

Ethics and Protecting *Human Subjects*

Class 22

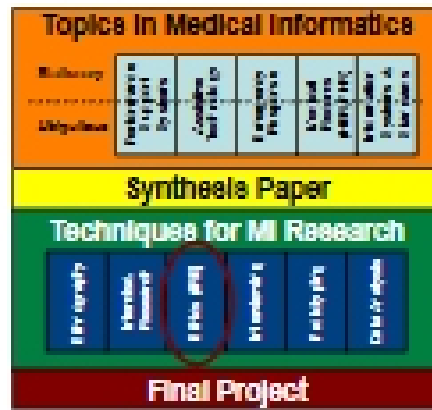
Agenda

- 3:00-3:15 Krista's Presentation
- 3:15-3:25 Quiz
- 3:25-3:50 Ethics and Protecting Human Subjects

Quiz

- What is the difference between tethered, interconnected, and standalone PHRs? What are the benefits of each?
- What are some barriers for PHR adoption?

Where are we?



Why Do We Need HIPAA/IRB?

Nuremberg Code

- Established 1948
- 23 Germans tried for war crimes
- Medical experiments on thousands of people without their consent
- *Result: Voluntary known subject consent is absolutely essential (voluntary participation and informed consent)*



Kefauver Amendments

- Established 1962
- Late 1950s pregnant women given thalidomide to reduce nausea and help with sleep
- Patients did not know thalidomide was not FDA approved
- Over 12,000 babies born with deformities
- *Result: Drug manufacturers must prove to FDA the effectiveness before marketing*



Belmont Report and IRB Creation

- Belmont (1979) & IRB (1974)
- In 1932 400 black, poor, low literacy share croppers were infected with syphilis
- Participants were not informed about the disease, just about incentives (free care, free hot meal, and \$50/\$50 in the event of death)
- In 1947 penicillin was invented... participants were not offered it.
- Study was not stopped until 1973!!!
- *Result: Informed consent; Independent review; Risks should not exceed benefits; Protect human subjects.*



Ethical Considerations from the Belmont Report

Principle	Application
Respect for persons <ul style="list-style-type: none"> • Individuals should be treated as autonomous agents • Persons with diminished autonomy are entitled to protection. 	Informed consent <ul style="list-style-type: none"> • Subjects to be able to give an opportunity to make a rational decision • The person must be able to: <ul style="list-style-type: none"> o understand o appreciate, and o voluntarily participate
Beneficence <ul style="list-style-type: none"> • Maximize benefits and minimize harms • The benefits and harms to be weighed in terms of burden and benefit to both subjects and society 	Assessment of risks and benefits <ul style="list-style-type: none"> • The magnitude, nature, and duration of risks and benefits must be weighed in a systematic manner
Justice <ul style="list-style-type: none"> • The benefits and burdens of research should be distributed fairly 	Selection of subjects <ul style="list-style-type: none"> • The search for the most vulnerable requires a distribution of research subjects
