



## Informed Consent

### INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Randomized Controlled Phase II Trial of Liver Resection Versus No Surgery  
in Patients with Liver and Unresectable Pulmonary Metastases from  
Colorectal Cancer  
2015-1133

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Study Chair: Yun Shin Chun

Participant's Name \_\_\_\_\_ Medical Record Number \_\_\_\_\_

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

#### STUDY SUMMARY

The goal of this clinical research study is to compare the effect of having liver resection with standard of care chemotherapy to having standard of care chemotherapy alone in patients whose colorectal cancer has spread to their liver and lungs.

**This is an investigational study.** Liver resection surgery for patients with colorectal cancer that is able to be resected can be done with standard techniques using FDA-approved devices. Liver resection surgery for patients with colorectal cancer that can only be partially resected is considered investigational.

Having liver resection surgery combined with chemotherapy may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You will be on study for up to 3 years.

You and/or your insurance provider will be responsible for the cost of the liver resection surgery, the cost of the chemotherapy, and all routine tests.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard treatment, such as radiation therapy or chemotherapy alone outside of this study. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

## 1. STUDY DETAILS

### **Screening Tests**

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible:

- You will have a physical exam.
- You will have a computed tomography (CT) scan, positron emission tomography (PET)/CT scan, or a magnetic resonance imaging (MRI) to check the status of the disease.
- Blood (about 4 teaspoons) will be drawn for routine tests. This routine blood draw will include a pregnancy test if you can become pregnant. To take part in this study, you must not be pregnant.
- Blood (about 2 teaspoons) will be drawn for biomarker testing. Biomarkers are found in the blood and may be related to your response to the study drug.
- You will complete a quality of life survey. It should take about 5 minutes to complete.

If you have had some of these tests recently, they may not need to be repeated.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

### **Study Groups**

If you are found to be eligible to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one study group is better, the same, or worse than the other group. You will have an equal chance to be assigned to either group.

- If you are assigned to Group 1, you will have liver resection surgery, followed by standard-of-care chemotherapy. The chemotherapy you receive will depend on what the doctor thinks is in your best interest.

- If you are assigned to Group 2, you will receive standard-of-care chemotherapy that your doctor thinks is in your best interest.

You will sign a separate consent form explaining how the standard-of-care chemotherapy works, the chemotherapy schedule, and its risks.

### **Group 1**

If you are in Group 1, you will have standard of care liver resection surgery. A portion of the liver that is affected by the tumor will be removed either with many small incisions or one large incision. An ultrasound device will be used to help the doctor see the affected area. The study doctor will explain this procedure in more detail, and you will sign a separate consent form explaining the standard-of-care surgery and its risks.

Up to 40 participants will take part in this study. All will be enrolled at MD Anderson.

### **Study Visits**

Both groups will have study visits every 3-6 months while on study. The following tests and procedures will be performed:

- You will have a physical exam.
- You will have a chest x-ray or CT scan to check status of disease.
- You will have an abdominal and pelvic CT scan, PET/CT scan, or an MRI scan to check the status of the disease.
- Blood (about 2 teaspoons) will be drawn for biomarker testing.
- You will complete the quality of life survey you completed during screening.

If you are unable to return to MD Anderson every 3-6 months, you or your regular care doctor will be contacted for follow-up information, and the tests listed above can be performed outside of MD Anderson. The study doctor will discuss this with you.

You will be taken off study if the disease gets worse or intolerable side effects occur.

## **2. POSSIBLE RISKS**

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after the surgery, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study procedures.

The **chemotherapy** you receive will depend on what the study doctor thinks is in your best interest. You will be given a separate consent form that describes in detail

the risks of the chemotherapy chosen for you, and it will be discussed with you.

**Liver resection surgery** may cause infection, bleeding, pain at the incision site, poor wound healing, and/or blood clots in veins, lungs, and/or other organs. You will be given a separate consent form that describes these risks in more detail, and it will be discussed with you.

**Blood draws** may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

**Questionnaires** may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

**X-rays** send a small amount of radiation through the body. All radiation adds up over a lifetime and may increase the risk of a new cancer forming.

**CT scans** send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

**A PET scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort, or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning

will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

This study may involve unpredictable risks to the participants.

## OPTIONAL PROCEDURES FOR THE STUDY

You do not have to agree to the optional procedure in order to take part in this study. There are no benefits to you for taking part in the optional procedure. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedure.

**Optional Procedure #1:** If you agree, during your liver resection surgery, a biopsy will be taken of the liver tissue that is removed. That tissue will be stored in a research bank at MD Anderson for use in future research related to cancer.

Before your samples can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

Your samples will be given a code number. No identifying information will be directly linked to your samples. Only the researcher in charge of the bank will have access to the code numbers and be able to link the samples to you. This is to allow medical data related to the samples to be updated as needed.

### Optional Procedure Risks:

MD Anderson and others can learn about cancer and other diseases from your banked samples. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot guarantee complete privacy. Sometimes your samples may be used for genetic research about diseases that are passed on in families.

**Genetic research** may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you compensation from such developments. The results of any genetic tests may be put in your health records. If this information were released, it could be misused. Such misuse could be

distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

If you withdraw your consent to the storage of leftover samples in the tissue bank, then they will no longer be collected for storage. Any of your samples that remain in the tissue bank will no longer be used for research and will be destroyed.

However, if any of your de-identified samples were already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy them.

**CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES**

**Circle your choice of “yes” or “no” for each of the following optional procedures:**

**Optional Procedure #1:** Do you agree to have the tissue removed during the liver resection procedure biopsied and stored in a research bank at MD Anderson for use in future research related to cancer?

**YES** **NO**

### 3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

### **Additional Information**

4. You may ask the study chair (Dr. Yun Shin Chun, at 713-563-9682) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.
5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can then decide if you need to have any visits or tests to check on your health. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. You may be removed from this study if you are unable to follow study directions or the study is closed.
7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.
8. MD Anderson may benefit from your participation and/or what is learned in this study.

### **Future Research**

#### **Data**

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

## **Samples**

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

## **Genetic Research**

Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurers or health plan administrators from requesting or requiring genetic information of you or your family members or using such information for decisions regarding your eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments. Please contact the study doctor if you would like more information about GINA and how it protects you from genetic discrimination.

## **Outside Care**

Part of your care may be provided outside of MD Anderson by your home doctor(s).

**Authorization for Use and Disclosure of Protected Health Information (PHI):**

- A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
  - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
  - The IRB and officials of MD Anderson
  - Study monitors and auditors who verify the accuracy of the information
  - Individuals who put all the study information together in report form
- B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.
- C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

- D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.
- E. 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.

### **CONSENT/AUTHORIZATION**

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

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SIGNATURE OF PARTICIPANT

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DATE

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PRINTED NAME OF PARTICIPANT

#### **WITNESS TO CONSENT**

I was present during the explanation of the research to be performed under **Protocol 2015-1133**.

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SIGNATURE OF WITNESS TO THE VERBAL CONSENT

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DATE

PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR)

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

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PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

#### **PERSON OBTAINING CONSENT**

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

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PERSON OBTAINING CONSENT

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DATE

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PRINTED NAME OF PERSON OBTAINING CONSENT

**TRANSLATOR**

I have translated the above informed consent as written (without additions or subtractions) into \_\_\_\_\_ and assisted the people  
(Name of Language)  
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

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NAME OF TRANSLATOR

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SIGNATURE OF TRANSLATOR

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DATE

Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

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SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION  
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,  
OR STUDY CHAIR)

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DATE

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PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION