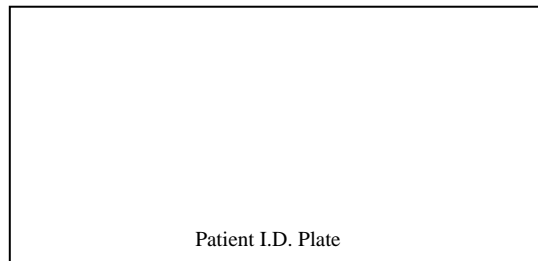




Approval Expires 11/19/2008

Date: November 20, 2007
Principal Investigator: Dung Le, M.D.
Application No.: NA_00012030

Site of Research:
**The Sidney Kimmel Comprehensive Cancer
Center At Johns Hopkins Hospital**



Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **A Phase I, Open-Label, Dose-escalation, Multiple Dose Study of
the Safety, Tolerability, and Immune Response of CRS-207 in
Adult Subjects with Selected Advanced Solid Tumors Who Have
Failed or Who are not Candidates for Standard Treatment (Cerus
Protocol VAC07001)**

Application No.: **NA_00012030**

Sponsor: **Cerus Corporation**

Principal Investigator: **Dung Le, M.D.**

Date: **November 20, 2007**

1. What you should know about this study:

- You are being asked to join a research study.
- This is the first study to test this experimental product in humans (called a Phase 1 study).
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- We may learn things during the study that might make you want to stop being in the study. If this happens, we will tell you about it. You can then decide if you want to stay in the study.

2. Why is this research being done?

This research is being done to see if an experimental product called CRS-207 can safely be given to people with advanced cancer of the ovary or pancreas, non-small cell lung cancer, or advanced malignant mesothelioma who have failed treatment using available therapies. An experimental product is one that has not yet been approved by the United States Food and Drug Administration (FDA). The FDA has however given permission for CRS-207 to be used in this study.

CRS-207 is a weakened form of the Listeria bacteria commonly found in the environment (called wild-type). Wild-type Listeria can contaminate food, and although infections with Listeria from eating contaminated foods can be very serious, they are not common. Antibiotics are available to treat infections with Listeria. The Listeria that is used in this research study has been altered in the lab in an attempt to reduce its ability to cause infection, while keeping its ability to stimulate the immune system (your body's system to fight infection or disease).

CRS-207 has also been genetically modified (changed in the lab) to release an antigen (a substance that, when introduced into the body, may stimulate the immune system) called Mesothelin. Mesothelin may be present at higher levels on tumor cells than on normal cells. CRS-207 stimulates an immune response to Mesothelin. Therefore, we would like to see if CRS-207 will boost the immune system in a way that targets the cancer.

We want to study carefully the amounts of CRS-207 that can be safely given to people and how it interacts with their immune system and cancer. The purpose of this study is to find the highest tolerable dose of CRS-207 in humans and to study how safe it is when given to humans.

CRS-207 has been given to mice and monkeys in controlled lab experiments that led to this study to test CRS-207 in humans. In addition, a similar weakened form of Listeria bacteria that does not release Mesothelin (called CRS-100) has been given to a small number of patients in a similar clinical trial. CRS-207 has not been tested in humans before and we do not know what dose is best for humans or if it will produce the same effects that it has in animal studies.

People with advanced cancer of the ovary or pancreas, non-small cell lung cancer, or advanced malignant mesothelioma who have failed treatment using available therapies or for whom there is no appropriate standard therapy can take part in this study. This research study may be conducted at up to 6 sites. The number of people who get CRS-207 in this study depends on how high a dose level we can safely give to patients without severe side effects. At least 3 people will receive each of the several different dose levels that are planned for the study. We expect that up to about 40 people may participate in the study. About 10 people will take part at Johns Hopkins.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Screen Visit # 1

Approximately 2 weeks before taking CRS-207 you will come in for the first screening visit. During this visit we will do tests to see if you can qualify for the study. Not everyone who wants to be in the study will be able to join. The screening tests include:

- A complete medical history and physical exam including vital signs (blood pressure, heart rate, breathing rate), temperature, height, weight, and pulse oxygen saturation (a measure of the amount of oxygen in your blood by using a device placed on your finger).
- A CT scan of your abdomen, chest, and pelvis if you have not had one recently. CT scan is a test that produces an image of your body using radiation. The image shows the body tissues and structures in three dimensions (3-D). The CT scan takes about 30-60 minutes. During the test you will lie on your back on a padded table. A strap will be placed across your body to prevent movement so that the x-ray will be clear. The table will slide into a large, donut-shaped machine. An X-ray tube will slowly move around your body, taking many pictures from all directions. You will receive an injection of a contrast material (dye) to improve the imaging of certain parts of your body.

The contrast agent is administered through an IV in your arm or hand. The IV will be placed using standard hospital techniques. In addition, the study doctor may decide that you need other tests to evaluate your cancer.

- Blood and urine tests for safety and research purposes.
- Tests for hepatitis and HIV virus (the virus that causes AIDS). For the HIV test, you will be given the State of Maryland HIV consent form as part of that process. If this test is positive, it does not always mean that you are infected with the HIV virus. It means you will need further testing and you will receive counseling. For both HIV and hepatitis tests, the law requires us to report positive tests to the health department. If you have HIV or hepatitis, you will not be able to take part in the study.
- Women who are able to have children will be tested for pregnancy. If you are pregnant, you will not be able to take part in the study.
- A stool (or rectal swab) sample to test for the presence of wild-type Listeria bacteria.
- An electrocardiogram (ECG) that measures the electrical activity of your heart.
- We will ask for access to a sample of your tumor tissue that has been taken from you previously for your cancer diagnosis or treatment so that it can be tested for Mesothelin at a later time.
- We will explain all the requirements for being in the study.

Screen Visit # 2

If it seems like you may qualify we will ask you to return for a second screening visit before we give you CRS-207. This visit will be approximately 1 week before taking CRS-207. At this visit we will:

- Make sure that you still want to participate in the study
- Update your medical history
- Do a brief physical exam including vital signs, temperature and weight
- Take blood samples for research purposes

Study Drug Administration (Days 0, 21, 42, and 63)

If you qualify for the study, one week later you will return to the Johns Hopkins Hospital (JHH) to be admitted for an overnight stay at the JHH to receive the CRS-207. CRS-207 is a liquid given through an intravenous (IV) infusion (a needle into your vein). You may receive up to 4 infusions with CRS-207, and these infusions will be given every 21 days. During the time that you are receiving infusions, we will be doing frequent tests to see how you are doing.

The first subjects who enter the study will receive the lowest dose of CRS-207. Each subject will receive up to 4 doses at the same dose level. If subjects do not have too many severe side effects at one dose level, we may increase the dose for the next subjects enrolled or have more people get the same dose. You will be closely monitored for any side effects or harmful events to better understand how safe each dose level is.

On each Study Drug Administration day **and before** you get the CRS- 207 we will:

- Update your medical history
- Do a brief physical exam including vital signs, temperature, weight and pulse oxygen saturation
- Take blood samples for safety and research purposes
- Take stool (or rectal swab) and urine samples

- Take a swab from the inside of your cheek for research testing (only done prior to first dose)
- Obtain a pregnancy test on women who are capable of having a child (this test must be confirmed negative before you receive each dose of CRS-207)
- Obtain an electrocardiogram (ECG)
- Start an intravenous (IV) line

You will then be given the CRS-207 as an IV infusion over 2 hours. CRS-207 must be administered through a peripheral IV and cannot be administered through a central catheter. Therefore, you may need to have a new IV line for CRS-207 injections.

We will be checking you frequently. It is very important to tell us how you are feeling. Do not wait for the next check-up if you are feeling different. Let us know right away.

After you get CRS-207, we will take your blood, stool (or rectal swab), and urine samples. In addition, your vital signs (pulse, heart rate, blood pressure, temperature and pulse oxygen saturation) will be monitored frequently during and after you receive CRS-207. In order to monitor your safety and reaction to the CRS-207 infusion, you will stay at the JHH overnight following each dose of CRS-207 given to you. However, if, 4 hours after the completion of the infusion, the study doctor determines that it is safe, you may be released without an overnight stay. If you are released early, you must return the following day for study tests. The study doctor's decision may be different from one dose to the next.

After you receive CRS-207, you will be under contact precautions until you are discharged to go home. This means that in addition to the standard precautions that we take for all patients, we will be using extra precautions. Your body fluids and secretions may be infectious. Contact precautions help to prevent the spread of any possible infection. What contact precautions means to you:

- If/when you are admitted to the study clinic, you will be in a private room or in a shared room with other study patients.
- Your room will be marked with a "Contact Precautions" sign. This will alert visitors and staff of the special precautions.
- An isolation cart will be outside your room to hold supplies.
- No one but you (or another study patient in a shared room) should use your bathroom.
- You should wash your hands frequently, especially after contact with any of your body fluids.
- Your visitors will need to wash their hands before entering and after exiting your room. They will need to wear gloves while in your room.
- People will wear gowns when they have contact with you or your secretions. They may also wear visors and masks.

After you are sent home from the JHH, you will need to take your temperature twice a day (once in the morning and once at night) and record any medications taken or side effects for at least 1 week (7 days) after receiving the CRS-207 dose. Before you leave the JHH after each infusion of CRS-207, we will give you a diary card and digital thermometer with instructions for their use. You must bring your diary card with you to each visit to review with the study doctor.

Since it is unknown if patients who have received CRS-207 can pass the bacteria on to other people, you will be advised about following good hygiene (e.g., hand washing) and other safety precautions (e.g., regular cleaning of toilet facilities with disinfectant) during the course of the study. You will be asked to limit your use of public restrooms as much as possible and add bleach to the toilet prior to flushing. Please talk to study personnel if you are in intimate, close contact with anyone who has defects in their

immune system (for example, newborn babies, people with HIV/AIDS or who are on chemotherapy), because this may affect your ability to participate in this study.

Visits on days between the Study Drug Administration Days (Visit Days 4, 7, 25, 28, 46, 49, 67, and 70)

After your discharge, you will return to the JHH on the 4th and 7th days after each infusion of CRS-207 that you receive. We will do the following on each of the visit days between the Study Drug Administration Days:

- Ask you if you have had any side effects or had any change in medications
- Review your diary card with you
- Do a physical exam including vital signs, temperature and weight
- Take blood samples for safety and research purposes
- Take stool (or rectal swab) and urine samples
- On Day 28 (7 days after the 2nd study injection) you will have your tumor assessed and a CT scan of your abdomen, chest, and pelvis and additional blood drawn for research purposes. The study doctor also may decide that you need other tests to evaluate your cancer.
- On Day 70 (or 7 days after your final dose of CRS-207), we will give you an antibiotic (amoxicillin) and draw additional blood for research purposes. You will begin taking the antibiotic on the day that we give them to you and will continue taking them for 10 days (taken by mouth, three times a day). You will be asked to bring the bottle of antibiotic with you to your next visit so that we may closely monitor your taking this medication. If you do not get all 4 doses of CRS-207, you will start the antibiotic 7 days after your last dose (or as soon as possible if it has been more than 7 days already).

Phone calls on days between the Study Drug Administration Days (Days 14, 35, 56, 77, and 84)

We will contact you by phone 14 days after each infusion of CRS-207 to check on you. In addition we will contact you 21 days after the 4th/final infusion. If the study doctor thinks it is necessary, you may be asked to come into the JHH for these check-ups.

Visit on Day 91 (last study visit; may be done before Day 91 if you stop the study early)

We will:

- Ask you if you have had any side effects or had any change in medications
- Review your diary for temperatures and antibiotic use
- Do a physical exam including vital signs, temperature and weight
- Take blood, stool (or rectal swab), and urine samples.
- Obtain an ECG.
- Obtain a CT scan of your abdomen, chest, and pelvis. In addition, the study doctor may decide that you need other tests to evaluate your cancer.

There are 24 visits planned during the study (approximately 16 weeks). The study doctor may ask you to come in for unplanned study visits if needed to follow-up on test results or side effects. There will be approximately 1-6 tablespoons of blood drawn at each visit that requires blood draws. If you complete all visits and tests, approximately 50 tablespoons (3 cups) of blood will be drawn over 16 weeks.

At the end of your participation in this study (if you have completed at least one infusion of CRS-207), you will be asked to participate in a study to learn about the possible long-term effects of CRS-207 on your body and your disease. You will be asked to return to the clinic 6 months after your last dose of CRS-207 and yearly after that, to draw blood and report any medications you are taking and any new medical problems. The study doctor will give you more information about this long-term study and ask you to sign a separate informed consent form if you want to participate. This long-term follow-up study is optional.

Because you are a study participant, researchers may ask your family for permission to do an autopsy (or obtain results of one) after your death, even though this may be years after the study. This may help researchers learn about the effects of CRS-207. By signing this consent form, you are not forcing your family to agree to this. You should talk about this request with your family and advise them of your wishes.

Future Contact:

We would also like your permission to contact you about other studies that you may be eligible for in the future.

Please initial your choice below on only one line:

_____ Yes, you may contact me in the future about other studies related to cancer.

_____ No, I do not want you to contact me about other studies.

4. What are the risks or discomforts of the study?**CRS-207**

This is the first time that CRS-207 is being given to humans so the side effects, risks and discomforts are unknown. It is possible that there may be serious and life-threatening reactions, including death, from CRS-207.

CRS-207 is a weakened form of the *Listeria* commonly found in the environment. *Listeria* infections can cause gastroenteritis (stomach problems, diarrhea, abdominal pain), meningitis (infection in your brain), septicemia (blood infections), late-term abortions, other infections, and death.

A similar drug (CRS-100), which is a weakened form of the *Listeria* bacteria that does not release Mesothelin, is being tested in another Phase 1 study in people with cancer. The 3 participants in the first dose group did not have major side effects, however those people only received one infusion of CRS-100 and at a dose lower than the doses given in this study.

When CRS-207 was tested in animals, the mice and monkeys had some side effects during the time it took them to clear the *Listeria* from their body. The most common side effects were temporary and included mild to moderate abnormalities in liver function, and decreases in blood counts like low red blood cells (anemia), low platelet count (thrombocytopenia), and low white blood cells (leukopenia). Studies in mice, but not monkeys, sometimes showed small blood clots in the kidney, although these did not appear to affect the function of the kidneys. In one study, a monkey had to be put to sleep (euthanized) when it became very sick. The monkey had received 2 high-dose infusions of CRS-207 (at

doses higher than those planned in this study) as well as a sedative to have blood drawn following the second dose. While the reason for death is unknown, CRS-207 cannot be ruled out as a possible cause.

It is possible that the Mesothelin will cause your immune system to have a reaction against your healthy cells/organs (lungs and heart, for example), although this was not seen in studies with animals.

Humans may have different side effects than the animals. As we learn more about CRS-100 and CRS-207 we will give you updates. If we find dangerous side effects in humans that may be related to the CRS-207 we will let you know as soon as possible.

We do not know how long it will take for the CRS-207 to be cleared from your system. This is one reason for the frequent testing at your visits. The antibiotics that you will take after your last dose of CRS-207 will help to remove any CRS-207 organism that your body's own immune system did not remove. Most animals tested in the lab were able to clear the CRS-207 from their bodies without the antibiotics. We will monitor you closely and if we think you may be developing an infection, you will start antibiotics earlier than planned.

It may be possible that you may develop an infection in your central nervous system (brain), urinary tract, liver, gall bladder, spleen, lymphatic system, joints or bones, eyes, heart, blood vessels, lung, or other areas of the body. These infections may cause you to have one or more of the following symptoms: headache, fever, chills, flushing, fatigue, and flu-like symptoms; gastrointestinal symptoms like nausea, vomiting, diarrhea, loss of appetite, stomach cramps; weight loss; sleeplessness; shortness of breath; trouble breathing; itchy skin; neck stiffness; trouble moving; seizures; muscle pain and weakness; joint pain; backache; skin rash; and changes in your mental status. Other signs and symptoms may be experienced. You may have abnormal liver and blood tests, and problems with your immune system and blood clotting.

It is possible that you may pass the CRS-207 to another person, and that person may become ill.

If we suspect infection with CRS-207, your doctor may consider more tests. This may include a lumbar puncture test, also known as a spinal tap. If more testing is needed we will discuss the risks associated with the test with you. You may be asked to sign another consent form for the testing.

You may have pain, redness, bruising, swelling, or itching around the IV site during or after you receive the CRS-207 infusion.

Blood Sampling

Taking blood may cause some discomfort, bleeding or bruising where the needle enters the body, and in rare cases, it may result in fainting. There is a small risk of infection. Some people have not felt well when having their blood taken. Some people have felt dizzy while having their blood drawn or later on. Let us know if you would prefer to lie down while you have your blood drawn. Some of the blood tests must be taken from your arm and cannot be taken from a central catheter.

Antibiotics

The antibiotics may have some side effects. Your doctor and nurse will give you more information about the antibiotics that are prescribed for you.

As part of this study, you will be given amoxicillin. Side effects of amoxicillin include diarrhea, nausea, rash and other allergic reactions.

CT Scan Risks

CT scans involve the risks of radiation. The radiation dose you will receive from participating in this study is equivalent to an exposure of approximately 3.6 rems to your whole body. Naturally occurring radiation (cosmic radiation, radon, etc.) produces whole body radiation exposures of about 0.3 rems per year. Occupationally exposed individuals are permitted to receive whole body exposures of 5 rems per year.

In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction. Reactions to the contrast agent are uncommon and occur in less than 1 in 1000 people. These may include mild reactions (itching, hives) to very rare serious reactions, including anaphylactic allergic reactions that can potentially lead to death. There is also a small risk of kidney damage from the contrast agent. Such damage is also rare and usually, but not always, reversible. You will not be able to undergo a CT with contrast agent if your kidney function is very impaired. Insertion of the IV (small plastic tube) may also cause minor pain, bruising, and/or infection at the insertion site..

Having a CT scan may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia when placed inside the CT scanner, or by lying in one position for a long time. If contrast material is used, you may feel discomfort when it is injected. You may feel warm and flushed and get a metallic taste in your mouth. Rarely, the contrast material may cause nausea, vomiting or a headache.

Additional Side Effects

There may be side effects and discomforts that are not yet known. We will keep you informed of any new findings about the study. This may include increased risks or new information about the experimental product, CRS-207.

5. Are there risks related to pregnancy?

Because this is the first time that CRS-207 is being tested in humans, risks to the embryo or fetus are currently unforeseeable. Women who are able to have children cannot become pregnant while taking part in this study. If you are a woman who is able to become pregnant, you will have a pregnancy test at the time of enrollment in this study and before each dose of CRS-207.

Both females and males who are sexually active must agree to be on an acceptable method of birth control to prevent pregnancy throughout the study (for 28 days after getting your last dose of CRS-207. Please talk to the study doctor to discuss the methods of acceptable birth control. If you suspect that you have become pregnant, you must tell us immediately. You should not breastfeed during the study. This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There is no direct benefit to you from being in this study.. If you take part in this study, you may help others in the future by allowing us to see if CRS-207 is safe to give to people with advanced cancer.

7. What are your options if you do not want to be in the study?

If you decide not to join this study, other options are available. You do not have to join this study to receive treatment for your cancer. There may be other treatment options available.

Your other choices may include:

- Not receiving any treatment or participating in any research studies
- Participating in another research study
- Receiving a different experimental or approved product for your cancer.

All options have risks and benefits that you should discuss with your doctor.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

The CRS-207 and antibiotics will be given to you free of charge.

All tests that are done strictly for research purposes will **not** be charged to you or to your insurance company, including the one night hospital stay.

Standard clinical blood tests, the CT scans, and health care provider charges that would normally be part of treating your disease will be billed to your insurance company and you will be responsible for any co-pay.

9. Will you be paid if you join this study?

No. However, you will receive meal and parking vouchers. These vouchers are good for up to 24 hours of parking at the parking garages at Johns Hopkins. You may use these parking vouchers for yourself or give them to your visitors, if you choose.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

12. How will your privacy be protected?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

Study records that identify you will be kept confidential as required by law. Because of the nature of this study, the general public and/or media may be interested in the progress of this study. Johns Hopkins and the Sponsor will make efforts to provide protection from the media and public in an effort to protect your privacy.

Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed later in this section of the consent form. Unless you give permission or the board that reviews research studies approves it, no one else will be able to see or use your information.

The people working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may collect other information including your name, address, date of birth, and other details.

The research team will need to see your information. Sometimes other people at Johns Hopkins may see or give out your information. These include people who review the research studies, their staff, lawyers, or other Johns Hopkins staff.

People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the company (Cerus Corporation) that is sponsoring the study and their representatives.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The health information about you may be used to create information that does not identify you. This is called "de-identified data". The de-identified data may be used and released by Researchers for this study, including use for other research purposes. However, you will not be identified by name in any resulting publication or presentation that utilizes the health information about you.

The use of your information has no time limit. You can cancel your permission to use and disclose your information at any time by calling the Johns Hopkins Medicine IRB at 410-955-3008 or by sending a letter to:

Office of Human Subjects Research
1620 McElderry Street
Reed Hall, Suite B130
Baltimore, MD 21205-1911

Your cancellation would not affect information already collected in this study.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

We will ask these other health care providers to give us ANY information about your health status or your health care.

14. What does a conflict of interest mean to you as a participant in this study?

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, we call this a conflict of interest. The investigator in this study has a conflict of interest in connection with this study and the following paragraph(s) tell(s) you about it.

Cerus Corporation will provide money and products to the University to do this study. The University and Cerus Corporation will work together on products used in the study. The work may result in additional money (royalties) for the University in the future. The study doctor, Dr. Jaffee, may also receive money (royalties) if the new products are sold in the future. Dr. Jaffee receives additional money from Cerus Corporation. The money is given to Dr. Jaffee because she gives advice to Cerus Corporation.

The University and Dr. Jaffee want to make sure that you understand this information. If you have any questions about this information, you can talk to someone in the IRB office (410 955-3008). You can also call Dr. Dung Le, at 410-955-8893 who does not own stock in or receive money from Cerus Corporation. Dr. Dung Le can give you answers to questions about the study.

15. What will the study sponsor pay if you are injured in this study?

In the event of a physical injury as a direct result of study procedures, you will be referred for appropriate medical care, and you and/or your insurance company will be expected to cover all costs. However, the Sponsor of this study (Cerus corporation) will accept responsibility for the costs of acute medical care arising from injuries that are the direct result of your participation in the study if such costs are not covered by your medical or hospital insurance or governmental programs providing such coverage and to the extent such injuries are not due to the negligence of the Institution, researchers or study doctor(s).

16. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other concerns or questions about the research.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Dung Le at 410-955-8893. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you have an urgent medical problem related to your taking part in this study, call Dr. Dung Le during normal business hours at 410-955-8893 and after normal business hours, call 410-955-4331 and ask for the medical oncologist on call.

Call the principal investigator, Dr. Dung Le, at 410-955-8893, if you think you are injured or ill because of this study.

Medical care at Johns Hopkins is open to you as it is to all sick or injured people. Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. The costs for any treatment or hospital care would be charged to you or your insurance company, except as explained in Section 15..

d. What happens to Data, Tissue, Blood and Samples that are collected in the study?

The researchers involved in these studies work to find the causes and cures of disease. The data, tissue, blood and samples collected from you during this study are important to both this study and to future research.

If you join this study:

- Johns Hopkins and/or its outside partners in this research will own these data, tissue, blood and samples.
- Scientists may only use materials or data that identify you for future research with your consent or IRB approval.
- If this material is used to create a product or idea, the scientists and Johns Hopkins will own that product or idea.
- You will not receive any financial benefit from the creation, use or sale of that product or idea.

e. What are the Organizations that are part of Johns Hopkins?

Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians.