The Art of

Informed consent

Informed Consent

20th-Century legal construct

INFORMED CONSENT – (noun) – process requiring TIME, EFFORT, & MULTIPLE ITERATIONS – best approached through a variety of formats.

Background of Informed Consent

- Individual right of AUTONOMY
- BENEFICENCE MODEL (based on Hippocratic notions of acting in the patients' best interest) (used until mid-20th century)
- The term *informed consent* was introduced in 1957 in"Salgo v. Leland Stanford Jr. University Board of Trustees case.

Informed Consent Process

- PHASE ONE: Activities designed to provide potential subjects with information designed to encourage participation
  - Advertising
  - Screening
  - Presentations
  - Secondary recruitment

Informed Consent Process

- PHASE TWO: Exchange of information
  - Evaluate understanding
  - Active discussion
  - Detailed information
  - Full Disclosure: Purpose, Risk, Benefits
  - All facts required for a decision
  - Voluntary

Informed Consent Process

- PHASE THREE: Documentation of Informed Consent
- ***Obtaining a signature is the least ethically substantive part of the process***
  - procedural aspect of regulatory compliance
- **Signature emblematic of ethical process**

Informed Consent Process

- PHASE FOUR: When does it end? Phase four begins *after* the consent form is signed.
- Encompasses the subject's study participation
- Ends when study participation is ended.
- Includes all exchanges
- Continuous renewal of agreement

Basic Elements of Consent

- Statement r/t "Research", purposes, duration, procedures, risks, benefits
- Alternative procedures
- Confidentiality
- Treatment for research-related injury
- Contacts
- Voluntary nature
- FDA inspection

Additional Elements (as needed)

- Unforeseeable risks
- Pregnancy issues
- Termination
- Costs
- Consequences of withdrawal
- How to terminate
- New findings will be disseminated
- Number of subjects
- IND/IDE
- Translations & certificates

Documentation of Consent

- Written consent
  - IRB approved
  - Signed, dated – possibly timed
  - Copy to participant
- "Face –to-face" process
- Documentation of process –where?
- Copy of consent to all medical records, original in research chart

Process of Informed Consent

- Subjects with mental & legal capacity
- Sufficient opportunity to consider participation
- Minimize undue influence
- Understandable language
- No exculpatory language
- Adequate information of all research aspects is the responsibility of the P.I.
- Consents are current for 30 days

Regulations regarding Process

- No investigator may involve a Human Subject without obtaining proper consent
- Consent obtained by P.I. or formally delegated designee
- Designee must be fully informed and able to answer questions appropriately
- Informed consent must be sought prospectively

DHHS 45 CFR 46.116; FDA 21 CFR 50.20; AAHRPP II.7A

3 Key Features of Informed Consent

- Disclosing the information required for ***informed decision making***
- ***Facilitating the understanding*** of what has been disclosed
- ***Promoting the voluntariness*** of the decision

Informed Consent

- Questions?