ADULT INFORMED CONSENT

COH Protocol # 16099
TITLE: COMBINING PEMBROLIZUMAB AND PALLIATIVE RADIOTHERAPY IN GASTROESOPHAGEAL CANCER TO ENHANCE ANTI-TUMOR T CELL RESPONSE AND AUGMENT THE ABSCOPAL EFFECT
Version date: 07/26/2017

PRINCIPAL INVESTIGATOR: Joseph Chao, M.D.

24-HOUR TELEPHONE NUMBER: (626) 471-7133
DAY TIME TELEPHONE NUMBER FROM THE HOURS OF 8:00 AM TO 5:00 PM: (626) 471-9200

EXPERIMENTAL PARTICIPANT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study, also known as an experiment or research study. As a research participant, you have the following rights:

1. To be told what the research study is trying to find out.
2. To be told what will happen to you and whether any of the procedures to be used are different from what would be used in standard practice.
3. To be told about the discomforts, side effects and risks of the things that will happen to you as part of the research study.
4. To be told if you can expect any benefit from participating in the research study.
5. To be told of the other choices you have and how they may be better or worse than being in the research study.
6. To be told what medical treatment is available if any complications arise.
7. To be allowed to ask any questions concerning the research study, both before agreeing to be in the study and during the course of the study.
8. To refuse to participate in the research study or to change your mind about participation after the study is started. To be informed that this decision will not affect your right to receive the care you would receive if you were not in the study.
9. To receive a copy of the signed and dated research study consent form.
10. To be free of pressure when considering whether you wish to agree to be in the research study.

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PRINCIPAL INVESTIGATOR: Joseph Chao, M.D.

You are invited to take part in a clinical trial, a type of research study, because you have esophageal or stomach cancer. We hope to learn if combining the immunotherapy drug pembrolizumab with a course of radiation treatment to an area of your cancer that is causing symptoms is an effective treatment. This research study is looking at combining pembrolizumab and radiation therapy as a possible future treatment for this diagnosis.

This research study is sponsored by City of Hope and Merck. Merck is the company that makes the drug pembrolizumab being tested. They are helping provide funding to cover the costs of conducting this study.

It is expected that about 14 people will take part in this research study.

Dr. Chao, the Principal Investigator, is paid as an advisory board member for Merck & Co., Inc., the company that provides the drug, Pembrolizumab, you will receive and supports this research. The City of Hope Conflict of Interest and Commitment Committee and the IRB have reviewed Dr. Chao's financial interest in Merck & Co., Inc. and found that this is very unlikely to affect how you will be treated or how the study results will be determined. If you have questions about this, please ask the Principal Investigator or contact the IRB at (626) 256-HOPE (4673), extension 62700. You may also contact the City of Hope Conflict of Interest Manager, at (626) 256-HOPE (4673), extension 62084.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future. Please take as much time as you need to read the consent form. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

Pembrolizumab is an immunotherapy drug that works by harnessing the immune system to attack cancer. The FDA (the U.S. Food and Drug Administration) has not approved

pembrolizumab for your specific disease but it has been approved for other uses. It has been found to be effective and is FDA approved for advanced melanoma and lung cancer. Trials are currently ongoing to evaluate if pembrolizumab is an effective treatment for esophageal and stomach cancer. These studies have found this treatment to be effective in small groups of patients.

We are conducting this study to determine if combining pembrolizumab with radiation therapy may be more effective at harnessing the immune system to attack esophageal and stomach cancers. Animal models of cancer have shown this approach to be a promising strategy to treat cancers. Tumor biopsies and blood samples will be obtained for laboratory tests to study the effects of this treatment on cancer cells and the immune system. Your treatment on this study may last for up to two years, as long as your cancer is not growing and you are not having any unmanageable side effects.

B. **WHAT IS INVOLVED IN THE STUDY?**

If you decide to take part, this is what will happen:

Before the research starts (screening):

After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

- **A medical history,** which includes questions about your health, current medications, and any allergies.
- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **An assessment of your tumor** by one or more of the following standard assessment tools: X-ray, CT (Computerized Tomography) scan, MRI (Magnetic Resonance Imaging) or PET (Positron Emission Tomography) scans
- **Blood tests** to check your blood counts and organ function (about 2 teaspoons of blood will be drawn from a vein in your arm or port-a-cath if you have one)
- **Blood tests** to check the status of your disease (about 1 teaspoon of blood will be drawn from a vein in your arm or port-a-cath)
- **Urine test**
- **Pregnancy test** if you are a woman of childbearing potential by drawing about ½ teaspoon of blood usually from a vein in your arm if a urine test is inconclusive.
- **An EKG (electrocardiogram)** to look at the electrical activity and rhythm of your heart.
- **A tumor biopsy** for research purposes to study the cancer and the immune system prior to start of treatment. The biopsy will be performed using a small needle may be

performed using a CT scanner or ultrasound to help place the needle. If you have fluid in your abdomen that needs to be removed this can also suffice for a tumor biopsy. If your tumor can only be biopsied by an endoscopic exam, this will be performed by a gastroenterologist. You will sign a separate consent form if you need to undergo this procedure.

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

Additional research procedures to be performed at the time of screening but not required to determine eligibility:

- **Blood tests** for research purposes to study the immune system and develop new blood markers to study the cancer (about 5 teaspoons of blood will be drawn from a vein in your arm or port-a-cath)
- **A stool test** for research purposes will be used to study the normal bacteria that live in your intestines and how they may impact the immune system. You will be provided a collection bag and swab kit by the research staff and instructed on how to swab some stool from toilet paper either during your screening visit or 1-2 days ahead of your first day of treatment.
- **An oral swab test** for research purposes will be used to study the normal bacteria that live in your mouth and how they may impact the immune system. A member of the research staff will perform a swab of both cheeks and tongue during your clinic visit.

Study Procedures:

If you are eligible to participate in this research study, the following test and procedures will occur. A chart summarizing the timing of these tests and procedures is also provided below. Some tests and procedures may be part of your standard of care.

- **Receive Study Drug:** You will be given the study drug, pembrolizumab, once every 3 weeks (equivalent to 1 cycle) into your vein (by intravenous infusion) over about 30 minutes. This may continue for up to 35 cycles.
- You may be pre-medicated with drugs to reduce the chance of having a sensitivity reaction to the study treatment. If you tolerate the study treatment without a reaction, then pre-medications may be changed by your doctor.
- **Radiation therapy:** You will receive radiation therapy as a standard of care treatment as determined by your treating physicians. Radiation will be given once a day for 10 days on a weekday.
- **Clinical Exams:** During this visit you will have a physical exam and you will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.

- **Performance status**, which evaluates how you are able to perform your daily usual activities.
- **Scans (or Imaging tests):** We will assess your tumor by conducting CT scans. MRI scans are acceptable if you are unable to undergo CT scans.
- **Blood tests**
    - **Blood tests** to check your blood counts and organ function (about 2 teaspoons of blood per blood draw will be drawn from a vein in your arm or a port-a-cath if you have one)
    - **Blood tests** to check the status of your disease (about 1 teaspoon of blood per blood draw will be drawn from a vein in your arm or port-a-cath)
    - **Blood tests** for research purposes to study the immune system and develop new blood markers to study the cancer (about 5 teaspoons of blood will be drawn from a vein in your arm or port-a-cath)
- **Urine test**
- **Tumor biopsies:** A second biopsy to study the cancer and immune system after you have started treatment will be performed in the same fashion as when you underwent the first biopsy that had occurred prior to starting treatment.
- **Stool test:** You will be asked to provide a stool sample two more times during the study. You can provide the sample during the scheduled clinic visit or be given a collection bag and swab kit by the research staff and instructed on how to swab some stool from toilet paper 1-2 days ahead of the scheduled day of treatment.
- **Oral swab test:** You will have two more oral swab samples collected by the study staff on the scheduled clinic visits.
- **Other Medications**: While you are receiving study treatment, you should not take other medications without first discussing them with the study doctor. These include high doses of steroid medications such as prednisone and dexamethasone, as well as herbal medications. The reason you should not take other medications is it may interfere with your study treatment.

Research Study Calendar:

	Visit 1 Screening	Visit 2 Day 1	Visit 3 Day 8	Visit 4 Day 15	Visit 5 Day 22	Visit 6 Day 43	Every 3 weeks	Every 6-9 weeks	Final Visit
Medical History & Physical Exam	X	X	X	X	X	X	X		X
Blood Test	X	X	X	X	X	X	X		X
Research Blood Tests	X					X			X
Research Stool and Oral Swab Tests	X					X			X
CT scan	X					X		X	
Tumor Biopsy (for research purposes)	X					X			
Pregnancy Test	X								
Urine Test	X								
EKG	X								
Receive study drug		X			X	X	X		
Radiation treatment (daily for 10 weekdays)		X	X						

Planned Follow-up:

We would like to keep track of your medical condition for the rest of your life. We would like to do this by calling you on the telephone once every 3 months to see how you are doing. Keeping in touch with you and checking your condition every 3 months helps us look at the long-term effects of the research study.

C. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be on study treatment for about 2 years provided your cancer is not growing and you are not having any unmanageable side effects from treatment. If your cancer regrows after you come off of 2 years of treatment, you may receive up to 1 more year of treatment.

D. WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

All cancer treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different cancer treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs to keep track of your blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study drug. Some side effects can be mild; but others can be long lasting and may never go away as noted below. Some may be life-threatening or fatal and are noted below. You will be monitored closely for any severe, life-threatening side effects listed

below. Some of these side effects may be permanent. Appropriate medical care will be provided, if necessary, including additional treatment, hospitalization and/or surgery.

Possible risks and discomforts you could experience during this study include:

Risks associated with pembrolizumab:

Commonly Occurring Side Effects (in at least 1 in 10 research participants)

- Itching of the skin
- Feeling tired, lack of energy
- Feeling not hungry
- Cough
- Rash

Occasional Side Effects (less than 1 in 10 research participants)

- Joint pain
- Fever
- Weakness
- Back pain
- Red Rash
- Loose or watery stools
- Infrequent or hard stools
- Vomiting

Rarely Seen Serious Side Effects (less than 1 in 100 research participants)

- Inflammation of the kidneys manifested as the kidneys suddenly not working normally
- Inflammation of the lungs, manifesting as shortness of breath particularly if you have cancer in your lungs. Rarely this might lead to death.
- Increased release of thyroid hormone which may manifest as anxiety, irritability, or trouble sleeping, weakness, trembling, sweating, feeling uncomfortable in warm weather, fast or uneven heartbeats, feeling tired, weight loss, and frequent or excessive bowel movements.
- Decreased release of thyroid hormone which may manifest as feeling tired, excessive weight gain, feeling cold, and infrequent or hard bowel movements.
- Inflammation of the large intestine (colon) that may manifest as frequent or excessive watery bowel movements.
- Inflammation of a gland in the brain (the pituitary gland), which may manifest as headache, nausea, a sensation of the room spinning around you, changes in behavior, double vision, weakness, vomiting and dizziness or fainting (low blood pressure).
- Inflammation of the liver that may manifest as yellowing of the skin and whites of the eyes, fever and belly pain

- Inflammation of pancreas (diabetes), with loss of insulin production, that may manifest as increased levels of sugar in your blood, thirst, and may lead to needing regular shots of insulin.
- Dizziness or fainting (low blood pressure), flushing, rash, fever, shortness of breath or nausea at the time of receiving your infusion (IV) or just after, or pain at the site of infusion.
- Inflammation of the skin, which may manifest as widespread peeling of the skin, itching, skin redness.
- Stevens-Johnson Syndrome – A severe skin and digestive tract reaction that may include rash and sloughing or breakdown of tissue. This may manifest as various blisters, hives, and other lesions in various locations on the body including palms and soles, face and other extremities. This is serious and may be fatal.
- Toxic epidermal necrolysis (TEN) – A rare, life threatening skin condition that is usually caused by a reaction to a drug. The top layer of skin detaches from the lower layers of skin all over the body. This is similar to the skin damage from a severe burn and is serious and may be fatal.
- Immune-mediated myocarditis – Inflammation of the heart muscle, which may be caused by a dysregulation of the normal immune response. This may be serious, require hospitalization and may be fatal.

Risks associated with radiation treatment:

Commonly Occurring Side Effects (affecting 20 out of 100 patients)

- Reddening, tanning, or peeling of the skin
- Mild pain
- Temporary hair loss
- Tiredness
- Loss of appetite, nausea, vomiting
- If the esophagus/stomach is targeted for radiation, possible inflammation of esophagus/stomach causing pain on swallowing, heartburn, sense of obstruction or indigestion
- Inflammation of the bowel causing cramping and diarrhea
- Sores in mouth and throat which may cause difficulty swallowing

Occasional Side Effects (affecting 4 to 20 out of 100 patients)

- Thickening and numbness of the skin
- Sores or ulcers on the skin or near the cancer location
- Permanent hair loss
- Anemia, which may require transfusion
- Infection, especially when the white blood cell count is low

Rarely Seen Serious Side Effects (less than 1 out of 100 patients)

- Damage to internal organs
- Abnormal opening in internal organs which may cause pain and bleeding
- Bone fractures in the treated area
- A new cancer caused by radiation
- Scarring and immobility of a joint if in the treated area
- Painful ulceration and infection in the treated area

Since the effect of the study treatment taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study and your research doctor will review this information with you.

Risks Associated with Blood Draw

Risks of blood draws include mild pain or discomfort, bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).

Cancer research often includes biopsies, scans, x-rays that are also provided as routine care. The following describes the side effects of procedures done only for the purposes of research.

Risks Associated with Biopsies:

Biopsies are normally performed under the guidance of an imaging technique. Each procedure requires a separate consent prior to the biopsy. The risks may include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.

Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

Risks Associated with Contrast Agents Used During Scans:

There is a small risk with using a contrast agent that is injected into a vein during the CT scan or MRI if you are unable to undergo a CT scan. The contrast agent is a special dye that highlights organs, blood vessels or tissue to make them more visible. Depending on the type of contrast agent that is used, it may cause decreased kidney function or worsen kidney function in people who already have decreased kidney function. Therefore, we will monitor your kidney function

closely while you participate in this study. If there is any change in your kidney function, we may have to remove you from the study.

Uncommonly, some people have allergic reactions (such as hives and itching) to the contrast agent. Serious reactions (for example, drop in blood pressure, difficulty breathing or severe allergic reaction and death) are rare.

Reproductive Risks:

The drugs used in this research study may affect a fetus. While participating in this research study, you should not become pregnant or father a baby, and should not nurse a baby. We can provide counseling about preventing pregnancy for either male or female study participants. Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child.

In the event that partner becomes pregnant, it may be critical to share information regarding your participation in this research study with that person. Your research doctor should also be told if this happens. The study sponsor may want to collect data on your partner's pregnancy.

You must use birth control while on this study. These are some birth control measures that you can use: hormonal contraceptives (birth control pills, patches, implants, rings, or injections), barrier methods (such as a condom or diaphragm) used with a spermicide, an intrauterine device (IUD), or surgical sterilization (hysterectomy or tubal ligation for women, vasectomy for men).

If you are breastfeeding and do not want to stop, you may not take part in this study.

Other Risks:

This study will involve analyzing the genes in the cancer and may lead to incidental discoveries of your genetic information. A new federal law, called the Genetic Information Nondiscrimination Act (GINA), generally 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:

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

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.

E. WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?

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.

F. HOW WILL YOUR INFORMATION BE KEPT CONFIDENTIAL?

We will take measures to protect the confidentiality and security of all your personal information, but we cannot guarantee complete confidentiality of study data. However, it is impossible to guarantee that information about you will not be mistakenly released. If information learned from this study is published, you will not be identified by name.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor and any drug company supporting the study.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov; as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

G. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS RESEARCH STUDY?

There is no guarantee that you will receive any benefits from this study. The possible benefit of the study drug in the treatment of esophageal and stomach cancer is not fully known. If you decide to participate in this study, your health will be monitored very closely. By being in this study, you will give doctors more information about how well the study drug works. It may help doctors understand your condition better and may help future patients with this medical condition.

H. WHAT OTHER OPTIONS ARE THERE?

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

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

I. ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

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

J. WHAT ARE THE COSTS?

The investigational drug, pembrolizumab, will be provided free of charge by City of Hope and Merck. It is possible that pembrolizumab may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

Radiation therapy to treat symptoms from your cancer is a standard of care procedure and will be the responsibility of you and/or your insurance carrier.

Other standard of care procedures provided to you will be the responsibility of you and/or your insurance carrier. You will be responsible for all copayments, deductibles, and other costs of treatment and diagnostic procedures as set forth by your insurance carrier. You and/or your insurance carrier will be billed for the costs of treatment and diagnostic procedures in the same way as if you were not in a research study.

However, neither you nor your insurance carrier will be responsible for the research procedures related to this study.

Financial counselors are available Monday through Friday, 8:00 a.m. to 5:00 p.m. For additional questions, please call City of Hope Financial Support Services: 626-256-HOPE (4673), extension: 80258.

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 or can be provided by the study team:
www.cancer.gov or 1-800-4-CANCER (1-800-422-6237)

K. WHAT HAPPENS IF YOU GET INJURED AS A RESULT OF THIS STUDY?

If you think you have been hurt by taking part in this study, tell the study doctor as soon as possible. It is a City of Hope policy that in the event of physical injury to a research participant, resulting from research procedures, appropriate medical treatment will be available at City of Hope to the injured research participant. However, financial compensation will not be available.

However, by signing this form you have not given up any of your legal rights.

There are no plans for any of the sponsors of this study to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

L. <u>WHAT ARE YOUR RIGHTS IF I TAKE PART IN THIS STUDY?</u> Your participation in this research study is voluntary. You are free to withdraw your consent for participation in this study without any loss of benefits, penalty, or interference with any future treatment at City of Hope.

M. <u>WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?</u>
The principal investigator, Dr. Joseph Chao or a colleague, Dr. _____, responsible for your care or treatment, has offered to and has answered any and all questions regarding your participation in this research study. If you have any further questions or in the event of a research related injury, you can contact Dr. Joseph Chao at (626) 471-9200 or Dr. _____ at (626) 256-HOPE (4673) ext. _____.

This study has been reviewed and approved by the Institutional Review Board (IRB). If you have any questions regarding your rights as a research participant, you may contact a representative of that Board, from the Office of Human Research Subjects Protection, at (626) 256-HOPE (4673) ext. 62700.

You will get a copy of this consent form.

N. SIGNATURE SECTION

SIGNATURE FOR CONSENT: By signing this consent form, you are making a decision to participate in this research study. Your signature on this informed consent form indicates that you:

1. Have read and understood the information in this form.
2. Have had the information in this form explained to you.
3. Have had a chance to ask questions and these questions were answered to your satisfaction.
4. Have been informed that you will receive a copy of this signed consent form, which includes the "Experimental Subject's Bill of Rights."

I hereby agree to be a research participant in this research study:

_____ _____ _____

Research Participant's Signature Date Time

(Date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

INDIVIDUAL OBTAINING CONSENT SIGNATURE

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent

FOR USE WITH IRB APPROVED TRANSLATED SHORT/LONG CONSENT FORMS FOR NON ENGLISH SPEAKING PARTICIPANTS ONLY

NOTE: To determine who should sign below, review the guidance document, *Consenting Non English Speaking Research Participants (Pediatric or Adult) – Who Signs What?*

Interpreter: By signing here, I attest that I have acted as interpreter and facilitated this consent process.

_____ _____ _____

Interpreter's Signature Date Time

_____

Print Interpreter's Name

FOR USE WHEN A WITNESS IS REQUIRED:

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name

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AUTHORIZATION TO USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI) FOR PURPOSES OF THIS STUDY:

I. **Purpose of this Authorization**: The information about your health is something that is protected by law and cannot, except for certain purposes, be disclosed (shared) without your permission. As part of this research, you are agreeing to allow City of Hope to use and share with others your protected health information ("PHI"), as needed for the research. If you agree to participate in the study named above (called the "Study"), you must sign this authorization in addition to the *Study Consent Form*.

II. **The Information About You that is Covered By this Authorization**: PHI refers to information that we maintain about you that identifies you and includes the information contained in your medical record. Your medical record consists of information related to your health and the treatment we provide to you, such as your medical history, the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures. If you sign this authorization, you are allowing City of Hope and the individuals indicated below to use and share any PHI we maintain about you that is required for your participation in the Study.

III. **Purposes for Uses and Sharing of your PHI; Who Will Use, Share and Receive your PHI**: Your PHI will be used and shared with others for the purpose of doing this research as described in the *Study Consent Form*. Your PHI will also be used to keep the research sponsor informed about this Study, for reporting to those individuals and authorities responsible for overseeing our research activities to make sure that the activities are properly conducted, and to report to regulatory agencies as required by the Study.

The people authorized to use and share your PHI for purposes of the Study include the Principal Investigator and the research staff supporting the

Study; your City of Hope physicians and the health care team; and the Health Information Management Services Department (i.e., Medical Records Department). This also includes any agents or contractors used by these individuals or groups for purposes of conducting or managing this Study. At the City of Hope, the Institutional Review Board ("IRB"), and other City of Hope research regulatory committees will have access to your PHI as necessary to monitor research.

You are also allowing your PHI to be shared with the Office for Human Research Protections ("OHRP") and with any person or agency as required by law. In addition, certain other regulatory agencies, including, the Food and Drug Administration ("FDA") and the National Cancer Institute ("NCI"), will have access to your PHI.

Use and disclosure of your PHI may also continue for as long as the sponsor needs to maintain the PHI for purposes of obtaining approval of the drug from the FDA or for other FDA reporting.

Your information will also be shared, with City of Hope and Merck**,** the "Research Sponsor" and its employees, agents or contractors who are involved in the administration of the Study.

This authorization will allow us to use and share your PHI for the Study. No other additional uses and disclosures other than for the purposes of the Study is included in this authorization. City of Hope's Notice of Privacy Practices will continue to protect your non-Study information. If necessary, another separate permission will be obtained from you for any non-Study uses or sharing of your PHI.

IV. **Expiration of this Authorization**: This authorization to use and share your PHI will expire twenty-five (25) years from the date that you sign this authorization.

V. **Further Sharing of Your PHI**: Your privacy is important and this is the reason for having rules which control who can use or see your PHI. City of Hope maintains control over your PHI at present, but once we share this

information with a third party (for example, an individual or agency outside of the City of Hope), then it is no longer possible to maintain the same level of protection. The persons outside our control may not be governed by federal or state privacy laws and it is possible that they could share your PHI with others for whom you have not given permission.

The information from this Study may be published in scientific journals or presented at scientific meetings but your identity will be kept confidential.

VI. **Your Rights Under this Authorization**: You may cancel this permission to use and share your PHI at any time by contacting City of Hope's Privacy Officer at (626) 256-HOPE (4673) ext. 64025. You should ask for the form, *Revocation (Cancellation) of Authorization for Use of Protected Health Information for Research*. Fill this form out and return it as the form instructs. Your cancellation begins when the Health Information Management Department of City of Hope receives this form. If you cancel this authorization to use and share your PHI, you will no longer be able to participate in the Study. This is because the research under this Study cannot be conducted without your PHI.

Once you cancel your permission to use and share your PHI, the researchers and others involved in conducting the Study will no longer be able to use or share your PHI for this research. PHI already used and shared up to this point as part of this Study will continue to be used for purposes of this research. This means that any uses of your PHI and any PHI shared about you by City of Hope prior to receiving your cancellation (revocation) form cannot be taken back. While no further PHI about you will be shared for the Study, your PHI already shared will continue to be used in the overall Study.

VII. **<u>Signing this Authorization is Your Choice</u>:** Your ability to obtain care at the City of Hope will not be affected by your decision to sign this authorization form. You will be able to continue to receive health care at City of Hope if you choose not to sign this authorization form or if you sign this form and later cancel your permission to use and share your PHI.

If you agree to the use and sharing of your PHI, please sign below. You will be given a copy of this authorization form.

_____ _____ _____

Research Participant's Signature Date Time
(date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

INDIVIDUAL OBTAINING CONSENT SIGNATURE

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent

FOR USE WITH IRB APPROVED TRANSLATED SHORT/LONG CONSENT FORMS FOR NON ENGLISH SPEAKING PARTICIPANTS ONLY

NOTE: To determine who should sign below, review the guidance document, *Consenting Non English Speaking Research Participants (Pediatric or Adult) – Who Signs What?*

Interpreter: By signing here, I attest that I have acted as interpreter and facilitated this consent process.

_____ _____ _____

Interpreter's Signature Date Time

_____

Print Interpreter's Name

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name