2010

# IRB basics

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# IRB BASICS

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# IRB Framework for Review

- Office of Human Research Protections (OHRP)
  - Federalwide Assurance
    - Follow regulations 45 CFR 46 (Common Rule)
    - Ethical principles of the Belmont Report: respect, beneficence, justice
- FDA regulations
- Association for the Accreditation of Human Research Protection Programs (AAHRPP)

# IRB Framework for review

- Regulations (Common Rule and FDA) +
- ethical principles +
- accreditation standards +
- IRB policies and procedures and other institutional policies =

<u>IRB framework for review</u>

# What do the regulations say?

- The IRB must consider the following elements when determining if a study is approvable:
  - Minimize risks
  - Risks reasonable in relation to benefits
  - Equitable subject selection
  - Consent process
  - Documentation of consent
  - Monitoring data to ensure safety
  - Provisions to protect privacy and maintain confidentiality

# Paper, Paper, everywhere….

- Paperwork is the essential connection between the IRB and the conduct of the research.
  - Your IRB approval is based on what is submitted in the IRB application.
  - Conduct your research within the scope of your IRB approval.
  - If there is a change in the conduct of the research (even for just one participant), this should be submitted to the IRB for approval prior to making the change
    - Unless to alleviate an immediate harm or hazard and then report to IRB afterwards

# Why is the paperwork so important?

- If you are doing something different than indicated in the IRB submission this will be considered noncompliance.
  - Non-compliance: Failure to follow any applicable regulation or institutional policies that govern human subjects research or failure to follow the determinations of the IRB.
- It is expected that the PI will delegate responsibilities, such as completing IRB paperwork
  - Communication is key!
  - Study team members should be comfortable approaching the PI with questions or concerns
  - Everyone should be on the same page.

# Practical example: Stolen laptop

- A laptop containing research data, including participant names and addresses, is stolen from the researcher's car.

How does this relate back to the paperwork?

# Practical example: Stolen laptop

- What will the IRB do?
  - Go back to the paperwork….
- The IRB application indicates the following:
  - "All research data will be coded and stored electronically on a WU secure server. The researcher's computer is password protected. The master list linking the code to individually identifying information will be stored in a locked cabinet in the researcher's office."

# Practical example: Stolen laptop

- The paperwork does not match up with what was really happening in the study and will be considered noncompliance.

- Procedures for maintaining confidentiality of the data were not followed.
  - Maintaining confidentiality of data is a criteria for IRB approval

# Practical example: Stolen laptop

- Does this mean you cannot use laptops in research studies?
- No, using laptops to store research data may be approvable in some scenarios.
- But you need to let us know so we can make this determination and ensure that you are properly maintaining confidentiality of the data.

# Practical example: Stolen Laptop

- What if the IRB submission had described the use of a laptop?
- The IRB will still need to consider what needs to happen to protect the affected participants but if you are following what was described in the IRB application it would not be considered noncompliance.

# Questions?