

Informed Consent Form (Sample)

Study Title:

Principal Investigator:

Co-Investigators:

Sponsor (if applicable):

This consent form will give you the information you will need to understand why this research study is being done and why you are being invited to participate. It will also describe what you will need to do to participate as well as any known risks, inconveniences or discomforts that you may have while participating. We encourage you to ask questions at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form to keep.

Purpose and Background

Be sure to include information on the following required items:

- Statement that study involves research
- Nature of the study
- Purpose and goals of the study
- A brief description of the study pool

Procedures

Be sure to include information on the following required items. Items in italics are required on an 'if applicable' basis:

- Step-by-step explanation of participation from a subject's point-of-view
- Length and frequency of each study procedure
- Total time commitment
- How data will be collected
- Where data collection will take place
- *Conditions (if applicable)*
- *Other options (if applicable)*

Risks

Be sure to include information on the following required items. Items in italics are required on an 'if applicable' basis:

- All possible risks and/or discomforts (physical, emotional, social, etc) and the level of risk
- Safeguards in place to minimize risks
- ***IF your research involves collecting a combination of demographic data regarding gender, age, race, and ethnicity, which could make a subject identifiable, include the following required language:***
 - "For this research project, we are requesting demographic information. Due to the makeup of [the study population], the combined answers to these questions

may make an individual person identifiable. We will make every effort to protect participants' confidentiality. However, if you are uncomfortable answering any of these questions, you may leave them blank."

- ***IF your research study involves possible physical risks, include the following required language:***
 - In the event you become sick or injured during the course of the research study, immediately notify your personal physician and the principal investigator.

Benefits

Be sure to include information on the following required items:

- All possible direct or indirect benefits to participants that may be reasonably expected as a result of the research
- If there are no benefits, indicate larger societal benefits

Extent of Confidentiality (or Extent of Anonymity)

Be sure to include information on the following required items. Items in italics are required on an 'if applicable' basis:

- Extent to which subjects will be identifiable
- Explanation if anonymity or confidentiality is promised
 - If anonymity is promised, provide the definition of anonymity and explain how this will be accomplished. (Anonymity = individuals cannot be identified by anyone, including the researchers)
 - If confidentiality is promised, provide the definition of confidentiality and explain how this will be accomplished. (Confidentiality = individuals can be identified directly or through identifiers, but the researchers promise not to divulge that information)
- Who will have access to data
- When data will be destroyed (must be kept for at least three years following the conclusion of the research study, per federal regulations)
- ***IF video and/or audio recordings are used, provide an explanation of their use***
- ***IF data will be published, please provide a statement saying data will be published***
- ***IF direct quotes will be used, inform subjects that direct quotes will be used. Provide an explanation of how the direct quotes will be used, if you will use identifiers with the quotes or if there is a possibility that the quote could identify that individual.***
 - ***Note: IF you are quoting with identifiers (e.g., name), you must give subjects the option of opting out of being directly quoted. They will need to indicate consent to be directly quoted with a separate "initial here" line in the Extent of Confidentiality/Anonymity section, or at the end of the consent form. Otherwise, they are agreeing to be quoted, but NOT identified.***
 - ***Sample language #1: "Your name will not be associated with your tapes or transcriptions and your name will not be used in any written reports or publications which result from this research. Your participation in this research study will be kept strictly confidential."***

- *Sample language #2: “All findings used in any written reports or publications which result from this evaluation project will be reported in aggregate form with no identifying information. It is, however, useful to use direct quotes to more clearly capture the meanings in reporting the findings from this form of evaluation. You will be asked at the end of the interview or focus group if there is anything you said which you do not want included as a quote, and we will ensure that they are not used.”*

Compensation

Be sure to include information on the following required items. Items in italics are required on an ‘if applicable’ basis:

- If subjects are not being compensated, state that subjects will not receive compensation for their participation in this research study.
- If subjects are receiving compensation, state that subjects will receive compensation, the amount of compensation, and how it will be received.
- *IF course/extra credit is being offered, state equitable alternatives that are available to subjects.*

Participation is Voluntary

Be sure to include information on the following required items. Items in italics are required on an ‘if applicable’ basis:

- Statement that subjects are free to withdraw from the research study at any time without penalty
- Statement that subjects are free to skip any question they do not feel comfortable answering without penalty
 - Sample Language: “You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time without consequences of any kind or loss of benefits to which you are otherwise entitled.”
- IF compensation is involved, statement explaining subjects will be compensated for their portion of the study

Questions

If you have any questions or concerns about your participation in this study, you should first talk with the principal investigator at **[insert e-mail and/or phone number of principal investigator here]**.

If you have questions about your rights as a research participant, you may contact the Berklee Institutional Review Board (IRB), which is concerned with the protection of volunteers in research projects at BerkleeIRB@berklee.edu

Documentation of Consent

I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement, and possible risks have been explained to my satisfaction. I understand I can withdraw at any time.

Printed Name of Study Participant

Signature of Study Participant

Date

Signature of Person Obtaining Consent

Date