Berklee Institutional Review Board
Informed Consent Guidelines
INSTRUCTIONS FOR INFORMED CONSENT DOCUMENTS

This document provides information for researchers when developing an informed consent form.

- Informed consent forms are for participants age 18 years or older.
- If participants are age 11-17, use an assent form along with parent/guardian permission form. See a sample assent form on Berklee's IRB website.
- A copy of the informed consent form must be given to the participant and a signed copy must be kept in the researcher's records for a minimum of three years.
- Informed consent forms should be written in the second person (*you* statements).
- Avoid scientific jargon. The information must be written at a reading level appropriate for the subject population. The Berklee IRB recommends an 8th grade reading level for the average adult participant. Microsoft Word has a tool that assesses readability.
- Informed consent forms must be free of spelling and grammatical errors. It is important for the participant to fully understand what they are agreeing to do in your research study. A form full of spelling and grammatical errors does not communicate and cannot serve its purpose. Please proofread your informed consent before turning it in to the IRB.
- When appropriate, include the full name of the study sponsor (e.g. National Institute of Health, National Science Foundation).
- Select a font type and size that is easy to read (e.g. Times New Roman 12-point font).
- You do not have to use the same format as our sample informed consent form, but the general requirements for informed consent must be included.
- When you submit a consent form, parental permission form, or an assent form to the IRB, you should submit it as a PDF file. The PDF file version should have the exact appearance and format that you want when you distribute the form to your participants in the study. If a form is part of an expedited or full review, the IRB will return the form to you with an approval stamp after your protocol has been approved. You will have very limited opportunity to make any changes at that point.

The Informed Consent Process

The informed consent process can take on various forms:

A. Signed informed consent is the standard expectation in research with human participants. This is in the form of a document with the elements of informed consent, signed and dated by the participant and kept as a record by the researcher.
B. In research with children (individuals under 18 years old), assent of the child and parental permission are standard requirements.
C. In some circumstances, investigators can seek alternatives to standard informed consent procedures, such as:
    a. A waiver of using a signed consent form (e.g. giving participants an information sheet but not collecting signatures).
    b. A waiver of written consent (e.g. using oral consent procedures).
    c. A waiver of some or all of the elements of informed consent (e.g. in research that involves deception).

Basic Elements of Informed Consent

A. A clear statement that the study involves research, purpose and expected duration, procedures to be followed, and identification of any procedures which are experimental;
B. A description of any risks or discomforts to the subject;
C. A description of any benefits to the subject or to others;
D. Alternative procedures or courses of treatment;
E. A statement describing how confidentiality will be maintained;
F. For research involving more than minimum risks, compensation for injury;
G. Research and research subjects' rights, and who to contact in the event of a research-related injury to the subject;
H. A statement that participation is voluntary.

INFORMED CONSENT CHECKLIST

(All checkboxes should be included in consent form, as applicable)

- ❏ Study Title
- ❏ Researcher(s) are listed as well as affiliation with Berklee (e.g. student, faculty, staff)
- ❏ Funding source(s) if applicable.

Purpose and Background

- ❏ Statement that study involves research
- ❏ Nature of the study
- ❏ Purpose and Goals of the study
- ❏ Brief description of the study pool (e.g., adult participants)

Procedures

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

Risks

- ❏ Lowest level (No more than minimal risk)
- ❏ All possible risks or discomforts (physical, emotional, social)
- ❏ Safeguards in place to minimize risks
- ❏ Required language if collecting a combination of demographic data that could make subject identifiable
- ❏ Required language if research involves serious psychological stress
- ❏ Required language if research involves serious physical risks

Benefits

- ❏ All possible direct or indirect benefits
- ❏ If no benefits, indicate larger societal benefits

Extent of Anonymity and Confidentiality

- ❏ Extent to which subjects will be identifiable
- ❏ Explanation if anonymity or confidentiality is promised
- ❏ Explanation of use of video or audio recordings
- ❏ Who will have access to data
- ❏ When data will be destroyed (must be kept for minimum of 3 years, per federal regulations)
- ❏ Statement if data will be published
- ❏ Explanation of use of direct quotes; if using identifiers or pseudonyms, etc.

Compensation

- ❏ Statement indicating subject will receive compensation or will not receive compensation
- ❏ Amount of compensation, how it will be received
- ❏ If offering extra/course credit, what equitable alternatives are available?

Participation is Voluntary

- ❏ Statement that subjects are free to withdraw from study at any time without penalty
- ❏ If compensation is involved, statement explaining subjects will be compensated for their portion of the study
- ❏ Statement that subjects are free to skip any question they do not feel comfortable answering without penalty

Questions

- ❏ Contact information for PI (and faculty sponsor for students)
- ❏ Contact information for the IRB office

Consent Documentation

- ❏ Statement of consent
- ❏ Signature line

Waivers

- ❏ If waiving signature line, waiver form submitted
- ❏ If waiving any of the required elements of consent, waiver form submitted

Other

- ❏ Language is free of scientific jargon
- ❏ Text is readable and appropriate for the age and population
- ❏ Free of exculpatory language in which the subject is made to waive or appear to waive any rights
- ❏ Free of grammatical and typographical errors
- ❏ Subject has been given a copy of the consent