|  |
| --- |
| Instructions for use of this template: * Use this template to create a **parental permission form** for parents/guardians to give permission for their children aged 12 or younger to participate in a research study. There is a separate template for a combined parental permission and child assent form for children aged 13-17 (see <https://www.cuny.edu/research/research-compliance/human-research-protection-program/hrpp-policies-procedures/>
* CUNY has two ways to construct a parental permission 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 “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 use may be modified for clarity.
* The submitted version of the permission 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 Parental Permission Form Template” into your permission form:
* If the entire permission 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 Parent** 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 parental permission (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 ClinicalTrials.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 FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY**

*<enter name of subject population if >1 permission form for the 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, if applicable>*

*<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>*

[Include **only if** entire permission form, not counting the signature page, exceeds 5 pages; otherwise, omit entire Key Information section] **Key Information**

* You are being asked to give your permission for your child to participate in a research study because *<explain why the participant is eligible to participate>*
* It is your decision if you would like to give permission. Participation is completely voluntary, and you are free to withdraw your permission at any point in time.
* The purpose of this research study is *<briefly explain the purpose of the research study>*
* If you agree for your child to participate, your child 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] Your child may refuse to answer any questions that they 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 permission 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 and your child will not directly benefit from your participation in this research study.
* [Include if there are direct benefits; otherwise, omit bullet] Your child might benefit from participation in this research study because <*describe the potential direct benefits to the prospective subject – note that payment is not a benefit*> Other ways your child could get these benefits are <*describe appropriate alternative procedures or courses of treatment*>

**Overview**

* You are being asked to give permission for your child to join a research study. This form gives you important information that will help you decide whether or not to give permission. It describes what would happen to your child in the study, and helps you understand the reasons why you might or might not want them to participate.
* [Include if child subjects may be between 3 and 13 years old; otherwise, omit bullet] Your child will be asked to agree to be in the study if they are 3 or older.
* To participate, your child 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 allow your child participate in this research study, we will ask your child 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 child’s interview will be audio recorded for later transcription and review by the research team. Your child can still/cannot participate in this study if you do not agree to audio recording.”>*
* [Include if parents 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 child’s 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 child’s 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 child’s 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 your child. However, there remains a risk that someone not involved in the research could access your child’s 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 your child may be upsetting, or your child may feel uncomfortable answering them. If your child does not wish to answer a question, they 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 if your child feels 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 your child to feel upset. These are some of the resources that can help your child: <*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 child’s 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 help your child 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 your child 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 your child 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 does have a formal data sharing plan, instead use the bullet from “Additional Language for Simplified Parent Permission Form Template”; otherwise, omit bullet] We might use the information collected from your child 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 child’s information will have a code instead oftheir name or other information that could identify them. 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, your child may not receive any benefit from their participation in this research study.
* [Include if the study has no potential direct benefit; otherwise, omit bullet]Your child will not directly benefit from their 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 your child participates in the study, *<describe any costs that may result from 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 your child participates in this research study.

**Payment for Participation**

* [Include if parents or children 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 your child completes. If your child leaves a session early, you will be given a $10 Amazon gift card when they leave. You will receive a $10 Amazon eGift card by email or text within one week after your child completes each follow-up electronic survey, and a $5 Amazon eGift card if your child ends a survey early. The total amount that you would receive if you child completes all sessions and surveys is $120.”>*
* [Include if participants will not receive payment; otherwise, omit bullet] You and your child will not receive any payment for your child’s participation 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 allow your child to participate, we will inform you as soon as possible. You will then have a chance to reconsider your child’s continuing participation in the research

**Participants’ Rights:**

* Your agreement to allow your child to participate in this research study is entirely **voluntary**. If you decide not to allow your child to participate, there will be no penalty to you or your child, and you and your child will not lose any benefits to which you or they are otherwise entitled.
* You can decide to withdraw your permission and stop your child from 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 your child does 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 child’s 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/specimens will be used or shared future research; otherwise, omit section] **Parent Choice for Future Use of Information**

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

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

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

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

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

Please indicate below if you permit the researchers to record your child 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 parent will sign the permission form, either physically or electronically (add specific directions as necessary for electronic signatures); otherwise, omit section] **Signature of Parent:**

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

* You have read this form
* You have had your questions answered
* You voluntarily agree to allow your child 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 Child Age of Child

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

Printed Name of Parent/Guardian Relationship to Child

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

Signature of Parent Date

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

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

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

Printed Name of Individual Obtaining Permission

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

Signature of Individual Obtaining Permission Date

[Include if parents will NOT sign the permission form; otherwise, omit section] **Agreement to Allow Your Child to Participate:**

If you agree for your child to participate in this research study, <*describe next step, such as “click on ‘I Agree’ / ‘Next’ below”, “tell the researcher”, “begin answering the questionnaire”, etc.>* [Include if the parent should print a copy themself; otherwise, omit sentence] Please print a copy of this permission form for your records. [Include if the parent will be given a paper copy of the permission form; otherwise, omit sentence] You will be given a copy of this permission form.

Your agreement indicates that:

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