



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 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 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 post-research/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 PI and student investigator (if applicable) for questions about the study
 - Give the contact information of the Brandeis University HRPP for questions about the subject's rights as a human subject or concerns about the research (irb@brandeis.edu or 781-736-8133)

***** Note: See page 2 for additional elements to include where appropriate and when applicable *****
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 Groups

- **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

- **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, the full intent of the research will not be provided until the completion of the study. At that time 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 (CoC) has been issued by NIH, CDC, FDA, HRSA, or SAMHSA

16. Certificate 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)