Principal Investigator:	Jeremy Kortmansky, MD	HIC #:	1605017852
Funding Source:	Yale Cancer Center	Protocol Version and Date:	5.0 dated 07-Jun-2018

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL: SMILOW CANCER HOSPITAL

Study Title: TAS-102 in Combination with Oxaliplatin (TAS-OX) for Refractory Metastatic Colorectal Cancer

Principal Investigator: Jeremy Kortmansky, MD
Principal Investigator's Phone Number: 203-407-8002
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Principal Investigator's Mailing Address: PO Box 208028, New Haven, CT 06520-8028
Funding Source: Yale Cancer Center

Invitation to Participate and Description of Project

You are invited to take part in a research study. The research study is designed to look at the safety and effects of TAS-102 in combination with oxaliplatin in subjects with metastatic colorectal cancer. You have been invited to take part because you have metastatic colorectal cancer that has returned after receiving standard chemotherapy, which included 5-FU, oxaliplatin, irinotecan, bevacizumab, and anti-EGFR monoclonal antibody (if you are RAS wild-type).

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: the purpose and nature of the research study, the procedures that will be performed, the risks of the study drug(s) and procedures, possible benefits, possible alternative treatments, your rights as a participant and other information about the research study. You should take whatever time you need to discuss the research study with your physician and family. The decision to participate or not is yours. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign and date where indicated on this form.

If you choose to participate, you will be told of any significant new findings that develop during the course of your participation in this study that may affect your willingness to continue to participate.

The research study is being funded by the Yale Cancer Center. Yale Cancer Center is providing research support. Dr. Jeremy Kortmansky is the principal investigator of this study at Yale Cancer Center.

APPROVED BY THE YALE UNIVERSITY IRB 6/21/2019

Purpose

This is a two-part study. The purpose of this study is to study the safety of the combination of TAS-102 and oxaliplatin. This study will also evaluate the effect the study drugs have on your kind of cancer.

The combination of study drugs that will be used in this research study, TAS-102 and oxaliplatin, is considered investigational. This means that the combination of study drugs has not been approved for commercial use by the United States Food and Drug Administration (FDA) in your type of cancer. On September 22, 2015, the United States Food and Drug Administration (FDA) approved TAS-102 (also known as Lonsurf) for the treatment of patients with metastatic colorectal cancer who have been previously treated with all standard approved drugs (i.e., fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biologic product, and an anti-EGFR monoclonal antibody, if RAS wild-type). Oxaliplatin and TAS-102 are individually approved by the FDA for the treatment of patients with colorectal cancer that is advanced or has come back. Since both drugs are approved for this setting of colorectal cancer, you or your insurance provider will be responsible for the costs of the commercially available drugs.

It is expected that up to 68 subjects will be enrolled at the Yale Cancer Center. Up to 18 will be enrolled to Part 1 and up to 50 will be enrolled in Part 2.

Study Procedures

This study will be conducted in two parts. The first part will be done to find the dose of study drugs, TAS-102 in combination with oxaliplatin, that can safely be given to subjects with your kind of cancer. This is called a run-in phase. The second part will be done to further investigate the safety of the study drugs and to determine if the study drugs work in your kind of cancer. This is called an expansion phase. In both parts, you will continue to receive the study drugs until your disease progresses or you experience unacceptable toxicity. The study procedures are the same in each part and are explained below. The dose of study drug you will receive will vary based upon the part in which you are enrolled. Your study doctor will inform you of the dose of study drugs you are to receive.

Tests and procedures that would be performed for your regular cancer care whether you are on this study or not, are called "standard of care." All of the tests and procedures listed below that will be performed at your study visits, should you choose to participate in this study, are standard of care unless noted with an asterisk (*).

Screening Period

If you agree to participate and sign and date this form*, you will need to undergo a series of tests and procedures within 14 days of your first dose of study drugs, unless otherwise specified below, to determine if you are eligible to participate in the research study. You will come to the study site for screening tests and it is possible that more than one screening visit may be needed. The following tests or procedures will be performed during the visit(s):

- Recording your demographic information including age, sex and race/ ethnicity

- Review of your medical and surgical history including a review of treatments and/ or surgeries previously received for your cancer
- Review of any medications you have previously taken or are currently taking including prescriptions drugs, over-the-counter medications, herbal drugs and dietary supplements
- Complete Physical examination
- Your physician will determine your activity level and your current ability to perform daily tasks called an Eastern Cooperative Oncology Group (ECOG) performance status
- Vital signs including measurement of your weight, height, blood pressure, heart rate, body temperature and oxygen saturation (the level of oxygen in your blood)
- 12-lead Electrocardiogram (ECG) to measure the electrical activity of your heart
    - An ECG requires temporary placement of electrical sensors on your chest near your heard, on your wrists, and on your ankles
- Routine laboratory tests of your blood to evaluate your blood cell counts, blood chemistry, kidney function, blood clotting ability, and any other safety evaluations.
- Serum or urine pregnancy test (for women of childbearing potential only). You will not be able to participate if your pregnancy test is positive.
- Computerized Tomography (CT) or PET/CT scan of your chest, abdomen and pelvis within 28 days of your first dose of study drugs. The scan measures size and location of your tumors. You may be asked to drink a large cup of liquid contrast agent.

If the exams, tests and procedures completed during the screening period show that you meet all of the trial eligibility criteria, and if you choose to continue, you will proceed to the main part of the trial.

Treatment Period
You will be asked to return to the clinic to see your study doctor to take the first dose of the study drugs. At this time, your doctor will tell you how many pills of TAS-102 you will need to take at home.

Please handle the TAS-102 as follows:
- Store the TAS-102 at room temperature.
- Keep the study drug in a safe place and out of reach of children.
- Take the study drug with water within 1 hour after your morning and evening meal.
- If you vomit after taking the study drug, do not take a replacement dose.
- Take your doses on schedule.
- Report any missed doses at your next study visit.

TAS-102 is taken in pill form with water within 1 hour of completing a meal and you will take the study drug orally (by mouth) twice a day from Day 1 through Day 5 of every cycle with the first dose in the morning of Day 1 and the last given in the evening of Day 5 (drug is taken every 8 to 12 hours). This is followed by a recovery period (i.e., no study drug given) beginning Day 6 through Day 14 of each cycle. The dose of TAS-102 to be given will be between 25 and 35mg/ m^2. The dose you receive will be determined by when you join the study. Your study doctor will tell you what dose you will receive.

Oxaliplatin is given as an intravenous (in a vein in your arm) infusion on Day 1 of each cycle when you are in the clinic for your study visits. The dose of oxaliplatin to be given is 85 mg/m^2. All subjects will get the same dose of oxaliplatin.

The following is a list of evaluations that you will undergo during the treatment period of the study:

Cycle 1 Day 1:

- Review of your medical history
- Review changes in your medications including prescriptions drugs, over-the-counter medications, herbal drugs and dietary supplements
- Physical examination
- Evaluate your ECOG performance status
- Vital signs
- Routine laboratory tests of your blood
- Blood sample to test your Serum carcinoembryonic antigen (CEA) levels. CEA levels are checked to monitor colorectal cancer and if the study drugs are working in your cancer.
- Receive a prescription for TAS-102 to be filled at your local pharmacy
- Receive a pill diary to record your doses of TAS-102 taken at home

Cycle 1 Day 8:

- Review changes in your health and/ or medications including prescriptions drugs, over-the-counter medications, herbal drugs and dietary supplements
- Physical examination
- Evaluate your ECOG performance status
- Vital signs
- Routine laboratory tests of your blood

Day 1 of each cycle thereafter (unless otherwise specified):

- Review of your medical history
- Review changes in your health and/ or medications including prescriptions drugs, over-the-counter medications, herbal drugs and dietary supplements
- Physical examination
- Evaluate your ECOG performance status
- Vital signs
- Routine laboratory tests of your blood
- Blood sample to test your Serum CEA levels starting with Cycle 3 and every odd cycle thereafter (i.e., Cycle 5, 7, 9, etc.)
- CT or PET/CT scan of your chest, abdomen and pelvis starting on Day 1 of cycle 5 and every 8 weeks thereafter or more frequently if clinically indicated. The frequency may be changed to every 12 weeks at the discretion of your study doctor after your first 2 scans are completed during the treatment period.

- Receive a prescription for TAS-102 to be filled at your local pharmacy
- Receive a pill diary
- Return your pill diary from the previous cycle

End of Treatment

The following procedures will be performed within 28 days of your last dose of study drugs, or prior to your next anti-cancer treatment, whichever occurs first:

- Review of your medical history
- Review changes in your health and/ or medications including prescriptions drugs, over-the-counter medications, herbal drugs and dietary supplements
- Physical examination
- Evaluate your ECOG performance status
- Vital signs
- Routine laboratory tests of your blood
- Return your pill diary from the previous cycle

Potential Risks, Side Effects, Discomforts and Inconveniences

Risks associated with TAS-102

As of 24 July 2016, a total of 2,480 subjects have been treated in clinical trials (Taiho sponsored or Investigator initiated). The side effects presented below include side effects reported by those subjects. However, the side effects shown below are not a complete list, because rare events of a non-severe nature were not listed; however, rare events of a severe nature are listed. The list includes effects that both may or may have not been related to TAS-102 and you may experience some other side effects that are not listed. Though many of the side effects reported were mild to moderate in nature, some side effects may become severe and life-threatening, and could potentially worsen, leading to death.

You should talk with your study doctor about any side effects that you have while participating in this trial.

Likely, occurring in >20% (all levels of severity) of participants:

- Digestive system: Nausea, vomiting, diarrhea
- Blood: Lowered white blood cell counts/neutrophils (white blood cells are important in helping people fight off or prevent infections); Lowered red blood cell count (anemia). Red blood cells are important for carrying oxygen in the blood and decreased amounts can lead to symptoms such as tiredness or shortness of breath. These side effects are typically mild in nature when subjects are taking TAS-102 alone and blood counts are often slow to return to normal. The effect on your blood counts may be more severe in nature due to combination of TAS-102 and oxaliplatin being used in this study.
- General: Tiredness
- Metabolism: Loss of appetite
- Infection: Infections, e.g. blood (can be fatal), lung, pelvis, eye, urinary tract, intestinal tract, skin, liver/biliary tract, medical device (such as an indwelling catheter)

Common, occurring in 3 -20% (all levels of severity) of participants:

- Digestive system: Sores in mouth (stomatitis), constipation, abdominal pain, indigestion
- Blood: Lowered platelet count (platelets are important in helping a person's blood to clot when they are bleeding)
- Skin: Hair loss, rash (changes in the color or texture of the skin, possible blistering and peeling
- Kidney: Leakage of protein in urine
- Nerve: Changes in sense of taste, headache
- Musculoskeletal: back pain, joint pain
- General: Fever, Weakness
- Metabolism: Decreased blood protein
- Psych: Anxiety
- Liver: Abnormally high levels of enzymes produced by the liver (meaning that your liver is not working properly)

Rare but severe, occurring in <3% (severity level 3 and above) of participants:

- Heart: Heart attack, heart muscle damage, chest pain, the heart beats too fast or too slow
- Liver: Liver damage, yellow color of skin or eyes (jaundice)
- Kidney: Kidney damage, blood in urine
- Brain: Effects on brain or nerve function, seizure, decreased level of consciousness, blood clot
- Digestive system: Inflammation of large bowel (symptoms with abdominal pain, diarrhea, and bloody stool), abnormal connection between digestive system and other areas (fistula), blockage of small or large bowel, accumulation of fluid in abdomen, bleeding, intestinal ulcer, inflammation of the pancreas
- Lung: Blood clots in lung, difficulties in or cessation of breathing, inflammation of lung, nosebleed
- Metabolism: Gout (high levels of uric acid with symptoms with red, tender, hot and swollen joints), dehydration
- Vascular: Fainting, blood clot in leg, decreased blood pressure, blood clotting disorder, hot flushes
- Nervous: Dizziness, Numbness and Tingling
- Musculoskeletal: Muscle pain
- General: Flu like symptoms, general physical health deterioration, swelling in legs

Post-marketing data

TAS-102 has been marketed in Japan as Lonsurf® since 26-May-2014. Approximately 7,000 subjects have been exposed to Lonsurf in clinical studies and clinical practice settings in Asia. The following events have been reported from these subjects.

- Blood: fever with low neutrophil count (can be fatal); blood clotting disorder (can be fatal); failure of bone marrow to produce sufficient numbers of red cells, white cells or

platelets (can be fatal); lowered platelet count (can be fatal); lowered counts of red cells, white cells and platelets together; lowered counts of red cells and white cells/neutrophils
- Digestive system: infected fistula; diarrhea; bleeding GI ulcer; block in small or large bowel; nausea; tear in small bowel; vomiting
- Eye: corneal disorder
- General: fever; feeling tired; death
- Heart: heart failure, heart beats too fast
- Infection: infection; infection in blood; shock; urinary tract infection
- Kidney: decreased kidney function
- Liver: yellow color of skin or eyes (jaundice); infection in gall bladder; abnormal liver function
- Metabolism: disturbance in electrolytes
- Nervous: blood clot in brain (can be fatal)
- Respiratory: pneumonia (can be fatal); interstitial pneumonia (can be fatal); respiratory distress syndrome (can be fatal); blood clot in lung

Risks associated with Oxaliplatin
The most common side effects include:
- sensory and/or motor neuropathy (damage to nerves resulting in pain, loss of sensation, or inability to control muscles)
- allergic reactions
- pharyngolaryngeal dysesthesia (tightness or discomfort in the throat making it seem difficult to breathe or swallow)
- interstitial lung disease or pulmonary fibrosis (damage to lung tissue)
- liver toxicity
- decrease in blood cells

Other Risks
Blood Collection and Intravenous (IV) catheter placement:
The risks of taking blood may include pain, redness, swelling and/or bruising where the needle enters your body, light-headedness and fainting. On rare occasions, local blood clot formation or infection with redness and irritation of the vein has occurred. The blood pressure cuff may cause discomfort or bruising to the upper arm.

Reproductive Risks:
Risks for Women
If you are pregnant or become pregnant, or if you are currently breastfeeding, you cannot take part in this study because you or your child may be exposed to an unknown risk. If you are a woman who can become pregnant, you must have a blood test that shows you are not pregnant before you can be enrolled in this study. If the blood test is positive, you will not be enrolled in this study.

If you can become pregnant, you must agree to remain abstinent or use two birth control methods that are judged to be highly effective by your study doctor from the time you sign this consent

document until 4 weeks after your last dose of study drugs. Acceptable methods of contraception include abstinence, tubal ligation, combined oral, transdermal or intra-vaginal hormonal contraceptives, medroxyprogesterone injections (e.g., Depo-provera), copper-banded intra-uterine devices, hormone impregnated intra-uterine systems and vasectomised partners. All methods of contraception (with the exception of total abstinence) should be used in combination with the use of a condom by a male partner.

Risks for Men
If your partner is able to become pregnant, you must agree to remain abstinent or use a condom plus from the time you sign this consent document until 4 weeks after your last dose of study drugs. If your partner is able to become pregnant and is not using effective contraception (see acceptable methods outlined above), you must agree to remain abstinent or use a condom during the study and for 6 months after your last dose of study drugs. Male subjects should avoid procreation during the trial and for 6 months after the last dose of study drugs.

Tell your study doctor right away if you suspect that you have become pregnant during the study. The study doctor or research staff will advise you of the possible risks to your unborn child and the options available to you. The study team will ask if you, or your pregnant partner, are willing to provide information about the pregnancy and the outcome. You, or your pregnant partner, will be asked to review and sign a separate research authorization form at that time.

There may also be side effects, other than listed above that we cannot predict. Other drugs will be given to make side effects that occur less serious and less uncomfortable. Many side effects go away shortly after the drug or procedure is stopped, but in some cases side effects can be serious, long lasting or permanent.

For more information about risks and side effects, ask the researcher or contact their office at 203-407-8002.

Benefits
If you agree to take part in this research study, we cannot guarantee that you will receive any benefits. We hope the information learned from this research study may benefit other patients with colorectal cancer in the future.

Economic Considerations
You will not be paid for taking part in this study. Tests and procedures that would be performed for your regular cancer care whether you are on this study or not are called "standard of care." All of the tests and procedures listed in this consent form that will be performed at your study visits are standard of care unless noted with an asterisk (*). The administration of the study drug, oxaliplatin, will be charged to you or your insurance provider. You or your insurance provider will be responsible for the cost of TAS-102 and oxaliplatin. There will be no charge to you or your insurance provider for tests or procedures noted with an asterisk as these are performed for study purposes only. All other tests and procedures will be charged to you or your insurance provider in the usual way as these are standard of care. This may include other tests and

procedures not listed in this consent if your doctor feels it is necessary for your care, such as additional laboratory tests.

Taking part in this research study may lead to added costs for you or your insurance provider. You are encouraged to speak with your insurance provider prior to entering the research study to find out your individual coverage. If you have difficulty determining your individual insurance coverage, you may call Dr. Jeremy Kortmansky's office for assistance at 203-407-8002.

You or your insurance provider will be charged for continuing medical care and/or hospitalization that are not a part of the research study.

Treatment Alternatives

You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for your cancer without being in a study including taking TAS-102, regorafenib alone or another oxaliplatin-based regimen if you have not taken these drugs before.
- Taking part in another study.
- Receiving no treatment at this time.
- Getting comfort care, also called palliative care; this type of care helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer.
  Comfort care does not treat the cancer directly but instead is meant to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Talk to your doctor about your choices before you decide if you will take part in this study.

Confidentiality and Authorization to collect, use and disclose Protected Health Information

For purposes of this study, Yale University, Yale-New Haven Hospital, and Dr. Jeremy Kortmansky will use medical information collected or created as part of the study, such as medical records and test results, which identifies you by name or in another way. Your consent to participate in the study means you agree that Yale University, Yale-New Haven Hospital, and Dr. Jeremy Kortmansky may obtain your medical information that they request for study purposes from your physicians and your other health care providers from the past or during your participation in the study.

The protected health information that will be collected in this study includes demographics, medical history, physical examinations, routine lab tests, review of adverse events and medications you take (past and present), vital signs, CT or PET/CT scans, pregnancy tests, and records about any study drug(s) that you received.

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or

elderly person, or certain reportable diseases such as HIV or hepatitis. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the study staff will get information that identifies you and your protected health information. This may include information that might directly identify you, such as your name, date of birth, and medical record number**.** We will replace your identifying information with a code that does not directly identify you. The study doctor will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the Principal Investigator or selected members of the study team. Any information that can identify you will remain confidential.

The records for this trial will be stored in locked cabinets and/or offices and password protected computers. The study team will only give this coded information to others to carry out this research study or to comply with federal laws and regulations. It is anticipated that records containing the information that links you to your coded information will be maintained indefinitely, as there are no plans at this time to destroy these records at the end of the study.

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g., health insurance company, disability provider.)

Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University and the Human Investigation Committee (the committee or Institutional Review Board that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential
- Your providers who are participants in the Electronic Medical Record (EMR) system
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The study doctor, Dr. Jeremy Kortmansky, and the Yale study team
- The U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about the new drug product involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported

- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at Yale School of Medicine and Yale-New Haven Hospital is required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Authorized representatives of the Food and Drug Administration (FDA**)** may need to review records of individual subjects. As a result, they may see your name, but they are bound by rules of confidentiality not to reveal your identity to others.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. However, you will not be allowed to look at or copy your study related information until after the research is completed.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

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.

In Case of Injury

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

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

Voluntary Participation and Withdrawal

Participation in this study is voluntary. You are free to choose not to take part in this research study. Refusing to take part in this research study will not lead to penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing From the Study:
If you decide to participate in this research study, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. They will make sure that proper procedures are followed and a final visit is made for your safety. This will cancel any future research study appointments.

The researchers may withdraw you from participating in the research if necessary. Your study doctor may end your participation in the study if you experience unacceptable toxicity, if you do not take the study drugs as directed and/ or if you do not follow the trial procedures as directed.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale-New Haven Hospital.

If you choose not to give your consent by not signing this document, or if you cancel your consent later, then you will not be eligible to participate in this study and will not receive any study drugs provided as part of the study. Unless and until you do cancel the consent, it will remain valid and effective.

Withdrawing Your Authorization to Use and Disclose Your Health Information:
You may withdraw or take away your permission to use and disclose your health information at any time. You do this by telling the study staff or by sending written notice to the study doctor, Dr. Jeremy Kortmansky, at the address listed on page one of this form. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Principal Investigator:	Jeremy Kortmansky, MD	**HIC #:**	1605017852
Funding Source:	Yale Cancer Center	**Protocol Version and Date:**	5.0 dated 07-Jun-2018

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

APPROVED BY THE YALE UNIVERSITY IRB 6/21/2019

Principal Investigator:	Jeremy Kortmansky, MD	HIC #:	1605017852
Funding Source:	Yale Cancer Center	Protocol Version and Date:	5.0 dated 07-Jun-2018

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project as described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use and give out information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to participate in this research.

Study Participant (print name)	Signature	Date
Person obtaining consent (print name)	Signature	Date
Person obtaining consent (print name) – only if applicable, otherwise blank	Signature	Date
Interpreter/ Witness (print name) – only if applicable, otherwise blank	Signature	Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Jeremy Kortmansky, at 203-407-8002. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

APPROVED BY THE YALE UNIVERSITY IRB 6/21/2019