

CUNY HRPP Guidance: Suggested Language for Consent Documents

Please use the suggested language included in this guidance document as applicable and appropriate. Note that you may need to edit some of this language to ensure accuracy in relation to your specific research protocol.

Audio Recording / Video Recording / Photographs

Confidentiality section

You have the right to review the recording / photographs taken as part of this research to determine whether they should be edited or erased in whole or in part.

Instruction: Explain who will have access to the tapes; whether they will be used for educational or other purposes; and if/when they will be erased.

Certificate of Confidentiality

Confidentiality section

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[<You may use the following language as applicable> The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by <the agency> which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

<Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.> The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of <list of mandated reporting requirements, such as child abuse and neglect, or harm to self or others>.

<Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.> The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document <restate what will be disclosed, such as including research data in the medical record>.

Child Assent Form

You can talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. Even if your parents say “yes”, you can still decide not to do this.

CUNY Employees as Research Participants

If you are a CUNY employee, your willingness to participate in this research study, or your request to withdraw from the research study, will not affect your employment with CUNY.

CUNY Students as Research Participants

If you are a CUNY student, your willingness to participate in this research study, or your request to withdraw from the research study, will not affect your grades or academic standing with CUNY.

Deception / Withholding Information

In introductory paragraph (note: only one of the three paragraphs will apply)

For scientific reasons, this consent form does not include complete information about the purpose of this research. You will be fully debriefed following your participation in the research.

We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these conditions, we will explain the procedure to you fully after your participation.

Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the research will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing, which will

include an explanation of the purpose of the research and other relevant background information pertaining to the research. You will also be given an opportunity to ask any questions you might have.

Focus Groups

Confidentiality section

All participants will be asked not to share the information discussed during the group discussion with anyone outside of the group. However, complete confidentiality cannot be guaranteed.

Future Recruitment

Signature of Participant section

On the checklist below, please indicate if you would permit the researchers to contact you in the future for participation in other research studies.

_____ I agree to allow the researchers to contact me for future research studies.

_____ I do not agree to allow the researchers to contact me for future research studies.

Randomization

Procedures section

Randomization is a procedure used to assign research participants by chance to one of two or more groups. It is used to make sure that study results are not influenced by the selection of participants in one group as compared to another. In this research, you have a <x> chance of being assigned to one of the following groups: <define each group and related procedures>.

Store and/or Share Data for Future Research

Signature of Participant section

On the checklist below, please indicate if you would permit the researchers to store and/or share your <describe data to be stored/shared> for future research.

_____ I agree to allow my <insert data type> to be stored for future research by the researchers of this study.

_____ I agree to allow my <insert data type> to be shared with other researcher for future research.

_____ I do not agree to allow <insert data type> to be stored or shared for future research.

Store and/or Share Samples for Future Research

Signature of Participant section

On the checklist below, please indicate if you would permit the researchers to store and/or share your *<describe samples to be stored/shared>* for future research.

_____ I agree to allow my *<insert sample type>* to be stored for future research by the researchers of this study.

_____ I agree to allow my *<insert sample type>* to be shared with other researcher for future research.

_____ I do not agree to allow my *<insert sample type>* to be stored or shared for future research.

Surveys, Questionnaires and Interviews

Procedures section

You may refuse to answer any questions that you do not want to answer and still remain in the study.

Potential Risks or Discomforts section

Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.