CUNY HRPP Policy: Informed Consent Process and Documentation

1. Purpose and Overview

The purpose of this document is to provide guidance regarding the process of obtaining and documenting informed consent of research subjects. Researchers are required to obtain legally effective informed consent of each research subject or their legally authorized representative, unless the CUNY UI-IRB has granted a waiver or alteration of informed consent.

This document provides guidance regarding the informed consent process and its documentation for adult subjects with the capacity to consent for themselves.

For information on parent or guardian permission for inclusion of children in research and related child assent process and documentation, please refer to CUNY HRPP Policy: Research Involving Children.

If a CUNY researcher is designing a research project that may require the inclusion of adult subjects who do not have the capacity to give informed consent for themselves, the researcher should contact the Research Compliance Staff for specific guidance regarding the process and documentation of obtaining informed consent from such subject’s legally authorized representative. NOTE: Inclusion of cognitively impaired subjects must be scientifically and ethically justified; such inclusion is generally limited to healthcare related research with potential for direct benefit to the subject.

2. Informed Consent Process

It is important to note that the informed consent process involves a dialogue between the researcher and the subject throughout the duration of the research. It is not merely limited to the presentation and signing of the consent document. For long-term/longitudinal studies, consideration should be given to the possibility of re-consenting at appropriate intervals.

2.1. Considerations for an Effective Informed Consent Process

Researchers and CUNY UI-IRB shall ensure the following when planning and evaluating an informed consent process:

- The consent process takes place in a manner and at a location that ensures subject privacy;
- Information is provided in a manner and language that is understood by the subject;
- Subject is given sufficient opportunity to consider participation;
- Researcher ensures that subject’s questions are answered;
- Researcher ensures that the subject fully understands the information that is provided;
- Researcher obtains subject’s voluntary consent;
• Researcher provides for sufficient opportunities during the course of the research to address additional questions and to permit voluntary withdrawal without penalty; and
• Individual obtaining consent is qualified to do so, given the nature of the study and the subject population.
  o NOTE: Only those individuals who are approved by the UI-IRB to obtain consent may do so.

2.2. Subject’s Legal Rights
Informed consent, whether oral or written, may not include exculpatory language through which the subject or the representative is made to a) waive or appear to waive any of the subject’s legal rights; or b) release or appear to release the investigator, the sponsor, CUNY or its agents from liability for negligence.

2.3. Group Consent
For research involving subject populations that require group consent, the UI-IRB may approve this procedure with appropriate description and written justification by the Principal Investigator (PI) for the use of group consent. The PI should also provide a method to obtain private or individual subject assent, where appropriate, and a method for protecting those who choose not to participate in the study.

3. Documentation of Informed Consent
• Unless the UI-IRB has granted a Waiver of Informed Consent or a Waiver of Documented Informed Consent in accordance with Section 4 or 5 below, informed consent must be documented by the use of a written informed consent form approved by the CUNY UI-IRB and signed by the subject or the subject’s legally authorized representative. A copy of the signed informed consent form must be given to the person signing the form.

• Unless the UI-IRB has granted a Waiver or an Alteration of Informed Consent in accordance with Section 4 below, the informed consent document must include all of the basic elements of informed consent outlined in Section 3.2 below.

3.1. Use of Appropriate Language
• Consent documents must be written in a language understandable to the subject or legally authorized representative.

• All technical terms or jargon, not expected to be understood by the subject population, should be explained using lay language.

3.2. Basic Elements of Informed Consent
The following basic elements must be present in all informed consent documents, unless the IRB has granted a waiver of specific elements:
• A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

• A description of any reasonably foreseeable risks or discomforts to the subject;

• A description of any benefits to the subject or to others which may reasonably be expected from the research;

• A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

• A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;

• For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available;

• An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

• A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3.3. Additional Elements of Informed Consent
When appropriate, the following additional elements should also be included in the consent documents:

• A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

• Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject's consent;

• Any additional costs to the subject that may result from participation in the research;
• The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;

• A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation must be provided to the subject; and

• The approximate number of subjects involved in the study.

3.4. **Conflicts of Interest**
When a researcher has an existing or potential financial conflict of interest or a conflict of commitment related to a given human subjects research protocol, a disclosure statement informing the subjects of the existing or potential conflict must be included in the consent documents.

3.5. **Non-English Speaking Subjects**
When a researcher expects to enroll non-English speaking subjects, the investigator must submit translations of the English language consent documents into all languages spoken by the expected subject population. Translations must be performed by one of the following:

• A certified translator
  - A certificate of translation must accompany the IRB submission.

• A bilingual member of the research team, who is fluent in both English and the language of the non-English speaking subject.
  - An explanation of the translator’s qualifications must be included with the IRB submission.

**NOTE:** It is recommended that the researcher obtain IRB approval of the English language consent documents prior to translating them into other languages. This will prevent the need for multiple rounds of translations should the IRB require revisions.

3.6. **Illiterate Subjects and Subject Populations Without a Written Language**
When a researcher expects to enroll illiterate subjects or subject populations with no written language, the UI-IRB may approve a consent process using a UI-IRB approved short form written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject’s legally authorized representative. The following requirements must be met when using a short form written consent document:

• An impartial witness must be present during the oral presentation;

• Researcher must use a UI-IRB approved written summary of what is to be said to the subject or the representative during the oral presentation;
• The subject or the representative shall sign or mark, as appropriate, only the short form;

• The witness shall sign both the short form and a copy of the summary;

• The person obtaining consent shall sign only a copy of the summary; and

• A copy of the signed summary and a copy of the signed short form shall be given to the subject or the representative.

4. Waiver or Alteration of Informed Consent
The UI-IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent outlined in Section 3.2 above or waive the requirement for informed consent, if it determines and documents that the research falls within one of the following two categories and meets each of the conditions listed for the category:

4.1. Minimal Risk Research
The UI-IRB may approve a waiver or alteration of informed consent for minimal risk research when:

• The research involves no more than minimal risk to the subjects;

• The waiver or alteration will not adversely affect the rights and welfare of the subjects;

• The research could not practicably be carried out without the waiver or alteration; AND

• Whenever appropriate, the subjects is provided with additional pertinent information after participation.

4.2. Public Benefit or Service Programs
The UI-IRB may approve a waiver or alteration of informed consent when:

• A research or demonstration project to be conducted by or subject to the approval of state or local government officials is designed to study, evaluate, or otherwise examine the following:
  o Public benefit or service programs;
  o Procedures for obtaining benefits or services under those programs;
  o Possible changes in or alternatives to those programs or procedures; OR
  o Possible changes in methods or levels of payment for benefits or services under those programs; AND
• The research could not practicably be carried out without the waiver or alteration.

4.3. **PI Responsibility**
When requesting a waiver or alteration of informed consent, the PI is responsible for completing UI-IRB Submission Form - Supplement E and for providing sufficient explanation of how the criteria in either Section 4.1 or 4.2 above are met.

5. **Waiver of Documentation of Informed Consent**
The UI-IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it determines and documents that the research falls within one of the following two categories and meets each of the conditions listed for the category:

5.1. **Minimal Risk Research**
The UI-IRB may approve a waiver of documented informed consent for minimal risk research when:

- The research presents no more than minimal risk of harm to subjects; AND
- The research involves no procedures for which written consent is normally required outside of the research context.

5.2. **Consent is the Only Link to the Subject**
The UI-IRB may approve a waiver or alteration of informed consent for minimal risk research when:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
- In such instances, each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

5.3. **Information Sheet for the Subjects**
When the UI-IRB grants a waiver of documented informed consent, it may require that the investigator provide the subjects with information sheet about the research.

5.4. **PI Responsibility**
When requesting a waiver of documented informed consent, the PI is responsible for completing UI-IRB Submission Form - Supplement E and for
providing sufficient explanation of how the criteria in either Section 5.1 or 5.2 above are met.

References


2. Code of Federal Regulations, Title 21 – Food and Drugs, Part 50 – Protection of Human Subjects