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 if appropriate to increase readability.

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 (if applicable)
   • Explain that the research data collected may be retained and used for additional or subsequent research, and if this is optional
   • Describe the possible future research
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 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)
13. Subject Consent
    Note additional elements on next page to be included prior to subject consent, when appropriate
    • 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.”
    • Example (if applicable): ☐ I do ☐ I do not give you permission to make audio/video recordings of me during this study
    • Example (if applicable): ☐ I do ☐ I do not give you permission to retain and use my data for future research
    • Signatures of subject and investigator
**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**

Confidentiality, continued

- Include language describing/explaining the Certificate of Confidentiality – suggested language (amend as appropriate):

  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 there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases); if you have consented to the disclosure; or if it 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 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.

  **Additional elements of informed consent to be used when appropriate**

  **(generally only necessary for biomedical/clinical research)**

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

15. **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

16. **Compensation or treatments in case of injury**
   - Include an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

17. **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

18. **Additional costs**
   - Describe any additional costs to the subject that may result from participation in the research

19. **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

20. **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

21. **Number of subjects**
   - State the approximate number of subjects involved in the study