Informed Consent

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

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

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.

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

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)