

Informed Consent

for more information, please visit <http://cumc.columbia.edu/dept/irb/>

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Basic Elements

...continued

3. Benefits
4. Alternative procedures or course of treatments that might be available to the patient
5. Availability of compensation and medical treatment if injury occurs
 - what compensation and treatment
 - how they may be obtained

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Informed Consent: What is It?

- VOLUNTARINESS
- COMPREHENSION
- INFORMATION
 - freely given consent to participate
 - by a competent person
 - in full possession of all pertinent information
 - with knowledge that this is research - not treatment

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Basic Elements

...continued

6. Confidentiality
 - Extent to which identifying information will be maintained and who may inspect records
7. Who to contact for:
 - questions regarding the research and subject's rights
 - in the event of research-related injury
8. Participation is voluntary
 - refusal will involve no penalty or loss of benefits
 - the subject may discontinue participation at any time

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Informed Consent: 8 Basic Elements

1. The study involves research
 - an explanation of the study purpose
 - expected duration of participation
 - a description of procedures to be followed
 - identification of which procedures are experimental
2. Risks or discomforts

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Informed Consent: Additional Elements

- Unforeseeable risks
 - to the subject
 - or to the embryo or fetus, if the subject is or may become pregnant
- Additional costs to the subject
- Termination of participation by the Investigator
 - Circumstances under which subject's participation may be terminated early without regard to the subject's consent

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Additional Elements

...continued

- The subject's decision to withdraw
 - the expected medical consequences
 - procedures for orderly early termination of participation
- Communication about new findings
 - The subject will be provided with any significant new findings during the course of the study which may modify the subject's willingness to continue in the study

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Students/Subordinates

- Students, employees and other individuals in subordinate positions may be unduly influenced to participate in a study against their better judgment.
- At Columbia, employees or students responsible to a study investigator may not be recruited as subjects unless responding to general advertising

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Ongoing Informed Consent

- A signed "Informed Consent" document is obtained prior to subject enrollment in the study
- **HOWEVER**, informed consent is a process of information exchange that must take place between the prospective subject and the investigator not only before the study but also during and sometimes after the study.

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Informed Consent and Minorities

- Translating informed consent developed in English to a different language
 - Translation must be an accurate rendition of the English original -- nothing is...
 - changed
 - added
 - taken away
 - All medical terms must be accurately translated
 - Grammar and syntax proper to the language
 - Standard language --- not resorting to slang or localisms only understood by a few

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Vulnerable Populations

- Those groups that do not have the autonomy to give informed consent
 - children
 - mentally impaired, individuals with dementia
 - prisoners
- or may be unduly influenced to participate
 - students
 - subordinates
 - pregnant women (actually, the fetuses)
 - patients (care-giver vs. researcher)

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