TITLE OF RESEARCH STUDY:

Title: World Trade Center Health Program: Mount Sinai First Responders Biobank

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Panagiotis Roussos MD PhD

Physical Address: 1470 Madison Ave, New York, NY 10029

Mailing Address: 1470 Madison Ave, New York, NY 10029

Phone: 212-824-8982

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 and will not affect your ability to be monitored and treated at the World Trade Center Health Program Clinical Center of Excellence (WTCHP CCE).

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 achieve an even better understanding of the health impacts of the WTC disaster by combining information already collected through the WTCHP CCE with information about your body's biology such as genetics. The research information that has been gathered from you and your brother and sister 9/11 responders in the WTCHP CCE since 9/11 has been extremely important in helping us to understand the impact on people's health related to the attacks on the WTC. This information has helped to make more accurate diagnoses on 9/11 responders. It is helping us to design better treatments. It is helping us to predict what health problems to expect among responders in the future.

You may qualify to take part in this research study because you are enrolled in the World Trade Center Health Program — Clinical Center of Excellence.

Funds for conducting this research are provided by Mount Sinai

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last up to 10 years

The total number of people expected to take part in this research study at World Trade Center – Clinical Center of Excellence at Mount Sinai is 21, 689.

DESCRIPTION OF WHAT'S INVOLVED:

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

If you agree to participate in this research study, you will undergo a blood draw that takes place once every year for up to 10 years. This means that during your annual Monitoring blood draw you will provide 3 extra tubes of blood (2 tablespoons) every year along with the regular Monitoring blood tests, Since this blood draw will occur at your regular WTCHP CCE visits at Mount Sinai; you do not need to come in for additional visits for this study. Upon signing this consent, you will continue to remain part of this study even if you are unable to provide a blood draw every year.

In addition, by consenting to participate, you are giving the research team permission to study for the remainder of your lifetime all of the data collected about you through the WTCHP, as well as your complete electronic medical record at Mount Sinai. This includes any data recorded from any period of time where you were treated either at WTCHP CCE or other sites of Mount Sinai. All analyses will be done on groups of participants and you will not be individually identified.

For this study, researchers will look at your bio specimens for information about your genes. Genes are made up of DNA, and have the information needed to build and operate a human body. Since there is not enough known about these genetic differences to conclude that one variation makes it more or less likely to suffer from a disorder, the results of the genetic testing will not be released to you. In other words, for this study, genetic tests will be done for research purposes only. Besides information of your genes, several other hormones, chemicals, proteins and other markers of exposures to occupational and environmental hazards potentially related to stress and risk of illness may also be measured from your bio specimen.

The researchers would like to ask your permission to keep study information (e.g. blood) 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 study information in future research studies. The researchers will store your study 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. Only the principal investigator and other approved members of the research team will have access to the list linking the code to health- protected information. Your answers to the following questions will not affect your eligibility to participate in this project:

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

Yes_____No_____

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

Yes_____No_____

(3) Do you give the researchers permission to keep the bio-specimen and information indefinitely and use it for future studies that are not related to the purpose of the current study? Please initial your choice:

Yes_____No_____

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

(4) Do you give permission to have portions of the bio-specimen and 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? If bio-specimen or information is shared with other researchers, they will not contain direct identifying information. It will be labeled in a way that is linked to your identity through the use of a code that can indicate the information came from you personally. However, outside researchers receiving study information will not have access to identifying information. Please initial your choice:

Yes_____No_____

(5) Do you give permission to have portions of the specimens and/or data deposited in large public repositories, (explained below) for use in research with the limits you may have chosen above? Please initial your choice:

Yes_____ No_____

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 Icahn School of Medicine at Mount Sinai or another institution, 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 for permission to use 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. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

Study ID #: HSM#18-01161 **Form Version Date: 11-9-18**

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: providing 3 tubes (2 tablespoons) of blood in addition to the regular blood draw that will happen at the time of your visit to WTCHP CCE for research purposes every year. Once you agree and sign the consent form it will indicate that you will also be responsible for allowing the researchers to have access to all your medical records.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

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

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be that the discoveries made will improve understanding of the health impacts of 9/11 and improved treatment of related medical conditions.

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.

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.

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.

If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

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

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

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator, Dr. Panagiotis Roussos, at phone number 212-824 - 8982.

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.

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, dates directly related to the individual (birth, admission, discharge, date of death, etc.), medical records number.

The researchers will get access to all information in your records at Mount Sinai and the WTCHP CCE. This includes your electronic medical record, as well as any information collected through research studies at the WTCHP CCE. Examples of this information include your age, sex, ethnicity/race, occupational history within and outside the World Trade Center experience, history of exposure to human remains, blood, and/or bodily fluids during the recovery activities at the World Trade Center site, and use of personal protective equipment during the WTC activities.

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 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 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.

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.

Study ID #: HSM#18-01161 **Form Version Date: 11-9-18**

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.

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 cons*ent process*	Time