Language for Parental Permission Forms

The purpose of the parental permission form is to give parents of potential child participants a single document that includes all the information they need to make an informed decision about allowing a child to participate in research and to indicate their agreement for their children to participate under the stated conditions.

The language below is intended to be used for all parental permission forms unless there is a specific reason for differences; any changes should be justified in the application. Note that clinical trials, commercially sponsored studies, and studies that involve whole genome sequencing require specific additional elements of parental permission or wording. These are presented at the end of this document.

All parental permission forms should be:

- Printed on NYU Departmental letterhead and clearly titled with Cayuse IRB number, e.g., Parental Permission Form for IRB-2018-1234.
- If different forms will be used for different groups, identify the group in the heading, e.g.: Parental Permission Form for College Applicants or Parental Permission Form for Minors 12-17 Years of Age.
- If a parent is participating in the research as a participant, e.g., being interviewed, filling out a survey or questionnaire, they should be given a separate form headed, Parental Consent Form. They must sign both a parental consent form and a parental permission form.
- Written at no higher than a 10th grade level, using language appropriate for the sample population, e.g., speakers of English as a second language. Avoid technical language or discipline-specific terms.
- Consistent about using “you” to refer to the parent, “your child” to refer to the potential child participant, and the investigator’s name or “the investigator” or “the researcher” to refer to the person carrying out the study.
- Designed to leave space (if appropriate) for material to be completed later, such as on-site telephone numbers, date of focus group, etc. Do not use brackets or underlining.
- Designed so that the subject’s signature is not on a separate page from meaningful text.
- Single spaced using 11 or 12 point type with no more than 1 inch margins.
- Numbered in the format “page 1 of 5” if the form is longer than two pages.

Be sure to check your Permission Form for the following:

- Spelling, typographical, and grammatical errors
- Inclusion of full contact information (address, telephone number, email, and international telephone codes if needed) for the investigator, the faculty sponsor, and the University Committee on Activities Involving Human Subjects (UCAIHS)
- All required signatures

Note that shaded areas indicate the information specific to your study to be filled in.
<table>
<thead>
<tr>
<th>Elements of Parental Permission</th>
<th>Parental Permission for a Child’s Participation in a Research Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Who is doing what and why:</strong></td>
<td>Your child has been invited to take part in a research study to learn more about [purpose of study]. This study will be conducted by [Principal Investigator (PI)], [PI’s NYU department &amp; school], New York University.</td>
</tr>
<tr>
<td>If the investigator is a student or not an NYU faculty member:</td>
<td>... as part of [his/her/their] [doctoral dissertation/master’s thesis/etc.], [His/Her/Their] faculty sponsor is [name of faculty sponsor], [NYU school/department].</td>
</tr>
<tr>
<td><strong>What will the subject be asked to do (description of procedures):</strong></td>
<td>If you give permission for your child’s participation in this study, your child will be asked to do the following: 1. [describe procedures in a detailed, easy to understand format] 2. [Second procedure, if applicable] (continue description of procedures, if necessary)</td>
</tr>
<tr>
<td>If audio or video recording will occur:</td>
<td>Your child will be [audio or video] recorded. He/She/They may review these recordings and request that all or any portion of the recordings [in a group situation, add “that includes his/her/their responses”] be destroyed.</td>
</tr>
<tr>
<td><strong>How much time will participation involve (total number / approximate length of sessions):</strong></td>
<td>Participation in this study will involve [two hours of your child’s time: 30 minutes to complete the questionnaire and approximately 45 minutes for each of the two interviews. The interviews will be held two weeks apart.]</td>
</tr>
</tbody>
</table>
| **Risks reasonably to be expected & assistance available, if needed (description of the degree and likelihood of any foreseeable risks or discomforts):** | There are no known risks associated with your child’s participation in this research beyond those of everyday life.  
*Or, for example:*  
Although every effort will be made to prevent it, your child may find the sensitive nature of some of the questions upsetting. In that event, the investigator will provide your child with a referral to a counselor with whom he/she/they may discuss his/her/their feelings.  
*Or, for example*  
There is a risk that your child may have some muscle soreness for about four days. |
| If there is more than minimal risk and there is any possibility of personal injury: | Federal regulations require that all subjects be informed of the availability of medical treatment or financial compensation in the event of personal injury resulting from participation in the research. New York University cannot provide either medical treatment or financial compensation for any personal injury resulting from your child’s participation in this project. You do not give up any legal rights to seek payment for personal injury by giving permission for your child to participate in this research. Inquiries regarding this policy may be made to the Principal Investigator or, alternatively, the NYU IRB at (212) 998-4808. |
| **Benefits reasonably to be expected (Please note: Incentives are not a benefit and should not be included as such.):** | Although your child will receive no direct benefits, this research may help the investigator understand [refer to purpose of study] better.  
*Or, for example*  
The study may [describe possible direct benefits to participants]. (Be sure to be reasonable in describing the likelihood and degree of possible benefits). |
| **Compensation, if any**  
For paid studies: | Your child will be paid $[amount/rate] for completing [number (e.g., one, both, five, all, etc.)] [interviews, surveys, research activities, etc.]. If your child withdraws before the end of the study, [describe the procedures for prorating payment, e.g., “only partial payment of (amount/rate) will be given” OR “they will receive the full payment amount”]. |
For studies in which students will receive course credit:

Your child will receive [amount/rate] hours of credit towards his/her/their course requirement for completing [number (e.g., one, both, five, all, etc.)] [interviews, surveys, research activities, etc.]; if your child withdraws before the end of the study, [describe the procedures for prorating credit, e.g., “only partial credit of (amount/rate) will be given” OR “they will receive the full credit amount”].

Extent to which subject’s confidentiality will be maintained:

Confidentiality of your child’s research records will be strictly maintained by [describe the specific ways to be used to protect subjects’ confidentiality (such as using codes or keeping signed consent forms separate from data to make sure that the subject’s name and identity will not become known or linked with any information they have provided)].

Information not containing identifiers may be used in future research or shared with other researchers without your additional permission or your child’s additional consent.

Your child’s information from this study will not be used for future research.

Your child’s responses will be kept confidential by the researcher, but the researcher cannot guarantee that others in the group will do the same.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify your child in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena. Exceptions include:

- A federal, state, or local law requires disclosure, such as [list possible examples applicable to the research, e.g., information about suspicion of child abuse or neglect, suspicion of harm to yourself or others, reporting of communicable diseases.]
- Your explicit approval for the researchers to release your child’s name and/or personally identifiable information.

We cannot keep information confidential if we have concerns that someone is hurting your child, or that your child might hurt himself/herself/themselves or someone else. In such cases, we will inform people in authority about our concerns.

If clinically relevant data will be collected (e.g., diagnostic data, biospecimens, etc.):

The following results from this study may be clinically relevant to your child: [list clinically relevant data – e.g., diagnostic assessment results, DNA sequencing, blood glucose levels, incidental findings from MRI]. You [will or will not] receive these results, [if applicable, “unless the results indicate a potential issue”]. [If applicable, explain the procedures and conditions under which clinically relevant individual results will be disclosed, including if results may be reported to the child but not to the parent (e.g., pregnancy tests)].

Voluntary nature of participation/right to withdraw or not to answer questions:

Participation in this study is voluntary. Your child may refuse to participate or withdraw at any time without penalty. For [interviews, questionnaires or surveys] your child has the right to skip or not answer any questions he/she/they prefer not to answer.

If subjects are students, patients, clients, employees, etc.:

Nonparticipation or withdrawal. . .

will not affect your child’s grades or academic standing. Or, for example

will not affect the services you or your child receive at [name of agency, program, etc.]. Or, for example

will result in no loss of services to which you or your child are otherwise entitled.
**Explanation & offer to answer questions:**

If there is anything about the study or your child’s participation that is unclear or that you do not understand, if you have questions or wish to report a research-related problem, you may contact [investigator name] at [PI’s phone] or [PI’s email].

**For questions about subjects’ rights:**

For questions about your child’s rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects, New York University, 665 Broadway, Suite 804, New York, NY 10012 at 212-998-4808 or ask.humansubjects@nyu.edu.

**If subjects’ statements may be quoted with their name/identity, include an attribution statement:**

Yes, I give the investigator permission to use my child’s name when quoting material from [our interview/survey/focus group] in his/her/their [dissertation, presentations, or publications].

___ No, I would prefer that my child’s name not be used.

**Copy of consent given to subject:**

You have received a copy of this parental permission document to keep.

**Parent’s agreement:**

**Permission for Child to Participate**

<table>
<thead>
<tr>
<th>Parent’s Signature &amp; Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Child</td>
</tr>
<tr>
<td>Parent’s Signature</td>
</tr>
</tbody>
</table>

**Additional Language**

**If the research is a clinical study:**

These procedures differ from the standard treatment in the following way(s), for example:

1. a new intervention/procedure will be used, such as [describe new procedure]; or
2. an existing intervention/procedure will be used in a new manner, such as [describe changes to procedure].

The investigator may withdraw your child from the study without your or your child’s consent if [briefly describe the circumstances under which participants may be withdrawn from the research without their consent (e.g., symptoms worsen, additional risks identified, participant no longer meets eligibility criteria)].

Your child could instead receive the following standard treatment: [describe alternative treatments that are available].

**If applicable for clinical studies:**

The treatment/intervention is experimental and may not perform as well as the standard treatment/intervention, which is [describe treatment/intervention].

**If the study is an NIH-funded clinical trial:**

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website may include a summary of the results, but will never include information that can identify your child. You can search this website at any time.

**If the study is commercially sponsored:**

This study is sponsored by [company name], owner of [the device/procedure/product to be studied].

**If the researcher(s) has an identified conflict of interest:**

This research is designed to test a product made by [company]. [Researcher name], one of the researchers in this study, [has an investment in, owns, etc.] this company. The financial value of this investment might be affected by the results of this study, which means that [researcher name] could gain or lose money depending on the results of this study.
<table>
<thead>
<tr>
<th><strong>researcher both hold equity but the IRB suggests beginning here and contacting the IRB for assistance with refining the disclosure language:</strong></th>
<th><strong>Or, for example</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>This research is designed to test a product made by [company]. [Researcher name], one of the researchers in this study, receives compensation for consulting services from this company. [Researcher name]'s consulting serves [are/are not] related to this study.</td>
<td><strong>Or, for example</strong></td>
</tr>
<tr>
<td>Research studies like this one are designed to determine whether the [test, treatment, etc.] is effective. [Researcher name], one of the researchers in this study is an inventor of the [test, treatment, etc.] being studied. [Researcher name] would receive a part of the profits from any sales of the [test, treatment, etc.].</td>
<td><strong>Or, for example</strong></td>
</tr>
<tr>
<td>This research is designed to test a product made by [company]. New York University [has an investment in, owns, etc.] this company. The financial value of this investment might be affected by the results of this study, which means that New York University could gain or lose money depending on the results of this study.</td>
<td><strong>If biospecimens are collected for whole genome sequencing:</strong></td>
</tr>
</tbody>
</table>
| This research may include the collection of the following biospecimens: [describe possible types of biospecimens, e.g., blood, saliva, etc.]. This research includes whole genome sequencing of these biospecimen samples. Whole genome sequencing is the process of determining your child’s complete DNA makeup. As with all information in this study, the researchers will make every effort to ensure that your child’s genetic information remains confidential; however, there is still a possibility that the information will be disclosed. Even without your child’s name or other identifiers, his/her/their genetic information is unique to him/her/them. The researchers believe the chance that someone will identify your child is very small, but the risk may change in the future as people come up with new ways of tracing information. In case your child’s information is disclosed, a federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against your child based on his/her/their genetic information. This law will protect your child in the following ways:  
- Health insurance companies and group health plans may not request your child’s genetic information that we get from this research.  
- Health insurance companies and group health plans may not use your child’s genetic information that we get from this research when making decisions regarding his/her/their eligibility or premiums.  
- Employers with 15 or more employees may not use your child’s genetic information that we get from this research when making a decision to hire, promote, or fire your child or when setting the terms of his/her/their employment. Be aware that this federal law does not protect your child against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect your child against genetic discrimination by all employers. Additionally, some people involved in genetic studies feel anxious about the possibility of learning about a genetic disease or disorder or of carrying an altered gene that they could possibly pass on to their children. | **If biospecimens may be used for commercial profit:** |
| Your child’s biospecimens may be used for commercial profit. You and/or your child [will or will not] share in this commercial profit. |