

How to Create an Informed Consent Form

The informed Consent Form must be a separate document from other documents. Except as provided in sections 4, 5 and 6 below, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subjects' legally authorized representative. A copy shall be given to the person signing the form. The full informed consent form must include:

Content of the written consent form

1. Statement that the activity involves research and a description of where the research activity will occur.
2. An explanation of the scope, aims, and purposes of the research, and the procedures to be followed (including identification of any treatments or procedures which are experimental) and the nature of the expected duration of the subjects' participation.
3. Description of any reasonably foreseeable benefits, if any, to the subjects or others that may result from the research.
4. A disclosure of appropriate alternative procedures or course of treatment (in instances where therapeutic procedures are involved), if any that might be advantageous to the subjects.
5. A statement describing the extent to which confidentiality or records identifying the subjects will be maintained except in unusual cases.
6. An offer to answer any questions the subjects may have about the research, the subject's rights or related matters, and the name of the person (together with address and telephone number) to whom the subjects may direct questions or must report an injury.
7. A Statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefit to which the subjects are otherwise entitled, and that the subjects may discontinue participation at any time without penalty or loss to which the subjects are otherwise entitled if they had completed their participation in the research.
8. For research which may involve more than minimal risk of injury the subject should be informed of the following statement which must appear in the consent form: (to be modified for off-campus research). **"In the unlikely event of injury resulting from this research, Andrews University is not able to offer financial compensation nor to absorb the costs of medical treatment. However, assistance will be provided to research subjects in obtaining emergency treatment and professional services that are available to the community generally at nearby facilities. My signature below acknowledges my consent to voluntarily participate in this research project. Such participation does not release the investigator(s), sponsor(s) or granting agency (ies) from their professional and ethical responsibility to me."**
9. A space for the dated signatures of the subject, the principal investigator, and a witness. In the case of a minor (the child must also sign if seven years of age or older) or a person unable to sign, a second authorizing signature is required from the parent, guardian, or other responsible person. The relationship must be specified.

In addition there is need to pay special attention to the following two definitions in your Informed Consent, since lack of coercion and confidentiality are required for approval:

a) **Coercion**

Coercion means to compel or force someone to participate in or perform an action that would not ordinarily be done of the individual's own free choice. Coercion may be present when recruiting

subjects for research. Participation should be free and voluntary, with no overriding statements. The following are ways that coercion can be introduced: The researcher is the supervisor or pastor of the participants. Telling subjects or their parents (when children are involved) how much they will be helping the investigator by participating in research can be interpreted as coercive. Mentioning a relationship that exists between the researcher and the potential subjects may be coercive. Subjects may feel obligated to participate because they know or have seen the researcher at various times. In cases of infants and children, mentioning that the researcher cares for or has cared for the child puts parents in a very awkward and unfair position. Face-to-face recruitment has the potential to be coercive. It is difficult for individuals to say no to someone who is directly in front of them and talking about his or her research. Inflection, tone of voice, and nonverbal cues can inadvertently slip into the recruitment process without the researcher's awareness. Coercion can be reduced if an impartial third party presents the request for participation. Subjects should be protected from coercion. If subjects are not protected, the IRB application must include an explanation of why coercion is necessary as well as any possible repercussions of the coercion. The methods to be used for coercing subjects must be detailed in the research proposal. A plan for informing subjects at the end of the research of how and why they were coerced must be fully explained (see Debriefing). Potential physical and/or psychological risks that may be incurred by subjects due to the coercion must be identified, and procedures for addressing the risks must be established as part of the debriefing procedures.

b) Confidentiality

Confidentiality refers to protection of subjects' privacy so that information collected about them, as part of the research process, is not disclosed. Information may be revealed in group form, or as individual examples, but not in a way that an individual may be identified. If the investigator collects information on subjects over a period of time, such as in test-retest reliability or in

Pretest-posttest study designs, there must be a mechanism to relate various data to the same subject. This may be done by using codes or identifiers (e.g., subject ID numbers) on both sets of data that only the researcher can trace to a master name-number list. Because names and numbers can be related, this list must be kept confidential by storing it in a private and secure location, such as a locked file cabinet. If data are recorded in cases where the researcher personally knows subjects, it must be acknowledged that the researcher knows the subjects personally, and the data must be treated confidentially, because anonymity is not possible. The data must be collected in such a way that the identity is not recorded. All data should be stored in a way that the person is not identified when the identity is not crucial for the research objectives. In other words, the IRB will require that data be collected in the least intrusive and most confidential way to serve the purpose of the research. In a focus group situation, it must be acknowledged that there is a lack of confidentiality due to the group situation. The consequences of this lack of confidentiality must be outlined. It is important to acknowledge

It is important to acknowledge that subjects may waive the right of confidentiality. This may occur, for example, when a subject specifically requests to be quoted. In the United States, all confidential data must be stored by the researcher for 3 years. In Canada, data must be stored for 6 years.

Consider also that ethical research requires that the researcher is qualified to do the research they are proposing.

Format of the Written Consent Form

1. The consent form should clearly identify the relationship of the researcher to Andrews University. The name of Andrews University should appear centered at the top of the consent form together with the name of the department with which the researcher is affiliated. In cases where an anonymously returned questionnaire substitutes as a form of implied consent, the cover letter accompanying the questionnaire should clearly identify how the research is connected with Andrews University and one of its academic departments.
2. The consent form should clearly indicate the name, address, and phone number of the investigator and an advisor or impartial third party whom the research subject may contact for additional information if desired.
3. Places for the dated signatures of the subject (and/or parent/guardian, if applicable), investigator, and witness should be included at the bottom of the consent form.

Retention of the Signed Informed Consent Form

1. A copy of the Informed Consent Form should be returned to the subject or the person legally appointed to sign the Informed Consent Form to retain for his/her review.
2. The responsibility for retaining signed copies of the Informed Consent Form lies with the principal investigator(s). These Informed Consent Forms should be kept in a secure depository along with the researcher's other records for a reasonable amount of time (not normally to exceed three years).

Use of Alternate and/or Simplified Consent Forms

Certain situations may justify the use of alternate and/or simplified consent forms. However, in all cases the investigator must demonstrate how the anonymity or confidentiality of the subject and his/her voluntary participation in the project will be assured and maintained.

1. **Oral Instructions Read to a Group.** In the case of no risk or minimal risk research where instructions are read to a group of subjects (e.g. a questionnaire passed out in a classroom setting, with prior written authorization of the instructor), a short form to document the oral instructions presented to the subjects may be used. A witness who heard the oral instructions read to the group must co-sign the short form along with the researcher. A written copy of the oral instructions that are to be read to the group must be submitted with the protocol. The items listed in Section 1 above should be included in the oral instructions.
Research using surveys or questionnaires and dealing with sensitive areas of the respondent's own behavior (illegal conduct, drug/alcohol use, sexual behavior, etc. See Appendix A, Exempt Review, item 4) require special consideration. Although the purpose and use of surveys or questionnaires in such research may be explained in a classroom setting (with prior documented permission of the instructor(s) involved), requesting respondents to actually complete survey instruments in the classroom setting is not recommended. Alternative methods of collecting forms completed at the discretion of the respondent and which thus insure the respondent's anonymity should be employed.
2. **Anonymous Surveys or Questionnaires.** In the case of risk or minimal risk research involving the use of surveys or questionnaires which are distributed individually and returned anonymously, the cover letter explaining the purposes and procedures of the research project may substitute for the consent form. Such a cover letter must be submitted with the protocol and should contain reference to the items mentioned in section 1 above. It should state in the cover letter as well as on the survey form itself that the return of the survey or questionnaire serves as a form of implied consent.

3. **Simplified Oral Interviews.** Investigators conducting simple oral interviews, the content of which qualifies as exempt from review, may submit an alternate form of written documentation in place of an informed consent form. Such documentation should describe how the interviewer will explain his/her research to the interviewee and how the researcher is prepared to insure the interviewee's confidentiality and his/her right to refuse participation in the interview.
In all cases, the researcher is responsible for the filing of all proof of compliance with the above procedures and to keep them for a period of three years

Waiving of Signed Consent Documentation

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that either of the following conditions exists:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether he/she wants documentation linking the subject with the research, and the subject's wishes will govern.
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Waiving the Consent Process

The IRB may under certain special circumstances approve a consent procedure which does not include or which alters some or all of the elements motioned above or may waive the requirement to obtain consent provided the Board verifies and documents each of the following items:

1. The research involves no more than minimal risk to the subjects
2. The waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.
3. The research could not practicably be carried out without the waiver or alteration.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Consent form from Attending Physician and/or Other Health Care Professionals

In situations where an individual is currently being treated/evaluated by a physician and/or other health care professional for a condition related to the objective of the research study, the researcher is required to obtain the consent of the physician and/or health care professional prior to involving such research subjects in the study.

Or faxed to attention IRB: (269) 471-6543

E-mail Letters: Letters may be sent as scanned email attachments to irb@andrews.edu.