



Language for Consent Forms

The purpose of the consent form is to give potential subjects a single document that includes all the information they need to make an informed decision about participating in research and to indicate their agreement to participate under the stated conditions.

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

All consent forms should be:

- **Printed on NYU Departmental letterhead.**
- Clearly headed, e.g. **Consent Form**. If different forms will be used for different populations or age groups, identify the group in the heading, e.g., **Consent Form for Adults** or **Consent Form for Minors 12-17 Years of Age**. When the form is being developed for parents who are not participating as subjects themselves, but only granting permission for a minor child to participate in the research, it should be headed, **Parental Permission Form**. If a parent is participating in the research as a subject (e.g., being interviewed, filling out a survey or questionnaire), they should be given a separate form headed, **Parental Consent Form**.
- Written at no higher than a 10th grade level, using language appropriate for the sample population (e.g., minors, speakers of English as a second language). Avoid technical language or discipline-specific terms.
- Consistent about using “you” to refer to the subject, 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” margins.
- Numbered in the format “page x of y” if the form is longer than two pages.

Be sure to check your Consent 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 UCAIHS.
- All required signatures.

Note that shaded areas indicate the information specific to your study to be filled in.

Elements of Informed Consent	Consent to Participate in a Research Study
Who is doing what and why?	You have 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 & school], New York University.
If the investigator is a student or not an NYU faculty member:	. . . as part of [his/her] [doctoral dissertation/master's thesis work/etc.]. [His/Her] faculty sponsor is [name of faculty sponsor], [NYU school/department/].
What will the subject be asked to do (description of procedures)?	If you agree to be in this study, you will be asked to do the following: <ol style="list-style-type: none"> 1. complete a questionnaire about your background (age, gender, education, etc.); 2. take part in two interviews concerning [subject matter of interviews]; and 3. [continue description of procedures, if necessary. _____].
If audio- or videotaping will occur:	Your interviews will be audio- or video-taped. You may review these tapes and request that all or any portion of the tapes be destroyed. [In a group situation, add "that includes your participation."]
How much time will participation involve (total number/approximate length of sessions)?	Participation in this study will involve [two hours of your 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.]
Risks reasonably to be expected & assistance available, if needed	<p>[There are no known risks associated with your participation in this research beyond those of everyday life.]</p> <p><i>Or</i></p> <p>[Although every effort will be made to prevent it, you may find the sensitive nature of some of the questions upsetting. In that event, the investigator will provide you with a referral to a counselor with whom you may discuss your feelings.]</p> <p><i>Or</i></p> <p>[There is a risk that you may have some muscle soreness for about four days.]</p>
If there is more than minimal risk and there is any possibility of physical injury.	Federal regulations require that all subjects be informed of the availability of medical treatment or financial compensation in the event of physical injury resulting from participation in the research. New York University can not provide either medical treatment or financial compensation for any physical injury resulting from your participation in this research project. Inquiries regarding this policy may be made to the principal investigator or, alternatively, the UCAIHS (212-998-4808).
Benefits reasonably to be expected	Although you will receive no direct benefits, this research may help the investigator understand [refer to purpose of study] better. (Please note: Incentives are not a benefit and should not be included as such.)
Fees or incentives, if any:	[You will be paid \$ _____ for completing both interview sessions; if you withdraw before the end of the study, [no payment/only partial payment of (amount)] will be given.] or [You will receive 1 hour of credit towards your course requirement for completing both the surveys; if you withdraw before the end of the study, [no credit/partial credit of (amount)] will be given.]

<p>Extent to which subject's confidentiality will be maintained AND</p> <p>If minors (< 18 years of age) are involved, mandated reporting</p> <p>If applicable, for focus groups or group interviews</p>	<p>Confidentiality of your research records will be strictly maintained by [describe the specific ways to be used to protect subjects' confidentiality (such as using codes or keeping 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)].</p> <p>Your responses will be kept confidential with the following exception: the researcher is required by law to report to the appropriate authorities, suspicion of harm to yourself, to children, or to others.</p> <p>Your responses will be kept confidential by the researcher, but the researcher cannot guarantee that others in the group will do the same.</p>
<p>Voluntary nature of participation/ right to withdraw or not to answer questions</p>	<p>Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. For interviews, questionnaires or surveys, you have the right to skip or not answer any questions you prefer not to answer.</p>
<p>If subjects are students, patients, clients, etc.</p>	<p>[Nonparticipation or withdrawal. . . will not affect your grades or academic standing. <i>or</i> will not affect the services you receive at [name of agency, clinic, program, etc.]. <i>or</i> will result in no loss of services to which you are otherwise entitled.</p>
<p>Explanation & offer to answer questions</p>	<p>If there is anything about the study or your 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 number, e-mail, University address] or the faculty sponsor, [faculty sponsor name] at [faculty sponsor phone number, e-mail, University address].</p>
<p>For questions about subjects' rights</p>	<p>For questions about your 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 .</p>
<p>If subjects' statements may be quoted, include an attribution statement.</p>	<p><input type="checkbox"/> Yes, I give the investigator permission to use my name when quoting material from our interview in his/her [dissertation, presentations, or publications] .</p> <p><input type="checkbox"/> No, I would prefer that my name not be used.</p>
<p>Copy of consent given to subject</p>	<p>You have received a copy of this consent document to keep.</p>
<p>Subject's agreement to participate</p>	<p><u>Agreement to Participate</u></p>
<p>Subject's Signature & date</p>	<p>_____</p> <p style="text-align: center;">Subject's Signature</p> <p style="text-align: right;">_____</p> <p style="text-align: right;">Date</p>

Additional Language

<p>If research is a clinical study:</p> <p>If there is a standard treatment other than that offered in the study, add:</p>	<p>These procedure differ from standard treatment in the following way(s), for example:</p> <p><u>1. a new drug/device/procedure will be used [describe];</u> <i>or</i> <u>2. an existing drug/device/procedure will be used in a new manner [describe].</u></p> <p><u>You could choose instead the following standard treatment: [describe].</u></p>
<p><u>If applicable for clinical studies:</u></p>	<p>The drug/device/procedure is experimental and may not perform as well as the standard drug/device/procedure, which is [describe drug/device/procedure].</p>
<p>If the FDA is involved, use this language for the Confidentiality Statement:</p>	<p>Confidentiality of your research records will be maintained to the extent provided by law.</p>
<p>If the study is commercially sponsored:</p>	<p>This study is sponsored by [company name], the maker of [the drug/device/procedure to be studied].</p>