Brandeis University

Human Research Protection Program

Elements of Informed Consent

Note: Always use lay language that is appropriate to the population being asked to sign the form. Use short paragraphs, bullets and subheadings to increase readability. See the **informed consent form template (pdf)** for more help and sample language.

1. Title of the Study

---

2. Names and Affiliations of the Primary Investigator

If a student is conducting the study, state the student's information first.

---

3. Purpose of the Study

Describe the general purpose of the study.

---

4. Subject Selection Criteria

Describe how the subjects were chosen.

---

5. Study Procedures

- In chronological order, describe what the subject will be asked to do (an activity, completing a survey).
- Describe the total length of time for participation (how long, how often).
- If applicable, explain that the investigator will be audiotaping or videotaping, and if this is optional.

6. Potential Risks and Discomforts

Describe any potential for psychological, social, legal or financial risk or harms to the subject and their probability as a direct result of participation in the research and/or from breach of confidentiality. (Remember: There is no such thing as risk-free human subject research.)

7. Potential Benefits

- Describe any expected benefits to the subjects themselves (clearly state if subject will not benefit directly from the study).
- Describe any expected benefits to society and/or science.

8. Cost and Compensation

- Describe any cost to the subject (include time spent).
- Describe any compensation the subject will be offered as a result of participation in the research (if partial participation will result in partial compensation, explain).

9. Future Use of Data

- Explain that identifiable private information/de-identified data may be retained and used for additional or subsequent research, and if this is optional .

– OR –

- State that the data collected will not be distributed for future research, even with the identifiers removed (note that some funders and journals require de-identified data to be made available to others postresearch/publication).

10. Confidentiality

- Describe the level to which subject information will be kept confidential (describe procedures that will be used to safeguard data, including where it will be kept, who will have access to it and at what point it will be destroyed; note the difference between anonymous and confidential).
- Note that data will only be kept confidential to the extent permitted by law.

11. Participation and Withdrawal

State clearly that participation is voluntary and that the subject may refuse to answer any questions or withdraw from the study at

any time without penalty (including loss of benefits to which they would otherwise be entitled).

---

12. Contact Information

- Give the contact information of the principal investigator and supervised researcher (if applicable) for questions about the study.
- Give the contact information of the Brandeis University HRPP (**hrpp-group@brandeis.edu** or 781-736-8133) for questions about the subject's rights as a human subject or concerns about the research.

---

13. Subject Consent

Example

- I have read (or had read to me) the contents of this consent form and have been encouraged to ask questions. I have received satisfactory answers to my questions. I understand that my participation is voluntary and that I may withdraw my participation at any time without penalty. I voluntarily agree to participate in this study.
- __ I do __ I do not give you permission to make audio/video recordings of me during this study (if applicable).
- __ I do __ I do not give you permission to retain and use my data for future research (if applicable).
- Signatures of subject and investigator.

Additional statement of confidentiality to be used for research involving focus groups:

14. Focus Group

Example

- Please be advised that although the researchers will take every precaution to maintain the confidentiality of what is discussed, the nature of focus groups prevents the researchers from being able to guarantee confidentiality. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.
- __ I agree to maintain the confidentiality of the information discussed by all participants and researchers during the focus group.

Additional statement of procedure to be used when appropriate for research involving

incomplete disclosure:

15. Incomplete Disclosure and Deception

Example

Research sometimes requires that information regarding its purpose not be shared with the research participants because its knowledge could impact the results of the research. While the tasks you will be asked to perform for this research have been explained, certain details have been left out of the description of the study, or intentionally mis-described. At the completion of the study you will have the opportunity to ask questions, including about the purpose of the study and the procedures used, and withdraw your data if you so choose. Note that none of the aspects of the research being withheld are reasonably expected to affect your willingness to participate.

Additional statement of confidentiality when collecting identifiable, sensitive information for research funded by NIH, or when a certificate of confidentiality has been issued by NIH, CDC, FDA, HRSA or SAMHSA:

16. Certificates of Confidentiality

Example

- To help protect your privacy, this research is covered by a certificate of confidentiality. This means that the researcher 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 — if there is a court subpoena, for example — unless you have consented to its use.
- Information, documents, or biospecimens protected by this certificate cannot be disclosed to anyone who is not connected with the research unless you report to the researcher information concerning child abuse or communicable diseases (if applicable); you have consented to the disclosure; or the information is used for other scientific research, as allowed by federal regulations protecting research subjects.
- 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 any other person not connected with the research, you must provide consent to allow the researchers to release it.

Additional elements of informed consent to be used when appropriate (generally only necessary for biomedical/clinical research):

17. Experimental Procedures

Identify and describe any procedures that are experimental.

---

18. Alternative Procedures

Include a statement of any alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

---

19. Possibility of Unforeseeable Risks

Include a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

---

20. Compensation or Treatment in Case of Injury

Explain whether any compensation or medical treatments are available if injury occurs, what they consist of, and where further information may be obtained.

---

21. Potential Termination Without Regard to Consent

Include a statement of anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

---

22. Additional Costs

Describe any additional costs to the subject that may result from participation in the research.

---

23. Consequences of Withdrawal

Review the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

---

24. Provision of Significant New Findings

Include a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

---

25. Number of Subjects

State the approximate number of subjects involved in the study.

---

26. Commercial Use of Biospecimens

A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

---

27. Clinically Relevant Research Results

A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

---

28. Genome Sequencing

A statement of whether the research will or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).