

Reed College Human Subjects Research Committee (HSRC)  
2007-2008  
**Guidelines for Obtaining Participant Consent**

“Informed consent is one of the primary ethical requirements underpinning research with human participants; it reflects the basic principle of **respect for persons**. It is too often forgotten that consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human participants will understand the nature of the research and can knowledgeably and **voluntarily** decide whether or not to participate. The assurance protects all parties --both the participant, whose **autonomy** is respected, and the investigator, who otherwise faces legal hazards.” Protecting Human Research Subjects: Institutional Review Board Guidebook, p. 3-11 (emphases in original).

There are two primary considerations in obtaining informed consent:

- (1) that participants be provided the information necessary for them to reach a decision regarding their willingness to participate in the research. Among other things, this requires that the relevant written or oral communication use language that is as simple and direct as possible. Special care must be taken in obtaining consent from special populations (e.g., children, individuals with limited ability in English or other difficulties understanding language). It may be appropriate to have the consent information translated into another language and/or read aloud.
- (2) that participants be allowed to provide consent in an atmosphere free of coercion and with an understanding that they may change their mind at any time without consequence.

#### BASIC ELEMENTS OF CONSENT

The style and formality of the consent interaction varies considerably as a function of the research context and of the investigator’s disciplinary identification. Individual departments and research disciplines have developed more detailed guidelines for and samples of consent forms and/or scripts.

In general, the following topics should be included in the consent interaction:

1. The name of the researcher and his or her affiliation.  
e.g., You are invited to participate in a research/senior thesis study conducted by NAME, a student at Reed College.
2. The purpose of the study.  
e.g., The researcher hopes to learn . . .
3. If appropriate, why the participant has been invited to participate.  
e.g., You have been invited to participate in this study because. . .

4. Description of what the participant will be asked to do (e.g., interview, tasks, surveys), including duration, frequency, and locale.
5. Potential risks and/or discomforts. If appropriate, this section includes information regarding the extent to which confidentiality can be maintained, and the procedures for doing so.
6. Benefits to participants, direct and indirect. This section may be inappropriate in contexts in which participants are not expecting any benefits. Incentives being offered for participation should be described in section 4.
7. An assurance that participation is voluntary and may be discontinued at any time without penalty.
8. If appropriate, assurance that the participant is old enough to provide legal consent to participate (in the US, individuals under 18 years of age require the permission of a parent or guardian).
9. Contact information, including address and telephone number, for researcher and for the Reed College Human Subjects Research Committee. Contact information for the thesis advisor can also be included. Contact information is usually provided in written form, even for oral consent procedures. For written consent procedures, the participant should receive a copy of the entire written consent form.
10. For written consent forms: signatures of participant and investigator.

## OBTAINING CONSENT

There are many ways in which consent can be obtained and documented, including those described below. The HSRC proposal form requires that you indicate how you will obtain consent and that you provide copies of written consent forms and oral consent scripts.

1. Written consent forms.
2. Oral consent. Eliminating the written consent form changes the process through which consent is obtained but does not change the essential consent elements. For brief, relatively structured interactions with participants (e.g., interviews), the existence of a consent script that can be read aloud and provided in written form to the participant is often desirable. For more informal interactions or for interactions evolving over a longer period of time, the investigator should provide to the HSRC a description of the context within which the consent interaction will occur and indicate what information necessary to obtaining consent will be communicated. Conditions under which the primary consent interaction may be conducted orally include:

- a. When the existence of a signed consent form provides a risk in itself. For example, in a study of homosexual couples, the existence of a signed consent form provides potentially stigmatizing information about the signator, even when separated from any other information collected in the study.
  - b. When there is reason to believe that the consent interaction can be better conducted orally because of linguistic or literacy demands of the written format.
  - c. When the process of obtaining written consent is inappropriate in the context of the research. For example, written consent documents may raise suspicions regarding the use of the information being collected or may violate cultural expectations of the research population. Written consent is often inappropriate when the project involves the development of long-term relationships with a study population.
3. Passive consent. Passive consent occurs when the consent elements have been communicated to potential participants in advance and the participant's choice to participate is reflected by an action. For example, on questionnaires or surveys, the necessary consent elements can be written at the beginning of the document or packet of documents and consent provided by the act of returning the document(s). The announcement of a meeting at which observations will be made or tasks performed can include the consent elements, and consent provided by participants choosing to be present. Note, however, that the HSRC does not allow consent to be provided by the failure to return a consent document (for example, parental consent cannot be inferred from the failure to return a consent document sent home with the child or mailed to the parent).

In some circumstances, waiver of consent is granted when it is not feasible to obtain consent from individuals. Two requirements for waiver of consent are: (1) the information to be used is either public or available to the investigators without permission, and (2) the information is maintained, analyzed and reported in a fashion from which individuals cannot be identified. Two examples: (a) an observational study in a public place in which the individuals being observed cannot be identified from the recorded observations, (b) analysis of data that exist in a database to which the investigators have access. If the data extracted from the database include information from which individuals can be identified, the identifying information cannot be made available to individuals not normally having access to the database. In addition, the use of any information that is publicly available does not require consent, including the statements and behavior of public officials and individuals running for public office.