

Guidelines for Constructing Research Consent Forms

- A. Use nontechnical language and first-person when possible.
- B. State the purpose and benefits of the research. Usually the research is not being done for the benefit of the subject but for information of potential future benefit to others. This broader social benefit should be made explicit. State terms of compensation, if any, to be paid to the subject.
- C. Indicate risks, potential discomforts, and inconveniences (including, when appropriate, risks and benefits of alternative treatments).
- D. Include a statement in which the subject affirms that s/he has received information about the benefits and risks of the research.
- E. Provide assurance that refusal to participate will not prejudice the person's future standing as a patient, student, employee, and so forth. Similarly, assurance should be given that the person may withdraw at any time without prejudice unless his/her health or safety is in clear jeopardy.
- F. Give the name, office address, and telephone number of the principal investigator or other responsible person who may be contacted for additional information, and concerns.
- G. When applicable, have the consent form also signed by the legal guardian of persons **under** age 18 or persons mentally disabled. (Guardians may consent to experimental procedures for minors and for individuals judged incompetent, if there is some direct benefit to the subject. Where no potential, direct benefit occurs, the legal validity of a guardian's consent is questionable.)
- H. The principal investigator or person administering treatment, not a subordinate, should obtain the consent.
- I. If applicable, include a statement to the effect that some information gained during the research may have to be disclosed as required by law (e.g., instances of child abuse). Therefore, absolute confidentiality or privilege of communication cannot be assured, although a vigorous effort will be made to provide anonymity for the subject and to give identifying information only to persons s/he specifically authorizes.
- J. Some consent forms include a statement in which the subject releases the experimenter and the institution from any future claims of harm (i.e., an "exculpatory clause"). Federally funded research projects should not include such a clause because federal agencies, as a matter of policy, have maintained that a clause of this kind may unreasonably inhibit a subject from seeking legitimate remedies for injuries caused by the negligence of the experimenter.
- K. Indicate whether or not monetary compensation or medical/psychological treatment will be available, and the nature of such (e.g., only to extent of insurance coverage, acute medical only at specified facility, financial compensation for wages lost) for any research-related injury.
- L. The sample consent forms that follow in this section of the appendix are presented as illustrations of various intervention agreements. There is no intention to suggest that these are the best possible forms in given circumstance or that they have legal effect and validity in a particular jurisdiction.

IDENTIFICATION

Name of research director:

Date: Time: AM/PM

Name of research organization:

Address:

Phone number:

Name of the research participant:

Title of the research project:

DESCRIPTION OF RESEARCH PROCEDURES

(Include the nature and purpose of the research, basic procedures, and the possible material or significant benefits and risks)

STATEMENT OF CONSENT AND AGREEMENT

I, _____ grant my permission to participate in the research described above and related incidental procedures. The nature and purpose of this research and the possible material or significant benefits and risks have been explained to me so that I understand them.

I am granting my participation without duress or coercion in exchange for expected benefits for me or for others. I understand that I may withdraw my consent at any time I wish without penalty or prejudice and may stop participating as soon thereafter as it is safe to do so. If I am being paid for my participation in this research, I may collect my entire fee at any time I choose to withdraw from the research.

If I am not satisfied with my participation, I will immediately inform the research director. I may also inform Winnie Wang, the Chair of Claremont McKenna College's Institutional Review Board, an independent advisory group interested in the opinions and welfare of research participants. Winnie Wang can be contacted by phone at (909) 607-9283, or via email, at winnie.wang@claremontmckenna.edu. I acknowledge that no guarantee or assurance has been made as to the results of my participation.

If I want any additional information, have any questions, or have any reservations I may now mention them to the people present or write them in the space below:

ANY ADDITIONAL UNDERSTANDINGS OR AGREEMENTS (note 1)

AUTHORIZING SIGNATURES (note 2)

All matters and issues mentioned above have been discussed to my satisfaction and agreement. My signature indicates that I have read and understood all of the above.

_____ (Signature of the research participant)

_____ (Signature of the research director or the signature, printed name, and address of an authorized agent of the research director)

Note 1 (optional clauses)

Assumption of Risk I realize that not all potential benefits or risks of research (personal, social, or physical risks) can be known ahead of time even when research is properly or well conducted. A major purpose of research is to find answers or to develop new knowledge. As a part of my contribution and participation in this research, I freely assume as my own these unknown or unexpected risks as well as the known risks described above.

I understand that the harm or danger from some of these risks may be very severe. I also realize that I may withdraw from participation, as mentioned above, whenever I feel that the potential risks might outweigh the benefits for me.

Release from Liability I understand that the research investigator is legally liable for the obviously negligent conduct of this research or for any acts intentionally done to harm me. I also understand that harm may occur in the absence of any clearly negligent or intentionally harmful act. Therefore, in return for being accepted as a research participant, I release the research investigator from all liability and waive all my rights and claims against him (or her) except those claims arising directly from clearly negligent or intentionally harmful acts by him (or her). This release from liability and waiver is made by me for myself, my heirs, and any person who might claim through me or on my behalf. It applies not only to the research investigator but also to his assistants and agents and to the research institution and its employees. It is understood that these persons, as well as the research investigator, remain liable for clearly negligent or intentionally harmful acts.

Consent to Recording and Photographs For the purpose of advancing knowledge, I consent to the taking and use of audio recordings, motion pictures, videotapes, or other pictorial representations of me appropriate for scientific, rehabilitative, or educational purposes. It is specifically understood that in any publication or use I shall not be identified by name.

(If the identity of the person is not to be provided, the following sentence may be substituted for the last sentence above.)

I understand that I shall in no way be identified by name or otherwise, and that every reasonable effort will be made to preserve my anonymity and to conceal my identity.

Note 2 (optional additional signature of legal guardians)

Because _____ (Name of research participant) is under the age of 18 years and/or is incompetent to give valid consent, I, _____ (Name of legal guardian) am also signing this agreement.

(Signature of legal guardian)