|  |
| --- |
| Instructions:   * This document contains the additional language that must be added when applicable to the simplified version of the consent form template (see <https://www.cuny.edu/research/research-compliance/human-research-protection-program/hrpp-policies-procedures/>) * Red text within [square brackets] provides instructions on when a section is needed. * Red *italicized* text within <pointed brackets> provides instructions on the content of study-specific information that must be provided. Actual wording should be in black and not italicized. * All added information should be in simple sentences in lay language, avoiding or defining technical terms. * The submitted version of the consent form should have no red text. |

[Include **only if** entire consent form, not counting the signature page, exceeds 5 pages; otherwise, do not add a Key Information section] **Key Information**

* You are being asked to consent to participate in a research study because *<explain why the participant is eligible to participate>*
* It is your decision if you would like to participate in this study. Participation is completely voluntary, and you are free to stop participating at any point in time.
* The purpose of this research study is *<briefly explain the purpose of the research study >*
* If you agree to participate, you will <*outline the main procedures to be followed in the research and include the expected duration of the prospective subject's participation*>
* [Include if the study uses surveys, questionnaires, interviews, or focus groups; otherwise, omit bullet] You may refuse to answer any questions that you do not want to answer and still remain in the study.
* One risk of participating is a breach of confidentiality. [Include if there are other reasonably foreseeable risks described in the consent form; otherwise, omit sentence] Other main risks or discomforts are <*describe the major reasonably foreseeable risks or discomforts to the prospective subject*>. More information about risks can be found later in this form
* [Include if there are no direct benefits; otherwise, omit bullet] You will not directly benefit from your participation in this research study.
* [Include if there are direct benefits; otherwise, omit bullet] You might benefit from your participation in this research study because <*describe the potential direct benefits to the prospective subject – note that payment is not a benefit*> Other ways to get these benefits are <*describe appropriate alternative procedures or courses of treatment*>

**Overview** additional language

* [Include if the study involves deception or incomplete disclosure with prospective agreement for the deception or incomplete disclosure, choose 1., 2., or 3 (changing the number to a bullet); otherwise, omit bullet]

1. For scientific reasons, this consent form does not include complete information about the purpose of this research. You will be fully debriefed following your participation in the research.
2. We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these conditions, we will explain the procedure to you fully after your participation.
3. Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the research will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing, which will include an explanation of the purpose of the research and other relevant background information pertaining to the research. You will also be given an opportunity to ask any questions you might have.

* [Include if the study is greater than minimal risk; otherwise, omit bullet] Approximately *<number>* individuals are expected to participate in the study [include if this is a multisite study; otherwise, omit phrase], *<number>* at CUNY and*<number>* at other sites.

[Include if a financial conflict of interest exists; otherwise, omit section] **Disclosure of Financial Interests**

* *<Describe conflict, such as payment from the sponsor of the research, intellectual property rights associated with the research, ownership of equity associated with the research, etc.>*. You may ask a member of the study team if you have questions about these financial interests.

**Procedures** additional language

* [Include if the study will collect biospecimens; otherwise, omit bullet] Biospecimen collection: *<specify the type of biospecimens, the collection method, analysis plan, etc.>*
* [Include if the study will collect biospecimens; otherwise, omit bullet] As mentioned above, we will collect <*specify type>* biological samples from you. [Include if genetic testing will NOT be done; otherwise, omit sentence] We will not do genetic testing on your samples. [Include if genetic testing WILL or MIGHT BE done; otherwise, omit sentence] We will do genetic testing on your samples as follows: *<describe what tests will be performed and what will be done with the information; include whether the testing includes whole genome sequencing and whether genetic counseling resources are available >*.
* [Include if the study involves randomization; otherwise, omit bullet] Randomization is a procedure used to assign research participants by chance to one of two or more groups. It is used to make sure that study results are not influenced by the selection of participants in one group as compared to another. In this research, you have a *<x>* chance of being assigned to one of the following groups: *<define each group and related procedures>*
* [Include if the study includes a request to obtain existing information about or biospecimens from subjects; otherwise, omit bullet] We would like to get some information about you and biospecimens from you <*include biospecimens only when applicable>* from *<list source of information or biospecimens>*. The information we will get is *<list information or biospecimens>.* We will use the information to *<describe reason for obtaining information or biospecimens>.* You can still be in this study if you do not agree to let us get this information or biospecimens <*include biospecimens only when applicable>*.
* [Include if the study will collect data relevant to the physical or mental health of the participant; otherwise, omit bullet] Some of the information we collect may be relevant to your health, including *<list measurements>*. [Include if the information WILL be communicated to the participant; otherwise, omit sentence] We will tell you the results *<describe what information will be disclosed and how>*. [Include if the information will NOT be communicated to the participant; otherwise, omit sentence] We will not tell you the results because *<describe why no information will be disclosed>*.

**Potential Risks or Discomforts** additional language

* [Include if the study will collect biospecimens; otherwise, omit bullet] Collection of biospecimens may *<describe reasonably foreseeable risks or discomforts of biospecimen collection>*
* [Include if the study is greater than minimal risk; otherwise, omit bullet] Research procedures described above may involve risks that cannot be anticipated at this time.
* [Include if the study involves MRI scans; otherwise, omit bullet] There is a possibility that the MRI scans taken as part of this research study will show an abnormality that we did not expect to see. This is called an "incidental finding." If the researchers suspect an incidental finding they may consult a radiologist. Depending on the nature of the incidental finding, the researchers may provide the radiologist with the scans (but will remove any identifying information to ensure participant privacy.) You will be informed of any incidental findings, as well as any context provided by the radiologist in the event they are consulted. Please be aware, however, that research staff are not trained medical doctors and may not have the skills to detect incidental findings and/or make diagnoses. Furthermore, the quality and types of MRI images that are taken as part of this study may not be sufficient to make clinical diagnoses. An incidental finding may be meaningless, but you may want to talk to a medical professional to find out. If there is an incidental finding and you decide to have further examinations, tests, and/or treatments, you and/or your insurer will be responsible for any costs of such examinations, tests, or treatments.
* [Include if the researcher might withdraw the participant from the research without regard to their consent; otherwise, omit bullet]You might have to stop being in the study even if you want to continue. This might happen *<describe the circumstances under which this may occur; and describe the procedure for withdrawing the participant.>*
* [Include if there are any risks or health consequences of a decision to withdraw from the study or any necessary procedures for withdrawing; otherwise, omit bullet] You are free to stop participating at any time without giving a reason. If you stop early, *<list risks of withdrawing>*. We ask that you let us know if you do not want to continue, so can do some things to help keep you safe. These things include *<list procedures for orderly withdrawal>*.

**Confidentiality** additional language

* [Include if any member of the study team is a mandated reporter, and this research study may result in information that they are mandated to report; otherwise, omit bullet]Disclosure of information obtained from you may be required by federal, state, or local law. In this study, we will have to report *<describe the possibility of mandated disclosures, such as child abuse and neglect, or harm to self or others >*
* [Include if the study has a Certificate of Confidentiality; otherwise, omit bullet]We have obtained for this project a Certificate of Confidentiality from the National Institutes of Health, which offers federal legal protection against forced disclosure of your personal identifiable information. This means that the researchers may not release or use your personal information in a court, police, or immigration authority proceeding unless you say it is OK. However, the Certificate does not stop reporting required by the law, such as for child or elder abuse, or threats to harm yourself or others. [Include if the study has a Federal sponsor or is under FDA jurisdiction; otherwise, omit sentence] The Certificate also does not prevent us from providing your information to the sponsor of this research for auditing or program evaluation purposes. You are free to see your data from this project and to share your data with others.
* [Include if the study gathers information on suicide ideation or attempts but does not obtain subject contact information; otherwise, omit bullet] Some of the questions ask about self-harm. We do not gather your contact information, so we will not be able to follow up with you if the questions upset you or you need help. Please call 988 or visit <https://988lifeline.org/> if you are having thoughts of suicide or self-harm.
* [Include if the study gathers information on suicide ideation or attempts and does obtain subject contact information; otherwise, omit bullet] Some of the questions ask about self-harm. Please call 988 or visit <https://988lifeline.org/> if you are having thoughts of suicide or self-harm. If we obtain information that you are in immediate danger of hurting yourself at any time, the study team will <*describe follow-up plan>*. Because study staff will be trying to protect you, it is possible that your information will be shared with others *<describe how and the extent to which the subjects’ participation and responses will be kept confidential>*.
* [Include if the study involves collecting genetic information; otherwise, omit bullet] The federal Genetic Information Nondiscrimination Act (GINA) prevents discrimination on the basis of your genetic information. GINA applies to health insurance companies and group health plans in determining your eligibility or premiums. GINA also applies to employers with 15 or more employees in making employment decisions. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. These companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question.

* Include if the study is or will be registered on ClincalTrials.gov; otherwise, omit bullet] A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Include if information will be collected or processed from individuals while they are physically located in an European Economic Area (EEA) country or if personal data collected from such individuals is transferred from an EEA country to a country outside of the EEA (note that this requires that the consent form be signed); otherwise, omit section] **European General Data Protection Regulation (GDPR)**

* **GDPR General statement**

Personal information about you is being collected by CUNY for the purposes set forth in this research “Consent Form”. Your personal information will be retained for the period necessary to fulfill the purposes outlined in the Consent Form or for a longer period as permitted or required by law. Access will be limited to those who need this information to fulfill these purposes.

* **GDPR Rights**

Your personal data will be treated in compliance with applicable data protection laws. In addition to being regulated by applicable US laws, if you reside in the European Economic Area during your participation in the research study, your “study data” may also be subject to the protections afforded by the European General Data Protection Regulation (“the GDPR”). Subject to applicable laws, these rights include:

* The right to request access to your personal information that you have provided;
* The right to request that your personal information be corrected if inaccurate;
* The right to request the deletion of your personal data, subject to certain limits regarding the integrity of the study and other legal requirements;
* The right to withdraw consent; even if you withdraw your consent, we will continue to process your personal information as allowed by European Union and/or EEA member state law and as required to comply with regulatory requirements applicable to the conduct of the study.
* The right to file a complaint with a data protection authority. Please notify the CUNY Research Compliance Administrator at 646-664-8918 or email HRPP@cuny.edu if you have a complaint related to the protection of your data in this study.
* **GDPR Data Transfer**

Information collected and transferred to the University will take place with the required safeguards to ensure data protection. If you give consent for CUNY to share your data with another institution, the institution receiving your information will be required to protect your data according to applicable laws.

* [Include if you are obtaining explicit consent to process special categories of personal data – see categories below] **GDPR Special Categories of Personal Data to be Collected**

As a participant in this research, the researcher will collect information about you which includes *<add applicable categories: information about racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, the processing of genetic data biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation>*. By signing this Consent Form, you give explicit consent to the processing of these specific categories listed above.

**Future Use** additional language

* [Include if the study has a formal data sharing plan; otherwise, omit bullet] We would like to keep the information and biospecimens <*include biospecimens only when applicable>* we collect from you and make it available to other researchers. Your information and biospecimens <*include biospecimens only when applicable>* will have a code instead ofyour name or other information that could identify you. Other researchers must agree not to try to find out your identity. [Include if the data will be entered into a formal database or repository; otherwise, omit sentence] Your information and biospecimens <*include biospecimens only when applicable>* will be entered into *<identify database or repository>*. [Include if the data to be shared includes genomic data; otherwise, omit sentence] The information includes data about your genetic material, and there is a chance that this can be used to identify you, now and in the future. Future researchers must obtain approval from *<entity>* to access your data and biospecimens <*include biospecimens only when applicable>*. Later in this form, you will be asked whether or not you agree to this future use of your research data and biospecimens <*include biospecimens only when applicable>*.

[Include if the study has the potential to directly benefit the participant; otherwise, omit section] **Alternatives to Participation**

* *<Describe any alternative therapeutic, diagnostic, or preventive procedures that should be considered before the participant decides whether to participate in the research.>*

**Payment for Participation** additional language

* [Include if the research collects biospecimens and could lead to commercial products; otherwise, omit bullet]The use of the <*specify type>* biospecimens we collect from you may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.

[Include if the study is greater than minimal risk; otherwise, omit bullet] **Research Related Injury**

* If you believe you have experienced a research-related injury, please contact the Principal Investigator using the contact information in the Questions, Comments, or Concerns section below. For medical emergencies, contact 911.
* *<Describe the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available. For example:* “*If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, medical care will not be provided by the research team. You should contact a medical care provider directly. Neither CUNY nor the research team will provide financial compensation or coverage for medical expenses resulting from research related injury.”>*

[Include if asking permission for future contact; otherwise, omit section] **Participant Choice for Future Contact**

Please indicate below if you permit the researchers to contact you in the future for participation in other research studies.

\_\_\_\_\_\_ I agree to allow the researchers to contact me for future research studies.

\_\_\_\_\_\_ I do **NOT** agree to allow the researchers to contact me for future research studies.

[Include if asking permission for obtaining existing information or biospecimens about subject; otherwise, omit section] **Participant Choice for Access to Existing Information and Biospecimens** <*include biospecimens only when applicable>*

Please indicate below if you permit the researchers to obtain existing information about you and biospecimens from you <*include biospecimens only when applicable>* as described above in this form.

\_\_\_\_\_\_ I agree to allow the researchers to obtain my information and biospecimens <*include biospecimens only when applicable>*.

\_\_\_\_\_\_ I do **NOT** agree to allow the researchers to obtain my information and biospecimens <*include biospecimens only when applicable>*.

[Include if participants will sign the consent form; otherwise, omit section] **Signature of Participant**

If you agree to participate in this research study, please sign and date below. You will be given a copy of this consent form to keep. Your signature indicates that:

* [Include if data/specimens will be stored or shared future research and agreement is required to participate; otherwise, omit bullet] You agree to allow your data and biospecimens <*include biospecimens only when applicable>* collected in this research to be stored and used for future research by the researchers in this study [include if data will be shared; otherwise, omit phrase] and shared with other researchers.
* [Include if participation requires allowing access to subjects’ existing data/specimens otherwise, omit bullet] You agree to allow the researchers to obtain existing data about you and biospecimens from you <*include biospecimens only when applicable>* as described above in this form.

[Include if the legally-authorized representative of participants will sign the consent form, either physically or electronically (add specific directions as necessary for electronic signatures); otherwise, omit section] **Signature of Legally-Authorized Representative of Participant**

If you are providing consent to participate in this research study on behalf of the participant, please sign and date below. You will be given a copy of this consent form to keep. Your signature indicates that:

* You have read this form
* You have had your questions answered
* You voluntarily give consent for the participant to take part in this research study [include if recording is required to participate; otherwise, omit phrase], including audio recording/ video recording/photography *<only include those that apply>*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Legally-Authorized Representative Relationship to Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legally-Authorized Representative Date

[Include if the individual obtaining consent from a Legally Authorized Representatives will sign the consent form; otherwise, omit section] **Signature of Individual Obtaining Consent from a Legally-Authorized Representative**

I have provided the Legally-Authorized Representative of this participant with information about this study that I believe to be accurate and complete. I believe that the Legally-Authorized Representative of this participant understands the nature of the study, including the risks and benefits of participating.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Individual Obtaining Consent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Individual Obtaining Consent Date