

CUNY HRPP Policy: 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. Requirements set forth in this Policy apply to all non-exempt human subject research, regardless of funding.

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. General Requirements for Informed Consent

It is important to note that the informed consent process involves a dialogue between the researcher and the subject or their legally authorized representative 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 for the prospective subject or their legally authorized representative:

- Information must be provided that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information;
- The consent process takes place in a manner and at a location that ensures privacy;
- Information is provided in a manner and language that is understood;
- Researcher ensures sufficient opportunity is given to consider participation;
- Researcher ensures that questions are answered;
- Researcher ensures that the information that is provided is fully understood;
- Researcher obtains 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.
 - **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 legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears 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

3.1. Unless the UI-IRB has granted a Waiver of Informed Consent or a Waiver of Documented Informed Consent in accordance with Section 7 or 9 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.

3.2. *Written, or in writing*, for the purposes of informed consent, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

3.3. Consent documents must be written in a language understandable to the subject or legally authorized representative.

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

3.5. Except for broad consent obtained in accordance with Section 4 below:

3.5.1 Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative 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;

- 3.5.2 Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
- 3.6 Basic elements of informed consent delineated in 45 CFR 46.116(b) must be present in all informed consent documents, unless the IRB has granted a waiver of informed consent or an alteration of informed consent, or has approved broad consent.
- 3.7 When appropriate, one or more of the additional elements of informed consent delineated in 45 CFR 46.116(c) shall also be provided to each subject or the legally authorized representative, unless the IRB has granted a waiver of informed consent or an alteration of informed consent, or has approved broad consent.
- 3.8 When a researcher has an existing or potential financial conflict of interest or a conflict of commitment related to a given human subject research protocol, a disclosure statement informing the subjects of the existing or potential conflict must be included in the consent documents.

4 Broad Consent

An IRB may allow broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or for non-research purposes).

- 4.1 When a researcher has an existing or potential financial conflict of interest or a conflict of commitment related to a given human subject research protocol, a disclosure statement informing the subjects of the existing or potential conflict must be included in the consent documents.
- 4.2 Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens delineated in 45 CFR 46.116(d) must be present in all broad informed consent documents.

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. Additionally, all subject materials, recruitment materials, and any other materials that a participant will view as a result of their participation in the study must also be translated to the native language when a researcher expects to enroll non-English speaking subjects.

- 5.1 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.

6 Waiver or Alteration of Informed Consent in Research Involving Public Benefit or Service Programs

The UI-IRB may waive or alter consent if the UI-IRB finds and documents that:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - Public benefit or service programs;
 - Procedures for obtaining benefits or services under those programs;
 - Possible changes in or alternatives to those programs or procedures; OR
 - 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.

6.1 If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, the UI-IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

7 General Waiver or Alteration of Informed Consent

The UI-IRB may waive or alter informed consent if it finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

- The waiver or alteration will not adversely affect the rights and welfare of the subjects; AND
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

7.1 If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, the UI-IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

7.2 If a broad consent procedure is used, the UI-IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

8 Screening, Recruiting, or Determining Eligibility Without Informed Consent

The UI-IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; OR
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

9 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 finds and documents ANY of the following:

- That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; OR
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an

appropriate alternative mechanism for documenting that informed consent was obtained.

9.1 Written Statement. In cases in which the documentation requirement is waived, the UI-IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

10 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 informed consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by Section 3.5.1 above was presented first to the subject, before other information, if any, was provided.

10.1 The UI-IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative.

10.2 When this method is used, there shall be a witness to the oral presentation. The witness shall sign both the short form and a copy of the summary.

10.3 Only the short form itself is to be signed by the subject or the legally authorized representative.

10.4 The person obtaining consent shall sign a copy of the summary.

10.5 A copy of the summary and a copy of the short form shall be given to the subject or the subject's legally authorized representative.

References

1. [Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects](#)
2. [Code of Federal Regulations, Title 21 – Food and Drugs, Part 50 – Protection of Human Subjects](#)