Informed Consent Form

Date (M D Y)	Location Service	
Age	Doctor	If No Plate, Print Name, Sex, and History No.

WEILL CORNELL MEDICAL COLLEGE

Consent Form for Clinical Investigation
(If necessary, translate into language of subject)

WCMC IRB
Approval Date: 03-23-2015
Expiration Date: 11-23-2015

Project Title: An Open-Label, Phase II Efficacy Trial of the Implantation of Mouse Renal Adenocarcinoma Cell-Containing Agarose-Agarose Macrobeads in the Treatment of Subjects with Treatment-Resistant, Metastatic Pancreatic Adenocarcinoma or Colorectal Cancer

Research Project #: 0911010739

Principal Investigator: Barry Smith, MD, PhD

INSTITUTIONS The Rogosin Institute
Weill Cornell Medical College

INTRODUCTION

You are invited to consider participating in a research study involving an investigational [not approved by the Food and Drug Administration (FDA)] cancer treatment. The study is called "An Open-Label, Phase II Efficacy Trial of the Implantation of Mouse Renal Adenocarcinoma Cell-Containing Agarose-Agarose Macrobeads in the Treatment of Subjects with Treatment-Resistant, Metastatic Pancreatic Adenocarcinoma or Colorectal Cancer". You were selected as a possible participant in this study because you have been treated for pancreatic or colorectal cancers, which no longer responds to standard therapies. This is a Phase II study, which means that the study will evaluate how well the treatment works and how safe it is.

Research participants in the study are also referred to as subjects.

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in clinical research studies:

(a) Taking part in the study is entirely voluntary.

(b) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others;

(c) You may decide not to participate in the study or you may decide to stop participating in the study at any time without loss of any benefits and medical care to which you are entitled.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with members of the research team. You should take whatever time you

need to discuss the study with your physician and family. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

For out-of-town study participants only: A copy of the current informed consent form will be sent to you for your review. The Principal Investigator will answer all questions regarding the protocol. You (the participant) can then sign and date/time the consent form and HIPAA authorization form and send it back to the Principal Investigator via electronic/regular mail. Once the investigator receives this document, study-screening procedures as mentioned in the protocol can be done locally. You must then sign another consent form and HIPAA authorization in person prior to the implantation. This is done only for out-of-town participants in order to eliminate a special visit to the investigator for signing consent. The investigator will document the oral consenting process along with a witness present as per WCMC IRB and FDA guidelines.

The Rogosin Institute is considered the sponsor of this study. Dr. Barry Smith is the primary investigator. If this treatment were found to be effective, the Rogosin Institute would profit from sales of the macrobeads.

Portions of the study may take place at the New York Presbyterian Hospital, where the investigators are members of the medical staff. New York Presbyterian Hospital is neither a sponsor nor an investigator for this study.

WHY IS THE STUDY BEING DONE?

We are doing this research to study the safety and efficacy of a new, investigational cancer treatment for pancreatic or colorectal cancer that does not respond to standard therapy. Standard treatments include surgery, radiation and chemotherapy. We will asses disease progression, possible cancer shrinkage and survival rate.

The therapeutic options available to you other than this study are:

1. More standard treatment, such as chemotherapy and/or radiotherapy, depending on treatments you already have had;
2. Enrolling in a different research study;
3. Treating symptoms only, with no more anti-cancer treatment.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 116 subjects, males and females, will take part in this study. Our site is the only participating institution.

WHAT IS INVOLVED IN THE STUDY?

The treatment being evaluated in this study consists of the placement of small sugar-coated beads containing cancer cells from a mouse kidney cancer cell line. The beads will be referred to as "mouse kidney cancer cell-containing macrobeads" or "RENCA macrobeads"[1]. The beads have been tested in laboratory animals and pet cats and dogs with naturally occurring tumors. In these animals, substances produced by the cells in the beads slowed the growth of various tumors. This is the second trial of this

[1] "RENCA" is an abbreviation which stands for mouse renal adenocarcinoma cells or mouse kidney cancer cells.

agent in humans. The previous, phase I study, focused on the safety and toxicity of the beads in various types of cancers. Currently fifty-four subjects have received the RENCA macrobeads.

The RENCA macrobeads have two layers of agarose, a biological product made from seaweed. Each bead is about the size of a small pea: 0.2 to 0.3 inch in its largest diameter, and 0.15 to 0.2 inch thick, making it about the size of a small pea. The inner layer of agarose has the cancer cells. The outer layer gives strength to the bead and protects the cancer cells from attack by your immune system. The number of RENCA macrobeads to be implanted in this phase II study will be determined by a participant's weight. Each participant will receive 8 macrobeads per kilogram.

If you decide to participate in this study, the surgeon will place the beads in your abdomen by a small surgical procedure. The beads might or might not have an effect on the tumor. They might or might not release factors or signals that lead the cancer cells in your body to slow and perhaps even stop growing. The beads may do nothing to the tumor. The beads could make the tumor grow, although no tumor grew in the animal studies or the first study in humans.

Researchers from The Rogosin Institute have developed the RENCA macrobeads in the past 10 years. The beads are experimental and are not approved by the FDA. So far the beads have been used in research in fifty-four subjects. We are studying the RENCA macrobeads under a FDA Investigational New Drug Application (IND).

Research has shown that the growth of cancer cells and the tumors is controlled by certain factors. Scientists think that cancer cells grow as fast as they can and are not regulated in the same way as normal, non-cancerous cells. Based on our research, we think that the cancer cells in the RENCA macrobeads behave differently than other cancer cells. Since they were made, the beads have been maintained in fluids called "media". These media were tested in the laboratory to study how fast cells grow in them. We found that cells grew slower, which suggests that the cancer cells in the macrobeads are releasing substances into the media that tell these cancer cells to slow or stop their growth.

In other tests, we placed the RENCA macrobeads in the abdomens of animals with cancer. In these animals, cancer cells grew slower in the presence of the beads. The RENCA macrobeads did not affect the normal cells in the animals' body. Unlike chemotherapy, the RENCA macrobeads do not seem to be dangerous to normal cells and body organs.

The investigational treatment tested in this study uses mouse kidney cancer cells to control the growth of human cancer cell. There is a risk that the mouse kidney cancer cells might escape from the macrobead and form tumors in your body. We did not observe tumors in rats deliberately injected with mouse tumor cells. Cats or dogs that had RENCA macrobeads in their abdomen for at least three years also did not grow mouse tumor cells.

Tumors spreading across species is unlikely, so we believe that mouse kidney cancer should not happen in humans. The scientific literature confirms this idea, because cells from a different species are likely to be recognized as "foreign" by the recipient's body and will be removed by the immune system.

Below are results from the first study of the RENCA macrobeads done in humans.

1. Macrobeads in the abdomen of the participants did not lead to local inflammation or peritonitis (inflammation of the tissue lining the inner wall of the abdomen and the pelvis).
2. No human caught any mouse viruses.
3. The beads may cause an inflammatory response that is visible by fever and changes in laboratory results. The intensity of the response was different among the participants.
4. All but one participant showed death of some cancer cells (an event called tumor necrosis), visible on imaging and certain laboratory tests.
5. Most participants told us that they felt better and had less pain.
6. Participants lived for different length of time after receiving the beads.

We cannot generalize these findings to predict how any other person will react to the macrobeads. The participants in this study had solid tumors that had spread to different organs. Most were not expected to live more than 6 months. Many had undergone surgery, radiation, and chemotherapy. In fact, some participants developed complications from their original cancers early in the study and died within months of implantation. There is no indication that the RENCA macrobead implantation made their health worse or made them die sooner, but the causes cannot be known.

In the first study, participants told us about many health problems. The problems were not specific to one organ system and were very different from participant to participant. Some problems were considered serious, meaning that participants had to be admitted to the hospital or had to stay longer in the hospital. Some problems were life threatening and some led to death. In most cases, these problems had no clear connection to the RENCA macrobead implantation, but seemed to be due to the initial disease getting worse.

The health problems reported by participants in the first study were: abdominal pain, anemia (low number of red blood cells and low hemoglobin in the blood), constipation, cough, decreased appetite, formation of blood clots in a vein, shortness of breath, accumulation of fluid around the lungs, fatigue, gastrointestinal bleeding, gout flare, blood in the urine, hives (rash), high blood pressure, low blood pressure, higher risk of bleeding, low grade fever, malaise, nausea, night sweats and vomiting.

We invite you to participate in this phase II study of the RENCA macrobeads because you have pancreatic cancer that has not gotten better with conventional or usual therapy. This study previously enrolled participants with colorectal cancer and pancreatic cancer. Currently, the enrollment is open only to pancreatic cancer participants as a separate protocol has been created which is open to enrollment exclusively for colorectal cancer participants.

Pancreatic cancer: this type of tumor has markedly increased during the past several decades but its cause is still poorly understood and it responds poorly to chemotherapy, radiation and surgery.

Colorectal cancer: in contrast, colorectal cancer is a highly treatable and often curable disease when localized in the bowels. Surgery is the primary form of treatment.

Before you can be a part of the phase II study, you will be carefully evaluated with the tests and procedures that are described below. The evaluations, implantations and follow-up procedures may involve up to a week in the hospital (although generally no more than a couple days) and regular follow-up and examination. Because the study uses of mouse cells, you will need to be examined regularly for possible reactions to the mouse tissue.

If you are a female, you will need to confirm that you are not currently pregnant to your knowledge and that you will use all appropriate contraceptive measures [a double barrier method of contraception (e.g., diaphragm and condom], an intrauterine device (IUD) or sexual abstinence for the duration of the study and for at least 6 months after study completion, and **potentially for a longer duration of ten or more years**, to prevent pregnancy). Women who are not of childbearing potential (greater than 55 years old) must be post-menopausal for at least two years or surgically sterile.

Study Procedures

If you take part in this study, you will undergo the tests and procedures indicated in the table below (Table 1). You may receive the RENCA macrobeads up to four times, depending on your overall state of health. After each beads placement, if all is well you might be discharged home the same day. At home, your family members and you will be responsible for recording your blood pressure, pulse, temperature and weight, as well as completing a daily activity and performance log and symptom checklist. You and one or more of your family members will be trained to take these various observations. The forms are simple, but it is important that you and your family recognize that a substantial daily commitment is required to ensure that the required observations are properly recorded.

Table 1 Outline of the schedule of events during the study. An "X" indicates that the procedure might take place. An empty cell indicated that no such procedure will occur at this visit.

	Evaluations (Physical exam, wound assessment, etc…)	**Vital Signs, Questionnaires, and other Procedures**	**Blood Draws**	**Imaging Studies**
Pre-Dose (screening)	X	X	X	X
Visit 1 Day 0	**IMPLANTATION 1**			
Visit 2 Week 2	X	X	X	
Visit 3 Month 1	X	X	X	
Visit 4 Month 2	X	X	X	
Visit 5 Month 3	X	X	X	X
Visit 6 Day 0	**IMPLANTATION 2**			
Visit 7 Week 2	X	X	X	
Visit 8 Month 1	X	X	X	
Visit 9 Month 2	X	X	X	
Visit 10 Month 3	X	X	X	X
Visit 11 Day 0	**IMPLANTATION 3**			
Visit 12 Week 2	X	X	X	
Visit 13 Month 1	X	X	X	

Table 1 Outline of the schedule of events during the study. An "X" indicates that the procedure might take place. An empty cell indicated that no such procedure will occur at this visit.				
	Evaluations (Physical exam, wound assessment, etc…)	**Vital Signs, Questionnaires, and other Procedures**	**Blood Draws**	**Imaging Studies**
Visit 14 Month 2	X	X	X	
Visit 15 Month 3	X	X	X	X
Visit 16 Day 0	**IMPLANTATION 4**			
Visit 17 Week 2	X	X	X	
Visit 18 Month 1	X	X	X	
Visit 19 Month 2	X	X	X	
Visit 20 Month 3	X	X	X	
Visit 21 Month 4	X	X	X	X
Follow-Up	X	X	X	X

More specifically, the screening will involve a full medical history, a complete physical examination with all vital signs, a neurological examination, an electrocardiogram, and collection of blood and urine samples for laboratory tests. Some tests are specific to your disease, such as tumor markers (CEA, CA19-9) while others are more general, like checking the cells in your blood (hematology profile), how your blood clots (coagulation profile). We will also check different chemicals in your blood, and we will do skin testing for a possible reaction to mouse proteins. This will be done with positive (histamine) and negative (saline or glycerin) skin test controls. You will also have imaging tests of the abdomen and pelvis. Subsequent visits will involve some or all of these tests.

Please advise the researchers of any medications you are taking. In addition, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the researchers.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 12 months with the regularly scheduled visits detailed above. However we will continue to follow you beyond that time and for the rest of your life at about 6-month intervals for 2 years, and yearly after that.

WITHDRAWAL FROM THE STUDY

You can stop participating in the follow-up visits at any time. However, if you decide to stop coming in for visits, we encourage you to talk to the researcher and your regular doctor first. You can withdraw from the study at any time without prejudice to your ongoing regular medical care.
You may decide at any time that you want to stop participating in the protocol. Such a decision would require that we do certain procedures, for the sake of both your own health and that of others. Most importantly, the senior investigator must decide if the beads need to be removed. At this time, no participant has asked to have

the beads removed, and it has not been attempted. There may be medical reasons requiring the removal of the beads. Because the beads are spread in your abdominal cavity, only a fraction of the total number of beads implanted will be removed (50 to 70%). You may also be required to have blood samples drawn after your withdrawal from the protocol to monitor you for any evidence of mouse virus infection (see RISKS section below). Thus, although you may be withdrawn from the protocol, there may be reasons why you need continued medical monitoring beyond your usual cancer or other medical care. We cannot specify how long you would need to be monitored, but it is likely to be for the rest of your life.

The study sponsor, The Rogosin Institute, will cover all costs and fees related to the removal of the RENCA macrobeads, if needed due to a medical necessity. The study sponsor will also cover all costs and fees related to the requirement of the need to be monitored through blood samples, for evidence of mouse virus infection throughout your life.

Withdrawal by investigators or sponsor for Medical Reasons

The investigators or sponsor may, for medical reasons related to the protection of your health, require the removal of as many of the macrobeads that have been implanted in your abdominal cavity as possible and/or require your withdrawal from the study. They can do this without your consent. One reason could be an unexpected adverse reaction to the beads or your development of another, unrelated medical condition, which could expose you (or someone else) to additional health risk or actually cause you injury. There may be risks, which are unforeseeable at present. If you are female, current or anticipated/unanticipated pregnancy excludes you from participating in this study or could cause your voluntary or involuntary withdrawal from it. Under circumstances of your involuntary withdrawal for any reason, the guidelines above for your voluntary withdrawal (with continued monitoring) will apply as well.

Consent to Postmortem Examination

You are asked, as a participant in this study, to voluntarily consent to an autopsy, should you die during the six-months of the formal study period or anytime during the follow-up, which will continue throughout your life. An autopsy will assist the investigators and the FDA in determining the safety and toxicity of this investigational drug, the RENCA macrobead, and may help other people in the future. **It should be emphasized, however, that you do not have to consent to an autopsy to participate in this study.** In addition, whatever decision you make with respect to this examination, your decision is not binding on your family in the event of your death. You are also free to change your own decision at any time.

WHAT ARE THE RISKS OF THE STUDY?

There are risks associated with participating in this study. They will be discussed with you by the research doctor and/or your regular doctor.

Risks and side effects related to this study include:

1. Risks related to the implantation of the RENCA macrobeads:

One possible effect is an inflammatory reaction to the placement of the beads in your abdomen. Although no significant reaction has been seen in mice, such a reaction was seen in cats and dogs implanted with the macrobeads. This reaction consists of a thickening of the lining of the abdominal cavity and also the coverings of the internal organs such as the intestines and spleen (this type of inflammation is called

peritonitis). In the previous human phase I study, participants experienced mild, intermittent fevers after implantation. You can also expect abdominal discomfort and pain, nausea, decreased appetite, vomiting, cramping, constipation, diarrhea, bleeding and even obstruction of your intestines.

Additional possible risks are: local irritation, localized ascites (accumulation of fluid in the abdominal cavity).

If there is a significant inflammatory response posing a hazard to your health, every attempt will be made to remove the beads, although as mentioned above, removal of all the beads will not be possible. Animal studies have shown that the remaining beads do not seem to present significant risks for the participants. Other treatments, depending on your symptoms, may include placement of a nasogastric tube (plastic tube going from your nose to your stomach to provide access to the stomach for diagnosis and treatment purposes), administration of steroids and/or antibiotics and other medications, and possibly even major abdominal surgery to relieve an obstruction, or remove beads as indicated above. However you should be aware that humans may experience reactions that are yet unknown and could be more **severe, permanent, life threatening or fatal**. So is chronic inflammation in the abdominal cavity.

2. Risks associated with the RENCA macrobeads:

RENCA macrobeads are tested for viruses before they are released for implantation, but it is not possible to rule out the presence of unknown viruses or 1 particular known virus, murine leukemia virus. This murine leukemia virus is derived from a mouse and is ecotropic, which means that it has not been shown to spread to human cells in a laboratory dish; it also has not been shown to produce disease in the human body.

In the nine years of experience with the RENCA macrobeads in animals with cancer and more than 90 human patients with various types of cancer, there has been no evidence of the spread of the ecotropic murine leukemia virus or infection by this virus. Thus, the risk of the spread of the murine leukemia virus or viral infection associated with treatment with RENCA macrobeads is extremely low. Since the possibility of the infection cannot be ruled out completely, you will be monitored closely for any possible infection with mouse leukemia virus; your full participation in the monitoring process is important for your protection.

The effects of a potential infection by the mouse virus are not known and cannot be predicted with any certainty at this time. You will be given whatever treatment is appropriate and available at the time, should any infection occur in you and you have symptoms of it. Such treatment may include the use of drugs that help stop the virus from multiplying and also reduce the effects of the virus on organs in your body. Because there may be viruses as yet unknown, the effectiveness of currently available treatments for mouse viral infections cannot be guaranteed.

Additionally, you will be tested by skin test for mouse antibodies, along with positive (histamine) and negative (saline) controls. You can expect a reaction to the positive histamine test, in the form of redness, itching and possibly discomfort at the site of the injection. This is the same type of reaction you would have with the mouse skin test if you have been contaminated with mouse viruses.

3. Risks associated with the surgery:

Surgery is required to place the RENCA macrobeads in your abdomen. This can cause you discomfort from the incision. As with all surgeries, you may also get an infection at the site of the opening. Although it is unlikely, there is the possibility of an injury to an organ in your abdomen (like damaging the bowel during the introduction of the beads). There is also a remote chance of ileus (temporary paralysis of a portion of the intestines which can happen after an abdominal surgery), which could lead to abdominal discomfort, constipation, nausea/vomiting and flatulence. As we are not cutting the bowel, we do not consider ostomy placement (surgical creation of an opening in the body for the discharge of body waste) a risk in this procedure. The risk of the anesthesia required for the surgical procedure should be no different from those of any other surgery. All the surgical risks are dependent on your own health situation and will be reviewed in details with you by the surgeon and anesthesiologist, as well as the responsible study doctor.

4. Risks associated with the blood draw/placement of intravenous lines:

Likely risks of drawing blood commonly include discomfort and/or bruising at the needle puncture site, and less commonly, the formation of a small blood clot or swelling of the vein and surrounding tissue. Bleeding from the puncture site may occur. There is also a slight possibility of infection, and you may feel faint. To decrease these problems, qualified medical personnel will perform these procedures with the usual sterile techniques of blood drawing and intravenous line placement, applying adequate pressure.

The total amount of blood drawn within the first 6 months of the study will be approximately 300 cc (about 20 tablespoons). The risk of mild anemia secondary to this blood withdrawal is minimal, but will be appropriately treated if present.

5. Risks associated with the imaging tests:

There are no known risks associated with ultrasound testing. For the CT-scan, the amount of X-ray you will be exposed to is similar to that of a skull or chest X-ray and should not present any unusual problems for you. Aside from the discomfort of lying on a hard flat surface and the possible sense of confinement of the MRI scan, there are no irradiation hazards with this device. A risk unique to the MRI scan relates to the strong magnetic field around the machine. Although no loose metallic object is permitted in the MRI room, the presence of such an object in the room can be dangerous to the MRI staff and you. PET scans will also be obtained during your participation in the study. They involve using a short-lived radioactive form of a sugar, which gives an indication of their growth potential. You will have to lie in the PET scan instrument itself for periods of up to 90 minutes. The hazards of the radioactive material itself are minimal because of the short time it remains radioactive (half the radioactivity is gone within 110 minutes).

6. Risks associated with the filling of questionnaires:

Filling questionnaires related to your state of health may make you anxious because you will be grading your level of pain or your symptoms. We encourage you to be open with the study team with such feelings.

7. Unknown risks:

Possibility of allergic reaction:

You may have an allergic reaction to the macrobeads, which may be life-threatening. The level of risk of such a reaction is not known. Although allergic reactions to the macrobeads have not been seen in the cats and dogs, they may happen in humans. Mouse proteins, cells or possibly even components used in the manufacture of the beads could cause these reactions. Although you do not have a history of allergic reactions and no participants who received the beads so far have had any reaction, it is still

possible that it could occur. You may experience skin rash, fever, swelling of your face or mouth, shortness of breath, low blood pressure, fainting and even death. If any of these reactions happens, you will be treated with various drugs to reduce or control the reaction.

Possibility of accumulation of RENCA macrobeads in the pelvic cavity:
Because we stand upright, complications are possible due to the accumulation of the macrobeads in the pelvic cavity. None are known at this time. Such complications could result from the weight of the accumulated beads and interfere with rectal, bladder or ureteral function. As a result, you could feel discomfort or even pain. The passage of stool or feces out of the rectum and urine out of the ureters, which carry urine from the kidneys to the bladder, and the bladder itself, could be blocked. Accumulation of macrobeads on the bladder could also cause frequent urination and pain. It could also weight on or irritate the pelvis and be painful. Due to the presence of the beads in the pelvis, women may also feel pain in the area of their reproductive organs, as well as dysfunction and even scarring.

Risk for pregnant women, the embryo, fetus (unborn child) or nursing infant:
The beads used in the study may involve risks that are not known at the time. If you are female, these risks mean that you cannot be or become pregnant during the study and possibly for a period of ten years or longer after the study. If you become pregnant, you must inform the study team immediately, and you will be withdrawn from the study. If you are male, you must always use a condom during sex to prevent the possible spread of unknown viruses to the female by semen.

There may also be side effects, other than listed above that we cannot predict. In some cases side effects can be serious, long lasting or permanent.

To minimize the risks and side effects associated with your participation in this study, you will be carefully screened (evaluated before each implantation of RENCA macrobeads) and monitored throughout the study. For more information about risks and side effects, ask a member of the research team. You must report any unusual health experience, injuries or side effects immediately to the study doctor or other members of the study team.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you will receive any benefits from this study. The implantation of RENCA macrobeads has been shown in animals of various species to be capable of slowing or stopping the growth of tumors. In animals, the beads may even cause them to shrink or die. There is evidence from the phase I study that the beads may have an effect on some of the tumors, but there may be no direct benefit to you in participating in this study. This phase II study is designed to evaluate the efficacy and safety of the RENCA macrobeads in human beings, but it is not intended primarily to treat your cancer. Your participation in this research study will, however, contribute to knowledge about the RENCA macrobeads and their potential usefulness in cancer patients. It may help others in the future.

WHAT OTHER OPTIONS ARE THERE?

At present, you have received the available, established treatments for your tumor, including surgery, radiation and chemotherapy as appropriate. However, your tumor is progressing. Instead of being in this study, you have these options:

1. More standard treatment, like chemotherapy and/or radiation, depending on the treatments you have already received;
2. Participation in a different research study;
3. Treat your symptoms only, without anti-cancer treatment.

The research therapeutic options available to you at present are experimental and unproven. The standard options indicated above may make you more comfortable, and decrease your symptoms. However, they may not slow or change the growth of your tumor as they are not designed to inhibit the growth or spread of the tumor itself.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Medical records of research study participants are stored and kept according to legal requirements. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as: study staff and investigators at The Rogosin Institute (including agents and/or representatives working on their behalf), Weill Cornell Medical College and its Institutional Review Board, the Weill Cornell Medical College Clinical and Clinical Translational Science Center (CTSC), the FDA (Food and Drug Administration), The New York Presbyterian Hospital and all appropriate federal research oversight agencies.

Some information about your participation in this study is stored in a computer. To protect it from unauthorized disclosure, tampering, or damage, it will be kept in a password-protected computer in a room with limited access. The room will be locked after hours. Any software used during the study are also protected with passwords. Other information will be kept on paper, in locked file-cabinets. Only study staff will have access to the information.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by United States Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS?

There is no cost to you for your participation in this study. Research participants will not receive any payment for their participation. The study sponsor, The Rogosin Institute, will pay all hospital care, diagnostic testing, scans including PET, as well as all laparoscopy (minimally invasive surgery of the abdomen involving small incisions) and surgery (operating room, surgeon's charges and anesthesiologist's fee) related to the study.

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

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

In accordance with Federal regulations, we are obligated to inform you about Weill Cornell Medical College's policy in the event physical injury occurs. If, as a result of your participation, you experience injury from known

or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalizations, if necessary will be available at the usual charge for such treatment. No monetary compensation is available from Weill Cornell Medical College or New York Presbyterian Hospital. The Rogosin Institute will be responsible for the costs of such medical treatment, however no monetary compensation will be provided directly to you. Further information can be obtained by calling (646) 962-8200.

Sponsor Injury Policy

The Rogosin Institute will be responsible for all hospitalization, testing, medications, and any other treatments directly related to this study. In the event that you believe that participation in this study has led to injury, all appropriate medical care to resolve the problem will be provided at no cost to you. You may contact Dr. Barry Smith at 212-746-1551 to identify the medical resources that are available to you and to assist you in obtaining appropriate medical care. The study sponsor, The Rogosin Institute, and the Federal Government do not have any program to provide compensation for persons who may experience injury while participating in research projects.

Medical or surgical treatments unrelated to this study will not be covered by the study sponsor. You will receive no monetary compensation for your participation in this study.

You will not lose any of your legal rights as a research participant by signing this consent form.

COMPENSATION FOR PARTICIPATION

You will not receive compensation for participating in this study.
You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

POSSIBLE CONFLICT OF INTERESTS OF INVESTIGATORS

The Rogosin Institute ("Institute"), a not-for-profit research institute, is the sponsor of this study. Dr. Barry Smith, an employee of the Institute, is the Principal Investigator for the study. The Institute owns the intellectual property rights for the RENCA macrobeads, the patented technology that is used in this study. Dr. Smith is one of the inventors of the macrobeads. The Institute, Dr. Smith and other investigators employed by the Institute could benefit financially from the macrobeads if it eventually becomes a marketed product.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with the Weill Cornell Medical College, your physicians, or other medical personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Barry Smith at (212) 746-1551 (office hours) or (212) 535-1120 (after office hours; be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the Weill Cornell Medical Center IRB Office. Direct your questions to:

Institutional Review Board at:
Address: 407 East 61st Street, 1st Floor Telephone: (646) 962-8200
New York, New York 10065

RESEARCHER'S STATEMENT

I have fully explained this study to the participant. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person obtaining the consent (Principal Investigator or Co-investigator)	Print Name of Person	Date / Time

RESEARCH PARTICIPANT'S STATEMENT

I, the undersigned, have had the opportunity to read the currently approved consent form, which explains the background and specific procedures of this protocol. I have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I understand what I read and voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Barry Smith and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

I also consent to a postmortem examination: Yes ☐ No ☐

_____	_____	_____
Signature of Research Participant	Print Name of Research Participant	Date / Time

Because of the potential implications of this study for my family, my spouse / significant other / other relative is also signing to indicate her/his/their understanding of the study and is hereby certifying the agreement of any family members likely to be affected by my participation in the study.

_____	_____	_____
Signature of Family Member	Print Name of Family Member	Date / Time

_____
Relationship to Research Participant

Family member not available ☐