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Phase Ib/II Trial of Nal-Irinotecan and Nivolumab as Second-Line Treatment in Patients  
With Advanced Biliary Tract Cancer

NCT03785873

## UNIVERSITY OF MICHIGAN

### CONSENT TO BE PART OF A RESEARCH STUDY

#### 1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

**Study title:** A Single Arm Phase Ib/II Study of Nivolumab in Combination with nanoliposomal-Irinotecan, 5-Fluorouracil, and Leucovorin as Second Line Therapy for Patients with Advanced Biliary Tract Cancer

**Company or agency sponsoring the study:** The University of Michigan.  
Support for this study is being provided by Bristol-Myers Squibb (BMS) and Ipsen.

**Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):**

**Principal Investigator:**

Vaibhav Sahai, MBBS, MS-Department of Internal Medicine, Hematology/Oncology, University of Michigan

#### 1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying the use of a new drug in small numbers of people to learn about its safety and its effect on your body at certain doses as a treatment for patients with advanced biliary tract cancer. Researchers want to understand how the drug works in your body and how your body will react to it. This study will be using the drugs nivolumab in combination with nanoliposomal-irinotecan, 5-fluorouracil and leuCoverin. You will receive nivolumab through a vein in your arm over 30 minutes and leuCoverin, nanoliposomal-irinotecan and 5-fluorouracil through a vein in the arm over a period of about 46 hours. Other procedures that will take place throughout the course of the study include physical exams, blood draws, scans of your cancer, along with other items listed later in this document. Your health-related information and biospecimens (blood and tissue) will be collected for this research study.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, a brief list of some of most commonly seen risks may include diarrhea, nausea,

vomiting, infection, loss of appetite, bruising, fatigue, rash, pain, hair loss and abnormal lab tests. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by helping people to live longer or improve the quality of life.

We expect the amount of time you will participate in the study to vary depending on how your disease responds to the study intervention and if you have any major side effects and could be up to 4 years.

You can decide not to be in this study. Alternatives to joining this study include receiving standard of care treatment for this disease, taking part in a different study, receiving palliative care, or having no treatment.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

## 2. PURPOSE OF THIS STUDY

### 2.1 Study purpose:

This is a Phase I/II study which means that the goals are to see if the combination of nivolumab, nanoliposomal-irinotecan, 5-fluorouracil, and leuCoverin is safe as well as whether it is effective in improving outcomes. The first part of the study will try to find out what effects, good and/or bad, this drug combination has on you and your cancer, and to find a dose to use in the second part of the trial.

Platinum-based combination chemotherapy, including gemcitabine and cisplatin is considered the standard of care treatment since it has demonstrated a survival benefit for patients with advanced biliary tract cancer. However, mostly all patients eventually develop resistance to platinum-based chemotherapy and their disease progresses. It is also challenging to continue chemotherapy beyond 4 or 6 months due to side effects. Therefore, there is an urgent need to develop effective therapies that can be used to treat this cancer beyond platinum-based chemotherapy.

The purpose of this study is to test the effectiveness (how well the drug works), safety, and tolerability of the investigational drug combination of nivolumab plus nanoliposomal-irinotecan, 5-fluorouracil, and leuCoverin for patients with advanced biliary tract cancer.

The combination of nanoliposomal-irinotecan plus 5-fluorouracil and leuCoverin (also known as FOLFIRI) is approved by the Food and Drug Administration (FDA) for the treatment of patients with advanced pancreatic cancer following gemcitabine-based therapy.

Nivolumab (Opdivo) is a type of immunotherapy. Immunotherapy works by encouraging the body's own immune system to attack the cancer cells. Nivolumab has been approved by FDA for the treatment of metastatic melanoma (a type of skin cancer) Hodgkin's lymphoma, urothelial cancer, colorectal cancer and previously treated advanced lung, head & neck, liver and kidney cancers.

The combination of nivolumab, nanoliposomal-irinotecan, 5-fluorouracil, and leuCoverin is considered investigational, which means that it has not been approved by the FDA.

### 3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

#### 3.1 Who can take part in this study?

Adult men or women who have adenocarcinoma of the biliary tract that cannot be treated with surgery, transplant or ablative therapies (therapies that destroy abnormal tissue without removing the tissue).

There are many other inclusion and exclusion criteria which the doctors will use to determine if you can participate in this study. It is important that you discuss your full medical history and all of your medications with your doctor.

#### 3.2 How many people (subjects) are expected to take part in this study?

A total of approximately 30-40 subjects at several institutions will take part in this study, including approximately 20 from the University of Michigan.

### 4. INFORMATION ABOUT STUDY PARTICIPATION

#### 4.1 What will happen to me in this study?

The study team will explain the research study and answer any questions you have about the study. If you want to participate in the study, the study team will request you to sign the consent form prior to any activities occurring that pertain to the study. Once your consent is obtained, the study team will look through your medical chart, ask you questions, and begin scheduling tests and procedures to determine if you are eligible for the study. The study team will inform you of the types of tests and procedures required before the study begins.

**Many of the procedures** that will be performed during the study, including routine blood tests, disease evaluations, physical examinations, vital signs (blood pressure, heart rate, breathing rate, and temperature) and measurement of height and weight, **would normally be done as part of your standard of care regardless of study participation.** However, some of these may be done more frequently as a result of your participation in this study. Tests and procedures that are done more often than your regular medical care because of your study participation and that are solely for research purposes will be identified below. The study staff will inform you of the types of tests and procedures you have to undergo during the study.

#### During the study you must:

- Follow the instructions you are given.
- Come to the study center for your visits with the study doctor.
- Tell the study doctor or study staff about any changes in your health and/or medications you are taking.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

**Before starting the study:** Some exams, tests, and procedures will be required to find out if you can be in this study. If you have had some of the tests recently, they may not need to be repeated. The screening tests and procedures do not have to be completed in one day and you are allowed to take breaks if you have multiple procedures in one day.

The following tests and procedures will be performed during screening and/or at one or more study visits. Refer to the study calendar below for information about which procedures will be performed at certain study visits.

- **Medical history:** including any past treatments, surgeries, infection and autoimmune diseases.
- **Medications review:** It is important that you tell your doctor about all of the medications that you have been taking, including over the counter medicines, vitamins or herbal treatments. Some enzymes in your body may interact with certain medications you might be prescribed, so please let your doctor know immediately if you're asked to take any of the following: St. John's Wort, ketoconazole, rifampin, phenytoin, carbamazepine, rifabutin, rifapentine, phenobarbital, clarithromycin, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telaprevir, voriconazole and/or atazanavir, gemfibrozil.
- **Physical exam/Vital Signs:** including measurement of your height, weight, blood pressure, heart rate, respiratory rate and temperature.
- **Performance status:** Your ability to perform day to day activities and care for yourself
- **Routine blood tests (approximately 2 teaspoons):** will be drawn for tests to check blood counts, chemistry, thyroid health and blood markers for cancer
- **Pregnancy test:** (urine or blood – approximately 1 teaspoon): if you are a woman able to have children
- **Scans of your cancer:** these could include Computed tomography (CT) of the chest, CT or magnetic resonance imaging (MRI) of the upper and lower belly. The scans will be sent to a central location in a coded format.
  - A CT scan uses special x-ray equipment to make detailed pictures of body tissues and organs. For the CT scan, you may be given a "contrast material" (a special dye that makes it easier for doctors to see different tissues in your body). You will be asked to lie still and may be asked to hold your breath for a few seconds. The CT scan is done in the Radiology Department and takes about half an hour.
  - A MRI scan takes an image of your head or body to observe the location and size of your tumor. For the MRI scan, you may be given a "contrast material" (a special dye that makes it easier for doctors to see different tissues in your body). You will be asked to lie down on a narrow bed which will slide into a tunnel that is 6 feet long by 22 inches across and is open at each end. You will be asked to lie quietly for about one hour, during which time you will hear a loud machine-like noise. A MRI scan takes about an hour and a half to complete.
- **Blood for biomarkers:** About 4 teaspoons of blood will be collected on some visits listed in the table below. *This is for research purposes and is optional.*

**For subjects at the University of Michigan only (use the below wording for tissue collection)**

- **Tumor tissue samples:** *This is for research purposes.*
  - a. Pre-treatment: Screening: A tissue block or slides from a previous biopsy will be collected for understanding the genetic and immune make-up of your cancer and its surrounding tissue. *This tissue has to be available for you to be able to participate in this study.*
  - b. On-treatment: Tumor tissue samples will be obtained by core needle biopsy after at least 6 weeks of therapy and up to 6 cores will be obtained, if possible. The cost of the biopsy will be covered by this clinical study.

- c. Post-treatment (optional): The tumor tissue samples will be obtained by core needle biopsy and up to 6 cores will be obtained, if possible. A CLIA certified 1600 targeted gene panel will be run on the tissue without additional cost to you and the report will be released with results to your treating doctor. If this OPTIONAL post treatment biopsy is for research only, it will not be billed to insurance.
- d. You can make your choice in Section 12 for optional biopsies.

**Study Intervention (for Research):**

If you qualify to participate in the study based on the results of the screening tests and procedures, you will return to the study doctor's clinic.

For this study a cycle is defined as 2 weeks.

For subjects in Phase I and Phase II:

On Day 1 of each cycle, you will receive the following study intervention:

- Nivolumab intravenously (through a vein in your arm or port) over a period of about 30 minutes.
- LeuCorvin, nanoliposomal -irinotecan intravenously (through a port) over a period of about 90 minutes, and 5-Fluorouracil intravenously (through a port) over a period of about 46 hours.

If you experience adverse events, you might have to stop taking all or some of the study drugs and if you recover from your adverse events, you may be able to restart the study drug(s).

You may continue to receive the study intervention for up to 2 years as long as you are tolerating the study intervention and your disease has not progressed.

**Follow-up:**

If you stop the study intervention for any reason you will be asked to return for end of treatment visit 30 days after your last dose of study intervention.

After you complete the study intervention visit you will have an office visit or be contacted by a member of the study team every 3 months for up to 2 years from when you stopped the study intervention.

See the table for a summary of the study intervention and procedures.

**Study Procedures Table:**

Procedures	Screening	Cycle 1	Cycle 2+	End of treatment Visit	Follow-Up
		Day 1	Day 1		
Medical History	X	X	X*	X	X
Medication Review	X	X	X*		
Physical Exam/Vital Signs	X	X	X	X	
Performance Status	X	X	X*	X	
Routine Blood tests	X	X	X	X	
Pregnancy Test	X	X	X		
Scans/Imaging of your Cancer	X		X <sup>+</sup>		
Research Blood		X	X	X	
Tumor Tissue	X		X	X	
Study Drug Administration		X	X		
Toxicity Evaluations		X	X*	X	X
Survival Follow-up					X

\* Cycle 2, 3 and then every odd-numbered cycle

<sup>+</sup> every 8 weeks (+/- 1 week) from C1D1. Subsequent scans will be performed every 8 weeks (+/- 1 week) from date of last scan

**OPTIONAL Research Samples Stored for Unspecified Future Research:**

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep some of your blood, tumor tissue and medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your blood, tumor tissue and medical information for future research.

If you give us permission, we will use your blood, tumor tissue and medical information for future research. Even if you give us permission now to keep some of your blood, tissue and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your blood and tissue, we may not be able to take the information out of our research.

We may share your blood, tumor tissue and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your blood, tissue and medical information with other researchers, we will not be able to get it back. Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your blood and tumor tissue samples. If you elect to proceed with the optional post-treatment biopsy, the results of the tests run on the tumor tissue samples will be released to your treating doctor. Allowing us to do future research on your blood, tissue and medical information will not benefit you directly.

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the future research on your blood, tumor tissue and medical information. You will not have rights to these discoveries or any proceeds from them.

You can make your choice about whether to participate in the Optional substudy (storage of research samples for future use) in Section 12 of the consent.

#### **4.2 How much of my time will be needed to take part in this study?**

The initial screening visit will take approximately 2-5 hours. Each office visit is expected to take approximately 4-6 hours. You will have an office visit or be contacted by a member of the study team every 3 months for up to 2 years after you have stopped taking the study intervention.

#### **4.3 When will my participation in the study be over?**

The maximum time you will be in the study can be up to 4 years, but will depend on how your disease responds to the study intervention and how well you tolerate the study intervention. After you stop taking the study intervention you will be asked to come back for an end of treatment visit and we will follow with you via telephone or office visit every 3 months for up to 2 years from when you stopped taking the study intervention or 3 years after the first date you started the study intervention. Your participation may end sooner if you decide to no longer participate, your study doctor feels it is in your best interest to stop your study participation, your disease progresses or the study is ended. You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor and your regular physician first.

#### **4.4 What will happen with my information and/or biospecimens used in this study?**

Your biospecimens and collected information may be shared with BMS and Ipsen. With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies. Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

### **5. INFORMATION ABOUT RISKS AND BENEFITS**

#### **5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?**

The drugs used in the study may cause certain side effects and discomforts. You may have all, some, or none of the known side effects. There is also a risk that other rare or unknown side effects may occur. 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. There is even a chance that a side effect may cause death. If you have any side effects, it is important that you report them to your study doctor or research staff.

These risks will be minimized by monitoring you carefully. We will provide the usual supportive care that would be routinely given to someone with your condition. If you have side effects from the study intervention,



we will make appropriate adjustments as defined by the study protocol. You may need to discontinue the study intervention if the side effects are too serious.

The known or expected risks are:

### Side Effects ASSOCIATED WITH IRINOTECAN

This medication has moderate influence on the ability to drive and operate heavy machinery. During treatment, you should observe caution when performing these tasks.

COMMON, SOME MAY BE SERIOUS In 100 people receiving Irinotecan, more than 20 and up to 100 may have:
<ul style="list-style-type: none"> <li>• Severe diarrhea</li> <li>• Constipation, nausea, vomiting</li> <li>• Infection, especially when white blood cell count is low</li> <li>• Hair loss</li> <li>• Loss of appetite, weight loss</li> <li>• Anemia which may cause tiredness, or may require a blood transfusion</li> <li>• Fever, pain</li> <li>• Dizziness, tiredness, weakness</li> <li>• Cough, shortness of breath</li> <li>• Sores in mouth</li> <li>• Rash</li> <li>• Bruising, bleeding</li> </ul>

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Irinotecan, from 4 to 20 may have:
<ul style="list-style-type: none"> <li>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat</li> <li>• Blood clot which may cause swelling, pain, shortness of breath</li> <li>• Scarring of the lungs</li> </ul>

RARE, AND SERIOUS In 100 people receiving Irinotecan, 3 or fewer may have:
<ul style="list-style-type: none"> <li>• Inflammation of the lining of the colon (colitis)</li> </ul>

### Side Effects ASSOCIATED WITH 5-FLUOROURACIL

COMMON, SOME MAY BE SERIOUS In 100 people receiving 5-Fluorouracil, more than 20 and up to 100 may have:
<ul style="list-style-type: none"> <li>• Hair loss</li> <li>• Redness, pain or peeling of palms and soles</li> <li>• Rash, increased risk of sunburn, itching</li> <li>• Diarrhea, nausea, vomiting, loss of appetite</li> <li>• Difficulty swallowing</li> <li>• Sores in mouth</li> </ul>

<p>COMMON, SOME MAY BE SERIOUS</p> <p>In 100 people receiving 5-Fluorouracil, more than 20 and up to 100 may have:</p>
<ul style="list-style-type: none"> <li>• Heartburn</li> <li>• Headache</li> </ul>

<p>OCCASIONAL, SOME MAY BE SERIOUS</p> <p>In 100 people receiving 5-Fluorouracil, from 4 to 20 may have:</p>
<ul style="list-style-type: none"> <li>• Chest pain</li> <li>• Blood clot</li> <li>• Belly pain</li> <li>• Internal bleeding which may cause black tarry stools</li> <li>• Infection, especially when white blood cell count is low</li> <li>• Anemia which may require blood transfusions</li> <li>• Bruising, bleeding</li> <li>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat</li> <li>• Confusion</li> <li>• Abnormal eye movement, blurred vision, watering eyes</li> <li>• Discomfort from light</li> <li>• Difficulty with balancing</li> <li>• Skin changes</li> <li>• Tiredness</li> </ul>

<p>RARE, AND SERIOUS</p> <p>In 100 people receiving 5-Fluorouracil, 3 or fewer may have:</p>
<ul style="list-style-type: none"> <li>• Damage to the heart which may cause shortness of breath</li> <li>• A new cancer resulting from treatment of a prior cancer</li> </ul>

## Side Effects ASSOCIATED WITH LEUCOVORIN

<p>COMMON, SOME MAY BE SERIOUS</p> <p>In 100 people receiving LeuCoverin, more than 20 and up to 100 may have:</p>
<ul style="list-style-type: none"> <li>• Diarrhea, nausea, vomiting</li> <li>• Sores in mouth which may cause difficulty swallowing</li> <li>• Tiredness</li> </ul>

<p>OCCASIONAL, SOME MAY BE SERIOUS</p> <p>In 100 people receiving LeuCoverin, from 4 to 20 may have:</p>
<ul style="list-style-type: none"> <li>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat</li> </ul>

<p>RARE, AND SERIOUS</p> <p>In 100 people receiving LeuCoverin, 3 or fewer may have:</p>
<ul style="list-style-type: none"> <li>• None</li> </ul>

## Side Effects ASSOCIATED WITH NIVOLUMAB

Nivolumab may cause one or more of the side effects listed below. This information is based on data from cancer subjects in other clinical trials with nivolumab. In addition, there may be side effects that are not yet known that may occur. You should tell your doctor or nurse right away about any possible side effects that you experience.

VERY COMMON Occurring in at least one out of every 10 patients:	
<ul style="list-style-type: none"> <li>• Fatigue</li> <li>• Skin rash</li> <li>• Skin itching</li> <li>• Diarrhea</li> </ul>	

COMMON Occurring in at least one out of every 100 patients and up to one out of every 10 patients:	
<ul style="list-style-type: none"> <li>• Abdominal pain</li> <li>• Alkaline phosphatase increased: lab test result associated with liver or bone abnormalities</li> <li>• ALT increased: lab test result associated with abnormal liver function</li> <li>• Allergic reaction</li> <li>• Amylase increased: lab test result associated with pancreas inflammation</li> <li>• AST increased: lab test result associated with abnormal liver function</li> <li>• Bilirubin increased: lab test result associated with abnormal liver</li> <li>• Chills</li> <li>• Constipation</li> <li>• Cough</li> <li>• Creatinine increased: lab test result associated with decreased kidney function</li> <li>• Decreased appetite</li> <li>• Dizziness</li> <li>•</li> <li>• Dry mouth</li> <li>• Dry skin</li> <li>• Fever</li> <li>• Headache</li> <li>• Lipase increased: lab test result associated with pancreas inflammation</li> <li>• Inflammation of the colon</li> <li>• Inflammation of the mouth</li> <li>• Infusion related reaction</li> <li>•</li> <li>• Joint pain or stiffness</li> <li>• Loss of color (pigment) from areas of skin</li> <li>• Low levels of sodium in blood</li> <li>• Low platelet counts (thrombocytopenia): this may increase your risk for skin bruising, nose bleeds, and bleeding from the gums</li> </ul>	

COMMON
Occurring in at least one out of every 100 patients and up to one out of every 10 patients:
<ul style="list-style-type: none"> <li>• Low red blood cell counts (anemia): this may make you feel weak and tired</li> <li>• Shortness of breath: Lung inflammation (pneumonitis - see details below)</li> <li>• Nausea</li> <li>• Pain in the muscles, bones, ligaments, tendons, and nerves</li> <li>• Redness of skin</li> <li>• Swelling, including face, arms, and legs (edema)</li> <li>• Thyroid gland function increased or decreased</li> <li>• Thyroid stimulating hormone increased: lab test result associated with abnormal thyroid function</li> <li>• Tingling, burning, numbness or weakness, possibly in arms, legs, hands and feet</li> <li>• Vomiting</li> </ul>

UNCOMMON
Occurring in at least one out of every 1000 patients and up to one out of every 100 patients:
<ul style="list-style-type: none"> <li>• Bronchitis: inflammation of the lining of the bronchial tubes, which carry air to and from the lungs</li> <li>• Decreased secretion of hormones produced by adrenal glands</li> <li>• Decreased thyroid stimulating hormone: a lab test associated with abnormal thyroid function</li> <li>• Decreased secretion of hormones produced by pituitary gland</li> <li>• Diabetes: a disease that results in too much sugar in the blood</li> <li>• Dehydration</li> <li>• Dry eye and blurry vision: inflammation of the eye</li> <li>• Erythema multiforme: a skin disorder that is considered to be an allergic reaction to medicine or an infection. Symptoms may include symmetrical, red raised skins areas that can appear all over the body, more noticeable on the fingers and toes. These patches often look like “targets” (dark circles with purple-grey centers)</li> <li>• Hair loss</li> <li>• Heart rate increased</li> <li>• Heart rhythm abnormal</li> <li>• Blood pressure: high or low</li> <li>• Hives</li> <li>• Inflammation of the stomach</li> <li>• Kidney function failure or kidney disease: inflammation of the kidney</li> <li>• Low white blood cell counts (neutropenia): these put you at higher risk for infection</li> <li>• Psoriasis: characterized by patches of abnormal, scaly skin</li> <li>• Respiratory failure: a condition in which not enough oxygen passes from your lungs into your blood, or when your lungs cannot properly remove carbon dioxide</li> <li>• Trouble falling and/or staying asleep (insomnia)</li> <li>• Upper respiratory tract infection</li> </ul>

<p style="text-align: center;">RARE</p> <p style="text-align: center;">Occurring in at least one out of every 10,000 patients and up to one out of every 1,000 patients:</p>
<ul style="list-style-type: none"> <li>• A malfunction of the immune system that produces autoantibodies, which attack red blood cells as if they were foreign substances to the body (autoimmune hemolytic anemia)</li> <li>• Severe allergic reaction: may include, but not limited to, high grade fever, rash, swelling and pain (Anaphylactic reaction)</li> <li>• Damage to the protective covering of the nerves in the brain and spinal cord</li> <li>• Diabetes complications resulting in excess blood acids and diabetic coma</li> <li>• Double vision</li> <li>• An autoimmune disorder associated with progressive muscle weakness or paralysis (Guillain-Barre syndrome)</li> <li>• Inflammation of blood vessels</li> <li>• Inflammation of the brain, potentially life-threatening or fatal</li> <li>• Lung infiltrates, associated with infection or inflammation</li> <li>• Muscle inflammation</li> <li>• Neurologic syndrome characterized by muscle weakness (Myasthenic syndrome) including, a nerve disease that may cause weakness of eye, face, breathing, and swallowing muscles (myasthenia gravis).</li> <li>• Swelling and irritation of the thin saclike membrane surrounding the heart (pericarditis)</li> <li>• An inflammatory disorder causing muscle pain and stiffness (Polymyalgia rheumatica)</li> <li>• Muscle fiber released into the blood stream which could damage your kidneys (Rhabdomyolysis)</li> <li>• Acne-like skin condition resulting in redness of face (Rosacea)</li> <li>• A disease involving abnormal collections of inflammatory cells (granulomas) in organs such as lungs, skin, and lymph nodes (Sarcoidosis)</li> <li>• Rupture of the intestine / hole in the intestine</li> <li>• Inflammatory disorder of skin and mucous membranes, resulting in blistering and shedding of skin (Stevens Johnson syndrome)</li> <li>• A potentially fatal disease characterized by blistering and peeling of the top layer of skin resembling a severe burn (Toxic epidermal necrolysis)</li> <li>• Disorder of the lymph nodes which causes the lymph nodes to become enlarged, inflamed and painful, commonly affecting lymph nodes of the neck and possibly associated with fever or muscle and joint pains (Histiocytic necrotizing lymphadenitis or Kikuchi lymphadenitis)</li> </ul>

The following events have been identified during post-approval use of nivolumab. Because reports are voluntary from a population of unknown size, an estimate of frequency cannot be made.

- Graft-versus-host-disease: a condition that occurs when donor bone marrow or stem cells attack the recipient
- Hemophagocytic lymphohistiocytosis (HLH) syndrome: a disease that may affect your body's defense system, called immune system. Certain white blood cells may attack other blood cells. These abnormal blood cells collect in your spleen and liver, causing these organs to enlarge. The symptoms may include fever, rash, and low blood cell counts
- Solid organ transplant rejection

Vogt Koyanagi Harada syndrome: a disease that affects the pigmented tissue; this may affect the eye leading to swelling, pain and/or blurred vision; the ear leading to hearing loss, ringing in the ears and /or the skin leading to

loss of skin color**Lung inflammation (pneumonitis):** It is possible that nivolumab may cause inflammation of the tissues of the lung. This adverse effect has been reported in patients treated with nivolumab. While many patients with x-ray or CT abnormalities have not developed any symptoms, some patients have developed mild to severe symptoms and in rare cases, death has occurred as a result of their lung inflammation. Signs and symptoms of lung inflammation may include difficulty breathing, pain or discomfort while breathing, chest pain, cough, shortness of breath, increased rate of breathing, fever, low blood oxygen levels, or fatigue.

Your study doctor and nurse will watch you closely for changes in your ability to breathe and for other signs or symptoms that might show you are developing this type of lung inflammation and will perform regular tests including physical exams, measurement of oxygen levels through non-invasive testing (i.e., pulse oximeter), blood tests, chest x-rays and/or CT scans. Complications, including fatal events, have occurred in patients who received allogeneic hematopoietic stem cell transplantation (HSCT) after nivolumab.

**Please inform your study doctor or nurse AT ONCE if you experience any of the following:**

- Any new or increased shortness of breath;
- Any new or increased chest pain;
- Any new or increased pain/difficulty while breathing;
- Any new or increased cough or any significant change in your type of cough; for example, any new or increased mucous or blood in your cough;
- Any change in the amount of oxygen you require;
- Any fever, fatigue, or other symptoms that occur at the same time as any changes to your breathing or other lung symptoms.

If you start to develop symptoms, your study doctor will ask you to return to the clinic for additional tests, which could include a physical exam, measurement of oxygen levels, blood tests, chest x-rays, and/or CT scans. You will be monitored very closely for changes in your overall lung symptoms, monitoring may require hospitalization. You may require specific treatment in order to control pneumonitis. You may also be seen by a special doctor called a pulmonologist, who has special training to be an expert in how your lungs work.

Prolonged treatment with medicines that suppress inflammation, sometimes needed to manage the side effects of nivolumab treatment, may lower your body's ability to fight off certain infections (i.e., opportunistic infections). These infections may require treatment with antibiotic or antifungal medications and may be fatal.

### **Risks of CT Scan**

The contrast substance injected during the CT scan may cause pain, burning feeling, sweating and rarely a serious allergic reaction that can be serious. If you know you're allergic to iodine you must inform your doctor immediately. The contrast agent used in the CT scan may cause kidney damage, especially if you're diabetic, dehydrated and if you're older. In addition, your thyroid function may be affected. Please inform your doctor if this is the case.

CT imaging uses ionizing radiation, which increases your risk to develop cancer. Everyone is exposed to naturally occurring ionizing radiation every day. The amount of radiation exposure from 1 CT scan is approximately comparable to 1-3 years of natural background radiation. The estimated additional lifetime risk of developing a fatal cancer from a standard CT scan is approximately 1 in 2,000.

### Risks of MRI Scan

Contrast is used to improve the pictures of the inside of the body made by the MRI. Common risks of MRI include: feeling fearful of being in a small enclosed space (claustrophobia) when you are lying inside the MRI scanner, feeling uncomfortable because of the loud noises made by the machines, and feeling uncomfortable with the physical sensations you may feel during the process. You are also exposed to some risk because of the injected contrast, gadolinium-DTPA, which may cause headache, nausea, and local burning sensation.

The contrast agent, gadolinium has been linked to development of Nephrogenic Fibrosing Dermopathy (NFD) (also known as Nephrogenic Systemic Fibrosis (NSF) This causes a thickening of the skin, organs and other tissues, and is a rare complication in patients with kidney disease that undergo an MRI with contrast material. To help prevent this, we will check how well your kidneys work before you have any MRIs. Because of the use of contrast, all female subjects who are able to have children will be required to use adequate birth control. If you have implanted metal objects such as a pacemaker, artificial limbs, or metal joints, you will not be able to have an MRI done, and may not be able to take part in this research.

### Other Risks

During treatment you should:

- Observe caution when driving or operating heavy machinery.
- Avoid using grapefruit juice, as it may give you increased exposure to study medication. Discontinue using it at least one (1) week prior to starting your study treatment.

### Blood tests

Blood samples will be taken from a vein in your arm during the study. The taking of a blood sample may cause some discomfort and bruising, and there is a potential for infection. Other risks, although rare, include dizziness and fainting.

### Tumor Biopsy

A piece of a tumor will be removed for testing. Potential risks and discomforts that you may experience as a result of the procedure depend upon the location of the tumor. The more common risks/discomforts include pain, bleeding, infection, damage to tissues, and healing complications. Your doctor will further explain any specific risks that may apply based on the procedure, and you will sign a separate consent for the procedure which will provide risk information in more detail. In order to make the procedure more comfortable, you will get a local anesthetic to numb the area. A mild sedative may also be given to you.

- Genetic material, including DNA and RNA, will be obtained from samples, stored in freezers, and used for profiling and analyzing your cancer. Specifically, the study includes DNA sequencing of your tumor and normal cells as a comparison. The goal is to identify key changes in the genes important to cancer cells that could potentially influence clinical decision making for your cancer. However, success or clinical benefits from the profiling of your cancer DNA is not guaranteed.
- Some cells from your tumor may be grown and used to create cell lines that can be used as an ongoing source of genetic material or used for laboratory research. Additional analysis of the sequencing data will be used for research purposes, for example to discover new, unknown associations between genes and cancer. This type of research may affect the lives of future patients with cancer.
- It is possible that a mutation found in the tumor DNA is also a mutation in your normal tissue (inheritable, or passed down in families). Your study doctor will discuss this result with you. If your test results show



that you have gene mutations that are inherited, your doctor should recommend that you meet with a genetic counselor. This referral is considered standard care and is not part of this study.

- As with all medical screening tests, there is a chance of a false positive or a false negative result. A “false positive” refers to the identification of a genetic change that is not present. A “false negative” is the failure to find a genetic change that indeed exists. The tests have been designed to ensure that the possibility of incorrect results is low.

### Research samples/Loss of Confidentiality

Your samples will be coded, however, there is a risk of loss of confidentiality of your information. If your samples are provided to research collaborators the following information may be made available: your diagnosis and treatments, the time the samples were collected in relation to your study regimen, your disease status, and demographic data (for example gender, race, age, etc.). See section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

### Pregnancy

If you are a woman of child bearing potential, you must not have sexual intercourse or you must use reliable birth control throughout the study and for 5 months after the last dose of study drugs.

If you are pregnant or become pregnant or are nursing a child during the study, there may be risks to your unborn baby or nursing child. Some drugs cause premature (early) birth or birth defects. Nobody knows what all of these risks are right now.

If you become pregnant or think you may be pregnant during the study, immediately stop using the study drugs and contact the study doctor's office **immediately**. You must not breast-feed an infant during the study. Please also inform the study doctor if you become pregnant up to 5 months after the completion of the study drugs. If there is ANY chance that you can get pregnant, you must either agree to not have vaginal intercourse or you must use TWO types of birth control (one from each list below) AT THE SAME TIME.

You must use two types of birth control at the same time for medical reasons all during study intervention (including during temporary breaks from study intervention), and for at least 5 months after study intervention has stopped. You must talk to the doctor before changing any birth control methods you have already agreed to use.

#### Primary forms

- tubal sterilization (tubes tied)
- partner's vasectomy
- intrauterine device

#### Secondary forms

- male latex condom with or without spermicide
- diaphragm with spermicide
- cervical cap with spermicide
- vaginal sponge (contains spermicide)

Any birth control method can fail. The reports of birth control failing are more frequent for female patients who use only a single form of birth control. Using two forms of birth control at the same time greatly reduces the chances of pregnancy.



## **MEN**

All men must use an acceptable form of birth control while taking part in the study and for 7 months after study intervention has stopped because the effects on sperm are not known. Acceptable forms of birth control are male latex condom (with or without spermicide) or vasectomy. Also, men should not donate sperm or semen while taking part in the study because the effects on sperm are not known.

The study doctor must follow up and document the course and the outcome of all pregnancies, even if you withdraw from the study or if the study has finished. If you become pregnant during the study, the study doctor or his/her staff will ask to contact you and your pregnancy physician for information about the pregnancy until the child is born and may share this information with the sponsor.

If you are male, you should advise your study doctor if you father a child while participating in this study. The doctor will advise you on medical attention for your partner should this be necessary. We will ask for your partner's permission to collect information about the pregnancy and health of the baby.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

As with any research study, there may be additional risks that are unknown or unexpected.

## 5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

## 5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

## 5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any direct benefits from being in this study. However, others may benefit from the knowledge gained from this study.

## 5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

## 6. OTHER OPTIONS

### 6.1 If I decide not to take part in this study, what other options do I have?

You do not have to be in this study to get treatment for your cancer. Other possible options include:

- Continue with your platinum-based chemotherapy
- Change treatment to other standard of care regimens such as oxaliplatin with 5FU (or FOLFOX), if appropriate.
- If you have an unresectable or metastatic MSI-H (microsatellite instability-high) or dMMR (mismatch repair deficient) solid tumor that has progressed after prior treatment you could change treatment to pembrolizumab if you have no satisfactory alternative treatment.
- You could participate in other research trials
- You could be a candidate for liver directed therapy or palliative radiation
- You may also choose not to receive any further treatment.

You should talk to your study doctor and your regular physician about each of your options and their risks and benefits before you decide if you want to take part in this study.

## 7. ENDING THE STUDY

### 7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

## 7.2 Could there be any harm to me if I decide to leave the study before it is finished?

If you decide to leave the study early, please notify someone on the study team. They will instruct you on how to stop the study safely and you will be advised whether any additional test may need to be done for your safety.

## 7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

## 8. FINANCIAL INFORMATION

### 8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

Nanoliposomal-irinotecan will be provided by Ipsen free of charge.

Nivolumab will be provided by BMS free of charge until trial completion. After the completion of the trial, BMS will not continue to supply nivolumab to study subjects.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- 5-fluorouracil, leuCorvin
- Items or services needed to give you study drugs or devices (such as the cost of the infusion)
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

Some health plans will not cover the cost of standard treatments when they are combined with investigational treatments. It is important that you work with the studyteam to confirm your health plan will cover the costs of the 5-fluorouracil and leuCorvin if you take part in the study.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study or study procedures have made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you will have to arrange for treatment on your own, as the study will not provide medical treatment or provide any compensation to you. You or your insurance provider will be billed for all costs of treatment for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

## 8.2 Will I be paid or given anything for taking part in this study?

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

## 8.3 Who could profit or financially benefit from the study results?

The companies whose products are being studied: Bristol-Myers Squibb, Ipsen

In the interest of transparency, we would like you to know that Dr. Sahai at the University of Michigan, who is in charge of this multi-site study, serves as a paid consultant for Ipsen Pharmaceuticals. He is not likely to benefit financially from the results of the study.

The University of Michigan is receiving payments from Bristol-Myers Squibb and Ipsen to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from Bristol-Myers Squibb or Ipsen for conducting this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

### 9.1 How will the researchers protect my privacy?

The University of Michigan has rules to protect information about you. Federal and state laws also protect your privacy. Upon enrolling in this study, you will be assigned a unique identification number. All records related to the study will use this identification number instead of your name or other personally identifying information whenever possible. We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file.

You have the right to request access to your protected health information that is used or shared during this research and that is related to your study treatment for your disease, but you may access this information only after the study is completed. To request this information, please contact the researchers listed in Section 10 "Contact Information" (below).

### **Genetic Risks:**

The federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:

- Health insurance companies and group health plans may not request your genetic information that we obtain from this research

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

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

- Members of the US Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)
- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

We will collect and store information about your genes. The DNA contained in your genes holds the instructions that your body uses to grow and function. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions.

Genomic information relates to the structure and function of all of the genetic material in the body.

We will submit your genomic information to a repository to be used for scientific purposes. A repository contains information from many people. Some repositories are maintained by the University of Michigan, some are maintained by the federal government, and some are maintained by private companies.

Researchers all over the world can take information from the repository and use it in their studies. Their studies may be similar to this one or may be completely different.

Some data collected from you may be deposited into the database of Genotypes and Phenotypes (dbGaP) but all identifiable information will be removed prior to submission so that the data cannot be linked to you in any way. The database of dbGaP is a database developed by the National Center for Biotechnology Information (a division of the National Library of Medicine) to archive and distribute the results of studies that have investigated the interaction of genotype and phenotype. All data submitted from this study will only be available through controlled access and restricted to cancer research studies. Any researcher requesting access to the data must formally apply to dbGaP and present a research study rationale for why they need access to the data. The data may also be submitted to other future database systems which will have similar access controls as dbGaP utilizes. Genomic summary results should be kept restrictive.

We will label your genomic information with a code, instead of your name or other information that people could use to directly identify you. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally.

If you allow us to put your genomic information in the repository, you can change your mind later and ask us to remove it. Keep in mind, however, that we cannot take back information that other researchers have already obtained from the repository.

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.

## 9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- HIV/AIDS status
- Sexually transmitted disease or other communicable disease status
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University of Michigan, Food and Drug Administration (FDA), and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- BMS, Ipsen, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Learn more about side effects
  - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular University of Michigan medical record.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

### 9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help the University of Michigan and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at

<http://www.uofmhealth.org/patient+and+visitor+guide/hipaa>

### 9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

## 10. CONTACT INFORMATION

### 10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Vaibhav Sahai, MBBS, MS

Mailing Address: Department of Internal Medicine, Division of Hematology/Oncology  
1500 E. Medical Center Drive  
C412 MIB, SPC 5848  
Ann Arbor, MI 48109-5848

Telephone: 734-936-4991 (Office)

734-936-4000 (Hospital Operator - 24-hour paging)

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)

2800 Plymouth Road

Building 520, Room 3214

Ann Arbor, MI 48109-2800

IRBMED Informed Consent Template—3-9-2018

Instructions revised 3-9-2018

DO NOT CHANGE THIS FIELD—IRB USE ONLY

Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)

Fax: 734-763-1234

e-mail: [irbmed@umich.edu](mailto:irbmed@umich.edu)

## 11. RECORD OF INFORMATION PROVIDED

### 11.1 What documents will be given to me?

Your signature in the next section means that you have received signed and dated copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)"
- Other (specify): \_\_\_\_\_

## 12. SIGNATURES

### Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with \_\_\_\_\_. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_



**Consent/Assent for Participating in Optional Research Biopsy**

This project involves optional biopsies for research purposes. I understand that it is my choice whether or not to take part in this optional research biopsy. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

**Post-treatment research biopsy**

\_\_\_\_\_ Yes, I agree to take part in the optional post-treatment research biopsy.

\_\_\_\_\_ No, I do not agree to take part in the optional post-treatment research biopsy.

Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_

For Blood for unspecified future research

**Consent/Assent to Collect and Store OPTIONAL Research Samples for Unspecified Future Research**

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to take part in this optional research. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

\_\_\_\_\_ Yes, I agree to let the study team keep and store my blood and tissue samples for future research.

\_\_\_\_\_ No, I do not agree to let the study team keep and store my blood and tissue samples for future research.

Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_

**Principal Investigator or Designee**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_

UMCC 2018.101

## PERSONAL CENSUS FORM

Name \_\_\_\_\_

Date \_\_\_\_\_

The National Cancer Institute requires that The University of Michigan Comprehensive Cancer Center report race and ethnicity information about people who participate in clinical research to ensure that all populations are offered the opportunity to participate.

☐ Check here if you do not wish to provide some or all of the information below.

1. What race do you consider yourself to be? ☐ American Indian/Alaska Native<sup>a</sup>  
(Please select *one or more*) ☐ Asian<sup>b</sup>  
☐ Black or African American<sup>c</sup>  
☐ Native Hawaiian or Other  
Pacific Islander<sup>d</sup>  
☐ White<sup>e</sup>  
☐ More than one race<sup>f</sup>

2. Do you consider yourself to be Hispanic<sup>g</sup>? ☐ Yes ☐ No

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<sup>a</sup> American Indian or Alaska Native- A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

<sup>b</sup> Asian- A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.

<sup>c</sup> Black or African American- A person having origins in any of the black racial groups of Africa. (Terms such as "Haitian" or "Negro" are sometimes used in addition to "Black" or "African American.")

<sup>d</sup> Native Hawaiian or Other Pacific Islander- A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

<sup>e</sup> White- A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

<sup>f</sup> More than one race- (It is preferred that this be selected in addition to the selection of the specific races listed above, but this may also be solely selected.)

<sup>g</sup> Hispanic or Latino- A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" is sometimes used in addition to "Hispanic" or "Latino."