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SBE Refresher 1 – Informed Consent

Yale University Training Opportunities - SBE Refresher 1 – Informed Consent

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Introduction

People have the right to expect that researchers will treat them as autonomous individuals, respecting their decisions about whether to take part in research and about what personal information they will or will not share with others. This is accomplished through a thorough informed consent process that is presented in a language understandable to the research subject.

Learning Objectives

By the end of this module, you should be able to:

- Identify the general requirements of informed consent.
- Identify the additional requirements of informed consent that may be

necessary depending on the research.

The Consent Process

The federal regulations at 45 CFR 46 (Protection of Human Subjects 2018) about informed consent list elements of information that the researcher must provide to subjects. The regulations divide the elements into two categories. One category includes basic elements to be provided to all subjects. The second set includes elements that must be provided when appropriate.

Consent should begin with a concise and focused presentation of the key information that is most likely to assist a subject in understanding the research, what is expected of them, and the potential risks of harm and benefits. Regulations (Protection of Human Subjects 2018) require that this information be understandable to the subject and presented in a way that facilitates comprehension. The emphasis is on subject (or legally authorized representative [LAR]) comprehension and presenting information that a "reasonable person" would want to have in order to make an informed decision to participate, and providing an opportunity to discuss.

This "key information" is not defined in the regulation, but examples of key information were provided in the preamble to the revised Common Rule (Protection of Human Subjects 2018):

- The fact that consent is being sought for research and that participation is voluntary
- The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research
- The reasonably foreseeable risks or discomforts to the prospective subject
- The benefits to the prospective subject or to others that may reasonably be expected from the research

- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

General Requirements of Informed Consent

Basic Elements - 45 CFR 46.116(b)

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or others that may reasonably be expected from the research
- 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 research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
- 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 subject
- 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
- One of the following statements about any research that involves the

collection of identifiable private information or identifiable biospecimens:

- 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 or the legally authorized representative, if this might be a possibility
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

Additional Elements - 45 CFR 46.116(c)

Depending upon the nature of the research and the risks involved, IRBs may invoke additional regulatory requirements, such as:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject
- The approximate number of subjects involved in the study
- 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

- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (in other words, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

Comprehension

Informed consent is not valid unless the researcher makes sure that the prospective subject understands the information that has been provided. The researcher must consider the following during the consent process: 1) characteristics of the proposed subject population's levels of cognition and literacy, 2) the complexity of the information to be conveyed, 3) each subject's emotional state, and 4) the setting under which the consent process will take place. These considerations will guide the researcher in determining the appropriate way to present the information.

Consent as an Ongoing Process

An initial decision to take part in research is not binding. Subjects may choose to stop participating for any reason or without cause. There may be cases in which elements of the consent process should be reviewed as the study progresses and additional opportunities for subjects to ask questions arise.

Summary

Informed consent includes many regulatory requirements designed to reflect the ethical principle of respect for persons and the preservation of autonomy.

Reference

- Protection of Human Subjects, 45 CFR § 46 (2018).

Original Release: May 2012

Last Updated: January 2018

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