Informed Consent

What is it?

What does it include?

More than a document

- Informed consent begins when you first approach a potential research subject.
- Informed consent is a process by which
  - You disclose relevant information about the research study – purpose, procedures, risks, benefits, etc.
  - You share that participation will be voluntary, confidential, anonymous.
- Subject indicates his/her willingness to participate in your research.

The consent form

- Is a permanent record of
  - The information you conveyed,
  - The fact that the process occurred,
  - The subject's willingness to participate.

General requirements

- Unless waived by the IRB, the PI
  - must obtain the informed consent of the subject or the subject's legal representative,
  - must provide the subject sufficient opportunity to consider participation,
  - must minimize undue influence.

Elements of Informed Consent
45 CFR 46.116

- Research Acknowledgement
  - Explain that this is research.
  - Explain what part is research.
  - Use the word research.

Elements of Informed Consent
45 CFR 46.116

- Purpose of the study
  - Why is this research being done?
  - Why are you asking the subject to participate?

Elements of Informed Consent
45 CFR 46.116

- Description of procedures
  - What happens to the subject?
  - What does the subject need to do as part of the research?
  - Expected duration, how long, how often?

Elements of Informed Consent
45 CFR 46.116

- Description of potential risks
  - What are the risks (physical, psychological, social, etc.)?
  - How likely is it they will occur?
  - What will be done if they do occur?

Elements of Informed Consent
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- Description of potential benefits
  - What are the potential benefits?
  - How likely is it they will occur?
  - What are the indirect benefits?

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- Participation is voluntary
  - Subject may choose to stop at any time.
  - Subject may choose not to answer any question.
- Alternatives
  - What happens if subject chooses not to participate?
  - Can subject get or do the same thing without participating?
  - What else is available to subject if he/she does not participate?

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- Confidentiality
  - How will the information obtained be kept confidential?
  - Who will know or need to know?
  - Where and how will data be stored?
  - Who will inspect or review records?

Elements of Informed Consent
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- Anonymity
  - How will you insure that responses are anonymous?

Elements of Informed Consent
45 CFR 46.116

- Who will answer questions
  - About the study?
  - About being a research subject?
  - About injuries or other unforeseen risks?

When subjects are minors

- You must receive informed consent from the parent or legal guardian of any minor subjects.
- When appropriate, you must also receive the assent of the minor.

Informed Consent Documentation

- Written form approved by the IRB
- Separated from other documents associated with the study
- Signed and dated by the subject or his/her legal representative
- Copy given to subject or representative
- PI retains copy for records

Other considerations

- Should be easy to read and understand.
- Use plain, simple language.
- Use short, direct sentences.
- Avoid legalist or specialized language.

More information online

- The ORGC website http://www.utm.edu/departments/rgc/irb.php
- The *UT Martin Faculty, Staff, and Student Handbook for Studies Involving Human Participants*
- An example of an informed consent document

Recommended training

- UT Martin subscribes to an approved online training program regarding Human Subjects Research
- This online training is available at no cost to faculty, staff, and students of UT Martin
- Contact the UT Martin ORGC for information on access to this training

Questions

- Contact
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  - Dr. Joan West, Director
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  - 731-881-7015
  - 731-881-7018, fax