New York University
University Committee on Activities Involving Human Subjects
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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.

You may also use our Consent Form Generator online.

All consent forms should be:

- Printed on NYU Departmental letterhead and clearly titled with Cayuse IRB number, e.g., *Consent Form for IRB-2018-1234.*
- 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, or 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 inch margins.
- Numbered in the format "page 1 of 5" 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 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.

Forms longer than 1000 words

If the consent form has **more than one thousand words**, then it must begin with a **concise** and **focused** presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one **might or might not want to participate in the research**. This part of the informed consent must be organized and presented in a way that facilitates comprehension. The following text should be on the first page of forms that have more than 1000 words:

"You have been invited to take part in a study to learn more about [purpose of study]. If you agree to be in this study, you will be asked to do the following:

1. [briefly describe procedures in an easy to understand, numbered format]
2. [Second procedure, if applicable]

Participation in this study will involve [describe the expected amount of time for the participant to complete the research activities]. [Briefly describe the likelihood and degree of any foreseeable risks. If there are no risks, then say "There are no known risks associated with your participation in this research beyond those of everyday life."] [Briefly describe the likelihood and degree of any possible direct benefits *to the participant*].

[If the purpose of the study is to evaluate the safety and/or effectiveness of an experimental treatment or intervention, then add (or similar language): "The purpose of this study is to evaluate the safety and effectiveness of an experimental treatment. You should know that if you are assigned to receive the experimental treatment, we cannot guarantee that it will be as effective as the standard treatment."]

[If applicable, add any additional key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research.]

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Please read the rest of this consent form for more information about the study."

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/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: 1. [describe procedures in a detailed, easy to understand format] 2. [Second procedure, if applicable] *(continue description of procedures, if necessary)*
If audio or video recording will occur:	You will be [audio or video] recorded. You may review these recordings and request that all or any portion of the recordings [in a group situation, add "that includes your responses"] be destroyed.
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 (description of the degree and likelihood of any foreseeable risks or discomforts):	There are no known risks associated with your participation in this research beyond those of everyday life. *Or, for example:* 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. *Or, for example* There is a risk that you 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 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 project. You do not give up any legal rights to seek payment for personal injury by consenting to 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 you 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).
Fees or incentives, if any For paid studies:	You will be paid $[amount/rate] for completing [number (e.g., one, both, five, all, etc.)] [interviews, surveys,

	research activities, etc.]. If you withdraw before the end of the study, only partial payment of [amount/rate] will be given.
For paid studies using Amazon Mechanical Turk:	You will receive [amount/rate] for completing the online [surveys, research activities, etc.]; if you withdraw before the end of the study, no payment will be given.
For studies in which students will receive course credit:	You will receive [amount/rate] hour of credit towards your course requirement for completing [number (e.g, one, both, five, all, etc.)] [interviews, surveys, research activities, etc.]; if you withdraw before the end of the study, only partial credit of [amount/rate] will be given.
Extent to which subject's **confidentiality** will be maintained: *AND* If *identifiable* data will be collected and de-identified data may be used for **future research**: *OR* If *identifiable* data will be collected and de-identified data will **not** be used for future research: *AND* If applicable, for **focus groups or group interviews**: *AND* If the study has an NIH **Certificate of Confidentiality** (*All NIH-funded studies collecting identifiable data receive a Certificate of Confidentiality):* *OR* If the study does NOT have an NIH Certificate of Confidentiality, *AND* If minors (< 18 years of age) are involved: If collecting information that may reveal suspicion of harm to oneself or to others:	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 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 consent. Your information from this study will not be used for future research. Your 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 you 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. [If applicable, add "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. ONLY include these examples if there is a law that mandates disclosure; many NYU researchers are not subject to mandated reporting laws in New York. Check laws for local states and municipalities in which the research may occur)]. • Your explicit approval for the researchers to release your name and/or personally identifiable information. We cannot keep information confidential if we have concerns that someone is harming children. In such cases, we will inform people in authority about our concerns. We cannot keep information confidential if we have concerns that someone is hurting you or that you might hurt yourself 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 you: [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].

Voluntary nature of participation/ right to withdraw or not to answer questions:	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.
If subjects are students, patients, clients, employees, etc.:	[Nonparticipation or withdrawal. . . will not affect your grades or academic standing. *Or, for example* will not affect the services you receive at (*name of agency, clinic, program, etc.*). O*r, for example* will result in no loss of services to which you are otherwise entitled.]
Explanation & offer to answer questions:	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] or [PI's email]
For questions about subjects' rights:	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.
If subjects' statements may be quoted with their name/identity, include an attribution statement:	Yes, I give the investigator permission to use my name when quoting material from [our interview/survey/focus group] in his/her [dissertation, presentations, or publications] . ___ No, I would prefer that my name not be used.
Copy of consent given to subject:	You have received a copy of this consent document to keep.
Subject's agreement to participate:	Agreement to Participate
Subject's Signature & Date:	_____ _____ Subject's Signature Date

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 you from the study without your 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).]
If there is a standard treatment other than that offered in the study, add:	You could choose instead 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 you. You can search this website at any time.

If the study is commercially sponsored: If the researcher(s) has an identified conflict of interest: *(These examples don't cover every possible situation, [e.g., University and researcher both hold equity] but the IRB suggests beginning here and contacting the IRB for assistance with refining the disclosure language.):*	This study is sponsored by [company name], owner of [the device/procedure/product to be studied]. 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. *Or, for example* 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. *Or, for example* 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.]. *Or, for example* 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.
If biospecimens are collected for whole genome sequencing:	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 complete DNA makeup. As with all information in this study, the researchers will make every effort to ensure that your genetic information remains confidential; however, there is still a possibility that the information will be disclosed. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In case your 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 you based on your genetic information. This law will protect you in the following ways: • Health insurance companies and group health plans may not request your genetic information that we get from this research. • Health insurance companies and group health plans may not use your genetic information that we get from this research when making decisions regarding your eligibility or premiums. • Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you 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 biospecimens may be used for commercial profit. You [will or will not] share in this commercial profit.