RUTGERS
New Jersey Medical School

Radiation Oncology
New Jersey Medical School
Rutgers, The State University of New Jersey
195 South Orange Avenue
Newark, NJ 07103-2785

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Selecting for Cetuximab Responders in Advanced Head and Neck SCC

STUDY DOCTOR:
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TELEPHONE NUMBERS: 973-972-5053 (24 hours)

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask the study doctor (the principal investigator, Dr. Kim) or another member of the study team (an investigator) and you should expect to be given answers that you completely understand. After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor or another member of the study team will also be asked to sign this informed consent form. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Sponsor of the study:
The Rutgers Cancer Institute of New Jersey is the sponsor of this research study.

Why is this study being done?
Oropharynx, hypopharynx and larynx are three common areas where head and neck cancer can start. These areas are basically the voice box, and the part of the throat that is behind the mouth and behind the voice box. Advanced head and neck cancer of these three areas are usually treated with a combination of radiation therapy and cisplatin (a chemotherapy drug) or cetuximab. Cetuximab is a targeted drug that blocks epidermal growth factor receptor (EGFR) a protein that affects cancer growth and many other functions. Studies have shown that adding cisplatin or

cetuximab to radiation is better than radiation alone. One study (RTOG 1016) found that in oropharynx cancer that is caused by the HPV virus, radiation given with cisplatinum was more effective than radiation given with cetuximab. So why is it ethical to do this present study? Because the patients in this study who received cetuximab were not selected to respond well to cetuximab, as they are in this present study. We know that patients who are selected because they develop a rash to cetuximab survive about three times longer than those patients who do not develop a rash.

Some patients who have been treated with cetuximab develop a skin rash on the face and upper body. The "cetuximab rash" is a "marker" (sign) that the cancer is responding to treatment.

The purpose of this study is to prove that the skin rash can be used as a marker (sign) that the cancer will respond to cetuximab. Cisplatin is a commonly used drug, but has certain side effects (that cetuximab does not) that can sometimes damage the kidneys, hearing, cause nausea or vomiting, or lower blood counts. Cetuximab has its own side effects, the most common being a skin rash. If this study is successful, then it may offer a great alternative to cisplatinum for the many head & neck cancer patients who cannot tolerate it.

In this study, cetuximab will be given once a week for 3 weeks. Patients who develop the cetuximab rash or who have documentation of tumor shrinking on CT scan during the 3 weeks will continue to receive radiation and weekly cetuximab. On the other hand, if a patient does not develop the rash and their tumor does not shrink on CT scan, he/she likely will not respond well to cetuximab, and will then receive radiation and cisplatin.

As part of the study, biopsy specimens will be obtained from the tumor or a neck lymph node before and after the 3 weeks of cetuximab, and a biopsy of the skin will also be taken (a total of 4 specimens will be taken). These biopsy samples will be tested to see what changes the cetuximab treatment causes in the tumor and skin. The hope is that the information learned from this study will improve our knowledge of why some tumors respond and some do not, and will also lead to a larger study.

Why have you been asked to take part in this study?
You have been asked to take part in this study because you have been diagnosed with advanced (stage III or IV) but possibly curable head and neck cancer that has not spread to other parts of your body.

Who may take part in this study? And who may not?
You may take part if you are male or female and 18 years of age and

- You have been diagnosed with advanced head and neck cancer of the larynx, oropharynx or hypopharynx
- You have read and signed this informed consent

You may not take part if:

- You have received radiation therapy or surgery (other than biopsy) to the head and neck area

- Your cancer has spread to other parts of your body beyond the head and neck
- You are pregnant or breastfeeding

How long will the study take and how many subjects will participate?
You will be on study for 2 years after your radiation is completed. About 27 patients will take part in this study. You will be one of approximately 22 patients to take part in this study from Rutgers New Jersey Medical School - University Hospital from Newark, NJ.

What will you be asked to do if you take part in this research study?

Study Treatment

- You will receive cetuximab once a week for 3 weeks.
- If you get the cetuximab rash or the CT scans show your cancer is shrinking, you will receive:
    - Radiation therapy Monday – Friday for 6-7 weeks and
    - Cetuximab treatment weekly

If you do not get the cetuximab rash **and** the CT scans show that your cancer has not shrunk, you will receive:

- Radiation Therapy Monday – Friday for 6-7 weeks and
- Cisplatin chemotherapy once every 3 weeks **or** weekly, this will be up to the study doctor

Before you begin the study:
You will have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and would be done even if you do not take part in the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- History and physical exam
- Blood tests (about 3 teaspoons from a vein in your arm)
- Biopsy of the head and neck cancer
- If you are a woman able to have children, you will be asked to give some urine or blood for a pregnancy test.
- PET/CT and CT scan of the neck with IV contrast
- An evaluation of your ability to chew and swallow and to see if a feeding tube is needed (only if the doctor thinks you need to have this evaluation)
- Dental evaluation (prior to starting Radiation Therapy)
- Speech Evaluation (this may be done after you have started treatment)

During the treatment:
If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

- Weekly history and physical exam
- CT of the neck with IV contrast after 3 weeks of cetuximab treatment
- Blood tests (about 3 teaspoons from a vein in your arm)

These procedures below are not part of regular cancer care. They are being done because you are taking part in the study. These will be done before starting cetuximab and after 3 weeks of treatment with cetuximab:

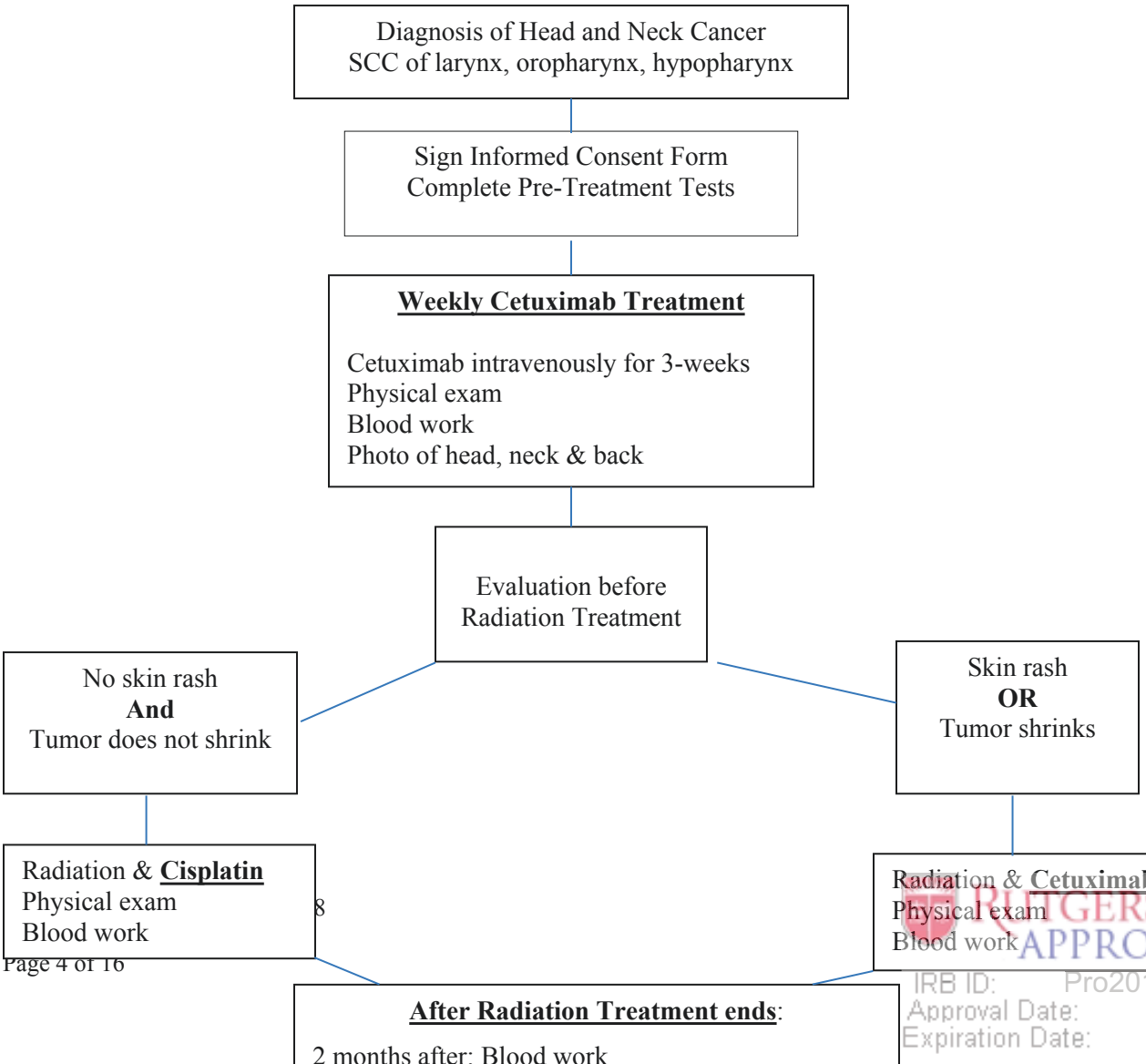
- Biopsies of the head and neck cancer (in addition to initial biopsy used to diagnose cancer)
- Biopsies of the skin of upper chest or back
- Have photographs taken of your face and upper chest.

Follow-up After you finish treatment you will have:

- A PET/CT scan 3 months after treatment is completed
- Visit with the study doctor every 3-4 months after treatment for at least 2 years
- Have a repeat biopsy of the cancer if the cancer comes back after treatment

STUDY CHART

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines



What are the risks and/or discomforts you might experience if you take part in this study?
You may have side effects while on this study. Most of the risks and discomforts described below may happen if you did not take part on this study. However, researchers don't know all the side effects that may happen. Some side effects go away soon after you stop radiation therapy or stop taking cetuximab or cisplatin.

Possible Side Effects of Radiation to the Head and Neck

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, more than 20 and up to 100 may have:
• Sores in the mouth and/or throat which can be painful and make it very difficult to chew and or swallow foods • Mouth dryness or changes in taste and/or smell that may be permanent • Thick saliva • Hoarseness • Tanning or redness and/or irritation of the skin in the head and neck area being treated with radiation • Ear pain and/or pressure • Fatigue • Weight loss • Permanent hair loss in the area treated with radiation (face, chin, neck) • Loss of teeth, or cavities in the teeth, if strict dental care is not followed and/or hypersensitivity of teeth

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, from 4 to 20 may have:
• Decrease in function of the thyroid gland that may require you to take thyroid replacement medicine to prevent you from feeling tired or sleepy • Serious damage to the spinal cord, nerves in the neck, jawbone, voice box, skin, or other parts of the head and neck that may require a major operation to correct and, rarely, can even be life threatening • Temporary pain or scarring around nerves in the shoulder that could cause numbness and/or weakness • Breathing problems • Difficulty with swallowing and eating for which you might need a long term or permanent feeding tube; possibility of inhaling food and/or liquids into the lungs – which could also result in pneumonia. This side effect is more likely for patients receiving radiation and cisplatin (Group 1). • Serious ear infections and/or hearing loss • Damage to the spinal cord leading to permanent weakness and/or symptoms like a "stroke" • Loss of hearing

Possible side effects related to cisplatin

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, more than 20 and up to 100 may have:
• Nausea, vomiting • Infection, especially when white blood cell count is low • Anemia, which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Kidney damage, which may cause swelling, may require dialysis • Hearing decrease, including ringing in ears • Change in taste

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, from 4 to 20 may have:
• Allergic reaction, which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Confusion • Difficulty with balance • Numbness in the fingers and toes • Low blood pressure • Low magnesium in the blood, which may cause heart beat irregularities that are possible life threatening

RARE, AND SERIOUS In 100 people receiving Cisplatin, 3 or fewer may have:
• Cancer of bone marrow later in life caused by chemotherapy • Seizure

Possible Side Effects of Cetuximab

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cetuximab, more than 20 and up to 100 may have:
• Change in nails • Swelling and redness of the area of radiation • Rash, itching, dry skin, acne • Dehydration, weight loss, loss of appetite • Sores in mouth which may cause difficulty swallowing • Constipation, diarrhea, vomiting, nausea • Difficulty sleeping • Headache, tiredness • Pain • Fever • Infection, especially when white blood cell count is low • Cough, shortness of breath

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cetuximab, from 4 to 20 may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Confusion, depression, worry • Fainting • Severe blood infection • Blood clot which may cause swelling, pain, shortness of breath

RARE, AND SERIOUS In 100 people receiving Cetuximab, 3 or fewer may have:
• Scarring of the lungs • Kidney damage which may require dialysis • Heart stops beating

Risks Associated with Cetuximab and Radiation Therapy:
The combination of cetuximab with radiation therapy could increase the likelihood and/or severity of the side effects of radiation therapy. The combination also could increase the risk of heart damage, including heart attack, abnormal heart rhythms, and/or heart failure, which could lead to death.

Risk of 3 Weeks of Cetuximab Treatment
When treating with cetuximab, the usual course is one week of cetuximab followed by radiation therapy combined with weekly cetuximab. In this study radiation therapy will start after 3 weeks (as opposed to one week) of cetuximab.

There is some theoretical risk your cancer may progress (get worse) during the 3 weeks of cetuximab treatment prior to radiation, though we believe that risk is very small. You will have a CT scan of your neck done prior to and then after the 3 weeks of cetuximab treatment, so we can assess how often this happens. However, in our experience, the usual time from biopsy to starting radiation is around 6 weeks, so we do not believe that patients on this study will have a significant delay in starting radiation compared to patients who are not take part on this study.

Reproductive risks
You should not become pregnant or father a baby while on this study because the radiation treatment and/or cisplatin or cetuximab in this study can affect an unborn baby. Women who are able to have children will have a pregnancy test before beginning treatment. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. The treatment in the study may make you unable to have children in the future. Women of childbearing age can ask their doctor for information about pre-treatment or post-treatment reproductive or fertility options prior to agreeing to participate in the study.

<u>Risks of Biopsy</u>
There are also additional biopsies of the tumor and skin in this protocol. The side effects from

biopsies include a small risk of infection or bleeding from the site of the biopsy.

Are there any benefits for you if you choose to take part in this research study?
Taking part in this study may or may not make your health better. The study doctors hope that the cetuximab rash may be used as a form of personalized treatment for head and neck cancer, and allow our head and neck cancer patients (as well as future patients) to be treated effectively with minimal side effects. The information collected from your biopsies will be tested, and may help doctors understand this disease and why some cancers respond differently to cetuximab than others. The information from this study may help future cancer patients.

What are your alternatives if you don't want to take part in this study?
Your other choices may include:

- Getting standard treatment , which is typically either radiation therapy and cisplatin or radiation therapy and cetuximab
- Receiving surgical resection. Whether you can receive surgery or not depends on the location and extent of your cancer. For the sites in this protocol (oropharynx, hypopharynx, larynx) radiation is the typical therapy, unless the cancer is small.
- Getting no treatment
- You may choose not to be treated for cancer, but you may want to receive comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Has anyone done a direct comparison study between cetuximab and cisplatinum?
One study (RTOG 1016) found that in oropharynx cancer that is caused by the HPV virus, radiation given with cisplatinum was more effective than radiation given with cetuximab. So why are we still doing this study? Because the patients in this study who received cetuximab were not selected to respond well to cetuximab, as they are in this present study. We know that patients who are selected because they develop a rash to cetuximab survive about three times longer than those patients who do not develop a rash.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to go on taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?
You and/or your insurance company will be billed for the costs of your treatment that are considered standard of care (for example, doctor/ Advanced Practice Nurse (APN) visits, nursing care to administer the treatments, routine lab tests, restaging scans, etc.) as you would have received these services even if you were not participating in this study. You will be responsible for any copayments due for office visits, co-insurances and deductibles due on any tests and/or procedures that are required and considered standard care.

Will you be paid to take part in this study?
You will not be paid to take part in this study.

How will information about you be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

A description of this clinical trial will be available on 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 website at any time.

What will happen if you are injured during this study?
If you take part in this study, you will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment. In addition, it is possible that during the course of this study, new adverse effects of cisplatin, cetuximab, or radiation therapy that result in personal injury may be discovered. Please refer to section "What are the risks and/or discomforts you might experience if you take part in this study?". The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?
Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to Sung Kim, MD, Rutgers New Jersey Medical School, 195 South Orange Avenue, Newark, NJ 07103.

Any data that has already been sent to the Cancer Institute and/or the Office of Human Research Services at the Rutgers Cancer Institute of New Jersey may not be withdrawn because there may not be any identifiers to link the data with you.

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the

study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Sung Kim, MD
Rutgers New Jersey Medical School
(973) 972-5053

If you have any questions about your rights as a research subject, you can call:

IRB Director (973) 972-3608

Where can you get more information?
You may call the National Cancer Institute's Cancer Information Service at: Voice: 1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/
For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

What are your rights if you decide to take part in this research study?
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

Consent to Store Tissue and/or Health Information for Future Research Use:

You will have tumor biopsies taken before and after 3 weeks of cetuximab treatment. The tissue will be tested to see what changes the cetuximab treatment causes in the tumor. The investigator is asking your permission to store any left-over tumor for future research studies. If you agree, the tumor tissue will be kept and may be used to learn more about cancer. You may still participate in the main study even if you do not agree to allow your tissue to be stored for future research.

How and where will your tissue and health information be stored and by whom?
The samples will be kept until they are used up or destroyed. The samples are given a code to protect your privacy before they are used. Any related information given to researchers will also be coded.

The samples and health information will be stored at the Rutgers Cancer Institute of New Jersey Biorepository Service (BRS). BRS is a tissue bank owned and operated by the Cancer Institute of New Jersey and located at 195 Little Albany Street in New Brunswick, NJ.

How will tissue samples and information be collected?
Your tumor tissue and health information will be collected by the study doctors. The samples will be processed and transferred to the BRS tissue bank. Information from your medical record will be collected, but will not contain any personal information. Any related information given to researchers will be coded.

What are the risks of harm to you?
Use of Your Personal Information: The greatest risk to you is release of your information from your health records. To reduce this risk your name and personal information (such as date of birth or medical record number) will not be used. Your samples will be coded with a study identification number to protect your personal information. The databases developed for this project will be secured and only the study doctors and authorized personnel will have access to it. However, people may develop ways in the future that would allow someone to link your medical information back to you. It is also possible the computer systems can be hacked by unauthorized people. We will do our best to protect your personal information.

Risk of Genetic Testing: Your tumor tissue will be used in the future to learn more about how to prevent, diagnose and treat cancer may be used for genetic testing. The results from the testing will not be placed in your medical records and used for research only.

Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. It may be possible that genetic information from them could be used to identify you. It may also be possible that genetic information from you could be used to help identify them.

New health information about genetic traits that might affect you or your blood relatives could be found during a research study. Very rarely health or genetic information could be misused by health providers, life insurance companies, and others. For example, life insurance companies may charge a higher rate based on this information. The risk of misuse of your genetic information is very small. This is because the researchers has taken special steps to keep your information and results confidential. There are state and federal laws that protect against genetic discrimination.

Genetic Information Law: There is a federal law call the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell

life insurance, disability insurance, or long-term care insurance.

There also may be other privacy risks that are unknown.

What are the benefits of participation?
You will not benefit personally from providing a sample. The research done on your samples may help investigators understand, prevent, or treat the diseases and conditions studied in the future.

How will information about you and your tissue samples be kept private and confidential?
Your samples will be given a code number. Information related to your age, sex, race, health condition and other important clinical information will also be given a code number. Your name, date of birth, address, or other personal identifying information, will not be linked with the samples you give.

Is there other important information to consider?

Cost
There is no cost to you if you agree to let us to store and use your tissue and information for future research.

You will not be paid for your samples and information. If any information from your tissue and information leads to making any drug, test or treatment, there is no plan to share any of the profits with you.

What are your rights if you agree to the storage and use of your tissue for future research?
You have the right to ask questions about any part of our storage and future research at any time. You should not sign this form unless you have a chance to ask questions and have been given answers to all of your questions. Your participation in storing tumor tissues in the BRS is voluntary. You do not have to participate. If you do, you can change your mind at any time.

What are the procedures for withdrawing consent?
We will keep records linking your identity with the tissue samples for a period of 10 years after the study has finished. If at any time you decide you no longer want your samples used for research, please write to Sung Kim, MD at Rutgers Cancer Institute of New Jersey Radiation Oncology, 195 Little Albany Street, New Brunswick NJ 08903. You may also tell him to destroy any personal and private health information that you provided.

If your samples and information have already been used for research before your request; it will not be possible to destroy them. However, any unused tissue samples will be destroyed. Your health information will no longer be used for research.

Permission to Store Tissue and Health Information for Future Research Use:
Please tell us if and how you wish your samples and information to be used for future research.

Initial next to ways you permit your samples and information to be used.

1. My samples **and** information may be stored and used for future research to learn about, prevent or treat head and neck cancers

_____YES _____NO
Initials Initials

2. My samples and information may be used in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease or heart disease):

_____YES _____NO
Initials Initials

Permission to Contact You with Additional Requests to Participate in Research

The investigators may contact me in the future to ask me to take part in more research.

_____YES _____NO
Initials Initials

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization (permission). If you sign this form, it will provide that authorization. The next few paragraphs tell you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Because we are committed to protecting your health information, some of the paragraphs that follow repeat what we described to you earlier in this consent form:

- what information we will collect about you
- how we will use it, when or if it will be shared with others, and
- The measures we will take to protect your privacy and the confidentiality of your personal information.

Please read this authorization section and the consent form carefully. Ask questions if anything is not understandable to you.

Do you have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study and receive any research related products. However, signing the form is not a condition for receiving any medical care outside the study.

If you sign, can you revoke your authorization or withdraw your information later?
If you decide to participate, you are free to withdraw your authorization regarding the use and

disclosure of your health information (and to discontinue any other participation in the study) at any time. After you withdraw your authorization, your health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your information. Therefore, you should be aware that the researchers may continue to use and disclose the health information that was provided before you withdrew your authorization if necessary to maintain integrity of the research or if the data had already been stripped of all identifiers.

If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you may do so in writing to Sung Kim, MD, Rutgers Cancer Institute of New Jersey, 195 Little Albany Street, New Brunswick, NJ 08903.

What personal information will be used or disclosed?
Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information gathered for this research about:
    - physical examinations
    - Laboratory, x-rays, MRI and other test results
    - Records about any medications you received

Who may use or disclose the information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- Rutgers University Institutional Review Board (IRB - a committee that reviews research studies to protect people participating in research.)
- Robert Wood Johnson University Hospital (RWJUH)
- Rutgers Cancer Institute of New Jersey
- Rutgers New Jersey Medical School
- University Hospital, Newark, New Jersey

Who may receive/use the information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- U.S. Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (DHHS)

Your information may be re-disclosed (shared) by the recipients described above, if they are not required by law to protect the privacy of the information.

When will your authorization expire?
There is no set date at which your authorization will expire. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Will access to your medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.

AGREEMENT TO PARTICIPATE
I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

I agree to take part in this study.

Subject Name: _____

Subject Signature: _____Date: _____

FOR NON-ENGLISH SPEAKING SUBJECTS:

Signature of Reader/Translator If the Subject Does Not Read English Well:

The person who has signed above, _____, does not read English well. You read English well and are fluent in _____*(name of the language),* a language that the subject (his/her parent(s)/legal guardian) understands well. You understand the content of this consent form and you have translated for the subject (his/her parent(s)/legal guardian) the entire content of this form. To the best of your knowledge, the subject (his/her parent(s)/legal guardian) understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and these questions have been answered (his/her parent(s)/legal guardian).

Reader/Translator Name: _____

Reader/Translator Signature:_____Date: _____

Witness Name: _____

Witness Signature:_____Date: _____

Signature of Investigator/Individual Obtaining Consent:
To the best of your ability, you have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research

subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent: _____

Signature:_____Date: _____ _____