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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: TAS-102 in Combination with Oxaliplatin (TAS-OX) for Refractory Metastatic Colorectal Cancer

Principal Investigator: Howard Hochster, MD
Rutgers Cancer Institute of New Jersey
195 Little Albany Street,
New Brunswick, NJ, 08903
732-235-2465 (24 hr. line)

Participating Sites:	
Cooperman Barnabas Medical Center 94 Old Short Hills Road Livingston, NJ 07039 Telephone Number: (973) 322-5200 (24 hours)	**Monmouth Medical Center** 300 Second Avenue Long Branch, NJ 07740 Telephone Number: 732-222-1711
Community Medical Center 99 Highway 37 West Toms Rivers, NJ 08755 Telephone Number: 732-557-8032	**Monmouth Medical Center-South** 600 River Avenue Lakewood, NJ 08701 Telephone Number: 732-222-1711
Trinitas Regional Medical Center 225 Williamson Street Elizabeth, NJ 07202 Telephone Number: (908) 994-8000 (24 hours)	

This informed consent form provides information about a research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, you should feel free to ask them and should expect to be given answers you completely understand. It is your choice whether to take part in the research. Your alternative to taking part is not to take part in the research.

After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this informed consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?
Dr. Howard Hochster is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research study. However, there are often other individuals who are part of the research team.

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

Sponsor of the Study: The research study is being funded by the Rutgers Cancer Institute of New Jersey.

Why is this study being done?
The research study is designed to look at the good and bad effects of TAS-102 in combination with Oxaliplatin in subjects with colorectal cancer that has spread to other parts of the body (metastasized).

TAS-102 (also known as Lonsurf) is a drug that is approved by the United States Food and Drug Administration (US-FDA) to treat metastatic colorectal cancer. Oxaliplatin is another drug (approved by US-FDA) used with other drugs to treat advanced colon cancer (-cancer has started spreading outside colon to the surrounding tissues). However, the combination of TAS-102 and Oxaliplatin that will be used in this research study, is new and considered investigational. Since both drugs are approved individually for colorectal cancer, you or your insurance provider will be responsible for the costs of the commercially available drugs.

What is the current standard of treatment for this disease?

When a cancer comes back (recurs) or does not respond to therapy (refractory), your doctor may recommend other anti-cancer drugs (chemotherapy), surgery, or radiation therapy. Initial treatment for colorectal cancer includes chemotherapy agents Oxaliplatin, Flouoropyrimidine, and Irinotecan. Antibodies (proteins attacking cancer targets) are also approved including those against blood vessel growth (anti-VEGF) or cell growth (anti-EGFR). For refractory metastatic colorectal cancer, TAS-102 or Regorafenib (a drug that blocks the action of certain proteins, which may help keep cancer cells from growing and may kill them) are considered standard treatment when given as single agents. These drugs are used in various combinations and sequences. Your physician can explain in more detail.

This study includes combining Oxaliplatin with TAS-102. These drugs attack tumor DNA to kill cancer cells by different and complementary actions. Please ask your doctor for information about refractory colorectal cancer and your available options.

Who may take part in this study and who may not?
You may take part in the study if:

- You have histologically confirmed (diagnosis confirmed after observing the tissues and cells under the microscope) stage IV (metastatic) colon cancer that has progressed after standard therapy
- If you are 18 years or older;
- You have ability to take oral medication;
- You are able and willing to comply with study procedures as per protocol.

You may not take part in the study if:
- If you have received the study drug TAS-102 previously;
- If you have received other investigational agents in past 4 weeks.

The information above does not include all considerations relevant to potential participation in the study. The study doctor and/or research team will also ask you other questions about your medical history and may conduct additional tests in order to see if you qualify to be in this study. After the screening period, your study doctor and the sponsor will decide if you qualify for this study.

Why have I been asked to take part in this study?
You have been invited to take part because you have metastatic colorectal cancer that has returned after receiving standard chemotherapy, which included 5-FU or Capecitabine, Oxaliplatin, Irinotecan, Bevacizumab, and an anti-EGFR monoclonal antibody (if appropriate for you), and if you are a candidate for further Oxaliplatin therapy.

How long will the study take and how many subjects will take part?
The study will take 36 months to complete. You will be receiving treatment in this study until your disease progresses. You will be one of 70 subjects who will be enrolled at the Rutgers Cancer Institute of New Jersey, Cooperman Barnabas Medical Center, Monmouth Medical Centers, Monmouth Medical Center Southern Campus and Community Medical Center.

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

Study Procedures:
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.

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 prior to 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, 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 heart, on your wrists, and on your ankles.

- Routine laboratory tests of your blood to evaluate your blood cell counts, blood chemistry, kidney function, and blood clotting ability.

- 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. CT scan uses X-rays to look at one part of your body. It may be done with or without contrast. Contrast means that a dye is injected into your vein to increase the differences between normal and abnormal tissue. You may be asked to drink a large cup of liquid contrast agent. Positron emission tomogram (PET), uses computerized images to look at the activity of tumor cells in your entire body and that requires injection of a special substance into your vein, such as sugar (glucose) combined with a low-dose radioactive substance (a tracer). A camera records the tracer's signal as it travels through your body.

If the exams, tests and procedures completed during the screening period show that you meet all of the research study 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.

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.

Oxaliplatin is given as an intravenous (given through a needle inserted into a vein usually in your arm) infusion on Day 1 of each cycle when you are in the clinic for your study visits.

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 to monitor your blood counts and kidney and liver function. Approximately two teaspoons (10 ml) will be collected for these tests.
- One teaspoon (5 ml) blood sample will be collected 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 to monitor 20 counts; and kidney and liver function. Approximately two teaspoons (10 ml) will be collected for these tests.

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. Approximately two teaspoons (10 ml) will be collected for these tests.
- One teaspoon (5 ml) blood sample will be collected 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 4 cycles thereafter or more frequently if clinically indicated. The frequency may be changed to every 6 cycles 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. Approximately two teaspoons (10 ml) will be collected for these tests.
- Return your pill diary from the previous cycle

What are the risks and/or discomforts I might experience if I take part in this study?

Risks associated with TAS-102:

As of 24 July 2016, a total of 2,480 subjects have been treated in clinical trials (Taiho Pharmaceuticals sponsored or Investigator initiated). The side effects presented below include side effects reported by those subjects. Only rare events of a severe nature are listed. The side effects shown below are not a complete list, because rare events of a non-severe nature are not 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 (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, nose bleed
- 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 in blood; 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 giving 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 intrauterine 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.

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.

Are there any benefits to me if I choose to take part in this study?
If you agree to take part in this research study, it is possible that you will receive no direct personal benefit from taking part in this study. We hope the information learned from this research study may benefit other patients with colorectal cancer in the future.

What are my alternatives if I do not want to take part in this study?
The following alternative treatments are available if you choose not to take part in this study:

- 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.

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

Will there be any cost to me to take 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.

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. 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. Howard Hochster, MD at 732-235-2465.

You or your insurance provider will be charged for continuing medical care and/or

hospitalization that are not a part of the research study.

Will I be paid to take part in this study?
You will not be paid for your participation in this research study.

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

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.

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.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if I am injured during this study?
Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which is discussed in the section *"what are the risk and discomforts I might experience if I take part in this study".* In addition, it is possible that during the course of this study, new adverse effects of study drug TAS-102 and Oxaliplatin that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such

programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

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

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Howard Hochster, MD at Rutgers Cancer Institute of New Jersey, 195 Little Albany Street, New Brunswick, NJ, 08903.

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

Who can I call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor: Dr. Howard Hochster at Rutgers Cancer Institute of New Jersey, 195 Little Albany Street, New Brunswick, NJ, 08903, Contact Number: 732-235-2465.

For questions about your rights while in this study, call the Rutgers Health Sciences Institutional Review Board at (732) 235-9806.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share protected health information from your electronic medical record in this research study. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your protected health information in the research and share it with others as described below. Ask questions if there is something your do not understand.

What is the purpose of the research and how will your information be used?

You are being invited to take part in this research study, which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- Hospital discharge summaries

- Radiology records or images (MRI, CT, PET scans)
- Medical history or treatment
- Medications
- Consultations
- Laboratory/diagnostic tests or imaging
- EKG and/or EEG reports
- Pathology reports, specimen(s) or slide(s)
- Operative reports (about a surgery)
- Emergency Medicine reports

Who may use, share or receive my information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University investigators involved in the study;
- Rutgers Cancer Institute of New Jersey
- Robert Wood Johnson University Hospital
- Cooperman Barnabas Medical Center
- Monmouth Medical Center
- Monmouth Medical Center – Southern Campus
- Community Medical Center
- Trinitas Regional Medical Center
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The U.S. Food and Drug Administration (FDA).
- Drug regulatory agencies in other countries
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review your research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Dr. Howard Hochster, Rutgers Cancer Institute of New Jersey, 195 Little Albany Street, New Brunswick, NJ, 08903.

How long will your permission last?

There is no set date when your permission will end. Your health information may be studied for many years.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered. I agree to take part in this research study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

FOR NON-ENGLISH SPEAKING SUBJECTS:

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

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

Reader/Translator Name:_____

Reader/Translator Signature:_____ Date:_____

Witness Name:_____

Witness Signature:_____ Date:_____