

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

Please check one of the following:

 You are an adult participant in this study. You are the parent or guardian granting permission for a child in this study.

Print child's name here: \_\_\_\_\_

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

Are you participating in any other research studies?  Yes  No**INTRODUCTION TO RESEARCH STUDIES**

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

**PURPOSE OF RESEARCH**

You are invited to participate in a research study of the treatment of squamous cell carcinoma of the head and neck (SCCHN) or nasopharyngeal carcinoma. We hope to learn the effect of a combination of docetaxel, cisplatin, and cetuximab in weekly treatment. While docetaxel and cetuximab are approved by the Food and Drug Administration for the treatment of SCCHN, cisplatin and carboplatin are FDA approved but not for this use. However, both cisplatin and carboplatin are routinely used to treat SCCHN and are universally regarded as acceptable drugs to use in the care of patients with SCCHN. This study hopes to determine if this combination of drugs on a weekly schedule is a safe and effective treatment for this condition. The combination of cisplatin or carboplatin combined with docetaxel and administered at higher doses every 3 weeks is an accepted standard of care. The addition of cetuximab to cisplatin or carboplatin based treatments is also an accepted standard of care and FDA approved. What is different about this study is that all drugs are to be given at lower doses weekly instead of giving the cisplatin or carboplatin and docetaxel at high doses every 3 weeks. Our theory is that giving all of the drugs at lower, more frequent doses will be associated with less severe side effects and will remain an effective anti-cancer treatment. You have been deemed to be eligible for this

Participant ID:

Page 1 of 16



STUDY

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

study because your doctors do not think your disease can be treated effectively with any combination of surgery, radiation and chemotherapy with curative intent.

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify at [REDACTED]

This research study is looking for up to 27 participants with squamous cell carcinoma of the head and neck or nasopharyngeal carcinoma at Stanford University and UC Davis.

**DURATION OF STUDY INVOLVEMENT**

This research study is expected to take approximately five years. Patients will receive treatment three weeks of every four week cycle until their disease worsens or unacceptable side effects related to the chemotherapy agents occur.

**PROCEDURES****Screening**

If you choose to participate, Dr. Colevas and his research study staff will complete the following procedures to determine if you are eligible.

- Obtain past medical history including prior SCCHN therapies and response
- Record concurrent medications
- Demographics collection
- Physical examination, including recording of height, weights, blood pressure, heart rate, temperature, and respiration rate
- Performance status assessment (how able you are to care routinely for yourself)
- Tumor measurement by CT scan or MRI
- Laboratory tests within one week prior to the first dose of study medication
  - Complete blood count (CBC) with differential, platelets
- Serum chemistry (albumin, alkaline phosphatase, total bilirubin, bicarbonate, BUN, calcium, chloride, creatinine, glucose, total protein, SGOT, SGPT, sodium)

**Treatment**

If you are eligible to participate, and choose to sign this consent form, you will be treated for 3 weeks of each 4 week (28 day) cycle with cisplatin, docetaxel, and cetuximab. In certain cases, carboplatin may be substituted for cisplatin.

Participant ID:

Page 2 of 16



STUDY

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

A dose maybe reduced or held only if the side effect(s) is/are related to the chemotherapy agent(s), otherwise the physician will continue to treat you as planned.

**Cetuximab Loading Dose (Cycle 1, Day 1)**

Cycle one will include the loading dose of Cetuximab (alone) and three doses of the triplet (Platinum/Docetaxel/Cetuximab) when the loading dose of cetuximab was given more than 5 days from scheduled triplet #1 dose. A scheduled break will occur after the third triplet treatment.

**OR**

Cycle one will include the loading dose of Cetuximab (alone) and two doses of the triplet (Platinum/Docetaxel/Cetuximab) when the loading dose of cetuximab was given  $\leq$  5 days from scheduled Platinum/Docetaxel dose. A scheduled break will occur after the second triplet treatment.

**Week of Scheduled Triplet Dose #1-Every Cycle**

Prior to treatment infusion, the following will be performed:

- Record concomitant medications
- Physical examination
- Vital signs, including weight
- Performance status assessment
- Complete blood count with differential, platelets
- Serum chemistry
- Adverse event evaluation

**Week of Scheduled Triplet Dose #2 & #3-Every Cycle**

Prior to treatment infusion, the following will be performed:

- Record concomitant medications
- Vital signs
- Complete blood count with differential, platelets
- Serum chemistry

You may receive up to 12 cycles (12 months, approximately) of cisplatin and docetaxel treatment as long as your tumors are responding and you are tolerating the treatment. Cetuximab will be continued until progression of disease. Tumor measurements will occur every 8 weeks by CT scan or MRI.

**End of Treatment Visit**

The following will be performed when you finish study treatment:

- Physical examination
- Vital signs, including weight
- Performance status assessment
- Complete blood count with differential, platelets

Participant ID:

Page 3 of 16



STUDY

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

- Serum chemistry
- Tumor measurements by CT scan or MRI

**MRI (Magnetic Resonance Imaging)**

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an X-ray or CT scan. You will be asked to lie on a long narrow couch for a certain amount of time while the machine gathers data. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive banging noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

**Risks:**

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. If you have kidney problems, please tell the operator.

**IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.**

**Women of Childbearing Potential**

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper

Participant ID:

Page 4 of 16



STUDY

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

**PARTICIPANT RESPONSIBILITIES**

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study drug as instructed
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors of each study.

**WITHDRAWAL FROM STUDY**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you withdraw from the study, or the study medication is stopped for any reason, all evaluations required at the End of Treatment visit will be performed. You are encouraged to seek additional follow up for any continuing health problems.

The Protocol Director may also withdraw you from the study and the study medication may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.

Participant ID:



**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

- Other administrative reasons.
- Unanticipated circumstances.

**POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES**

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. Certain side effects and discomforts of the treatment may happen. You may have all, some, or none of the known side effects. Your doctors and nurses will check you closely for side effects, and may give you medicines or other treatments to stop or reduce some of these effects. Some side effects may go away soon after the study medication is stopped, but in some cases, side effects may be serious, long lasting, and/or permanent.

**Side effects of Cisplatin:**

1. Kidneys: Kidney injury can occur but adequate water intake and increased urine output usually minimize the risk. Kidney damage can occur in up to 10% of patients.
2. Neurologic: Ear damage, shown by high-frequency hearing loss and ringing in the ears, occurs in about 30% of patients, but usually it is not severe. Tingling of the skin, decreased vibration, and touch sensations are less common.
3. Blood: A mild decrease in white blood cells and platelets occurs in 25-30% of patients. A decrease in red blood cells is less common. A potentially fatal infection in the digestive system that destroys red blood cells has been reported.
4. Gastrointestinal: Severe nausea and vomiting occur in almost
5. 100% of patients unless adequate premedication is given. Anorexia and taste changes may also occur. Based upon prior experience, nausea is usually well controlled by anti-nausea medication when giving cisplatin on this schedule.
6. Allergic reactions: Allergic reactions are reported in up to 20% of patients.
7. Symptoms include: rash, facial swelling, wheezing, low blood pressure, and
8. rapid heart rate. Life-threatening reactions are rare.
9. Other: Inability of the kidneys to release acid into the urine (magnesium, potassium and sodium), and eye nerve inflammation have been reported.

**Side effects of Carboplatin:**

1. A decrease in blood cell production is the major side effect. A decrease in platelets, white blood cells, and red blood cells is common.
2. Allergic Reactions: Sensitivity to carboplatin has been reported in 2% of patients receiving the drug. Symptoms include rash, hives, redness, itching, and rarely airway obstruction and low blood pressure.
3. Neurologic: Nervous system damage has been observed in 4% of patients receiving carboplatin with mild numbness and tingling being the most common effect.
4. Gastrointestinal: Nausea and vomiting are the most common GI events; both usually resolve within 24 hours and are generally well controlled with anti-nausea medication. Other GI events include diarrhea, weight loss, constipation, and gastrointestinal pain.

Participant ID:

Page 6 of 16



STUDY

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

5. Liver Harm: Elevated alkaline phosphatase, total bilirubin, and SGOT have been observed.
6. Other: Pain and loss of strength are the most common miscellaneous adverse events. Hair loss has been reported in 3% of the patients taking carboplatin.

**Side effects of Docetaxel:**

1. Decrease in blood cell production
2. Allergic reactions: Minor symptoms include low blood pressure, flushing, chest pain, pain in the abdomen, legs, or arms, skin reactions, itching, shortness of breath, and rapid heart rate. More severe reactions include low blood pressure requiring treatment, shortness of breath with obstruction of your airways, hives, and swelling. The majority (53%) of the reported reactions occurred within 2-3 minutes of initiation of treatment and 78% occurred within the first 10 minutes. Reactions usually occurred with the first and second doses.
3. Cardiovascular: abnormal heart rhythm, rapid heartbeat; significant events include loss of consciousness, low blood pressure, other heart rhythm abnormalities, and complete heart block requiring pacemaker placement, and heart attack. High blood pressure may also occur.
4. Neurologic: Sensory changes (taste changes); damage to the nervous system; joint and muscle pain; seizures; mood alterations; numbness in fingers and toes, alcohol intoxication.
1. Dermatologic: hair loss, injection site reactions (redness, hardening, tenderness, skin discoloration); accumulation of abnormal tissue cells; and rash.
5. Gastrointestinal: Nausea, vomiting, diarrhea, inflammation of the lining of body cavities and organs, inflammation of the pharynx (the cavity behind the nose and mouth that connects to the esophagus, inflammation of the beginning of the large intestine, inflammation of the inner lining of the colon, and inflammation of the pancreas.
6. Liver: Increased SGOT (AST) and SGPT (ALT)- enzymes that are normally present in liver and heart cells, bilirubin (a compound produced by the breakdown of red blood cells), alkaline phosphatase (an enzyme made in the liver) ; liver failure.
7. Other: Fatigue, headaches, light-headedness, muscular disease, elevated serum creatinine, elevated serum triglycerides, and visual abnormalities (sensation of flashing lights, blurred vision).

**Side effects of Cetuximab: the most common effect is an acne-like rash.**

1. Infusion reaction: Characterized by airway obstruction (e.g., muscular spasms, hoarseness), hives, low blood pressure; infusion reactions occur in about 3% of patients, rarely with fatal outcome.
2. Pulmonary: lung disease, blockage of the lung's main artery, shortness of breath, increased cough.
3. Blood: decrease in white blood cells, decrease in red blood cells.
4. Gastrointestinal: Nausea, vomiting, diarrhea, constipation, indigestion, abdominal pain, anorexia, kidney failure

Participant ID:

Page 7 of 16



STUDY

**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

5. Dermatologic: Rash, acne, dry skin, itching, ulceration, hair loss, nail disorder
6. Circulatory: Blood clotting in the veins of the inner thigh or leg
7. Neurological: Headache, depression
8. Allergy: Allergic reaction
9. Ocular: infection of the eyelid lining
10. Other: low magnesium, loss of muscle strength, weight loss, dehydration, fatigue.

**POTENTIAL BENEFITS**

Your participation in the study may lead to possible improvements in the symptoms of your disease. If your tumors shrink, eventual side effects from your tumors may be delayed. You will also be provided with a thorough review of your health status during the study that may be of medical value to you. Your part in the study may contribute to information about squamous cell carcinoma or the study drugs and may benefit other patients in the future.

However, there is no guarantee that you will benefit from taking part in this research study. Your disease may improve, stay the same, or get worse due to your participation in this study. It is possible that the drugs may not provide any benefit to you or that participation could be harmful to you.

**WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.**

**ALTERNATIVES**

Taking part in this study is voluntary. You do not have to participate in this study to receive treatment for your cancer. Alternative treatments for your disease may include supportive care, drugs, or combinations of drugs that are currently approved or are being evaluated in other clinical studies investigating the treatment of cancer. You may also choose to have no further treatment for your cancer.

It is important that you talk to the study doctor about your options before you agree to enter the study, and about other options that may become available during the study.

**PARTICIPANT'S RIGHTS**

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

If you decide not to participate, tell the Protocol Director. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

Participant ID:



**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

**CONFIDENTIALITY**

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of the combination therapy of docetaxel, cetuximab, and cisplatin/carboplatin; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Participant ID:



## **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. If you sign this form, it will provide that authorization. The form is intended to inform 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. Please read it carefully before signing it.

### **What is the purpose of this research study and how will my health information be utilized in the study?**

The purpose of this study is to determine if combination therapy of docetaxel, cetuximab, and cisplatin/carboplatin are effective for treatment of squamous cell carcinoma of the head and neck. If you choose to participate, the study staff will obtain personal information about you for research purposes. This may include medical and research records that may identify you and that may describe your health. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations without written permission from you.

### **Do I 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 including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

### **If I sign, can I revoke it or withdraw from the research 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 any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Participant ID:



**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

Dr. Dimitrios Colevas  
Division of Medical Oncology  
Stanford University Medical Center  
875 Blake Wilbur Drive  
Stanford, CA 94305-5826

**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, information related to your medical condition, blood tests, pathology, and medical imaging results.

**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:

- The Protocol Director: Dr. Dimitrios Colevas
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

**Who May Receive or 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:

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

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

**When will my authorization expire?**

Your authorization for the use and/or disclosure of your health information will end on December 31, 2061 or when the research project ends, whichever is earlier.

Participant ID:



**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

**Will access to my 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 was used to make a medical or billing decision about you (e.g., if included in your official medical record).

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Adult Participant

\_\_\_\_\_  
Signature of Legally Authorized Representative (LAR)  
(e.g., parent, guardian or conservator)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of LAR

\_\_\_\_\_  
LAR's Authority to Act for Participant  
(e.g., parent, guardian or conservator)

Participant ID:



## STANFORD UNIVERSITY Research Consent Form

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

### FINANCIAL CONSIDERATIONS

#### Payment

You will not be paid to participate in this research study.

#### Costs

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.

The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. **You will be responsible for any co-payments and/or deductibles as required by your insurance.**

### COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

### CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Dimitrios Colevas at [REDACTED]

Participant ID:



**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at [REDACTED]. You can also write to the Stanford IRB, Stanford University

**EXPERIMENTAL SUBJECT'S BILL OF RIGHTS**

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

Participant ID:



**STANFORD UNIVERSITY Research Consent Form**  
Protocol Director: Dimitrios Colevas, MD ep 22329

*IRB Use Only*  
Approval Date: August 23, 2016  
Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Adult Participant

\_\_\_\_\_  
Signature of LAR (Parent, Guardian or Conservator)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of LAR

\_\_\_\_\_  
Authority to act for participant

\_\_\_\_\_  
(If available) Signature of Other Parent or Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Other Parent or Guardian

\_\_\_\_\_  
Authority to act for participant

The IRB determined that the permission of two parents is required for research to be conducted under 21 CFR 50.52, in accordance with 21 CFR 50.55 unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child. Not reasonably available means that the other parent is not present during the consenting process, or will not be available prior to the start of research procedures.

Person Obtaining Consent

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Person Obtaining Consent

Participant ID: \_\_\_\_\_



**STANFORD UNIVERSITY Research Consent Form**

Protocol Director: Dimitrios Colevas, MD

ep 22329

*IRB Use Only*

Approval Date: August 23, 2016

Expiration Date: August 23, 2017

Protocol Title: Weekly Docetaxel, Cisplatin, and Cetuximab (TPC) in palliative treatment of patients with SCCHN

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

\_\_\_\_\_  
Signature of witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Witness

(e.g., staff, translator/interpreter, family member, or other person who speaks both English and the participant's language)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*

Participant ID: \_\_\_\_\_

