The Consent Process: It’s More Than Just a Form

A

“10 Minute Training”

Brought to you by
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Introduction

Training Goal:
• *All* research team members are knowledgeable about the process of obtaining and documenting informed consent for study participation.
• Informed consent is obtained in compliance with OHRP, FDA, IRB, and ICH guidelines for Good Clinical Practice.

Performance Objectives:
At the end of this training session you will know Who, What, When, Why, and How to carry out the informed consent process.
Definition

“Informed consent is a vital part of the research process, and as such entails more than obtaining a signature on a form. Investigators must educate potential subjects to ensure that they can reach a truly informed decision about whether or not to participate in the research. Their informed consent must be given freely, without coercion, and must be based on a clear understanding of what participation involves.”*

The documentation of informed consent (i.e., signing of the consent form) is also a vital part of the research process.

*Partners Healthcare: Founded by Brigham & Women’s Hospital & Massachusetts General Hospital
Ethical Principles - Why

- **Nuremberg Code**: “The voluntary consent of the human subject is absolutely essential”. This means that the person involved should have legal capacity to give consent, without any intervention of deceit or coercion; and should have sufficient knowledge and comprehension of the subject matter. (Nuremberg Code, 1949)

- **Declaration of Helsinki**: “…the well-being of the individual research subject must take precedence over all other interests.” (Declaration of Helsinki, 1964)

- **Belmont Report**: “…respect for persons demands that subjects enter into the research voluntarily and with adequate information.” (The Belmont Report, February 1976)
The Informed Consent Process - Who

Who Must be Consented?
• Potential subjects who are thought to fulfill the inclusion/exclusion criteria for the study.

Who May Obtain Consent?
• Qualified research team members trained in Human Subject Protection & with sufficient knowledge about the specific study. This may include the Principal Investigator (PI), sub-investigators, research coordinators or other research team member approved by the IRB.
• Though the PI may delegate obtaining consent to other team members, proper oversight and execution is always the PI’s responsibility.
The Informed Consent Process - What

8 Required Elements of Informed Consent:

1. **Research** – statement that study involves research, its purpose, duration, procedures, & identification of experimental procedures.
2. **Risks** - or discomforts, that are reasonably foreseeable.
3. **Benefits** – to subject or others, that are reasonably expected.
4. **Alternative** - procedures or treatments available, if any.
5. **Confidentiality** - of records identifying subject, though may be inspected by authorized entities (*i.e.*, FDA, IRB, UCD/UCH, Sponsor).
6. **Research-Related Injury** – available treatment & compensation (if study is greater than minimal risk).
7. **Contact** – person for questions regarding the study, subject’s rights, or research-related injury.
8. **Voluntary** – no penalty or loss of benefits for choosing not to participate & may discontinue at any time.

FDA 21 CFR 50.25 & 45 CFR 46.116
The Informed Consent Process - What

Additional Elements of Informed Consent:

1. **Unforeseeable Risks** – may be involved.
2. **Participation Termination** – circumstances under which PI may terminate subjects participation without their consent.
3. **Additional Costs** – to subject due to participation.
4. **Withdrawal** – consequences of subject’s decision to withdraw & withdrawal procedures.
5. **Significant New Findings** – subjects will be notified of new findings which develop during the course of research that may relate to their willingness to continue participation.
6. **Subject Numbers** – approximate number involved in study.

The **8 basic** elements are required in all consents. **Additional** elements are used when appropriate and as required by IRBs. They are typically incorporated in the IRB templates with instruction for use.
The Informed Consent Process - When

Informed consent must be obtained:

• **Prior** to conducting any study related tests, procedures, treatments, or questionnaires.

• Using the current IRB approved consent form (HRRC approval is also required prior to consenting any subjects if using UCH facilities).

• Re-consent is required if there is new information that would effect the subjects willingness to continue participation or as directed by the IRB.
The Informed Consent Process - How

- Identify potential study participants based on study criteria.
- Describe the study verbally, as outlined in the approved consent, using non-technical language. An interpreter should be involved if necessary.
- Invite questions and ensure all are answered satisfactorily.
- Allow time to review the consent alone or with physician, family or friends if desired.
- Assess understanding of the major elements of the consent.
- If there is voluntarily agreement to participate, obtain signature, initials where indicated, and date from the subject.
- Consenter must also sign and date, as must the PI if there is a PI signature line on the consent form.
- Provide a copy to the subject and maintain the original in the subject’s study file.
- Complete the Consent Process Documentation form & file.
Summary

• Consent is an ethical obligation governed by federal regulation, which requires the use of current IRB approved consent forms.

• Consent must be informed and voluntary.

• Consent must be completed prior to any study-related activity.

• Documentation of the consent process (by signing the consent form) is required for most studies.

• Obtaining consent may be delegated to trained research team members, but is always the PI’s responsibility.

Consent is a Process – Not just a Form!