Peng Wang, MD. He will determine what type of treatment, if any, that is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research related harm will be your responsibility. It is possible that these costs may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); or may be paid by Medicare or Medicaid if you are covered by Medicare, or Medicaid (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.

A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be substantial.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Peng Wang, MD at 859-323-6522. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

POTENTIAL FUTURE USE

Banking biologic material (tissues/specimens) for future use

WHAT IS THE PURPOSE OF THE BANK?

The purpose of the bank is to collect and store leftover samples of tissue and blood along with health information for research purposes. Researchers can then use the stored materials for future research studies to learn more about cancer.

The goal of the study is to ask 18 patients if they would like to participate. Having samples from many people allows the researchers to identify trends and discover better ways to diagnose, prevent, and treat many conditions.

The researchers who obtain your samples from the may use the genetic material (genes, DNA, RNA) in your sample to learn about the role genes play in heath and disease. Results of genetic studies may also reveal information about your family members.

WHERE WILL SAMPLES AND INFORMATION BE STORED AND FOR HOW LONG?

The samples and information will be stored at the University of Kentucky Markey Biospecimen and Tissue Procurement Shared Resource Facility for 5 years or until they are all used up.

WHAT WILL THE BANK COLLECT AND STORE FOR RESEARCH?

During the main study about Ten to 30 mL (about 2 tablespoons) of blood and a tissue sample will be collected for analysis. Dr. Peng Wang would like to keep some of the blood and tissue that remains after this testing has been completed for the purpose of future testing. No additional blood or tissue will be taken.

We also would like to have permission to look at your medical records from time to time. We would collect general information related to your health such as test results, treatments, and doctor's notes. Medical records may also include psychiatric, genetic, HIVAIDS, alcohol/substance abuse information. The confidentiality section below provides details about how we will keep your information private.

WILL YOU BE CONTACTED ABOUT FUTURE RESEARCH?

The researchers who access samples or information related to them will not contact you about future research. If you wish to participate in research studies, you may find information at www.ukclinicalresearch.com.

HOW WILL THE BANK SHARE SAMPLES AND INFORMATION WITH OTHER RESEARCHERS?

Your sample or information may be shared with University of Kentucky (UK) researchers and researchers outside of UK.

Researchers may contact the bank to request permission to use samples or information for their studies. An oversight committee will review the researcher's qualifications and proposed research. The committee will also determine if any additional review or approval is necessary.

The bank will remove all information that could identify you such as your name, address, medical record number, etc, before sharing with researchers. The bank will use a code to match your samples with your medical information without releasing your identity. The researchers will sign an agreement promising not to try to use any of the sample or information to identify you. The bank will not share information that could identify you without your permission.

WILL YOU BENEFIT FROM TAKING PART IN THE (*BANK*)?

There is no direct benefit to you. The knowledge gained from research on your sample may help others in the future.

ARE THERE RISKS FROM TAKING PART IN THE (BANK)?

Physical:
There is no additional physical risk from collecting leftover tissue from a procedure that is being done as part of your clinical care.

Blood draw
Risks associated with blood sampling are generally slight, but may include soreness, bruising, pain, infection, possible fainting, bleeding.

Privacy and Social/Psychological:
There is a risk that someone could get access to the information stored in the bank. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

Even without your name or identifiers, genetic information is unique to you making it possible for someone to trace it back to you. The results of genetic research apply to both you and your family members. In some cases, it could be used to make it harder for you to get or keep a job or insurance. Genetic information could be used in ways that could cause you or your family distress.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease.

Unknown:
There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.

HOW IS YOUR PRIVACY AND CONFIDENTIALITY PROTECTED?

The bank will take careful steps to keep your information confidential. Electronic records will only be accessible to authorized personnel and will require passwords for access.

We will remove information such as your name or other direct identifiers from your sample and medical information. We will label your samples and information with a code. The coded samples will be kept in locked facilities only accessible by authorized research staff. Data will be store in a password protected database.

Only select bank staff will have access to the list that links the code to you. The bank staff members sign an agreement to keep your identity a secret to the extent allowed by law. In very unusual cases, staff at the bank may be required to release your identifiable medical and research information in response to an order from a court of law.

Officials of the Food and Drug Administration, the National Cancer Institute (NCI) and the University of Kentucky may look at or copy pertinent portions of records that identify you.

DOES TAKING PART IN THE BANK COST ANYTHING?

There will be no additional costs or charges to you for taking part in the bank. You will not need to pay for sample collection or blood test done just for the bank.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THE BANK?

You will not be paid for donating your sample or information to the bank. The sample and information that you are donating will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Do you give permission for Peng Wang, MD to contact you with information about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

☐ Yes ☐ No _____Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Peng Wang, MD M.D. c/o Markey Cancer Center Clinical Research Organization, cc140 Markey Cancer Center, 800 Rose Street, Lexington, KY. 40536-0093.

Are there other choices if you do not want to participate in the repository?

If you do not want to take part in the repository, there are no other choices except not to take part. Your decision will not affect your current or future medical care.

WHAT IF YOU CHOOSE NOT TO PARTICIPATE OR CHANGE YOUR MIND AND WANT TO WITHDRAW FROM TAKING PART IN THE BANK?

Taking part in the bank is voluntary. Choosing not to take part will not affect your care or cause you to lose benefits to which you are entitled. You may withdraw your permission to continue taking part in the bank at any time. To do so, you must send a written withdraw request to the bank at Peng Wang, MD M.D. c/o Markey Cancer Center Clinical Research Organization, cc140 Markey Cancer Center, 800 Rose Street, Lexington, KY. 40536-0093. The bank will destroy any remaining samples and information that has been stored. In addition, it may be possible for the bank to destroy the code that links you with your sample and medical information. However, the samples and information that has already been shared with other researchers or placed in shared databases cannot be withdrawn.

Please read each sentence below and think about your choice. After reading each sentence, mark "yes" or "no". If you have questions, please talk to the investigator or staff. Remember, no matter what you decide to do about the storage, or banking, and future use of your blood and tissue samples, you may still take part in the main study. If you answer yes to either choice below you also give your authorization for your accompanying health information to be used and disclosed along with the blood.

1. Do you give permission for your blood and tissue to be kept by Dr. Wang in a central location/specimen bank at the University of Kentucky Markey Biospecimen and Tissue Procurement Shared Resource Facility until they are used up but no longer than 5 years for use in

future research to learn more about how to prevent, detect or treat squamous cell carcinoma of the head and neck?

☐ Yes ☐ No _____Initials

2. Do you give permission for your blood and tissue samples to be used for future research about other health problems?

☐ Yes ☐ No _____Initials

The sample(s) (blood and tissue) you are giving will no longer belong to you and might be used in studies that lead to new products for research, diagnosis or treatment. These products might have some commercial value. There are no plans to provide financial compensation to you should this occur.

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data/tissue/specimens/blood collected from you may be shared with other investigators in the future. If that is the case the data/tissue/specimen/blood will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

The Markey Cancer Center is providing financial support and/or material for this study.

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

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic Information (Example: Sex, race & age, etc.)
- History and diagnosis of your disease
- Specific information about treatments you have received
- Past and present medical records pertaining to your health condition
- Your entire research record
- Information about other medical conditions that may affect your treatment
- Medical data, including physical examinations, laboratory test results, tumor measurements, CT scans, MRIs, X-rays, photographs of radiation therapy target areas, and pathology results
- Information on side effects (adverse events) you may experience, and how these were treated

- Long-term information about your general health status and the status of your disease
- Tissue and/or blood samples, associated data related to the analysis of the samples

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- Authorized representatives of the University of Kentucky, UK Hospital, and Markey Cancer Center
- Representatives of the Kentucky Cancer Registry
- Representatives of the U.S. Food and Drug Administration (FDA)
- The National Institutes of Health and its affiliates including the for Human Research Protections (OHRP) and the NCI (National Cancer Institute) and their affiliates

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

If you become pregnant anytime during the study or within **90 days** after stopping the study drug, you must inform the study doctor. The study doctor must then report the outcome of your pregnancy to the sponsor and/or the FDA.

You may not be allowed to participate in the research study. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans (if applicable)**
- **Eligibility for benefits (if applicable)**

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Peng Wang, MD M.D. c/o Markey Cancer Center Clinical Research Organization, cc140 Markey Cancer Center, 800 Rose Street, Lexington, KY. 40536-0093 to inform him of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

_____ _____
Signature of research subject Date

_____
Printed name of research subject

_____ _____
Name of [authorized] person obtaining informed consent/HIPAA authorization Date

_____
Signature of Principal Investigator or Sub/Co-Investigator