PROTOCOL TITLE: A Phase II Study of Proton Radiotherapy with Chemotherapy for Nasopharyngeal Carcinoma

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A. INTRODUCTION

We are inviting you to take part in a research study. Research is a way of gaining new knowledge. If you decide to take part, you will be known as a "participant" rather than a "patient". This is a research study of a different type of radiation therapy called proton beam radiotherapy.

You are being asked to take part in this study because you have nasopharyngeal cancer. Nasopharyngeal cancer is usually treated with concurrent (meaning at the same time) chemotherapy and radiation therapy followed by an additional course of chemotherapy alone.

The type of radiation normally given to treat your tumor uses a photon beam. This study involves the use of a different type of radiation using a proton beam to deliver your treatment. In this study you will receive both the photon and proton beam radiation. Most of the radiation will be delivered using proton beam. A portion of the treatment will be delivered using photon as to provide the best optimal radiation dose distribution and delivery.

About 25 people will take part in this study throughout the Dana-Farber/Harvard Cancer Center (DF/HCC).

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you need to do to participate and any possible risks, inconveniences or discomforts that you may have while participating. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form.

If you do sign this consent form, you will first need to be evaluated by the study doctors to see if you can be in the study. This is called screening. The study has eligibility requirements that must be met.

If the screening tests show you can be in the study, you will be able to start on the study treatment. If the study doctor feels the results of these tests show that you cannot be in the study, you will not be able to start on study treatment. This is done for safety reasons.

We encourage you to take some time to think this over and to discuss it with your family, friends and doctor. We also encourage you to ask questions now and at any time.

B. WHY IS THIS STUDY BEING DONE?

The standard treatment for your type of cancer is concurrent chemotherapy and photon radiation therapy followed by additional chemotherapy alone. If you choose to participate in this study, you will be given concurrent chemotherapy using cisplatin combined with proton-photon beam radiation. This will be followed by an additional course of chemotherapy using cisplatin and 5-fluorouracil. The use of combined proton and photon instead with photon alone will be investigated in this study.

Photon beam radiation is the standard type of radiation used to treat your type of cancer. Photon beam radiation enters the body and passes through healthy tissue, encounters the tumor, and then leaves the body through healthy tissue. In this study, we use combined proton beam and photon radiation therapy to treat your tumor. Most of the radiation will be delivered using proton beam. Proton beam radiation has been shown to have the same effect on tumors as photon beam radiation, but has some other advantages. When using proton beam radiation, it enters the body, passes through healthy tissue, and encounters the tumor, but then stops. This means that less healthy tissue is affected by proton beam treatment than by photon beam treatment and that more of the energy of radiation goes right into the tumor.

The reason that proton beam radiation is not used more widely is that it is only available at a few hospitals around the world.

The purpose of this study is to determine the effectiveness of proton beam radiation in treating your cancer and reducing the acute and long-term side effects from your treatment. This study will also test to see if the sparing of the healthy tissue can improve your quality of life after radiation treatment.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this study is voluntary and you may choose not to participate. Other treatments that may be considered for your condition include the following:

- Concurrent chemotherapy and radiation therapy using photon beam such as conventional photon radiation or intensity modulated photon radiation.
- Concurrent chemotherapy and radiation therapy using photon beam followed by additional chemotherapy
- Radiation therapy alone using either photon and or proton beam techniques
- Induction chemotherapy followed by radiation therapy with or without concurrent chemotherapy
- Chemotherapy alone
- Investigational treatments that may be available to you
- Comfort care, also called palliative care. This type of care may help to reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to treat the symptoms.

Your doctor can tell you more about your condition and the possible benefits of the different available treatments. Please discuss these and other options with your study doctor.

D. WHAT IS INVOLVED IN THE STUDY?

After signing this consent form, and before you begin the study, you will need to have the following tests or procedures to find out if you can be in the study. These tests and procedures are part of regular cancer care and may be done even if you don't join the study. If you have had some of these tests or procedures recently, they may not have to be repeated. This will be up to your study doctor.

Standard procedures that are part of regular cancer care that will be done even if you are not a part of this study:

- Medical History and Physical Examination
- Routine blood tests, approximately 1- 2 –teaspoons of blood will be taken.
- Chest CAT scan

- Endoscopic evaluation (fiberoptic endoscopic examination). This requires a scope be passed through your nose to examine your nasopharynx (the upper part of the throat behind the nose) and other sites of the head and neck area.
- Dental and nutritional evaluation
- A hearing test called an audiogram
- PET scan, if your study doctor thinks it is necessary
- MRI and CAT scan of the head and neck
- CT scan of the liver, if your study doctor thinks it is necessary
- Bone scan if your study doctor thinks it is necessary

If these tests show that you are eligible to participate in the study, you will begin the study treatment. If the tests show that you do not meet the eligibility criteria, you will not be able to participate in the study.

Before you begin the study treatment, you will be asked to fill out Quality of life (QOL) questionnaires, a Speech Assessment, a ChemoSensory Questionnaire, a Patient Swallowing Diary, a Swallowing Study, Salivary Tests, and a Trismus Assessment.

You will need to go to the Massachusetts Eye and Ear Infirmary (MEEI) or Massachusetts General Hospital to have the swallow and saliva tests done.

- **Quality of Life Questionnaire-** You will be asked to fill out four questionnaires. Two of the questionnaires contain questions about your general health, your symptoms, well-being, and concerns related to your cancer. If the study doctors think that you are not doing well emotionally, they will recommend that you meet with a mental health professional. The study doctors will give you the information you need to set up a time to meet with someone to help you. Another questionnaire is about tobacco and alcohol use and the last one is about any difficulty you may have with swallowing.

- **Swallow Study-** You will be asked to swallow multiple samples of various food consistencies in varying amounts. The consistencies included thin liquid barium (diluted with water) followed with non-diluted barium, followed with a puree, soft food (fruit mixed with barium), and a solid (shortbread cookie) coated with barium.

- **Saliva Study: Unstimulated Saliva-** You should refrain from eating, drinking or dental hygiene (brushing your teeth or using mouthwash) for at least 60 minutes before this procedure. During this procedure, you will be seated and instructed to

minimize facial movements and not to attempt to influence salivary flow (such as sucking or swallowing). Just before the collection, you will be instructed to swallow. You will then be asked to allow saliva to accumulate in the floor of your mouth for 60 seconds without swallowing.

The saliva will be collected; you will be instructed not to swallow during the entire collection procedure.

- **Saliva Study: Stimulated Saliva-** After the collection of unstimulated saliva, you will have 2% citrate solution applied with a cotton tipped applicators to the both sides of your tongue for five times over a two minute period (0, 30, 60, 90 and 120 seconds). Saliva will then be collected for five minutes, using the same method as for unstimulated saliva.

- **Speech Assessment**
  You will be asked to fill out a speech assessment questionnaire. Nine functional and five attitudinal speech items will be asked. You will assess your speech on a scale of 5 to 1 and 1 represents the most impaired function and the highest value of 5 represents normal or optimal function.

- **ChemoSensory Questionnaire (CSQ)**
  You will be asked to fill out a questionnaire on smell and taste. Four questions on smell and taste will be used respectively. A minimum score of 4 and a maximum of 20 for the smell scale and taste scale are possible with a higher score indicating better function.

- **Trimus Assessment**
  In order to assess your ability to open your mouth after treatment, serial measurements of the maximum distance you can move your jaws will be taken between before radiation treatment and at certain time points after radiation.

- **Patient Swallowing Diary**
  You will be asked to fill out a questionnaire about your swallowing function before radiation treatment, each day during radiation treatment, and at certain time points after radiation. The questionnaire consists of five questions that measure your ability to swallow solids or liquids.

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Study Treatment

SCHEMA

I. Concurrent Radiotherapy and Chemotherapy (Chemoradiation)

RADIOTHERAPY* Days 1 ——————————→ 54

CISPLATIN** X

*Administered Monday through Friday, start date may be on a Monday, Tuesday,Wednesday or Thursday.

* *Cisplatin infusion to be given every 21 days during RT. First dose to be administered within the first three days of the start of radiation.

II. Adjuvant Chemotherapy – *to begin 3-8 weeks after completion of chemoradiation*

Day	**1**	**2**	**3**	**4**	**29**	**30**	**31**	**32**	**57**	**58**	**59**	**60**
Cisplatin	x				x				x			
5-FU	x	x	x	x	x	x	x	x	x	x	x	x

Radiation therapy will be given once a day, five days a week, for seven weeks. This will be given as part of outpatient care at the Francis H. Burr Proton Therapy Center (proton component of the treatment) and The Massachusetts General Hospital (photon component of the treatment).

The Francis H. Burr Proton Therapy Center and the Massachusetts Eye and Ear Infirmary are located next to the Massachusetts General Hospital.

You will also receive chemotherapy during and after your radiation treatments at the Massachusetts General Hospital or other sites of the Dana-Farber/Harvard Cancer Center.

During your radiation treatments, you will receive the chemotherapy drug cisplatin in your vein. This drug will be given once every 3 weeks starting at the time of radiation. This 3-week period is called a cycle of treatment, you will receive 3 cycles of cisplatin.. Both before you receive the cisplatin and after you receive the cisplatin, you will receive additional fluids in your vein, and you may also be given additional fluids by mouth. The length of stay to receive chemotherapy is at least eight hours.

When you complete your radiation treatments, you will again receive cisplatin same as above, for three cycles. This will be done once every 4 weeks., Another drug will also be given called fluorouricil or 5-FU following the cisplatin. The 5-FU will be given by continuous infusion in your vein over 4 days starting on the day you receive the cisplatin. A venous access device and an ambulatory pump will be used to deliver the continuous 5FU infusion.
In general, this can be done as an outpatient at your institution. However, depending on a number of factors, the chemotherapy treatments may require admission to the hospital.

Tests and procedures you will have while you are on this study.

During your radiation and chemotherapy treatment, you will have physical examinations and blood (about 1-2 teaspoons) will be drawn weekly to monitor your health. The weekly blood draws will continue during your chemotherapy treatments that you receive after radiation.

An MR/CT scan of the head and neck will be done 2 months after the radiation treatment.

After the study treatment has ended we would like you to come for follow up visits for the rest of your life. These visits will occur once every 3 months for 2 years, then once every 6 months during years 3-5, then annually at the Massachusetts General Hospital.

During these follow up visits, you will have the following tests and procedures:

- Physical examination
- Blood will be drawn (about 1-2 teaspoons) for routine testing.
- A chest CT scan and the CT/MRI of the head and neck will be repeated once every 6 months during the first 3 years you are on this study.
- Swallow study - 3, 12, and 24 months after study treatment has ended.
- Salivary study - 3, 6, 12, and 24 months after study treatment has ended.
- QOL questionnaires 1.5, 3, 6, 12, and 24 months after study treatment.ended.
- The swallowing diary (a questionnaire that describes your swallowing ability and your symptoms during swallowing) will be filled out each day during radiation treatment, then approximately 1.5, 3, 6, 12 and 24 months after study treatment has ended.
- Speech Assessment 1.5, 3, 6, 12, and 24 months after treatment completion
- ChemoSensory Questionnaire 1.5, 3, 6, 12, and 24 months after treatment completion

- Trismus Assessment 1.5, 3, 6, 12, and 24 months after treatment completion

Any of the tests and procedures can be done more frequently if your study doctor thinks they are needed.

E. HOW LONG WILL I BE IN THE STUDY?

You will receive study treatment for about 5 months. The follow up visits occur occasionally for the rest of your life.

F. WHAT ARE THE RISKS OR DISCOMFORTS OF THE STUDY?

Proton beam therapy may be less effective in treating your cancer than conventional photon beam therapy. However, previous experience treating participants with head and neck tumors and other types of tumors with proton beam therapy, has shown no decreased effectiveness compared to photon beam therapy.

While on this study, you are at risk for the side effects described below. You should discuss these with your doctor. There may also be other side effects that we cannot predict. You may receive medications to make side effects less serious and uncomfortable. These side effects generally go away days or weeks after radiation therapy has stopped, but in some cases, side effects can be permanent and may require treatments. A risk to taking part in this study is that the treatment you receive may not be effective in helping to treat your disease. You may also experience side effects undergoing proton beam radiation that does not provide you with any health-related benefits. Other less common or unexpected side effects may also develop and may be irreversible. During your therapy, you will be monitored closely for potential side effects. You are expected to report to the study doctor(s) any adverse sign(s) or symptom(s), which may develop while you are on this study.

For your safety, please tell the study doctor about all of your present and past diseases and allergies that you are aware of. It is also important that you tell the study doctor about any prescription and/or over-the-counter drugs, herbal preparations and nutritional supplements that you are taking. All chemotherapy drugs have side effects, which can be anything from mild and reversible to severe, long-lasting and possibly life threatening. You need to tell your study doctor or a member of the study team immediately if you experience any bad side effects.

As with most types of chemotherapy, the drugs used in this study have the potential to affect healthy cells in your body as well as cancerous ones. The healthy cells most often

affected are blood cells that help to fight infection (white blood cells), blood cells that help the blood clot (platelets), and blood cells that carry oxygen in your body (red blood cells).

When chemotherapy drugs cause a decrease in these blood cells, it is called bone marrow suppression. While you are undergoing chemotherapy, your blood cell levels will be monitored closely. If any of the following occur, notify your nurse immediately:

- A fever of 100.5 or above.

  This could be a sign of an infection. If you have a low white blood cell count, this can be serious or life threatening. Admission to the hospital and antibiotic therapy may become necessary.

- Low energy or shortness of breath.

  This could be a sign of anemia. If this becomes severe, you may need to come into the clinic or hospital to have a transfusion of red blood cells.

- Tendency for bleeding not to stop or bruising easily.

  This could be a sign that your platelets are low. This could be serious or life threatening. You may need to come into the clinic or hospital for a transfusion of platelets.

Another risk of chemotherapy drugs is to have blood clots form that can lead to swelling in the legs and arms. These clots may travel to the lungs causing shortness of breath or to the brain causing a stroke. This may become serious and life threatening.

Other common side effects include nausea, vomiting, and loss of appetite. You may also experience loose stools or diarrhea. It is important to increase your fluid intake if diarrhea occurs.

While on this study, you may experience the additional side effects listed below. Everyone 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. Some side effects may go away after you stop the study treatment.

The study doctors may give you some medicine that will help with some side effects. Some side effects can be long lasting and may never go away and may be fatal. You should talk to your study doctor about any side effects that you have.
During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

Risks Associated with Radiation Therapy

Very likely (meaning more than 50 % chance this will happen)

- Fatigue
- Hair loss at the treatment area most likely permanent
- Redness and irritation of skin within the treatment area
- Difficulty, pain, or burning sensation when swallowing
- Dry mouth that remains after treatment
- Mouth sores
- Nausea and/or vomiting
- Loss of appetite and/or taste
- Skin in treatment area may remain permanently dry

If you have these symptoms you should report them to your study doctor who will determine if they are related to the radiation treatments or to infection. If radiation is the cause, the symptoms are usually temporary and relieved with medication. With dietary care and medication for pain, you should be able to eat soft or liquid food and complete the study treatment.

Less likely (meaning between 10% to 50% this will happen)

- Voice hoarseness may remain after treatment
- Thyroid gland dysfunction requiring thyroid hormone pills in the future. Without the hormone pills you could experience weight gain, cold intolerance, and fatigue.

Less likely, but serious

- Injury to the brain that may cause neurological symptoms such as headache, seizures, or speech dysfunction. May require medical or surgical treatments.
- Injury to the pituitary gland requiring hormonal treatments. Without hormonal replacement, you could experience weight gain, infertility, or decreased growth.
- Injury to the eye structures that may lead to visual impairment.
- Injury to the jaw or tissue of the neck that may need to jaw or neck stiffness.
- Irritation of the spinal cord that could result in numbness/tingling or very rarely paralysis.
- Second cancer that could be benign or malignant

Risks Associated with Cisplatin

Very likely (meaning more than 50 % chance this will happen)

- Decrease in blood counts which can lead to a risk of infection and bleeding
- Loss of appetite and/or taste; metallic taste in your mouth
- Nausea and/or vomiting
- Fatigue
- Hearing loss or ringing in the ears
- Numbness or tingling in the hands or feet

Less likely (meaning between 10%-50% chance this will happen)

- Muscle cramps or spasm
- Loss of coordination
- Involuntary movements or shaking
- Rash
- Loss of hair which is temporary

Less likely, but serious

- Loss of muscle or nerve function, which may cause weakness or numbness in your hands and feet
- Facial swelling that could cause airway obstruction

- Decreasing ability of the kidneys to handle the body's waste, which may be permanent
- Allergic reactions, which can cause difficulty in breathing, fast heartbeat, and sweating
- Abnormally high levels of enzymes produced by the liver meaning that your liver is not functioning properly and can cause fatigue, and jaundice (yellowing of the skin and eyes). Although this is usually mild and reversible, this can be serious or life threatening.
- Other cancer called acute leukemia (cancer of blood and bone marrow).

Risks Associated with 5-FU (5-Fluorouracil)

Very likely (meaning more than 50% chance this will happen)

- Decrease in blood counts, which can lead to a risk of infection and bleeding
- Loss of appetite
- Nausea and/or vomiting
- Diarrhea with cramping or bleeding
- Skin rash
- Fatigue
- Headaches
- Hair loss, which is temporary
- Mouth sores
- Sore throat

Less likely (meaning between 10% to 50% chance this will happen)

- Confusion
- Inflammation of the fingers and toes
- Increased sensitivity to sunlight
- Darkening of the skin, nails, or veins
- Loss of coordination or balance
- Inflammation of the veins that may lead to clots or stroke

Less likely, but serious

- Damage to the heart that causes chest pain and lead to a heart attack

Risks associated with MRI

MRIs use powerful magnets to make images. Therefore, persons with metal implants, such as surgical clips or pacemakers should not have an MRI. However, there are no known health risks associated with this exposure. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow cylinder. The MRI makes loud banging noises as it takes images. Earplugs can be used to reduce the noises. The MRI can be stopped at any time at your request.

Risks associated with CT/PET scan

The radiation associated with these diagnostic x-ray studies will not adversely affect the treatment of your disease.

Risks associated with blood drawing

You may experience some discomfort, bruising and/or bleeding at the site of the needle insertion. Occasionally, some people experience dizziness or feel faint. In rare instances, infection may develop at the site of the needle insertion.

Reproductive risks

Because the drugs and radiation in this study can affect an unborn baby, you should not become pregnant or father a baby while on this study. You should also not nurse your baby while on this study. If you are pregnant, you will not be enrolled in this study. Both men and women of reproductive potential must agree to use appropriate methods of birth control throughout their participation in this study.

Non-physical risks

Because of side effects or the time required for tests and clinic visits while you are on this study, you may be unable to keep up with your normal daily activities such as running errands or going to work.

G. WHAT ARE THE BENEFITS OF THE STUDY?

Taking part in this study may or may not make your health better. We hope the information learned from this study will help doctors learn more about proton therapy as a treatment for nasopharyngeal cancer in the future.

H. CAN I STOP BEING IN THE STUDY AND WHAT ARE MY RIGHTS?

Yes. Taking part in this study is your choice. You can stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the study will not affect your medical care. You can still get your medical care from your hospital or doctor. We will provide you with any new information that may affect your willingness to continue to take part in this study.

It is important to tell the study doctor if you are thinking about stopping so any risks from the radiation therapy and chemotherapy can be evaluated by your doctor. In some cases, the abrupt stopping of a drug can have risks in itself, so it is important to discuss stopping with the study doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

If you do change your mind about taking part in this study, please let us know. You have the right to withdraw your permission for the use of your study information. This information will be removed unless we have already used it or if it becomes important for us to have a record of the people who start the study, not just those who finish it. If you decide to withdraw this permission, you must do so in writing by contacting the researchers listed as the Study Contact. Once you withdraw from the study, we will not collect new information about you.

The study doctor or the study sponsor may decide to remove you from this study without your permission for many reasons:

- If you do not follow the study requirements
- If the study procedures are found to be unsafe
- If the study procedures are found to be ineffective
- If you experience severe side effects

If you are removed from the study, the study doctor will explain to you why you were removed. The study doctor and research team will help arrange for your continued care.

I. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will not be paid to take part in this research study.

J. WHAT ARE THE COSTS?

Taking part in this study may lead to added costs to you or your insurance company. Please ask you doctor about any expected added costs or insurance problems.

You or your insurance company will be charged for all the procedures, tests, and treatments that are being done in this study. You may be responsible for any co-payments and deductibles that are standard for your insurance company.

If you have any questions about your insurance coverage or the items you might be required to pay for, please call financial services for information. The contact information for financial services:

- Dana Farber Cancer Institute: 617-632-3455
- Massachusetts General Hospital: 617-726-2191
- Brigham and Women's Hospital: 617-732-5524 or 617-732-7485

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below.

http://www.cancer.gov/clinicaltrials/learning/insurance-coverage

You will receive no payment for taking part in this study.

K. WHAT HAPPENS IF I AM INJURED OR SICK BECAUSE I TOOK PART IN THIS STUDY?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for Dana-Farber Cancer Institute (DFCI), Massachusetts General Hospital (MGH), or Brigham & Women's Hospital (BWH) to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

L. WHO IS FUNDING THIS STUDY?

The National Cancer Institute (NCI) is funding this research study. This means that the Dana-Farber/Harvard Cancer Center is receiving payments form the NCI to support the activities that are required to conduct the study.

M. WHAT ABOUT CONFIDENTIALITY?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this study may become part of your hospital medical record. Information that does not become part of your medical record will be stored in your study file. Study files are coded and not labeled with your name. The code linking your name to the file will be kept in a safe location.

Information contained in your records is used by study staff and in some cases it will be shared with the sponsor of the study. If your information is being shared with the sponsor, no information that could identify you will be given to the sponsor. Occasionally, a sponsor representative may come to the study site to review your study files. This person will never take any information that can identify you back to the sponsor. There may be times when we are required by law to share your information. In those cases, we do not need your permission.

The results of this study may be published. You will not be identified in any publication without your permission.

N. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

You are encouraged to ask questions about the study or your role as a participant at any time.

For questions about the study or research-related injury, contact:

MGH Annie Chan MD (617-726-4212)
DFCI Roy Tishler MD (617-632-2148)

24-hour contact: MGH: 617-724-1159

For questions about your rights as a research participant, please contact a representative from the Office for Human Research Studies (OHRS) at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under any pressure to enroll in this study or to continue to participate in this study.

O. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana Farber/Harvard Cancer Center (DF/HCC) and its affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health and conditions ("protected health information"). If you enroll in the research described in this consent form, your "protected health information" will be used and shared with others as explained below.

A. What protected health information about me will be used or shared with others during this research?

- Existing medical records
- New health information created from study-related tests, procedures, visits, and/or questionnaires

B. Why will protected information about me be used or shared with others?

The main reasons include:

A. To conduct and oversee the research described earlier in this form
B. To ensure the research meets legal, institutional, and accreditation requirements
C. To conduct public health activities including reporting of adverse events or situations where you or others may be at risk of harm
D. Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this study may become part of your hospital medical record because the information may be necessary for your medical care. In order to provide you with routine care, other people at the hospital may need to review the health information we put into your record.

This would include such people as your regular doctors and nurses and the hospital's billing department. You will also be given a notice for use and sharing of protected health information.

C. Who will use or share protected health information about me?

E. DF/HCC and its affiliated researchers and entities participating in the research will use and share your protected health information. In addition, the DF/HCC review board that oversees the research at DF/HCC and its affiliated staff who have a need to access this information to carry out their responsibilities (for example, oversight, quality improvement, and billing) will be able to use and share your protected health information.

D. With whom outside of DF/HCC may my protected health information be shared?

All reasonable efforts will be made to protect the confidentiality of your protected health information. We may however, need to share this information with the following people or groups so they can carry out their duties related to this study:

- Outside individuals or entities that have a need to access this information to perform functions on behalf of DF/HCC and its affiliates, for example data storage companies, insurers, or legal advisors)
- The sponsor(s) of the study, NCI, its subcontractors, and its agents: Other researchers and medical centers participating in this research, if applicable

- Federal Agencies such as the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institutes of Health, and/or the Office for Human Research Protections (NIH/OHRP
- Hospital accrediting agencies

Those who receive your protected health information may share it if they are required to do so by law. They may not be required to obey the federal privacy rules that the hospital and researchers must follow and may share your information with others without your permission.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, neither your name nor other identifiers will be used in any publication or teaching material without your specific permission.

E. For how long will protected health information about me be used or shared with others?

F. If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. Research information may be analyzed and re-analyzed in light of scientific and medical advances, or reviewed for quality assurance, oversight or other purposes.

G. We can only use your protected health information again if a special committee in the hospital (the IRB) gives us permission. This committee may ask us to talk to you again before doing the research. However, the committee may also let us do the research without talking to you again if we keep your health information confidential.

F. Statement of privacy rights:

H. You have the right to withdraw your permission for the use of your information at anytime. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or to ensure quality of the study. If you withdraw your permission, you must do so in writing by contacting the researcher listed as the Study Contact.

I. You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study. However, refusing to sign will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.
J. You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed under Study Contacts on the consent form.

O. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

_____ _____

Signature of Participant or Legally Authorized Representative — Date

_____

Relationship of Legally Authorized Representative to Participant

DFCI IRB Protocol Number: 05-089	Date DFCI IRB Approved this Consent Form: February 9, 2012
Date Posted for Use: March 30, 2012	Date DFCI IRB Approval Expires: June 15, 2012
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Adult Participants

To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

For Adult Participants

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is illiterate

The consent form was read to the participant who was given the opportunity to ask questions.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate

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