

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai
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Study ID #: 10-1180

Form Version Date: 03/11/2019

TITLE OF RESEARCH STUDY:

Title: GU Cancer Database and Biorepository:

Discovery and Validation of Biomarkers associated with Clinical Outcomes

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: William K. Oh, M.D.

Physical Address: 1425 Madison Avenue, Icahn Building, 1st floor, NY, NY 10029

Mailing Address: 1 Gustave Levy Place Box 1079, NY, NY 10029

Phone: 212-659-5429

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 create a bank of stored tissue specimens, blood, body fluids, and/or urine for the purposes of present and future biomedical research about conditions similar to yours. Stored tissue specimens are groups of cells taken from your body that are preserved so that they can be examined later. Biomedical research is a systematic investigation to aid and support medical knowledge.

You may qualify to take part in this research study because you have or have had a genitourinary (GU) tumor mass and you may be scheduled for or have already had surgery at Mount Sinai Medical Center or another hospital.

The study is financed through a departmental grant awarded to the Principal Investigator, Dr. William K. Oh, M.D.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last until you request to terminate your participation. Otherwise your participation will last indefinitely.

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The number of people expected to take part in this research study at Mount Sinai is approximately 500 patients annually.

DESCRIPTION OF WHAT'S INVOLVED:

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

At the first visit following the signing of the consent form, you will be asked to:

- 1) Allow us to enter information already in your medical record **and Mount Sinai's Data Warehouse** into a database
- 2) Allow us to enter new information added to your medical record into a database.
- 3) Give up to 44.5 ml blood sample for research purposes. If your doctor has ordered blood tests for you, we will collect additional tubes of blood; you will not need to have a second needle stick. If your doctor has not ordered blood tests for you, you will have one needle stick in order to obtain a blood sample for research purposes.
- 4) Give a urine sample for research purposes in some cases.
- 5) Complete a short questionnaire asking about your health at the end of this visit.

Every time that you return to this clinic for follow-up visits with your doctor, you will be asked to:

- 1) Allow us to enter new information added to your medical record **and Mount Sinai's Data Warehouse** into a database.
- 2) Give up to 44.5 ml blood sample for research purposes. If your doctor has ordered blood tests for you, we will collect additional tubes of blood; you will not need to have a second needle stick. If your doctor has not ordered blood tests for you, you will have one needle stick in order to obtain a blood sample for research purposes. Blood will not be drawn more than two times per week and will not draw more than 50 ml in an 8 week period.
- 3) Give a urine sample for research purposes in some cases

If you undergo a biopsy or surgery related to your cancer after enrolling in this study, we will take a piece of your body part that has cancer. This is known as a tissue specimen and is ordinarily removed and inspected by your doctor. Sometimes, there is extra tissue that is not needed by your doctor and is usually thrown away. We ask that you allow us to have this extra tissue for biomedical research. This extra tissue will be linked to your clinical information but the key will only be known to study staff. In some cases, pieces of tissue specimens from procedures such as cystectomy (removal of bladder) and transurethral resection of bladder tumor (TURBT) may be collected in the operating room and provided to a research laboratory without submission to surgical pathology. If you have your biopsy or surgery outside of Mount Sinai, we will ask you to complete a release form so that we can get any extra tissue that is still available. Your decision to let us have this extra tissue will not alter your treatment or surgery in any manner.

If you have undergone a biopsy or surgery related to your cancer before enrolling in this study, any not needed extra tissue collected will then be linked to your clinical information, but the key will only be

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known to study staff. If you have your biopsy or surgery outside of Mount Sinai, we will ask you to complete a release form so that we can get any extra tissue that is still available. Your decision to let us have this extra tissue will not alter your treatment or surgery in any manner.

If you undergo a surgery related to your cancer, you will receive two short questionnaires by mail to complete both before and after the surgery with stamped pre-addressed return envelopes. Also, if you have a bladder cancer diagnosis, you may be approached to complete an additional 30 minute questionnaire, in person or by phone, regarding your health and lifestyle. If you decide not to complete these questionnaires, it will not impact your participation in the study. We would also like to find out how you are doing after surgery. If you receive post-operative care at Mount Sinai, we will access your medical records for this purpose. We may need to contact you or your doctors to gather additional information about your health status. If you receive care outside of Mount Sinai, we will ask that you sign a Release of Record Form so that we can access this information.

All specimens collected will be indefinitely stored for use in present or future research. These studies may be performed here at Mount Sinai, or in other institutions, for research either directly or not directly related to your condition. For use of biospecimens and/or clinical data by investigators not affiliated with this study, there will be a scientific review of their research to be sure that it has approval by the appropriate biomedical research regulatory board. If you choose not to let us collect your excess tissue from biopsies and surgeries, this tissue will be disposed of by your treating doctor.

The research requires that we know who the specimens came from and certain health information about you. Thus, we are requesting your permission to link information collected from your medical reports to your specimens so that we may better understand the importance of the results of the research done on these specimens. Clinical information may be shared with other investigators at other institutions in a totally confidential manner, without the use of your name or other identifying factors such as your social security number.

Approved present or future researchers may utilize different study techniques known as diagnostic assays (tests), including genetic testing, aimed at better understanding and treating conditions similar to yours. **Genetic testing allows for the analysis of a person's unique DNA, RNA, and related proteins to check for mutations (changes) that carry an increased risk of or predisposition to cancer. DNA contains the instructional "blueprint" used for the development and functioning of all known living cells. RNA uses this "blueprint" to create related proteins. Proteins control biochemical reaction and determine the physical structure of each cell.** These tests will help us to better understand the events associated with the development of GU cancers as well as their possible reappearance following treatment. It is possible that researchers may identify substances from or in your DNA, RNA, and related proteins that have good treatment value, and therefore commercial value. You will not receive monetary reimbursement if this occurs.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most large employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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There are currently no plans to contact participants to inform them about any finding of the study. The results of this research study may be published. You will not be identified in publications without your permission.

In summary, it will be possible to identify you as the donor of the specimen; this link to your identifying information will be known only to database staff. If you decide not to participate after enrolling in the study and ask in writing, we will destroy the specimen. If we have already provided your specimen to a researcher, we will ask that he/she destroy the specimen as well.

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by the Icahn School of Medicine at Mount Sinai, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." **A researcher who wants to study the information must apply to the database.** Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

The researchers would like to ask your permission to keep blood, urine, tissue, and other body fluid specimens collected from you during routine clinical care to use them in future research studies. They would also like to know your wishes about how they might use your specimens in future research studies. You should also know that it is possible that products may someday be developed with the help of your specimens, and there are no plans to share any profits from such products with you.

- (1) Do you give the researchers permission to collect blood from you for research purposes during a regularly scheduled clinic visit as outlined above? Please initial your choice:

Yes _____ No _____

- (2) Do you give the researchers permission to collect future tissue samples from you for research purposes as outlined above? Please initial your choice:

Yes _____ No _____

- (3) Do you give the researchers permission to obtain pieces of tissue samples directly from the operating room without evaluation by surgical pathology?

Yes _____ No _____

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- (4) Will you allow the researchers to retrieve relevant clinical information from your medical records, **Mount Sinai's Data Warehouse**, laboratory tests, radiology reports, operative notes, pathology reports, and discharge summaries for purposes not related to the current study? Please initial your choice:

Yes _____ No _____

- (5) Do you give the researchers permission to contact you in the future to collect additional information about you, discuss how your specimens might be used, or to discuss possible participation in another research project? Please initial your choice:

Yes _____ No _____

- (6) Do you give the researchers permission to keep the specimens indefinitely and use them for future studies that are not related to the purpose of the current study (for example, a different area of research)? Please initial your choice:

Yes _____ No _____

(a) If the future research in a different area can be done without having to know that the specimens came from you personally, that will be done.

(b) If the future research in a different area requires that it is known specifically who the specimens came from, then one of the following will be done:

(i) If you allowed the researchers to contact you in the future, they will be able to contact you to explain why your specimen is needed and what will be done with it. Your permission will be asked to use your specimens in that research project.

(ii) If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical, for example, because you have moved, your specimens may still be used. Either all links to your identity will be removed from the specimens, or an Institutional Review Board will be asked for permission to use the specimens linked to your identity. The Institutional Review Board (IRB) is a committee of doctors and scientists and non-scientists and people not associated with this hospital or medical school whose job it is to protect people who participate in research. The IRB can give permission for researchers to use and share health information connected to specimens that are linked to people's identities, but only if it determines that doing this will not be more than a minimal risk to people or their privacy.

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: continue to see your doctor for your regular clinic visits.

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- 2) Allow us to enter new information added to your medical record into a database.
- 3) Give up to **44.5 ml blood sample for research purposes**, if you have initialed "Yes" to question 1.
- 4) Give a urine sample for research purposes in some cases.
- 5) Complete a short questionnaire asking about your health at the end of this visit.

Every time that you return to this clinic for follow-up visits with your doctor, you will be asked to:

- 1) Allow us to enter new information added to your medical record into a database.
- 2) **Give a 44.5 ml blood sample for research purposes**, if you have initialed "Yes" to question 1.
- 3) Give a urine sample for research purposes in some cases

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.

POSSIBLE BENEFITS:

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others include the development of better diagnostic and treatment programs for GU cancers.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Group Risks

Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

Privacy Risks

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database includes genetic information,

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a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

Risks of providing samples for DNA sequencing: There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers over 15 people to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Risks of questionnaires: In the event that investigators ask you to complete questionnaires, you may be asked questions that make you feel uncomfortable. You do not need to answer any question(s) that you prefer not to answer.

Risk of loss of private information: this risk always exists, but there are procedures in place to minimize the risk.

The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

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.

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.

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 stop being in the research study, please contact the Principal Investigator or the research staff. You may withdraw permission for use of your specimen(s) and request that they be destroyed at any time by contacting the Principal Investigator at the address listed on page 1 of this form. This request must be made in writing. If you decide to have your specimen(s) destroyed, any data or analysis that were done before your request will not be removed from the study; however, all of your remaining specimen(s) will be destroyed, and no additional analysis will be done with your

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specimen(s). If we have already provided your specimen(s) to another researcher, and that specimen has not already been used, we will ask that he/she destroys the specimen(s) as well.

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 212-659-5429.

If you experience an emergency during your participation in this research, contact the Principal Investigator at 212-659-5429, call 911 or go to the emergency room.

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.

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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.

What protected health information is collected and used in this study, and might also be disclosed (shared) with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, dates directly related to individual (birth, admission, discharge, etc.), telephone number, and medical records number. The information in the medical record and Mount Sinai's Data Warehouse may include medical history, including current or past medications or therapies, illnesses, conditions or symptoms. We will gather information about your health, or results of blood, or radiological studies (x-rays, CT scans, MRI scans, etc.).

The researchers will also get information from your medical record information from Mount Sinai Hospital, Mount Sinai Outpatient Clinics, Mount Sinai Faculty Practice Associates, and your primary medical doctor pertinent to your medical condition.

During the study the researchers will gather information by:

- 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.

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

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list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- 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, 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.

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

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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.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

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.

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Form Approval Date: **04/10/2019** DO NOT SIGN AFTER THIS DATE → **09/15/2019**

Rev. 4/1/15

IRB Form HRP-502a

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai
Page 12 of 12



Study ID #: 10-1180

Form Version Date: 03/11/2019

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 →

09/15/2019

Signature of subject

Date

Printed name of subject

Time

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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