The Art of

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