

CUNY HRPP Guidance: Informed Consent Document Development

1. Purpose

The purpose of this guidance document is to assist CUNY researchers in developing informed consent documents for non-exempt human subject research.

NOTE: This guidance is a supplement to [CUNY HRPP Policy: Informed Consent Process and Documentation](#) and [CUNY HRPP Policy: Children as Research Subjects](#). Researchers must comply with the requirements of the Policies.

2. Required Formatting

- Upon approval, the consent documents will be stamped with an approval stamp on the bottom right corner of each page. The size of the stamp is LxW 3"x1". Researchers are required to leave sufficient space at the bottom of each page of each consent document to allow for the stamp.
- Include page numbers

3. Recommended Formatting

- Use reader-friendly formatting so that the document looks easy to read.
- Use headings, sub-headings, bulleted or numbered lists and/or tables or images, as appropriate, to assist in clarity.

4. Types of Informed Consent Documents

Depending on the type of research, one or more of the documents described below may be approved by the IRB. Researchers are required to use CUNY templates for developing each of these documents in order to ensure that all CUNY requirements are met.

- **Informed Consent Form**

An informed consent form is used to obtain documented consent from:

- An adult human subject who has the capacity to consent for him/herself; or
- The legal representative of an adult human subject who does not have the capacity to consent for him/herself.

- **Child Assent Form (Adolescents ages 13-17) / Parental Permission**

Since all informed consent documents are expected to be at a reading level of 8th grade or lower, the child assent form for adolescent subjects (ages 13-17) also serves as the parental permission form. Only one document is required.

- **Child Assent Form (Children ages 7-12)**

This simple one page document is used to obtain assent from children ages 7-12. Children are not required to sign the assent form. The individual obtaining assent is required to document in the research records that child assent was obtained.

- **Parental Permission Form**
This document is used for obtaining parental permission from parents of minor subjects ages 7-12.
- **Research Information Sheet**
An information sheet is used in lieu of an informed consent form when the IRB has approved a waiver of documented informed consent for some or all research procedures. This document should be developed using the Informed Consent Form template, and removing the signature lines at the bottom.
- **Oral Informed Consent Script / Internet Based Informed Consent Language**
When the IRB approves an oral or Internet based informed consent process, i.e. the IRB grants a waiver of documented informed consent, researchers must use an IRB approved oral informed consent script or language that will be used to obtain Internet based informed consent. The individual obtaining oral consent is required to document in the research records that participant consent was obtained.
- **Addendum to the Informed Consent**
An Addendum to the Informed Consent is used to provide new information that has become known after the initial informed consent was obtained, and that may affect the risk/benefit ratio of the research, and/or may affect the subject's willingness to continue participation.
- **Screening Script**
A Screening Script is used to obtain oral or Internet based informed consent for conducting eligibility screening procedures when the IRB has approved an oral or Internet based screening consent process, i.e. granted a waiver of documented informed consent for screening purposes. The individual obtaining oral consent is required to document in the research records that participant consent was obtained.