Topics

- § 46.116: General requirements for informed consent
- § 46.117: Documentation of informed consent
- OHRE SOP 1101: Obtaining Informed Consent from Research Subjects

What is consent? Why is it important?

- Partnership contract with the subject
  - The more a subject knows about the study purpose, the better a resource they can be.
- First Principle of The Belmont Report – Respect for Persons
- Good etiquette to ask subject & inform them of what will be involved, therefore **informed** consent

General Regulatory Requirements

1. Before research begins must have subject's legally effective consent of subjects or LAR.
2. No Research with Subjects until ICF is signed
3. Informed consent sought only under circumstances that provide the prospective subject or LAR **sufficient opportunity to discuss & consider whether or not to participate and that minimize the possibility of coercion or undue influence.**

General Regulatory Requirements

- The prospective subject or the legally authorized representative 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.

- No informed consent may include any **exculpatory language** through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

General Regulatory Requirements

- 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; and

General Regulatory Requirements

One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

i. 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

ii. 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 of Informed Consent

- 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;

Additional Elements of Informed Consent

- **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;
- **Approximate number of subjects** involved in the study;
- **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;
- **If individual research results will be disclosed to subjects,**
- **Whether the research will (if known) or might include whole genome sequencing**

Broad Consent

Elements of broad "consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens."

Broad consent not adopted by UNC.

Requirements for Waiver and Alteration

In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

i. The research involves **no more than minimal risk** to the subjects;

ii. The research **could not practicably be carried out** without the requested waiver or alteration; *(not just inconvenient or hard)*

iii. If the research involves using identifiable private information or identifiable biospecimens, **the research could not practicably be carried out without using such information or biospecimens in an identifiable format;**

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

v. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Screening, Recruiting, or Determining Eligibility

An IRB may approve research obtaining information or biospecimens without consent of prospective subjects if either of the following:

- Information is obtained with oral or written communication with possible subject or LAR OR
- Researcher accesses records or stored biospecimens.

Revised Common Rule (at 45 CFR 46.116(h))

"For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site…"

§46.117 Documentation of Informed Consent

- Documentation of consent is required &
- Subjects must receive a copy of the consent

Waiver of Consent Signature

- Signed ICF poses a risk to subject in case of breach of confidentiality.
- Research is no more than minimal risk
- Cultural norms do not provide for signatures; but alternative documentation method needed.

Waiver of Consent Signature

- When waived the IRB can require researcher to provide subjects or LAR with a written statement about the research.

Session Summary

- Review of the regulatory required and optional elements for valid informed consent of human subjects enrolled in research
- Reviewed waivers of elements & documentation of consent
- Reference OHRE SOP 1101: Obtaining Informed Consent from Research Subjects