|  |
| --- |
| Instructions for use of this template: * Use this template to create a **combined permission and assent form** for parents/guardians to give permission and children aged 13-17 to assent to participate in a research study. There is a separate template for a parental permission form for participation of children aged 12 or younger(see <https://www.cuny.edu/research/research-compliance/human-research-protection-program/hrpp-policies-procedures/>)
* CUNY has two ways to construct a combined permission and assent form from a template:
1. A simplified version – **this version** – that includes language for the most common situations – the user adds in any additional applicable language from a separate the “applicable language” document.
2. A comprehensive version that includes language for most possible components of a study – the user deletes all inapplicable language and sections – the comprehensive version can be found at <https://www.cuny.edu/research/research-compliance/human-research-protection-program/hrpp-policies-procedures/>.
* Red text within [square brackets] provides instructions on whether a section is needed or should be deleted.
* 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.
* If the submitted version omits or substantially edits a required element, be sure that the IRB application explains the omissions or edits and includes a request for an alteration of consent if applicable.
* Headings may be omitted if the form is comprehensible without them, and wording in black at the start of a sentence completed by the user may be modified for clarity.
* The submitted version of the permission and assent form should have all red text deleted, including this instructions box.
* See “CUNY HRPP Policy: Consent Process and Documentation” and “CUNY HRPP Policy: Children as Research Subjects” for additional information
* **Checkboxes:** Examine each checkbox below to determine whether you will need to copy additional language or sections from the “Additional Language for Simplified Consent Form Template” into your combined permission-assent form:
* If the entire consent form, not counting the signature page, exceeds 5 pages, add a **Key Information** section above the **Overview** section
* If the study involves deception or incomplete disclosure with prospective agreement, add specific language to the **Overview** section
* If the study is greater than minimal risk:
* Add specific language to the **Overview** section
* Add specific language to the **Potential Risks or Discomforts** section
* Add a **Research Related Injury** section with specific language
* If an investigator has a financial conflict of interest, add a **Disclosure of Financial Interests** section after the **Overview** section
* If the study involves randomization, add specific language to the **Procedures** section
* If the study will collect or use biospecimens:
* In the **Procedures** section, include bullets on procedures for biospecimen collection and genetic testing
* In the **Potential Risks or Discomforts** section, include a bullet for risks of biospecimen collection
* Add specific language to the **Confidentiality** section if the study involves collecting genetic information
* Add “and biospecimens” after “information” in the header and all choices in the **Future Use** section and in the **Participant Choice for Future Use of Information** section and/or the **Participant Choice for Access to Existing Information** section if included
* Add specific language to the **Payment for Participation** section if the study could lead to commercial products
* If the study involves obtaining existing information (or biospecimens) from participants:
* Add specific language to the **Procedures** section
* Add a **Participant Choice for Access to Existing Information** section to the **Signature of Participant** section
* If the study will collect data relevant to the physical or mental health of the participant (for example, diagnostic tests), add specific language to the **Procedures** section
* If the study involves MRI scans, add specific language to the **Potential Risks or Discomforts** section
* If the researcher might withdraw the participant from the research without regard to their consent (for example, if the participant does not follow study directions), add specific language to the **Potential Risks or Discomforts** section
* If there are any risks or health consequences of a decision to withdraw from the study or any necessary procedures for withdrawing (for example, needing alternative treatment), add specific language to the **Potential Risks or Discomforts** section
* 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, add specific language to the **Confidentiality** section
* If the study has a Certificate of Confidentiality, add specific language to the **Confidentiality** section
* If the study gathers information on suicidal ideation or suicide attempts, add specific language to the **Confidentiality** section
* If the study involves collecting genetic information, add specific language to the **Confidentiality** section
* If the study is or will be registered on ClincalTrials.gov, add specific language to the **Confidentiality** section
* 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, add an **European General Data Protection Regulation (GDPR)** section with specific language
* If the study involves a formal data sharing plan, add specific language to the **Future Use** section
* If the study has the potential to directly benefit the participant, add an **Alternatives to Participation** section with specific language
* If participants will be asked to give permission for future contact, add a **Participant Choice for Future Contact** section
 |

**THE CITY UNIVERSITY OF NEW YORK**

**PERMISSION AND ASSENT TO PARTICIPATE IN A RESEARCH STUDY**

*<enter name of subject population if >1 permission and assent form for study>*

**Title of Research Study:** *<enter title of study>*

**Principal Investigator:** *<enter name and degree(s) of PI>*

 *<enter CUNY title of PI>*

 *<enter CUNY department and college of PI>*

[Include if there is a Faculty Advisor; otherwise, omit section] **Faculty Advisor:**   *<enter name and degree(s) of Faculty Advisor>*

*<enter CUNY title of Faculty Advisor>*

 *<enter CUNY department and college of Faculty Advisor, if different from PI’s>*

[Include if there is a Sponsor; otherwise, omit section] **Research Sponsor**: *<enter name of research sponsor/funder>*

In this form, the word “you” refers to the child who is being asked to agree to be in this research study. Parents or guardians must also give permission, and should read this form to understand what is being asked of their child.

**Overview**

* You are being asked to join a research study. This form gives you important information that will help you decide whether or not to take part. It describes what would happen to you in the study, and helps you understand the reasons why you might or might not want to participate.
* To participate, you must *<briefly describe inclusion/exclusion criteria>*.

**Purpose**

The purpose of this research study is *<explain the purpose of the research study>*

**Procedures**

If you agree to participate in this research study, we will ask you to do the following:

* *<Describe each procedure as a separate bullet. Identify any therapeutic procedures that are experimental. For each procedure, state when and where procedures will take place and include approximate duration. Include a description of the types of questions that will be asked in surveys, interviews, or focus groups. Use tables for complex studies involving multiple visits and procedures.>*

[Include if the study involves any recording – edit heading as applicable; otherwise, omit section] **Audio Recording/Video Recording/Photographs** *<only include those that apply>***:**

* *<Describe which procedures will be recorded, for what purpose, and whether recording is optional. For example, “To ensure the accuracy of our findings, your interview will be audio recorded for later transcription and review by the research team. You can still/cannot participate in this study if you do not agree to audio recording.”>*
* [Include if participants will review recordings or transcripts; otherwise, omit bullet]You may review the recording/photographs/ transcripts *<only include those that apply>* for accuracy. If you wish to do so, *<describe the process for review>.*
* *<Describe who will have access to the recordings/transcripts for research, educational, or other purposes; and if/when they will be erased.>*

**Time Commitment**

* [Include if subjects will complete procedures only once; otherwise, omit bullet] Your participation in this research study consists of *<describe procedure>*. This will take about *<specify length of procedure>*.
* [Include if subjects will complete procedures more than once; otherwise, omit bullet] Your participation in this research study consists of *<describe procedures and total number>*. Each *<procedure>* will take about *<specify length of procedure, repeat sentence for multiple procedures>*. Your total participation in this research study is expected to last for about *<specify study duration>.*

**Potential Risks or Discomforts**

* We will do our best to protect the information we collect from you. However, there remains a risk that someone not involved in the research could access your data. The measures we are taking to reduce the risk are discussed in the **Confidentiality** section below.
* [Include if the study includes surveys, questionnaires, interviews, or focus groups with questions that might cause discomfort; otherwise, omit bullet] Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question. [Include if the study will provide resources to mitigate psychological risk from surveys, questionnaires, interviews, or focus groups; otherwise, omit sentence] These are some of the resources that can help you if you feel upset: <*list resources>*
* [Include if the study will provide resources to mitigate psychological risk from procedures other than surveys, questionnaires, or focus groups; otherwise, omit bullet] Some of the research procedures may cause you to feel upset. These are some of the resources that can help you: <*list resources>*
* *<Describe other reasonably foreseeable risks or discomforts (if any) that the participant may experience due to study procedures as separate bullets>*

**Confidentiality**

* We will make our best efforts to maintain confidentiality of any information that is collected during this research study. We will protect your confidentiality by *<describe how you will safeguard participant data, including any coding procedures, where data will be stored, who will have access to the data, etc.>*
* [Include if the study involves self-administered or video/phone surveys, questionnaires, interviews, etc.; otherwise, omit bullet] Please be sure to choose a private and safe location for the *<describe procedures that require privacy>*
* [Include if the study involves focus groups; otherwise, omit bullet]All focus group participants will be asked not to share the information discussed during the group discussion with anyone outside of the group. However, complete confidentiality cannot be guaranteed.
* The research team, authorized CUNY staff, *<the research sponsor (include only when applicable)>* and government agencies that oversee this type of research may have access to research data and records in order to monitor the research.
* Publications and/or presentations that result from this study will not identify you by name.

**Future Use**

* [Include if individual-level data will not be used or shared for future research, even if identifiers are removed; otherwise, omit bullet] The information and biospecimens <*include biospecimens only when applicable>* that we collect from you as part of this study will not be used or distributed for future research.
* [Include if data might be used or shared for future research and there is not a formal data sharing plan (if the study has a formal data sharing plan, instead use the bullet from the “Additional Language for Simplified Consent Form Template”); otherwise, omit bullet] We might use the information collected from you as part of this study for future research by the researchers of this study and by other researchers <*include other researchers only when applicable>*. Your information will have a code instead ofyour name or other information that could identify you. You will be asked later in this form about your choice of whether or not to allow this future use.

**Potential Benefits**

* [Include if the study has potential direct benefits to the participant; otherwise, omit bullet] *<Describe any potential benefits to the participant, including if there is a control group that would not be expected to benefit.>* However, you may not receive any benefit from your participation in this research study.
* [Include if the study has no potential direct benefit; otherwise, omit bullet]You will not directly benefit from your participation in this research study.
* The knowledge gained from this study may help *<describe expected benefits to science or society.>*

**Costs**

* [Include if participants will bear some costs due to participation in research; otherwise, omit bullet] If you participate in the study, *<describe any costs to subjects that may result from their participation in the study.>*
* [Include if participants will not bear any costs due to participation in research; otherwise, omit bullet] There will be no cost to you if you participate in this research study.

**Payment for Participation**

* [Include if participants will receive payment, monetary or non-monetary; otherwise, omit bullet] *<Describe the payment. Include the type of compensation (cash, check, gift card – specify the type of gift card, course credit, etc.), the amount for full and for partial completion of the study (or for raffles, the amount and odds of receiving payment), when participants will receive compensation for full and for partial completion of the study, how participants will receive compensation (in person, electronically, etc.), and the maximum total amount that a participant could receive (if more than one payment). For example, “You will be given a $20 Amazon gift card immediately at the end of each in-person study session that you complete. If you leave a session early, you will be given a $10 Amazon gift card when you leave. You will receive a $10 Amazon eGift card by email or text within one week after completing each follow-up electronic survey, and a $5 Amazon eGift card if you end a survey early. The total amount that you would receive if you complete all sessions and surveys is $120.”>*
* [Include if participants will not receive payment; otherwise, omit bullet] You will not receive any payment for participating in this research study.

[Include unless the study the study does not collect participants’ contact information; otherwise, omit section] **New Information:**

If we learn of anything that may affect your decision to participate, we will inform you as soon as possible. You will then have a chance to reconsider your continuing participation in the research

**Participants’ Rights:**

* Your participation in this research study is entirely **voluntary**. If you decide not to participate, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.
* You can decide to withdraw your permission and assent and stop participating in the research at any time, without any penalty. [Include if participants will receive payment; otherwise, omit bullet] You will not be paid for the study activities that you do not participate in after withdrawing.
* You are not giving up any of your legal rights by agreeing to participate.

**Questions, Comments or Concerns:**

If you have any questions, comments or concerns about the research, you can talk to:

* *<List name, title, and contact information for at least one researcher.>*
* [Include if the study has a Faculty Advisor; otherwise, omit bullet] *<List name, title, and contact information for Faculty Advisor>*

If you have questions about your rights as a research participant, or you have comments or concerns that you would like to discuss with someone other than the researchers, please call the CUNY Research Compliance Administrator at 646-664-8918 or email HRPP@cuny.edu.

[Include if data will be used or shared future research; otherwise, omit section] **Participant Choice for Future Use of Information**

Please indicate below if you permit the researchers to use your information as described above for future research.

\_\_\_\_\_\_ I agree to allow my information to be used by the researchers of this study for future research.

\_\_\_\_\_\_ I agree to allow my information to be shared with other researchers for future research.

 \_\_\_\_\_\_ I do **NOT** agree to allow my information to be used for future research.

[Include if recording will occur but recording is not required for participation; otherwise, omit section] **Participant Choice for Audio Recording/Video Recording/Photography** *<only include those that apply>*

Please indicate below if you permit the researchers to record you as described above in this form.

\_\_\_\_\_\_\_\_\_ I agree to audio recording/video recording/photography *<only include those that apply>.*

**\_\_\_\_\_\_\_\_\_** I do **NOT** agree to audio recording/video recording/photography *<only include those that apply>.*

[Include if participants will sign the form, either physically or electronically (add specific directions as necessary for electronic signatures); 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 form to keep. Your signature indicates that:

* You have read this form
* You have had your questions answered
* You voluntarily agree 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 Age of Participant

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

Signature of Participant Date

**Signature of Parent/Guardian of Participant:**

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

* You have read this form
* You have had your questions answered
* You voluntarily give permission for your child 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 Parent

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

Printed Name of Parent/Guardian Relationship to Participant

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

Signature of Parent/Guardian Date

[Include if the individual obtaining permission and assent will sign the form, either physically or electronically; otherwise, omit section] **Signature of Individual Obtaining Permission and Assent**

I have provided the participant and their parent/guardian with information about this study that I believe to be accurate and complete. I believe that the participant and their parent understand the nature of the study, including the risks and benefits of participating.

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

Printed Name of Individual Obtaining Permission

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

Signature of Individual Obtaining Permission Date

[Include if participants and parents will NOT sign the form; otherwise, omit section] **Agreement to Participate:**

If both the parent and child agree for the child to participate in this research study, <*describe next step, such as “click on ‘Child Assent’ and ‘Parent Permission’ below”, “tell the researcher”, “begin answering the questionnaire”, etc.>*

[Include if the parent and participant should print a copy themselves; otherwise, omit sentence] Please print a copy of this form for your records. [Include if the parent and participant will be given a paper copy of the form; otherwise, omit sentence] You will be given a copy of this form.

Your agreement indicates that:

* You have read this form
* You have had your questions answered
* You voluntarily agree to take part in this research study