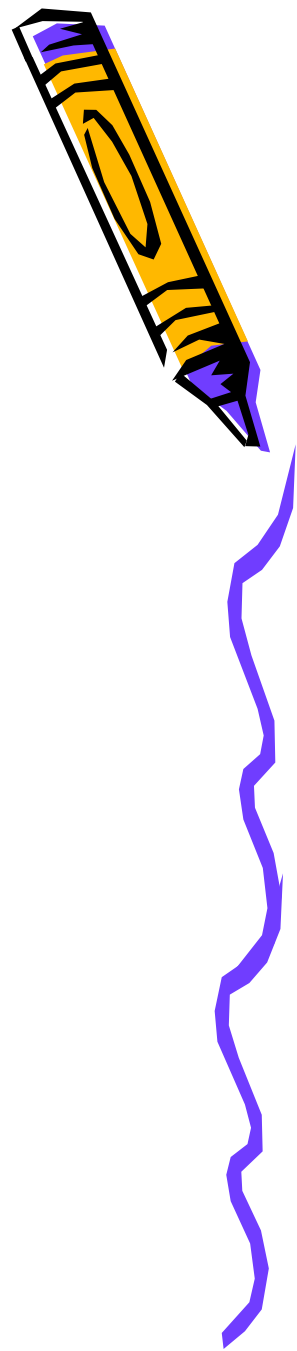


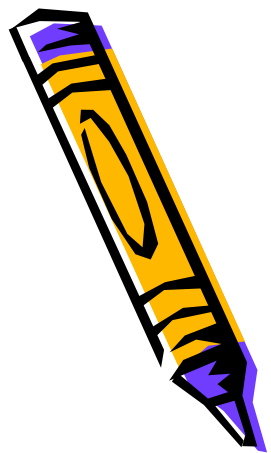
Consent

- Simple or Mere Consent
- Informed Consent
 - Concepts
 - Risks
 - Inherent
 - Material
 - Exceptions



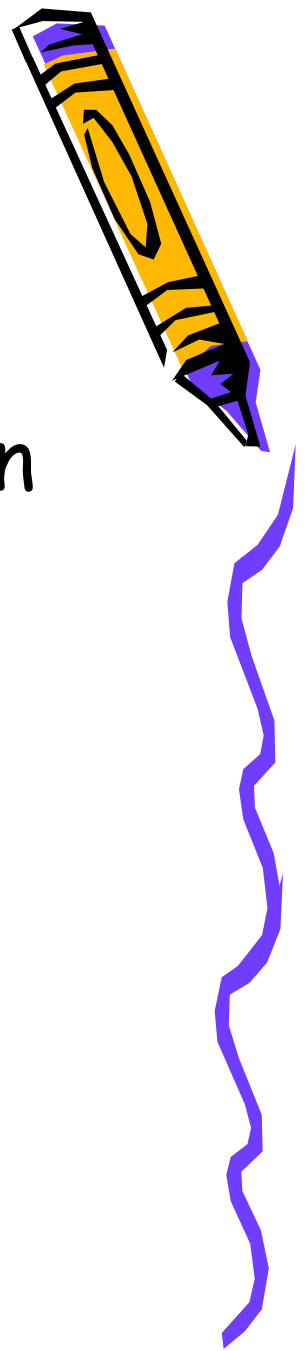
Consent

- Standards (Yardsticks) to measure
 - "Reasonable" Physician's Information Provided to a patient.
 - "Reasonable" patient Standard.
 - "Patient" Standard.



Capacity & Competency

- Capacity - medical determination
 - Capable of understanding
 - Appreciating consequences
- Competence - judicial determination by the court





Competency - Definition

- Minimal mental, cognitive, or behavioral trait, ability, or capability
- Required to perform a particular legally recognized act
- Or assume some legally recognized role.
- Cognitive capacity.



Competency - Legal



- Adults 18 years and older are presumed competent.
- Law recognizes decisions or choices made by a competent individual.
- Issue of competency arises in minors and mentally impaired,

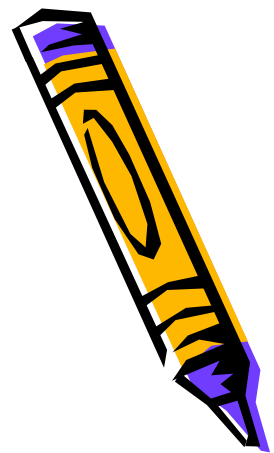


Incompetent - Legal

- Individual whose actions fail a legal test of capacity
- Judicially determined incompetent
- Incapacitated by a medical condition or emergency



Legal: Incompetency

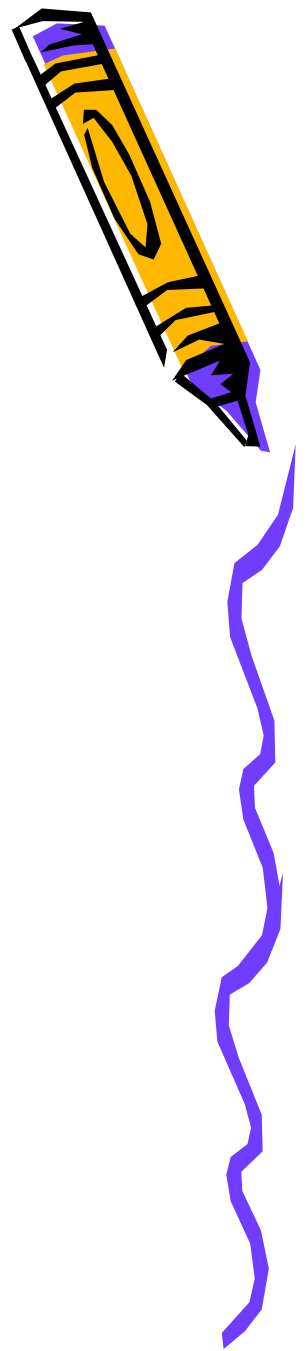


1. Subject or task specific.
2. Does not translate into and should not be interpreted as a finding of mental illness.
3. Not synonymous with the need for psychiatric treatment.
4. *Incompetency* and *insanity* are two entirely distinct concepts.



Consent To Medical Rx

- Only a competent person is legally recognized as being able to give informed consent.



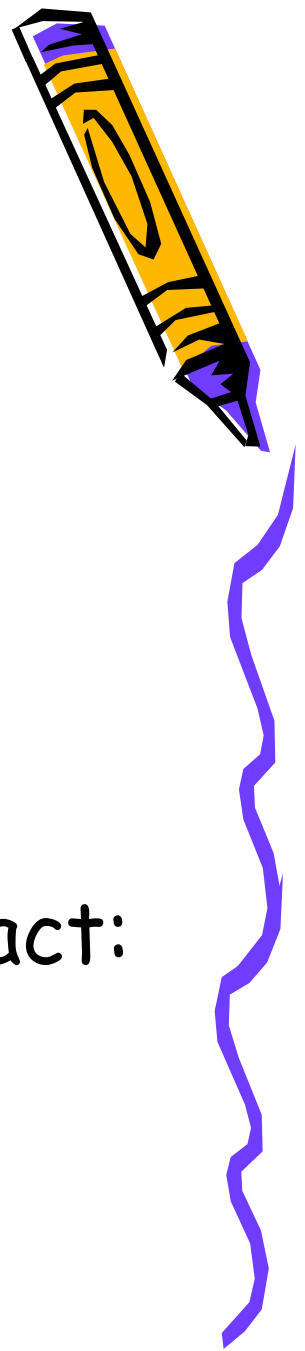
Capacity - Medical

- Capacity refers to an individual's actual ability to understand, appreciate, and form a relatively rational intention with regard to some act.



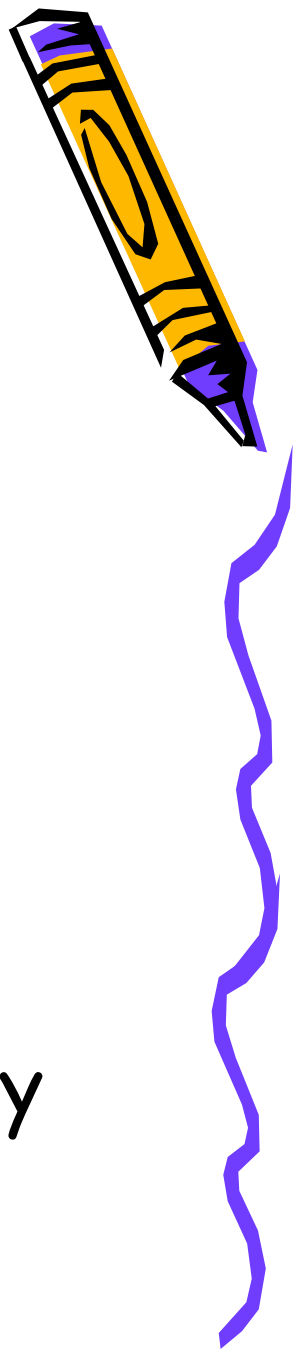
Cognitive Capacity

- Competent individuals require cognitive capacity to give free & knowing consent to enter into an agreement or contract.
- Minors & the mentally incompetent lack cognitive capacity.
- Lack of cognitive capacity to contract:
 - Total or Partial



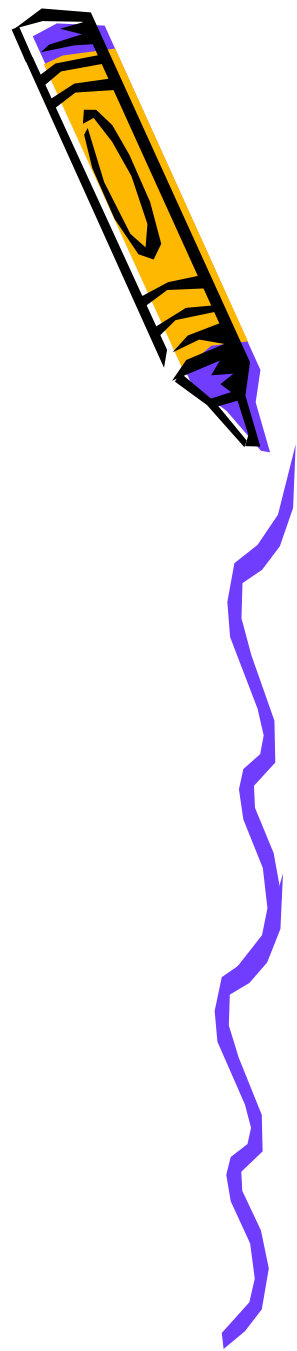
Competency & Capacity

- Wills and testamentary capacity
- Guardianship
- Competency to testify
- Criminal law
 - Standards and assessment of competency to stand trial
- Judicial evaluation of competency



Competency Issue

- May raise at any stage of the proceeding.
- Prima facie evidence must be presented.
- Must be resolved before proceeding with trial.



Informed Consent

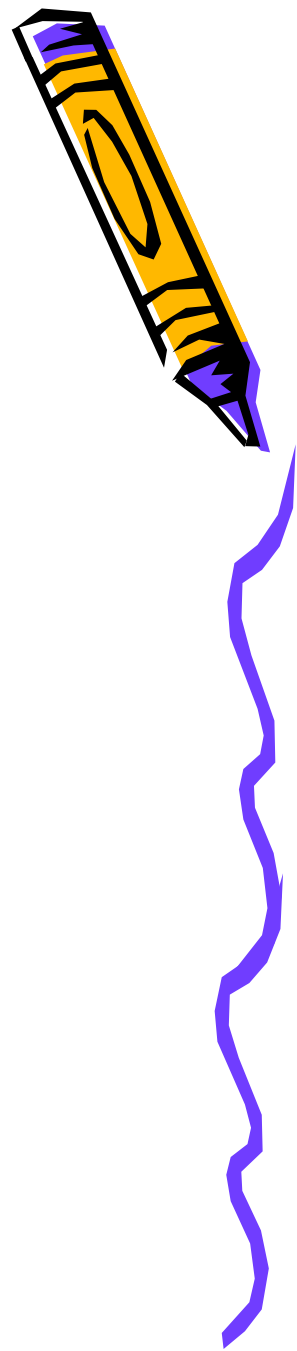


- Biomedical Research
 - Institutional Review Board
 - Full and complete written informed consent
 - Protection of human subjects



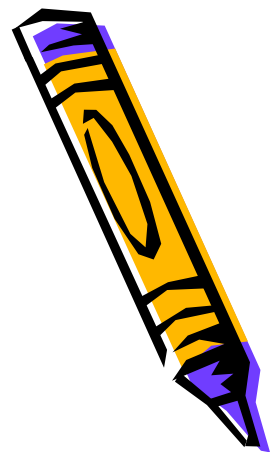
Informed Consent

- Information/Disclosure
- Comprehension
- Volition
- Competence



Informed Consent

- **Consent Form** - helpful
- **Consent Refused** - Informed Refusal Documented in Medical Record
- **Capacity to Consent** - Cognition Documented after testing
- **"Ghost" Surgery (& Rx)** - practice of substituting one surgeon for another without the patient's knowledge.



Informed Consent

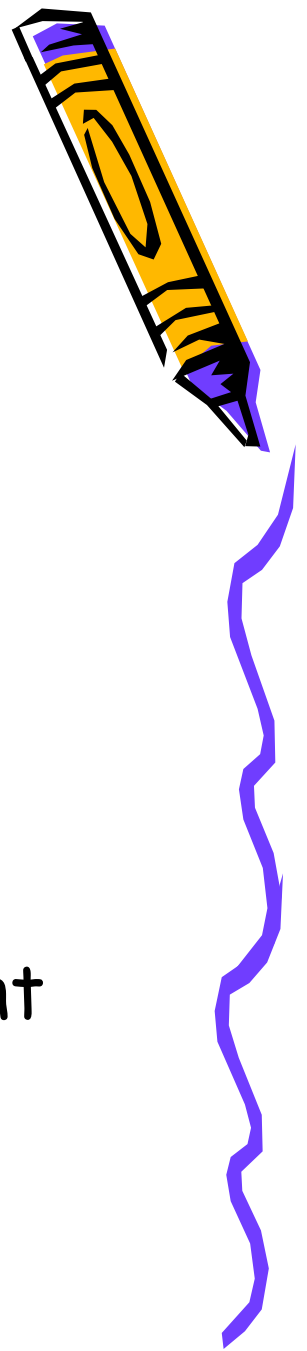


Traditional Components

1. A medical condition that requires the proposed therapy
2. Proposed therapy's purpose, description of what is involved, and probable outcome
3. Likely benefits of the therapy
4. Probable complications, temporary pain
5. Probable permanent results (disfigurement, disability, or scarring)



Informed Consent



Traditional Components

6. Known, anticipated or foreseeable material risks
7. Alternative therapy and its known side effects, risks and benefits (including no treatment)
8. Consequences and rights of the patient to refuse or withdraw consent for any reason, at any time



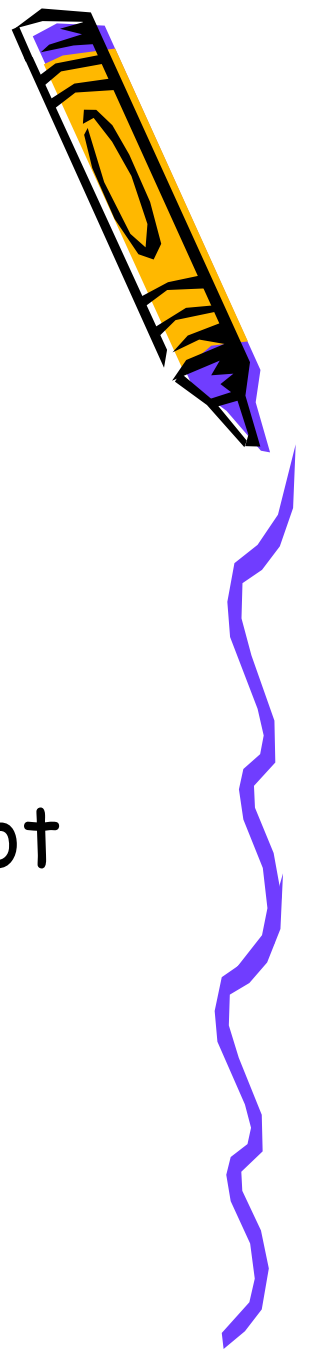
Oklahoma Informed Consent

as it was adopted in *Scott v. Bradford*, 606 P.2d 554 (Okla. 1980), entails three basic elements:

- 1) Nondisclosure,
- 2) Causation, and
- 3) Injury.



Informed Consent

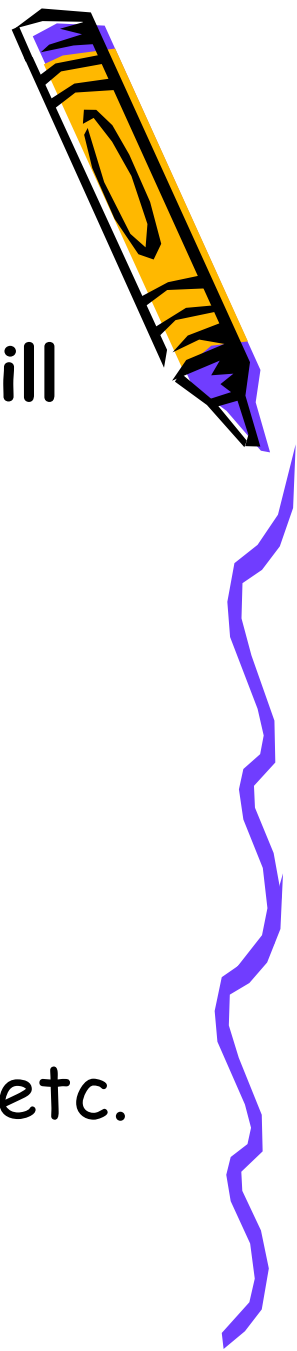


Medicare Changes

- Disclose even if anxious; no *therapeutic privilege*
- Patient must understand
- Inadequate informed consent is not consent
- Disclose "who" and "what" Rx



Informed Consent



If someone other than chief surgeon will perform surgery

- "Who"
 - Physician's assistant, nurse practitioner, etc.
 - Resident, 1st, 2nd, 3rd year
- "What"
 - "Opening", "closing", "harvesting", etc.



Informed Consent-NY Statute



- “Lack of informed consent” means failure to disclose in a manner permitting knowledgeable evaluation:
 - Alternatives, Risks & Benefits
- Test: Generally, “Reasonable” Practitioner

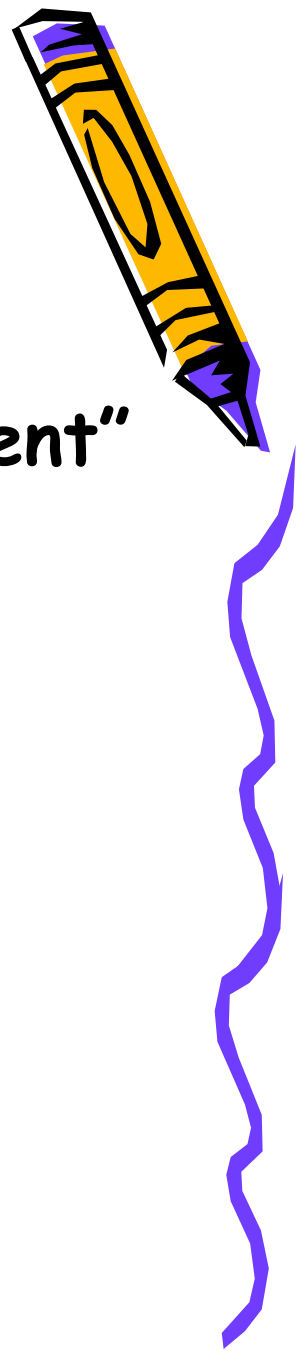


Informed Consent- New York Statute

Legal action for “lack of informed consent”
is limited to:

- Non-emergency treatment
- Invasive/disruptive diagnostic procedure

Necessary element: Reasonably prudent patient would not have undergone procedure, if fully informed.



Informed Consent- New York Statute



Affirmative Defenses:

- Common risk
- Patient would have to undergo procedure, despite risks
- Patient did not want to be informed
- Consent not reasonably possible
- Disclosure would adversely affect patient's condition

