



TIPS ON INFORMED CONSENT

The process of obtaining informed consent must comply with the requirements of [45 CFR 46.116](#). The documentation of informed consent must comply with [45 CFR 46.117](#). The following comments may help in the development of an approach and proposed language by investigators for obtaining consent and its approval by IRBs:

- Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through the giving of thoughtful consent information for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation must be written in "lay language", (i.e. understandable to the people being asked to participate). It primarily takes the form of a letter of invitation to participate in research and the tone is generally conversational. The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process. Any revision must be approved by the Human Subjects Committee before being used. Once a revision is determined necessary, recruitment should stop until the new form is approved.
- Second person (e.g., "You are invited to. . .") should be used in all consent forms. Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
- **Describe the overall experience that will be encountered.** Explain the research activity, how it is experimental (e.g., extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). Inform the participants of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are recontacted or newly contacted.
- **Describe the benefits that subjects may reasonably expect to encounter.** There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution and is not considered a benefit. The intent of reward is to offset the inconvenience of participating, not to convince an otherwise unwilling person to participate. Payment & credit cannot be given for completion of the project alone. The reward must be pro-rated across the time spent in the study.
- **Describe any alternatives to participating in the research project.** This requirement is meant for studies that are meant to help or treat the participant in some way. If there are alternative resources for providing the assumed benefit to the participant, the consent form must include them. A reasonableness test should be applied.
- **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence.** For example, some studies need no identifiable information. Some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality which protects the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of research subjects. Only collect identifiable information if it is absolutely necessary to your research. The best protection for your participants is anonymity. For research purposes, anonymity is defined as unidentifiable. No combination of personal information should be able to identify an individual to anyone. Federal Regulations require the HSC to make the final determination of whether adequate confidentiality

procedures are being used to ensure that participants are exposed to the minimum amount of risk possible and whether the residual risks are outweighed by the benefits.

- **If research-related injury** (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see 45 CFR 46.102[g]), an explanation must be given of whatever voluntary compensation and treatment will be provided. Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation. The University of California's policy that should be added to consent forms where it is appropriate is:

"The University of California does not provide compensation for injury to human subjects of research except that the University will provide for any medical care required to treat any injury resulting from participation as a human subject in a University-approved activity. If you have any questions concerning this or any other matter relating to your participation in this activity, please call the Human Subjects Committee (HSC) at (805) 893-3807 or e-mail hsc@research.ucsb.edu

- **The regulations prohibit waiving or appearing to waive any legal rights of subjects.** Therefore, for example, consent language must be carefully selected to keep the appearance of a waiver of legal rights out of the consent form. Terms like "agree", "understand", "waive", "relinquish" do not belong in a consent form.
- **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation.** Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) should be addressed by the HSC. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas. If long distance phone calls are required for participants to contact either the researcher or the HSC, they should be instructed to call collect.
- **The statement regarding voluntary participation and the right to withdraw at any time.** ([45 CFR 46.116](#)[a][8]). It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of either not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.
- Don't forget to ensure provision for appropriate **additional requirements** which concern consent. Some of these requirements can be found in sections [46.116](#)(b), [46.205](#)(a)(2), [46.207](#)(b), [46.208](#)(b), [46.209](#)(d), [46.305](#)(a)(5-6), [46.408](#)(c), and [46.409](#)(b). The IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.
- At UCSB, the consent form should inform participants that you are required to report child abuse to the appropriate authorities. This warning should be included in any project where it is reasonable to think researchers will come across child abuse. Some common situations are: research conducted in a private home with children present, open ended interviews about parenting or with children, observation research including adults & children interacting.