TITLE OF RESEARCH STUDY:

Title: New York Area Workers Cohort

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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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 be available to explain this research study to you, either in person or by phone. 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 increase our knowledge about workers' health. Workers in a variety of occupations encounter workplace exposures that may have health effects. These exposures can include chemicals and/or physical/mental stressors.

The overall goal of our study is to create a large group of workers who provide information on their health and well-being in a way that is similar to the information provided by the World Trade Center General Responders. Using your information in combination with others like you, we hope to gain a better understanding of workers' health and compare your health to that of the World Trade Center General Responders. You may qualify to take part in this research study because you are employed or retired and you are not eligible for participation in the World Trade Center Health Program.

Funds for conducting this research are provided by the Centers for Disease Control and Prevention/ The National Institute for Occupational Safety and Health (CDC/NIOSH).

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last for your lifetime. The number of people expected to take part in this research study is 11,200.

DESCRIPTION OF WHAT'S INVOLVED:

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

- Your participation in this research study will take place either at the location where you were enrolled, for example the Mount Sinai Selikoff Occupational Health Clinic, or online through our secure website.
- You will provide answers to a set of questions that collect information on the following topics:
  - Time you may have worked or spent at the World Trade Center site or related areas, for example, the Staten Island Landfill after September 11, 2001.
  - Your age, sex, race/ethnicity, height, weight, socioeconomic status, education, current occupation and occupational history, physical activity and reproductive history.
  - Your medical history included physician diagnoses of health conditions as well as family medical history, and smoking and alcohol consumption.
  - Your mental health status including, general health and different mental health symptoms, such as anxiety or depression.
- The completion of the questionnaire should take 30-45 minutes.
- Periodically (every one to two years) we will contact you and ask you to complete a follow-up questionnaire similar to the first one. We will ask you to provide updates on your physical and mental health as well as changes to your work status. Completion of the follow-up questionnaire should take 20-30 minutes.
- If you complete a questionnaire in person, there will be a research staff member available to assist with any questions you may have. If you complete a questionnaire through our secure study website, study staff will be available by phone or by email (the phone number and email address will be on the website).
- If you receive medical care through the Mount Sinai Health Care System, we will review your electronic medical records for information on any pulmonary function test results and routine physical exams to collect data on heart rate and other vital signs, blood pressure, weight and height, as well as other physical or mental issues. If you receive medical care from the Selikoff Occupational Health Clinic, we will collect the detailed occupational history (past and current) that is provided in the clinic records.

- In the future, you may be asked to provide biological samples. For example, a blood sample (about 2 teaspoons), a urine sample (3-4 Tablespoons), or a saliva sample (1/2 teaspoon). These samples will be collected either at Mount Sinai or at a commercial clinical laboratory located near you. Donating these samples should take 10-20 minutes.

  Would you be willing to provide biological samples in the future? Please initial your choice:

  Yes_____ No_____

- The researchers would like to ask your permission to keep specimens (blood, urine and/or saliva) and information collected from you during this study to use them in future research studies. They would also like to know your wishes about how they might use your specimens and information in future research studies. You should also know that it is possible that products may someday be developed with the help of your specimens or information, and there are no plans to share any profits from such products with you.

(1) Will you allow the researchers to store your specimens and information to use in future research studies? Please initial your choice for each:

Specimens	Information
Yes _____ No _____	Yes _____ No _____

If no for both specimens and information, please stop here and continue to the next section (Your Responsibilities). If yes for either, please continue to the next question.

(2) The researchers will store your specimens and information in a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally). Are you willing to have your specimens and information stored this way? Please initial your choice for each:

Specimens	Information
Yes _____ No _____	Yes _____ No _____

If no for both specimens and information, please stop hereand continue to the next section (Your Responsibilities). If yes for either, please continue to the next question.

(3) 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_____

(4) Do you give the researchers permission to keep the specimens and information indefinitely and use them for future studies that are **directly related** to the purpose of the current study? Please initial your choice for each:

Specimens	Information
Yes _____ No _____	Yes _____ No _____

(5) Do you give the researchers permission to keep the specimens and information 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 for each:

Specimens	Information
Yes _____ No _____	Yes _____ No _____

(a) If the future research in a different area can be done without having to know that the specimens and information 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 and information 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 and information is needed and what will be done with it. Your permission will be asked to use your specimens and information 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 and information may still be used. Either all links to your identity will be removed from the specimens and information, or an Institutional Review Board will be asked for permission to use the specimens and information linked to your identity. The Institutional Review Board (IRB) is a committee of doctors and scientists and nonscientists 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 and information 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.

(6) Do you give permission to have portions of the specimens or information **given to other researchers** at Mount Sinai or other institutions for use in research that is either related or not related to the purpose of this study? Please initial your choice for each:

Specimens	Information
Yes _____ No _____	Yes _____ No _____

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:

- Completing an initial study questionnaire either at an in-person interview or through an online questionnaire.
- Agreeing to participate in subsequent study follow-ups for updates on your health, employment and other information.
- If you choose to, as part of future study follow-up, providing biological samples such as blood, urine or saliva.
- Letting the research staff know when your contact information has changed so that we can stay in touch with you.
- Responding to the researchers who may contact you for follow up and/or to obtain additional information or records regarding conditions that may be related to your current or former employment.

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.

Once you have completed an initial study questionnaire, you will be entered into a monthly drawing for a $50 electronic Amazon gift card.

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 increasing our knowledge about World Trade Center General Responders' health.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- You might feel uncomfortable answering some of the questions. You may decline to answer questions that you do not feel comfortable answering.
- 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.

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. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but <u>you must do so in writing</u> 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.

<u>Withdrawal without your consent</u>: 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 212-824-7105.

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.

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.

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

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, dates directly related to the individual (birth,

admission, discharge, date of death, etc.), e-mail/internet protocol (IP) addresses, social security number, and medical records number.

The researchers will also get information from your medical record if you have received medical care in the Mount Sinai Health System.

During the study the researchers will gather information through your completion of the questionnaires 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 list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: Centers for Disease Control and Prevention (CDC)
- The United States Department of Health and Human Services and the Office of Human Research Protection.
- Cancer Registries to confirm any cancer diagnoses you may report

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 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.

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.

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