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|  | **SUNY DOWNSTATE MEDICAL CENTER**  **BROOKLYN, NY 11203**  **INFORMED CONSENT & AUTHORIZATION TO USE INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION**  **ADDENDUM FOR RESEARCH APPROVED BY THE NATIONAL CANCER CENTER INSTITUTIONAL REVIEW BOARD** |
| **TITLE OF RESEARCH STUDY:**  **Protocol Number:**  **Version:**  **Location/Department:**  **Principal Investigator:** | |

**Introduction**

This form includes important additional information for you to consider when deciding if you want to be in a research study approved by the National Cancer Institute Central Institutional Review Board (NCI CIRB) and the Downstate Medical Center IRB. The IRBs ensure the conduct of research is in accordance with all federal, institutional, and ethical guidelines.

We provide the following information during the informed consent process, using forms approved by the NCI CIRB:

* the purpose of the research,
* the expected duration of your participation in the research,
* the procedures that will be followed,
* any procedures which are experimental,
* any reasonably foreseeable risks, discomforts, or benefits,
* whether there are any potential beneficial alternative procedures or treatments, and
* how your privacy and confidentiality will be protected and who will see your information.

When applicable, the investigator must also tell you about:

* any available compensation or medical treatment if injury occurs
* the possibility of unforeseeable risks to you or to your child, if you are pregnant or become pregnant,
* circumstances when the investigator may stop your participation,
* any added costs to you,
* what happens if you decide to stop participating,
* when you will be told about new findings which may affect your willingness to participate,
* how many people will be in the study,
* any genetic testing that may take place,
* whether clinically relevant research results will be returned to you and, if so, under what conditions,
* if your specimens or your information will be stored for future studies,
* whether it is ok to contact you in the future to seek additional information or specimens or to discuss participation in another research study, or
* the types of specimens or information that will be collected and the time period for which they will used for research.

**If you have any questions or problems, whom can you call?**

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| **questions about:** | **May be directed to:** |
| * The research * Research related injury * How to withdraw from a study | **Dr. Iuliana Shapira**  Office: (718) 270-1500  Cell: (718) 406-4359  Pager (917) 218-1591  **Dr. Ovadia Abulafia**  Office: (718) 270-1900 |
| * Your rights * Privacy rights * How to withdraw from a study * Concerns to be directed to an institutional representative who is not part of this research study | **National Cancer Institute’s Central IRB:** (888) 657-3711  **SUNY Downstate Medical Center IRB:** (718) 613-8480 |

**Does this study involve any genetic testing?**

*The researchers must check one of following, as applicable to the research:*

(A): We will NOT obtain diagnostic genetic test results about you.

(B): **We will obtain diagnostic genetic test results about you.** After completing the diagnostic genetic tests, we would like to be able to contact you in order to get more information needed for this research and/or to explain the results of this research study. Under New York law, you must provide your consent to such future contact. The risks of allowing us to contact you are that we may have information that causes some emotional distress, but the benefits are that we may have information that could help you in your medical planning and decision-making. If you allow us to contact you in the future, we will not disclose your medical information or the results of the genetic tests of the research study to anyone for any reason without your further specific written informed consent. If we think your family members could benefit from knowing any information we have received about you during this research study, we may ask for your permission to contact them and would explain our reason to you for wanting to do so.

If box (B) is checked, please answer the following question:

**Can the researchers contact YOU (and only you) in the future to obtain or share information related to diagnostic genetic testing?**

\_\_\_\_\_ (initials) YES. \_\_\_\_\_ (initials) NO.

**What information do we keep private?**

We will keep information about you in a secure location with limited access. We will not reveal your identity in any publication or public presentation of the results of the study.

Federal law protects your right to privacy concerning Protected Health Information (PHI). There are certain things you need to know. PHI is any information from your medical record or obtained from the study linked to you and that refers to your mental or health conditions in the past, the present or the future.

For the purposes described in this form, the research team will create, use or report PHI from your medical records or research records including the information outlined in the consent form approved by the NCI CIRB.We will create, use or report PHI until the end of the research study or as otherwise specified on the consent form approved by the NCI CIRB.

The researchers, their staff and the staff of SUNY Downstate Medical Center, including the University Hospital at Brooklyn, participating in the research will use your protected PHI related to this research study and will share your PHI with the following persons or agencies for purposes related to the conduct of the research:

* The research staff approved by the Institutional Review Board (IRB)
* The National Cancer Institute Central IRB
* The SUNY Downstate Medical Center (DMC) IRB
* DMC officials and staff who supervise the way research is done and run the business operations
* The Federal agencies that supervise the way research is conducted, such as the Department of Health and Human Services Office for Human Research Protections, the Food and Drug Administration*,* the National Institute of Health or other government agencies
* Any of the following when checked:

Collaborating research sites approved by the IRB, including:

The Sponsor(s) of this study, listed here:

The Lead Organization(s) of this study, listed here:

The Data Safety Monitoring Board (DSMB) that reviews the safety of this study

Contracted organizations that help manage the study:

Your insurance company (check if 3rd party payment is expected)

As required by law, the research team may share your PHI with the relevant agency to:

* Report suspected child abuse or neglect
* Report certain communicable diseases
* Report a possible threat or harm to yourself or others

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop. However, any information collected about you prior to withdrawal must remain in the records, when required by the government regulations or when approved by the IRB. You can withdraw this authorization for the use or reporting of your PHI. If you withdraw, we will stop collecting and accessing your PHI, but we will collect and report any adverse event (bad effect) that you had in the study. We will still use and report your PHI collected before you withdraw your authorization. If you withdraw your authorization, you can no longer be in the study. You have to write to us to withdraw. To withdraw, please write to: Dr. Iuliana Shapira

SUNY Downstate Medical Center, 450 Clarkson Avenue, Brooklyn, NY 11203.

You have a right to refuse to sign this form. If you do not sign this form, your health care treatment, your enrollment for benefits, your payment for the health care outside of the study, and your health care benefits are not affected. However, you will not be able to participate in this research study if you do not sign this form.

You need to know that some of the individuals or groups mentioned above who may receive your health information may not be required by federal privacy laws to protect your PHI. They may share your information with others without your permission if permitted by the laws governing them. For example, the sponsor, contracted organizations, or the DSMB may not have the same obligations as your research team and may no longer protect your PHI.

*The researchers must check one of following, as applicable to the research:*

(A) This study involves an investigational agent; therefore, we will file a copy of the consent forms in your medical record. We will place a note in your medical record to let other healthcare providers know that you are participating in a clinical trial.

(B) We will not disclose any information about this research in your medical record.

*The researchers must check one of following, as applicable to the research:*

(A) We can share all PHI obtained in this study during the course of the research.

(B) We cannot share some of the PHI obtained in this study during the course of the research; however, we can share it with you at the end of the study. This includes:

*The researchers must check one of following, as applicable to the research:*

(A) The research does not involve any HIV-related information about you.

(B) The research involves HIV Information about you.

*If box (B) is checked, the following notice applies:* Recipients of HIV-related information may not re-disclose your HIV-related information without your authorization unless permitted to do so under federal or state law. You have a right to request a list of people who may receive or use your HIV-related information without authorization, as well as a list of any disclosures made pursuant to this research authorization. For more information about HIV confidentiality, call the New York State Department of Health HIV Confidentiality Hotline at 1-800-962-5065; for more information regarding federal privacy protection, call the Office for Civil Rights at 1-800-368-1019. You may also contact the NYS Division of Human Rights at 1-888-392-3644.

*The researchers must check one of following, as applicable to the research:*

(A) We will not obtain any video, audio, or images of you for research purposes.

(B) We will obtain video, audio, or images of you, such as:

*If box (B) is checked, the following notice applies:*

Only the research staff approved to be on this study may have access to these materials. These materials will be stored in a locked cabinet and used only for the research as approved by the IRB. The investigators will save these materials as follows:

The investigators will save the materials until:

The investigators will save the materials for the required retention period after the study has ended.

The investigators will save the materials indefinitely but only use them for purposes approved by the Institutional Review Board

The investigators will destroy audio records after verifying their written transcription is accurate.

The investigators will destroy these materials as follows:

N/A – The investigators will save the materials indefinitely.

The investigators will destroy the materials according to SUNY Downstate data destruction policies.

**Is there any available compensation or medical treatment if injured in the study?**

Immediately call the study doctor if you experience an injury, adverse event, emergency care, or hospitalization related to the research. The study doctor will help you obtain medical treatment. Treatment is available to you at this site or you could go to any other facility of your choosing. No additional funds from Downstate Medical Center have been set aside to cover compensation for a potential study-related injury.

You do not give up any legal rights by signing this consent form, such as seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

**Signatures**

Please read this consent form carefully. Ask any questions you have before you decide. The study doctor will answer your questions. Take your time. You may consult with your family or friends.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the Name of the Adult Research Participant**  (18 years of age or older) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of the Adult Research Participant**  I have read this form and all of my questions about this research have been answered to my satisfaction. I volunteer to participate in this research study. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Impartial Witness**  An impartial witness cannot be a member of the research team. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Impartial Witness**  I was present during the entire consent process. The person authorizing the research voluntarily provided their consent. The investigator answered all questions. The consent process was adequate and the information accurately convened. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Interpreter**  (Applicable when the person authorizing the research has limited English proficiency or uses sign language)  Check this box if not applicable for this enrollment.  *NOTE: The interpreter may also serve as a Impartial Witness, if they are not a member of the research team.* | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Interpreter (if applicable)**  I have provided interpreter services to convey all of the information on this form to the person authorizing the research. I have assisted the investigator explaining the research study and have assisted in answering all questions to the satisfaction of the subject.  Check this box if the Interpretation took place over the phone by a translation service. Mail the original source document with Interpreter signature to the research team. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date Signed |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator Obtaining Informed Consent**  In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I offered an opportunity to answer any questions and further explain the risks and discomforts associated with this research. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |