IRB SOP 701
Informed Consent

Purpose

Direct intervention or interaction with subjects.
Obtaining private identifiable data, specimens, or records from subjects (including medical records).

2.0 A process, not a document

Obtaining consent is an active ongoing process, not a signature on a document. The process involves an information exchange and on-going communication that takes place between the researcher and the prospective subject.

The process begins with the initial approach to the potential subject (e.g., through a flyer, brochure, discussion, or any advertisement) and continues until the subject decides to end his/her participation or the study ends.

2.1 Obtaining a signature on a consent form does not complete the consent process. For example, researchers are required to provide subjects with any new information that arises during the study that may affect the subject's decision about whether to continue participation. In addition, ensuring an adequate consent may require repeating or supplementing the initial consent procedure.

3.0 Key features

The consent process involves three key features:

3.1 Disclosing to potential subjects the information needed to make an informed decision about whether to participate;

3.2 Facilitating the understanding of what has been disclosed (for example, by providing ample opportunity to ask questions and by communicating with subjects in terms and language they can understand);

3.3 Promoting the voluntariness of the decision about whether to participate.

4.0 Waiver of consent requirements

The IRB may waive the requirement to obtain consent, or it may approve a consent process that does not include, or that alters, some or all of the required elements of consent. Waivers of consent or of consent elements can be granted only under conditions specified in federal regulations.

4.1 IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No more Than Minimal Risk

4.1.1 The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3[k] and 102[(i)]) to the subjects;

4.1.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;

4.1.3 The clinical investigation could not practicably be carried out without

the waiver or alteration; and

4.1.4 Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

5.0 Exception from Consent Requirements for FDA-Regulated Products (i.e. Emergency Use)

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8.3 Basic elements of informed consent

injury to the subject. [Note that the regulations do not limit “injury” to physical injury; this is a common misconception.]

8.3.14 An explanation of how to contact the research team for questions, concerns, or complaints about the research.

8.3.15 An explanation of how to contact someone independent of the research team for questions, concerns or complaints about the research, questions about the subject’s right to obtain information, or to offer input.

8.3.16 A statement that participation is voluntary.

8.3.17 A statement that refusal to participate will involve no penalty or loss of benefits to wuh(w)5 (u)-4 ()-4 (h)5 (e)-5 (re)-2 (se)suo etelo

8.5 Requirements of the Food and Drug Administration

There are additional requirements for research that is subject to the FDA regulations:

7.5.1 Study withdrawal or termination The subjects should be informed that if they decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about them up to that point will remain part of the study and may not be removed from the study database.

7.5.2 FDA access to study records. Subjects should be explicitly informed that the FDA may have access to the study data and records. This may be worded as "The Food and Drug Administration may inspect the records."

7.5.3 Public information about the study. The FDA requires that the following statement be provided to subjects in most clinical trials as an element of the consent process, without alteration:

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

8.6 Requirements of other agencies

There may be additional requirements associated with specific federal and state agencies and regulations. For example, there may be state reporting requirements (e.g., child abuse, elder abuse, domestic violence) that are relevant to the research and should be explained to the subjects.

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8.8.9 Reportable Income

8.8.10 Deception Debriefing

8.9 Deception and concealment

8.9.1 The use of deception or concealment in research is not prohibited by federal regulations or by the USA IRB.

Deceptionmeans deliberately misleading subjects about some aspect of the research. Concealment means deliberately withholding certain information. Examples include:

Withholding specific information about the true purpose of a study (concealment).

Misinforming subjects about the purpose of a study (deception).

2.2.4 The IRB application should describe who will serve as interpreter, and the nature of the qualifications. See the *SOP 705: Translation and Interpretation.*

2.2.5 In addition to providing in-person interactions and written documents in the language of the subjects, researchers may consider additional methods of communication as well – such as showing a video of someone speaking about the research in the subject's language.

2.2.6 If appropriate, researchers should have an ongoing arrangement for an interpreter, to convey the subject's questions and concerns throughout the study. For example, a study involving an investigational drug may need to have an interpreter on call, should a subject have an urgent question or problem related to the drug.

2.2.7 The IRB has the authority to require revisions or additions to the consent process to ensure that non-English speaking subjects are adequately informed and are providing truly voluntar7 ⊖1l6peq ion to iuint.7 inrgqio.7 infreq-4 (a(c)