
Yale University Institutional Review Boards Procedure

Procedure 200 PR.1

Informed Consent for Research Participation:

Competent Adult Participants

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Overview

The procedures required to obtain truly informed and voluntary consent require attention not only to written documentation but also to the presentation and context of the information. This procedure provides information on how to obtain informed consent for research participation in competent adults. IRB Policies 340 and 310 should be consulted when working with incompetent adults or children.

Informed Consent Process

Informed consent begins at recruitment. From the start, potential participants must be accurately informed regarding the nature, purpose, risks, and benefits of the study (see IRB Policy 410 Recruitment).

Individuals who show interest in participating based on the recruitment information may be provided with informed consent information in a variety of ways as described below. All methods are subject to IRB approval. The choice of consent method should reflect consideration of 1) the complexity of the research; 2) the risk level of the research; 3) the timing of the research procedures; and 3) the cultural context of the research (see also IRB Policy 450 International research). The approach to be taken should be justified in the IRB application.

Regardless of the format, the potential participants must be provided with information pertinent to their decision regarding participation and be provided with the opportunity to ask questions regarding the research and be provided with answers to those questions. Depending on the complexity of the research and the expected cognitive abilities of the participants, the investigator may institute an assessment of the participant’s understanding prior to enrolling the subject (c.f. Policy 340 Participation of Individuals with Impaired Consent Capacity)

Except in cases where there is no direct interaction between the research team and the participants, such as on-line surveys, the consent process must be conducted by an individual who is knowledgeable about the specific research project and who can answer questions about the research. This may or may not be the principal investigator but must be someone listed on the IRB protocol with appropriate training in both the research project and the conduct of human subjects research.

Care must be taken to ensure that the research team members involved in the consent process are unlikely to exert undue influence over the prospective participants. For example, prospective participants who are students of the faculty member conducting the research may be concerned that their decision to participate will impact their academic standing and thus agree to participate in studies that they otherwise

would not. Such concerns can arise irrespective of reassurance to the contrary provided by the faculty member. In such cases it is preferable whenever possible to have the consent discussion performed by a member of the research team who does not have a supervisory or other relationship with the prospective participant. (see also IRB Policy 500 COI and IRB Policy 410 Recruitment).

Individuals considering participating should be allowed time to reflect on the informed consent information prior to agreeing to participate. The length of time needed will vary according to the study, with little time needed for brief surveys to several days for more involved clinical studies. Studies which involve greater than minimal risk to participants and which propose to obtain consent on the same day as initiating study procedures require explicit approval of the consent process by the IRB. Same-day consent must be found by the IRB to be necessary to the research and to not place undue pressure on individuals to participate. Prospective participants should be provided with a written copy of the relevant information to aid their decision.

Informed Consent Forms

Informed consent may be provided and documented using an informed consent form which includes all the required statements as described in Policy 200 (Informed Consent for Research Involving Human Participants). The information should be presented in an easily read format and in simple lay language. For the general population, 12 point font and an 8th grade reading level is recommended. When the participants are anticipated to largely consist of individuals with a higher or lower reading abilities the consent form should be tailored accordingly. Consent form templates are available at <http://info.med.yale.edu/hic/forms/index.html> and www.yale.edu/hsc.

During the course of the study, additional information may be provided to participants via a consent form addendum which describes the additional consent information or changes to the initial consent information. For example, newly identified risks or changes in contact information may be presented to current participants through consent addenda. Templates are available at <http://info.med.yale.edu/hic/forms/index.html>

Individuals who agree to participate are required to sign the consent form and are provided with a copy of the form for future reference.

Consent forms and addenda must be approved by the IRB and only the approved version may be used to enroll participants.

“Short Form” Consent

Short Form consent is a process whereby participants are provided with the consent information orally and the oral presentation is documented through an abbreviated or “short form”. The short form must state that all the required elements of consent have been presented to the participant or his/her legally authorized representative (LAR). The participant or his/her LAR must sign the short form.

The presentation of information must be witnessed and the witness must sign the short form as well as an IRB approved written summary of what is to be said to the participant. The summary must also be signed by the individual obtaining consent.

Participants are to be provided with a copy of both the short form consent and the written summary.

Short form consent may be useful where some of the prospective participants do not speak and/or read English fluently.

Verbal Consent

Consent to participate may be obtained verbally when the IRB has approved a waiver of documentation of consent. Verbal consent requires that all of the information which is normally provided in written form is provided either orally or in writing and the participant agrees to enroll verbally or behaviorally. The only difference in verbal consent is that there is not a “consent form” for signature. Verbal consent should be documented in either the written study record or included in any audio or video recordings. Participants

should be provided an information sheet as described below except in cases where it is infeasible, such as phone surveys, or if possession of the information sheet would increase the risk level for the participants. In the latter case, contact information for the investigator and IRB may be provided using a business card.

Information Sheets

When documentation of consent has been waived by the IRB, investigators are still expected to provide consent information to participants in writing through an “information sheet.” Information sheets provide the same information as would be required in an informed consent form with the exception of a location for the participant’s signature.

Information sheets are commonly used as the front page of anonymous surveys. Completion of the survey indicates participant consent.

On-line Consent

On-line surveys do not easily lend themselves to obtaining documentation of informed consent and hence most on-line surveys must qualify for waiver of documentation of consent (see IRB Policy 200 Informed Consent). Informed consent information can be provided on –line and those interested in participating are asked to click an “I Agree” button in order to continue.

Languages Other than English

Informed consent must be obtained in a language understandable to the participant. If participants who are not fluent in English are to be recruited, the investigator must involve individuals who can speak the appropriate language and conduct the consent discussion. Consent forms will also need to be translated into the appropriate language at the same reading level as the English versions. The documents may be either a standard consent form or “short-form consent” as described above. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The IRB may review these documents with outside experts to ensure that the translation is appropriate.

Illiterate Participants

Participants known to be illiterate should be provided with an opportunity to involve a study partner who can confirm the consistency of written consent materials and other documents that will necessarily need to be provided to the participant orally. When written documentation of informed consent is required, a short form consent may be used or a witnessed informed consent form where the witness’s signature attests to the information having been provided to the participant in a format understandable to the participant, such as orally.

IRB Submission Requirements

Copies of all consent forms, consent addenda, scripts for verbal consent, information sheets, translations and any other consent related information must be submitted to the IRB for approval prior to implementing the documents. Documents should be in their final form.

Record Keeping

Informed consent forms should be retained for at least three years from the date the study is completed. Longer retention intervals may be required in some cases such as when required by sponsoring agencies, in the course of applying for patents, or in the case of legal disputes.

Consent forms should generally be maintained confidentially with only those members of the research staff who need to review the forms having access to consent records. However, in cases where the knowledge of study participation could influence health care decisions, or where consent is required to obtain copies of medical or other individual records, a copy of the signed consent form may be included in the participant's medical or other confidential record set.