Issuing Department: Human Subjects Protection Office
Policy Number: 2011-008.0
Policy Title: Informed Consent Forms

Purpose

The purpose of this policy is to describe the required elements of an informed consent form.

Definitions

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

Informed Consent Form

Policy

The informed consent form (ICF) is to be written in lay terms and in a language understandable to the subject, preferably the subjects' native language.

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 be included in the ICF or the consent discussion.

A valid ICF will include the required elements* noted in federal regulations pertaining to informed consent. The Institutional Review Board (IRB) may require additional elements; or may waive or alter some of the required elements. Federal and local requirements will be listed on the informed consent checklist form. The Principal Investigator (PI) or designee is required to use copies of the most recently approved ICF when obtaining consent.

The PI will decide whether the ICF will be placed in a subject's medical record and/or in the research record and inform the subject of such.

The IRB may require an ICF and/or information sheet for exempt research.

** Elements:*

- a statement that the study involves research,
- an explanation of the purposes of the research,
- an explanation of why the subject is being invited to participate,
- the expected duration of the subject's participation,
- a description of the procedures to be followed,
- identification of any procedures which are experimental,
- a description of any reasonably foreseeable risks or discomforts to the subject,
- a description of the safeguards to be used to protect subjects from incurring the risk,
- a description of any benefits to the subject or to others which may reasonably be expected from the research,
- if applicable, a statement that subjects will not benefit directly,
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject,
- a statement describing the extent , if any, to which confidentiality of records identifying the subject will be maintained

- for studies involving the use of drugs, devices or biologics (marketed or investigational), indicate that the FDA and sponsor may inspect records,
- for applicable clinical trials subject to FDA regulation the following required statement: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.",
- an explanation as to whether subjects will be compensated for participation and if so the terms of the compensation,
- for studies above minimal risk, an explanation as to whether any compensation is available if injury occurs, and, if so, what it consists of, or where further information may be obtained,
- for studies above minimal risk, an explanation as to whether any medical treatment is available if injury occurs and, if so, what it consists of, or where further information may be obtained,
    - Written agreements with sponsors may be negotiated by either the Office of Clinical and Translational Research or the Office of Research Administration and Finance. The IRB need only review those agreements that contain subject injury language. The review is conducted by the IRB Chair to ensure that the language in the informed consent form is consistent with the language in the contract.
- an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subjects, and
- a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- a signature and date line for the subject and person obtaining and, as needed, for persons providing assent, witnessing, or acting as a legally authorized representative.

And as applicable,

- a statement that the particular treatment or procedure may involve risk to the subject which are currently unforeseeable (required when the study involves the use of investigational, drugs, devices or biologics, or drugs for which post marketing safety/efficacy data are being collected)
- a statement the particular treatment or procedure may involve risks to the embryo or fetus, if the subject is or becomes pregnant, which are currently unforeseeable (required when the study involves the use of investigational drugs, devices or biologics and subjects are or may become pregnant or when there are insufficient data on how a marketed drug impacts embryos or fetuses and subjects are or may become pregnant)
- anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent (required when the investigator may remove a subject from a trial due to medical /safety issues, subjects inability to continue to provide informed consent, subject's non-compliance with the direction of the investigator, or other situations when the investigator may determine it is in the best interest of the subject to withdraw him/her from the trial)
- any additional costs to the subject that may result from participation in the research (required if the subject will incur any permanent or temporary out-of-pocket expense related to participation in the trial, e.g. for procedures, drugs, research related injury etc.)
- the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (required if the a subjects decision to withdraw

will raise safety concerns, e.g. withdrawal from medications that should be tapered rather than abrupt)
- a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject (required for treatment trials or trials of moderate or more risk)
- a statement indicating the approximate number of subjects involved in the study.

And as applicable, local requirements as noted on the informed consent checklist

And as applicable additional requirements imposed by a funding agency (e.g. refer National Institute of Justice consent checklist addendum).

And as applicable to genetic research,
- disclosure that a family member may become aware of the information related to the study and subject, and/or that the subjects may become aware of information about themselves or family members that they would preferred not to have known.
    - Consent from the subject for disclosure of relevant information to relatives when the release of that information may improve the prognosis of the relatives will be sought. However the subject must be made aware of the possibility of such a disclosure without consent. Disclosure that breaks confidentiality may occur if there is a treatment that will help the prognosis of the family member(s). To break confidentiality the following conditions outlined by the President's Commission (1983) must be satisfied:
    - reasonable efforts to obtain voluntary consent for disclosure have failed;
    - there is a high probability that harm will occur from withholding the information and that the disclosure will avert that harm; and
    - the harm that would likely occur would be serious.
    - only the information needed for diagnosis and treatment is disclosed.
- a statement that the action of the subjects may place them risk (e.g. if they self disclose to their employer)
- a detailed description of what information will be presented to subjects including:
    - what type of information will be provided to them or others,
    - who will provide the information,
    - how the information will be communicated,
    - at what point in the study it will be provided,
    - whether interim findings will be disclosed or not,
    - the reliability of the information being provided, and
    - what information will not be provided to them.
- if study information is intended to be shared with subjects, the consent form must include an option whereby subjects retain the choice of being told or not being told that information. An exception to the right not to know may occur when treatment could improve the prognosis. The PI must explain to the subject within the consent form whether the right not to know will be honored in such a circumstance.
- if the study is likely to yield unexpected or unrelated findings the consent must:
    - state that findings that do not affect the health of the subject or health of family members, for example issues of maternity or paternity, will not to be disclosed.

    - Either provide subjects with an option of receiving or declining to receive information on unexpected and/or unrelated findings that are health-related, or
    - Inform the subject that such information will be disclosed.
- information regarding genetic counseling by qualified genetic counselors if a study may reveal important genetic information, e.g., being a carrier for an illness that has not yet manifested,. At whose expense the counseling is provided must also be disclosed. The PI must also inform participants of existing support groups.

Procedure

The PI and the IRB staff will use the informed consent checklist(s) to ensure that the regulatory and local elements of consent are included in the ICF. The PI may also use the IRB ICF template, which addresses the regulatory and local requirements, to develop the study specific ICF.

The PI submits the completed informed consent checklist(s) and the ICF to the IRB for review. Screening and review procedures discussed in the polices for expedited review and full board review are used.

Upon approval of the ICF by the IRB, IRB staff will at a minimum record the date of IRB approval on the ICF and return it to the PI with other routine approval paperwork.

Related Policies

2011-007.0 – Definitions Applied to Policies
2011-008.1 – Informed Consent – Process
2011-008.2 – Informed Consent – Waivers and Alterations
2011-008.5 – Informed Consent – Providing and Obtaining Informed Consent
2011-009.3– Review by Expedited Procedures
2011-009.5 – Review by Convened Board
2011-013.0 – Translation Policy
2014-028.0 – National Institute of Justice Additional Requirements

Basis

45 CFR 46.109(b)(c) 46.116(a)(1-8) 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:

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