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## TITLE OF RESEARCH STUDY:

The Insulators' Tissue Bank

## PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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## WHAT IS A RESEARCH TISSUE BANK?

A research tissue bank is when scientists collect body tissues to 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 tissue bank. 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 tissue bank to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research tissue bank which might make you change your mind about participating will be given to you promptly.

## PURPOSE OF THIS RESEARCH TISSUE BANK:

The purpose of this research tissue bank is to collect asbestos-related-tumor tissue and blood specimens from people exposed to asbestos.

Asbestos workers have high rates of lung cancer and mesothelioma and tissue from any asbestos-related medical conditions that they might develop are very helpful to research that aims to understand how asbestos causes cancer or develop better treatments for asbestos-related cancer.

You may qualify to take part in this research tissue bank because you are currently or were previously exposed to asbestos.

Funds for conducting this research tissue bank are provided by the International Association of Heat and Frost Insulators and Allied Workers. The IAHFIAW does not have access to information about who has or has not chosen to participate in this research tissue bank.

## LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research tissue bank will last indefinitely (even after your death), or until you withdraw from the study.

The number of people expected to take part in the tissue bank is up to 30,000, throughout both the U.S. and Canada. Participation in the tissue bank is different from donating tissue. Participation in the tissue bank means agreement to donate tissue if you undergo a procedure for the diagnosis or treatment of an asbestos-related condition. Being a donor means that you actually donate tissue. You might never develop an asbestos-related condition so, although you will be a participant, you might not ever be a donor. Donors will donate tissue when they undergo a medical procedure to diagnose or treat an asbestos-related condition. Examples of such procedures are biopsy and surgery. The number of expected donors at Icahn School of Medicine at Mount Sinai is up to 50 a year. The number of expected donors at all other Medical Centers throughout North America is up to 450 a year.

## DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research tissue bank, the following information describes what might be involved and, at the end, gives you the opportunity to agree to be involved in, or elect to not be involved in, each aspect of the tissue bank.

*How the tissue bank can find out that you are going for a surgical procedure*
If you ever go in for a surgical procedure (examples are: biopsy, CT-guided biopsy, thoracoscopy, wedge resection, lobectomy, pneumonectomy) for an asbestos-related condition (mesothelioma, lung cancer) we will need to know. You can call us, or, with your permission: *(a)* your primary care physician or surgeon can let us know (we will be sending him/her information on the tissue bank); or *(b)* if you happen to have told your union, your union can let us know.

*What will be involved if you do ever go for a surgical procedure - tissue*
Participation in this study will also involve, if you ever undergo a procedure for the diagnosis or treatment of an asbestos-related condition, the donation of some of the spare tissue that is obtained during the normal course of some procedures, but which is not required for your routine care. If the particular procedure you undergo does not result in spare tissue, then no tissue will be available for the tissue bank – we will not be asking for any tissue to be obtained explicitly for the tissue bank We ask only that you allow us to use your spare tissue for biomedical research. Donating tissue to the Insulators' Tissue Bank does not require you to undergo any extra diagnostic or treatment procedures, and does not change in any way how diagnostic or treatment procedures are done.

*What will be involved if you do ever go for a surgical procedure - blood*
In addition to the tissue you donate, we would like to get some of your blood because blood is also useful for research purposes. Routine before-surgery and after-surgery care sometimes requires blood

samples to be drawn. If such samples yield spare blood, we will collect that. If there is no spare blood from your routine pre-operative or post-operative blood draws, we would like to draw 6 teaspoons of blood for the purposes of the tissue bank. Blood will be collected with a needle from a vein in your arm. We would like to do this each time you undergo surgery.

*How tissue and blood samples will be collected and stored*
We need to know who the tissue and blood samples come from, and health information about you, but any samples you might donate will not be stored labeled with your name or your social security number or with anything else that can be used to identify you directly. Instead, any tissue samples you might donate will be stored labeled with a coded 'donor identification number' (samples labeled in this way are referred to as being 'identifiable') that will be created especially for. In this way, only the staff of the Insulators' Tissue Bank at Mount Sinai will be able to link the tissue samples you donate back to your name. Researchers not involved in maintaining the tissue bank will have no access to your identity. If a research project ever requires identifiable information about you, you will be re-contacted to give you the opportunity to consent or decline to participate in that particular research project. It is also possible that under some particular circumstances an ethical review board, either at Mount Sinai or at the researching institution might grant the particular project a waiver of informed consent.

The instructions to the medical center where your spare tissue/blood is collected will dictate that your samples be collected into tubes that are labeled with a personal identifier such as your name, rather than the donor identification number we provide to them. If this happens, your samples will be transferred, when they arrive at Mount Sinai into containers that do not identify you by way of a personal identifier but which, instead, identify you by way of your donor identification number.

*How long your tissue, blood and information will be stored*
Your samples and information will be stored for use in research indefinitely, or until you withdraw from the study.

*Access to your identifiable information*
We will remove your identifiable health information, and use the linked code when your samples are distributed for research. It is, however, possible that your doctor might also be a researcher in another study that wishes to use samples you have agreed to donate. If this happens, your doctor might have access to your identifiable information by way of his or her own medical records, but your doctor will not have access to your identifiable information by way of the Insulators' Tissue Bank.

Your health information will not be available to your union, employers or insurance companies, and will not be put in any of your medical records, either while you are alive, or in the event of your passing. Neither will your health information be available to your family while you are alive. If, however, you wish, we will make your health information available to your family in the event of your passing.

*Contacting your doctors*
If there are questions you cannot answer about your health, we may need to contact your personal physician(s) and/or any medical centers at which you might have been seen for diagnosis or treatment of asbestos-related medical conditions, so that we can gather information about your health status. If you receive care at Mount Sinai, we will access your medical records.

*What your tissue samples, blood and information could be used for*
Your donated tissue samples and health information will be used in future studies at Mount Sinai or other institutions to conduct research into the causes of, interventions for, and treatments for asbestos-related illnesses and conditions (principally mesothelioma and lung cancer). Also, if you so wish, the tissue samples you donate will be used for research into cancers other than mesothelioma and lung cancer, and, again, if you wish, medical conditions other than cancer. Your wishes with regard to the purpose(s) for which the tissue samples you donate is (are) used are recorded by way of your answers to the questions below.

The research studies that use the tissue samples you donate might be performed at Mount Sinai, or might be performed at other institutions. In all cases, there will be a scientific review of the research to be sure that it has approval by the appropriate biomedical research regulatory board. You should be aware that, even though such research might not start out by being directed to developing a commercial/for-profit product, researchers might make discoveries using the tissue samples you donate, that lead to the commercial/for-profit development of products, diagnostic tests or treatments, and that you will not have any intellectual property rights, nor will you receive any direct financial benefit from any such developments that arise.

It is possible that a biotechnology or pharmaceutical company might wishing to do research using samples from the tissue bank, possibly including the tissue samples you donate, for the purposes of developing drugs, treatments, or tests for medical conditions like yours. A commercial/for-profit product may result from the use of your specimens, but you will not have any intellectual property rights to such products, nor will you receive any direct financial benefit from the development of such products.

You should also be aware that the tissue bank will charge users a fee for the use of tissues, and will charge commercial (e.g. drug company) researchers more than it charges academic (e.g. university) researchers. It is hoped that the fees charged will eventually fully support the running of the tissue bank, but this is not likely to be the case for several years.

Not all research studies that might want to use the tissue samples you donate can be anticipated at this time. We would therefore like to be able to contact you in the future for the purposes of explaining to you any future studies, so that you can be properly informed before you agree to participate.

Some future research is likely to include genetic testing (genetic testing studies DNA and RNA that contains the genetic information that is unique to you but can reveal information about conditions that are passed on in families) to better understand how different individuals respond differently to exposure to asbestos, and to treatment for mesothelioma and lung cancer, other cancers, and other medical conditions. In general, results of any such genetic testing will not be disclosed to you, nor to your doctor. If, however, research conducted on your tissues results in genetic findings which are subsequently confirmed by another laboratory and which the Scientific Advisory Committee of the tissue bank (a body made up of doctors, researchers and organized labor representatives) considers to be of sufficient importance to you for you to be informed (even though you might not be able to do anything about the results because they are based on your genes) then, you will be told of the results if you so wish (the question recording your wishes can be found below) and if the currently applicable institutional, state and federal regulations permit.

It is also possible that future genetic research may identify substances from or in your DNA or RNA that are helpful for treatment, and therefore commercial/for-profit value. You will not receive monetary reimbursement if this occurs.

*Access to your research results*
Neither you, your family, nor your health care provider will receive the results of the research performed on the tissue samples you donate. The ITB will, however, be asking all researchers that request ITB tissue to inform the ITB of the overall (aggregate) findings which the ITB intends to communicate to all the ITB participants *via* newsletter. The ITB will be requesting your individual results to be returned to the ITB so that they can be shared with future requestors of tissue, in order to make the research process more efficient. Any research results that are provided to the ITB by researchers will therefore be linked to linked to your other information (for example, your clinical data).

The results of any research conducted on the tissue samples you donate will <u>not</u> be available to your union, employers or insurance companies, and will not be put in any of your medical records, either while you are alive, or in the event of your passing. Neither will your research results be available to your family, neither while you are alive nor in the event of your passing.

Finally, if you choose to participate in this study, it will be important for us to keep in contact with you and find out how you are doing once a year, by telephone. If we lose contact with you, we would like to be able to contact your union to see if they have updated contact information for you. Your wishes with regard to these aspects of the study are recorded by way of your answers to the questions below.

1. Do you give us permission to collect, store and use tissue samples you donate, as described in the paragraphs above?

   (Please initial either 'Yes' or 'No') _____Yes _____No

(If your answer to 1. is 'no', please sign, date and print your name at the end of the consent form, without answering any further questions, and send it back to us.)

2. Do you give permission for your personal physician or surgeon to let us know when you are going for surgical testing or treatment for asbestos or mesothelioma?

   (Please initial either 'Yes' or 'No') _____Yes _____No

3. Do you give permission for your union to let us know when you are going for surgical testing or treatment for asbestos or mesothelioma?

   (Please initial either 'Yes' or 'No') _____Yes _____No _____Not Applicable

4. Do you give us your permission to contact, in the future, your doctors and/or any medical centers at which you might have been seen for diagnosis or treatment of asbestos-related medical conditions if there are questions you cannot answer about your health, so that we can gather information about your health status?

   (Please initial either 'Yes' or 'No') _____Yes _____No

5. Do you give us permission to collect and store 6 teaspoons of your blood, if there is no spare blood from either the before-surgery or after-surgery blood drawings that are a standard part of your clinical care, or if there is no blood drawn for as part of your standard clinical care?

   (Please initial either 'Yes' or 'No') _____Yes _____No

6. Do you give us your permission to contact you for the purposes of explaining to you any future studies, so that you can be properly informed before you agree or decline to participate in them?

   (Please initial either 'Yes' or 'No') _____Yes _____No

7. If research conducted on your tissues results in genetic findings which are subsequently confirmed by another laboratory and which the Scientific Advisory Committee of the tissue bank (a body made up of doctors, researchers and organized labor representatives) considers to be of sufficient importance to you for you to be informed, do you wish to be told of the results, if we are permitted to do so by the currently applicable institutional, state and federal regulations?

   (Please initial either 'Yes' or 'No') _____Yes _____No

8. In the event of your death, do you grant permission to your family members to have access to your research records from this study, to the extent permitted by regulations and law?

   (Please initial either 'Yes' or 'No') _____Yes _____No _____Not Applicable

If you choose to participate in this study, we will need to keep in contact with you, and would like to find out how you are doing once a year, by telephone.

9. Do you give us permission to contact you periodically, to keep in contact with you and to find out how you are doing?

   (Please initial either 'Yes' or 'No') _____Yes _____No

10. Do you give us permission to contact your union if we lose contact with you and/or for your union to give us your updated contact information if they become aware of it?

    (Please initial either 'Yes' or 'No') _____Yes _____No _____Not Applicable

## YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research tissue bank you will not be responsible for doing anything. However, the tissue bank will be more useful if we can get your spare tissues if you go for testing (for example, biopsy, thoracoscopy) or treatment (for example, surgery) for mesothelioma or lung cancer. For us to do that, we are going to want you to let us know if you go for testing (for example, biopsy, thoracoscopy) or treatment (for example, surgery) for mesothelioma or lung cancer. If you consent to blood collection, you will also need to undergo blood collection.

## COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research tissue bank. Being in this research tissue bank will not lead to extra costs to you.

## POSSIBLE BENEFITS:

You are not expected to get any benefit from participating in, or donating to, this research tissue bank. Others might not benefit either. We hope that the Insulators' Tissue Bank will provide tissue samples to research studies that will generate knowledge that will benefit others in the future.

## REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Participating in this research tissue bank will not pose any risks to you from diagnostic or treatment procedures for any medical conditions you might develop in the future because participation in the tissue bank does not require any additional procedures nor the alteration of any routine procedures.

If we obtain a blood sample from you, rather than getting excess, routine pre-operative or post-operative blood, you should be aware that taking blood might result in some temporary pain and bruising where the needle enters the body, and, rarely, fainting. There is a very slight risk of developing an infection at the site of the needle stick; this is minimized by the use of sterile techniques and trained personnel.

**Physical Risks**
•If a blood sample is not taken from you, there are no physical risks associated with this project.
•If a blood sample is taken from you, there are very few physical risks. Possible side effects from drawing the blood sample include mild pain, bleeding, bruising, and infection at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually last only a few minutes.

**Psychological or Social Risks Associated with Loss of Privacy**
•Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measure that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.
•While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare

information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.
•Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to employers, health providers, insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease or by leading to the denial of employment or insurance for you (or a relative).
•There also may be other privacy risks that we have not foreseen.

While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. There are some state laws that protect against genetic discrimination by employers or insurance companies, but there is no federal law yet that prohibits such discrimination. We believe that the benefits of learning more about diseases outweigh these potential risks.

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 of 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.

## OTHER POSSIBLE OPTIONS TO CONSIDER:

Because we are not inviting you to consent to any additional or altered diagnostic or surgical procedures (instead, we are inviting you to consent to the storage some of your spare tissues from regular diagnostic or surgical procedures), the only other possible option to consider is not participating in the tissue bank.

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

## IN CASE OF INJURY DURING THIS RESEARCH TISSUE BANK:

If you believe that you have suffered an injury related to this research as a participant in this research tissue bank, you should contact the Principal Investigator.

## ENDING PARTICIPATION IN THE RESEARCH TISSUE BANK:

You may stop taking part in this research tissue bank 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 any other hospital, to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research tissue bank, please contact the Principal Investigator at the address on the first page.

If you stop participating, already collected information will be removed from the tissue bank database and any remaining stored tissue samples of yours will be discarded. We will also request each researcher who has received any samples of the tissue you donated destroy them too but will not be able to enforce this request so you should therefore be aware that researchers who have already received samples of your tissue might continue research with these specimens.

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 tissue bank may still use the information that was already collected if that information is necessary to complete the research tissue bank. 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 tissue bank.

Withdrawal without your consent: the Principal Investigator or Mount Sinai can stop your involvement in the tissue bank at any time without your consent. This might happen if, for example, the tissue bank is being stopped; if the Principal Investigator believes it is in your best interest, or for any other reason. specimens or data stored as part of the tissue bank can also be destroyed without your consent.

## CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research tissue bank, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator, Prof. Todd, at 212-824-7053.

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 following 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.

## 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, telephone/fax numbers, date of birth, date(s) of diagnostic and treatment medical procedures for asbestos-related conditions, date(s) of admission(s) and discharge(s) from hospital, date of death, e-mail address (if you wish us to communicate with you *via* email), medical records number(s).

The researchers will also get information from your medical records of both your personal physician(s) and any medical centers at which you might be seen for diagnosis or treatment of any asbestos-related medical conditions.

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.)

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

- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In almost 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. 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 Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will 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, 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. They 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 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 Mount Sinai Hospital Notice of Privacy Practices that contains more information about how Mount Sinai 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.

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**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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Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, it is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

## 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 →** **12/31/2017**

| | |
|---|---|
| Signature of subject | Date |
| Printed name of subject | |

## Person Explaining Study and Obtaining Consent

| | |
|---|---|
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | |

***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* | |