Mount Sinai St. Luke's
Mount Sinai Roosevelt

Institutional Review Board

Institute for Health Sciences
Institutional Review Board
One Gustave L. Levy Place; Box 1627
New York, NY 10029

APPROVAL OF RESEARCH

Date: 8/7/2015

To: **Richard Whelan, MD (Rwhelan@chpnet.org)**

On **8/6/2015**, an Institutional Review Board of St. Luke's-Roosevelt Hospital Center, in accordance with its Federal Wide Assurance (FWA#00003834) to the Department of Health and Human Services approved the following human subject research from **8/6/2015** until **8/5/2016** inclusive:

Type of Review:	**Continuing Request for Approval**
Project Title:	**Tumor, perioperative blood sample, and clinical data banking for cancer, physiology, immunology, and other research studies**
Investigator:	**Richard Whelan, MD (Dept: SU - Surgery)**
Project Information:	**HS#: 09-113**
Sites:	**Roosevelt Hospital, St. Luke Hospital**
IND or IDE (if any):	**No INDs;No IDEs;**
Submission Details (if any):	**♦ Consent Addendum to allow for samples to be obtained from subjects in the first 4 years after surgery.** **♦ Removal of Co-Investigators David Gaita, Eric Moore, and Beverly Wang.** **♦ Addition of Dr. Geoff Bellini and Dr. Ellie Sutton as Co-Investigators**

Between **6/21/2016** and **6/24/2016**, or within 30 days prior to study close, whichever is earlier, you are to submit a completed FORM HRP-212: Continuing/Final Review Progress Report and required attachments, in order to request continuing IRB approval or study closure. If IRB continuing review approval is not granted before the expiration date of **8/5/2016**, IRB approval of this research expires on that date.

- The IRB has determined that this research involves no greater than MINIMAL RISK. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45CFR.46.102; 21CFR50.3k).
- The IRB approved this research under **expedited review procedure category(ies) 2 and 5**

In conducting this research you are required to follow the requirements listed in the **Investigator Manual**. If stamped approved consent forms are attached, use copies of these forms to document consent. IRB approval does not constitute or imply institutional support for the conduct of this research. Additionally, all required local committee approvals at each **research affiliate** site must be obtained prior to initiation.

cc: Study Contact(s): Cekic, Vesna (vcekic@chpnet.org)

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Study ID #:09-113 **Form Version Date: 05/01/15**

TITLE OF RESEARCH STUDY:

Title: **Tumor, perioperative blood sample, and clinical data banking for cancer, physiology, immunology, and other research studies**

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Richard L. Whelan MD.

Physical Address: 425 W 59TH Street Suite 7B New York, NY 1019

Mailing Address: 425 W 59TH Street Suite 7B New York, NY 1019

Phone: 212-523-8172

WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to build and maintain tissue "banks" or collections of cancer and blood samples taken from patients undergoing surgery. Together with these tissue banks, for patients who give their permission, a data bank containing the results and outcomes of surgery will also be developed.

What is the purpose of tissue banks? Tumor and blood sample banks, alone and together with a clinical data base, allow the performance of a wide variety of research studies concerning cancer and the operations used to treat them. Obviously, tumor samples can only be taken from patients who have a malignancy. Tumor banks permit detailed analyses of cancers that allow researchers to determine the relationship between various genetic characteristics of the tumor and the tumor's ability to grow and invade. Such tumor analysis can also lead to new treatment approaches that are more specific and, in general, less toxic than standard chemotherapy drugs. In patients who received chemotherapy or radiotherapy before their tumor was resected, the tumor bank can also reveal to researchers the effects of the preoperative treatment on the tumor.
Blood sample banks allow measurement of the levels of proteins and other factors known to affect our physiology, immune system function, and the blood's ability to support or inhibit tumor growth. A

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blood sample bank that contains specimens from before and after surgery also allows studies that will help us better understand how surgery affects the body. Furthermore, blood banks also allow study of the various cells that circulate in the bloodstream**.** Genetic testing will not be done on the blood specimens obtained for this tissue banking study. The results of the blood tests that are done on your blood specimens will not be shared or given to you unless these results might have a bearing on your condition or overall health.

Postoperative blood specimens are useful for a variety of reasons. Early postoperative specimens can be used for studies that assess the impact of cancer removal and surgery in general. Later postoperative specimens, when utilized in conjunction with the preoperative samples, can be used to look for blood markers of tumor recurrence that usually occur during the first 2-5 years after surgery. If you agree to this portion of the study, between 4 to 10 blood samples would be taken intermittently during the first 5 years after surgery. A total of 15 cc of blood (about 3 teaspoons) will be taken for each sample.

All tissue samples and clinical data in the tissue and data bank are de-identified which means that the names and other information regarding patients who agree to contribute tissue and data to the bank are kept fully confidential. When tissue samples are utilized for studies they are identified by number; no names or other identifying information is associated with the data.

You may qualify to take part in this research study because you are to undergo a surgical resection. Patients with and without cancers are also candidates for the blood sample portion of the study. Participation in this study will have no impact on the operation to be performed or the surgical method to be used for your operation. As with any operation, you and your surgeon will discuss the options and agree on which method is to be used. The decision concerning your operation will be made independently of whether or not you decide to enter this study.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study can vary from one day to 5 years depending on which parts of the study you agree to participate in.

The number of people expected to take part in this research study is unlimited.

The total number of people expected to take part in this research study is several thousand.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

The research activities will take place at Mount Sinai Roosevelt Hospital Center. If you have a malignancy and agree to enter the tumor banking portion of this study, after your tumor has been resected a pathologist will examine the specimen and determine if it is reasonable for a sample to be taken for the tumor bank. Only if the taking of a small tumor sample will not affect the pathologist's

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ability to analyze the tumor will a sample be taken for the bank. If a tumor sample is taken, an accompanying small piece of normal tissue will be obtained as well; both samples will be frozen and placed in the tissue bank for research purposes**.** When studying tumors it is useful to have a sample of normal tissue from each patient for comparison. Also, additional tumor samples, if the size of the tumor permits, may be taken and chemically fixed in formalin after which they are also stored for later research use. The frozen and formalin fixed samples are useful for different types of research analyses.

Furthermore, provided you give a separate permission, blood samples would be taken a total of 4 to 10 times during the first 5 years after your surgery, the majority of which are taken during the first 3-4 months. Any patient undergoing surgery (with or without a tumor) can enter the blood sample portion of this study. Where possible, the early post-surgery samples will be taken at the time that the routine postoperative blood tests (ordered by your surgeon) are taken, thereby eliminating the need for a separate needle puncture. The samples taken after discharge are usually carried out at the time of your postoperative office visits. Each sample will be about 3 teaspoons in size (15 cc).

Cancer patients are asked to periodically see the surgeon after surgery for the first 5 years so as to assess their condition and to ensure that the proper follow up tests are being done (CT scan, colonoscopy, etc.). For patients who give their permission to the clinical data part of the study, follow up information will be taken and stored in a computerized data base in a de-identified manner (names and identifying information not included); in this way the patients privacy is fully protected. Patients who have given their consent to the data or blood portion of this study who do not return to the surgeon may be contacted via letter or phone by their surgeon or tissue bank personnel. The purpose of these calls is to remind the patient that they had agreed to participate in the data and/or blood bank portion of the study. An appointment with the surgeon would be offered and, if declined, questions would be asked regarding the patient's condition and the results of recent follow up tests. If the patient returns to the surgeon's office and agrees, a "late" blood specimen would be obtained. Whether in person or via phone, it will be made clear that the patient can refuse to give the blood or follow up data if they so choose.

How often you visit your surgeon after the operation and the length of time that your surgeon will follow you in the office will not be affected by your decision to participate in this study. Similarly, your doctors will decide when and how often radiologic (X-ray), endoscopic, or blood tests are done in the years following your surgery. Provided you have given permission to the data banking part of the study, the results of the tests that you undergo in the years following surgery will be tracked closely as will your overall condition.

The de-identified (no name attached) long term outcome data is important because it will allow researchers to determine the importance of each tumor's genetic characteristics as well the meaning of changes in the blood's makeup noted before and after surgery. This information will also help researchers determine the effect(s) of postoperative anti-cancer treatments in relation to the genetic and structural characteristics of their tumor.

To summarize, this study concerns the collection of tumor and blood samples as well as clinical outcome information. Although it is hoped that most patients will agree to all 3 portions of this study a patient can agree to only 1 or 2 parts of the study. Patients who are having surgery for benign

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conditions are not eligible for the tumor banking part of the study. Please note that you may choose not to participate in this study altogether. This decision will not, in any way, have an impact on the planned surgery.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: allowing study personnel to collect tumor, blood, and/or data samples depending on which parts of the study you have given permission. In all likelihood, the blood tests will be done while you are in the hospital or in your doctor's private office. Rarely, and only if the you agree, a blood sample may be obtained between postoperative office visits. In this case a hospital researcher may come to your home or at another agreed upon location to obtain the blood sample. You will not be required to make extra trips to the medical center

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study and you will not be charged for study related blood tests, tumor sampling, or the tracking of your progress over the years.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research.

The tumor and blood banks that result from this study will help doctors to understand tumors, in general, and the blood compositional changes associated with cancers. However, possible benefits may be that new anti-cancer drugs may be developed as result of studies done with the tissue samples in the bank. The postoperative blood bank specimens and the clinical data base will help researchers determine how the various operations done to remove cancers and benign problems affect the composition of the blood and how they alter physiologic function. Other important immunologic effects or growth factors may also be discovered as a result of this study. These discoveries, may, in turn, lead to new treatments or drugs that would lessen the stress that surgery induces. It is also possible that use of the tissue samples in the bank may lead to blood test(s) helpful in the diagnosis of cancer or tumor recurrences.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The risks of the surgery you are to undergo are not changed in any way by your participation in this study. There are minimal risks associated with venipuncture (the taking of blood samples) including: discomfort and hematoma or bruising at the site of phlebotomy. Very rarely, a localized infection around the blood drawing site can develop which can be treated with antibiotics, warm soaks, and elevation. Another potential risk is the loss of blood caused by the venipuncture. The total amount of blood removed will be between 4 ½ and 9 tablespoons; it is highly unlikely the blood loss associated with this banking study would be the cause of any serious problems

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Study ID #:09-113 **Form Version Date: 05/01/15**

Risk of loss of private information in the data bank; this risk always exists, but there are procedures and mechanisms in place to minimize the risk.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. The alternative to participating in this study would be to have your scheduled surgery as planned without the blood tests, tumor sampling, and data collection called for in this study. This study in no way alters or delays the surgical procedure you will undergo: the choice of procedure will be decided by you and your surgeon. You alone will decide whether to participate or not in this study.

I have discussed this study with Dr._____ to my satisfaction. I understand that my participation is voluntary and that I can withdraw from this study at any time without prejudice. I have read the above and agree to enter this research study. Signing this form does not waive any of my legal rights.

Yes / No (Please circle): I consent to the blood testing portion of this study (4-10 samples over 5 years).

Yes / No (Please circle): I consent to a single preoperative blood specimen.

Yes / No (Please circle) I consent to the tumor (and normal tissue) sampling from the surgical specimen.

Yes / No (Please circle) I consent to the clinical data collection portion of this study.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator, Dr. Richard L.Whelan, at 212 523 8172.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to end your participation in one, several, or all parts of this research study, please contact the Principal Investigator, Dr. Richard L. Whelan, or the research staff either in person or via phone at (212)523-8172. If you so direct, at the time you end your participation in the tissue bank, you can request that your tissue specimens not be used in any future research studies. In this case, your

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frozen and paraffin imbedded tissue samples will withdrawn from the bank and destroyed and disposed of in accordance with standard procedures.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. However, no additional data or information would be entered into the data bank. Also, the investigators will not review your medical records or other confidential records requiring your consent. However, the investigators may consult public records, such as those establishing survival status.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number 212-523-8172

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our

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website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

The tumor and blood bank portions of this study contain the following de-identified data for each patient in order to allow the specimens to be categorized: age, sex, other medical problems and conditions, main diagnosis, pathology results, and tumor stage (where applicable). The long term cancer outcome data to be included in the clinical outcome data base portion of this study includes the following de-identified information (in addition to items listed immediately above): 1) results of all radiographic tests done in follow up for the purposes of detecting cancer recurrences or growth of persistent tumors (including CT, PET, MRI, ultrasound or other tests); 2) new historical and physical examination findings obtained during follow up evaluations, 3) relevant blood test and/or future biopsy results relating to the cancer, 4) information regarding chemotherapy or radiotherapy treatments received before or after the cancer resection, and 5) outcome data obtained from your medical or radiation oncologist or other of your physicians. One method by which researchers will get information regarding your operation, tests, and other treatments is from your medical records at Roosevelt Hospital and from your surgeons office.

As mentioned above, all of your data that is used for research purposes will be kept in a de-identified data base in which you will be assigned a number. There will be a single "key" file that will contain the names, dates of birth, addresses, medical record numbers, social security numbers, key dates (admission, discharge, and operation dates) and telephone numbers of study patients. Only the Principal Investigator and the tissue bank manager and study coordinator will have access to this "key". This information will not be shared with any collaborating investigators.

During the study the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study

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will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project: Dr. John Robertson, University of Nottingham England
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

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Study ID #:09-113 **Form Version Date: 05/01/15**

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Study ID #:09-113 **Form Version Date: 05/01/15**

Signature Block for Capable Adult

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

DO NOT SIGN THIS FORM AFTER THIS DATE → **08/05/2016**

Signature of subject	Date
Printed name of subject	Time [required if used for FDA documentation purposes]

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	*Date*
Printed name of person witnessing consent process	Time

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Study ID #: 09-113 **Form Version Date:** 5/20/2015

TITLE OF RESEARCH STUDY:

Title: **Tumor, perioperative blood sample, and clinical data banking for cancer, physiology, immunology, and other research studies**

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Richard L. Whelan MD

Physical Address: 425 W 59TH Street Suite 7B New York, NY 1019

Mailing Address: *425 W 59TH Street Suite 7B New York, NY 1019*

Phone: 212-523-8172

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A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

At the time of your surgery 1 to 4 years ago you agreed to contribute blood and, if you had a cancer, possibly a sample of your tumor to a "Tissue Bank". The goal of that effort was to build and maintain collections of cancer and blood samples that would be used for future research studies concerning cancers and the surgery used to remove them. The permission you signed before your surgery gave permission for blood samples to be taken up until 1 year after your surgery. You are now being asked to give permission for additional blood specimens to be taken during the 2nd through the 5th year after your surgery. These new blood specimens are to be used in conjunction with your preoperative blood specimen that was taken before your past surgery for new and future studies.

What is the purpose of tissue banks? Tumor and blood sample banks, alone and together with a clinical data base, allow the performance of a wide variety of research studies concerning cancer and the operations used to treat them. Obviously, tumor samples can only be taken from patients who have a malignancy. Tumor banks permit detailed analyses of cancers that allow researchers to determine the relationship between various genetic characteristics of the tumor and the tumor's ability to grow and invade. Such tumor analysis can also lead to new treatment approaches that are more

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specific and, in general, less toxic than standard chemotherapy drugs. In patients who received chemotherapy or radiotherapy before their tumor was resected, the tumor bank can also reveal to researchers the effects of the preoperative treatment on the tumor.

Blood sample banks allow measurement of the levels of proteins and other factors known to affect our physiology, immune system function, and the blood's ability to support or inhibit tumor growth. A blood sample bank that contains specimens from before and after surgery also allows studies that will help us better understand how surgery affects the body. Postoperative blood specimens are useful for a variety of reasons. Early postoperative specimens can be used for studies that assess the impact of cancer removal and surgery in general. Later postoperative specimens, when utilized in conjunction with the preoperative samples, can be used to look for blood markers of tumor recurrence that usually recur within 5 years of surgery.

The results of the blood tests that are done on your blood specimens will not be shared or given to you unless these results might have a bearing on your condition or overall health. If you agree to this "addendum" consent then 1 to 3 blood samples would be taken from you between the start of the 2nd and the end of the 5th year after your surgery. A total of 15 cc of blood (about 3 teaspoons) will be taken for each sample.

All tissue samples and clinical data in the tissue and data bank are de-identified which means that the names and other information regarding patients who agree to contribute tissue and data to the bank are kept fully confidential. When tissue samples are utilized for studies they are identified by number; no names or other identifying information is associated with the data.

Funds for conducting this research are provided by Dr. Richard Whelan MD and the Mount Sinai Roosevelt Hospital.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

You have already agreed, at the time of your surgery 1 to 4 years ago to contribute blood specimens for research purposes during the first year after surgery (if you had a cancer you most likely also gave permission for a piece of your cancer to be taken and stored). This consent addendum is now asking you to allow 1 to 3 additional blood samples to be obtained during the second until the end of the 5th year following your surgery. It is hoped that between 60-70 patients who underwent surgery 1 to 4 years ago will participate in this effort.

DESCRIPTION OF WHAT'S INVOLVED:

One to 4 years ago, when you underwent surgery at Roosevelt Hospital in New York City, you voluntarily enrolled in a tissue banking study wherein samples of your blood and, if you had a cancer, a tumor sample was taken for research purposes. As part of that study, blood samples were taken before your operation and, in some cases, at multiple time points after surgery. These blood and tumor samples were to be used for research studies that would increase our knowledge about cancer and hopefully lead to new ways to diagnose and treat cancer. The Mount Sinai Roosevelt (the

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hospitals new name) tissue bank is now participating in a study that is investigating a new diagnostic blood test that it is hoped will allow for early detection of cancer recurrences. In order to do this study, samples of blood taken 1 to 5 years after surgery from cancer patients and patients who had surgery for benign problems (example: diverticulitis, polyp, etc.) are needed. The purpose of this consent is to get your permission to take a blood sample from you for this new study. Because the study consent that you signed before your operation only allowed for blood samples to be taken for 1 year after surgery, a new signed consent is needed before new samples can be taken. If you agree, a total of 15 cc of blood would be taken (about 3 teaspoons) 1 to 3 times. No samples can be requested or taken beyond the 5 year point after your surgery. The blood would be used for the above mentioned study and, possibly, for future studies.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: allow 1 to 3 blood samples to be taken during the 2nd through 5th years following your surgery.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you. You will not be reimbursed for your travel or time that may be required for study visits.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. The tumor and blood banks that result from this study will help doctors to understand tumors, in general, and the blood compositional changes associated with cancers. However, possible benefits may be that new anti-cancer drugs may be developed as result of studies done with the tissue banks. The postoperative blood bank specimens and the clinical data base will help researchers determine how the various operations done to remove cancers and benign problems affect the composition of the blood and how they alter physiologic function. Other important immunologic effects or growth factors may also be discovered as a result of this study. These discoveries, may, in turn, lead to new treatments or drugs that would lessen the stress that surgery induces.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

IRB Approved

Study ID #: 09-113 **Form Version Date:** 5/20/2015

There are minimal risks associated with venipuncture (the taking of blood samples) including: discomfort, hematoma or bruising at the site of phlebotomy. Very rarely, a localized infection around the blood drawing site can develop which can be treated with antibiotics, warm soaks, and elevation. Another potential risk is the loss of blood caused by the venipuncture. It is highly unlikely the blood loss associated with this banking study would be the cause of any serious problems.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

I have discussed this study with [**my surgeon, Dr. Whelan, Tissue bank member _____ (circle one)**] to my satisfaction. I understand that my participation is voluntary and that I can withdraw from this study at any time without prejudice. I have read the above and agree to enter this research study. Signing this form does not waive any of my legal rights.

Yes / No (Please circle): I consent to 1 to 3 additional blood samples to be taken during the 2nd through 5th year following my surgery.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator, Dr. Richard L. Whelan, at 212 -523-8172

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to end your participation in this study and not permit further blood samples to be taken, please contact the Principal Investigator, Dr. Richard L. Whelan either in person or via phone at (212)523-8172. If you so direct, at the time you end your participation in the tissue bank, you can request that your tissue specimens not be used in any future research studies. In this case, your frozen and paraffin imbedded tissue samples will withdrawn from the bank and destroyed and disposed of in accordance with standard procedures.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. However, no additional data or information would be entered into the data bank. Also, the investigators will not review your medical records or other confidential records requiring your consent. However, the investigators may consult public records, such as those establishing survival statuses.

IRB Approved

Study ID #: 09-113 **Form Version Date:** 5/20/2015

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator, Dr. Richard L. Whelan at 212-523-8172

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

IRB Approved

Study ID #: 09-113 **Form Version Date:** 5/20/2015

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

The tumor and blood bank portions of this study contain the following de-identified data for each patient in order to allow the specimens to be categorized: age, sex, other medical problems and conditions, main diagnosis, pathology results, and tumor stage (where applicable). The long term cancer outcome data to be included in the clinical outcome data base portion of this study includes the following de-identified information (in addition to items listed immediately above): 1) results of all radiographic tests done in follow up for the purposes of detecting cancer recurrences or growth of persistent tumors (including CT, PET, MRI, ultrasound or other tests); 2) new historical and physical examination findings obtained during follow up evaluations, 3) relevant blood test and/or future biopsy results relating to the cancer, 4) information regarding chemotherapy or radiotherapy treatments received before or after the cancer resection, and 5) outcome data obtained from your medical or radiation oncologist or other of your physicians. One method by which researchers will get information regarding your operation, tests, and other treatments is from your medical records at Roosevelt Hospital and from your surgeons office.

As mentioned above, all of your data that is used for research purposes will be kept in a de-identified data base in which you will be assigned a number. There will be a single "key" file that will contain the names, dates of birth, addresses, medical record numbers, social security numbers, key dates (admission, discharge, and operation dates) and telephone numbers of study patients. Only the Principal Investigator and the tissue bank manager and study coordinator will have access to this "key". This information will not be shared with any collaborating investigators.

The researchers will also get information from your medical record

During the study the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

IRB Approved

Study ID #: 09-113 **Form Version Date: 5/20/2015**

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project: Dr. John Robertson, University of Nottingham England
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

IRB Approved

Study ID #: 09-113 **Form Version Date: 5/20/2015**

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Study ID #: 09-113 **Form Version Date: 5/20/2015**

Signature Block for Capable Adult

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

DO NOT SIGN THIS FORM AFTER THIS DATE → **08/05/2016**

Signature of subject	Date
Printed name of subject	Time [required if used for FDA documentation purposes]

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	*Date*
Printed name of person witnessing consent process	Time