Issuing Department: Human Subjects Protection Office
Policy Number: 2011-008.5
Policy Title: Providing and Obtaining Informed Consent

Purpose:

The purpose of this policy is to describe who may give and obtain informed consent.

Definitions:

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

Assent	Healthcare Representative	Informed Consent Process
Informed Consent Form	Legally Authorized Representative	

Policy:

Obtaining Consent: The individual who obtains consent from a research subject must have an in-depth knowledge of the study such that s/he can adequately explain the study to the potential participant and answer questions posed by the potential participant.

The Institutional Review Board (IRB) requires that subjects be re-consented if there have been developments that may affect a subject's willingness to continue to participate. Re-consenting a subject will serve to demonstrate that s/he has been informed of the additional information and that s/he willingly consents to continued participation.

Subjects who are actively participating in a study when they reach the age of majority should be re-consented at the next regularly scheduled visit.

If procedural changes are made to the informed consent form and those changes are not pertinent to an individual subject there is no need to re-consent. For example if a procedure is added to the first visit and some subjects have already progressed beyond that phase of the study they do not have to be re-consented.

The IRB may require that an individual obtaining consent also seek feedback from the potential subject as a means of evaluating his/her level of understanding of the study.

If there are administrative changes to a consent document, e.g. in terms of contact names or numbers, subjects still actively enrolled may be re-consented but it is not a requirement. However, the PI must ensure that the subjects are provided with the revised information by letter, post-card or some other means approved by the IRB.

With the exceptions of the short form consent process and consenting illiterate subjects, the consent process generally does not have to be witnessed. However 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 may determine who may serve as the witness.

Providing Consent: With the few exceptions noted below, consent must be obtained from individuals of at least 18 years of age who are competent to give informed consent. Such individuals are considered to have decision-making capacity if (1) they have not been declared incompetent by a court and (2) they are generally capable of understanding the consequences of alternatives, weighing the alternatives by the degree to which they promote their desire, and choosing and acting accordingly.

- Emancipated individuals between the ages of 16 - 18 may provide consent to participate in research activities. An emancipated individual does not meet the federal definition of child and therefore subpart D is not applicable.

- In the specific circumstances individuals under the age of 18 may provide consent to participate in research without demonstrating emancipated status when the research is limited to the categories noted below. In such circumstances the individuals are not considered children and therefore subpart D is not applicable.
    - All individuals under 18 years of age, if the research procedures are limited to:
        - HIV testing, counseling, and treatment
        - Outpatient mental health services
        - Testing or treatment for sexually transmitted diseases
        - Treatment or rehabilitation for alcohol or drug dependence
        - Abortion counseling and treatment
    - All individuals between 16 and 18 years of age, if the research procedures are limited to:
        - Inpatient mental health services
    - All individuals between 17 and 18 years of age, if the research procedures are limited to donation of blood or any component thereof and to the withdrawal of blood in conjunction with any voluntary blood donation program.

If a mentally retarded adult has not been declared incompetent, the Principal Investigator (PI) must decide if the subject is capable of understanding the elements of informed consent. The IRB may direct that a family member or other representative co-sign as a witness. If the investigator determines the subject is not capable of providing consent, a legally authorized representative (e.g. guardian) must be appointed and must provide consent before the subject can be enrolled.

Consent from Illiterate Subjects: At the onset of the consent process the PI or designated individual authorized to obtain consent must ask the subject if any special provisions are required by them for the consent process, including having the consent document read to them. A witness to the process is required when obtaining consent from illiterate subjects. An illiterate subject may make his/her mark on the consent form to indicate a willingness to participate. A video or audio tape of the process is recommended but the subject must consent to the taping and that consent must be on the tape. If taped, a copy of the tape must be provided to the subject and a copy must be retained with the study records.

Consent from Legally Authorized Representatives: When a potential subject is unable to provide consent because of impaired competency, consent must be obtained from a legally authorized representative of the subject. Documentation of this status must be obtained except when the LAR is the parent of a participant who has not yet reached the age of majority. Mentally retarded adults who have been declared incompetent must have an appointed legal guardian provide consent to participate in research. The natural parents of the adult are not authorized to give permission unless they have been appointed legal guardian(s).

When research is conducted in Connecticut, the persons who meet the definition of a legally authorized representative are a child's parent(s), court-appointed conservators or guardians, individuals designated as having power of attorney for health care, or individuals designated as health care representatives. Consent from next-of-kin is not acceptable absent one of the prior designations. When research is conducted outside of Connecticut, and review and approval by a local IRB or its equivalent is not required, the investigator must consult with legal counsel as to who can serve as the legally authorized representative and submit documentation of legal counsel's opinion.

In Connecticut when a patient authorizes another to consent to medical treatment and/or decisions on his/her behalf, said consent extends to research in the following contexts:

- If a legal guardian has been appointed for a patient, informed consent is obtained from the named individual, providing that the guardian has been given the authority to consent to medical treatment or medical procedures.

- If a power of attorney (which specifically includes medical treatment and/or decisions) has been given to an individual, informed consent is obtained from the named individual.

- If a health care representative, as that term is defined in Connecticut General Statutes § 19a-570(5), has been appointed for a patient, informed consent is obtained from the named individual provided that the procedures involved in the research are the type of procedures that normally occur in the context of medical care.

Observation: The consent process may be observed by the Research Compliance Monitor or other representative of the HSPO or IRB. The observation will be done to ensure compliance with regulations and policy, for quality improvement and/or for educational purposes. Verbal consent of the subject may be sought prior to the observation.

Procedure:

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

The principal investigator will designate on the IRB application the names of individuals authorized to obtain consent and also indicate whether the subject or legally authorized representative will be providing consent.

Standard screening and review procedures described in policies ofr expedited and convened board review apply.

The IRB may impose requirements on the proposed consent process such as:

- requiring 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 otherwise 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 principal investigator to develop the questions and submit them to the IRB for review/approval.
- requiring a witness
- requiring observation of the consent process

The PI will demonstrate any necessary re-consenting of a subject in one or more of the following ways:

- Obtaining the signature of the subject on a revised IRB-approved consent form at the next regularly scheduled visit
    - If the consent document has not yet been approved by the IRB at the time of the visit a qualified member of the research team must provide a verbal explanation of the information to the subject and document the explanation in the research or medical record as appropriate to the study.
    - The subject is to sign the revised consent document at the next available opportunity.
- If the new information warrants immediate contact (e.g. the principal investigator learns that a drug is causing life threatening adverse events), the PI will determine the best way to communicate the information to the subjects in the study and may do so prior to approval of the revised consent form. Consideration must be given to the subject's underlying condition, available support systems, and the nature of the information being conveyed.
    - The PI must document the contact with the subjects, inform the IRB of the contact, and if the subjects chooses to continue, obtain their signature on the revised consent form at the next available opportunity.
- Obtain the signature of subject who has reached the age of 18 on the approved consent form at the next regularly scheduled visit

Related Content

2011-007.0 – Definitions Applied to Policies
2011-008.0 – Informed Consent -Forms
2011-008.1 – Informed Consent – Process
2011-009.3 – Institutional Review Board – Expedited Review
2011-009.5 – Institutional Review Board – Review by the Convened Board

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)

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Signed RS 5/12/13

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