



Guidelines for Constructing Informed Consent Forms

CHECKLIST

The Informed Consent Form should state, in clear, non-technical language:

- that participants are being asked to participate in a research study
- the names of the investigators and their affiliations
- the purposes of the research, simply explained
- what the procedures will be
- the expected duration of participation
- any reasonably foreseeable risks or discomforts
- any safeguards to minimize the risks
- any benefits to the participant or to others that may reasonably be expected from the research. (In most cases, the research is not being carried for the benefit of the participants but for the potential benefit of others. This broader social benefit to the public should be made explicit.)
- in cases where an incentive is offered, a description of the incentive and of how and under what conditions it is to be obtained
- appropriate alternative procedures or courses of treatment, if applicable
- the extent, if any, to which confidentiality of records identifying the participant will be maintained (*not an issue unless participant can be identified*)
- any restrictions on confidentiality (for instance, if any of the some information gained during the research might have to be disclosed as required by law, as in instances of child abuse. In such cases, absolute confidentiality cannot be assured.)
- what monetary compensation or medical or psychological treatment will be provided for any research-related injury (*if more than minimal risk*)
- contact information for questions about the study (name, office address, and phone contacts for the researcher, faculty advisor, and IRBoard staff). Do not include home phone numbers.
- that participation is voluntary, and that the participant may discontinue participation at any time without penalty or loss of benefits to which he or she is otherwise entitled (e.g., in their standing as a patient, student, employee, and so forth).
- that the researcher will keep one copy of the signed consent form and give another signed copy to the participant.

NOTE: For federally funded projects, consent may not include a clause waiving the legal rights of participants.

General Guidelines:

- Form should be printed in no smaller than 11 point type (no fine print)
- Form should be free of technical jargon and written at sixth- to eighth-grade level
- Form should not be written in the first person (avoid phrases like “I understand ...”)
- Consent should be obtained by the principal investigator or person administering treatment, not by a subordinate.
- When applicable, have the consent form signed by the legal guardian of persons under age 18 or persons who are mentally disabled. (Guardians may consent to experimental procedures for minors and for persons 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.)

The sample consent forms that follow are illustrations. There is no intention to suggest that these are the best possible forms in all circumstances or that they have legal effect and validity in a particular jurisdiction.

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.

Emergency Care (if more than minimal risk): Federal regulations require that all participants be informed of the availability of medical treatment or financial compensation in the event of physical injury resulting from participation in the research. I am in good health and able to participate in this project. I voluntarily assume the risk of possible injury or death that my participation in this study may cause. If I need emergency medical treatment, I agree to be financially responsible for any costs incurred as a result of such treatment. I understand and acknowledge that Claremont McKenna College does not provide health or accident insurance. I have been advised to carry medical and hospital insurance of my own.

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 consideration of my participation in this research project, and the benefits I will receive from my participation, I release the principal 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.

For Mandated Reporting: Your responses will be kept confidential with the following exception: the researcher is required by law to report to the appropriate authorities, suspicion of harm to yourself, to children, or to others.

Consent to Recording and Photographs. I consent to the taking and use of audio recordings, motion pictures, videotapes, or other pictorial representations of me. I may review these tapes and request that all or any portion of the tapes be destroyed. I understand that every reasonable effort will be made to preserve my anonymity and to conceal my identity. I understand that all tapes will be destroyed within five years from the completion of the study.

Signature of Parents/Guardians

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

(Signature of parent/legal guardian)

(Date)

Consent to Participate in a Research Study

<i>Purpose of study:</i>	You have been invited to take part in a research [study/project] to learn more about [purpose of study]. This study has been approved by the Claremont McKenna College Institutional Review Board (IRB).
<i>If faculty/staff investigator:</i>	This research [study/project] will be conducted by [Principal Investigator], [PI's department and school].
<i>If student investigator:</i>	This research [study/project] will be conducted by [student investigator], as part of [his/her] [graduate work/etc.] [His/her] faculty advisor is [name of faculty advisor], a Professor of [discipline] in the department of [department name] at Claremont McKenna College.
<i>Description of procedures:</i>	If you agree to be in this research study, you will be asked to do the following: <i>Examples:</i> <ol style="list-style-type: none"> 1. Complete a questionnaire about my background (age, gender, education, etc.) 2. Take part in two interviews concerning (<i>subject matter of interview</i>); and 3. (Continue description of procedure.) Include several examples of the typical questions to be asked or tasks to be performed.
<i>Duration of participation:</i>	Participation in this study will involve [about one hour of your time: 30 minutes to complete the questionnaire and approximately 15 minutes for each of the two interviews.]
<i>Risks:</i>	There are no known risks associated with your participation in this research beyond those of everyday life. <i>Or:</i> You may find the sensitive nature of some of the questions upsetting. In that event, the researcher will provide you with a referral to a counselor. <i>Or:</i> Describe the risks and the safeguards planned to minimize them.
<i>Benefits:</i>	Results from this study may add to our knowledge of [fill subject matter of research]. <i>Or:</i> Describe benefits expected for participants.
<i>Fees or Incentives:</i>	You will be paid \$ _____ for completing both interview sessions. Should you withdraw before the end of the study, [no payment or only partial payment] will be given.
<i>Confidentiality:</i>	Confidentiality of your research records will be strictly maintained by [describe means to protect participants' confidentiality]. Personal identifying information about participants will be stored separately from all study records. <i>Or:</i> Confidentiality of your research records will be maintained to the extent provided by law. <u>For recordings or tapes, include the following:</u> Recordings or tapes of participants will be kept in a locked cabinet and

	available only to the PI and his/her research associates. These recordings will be destroyed no later than five years after the study is completed.
Contacts	<p>If you have additional questions or wish to report a research-related problem, you may contact the researcher at [PI's phone number; email, University address, etc.]</p> <p>For questions about your rights as a research participant you may contact the chair of Claremont McKenna College's Institutional Review Board, Michael O'Neill at 909-607-8336, or via email at moneill@cmc.edu.</p>
Voluntary nature of participation	<p>Participation in this study is voluntary. You may refuse to participate, skip any question, or withdraw at any time without penalty.</p> <p>Nonparticipation or withdrawal will not affect my grades or academic standing.</p> <p>Or:</p> <p>Nonparticipation or withdrawal will not affect the services I receive at [<i>name of agency, clinic, program, etc.</i>].</p>
Agreement to participate	<p>The researcher has explained this study to me and answered my questions. My signature indicates that I have read and understood all of the above.</p> <p>_____ (signature of the research participant)</p> <p>_____ (signature of the research director or the signature, printed name, and address of an authorized agent of the research director).</p>