NYU Langone Health

INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

Title of Study: **NYU/Bellevue WTC Health Impacts Research Registry**

Principal Investigator:
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1. What is the purpose of this research registry?

Many advances in medicine have resulted from the study of information in the medical records of patients with a certain disease or condition. Because you are being seen as part of the World Trade Center Environmental Health Center, we are asking for your permission to allow us to place your past, current and future medical record information into a New York University/Bellevue World Trade Center Health Impacts Research Registry (NYU/Bellevue WTC Health Impacts Research Registry). Prior studies have suggested that exposure to WTC dust can be associated with new onset or worsening of some medical symptoms. By placing the medical record information of many patients such as you into a Research Registry, researchers will be able to conduct studies to increase knowledge about the health effects of exposure to World Trade Center dust. The Principal Investigator, Dr. Joan Reibman, will maintain the Research Registry and will only allow the Registry to be used for research as permitted by Institutional Review Board (IRB) policies and federal regulations.

The Research Registry will assist our investigators in two important ways:

First, it will allow researchers to review and study the medical records of many individuals to answer questions about the nature and treatment of environmental exposures such as yours.

Second, it will help researchers identify and recruit patients who are eligible for participation in future research studies.

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2. How long will I be in the study? How many other people will be in the study?

We estimate that the following number of subjects will enroll in this study across all sites: 20,000

SUBJECT PARTICIPATION:
☐ Inpatient
☒ Outpatient
☒ other [healthy subjects, etc.] Please specify: Healthy subjects

We will continue to place your medical record information into the NYU/Bellevue WTC Health Impacts Research Registry until 1) you are no longer living; 2) you withdraw your permission for participation in the Research Registry; or 3) you revoke your HIPAA Authorization (described below).

Your medical record information contained within the NYU/Bellevue WTC Health Impacts Research Registry will be used and disclosed for research purposes for an indefinite period of time.

If you receive medical care outside of the WTC Environmental Health Center, we will contact that medical provider for a request of your medical records. You will be asked to sign a separate medical release form for those medical records.

3. What will I be asked to do in the study?

We are asking for your permission to put your medical record information in the NYU/Bellevue WTC Health Impacts Research Registry. Identifiers will be removed from the identifiable private information. After such removal the information may be used for future research studies or shared with other researchers and we will not request additional informed consent from you to use these specimens as we have noted here.

4. What are the possible risks or discomforts?

There are no risks of physical injury associated with your participation in the NYU/Bellevue WTC Health Impacts Research Registry. Participation in this Research Registry does involve the possible risk that information about your health might become known to individuals outside of the World Trade Center Environmental Health Center.

We will attempt to preserve your confidentiality by assigning a special research code number to your medical record information stored in the Research Registry, and by removing personal identifiers (for example, your name, social security number, medical record number) from information stored in the Research Registry. Information linking the Registry code number to your name and these personal identifiers will be stored in a separate secure location.

5. What are the possible benefits of the study?

It is unlikely that you will receive any direct benefit as a result of your participation in the NYU/Bellevue WTC Health Impacts Research Registry.

However, medical record information contained within the Research Registry will be used for research studies directed at improving our knowledge and treatment of the health effects of exposure to WTC dust and this knowledge may benefit patients with similar conditions in the future.

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6. Will I be paid for being in this study?

You will not receive any payment for participating in this Research Registry. If new products or treatments are developed from research using Registry information, you will not benefit financially.

7. How will you protect my confidentiality?

Private information that could identify you will be used and shared to create the Research Registry and to provide Registry data to researchers. This section of the consent/authorization form describes how your information will be used and shared and the ways in which NYU School of Medicine will safeguard your privacy and confidentiality.

As described above, certain identifiers (e.g., your name, social security number, and medical record number) will be removed from your health information before it is placed in the Research Registry. Information from the Registry will only be used or disclosed for research that meets the requirements of the IRB and federal regulations; however, organizations or entities that oversee research, including federal and state regulatory agencies, and IRB(s) overseeing the research may receive your information, including identifiable information, if necessary to ensure that research meets legal and ethical requirements.

Researchers at this or other institutions may wish to study Registry information in future research. Before your information in the Research Registry may be used for a research project, all direct identifiers will be removed or the researcher must obtain approval from the IRB.

Confidentiality of Your Medical Records

Your medical records will be maintained in accordance with state and federal laws concerning the privacy and confidentiality of medical information. The confidentiality of your medical record is protected by new federal privacy regulations, as described below.

Confidentiality of Your Study Information

This Registry will include information that may identify you, either directly or indirectly. We will try to keep this information confidential, but we cannot guarantee confidentiality. Researchers using Registry data will be required to remove any identifying information before publishing the results of their research.

Retention of Your Study Information

Information placed in the Research Registry will be kept there and used for research indefinitely.

8. HIPAA Authorization.

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

If you sign this form you are giving your Authorization for the uses and sharing of your protected health information as described in this Consent/Authorization form. You have a right to refuse to sign this form. If you do not sign the form your information will not be placed in the Research Registry, but refusing to sign will not affect your health care, participation in the WTC Environmental Health Center, or payment for your health care.

This Authorization will not expire unless you revoke it in writing. You have the right to revoke your Authorization at any time, except to the extent that NYU/Bellevue has already relied upon to disclose data to the Research Registry. The procedure for revoking your authorization is described below.

By signing this form you authorize the use and disclosure of the following information to the Research Registry:

- Your medical records
- Results of laboratory tests performed in connection with your treatment

By signing this form you authorize the following persons and organizations to use or disclose information to create and maintain the Research Registry

- Every facility where you have received treatment or participated in research, including this hospital, and including each sites' research staff and medical staff
- Every NYUSM or Bellevue Hospital health care provider or affiliated provider who provides services to you
- Any laboratories and other individuals and organizations that analyze your health information in connection with your treatment or research participation at NYU/Bellevue Hospital or an NYU affiliate
- The members and staff of the site's affiliated Institutional Review Board
- The members and staff of the site's affiliated Privacy Board
- Principal Investigator: Joan Reibman, MD
- Research Coordinator
- Members of the Principal Investigator's Research Team
- The Patient Advocate or Research Ombudsman (GCRC)

Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule, the information is no longer protected by the Privacy Rule and may be subject to re-disclosure by the recipient.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study. Refusing to sign will not affect your health care, participation in the WTC Environmental Health Center, or payment for your health care.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form.

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How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

9. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

10. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

11. Permission to contact you about future research

This section authorizes the principal investigator and his or her co-investigators to contact you about future research. If you agree, then someone from Dr. Reibman's research staff might contact you in the future and he or she will tell you about a research study being conducted by the principal investigator and co-investigators or by external researchers with an IRB approved research study. At that time, you can decide whether or not you are interested in participating in a particular study. You will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

☐ I agree to be contacted by the Principal Investigator or Co-Investigators for future research studies.
☐ I **do not** want to be contacted by the Principal Investigator or Co-Investigator for research studies.

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care at any of the WTC EHC clinics. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for a future research study. It does not mean that you must join in any study.

12. Signature to participate in the Research Registry

When you sign this form, you are agreeing to take part in this research registry as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

For subjects unable to give consent, the consent for study participation and authorization to collect and use protected health information is given by the following authorized subject representative:

Name of Authorized Subject Representative (Print)	Signature of Authorized Subject Representative	Date

Select the category that best describes the above Authorized Subject Representative:

- ☐ Court-appointed guardian
- ☐ Health care proxy
- ☐ Durable power of attorney
- ☐ Family member/next of kin; for this category describe relationship below:

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Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date

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