



NYCHP IRB Short Form Consent

Who can use the Short Form Consent?

This form is intended for studies that meet **all** of the following criteria:

1. The study is considered a biomedical research study, which is defined as:
 - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
2. The majority of participants that will be enrolled in the study are English speakers, but there may be potential participants who will not be able to understand consent form in English.
 - For further information regarding the use of a Short Form, please see the *NYCHP IRB Consent Short Form Guidance* on the next page.

Instructions for using the Short Form Consent

- Read all instructions and guidance prior to submitting your IRB submission.
- **DO NOT** alter any of the text in this form. It must be used with the text exactly as it appears here.
- **DO NOT** alter the letterhead, header/footer, side margins, font size (11 point), or font style (Arial) of this template.

Before you attach the Short Consent Form to your IRB submission, you MUST:

- You **must** provide assurance in your IRB Submission that you will use the NYCHP IRB Consent Short Form.
- Delete this instructions page and the guidance page that follows.

What is a Short Form?

A Short Form is a written document listing the elements of informed consent required by 45 CFR 46.116 and stating that study-specific information has been orally described to and understood by the participant or their legally authorized representative. The oral description of the study-specific information must cover the study procedures, risks, benefits, etc. based on the IRB approved informed consent form.

When can a Short Form be used?

A Short Form can be used when the majority of participants in the study are English speakers, but there are potential participants who will not be able to understand consent form in English. A Short Form can be used under these circumstances to obtain informed consent ensuring equal access for all potential participants. Investigators need to indicate on their **New Protocol Submission Form** if they anticipate the need to use a Short Form or file an **Amendment Form** to modify the study.

When a Short Form cannot be used?

1. If there is no potential harm to delaying participant enrollment, the study team must obtain IRB approval of a translated **Informed Consent Form**.
2. If the majority of the anticipated participants to be enrolled do not speak English or will be unable to understand the consent form in English, the short form may not be used. A consent form translated into a language understandable by the participants must be used and receive IRB approval.

How is a Short Form used?

The Short Form consent process involves three people: the person seeking consent, the potential participant, and a witness to the process. The witness cannot be a member of the study team and must speak both English and the language of the participant fluently. The witness can be a translator or another individual.

The investigator reads an oral summary of the study to the potential participant, or their representative, and the witness. This oral summary must be approved by the IRB and is usually based on the **English Informed Consent Form**. A copy of the Short Form and a copy of the oral summary must be given to the participant or their representative.

The following signatures are required if the participant agrees to take part in the study:

1. **Short Form** – Participant or their representative and the Witness
2. **Copy of Oral Summary** – Witness and the Person obtaining consent

What must be approved by the IRB?

1. Justification for the use of short forms.
2. A summary of what will be presented to the participant or their representative.
3. Assurance that **NYCHP IRB Consent Short Form** will be used.

What is this form?

You are being asked to take part in a research study.

Before you agree to take part, someone will explain to you:

- Why you are being asked to take part in research
- The purposes of the research
- How long you will be in the research
- What will happen to you
- What is experimental
- Risks or discomforts to you
- Benefits to you or others
- Other choices you might have
- Who will see your information
- You volunteer to be in a research study
- Whether or not you take part is up to you
- You can choose not to take part.
- You can agree to take part and later change your mind
- Your decision will not be held against you
- You can ask all the questions you want before you decide

Who can I talk to about the study?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem, which may be related to this study, please contact the research team with the information provided to you on the oral summary sheet.

Research Participants Rights

For questions/concerns regarding your research rights, please contact:

Institutional Review Board
New York College of Health Professions
(516) 000-000 / Toll Free: 1-800-922-7337
IRB@nycollege.edu

You may also visit the NYCHP IRB website at <https://nycollege.edu> for further information regarding your rights as a research participant.

When applicable, someone will explain to you:

- Whether you will get treated or paid if injured
- The possibility of unknown risks
- When you may be taken off the research without your agreement
- Added costs from taking part
- What will happen if you stop taking part
- Steps to safely stop taking part
- When new information will be told to you
- The number of people expected to take part
- That the US Food and Drug Administration may inspect the records
- What happens to collected data if you stop taking part



- An explanation of www.ClinicalTrials.gov

Research Consent & Authorization Signature Section

Adult Signature Section

Your signature documents your permission to take part in this research study.

Printed Name of Participant

Signature of Participant

Date

Printed Name of Witness

Signature of Witness

Date