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.

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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.

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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

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☐ Purpose of the study
  ■ Why is this research being done?
  ■ Why are you asking the subject to participate?
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- 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?
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- 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?
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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?
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- Anonymity
  - How will you insure that responses are anonymous?
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- 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

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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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