جامعة نيويورك أبوظبي

NYU | ABU DHABI

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.

Excluding studies that involve particular medical or research equipment (e.g. MRI, MEG, EEG), the NYUAD IRB does not require research teams to use particular consent form templates. Investigators are free to design their own consent forms as long as the relevant elements (listed below) are addresses adequately.

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 form. Note that clinical trials, FDA, and commercially sponsored studies require specific additional elements of consent or wording, please contact the IRB Office (irbnyuad@nyu.edu) for details on this.

Informed Consent:

Your consent forms/texts should include the following elements (*additional information may be required*):

1. Statement that the purpose of the study is research.
2. An explanation of the purposes of the research.
3. The expected duration of the subject's participation.
4. A description of the procedures to be followed.
5. A description of any incentives/allowances for participation.
6. Identification and description of any procedures which are experimental.
7. **A description of any reasonably foreseeable risks** or discomforts to the subject.
8. **A description of any benefits** to the subject or to others which may reasonably be expected from the research.
9. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (*if applicable*).
10. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

11. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.

12. Contact information for: (a) Who to contact for questions about the research and in the event of research-related injury, (b) Who to contact for questions regarding rights as research subjects.

13. **Participation is voluntary** and the participant may refuse to participate and may discontinue participation at any time with no penalty or loss of benefits (if any).

Note:

1. For research involving minors (under 18 years of age):
    - In all cases in which subjects will be minors (under 18 years of age), a **parental permission** form is required. This serves as a consent form for parents and should include all the information normally included in a consent form.
    - For minors **aged 4 -7**: an age-appropriate oral assent is required.
    - For minors **over the age of 7**: an age-appropriate written **assent is required**.

2. If **video- or audiotapes are involved**, the consent/permission form should indicate that the subject has the right to review all or any portion of the tape and request that it be destroyed. Parents may not review audio/videotapes of children.

3. If the investigator might wish to **quote** or otherwise identify a subject in any publication, an **attribution statement** must be included in the consent form and a justification for requesting attribution.

4. When subjects are **employees or students**: include explanation that their participation and performance will not affect their records and/or employment.

5. If the study involves **focus group participation or other group activities**, the consent form must include a statement of the limits of confidentiality in group settings, that is, while the investigator may hold all individual information confidential, he/she cannot guarantee that other members of the group will do so.

6. Subjects must be **given a copy of the unsigned consent form** before subjects' participation begins.

7. For **research subject to expedited or full board review**, where the **length of the consent form is 3 pages or more**: A "Key information" section should be presented at the beginning of the consent form covering the following:
    - A statement that the project is research and participation is voluntary.
    - A summary of research purpose, duration and list of procedures.
    - Any reasonable, foreseeable risks or discomforts.
    - Reasonable, expected benefits.
    - Alternative procedures or course of treatment (*if applicable*).

8. (*If applicable*) the consent form should include a statement describing what actions will be taken should the research reveal the possibility of a medical or other potentially troublesome condition, emotional distress in reaction to sensitive questions, or other adverse effects.