Issuing Department: Human Subjects Protection Office
Policy Number: 2011-008.1
Policy Title: Informed Consent Process

Purpose

The purpose of this policy is to describe the informed consent process and provide examples of acceptable methods for obtaining informed consent.

Definitions

See policy 2011-007.0 for definitions of the following terms:

Coercion	Informed Consent Process	Informed Consent Form
Legally Authorized Representative	Undue Influence	

Policy

Unless waived by the Institutional Review Board (IRB), an informed consent process must be conducted with a potential subject prior to any involvement (including screening) of the subject in non-exempt research to ensure that the subject has an appreciation for the study (e.g. understanding of the purpose, risks, benefits) in which s/he may enroll. The process of consent should continue throughout the study, for example by explaining each visit as it occurs and ensuring the subject is still willing to participate, or by providing new information to subjects as it is learned to ensure they are still willing to participate.

Consent can be sought only under circumstances that provide the prospective subject or the legally authorized representative (LAR) sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The consent process must also be conducted in a setting that affords sufficient privacy to the potential subject and the information that is given to the subject or the LAR shall be in language understandable to the subject or LAR. As necessary, the Principal Investigator (PI) must address other special provisions required by the subject, e.g., hearing impaired individuals may want a sign language interpreter present or individuals with dyslexia may prefer to have the document read to them.

Exculpatory language which releases or appears to release the institution, sponsor or investigator from liability or which makes or appears to make subjects waive any legal rights cannot under any circumstance be included in the informed consent process.

Individuals conducting the consent process must have in depth knowledge of the research protocol and the ability to answer questions that may be posed by the potential subject. The individual obtaining consent is required to have completed education in the protection of human subjects in research.

The informed consent process is most often documented by use of an IRB approved informed consent form. Documentation of the initial informed consent process may be supplemented by notes in a research chart that indicate on-going discussions with the subject at subsequent study visits.

Consenting a subject, including consent from legally authorized representatives, is a process that should occur in person. Only for extenuating circumstances will the IRB consider the possibility of obtaining consent by phone / fax. The IRB may require a consent process for exempt research. The IRB may

impose additional protections as part of the consent process. For example, the IRB may require the use of the consent feedback form, a witness to the consent process or videotaping the consent process.

With the exception of the short form consent process, obtaining consent from illiterate subjects, and obtaining consent by phone/fax, the consent process generally does not have to be witnessed but the IRB may require this. When an individual is signing the form as a witness s/he must indicate whether s/he is a witness to the signature only or a witness to the entire consent process. The IRB reserves the right determine who may serve as the witness.

Subjects in long-term follow-up must be informed of outcome data and safety related information. The PI will determine the mechanism of communication, giving consideration to the subject's underlying conditions, available support systems and the nature of the information being conveyed. They do not have to be re-consented regarding changes to the protocol if they are no longer in the active phase of the study.

Techniques that may be used in the consent process included but are not limited to, the following:

Waiting Period Requirement: The IRB may require a waiting period between the time that a study is explained to a potential subject and /or the potential subject's representative, and the time that consent is sought from the potential subject or representative. Situations when this option may be exercised include, but are not limited to, studies that involve vulnerable populations or studies that are of high-risk.

Staged Consent Process: The IRB may require a staged consent process whereby consent is obtained at various points in the study to ensure that the subject is still willing and / or still able to provide consent. Situations when this option may be exercised include, but are not limited to, studies that involve vulnerable populations, for example populations with diminishing capacity, or studies that are of high-risk.

Summary of process: The IRB may require that an individual obtaining consent also ask the subject to provide a summary of the study after the initial discussion occurs as a means of evaluating his/her level of understanding of the study. The IRB may require that the individual obtaining consent ask the subject to explain in his/her own words the purpose of the study, the risks involved, the potential benefits, the alternatives available etc. and may require that the responses be documented. If the potential subject is unable to demonstrate an understanding of the study either consent from a legally authorized representative must be obtained or the subject may not be enrolled into the study. The IRB may provide the questions to be used to solicit feedback, or may require the PI to develop the questions and submit them to the IRB for review/approval.

Procedure

General:

When submitting an application to the IRB, the PI must respond to questions within the IRB application regarding the process for obtaining initial and on-going consent from subjects.

The PI will designate on the IRB application the names or positions of individuals authorized to obtain consent and also describe who will be providing consent (e.g. subject or legally authorized representative).

Unless waived by the IRB, the process of consent will be documented on an IRB approved consent form to be signed and dated by the subject (or legally authorized representative) and the person obtaining consent.

- For embryo donation both the egg and sperm donor must sign the consent form.
- The person obtaining consent must provide the subject (or the subject's legally authorized representative) with a copy of the signed and dated document, including any relevant addendums, appendices, attachments etc.
- An emancipated subject must provide proof of emancipated status. The person obtaining consent must attach this proof to the informed consent form.
- A legally authorized representative, other than a parent of a minor child, must provide proof of such status. The person obtaining consent must attach this proof to the informed consent form.

Standard screening and review procedures are used as described in the procedures for Expedited and Full Board reviews.

Consent by Phone / Fax

Procedure 1:

- the potential subject must be given a copy of the approved, IRB-stamped consent document (either by mail, fax or e-mail of scanned document) prior to the phone conversation and with enough time allowed to read the document prior to the conversation;
- the individual obtaining consent must have a witness present for the entire conversation;
- subject must be informed that the witness is present and consent to the witness listening to the entire conversation (via speaker or extension phone);
- subject must be instructed that if s/he agrees to participate s/he must return the signed and dated consent document (either by mail, fax or e-mail of scanned signed document); and
- the individual obtaining consent and the witness must sign, and date the IRB approved consent document upon completion of the phone conversation;
- the two forms are joined together upon receipt
- research can begin after the forms are joined; or

Procedure 2:

- the investigator requests a waiver of the requirement to document consent at the time of initial application or via a request for modification using the form to request such a waiver.
- an IRB approved script incorporating the elements of consent is presented over the phone to the subject
- the IRB may require that the investigator provide subjects with a copy of the script (via mail, e-mail or fax) regarding the research.

Related Policies

2011-007.0 – Definitions Applied to Policies
2011-008.0 – Informed Consent - Forms

2011-008.2 – Informed Consent – Waivers and Alterations
2011-008.5 – Informed Consent – Providing and Obtaining Informed Consent
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board
2011-013.0 – Translation Policy
2011-023.0 – Educational Requirements

Basis

45 CFR 46.116(a)(1-8) and 46.117
21 CFR 50.20, 50.25 and 50.27
45 CFR 46.116(b) (1-6), 21 CFR 50.25(b)(1-6)

Document Attributes

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Reviewed and Approved By:

Signed RS 5/12/13
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Director Human Subjects Protection Office