



# RAMP

## *Research Administrators Management Program*



*IRB – Institutional Review Board*

*Deb Paxton*

# Objectives

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- To provide the basic background for human subjects protections
- To help administrators recognize research with human subjects
- To empower administrators to help researchers navigate IRB review



NC STATE UNIVERSITY

# North Carolina State University Institutional Review Board

Protecting the Rights and Welfare  
of Human Research Subjects



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## 45 CFR 46 (a.k.a. “the regulations”)

- Contains the minimum requirements for protecting the rights and welfare of human research subjects
  - Describes the IRB and defines its role, responsibilities, and authority



# The history behind the regulations

- Nuremberg Trials
- Henry Beecher Article (NEJM, 1966)
- Tuskegee Syphilis Scandal



# The Belmont Report

- Beneficence
  - “Do no harm”
  - Risks balanced with benefits
- Justice
  - Equality in participation
- Respect for persons
  - Respect of subject autonomy
  - Informed consent



## 45 CFR 46

- Written with the principles of the Belmont Report as a guideline
  - Adopted by 16 federal agencies - called the Common Rule
  - Any research funded by one of those federal agencies must comply with 45CFR46
  - **A contract with the government (called an assurance) defines the conditions with which the institution must comply in order to receive federal funding for research. One of the conditions is that all research at the institution will comply with 45CFR46, regardless of the funding source**
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# So...what does this mean for you?

It means that, regardless of funding source, ANY research that is defined by the regulations as involving human subjects must be compliant with the federal regulations and undergo IRB review.



# Definition of research

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

- At NCSU, we interpret this definition as “Collecting information in an organized manner, with the intent to share it with others” – this includes qualitative research methods
- Evaluation vs. Research
- Distinguishing research in larger projects



# Definition of human subject

A 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



# Responsibilities

The responsibility for running a study in an ethical and compliant manner is ultimately the Investigator's, but it's our job to facilitate compliance

- IRB approval must be obtained before any contact with potential subjects is made
- ANY changes to the research must be approved by the IRB prior to their implementation
- IRB approval is good for one year at most – it must be renewed yearly if the project is ongoing
  - Expedited and full board review only
  - Analysis of identified data is considered ongoing research
- Unanticipated problems must be promptly reported to the IRB
- Consent must be adequately documented and retained



# Flexibility of IRBs

- The IRB has the ability to be flexible regarding research. The amount of flexibility available is based on the risk of the research – the riskier a project is, the less flexibility is allowed
- Those studies deemed “minimal risk” can receive simpler, faster reviews, and have more flexibility than other research
- The IRB makes a determination of the risk of the research and flexibility of the rules – not the PI



# Different types of IRB review

There are strict rules about what kinds of research may receive which review

- Administrative – fastest and easiest for research that meets very specific criteria (1 – 2 weeks for review)
  - This research does not need annual review, but changes must be reported
- Expedited – review by one IRB member; applies to research that meets other criteria (2 – 4 weeks for review)
- Full Board – for research that is considered by the IRB office to be more than minimal risk (review takes place at monthly meetings)

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# What is minimal risk?

Defined by the regulations as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”

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# For any IRB review

- Obtain the proper form from the NCSU IRB website
- Complete the application, describing the study's intent, procedures, and collection of identifiers as fully as possible
- Include any materials given to subjects (advertisements, surveys, forms, etc.), and/or interview outlines
- Include any necessary informed consent, or parental permission forms



# Basic components of IRB review

- Risks to subjects are minimized
- Risk are balanced with benefits
- Selection of subjects is equitable
- Informed consent will be sought and documented
- Adequate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data
- Additional safeguards are in place for research involving vulnerable populations
  - Children
  - Prisoners
  - Pregnant women and fetuses
  - Employees/Students
  - Others



# After the review – four possible decisions

- Approve
- Approve with modifications
- Defer
- Disapprove



# Anonymity vs. Confidentiality

- Anonymous data means that not even the researcher can trace a subject from his/her data
- Coded data is NOT anonymous because there is a traceable link between the subject and his/her data
- 3<sup>rd</sup> party subjects
  - 3<sup>rd</sup> party subjects are people about whom information is gathered, but who are not actually participating in the study. For example, if a study asks about a subjects' family members – those family members are considered 3<sup>rd</sup> party subjects
  - 3<sup>rd</sup> party subjects need protection, too



# Contact Information

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