II3F PR1 Informed Consent for Competent Adults to Participate in Research

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 for University of Nevada, Reno and affiliate investigators the informed consent process for research involving competent adults. Investigators enrolling children should consult IRB Policy and II4A-D and the related procedures. Those enrolling incompetent adults should consult IRB Policy II4F and the related procedures.

II3F1 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 II3C Recruitment of Research Participants and the related procedures and guidance). 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 Institutional Review Board (IRB) approval. The choice of consent method should reflect consideration of the

1. complexity of the research,
2. risk level of the research,
3. timing of the research procedures, and
4. cultural context of the research (see IRB Policy I3 Conducting Human Subjects Research Outside the United States and US Territories).

The method used to obtain informed consent must be described and justified in the appropriate section of the IRB protocol application. For research involving multiple populations, the consent process may differ among the populations. All methods must be described with identification of the populations to which the methods apply.

Regardless of the process used, potential participants must be provided with information pertinent to their decision regarding participation, and must be provided with the opportunity to ask questions regarding the research and to receive answers to their 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 (see Policy II4A-E Participation of Individuals with Impaired Consent Capacity and the related procedure II4A-E PR1).

Except in cases where there is no direct interaction between the research team and the participants, such as on-line or surveys sent via postal mail, 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 not likely 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 in which they otherwise would not. Such concerns can arise irrespective of assurances 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 prospective participants. (See the following IRB Policies and related procedures: II4A for information about conducting research with students and II3C for information about 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 and perhaps 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.

II3F2 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 II3F Informed Consent. 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 online at http://www.unr.edu/ohrp/forms.html

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. For research studies requiring a consent form

addendum, the investigators may wish to contact an IRB Program Manager in the Office of Human Research Protection.

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

Individuals who agree to participate are required to sign the consent form and are provided with a copy of the form for future reference. The copy provided to subjects need not be the signed version.

The person obtaining consent also signs the form.

II3F3 Short Form Consent

Short Form Consent is a process whereby participants are provided with the consent information orally and the completeness of the oral presentation is documented through an abbreviated (i.e., short form). The short form must state that all the required elements of consent have been presented to the participant or her or his legally authorized representative (LAR). The participant or her or his 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 was said to the participant or her or is LAR. The individual obtaining consent also signs the summary.

Participants are to be given 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 fluently speak, read or both English (see II3F GD2 Use of Short Form to Obtain Consent from Non-English Speaking Participants). Short form consent is not applicable to research in which the majority of subjects are not fluent in English.

II3F4 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 between the process for obtaining signed consent and that for verbal consent is the absence of a consent form for subjects to sign. Investigators must describe the processes by which verbal consent will be obtained. Participants should be provided an information sheet as described below except in cases where it is not feasible, such as phone surveys, or if possession of the information sheet would increase the level of participant risk. In the latter case, contact information for the investigator and IRB may be provided using a business card.

II3F5 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 must

contain the same information that would be provided in a consent form with the exception of signature lines (see IRB guidance II3F GD4 Information Sheet or Script...). Although the same elements must be addressed, the depth and complexity of the information provided need not be as robust as that for a consent form. This is especially true when an informative cover letter or introductory page are enclosed with or attached to survey instruments for minimal risk research. Information sheets are commonly used as the front page of online and paper and pencil surveys. Completion of the surveys imply participant consent.

II3F6 Consent for Research Conducted Online

Online surveys and other online research do not easily lend themselves to obtaining documentation of informed consent. Consequently, on-line surveys must qualify for waiver of documentation of consent (see IRB Policy II3F Informed Consent) or the investigators must include a mechanism for obtaining signed consent from participants before they complete any instruments. Informed consent information can be provided online as the cover page to the research and those interested in participating select one of two choices with one indicating agreement to participate and one, declining to do so.

II3F7 Languages Other than English

Informed consent must be obtained in a language understandable to the participant. (See IRB guidance IIEF GD1 Inclusion of Non-English Speaking Participants) .If participants who are not fluent in English are to be recruited, consent forms will need to be translated into the appropriate language at the same reading level as the English versions. Additionally, the investigator must involve individuals who can speak the appropriate language to conduct the consent discussion. Consent may be obtained using a standard consent form or when applicable to the sample population, a short-from 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 translated documents with outside experts to ensure that the translations are consistent with the content of the approved English version of the documents.

II3F8 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. (see IRB guidance II3F GD2 for information about the short form consent process.)

II3F9 IRB Submission Requirements

Copies of all consent forms, consent addenda (when indicated), summaries for short form consent, scripts for verbal consent, information sheets and any other consent related information must be

submitted to the IRB for approval prior to implementing the documents. All documents should be in their final form except the translations. Investigators may opt to wait to have the documents translated until the IRB indicates that the content is satisfactory; however, investigators must submit the final forms of the documents in English. This prevents investigators from translating documents for which the IRB requests revisions.

II3F10 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 and should be stored separately from the research data and the master code list. 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.

Researchers conducting clinical investigations at the VA Sierra Nevada Health Care System must place a copy of the signed consent form in each participant's medical record and must maintain a master list of all subjects from whom consent has been obtained whether the IRB granted a waiver of documentation of consent.