HUMAN RESEARCH PROTECTION

Informed consent

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Resource type GUIDANCE

This guidance outlines the required elements of informed consent for human research to be included when conducting informed consent.

A) Minimum requirements

- ✓ **The consent begins with a concise summary of key information (including as appropriate, but not limited to items 1-9 below):**
  1) The study involves research
  2) Participation is voluntary
  3) The purpose of the research
  4) The expected duration of the subject's participation
  5) The procedures to be followed
  6) Identification of any procedures, which are experimental **Can be omitted if there are none*
  7) Any reasonably foreseeable risks or discomforts to the subject **Can be omitted if there are none*
  8) Any benefits to the subject / others, which may reasonably be expected from the research **Can be omitted if there are none*
  9) Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject **Can be omitted if there are none*
- ✓ The extent, if any, to which confidentiality of records identifying the subject will be maintained **Can be omitted if there are none*
- ✓ How to contact the research team for questions, concerns, or complaints about the research
- ✓ How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input
- ✓ Whom to contact in the event of a research-related injury to the subject
- ✓ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
- ✓ Whether subjects will be compensated for their participation
- ✓ The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

For research that involves the collection of identifiable private information or identifiable biospecimens, one of the following statements:

- 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;

OR

- 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

B) Additional requirements, if applicable

- The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable
- If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject'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
- Procedures for orderly termination of participation by the subject
- 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
- Approximate number of subjects involved in the study
- Amount and schedule of all payments
- 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 (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

C) Additional requirements for *greater than minimal risk* research

- ✓ Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
- ✓ Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

D) Additional requirements for clinical trials that follow ICH-GCP

- ✓ The approval of the IRB.
- ✓ The probability for random assignment to each treatment.
- ✓ The subject's responsibilities.
- ✓ When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
- ✓ The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
- ✓ When there is no intended clinical benefit to the subject, a statement to this effect.
- ✓ The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.

- ✓ If the results of the trial are published, the subject's identity will remain confidential.

E) Additional requirements for FDA-regulated research

- ✓ The possibility that the US Food and Drug Administration may inspect the records.
- ✓ The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
- ✓ The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.
- ✓ For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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."
- ✓ Trials including children as research subjects, if the parent or guardian initially documents the child's assent, procedures are in place to verify the child's identity and assent when the child initially presents to the investigator.

F) Additional requirement for NIH-funded clinical trials (even if not FDA-regulated)

Required text: *A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by NIH Policy. 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*.

G) Additional requirement for research with a Certificate of Confidentiality

An explanation of the protections afforded by the Certificate of Confidentiality and any exceptions to that protection.

H) Additional requirements for research funded by the National Institute of Justice (NIJ)

An explanation that the study is funded by NIJ and that identifiable data collected with DOJ funds can only be used for research and statistical purposes, and no other purpose without the subject's consent. Current or past abuse is **not** reportable, unless a separate consent to allow reporting is obtained from the research subject, in addition to a consent to participate in the research study. See https://www.nij.gov/funding/humansubjects/Pages/faqs.aspx

I) Additional requirements for genetic research (as recommended by OHRP)

- ✓ Language regarding the protections provided by the federal Genetic Information Nondiscrimination Act (GINA), and the impact of GINA on the risks and confidentiality protections for such research. See https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html
- ✓ Any additional information that should be given to subjects, when in the IRB's judgement, the information would meaningfully add to the protection of the rights and welfare of subjects.[i]

J) Additional requirements research involving electronic consent

- ✓ The date of the electronic signature is captured (not applicable if a waiver of documentation of consent is approved)
- ✓ Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures
- ✓ Electronic consent process includes age appropriate materials to facilitate comprehension
- ✓ Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject's needs
- ✓ Electronic consent document/process allows subjects to proceed forward or backward or pause for review later
- ✓ Measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents
- ✓ Plans are adequate to maintain external hyperlinks or documents, and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures
- ✓ The informed consent process outlines in detail how any included documents will be used

- ✓ Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team

K) Requirements for research using *short form* of consent documentation

- ✓ The written consent document states that the elements of consent have been presented orally to the subject or the subject's legally authorized representative
- ✓ There is a written summary of what is to be said to the subject or the legally authorized representative that embodies the required and appropriate additional elements (see sections A and B)
- ✓ The consent document and summary are accurate and complete
- ✓ An impartial witness is present during the entire consent discussion
- ✓ For subjects who do not speak English the witness is conversant in both English and the language of the subject or the subject's legally authorized representative
- ✓ The subject or the subject's legally authorized representative will sign and date the short form consent document
- ✓ The witness will sign and date the short form consent document and the summary
- ✓ The person obtaining consent will sign and date the summary
- ✓ When a subject or the subject's legally authorized representative is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that consent was freely given.
- ✓ A copy of the signed and dated summary will be given to the person signing the document
- ✓ A copy of the signed and dated consent document will be given to the person signing the document
- ✓ If there is a signature line for a legally authorized representative or parent, the IRB has approved inclusion of adults unable to consent or children

[i] 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.