IRB BASICS AND CONSENT CONSIDERATIONS

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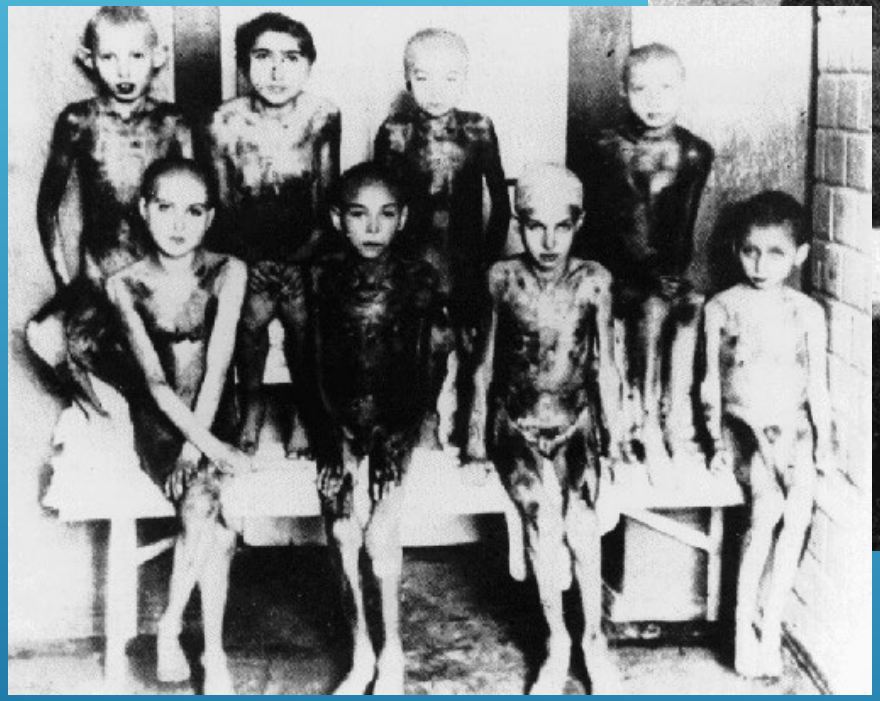
TODAY'S GOALS:

- Define "IRB"
- Give a brief history of human subjects' research
- Define IRB terminology
- Give helpful resources for research
- Review Researcher Responsibilities
- Review informed consent as a "process"
- Review requirements of human subjects' research
  - Federal policy
  - UF policy

Nazi Experimentation



http://www.ushmm.org/research/doctors/indiptx.htm

Tuskegee Syphilis Study

1932-1972

http://www.cdc.gov/nchstp/od/tuskegee/time.htm

IRB =

Institutional Review Board

Primary Mission

Protect **rights** and **welfare** of human research subjects / participants

NATIONAL RESEARCH ACT 1974

BELMONT REPORT REIMAGINED

Respect for Persons

- Informed Consent process
  - Trainings including cultural competency
  - SOP with periodic team assessments
  - Subject assessment of team/study design

Beneficence

- Do no harm
- Risk/Benefit Analysis
  - Effects on the image of research
  - Impact on future research participation

Justice

- Equitable distribution of risks and benefits
  - Actively recruiting diverse team and subjects
  - Considering multiple types of compensation and asking questions more than one way

https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

FEDERAL REGULATIONS

OHRP	45 CFR 46
FDA	21 CFR 50, 54, 56, 312, 812
OCR	HIPAA
VA	1200.5 + 38 CFR 16

Problems protecting subjects continue…

- **Dr. Roger Poisson, St. Luc's Hospital**
  - 22 studies
  - Enrolled ineligible
  - Falsified and fabricated study data
- **Dr. Eric Poehlman, University of Vermont**
  - Internationally recognized gerontologist
  - Over 200 publications
  - Findings incorporated into medical school curriculum
  - Lifetime federal government disbarment
  - 18 months in prison

1940

1950

1960

1970

1980

1990

2000

Nuremberg Trials 1940s

US Scandals

Tuskegee 1972

CAUSE

Jesse Geslinger

Stratton VA

Nuremberg Code

Declar. Helsinki

OPRR

Natl Rsch Act

Belmont Report

FDA Regs

EFFECT

HIPAA

VA Accreditation

HUMAN SUBJECT

*Living** individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual, or
2. identifiable private information.

45 CFR 46.102.(f)

RESEARCH

A systematic investigation, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge**.

45 CFR 46.102.(d)

EXAMPLES OF RESEARCH

- Clinical Trials (therapeutic research)
- Survey, observational, or educational research

- Review of medical records or databases
- Tissue or data
  - Identifiable vs. coded vs. anonymous
  - Existing?

IRB APPROVAL REQUIRED

REQUIRED: ALL RESEARCH

- Research must be approved **before** being conducted

Increasing Involvement Or Risk

Increasing Protection, Requirements, & Paper Work

4. Full Board
3. Expedited
2. Exempt
1. Non-Human

REVIEW PROCESS

TYPES OF RESEARCH

- Non-Human
- Exempt
- Expedited
- Full Board
- Banks (Tissue/Data)
- HUD/HDE
- Emergency Use

FULL BOARD VS. EXPEDITED

- **Full Board**
  - IRB-01 = 1st and 3rd Wednesday of each month (Deadlines)
- **Nonhuman, Exempt, or Expedited**
  - forwarded "daily" to vice-Chairs

"OUTSIDE" ISSUES

- Secondary subjects: anyone you collect data on is a subject
- Conducting research at other locations
  - International Research
- Involving outsiders in research
- Conflict of Interest

Privacy & Confidentiality

- Privacy
  - Subject's ability to control how other people see, touch, or obtain information about the subject.
- Confidentiality
  - the ways identifiable information will be stored and shared

NON-COMPLIANCE

- Conducting before approval
- Not maintaining IRB approval
- Revisions before IRB approval
- Over-enrolling

NON-COMPLIANCE

- Enrolling subjects who do not fit enrollment criteria in protocol
- Failure to obtain/document consent
- Losing copies of signed Consents
- Failure to document procedures

"If it's not documented it didn't happen"

LOCAL INFO: IRB-01

https://my.irb.ufl.edu

- 352-273-9600
- http://irb.ufl.edu/contact-us.html

REQUIRED TRAINING!

- HIPAA for Researcher training
  - Maintained by the Privacy Office
- IRB training
  - IRB803: Local IRB video/refresher (1 hr) – Every 3 years
  - NIH funding requires GCP training

RESEARCHER "TO DO"

- Required Reading
  - Belmont Report
  - 45 CFR 46
  - IRB-01 Policies & Procedures
- Researcher responsibilities
  - http://irb.ufl.edu/irb01/researcher-information/researcherresponsibilities.html

INVESTIGATOR RESPONSIBILITIES

Investigators have the primary responsibility for protecting the rights and welfare of human research subjects and are responsible for complying with all applicable provisions of their institution's Assurance.

Investigators are expected to be knowledgeable about the requirements of the Federal regulations, applicable state law, their institution's Assurance, and institutional policies and procedures for the protection of human subjects.

INVESTIGATOR RESPONSIBILITIES CONT.

IRB RESPONSIBILITIES

- Authority to approve, request modification in, and/or disapprove research.
- Authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects.
- To observe, or have a third party observe, the conduct of the research.
- To observe, or have a third party observe, the consent process.

RESOURCES

- **IRB researcher listserv**

  send a message to listserv@lists.ufl.edu with only the following information in the body of your e-mail: subscribe IRBMAIL-L

- **Newsletter**

  http://irb.ufl.edu/irb01/education-2/investigators.html

- **Researcher Manual**

  http://irb.ufl.edu/wp-content/uploads/Researcher-Manual_FINAL.pdf

- **Assistance with NEW studies**

  Allison Faunce afaunce@ufl.edu

HIPAA

- UF Privacy Office
  - http://privacy.health.ufl.edu/

- Terra DuBois, JD, CCEP
  Chief Compliance, Ethics, and Privacy Officer
  (352) 294 8720
  tdubois@ufl.edu
- Margaret Hamer – IRB HIPAA Coordinator
  273-9607 – mjn18@ufl.edu

SUMMARY

IRB =

Protect rights and welfare of subjects

- The ends do NOT justify the means
- Research is a privilege

REMEMBER…..

CONSENT PROCESS

THE "PROCESS"

- Informed consent involves a process that includes
  - Discussions (before, during, and after) signing the Consent Form
  - Training for staff delegated this duty
  - Designed with targeted population in mind

FEDERAL POLICY

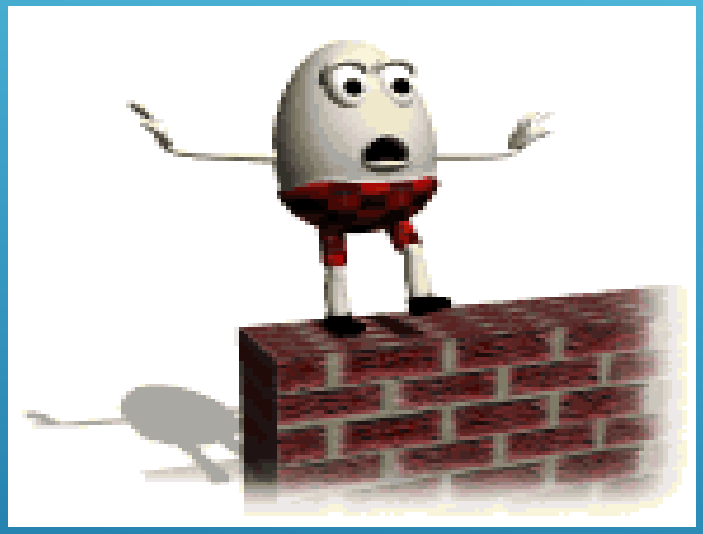
- 45 CFR 46 subpart A
  - DHHS
- "…legally effective informed consent"
- "Sufficient opportunity to consider…."
- "Language understandable to the subject"
- Participants to receive a copy
- Retain for the appropriate length of time

UF POLICY ON INFORMED CONSENT

- UF Informed Consent template
  - Consistent with Protocol
  - Consistent with SmartForm responses
- Standardized language
- 8th grade reading level
  - 12 point font size, Times New Roman
- Use of approved (watermarked) Informed Consent Form
  - Consistent with enrollment dates

WILLOWBROOK STATE SCHOOL

Responsibilities



The future of science depends on the goodwill and trust of the public. Investigators must understand this and meet their duty to human subjects.

SURVIVAL TIPS FROM THE IRB

- Be consistent
  - Across all IRB forms and SmartForm responses
- Provide accurate information
  - Between submissions
  - Year to year

REDUCE THE NEED TO REVISE

- Write a flexible Protocol
- Provide broad ranges and few limits
- Anticipate difficulties with conduct of the study
  - Accommodate for them in the Protocol
- Consider other options when writing the Protocol

SURVIVAL TIPS FROM THE IRB

- Keep organized
  - Regulatory binder for all correspondence with IRB
  - Research records
    - Keep original Informed Consent Forms separate from the research records
    - All records related to individual studies should be kept together, in a labeled file folder
    - Use color coded stickers or sheets of paper

- Use the IRB Tracking Log
  - Update your interactions with the IRB
  - Avoid the "cracks"

- Use an Enrollment Log
  - Track the number of enrolled participants
  - Track the dates of enrollment

SURVIVAL TIPS

MORE ON ORGANIZATION

Questions?

Please complete the survey:

https://ufl.qualtrics.com/jfe/form/SV_1WVLQUcrykr7YFM