

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

Purpose

The purpose of this policy is to describe the elements of an informed consent form and when those elements apply.

Definitions

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

Informed Consent Form

Policy

For purposes of this policy the term subject is inclusive of the subject or the subject's legally authorized representative. If the proposed provision for broad consent is adopted into regulation, UConn Health will not utilize the broad consent provision therefore this policy is exclusive of the elements for broad consent.

While the applicable regulatory criteria for consent will be used as the general premise for all consent forms, when the research is not federally funded or supported, nor subject to FDA oversight, the IRB may exercise judgement as to whether the elements noted below are required. In all cases the consent form must provide sufficient detail for the potential subject to make an informed decision.

The Institutional Review Board (IRB) may require additional elements of consent and may require an informed consent form and/or information sheet for exempt research. The Principal Investigator (PI) or designee is required to use the most recently approved and stamped version of the consent form when obtaining consent.

Consent forms for studies that involve clinical procedures should be placed in the medical/dental record and this should be disclosed within the consent document.

Unless otherwise waived or altered by the IRB, the following table presents the requirements of consent for federally funded or supported (FFS) research, and the requirements for FDA regulated research. Elements noted with a + are elements proposed in the revised version of 45 CFR 46. These elements will become required for FFS research only if the proposed revised regulation is implemented. If implemented the elements will be required for FFS research initially approved after the effective date of the regulation or for FFS research approved prior to the effective date of the revised rule that is still enrolling subjects and that is being transitioned to review under the revised rule. If the proposed revised rule is implemented, unless consent has been completely waived, the elements noted with an * cannot be omitted or altered for FFS research approved in accordance with the revised regulation.

FDA	FFS	ELEMENT
X	X	Before involving a human subject in research an investigator shall obtain the legally effective informed consent of the subject. *

X	X	Informed consent will be sought only under circumstances that provide the prospective subject sufficient opportunity to discuss and consider participation and that minimize the possibility of coercion or undue influence.*
X	X	The information that is given to the subject shall be in a language understandable to the subject,* (preferably the subjects' native language).
X	X	Exculpatory language which releases or appears to release the institution, sponsor or investigator from liability or which makes or appears to make a subject waive any legal rights cannot be included in the ICF *
	X	The prospective subject must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information ^{+ *}
	X	Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's understanding of the reasons why one might or might not want to participate. ^{+ *}
	X	The ICF must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. ^{+ *}
X	X	a statement that the study involves research
X	X	an explanation of the purpose of the research
X	X	the expected duration of the subject's participation
X	X	a description of the procedures to be followed
X	X	identification of any procedures which are experimental
X	X	a description of any reasonably foreseeable risks or discomforts to the subject
X	X	a description of any benefits to the subject or to others which may reasonably be expected from the research
X	X	a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
X	X	a statement describing the extent , if any, to which confidentiality of records identifying the subject will be maintained
X		for studies involving the use of drugs, devices or biologics (marketed or investigational), a statement that indicates that the FDA and sponsor may inspect records
X	X	for applicable clinical trials subject to FDA regulation and/or funded by NIH 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."
X	X	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,
X	X	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

X	X	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
X	X	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.
	X	one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: ⁺ <ul style="list-style-type: none"> ○ a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject if this might be a possibility; or ○ a statement that the subjects information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
X	X	a signature line for the subject (note the IRB also requires that the subject date the form, the electronic signature of the subject may be acceptable).
And as applicable		
X	X	a statement that the particular treatment or procedure may involve risk to the subject (or to the embryo or fetus, if the subject is or may become pregnant) 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 or when there are insufficient data on how a marketed drug impacts embryos or fetuses and subjects are or may become pregnant)
X	X	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)
X	X	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.)
X	X	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)
X	X	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)
X	X	a statement indicating the approximate number of subjects involved in the study

	X	A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit ⁺
	X	A statement regarding whether clinically relevant research results, including the individual research results, will be disclosed to subjects, and if so, under what conditions ⁺
	X	For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). ⁺

As applicable to the research the following additional elements may also pertain:

- Local requirements as noted on the informed consent checklist, inclusive of the signature and date of the person obtaining consent.
- Requirements imposed by a funding agency (e.g. refer National Institute of Justice consent checklist addendum).

For 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 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.

Posting of Clinical Trial Consent Forms:

The requirement for posting of clinical trial consent forms for federally funded/supported research will apply only if the proposed provision is adopted into regulation. For each federally funded or supported clinical trial one IRB-approved informed consent form used to enroll subjects must be posted by the awardee of the Federal department or agency component conducting the trial on a publicly available Federal website that acts as a repository for such informed consent forms. The informed consent form must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol. Principal investigators are responsible for working with the funding agency to address this requirement.

Electronic Informed Consent (eIC) Documents

If e-consent is proposed within a study the applicable regulatory elements must be included and the investigator must provide the IRB with all material (e.g. the consent form, videos, web-based presentations, supplemental materials) that will be presented to the subject as part of the e-consent form. This is inclusive of supplemental material that may be accessed by hyperlinks so that the IRB can evaluate the content of that hyperlink to determine if it is accurate and appropriate, and of questions that may be used to gauge a subject's level of comprehension. When an e-conesnt form is proposed subjects must still be provided the option of reviewing and signing a paper based consent form.

A written copy of the consent form is to be provided to the subject.

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 informed consent. The PI may also use the IRB consent form template, which addresses the regulatory and local requirements, to develop the study specific consent.

The PI submits the completed informed consent checklist(s) and the consent form to the IRB for review. Screening and review procedures discussed in the policies 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 consent form 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
21 CFR 50

Document Attributes

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Reviewed and Approved By:

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Date: