

Below is an example of an Informed Consent form. Informed consents should include the information listed below.

Informed Consent

Title of Research:

Principle Investigator, Affiliation and Contact Information:

Additional Investigators and Affiliations:

Institutional Contact: **Institutional Review Board**
Hofstra University
Office of Research and Sponsored Programs
516-463-5054

1. Introduction and Purpose of the Study

Include a brief overview of the study on a level of understanding for the person who will be signing the form. Remember that the general population might not understand what you consider basic terminology. A general rule is to keep the wording at no more than an 8th grade reading level.

2. Description of the Research

Include a description of what participation in the study entails.

Example: “When you enter into the program, you will be asked to complete two questionnaires. You will then be asked to participate (**EXPLAIN INTERVENTION IN BASIC TERMS**). After you have completed the (intervention), you will be asked to complete two more questionnaires.

3. Subject Participation

Give an overview of what participant characteristics are needed for the study.

Example: We estimate that 20 participants who (describe population) will enroll in this study. Participants must have (describe inclusion criteria, for example: participants has some motor ability in both hands and can verbally communicate). Your participation will involve one visit, approximately 50 minutes in length.

4. Potential Risks and Discomforts

In this section include any potential risk or discomforts, and how those risks will be addressed if they arise (call 911, refer to mental health clinic, etc.). If you believe there are no risks involved, since there is never a guarantee, state that there are “no known risks”.

5. Potential Benefits

Include a statement about potential benefits for participating in the study.

***Example:** People who participate in this study may have a better understanding of additional treatment methods that enable individuals to experience and increase their overall sense of well-being.*

6. Confidentiality In this section let the participant know the level of identity protection of any personal information collected for this study. Will their identity be fully protected, and if so how, if not, then to what level and what will be publicly available?

***Example:** All information taken from the study will be coded to protect each subject's name. No names or other identifying information will be used when discussing or reporting data. The investigator(s) will safely keep all files and data collected in a secured locked cabinet in the principal investigators office. Once the data has been fully analyzed it will be destroyed.*

***Example:** Your responses are completely anonymous. No personal identifying information or IP addresses will be collected. Data will be aggregated via the Qualtrics reporting function. Quantitative results will be shared with the Chairperson and the faculty in the academic unit. Qualitative results will be shared with the Chairperson and the Provost's Office.*

***Example:** I would like to interview you "on the record" so that I can identify you in publications resulting from this research. However, if you wish to remain anonymous, I will keep your name separate from your words; I will not use your name in any quotations or reports of my findings; I will use a pseudonym of your choosing; and I will omit or obscure any identifying details.*

If the research will be collecting audio or video recordings, there must be a statement explaining how the recording will be handled and at what point destroyed.

***Example:** Once audio recordings are coded and transcribed they will be destroyed.*

***Example:** I will store audio recordings and any electronic or printed transcripts in encrypted files or in a locked, secure location for five years after the publication of this research, after which, all files will be destroyed.*

Authorization

***Example:** By signing this form, you authorize the use and disclosure of the following information for this research: **Example:** I authorize the use of my records, any observations, and findings found during the course of this study for education, publication and/or presentation.*

7. Compensation In some research studies participants will receive some type on compensation. This could be in the form of money, gift card, or items. In this area you must state if there is, or isn't, compensation. If so, explain in what form and when it will be issued.

***Example:** Subjects will not be compensated for participation in this study. **Or:** Each participant will receive \$10.00 at the conclusion of the study.*

8. Voluntary Participation and Authorization Participants need to be made aware that they do not have to participate in the study, and that it is fully voluntary. If they decide not to participate they must be informed that it will not affect any relationships they have with the researcher and/or facility in which it is administered.

Example: Your decision to participate in this study is complete voluntary. If you decide to not participate in this study, it will not affect the care, services, or benefits to which you are entitled.

9. Withdrawal from the Study and/or Withdrawal of Authorization Participants also need to know that they can withdraw at any point if they choose not to continue. In this section you can put in a withdrawal process, such as they need to inform the research(s) in writing. Additionally, if appropriate to the study, if data has already been collected, they can be informed that anything collected prior to withdrawal will be included in the study.

Example: If you decide to participate in this study, you may withdraw from your participation at any time without penalty.

10. Cost/Reimbursements Here you will let the participant know if there will be any fees attached to their inclusion in the study. Will they have to pay for the materials, supplies, transportation, etc? *Example: There is no cost for participating in this study. Any medical expenses resulting from participation in this study will not be reimbursed by the investigators.*

I voluntarily agree to participate in this research program

Yes

No

I understand that I will be given a copy of this signed Consent Form.

Name of Participant (print): _____		
Signature: _____		Date: _____
Name of Witness (print): _____		
Signature: _____		Date: _____
Person Obtaining Consent: _____		
Signature: _____		Date: _____

Note: A copy of the signed, dated consent form must be kept by the Principle Investigator(s) and a copy must be given to the participant.