Informed Consent

Office of Research and Sponsored Programs
The University of Tennessee at Martin
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More than a document

Informed consent begins when you first approach a potential research subject.

Informed consent is disclosing relevant information about the research study, such as purpose, procedures, risks, and benefits, and that participation will be voluntary, confidential, and anonymous.

Subject indicates willingness to participate in your research.

The consent form is a permanent record of the information you conveyed, the fact that the process occurred, and the subject’s willingness to participate.
General Requirements

Unless waived by the Institutional Review Board (IRB), the Principal Investigator (PI) must do the following:

- Obtain the informed consent of the subject or the subject’s legal representative
- Provide the subject sufficient opportunity to consider participation
- Minimize undue influence
## Elements of Informed Consent

45 CFR 46.116

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
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<tbody>
<tr>
<td>Research Acknowledgement</td>
<td>- Explain that this is research.</td>
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<td></td>
<td>- Explain what part is research.</td>
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<td></td>
<td>- Use the word research.</td>
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<tr>
<td>Purpose of the Study</td>
<td>- Why is this research being done?</td>
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<td>- Why are you asking the subject to participate?</td>
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<tr>
<td>Description of Procedures</td>
<td>- What happens to the subject?</td>
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<td>- What does the subject need to do as part of the research?</td>
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<td>- Expected duration, how long, how often?</td>
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<tr>
<td>Description of Potential Risks</td>
<td>- What are the risks (physical, psychological, social, etc.)?</td>
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<tr>
<td></td>
<td>- How likely is it they will occur?</td>
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<td></td>
<td>- What will be done if they do occur?</td>
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</table>
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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?

**Voluntary Participation**
- 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?

Anonymity
- How will you ensure that responses are anonymous?

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

- Written form approved by the IRB
- Separated from other documents associated with the study
- Signed and dated by the subject or legal representative
- Copy given to subject or legal representative
- PI retains copy for records
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.
Ensure form is easy to read and understand.

Use plain, simple language.

Use short, direct sentences.

Avoid legalist or specialized language.
Additional Resources

  - The *UT Martin Faculty, Staff, and Student Handbook for Studies Involving Human Participants*
  - Sample informed consent document
  - Sample minor assent form
- UT Martin subscribes to an approved online training program regarding Human Subjects Research which is available at no cost to faculty, staff, and students. Contact the ORSP for more information.
For questions or more information, please contact:

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