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Consent

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Recommended Citation

Green, Jonathan, "Consent" (2011). *Human Research Protection Program (HRPP) Education*. Paper 23.
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CONSENT

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Consent

- ▣ Informed Consent is a process
 - Process is important in the initial obtaining consent, but it is not limited to having the subject sign the document.
 - Consent is an ongoing process that lasts the entire time of the subjects participation in the study

Why do I have to get consent?

- ▣ The obligation to obtain consent flows from the ethical principle of “Respect for Persons”.
- ▣ People have a fundamental right not to be used for research without their express permission.
- ▣ This includes not having their private information used without their knowledge and permission.
- ▣ When people are hospitalized, they have a reasonable expectation of privacy.

The purpose of informed consent

- ▣ In performing human experimentation, we are not only allowing, but often facilitating, people placing themselves in harms way.
- ▣ We allow people to accept this risk only if they are adequately informed.
- ▣ The consent document is only one part of this, but it is an essential written statement of all the information that the subject needs to know to make an informed choice.

The process of consent

- ▣ Obtaining Consent:
 - Is much more than having the subject sign the paper.
 - In obtaining consent, there must be a discussion between the investigator and the subject. If it is delegated to another individual, they must be fully trained and aware of all aspects of the study, and the PI must be available to answer questions if needed.
 - Consent must be obtained under circumstances that allow the subject to fully consider whether they wish to participate, without time pressure or coercion.

Consent is ongoing

- ▣ The obligation to inform the subject does not end after he or she signs the consent document.
- ▣ It is expected that throughout the study the investigator will be communicating with the subject, soliciting questions, facilitating the ability of the subject to report any potential adverse reactions or other relevant information.

The Consent Document

- ▣ The consent document is the only written record we have that says exactly what it is that you will tell the subject.
- ▣ It must contain all information that a reasonable person needs, and that would be expected to want to know to decide whether or not to participate in the study, in a way that is understandable.
- ▣ It must contain information that addresses specific regulatory requirements.

Minimum regulatory requirements

- ▣ A statement that this is research, why you are doing the study, what the subject will have to do to participate
- ▣ What is the potential for harm in participating in the study (risk)
- ▣ Is there a prospect for benefit, individually to the subject or to society?
- ▣ Are there alternatives to participation (usual care)?
- ▣ How will you protect privacy and confidentiality?
- ▣ Is there compensation, and what you will do if there is a research related injury.
- ▣ Who to go to for questions and help
- ▣ That participation is voluntary, and there is no penalty for not participating.

Take home points

- ▣ The consent process is a critical element of good human subjects research.
- ▣ Consent is an ongoing process that starts with the document, and lasts the length of the research
- ▣ Give a copy of the **SIGNED** consent document to the subject, and keep the original. Loss of consent document may be interpreted as no consent obtained, and may mean you lose that subjects data.

Eligibility Criteria

- ▣ Eligibility criteria define your study population
- ▣ They should be:
 - Clear
 - Well defined
 - Consistent

Eligibility

- ▣ Can I enroll a subject that does not meet my criteria, if I think they would be a good candidate and there is no increased risk to them?
- ▣ When you get IRB approval, you are approved to enroll only subjects that meet the criteria you specified in your application.
- ▣ If you want to enroll a subject that does not meet the criteria, you must ask the IRB first.

Eligibility

- ▣ If you enroll first, and then ask, you will likely be considered to be non-compliant.
- ▣ You may not be allowed to use data obtained from that subject, therefore you will have unnecessarily exposed them to risk.
- ▣ Continued violations may be considered serious noncompliance, which must be reported to OHRP.