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| **SUNY DOWNSTATE MEDICAL CENTER**  **& NYC Health + Hospitals, Kings County**  **BROOKLYN, NY 11203**  **Consent for Research Participation** |
| Title:  Researcher(s):  Researcher Contact Information:  Sponsor: |

*HELPFUL TIPS:*

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| * *This “SIMPLE” template does not include general guidance and does not include elements related to the following topics.*   + *Requests for permission of parent or legal guardian permission*   + *Surrogate consent for cognitively impaired adult*   + *Alternatives to research participation*   + *Research which is greater than minimal risk*   + *Clinical investigations*   + *Anticipated screening and enrollment numbers*   + *Research involving Protected Health Information (PHI)*   + *Specimens*   + *Options to participate in future research*   + *Collection of information about others*   + *Diagnostic genetics testing*   + *Significant financial interests or conflict of interest management plans*   + *Video, audio records, pictures, or images*   + *Genetic testing*   + *Research which must comply with the EU General Data Protection Regulation (GDPR) or outreach and recruitment of individuals who are located in the European Economic Area (EEA)*   + *Education about HIV/AIDS or consent for HIV testing*   + *Research covered by a Certificate of Confidentiality*   + *Information about ending participation early*   + *Additional requirements of other federal, state, local laws, or tribal laws*   + *Information regarding gifts, rewards, compensation or reimbursement*   + *Return of research results and/or clinical test results*   + *Additional required signature lines* * *Please refer to the “All-In-One” template for guidance on the above topics and additional general guidance. Include all relevant topics in this consent.* * *Remove all guidance and instructional text before submitting to the IRB.* |
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**Key Information for You to Consider:**

Researchers are asking if you would like to be in a research study. The boxes below provide key information about this research to help you to consider whether to participate. Please consider all of the details on the pages that follow.

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| **What is the purpose of this research?** |  |
| **What will happen to you during the study?** |  |
| **How long will you be in the research?** |  |
| **Could being in this research harm you?** |  |
| **Will being in this study help you in any way?** |  |
| **Are there any costs to participate?** |  |
| **How do researchers protect your information?** |  |

**Additional Detailed Information:**

Please review the rest of this document for additional details before making a decision about whether to participate in this research.

**Could being in this research harm you? (Detailed Risks)**

**How many people will participate in this research study?**

**Who can you talk to about the research?**

If you have questions, concerns, complaints, or think the research hurt you, please contact the researcher(s) listed on the top of the first page.

This research is reviewed and approved by an Institutional Review Board (IRB). An IRB is a committee that provides ethical and regulatory oversight of human research. You may talk to the SUNY Downstate Medical Center IRB & Privacy Board by calling (718) 613-8480, if

* You have questions about your rights as a research participant
* Your questions, concerns, or complaints are not being answered by the research team,
* You cannot reach the research team,
* You want to talk to someone besides the research team, or
* You want to get information or provide input about this research.

**What happens to the information collected for this research?**

Researchers will securely store your information in a coded format. The code can be used to link to materials back to you. Only the researchers approved by the IRB may have access to the code.

The researchers will not use or distribute your identifiable private information collected for this research for future research studies, even after removal of identifiers.

**How do researchers protect your information?**

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

The researchers will destroy your information after the study is complete. The researchers will not use your information for future studies; however, the researchers will keep information about you as long as required by regulations and institutional policy.

**What additional information should I know?**

The researchers will inform you of any significant new information that may affect you in a timely manner. Such information may help you decide if you want to stay in the study. The researchers will share any new information with you if it affects your ability to stay in the study.

**Signatures:**

You have read this document and were told of the risks and benefits and a member of the research team answered questions to your satisfaction. A member of the research team will answer any future questions. You voluntarily agree to join the study and know that you can withdraw from the study at any time without penalty. You do not waive any legal rights by signing this form.

You will receive a signed copy of this document.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the Name of the Adult Research Participant**  (18 years of age or older) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of the Adult Research Participant** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |