Informed Consent

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

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

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

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

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

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

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

Ongoing Informed Consent

- A signed “Informed Consent” document is 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.

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)

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

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