IRB and Consent

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Disclosures

- No relevant financial disclosures

- I will be discussing the generic Institutional Review Board
  - Extremes (both good and bad) exist

Outline

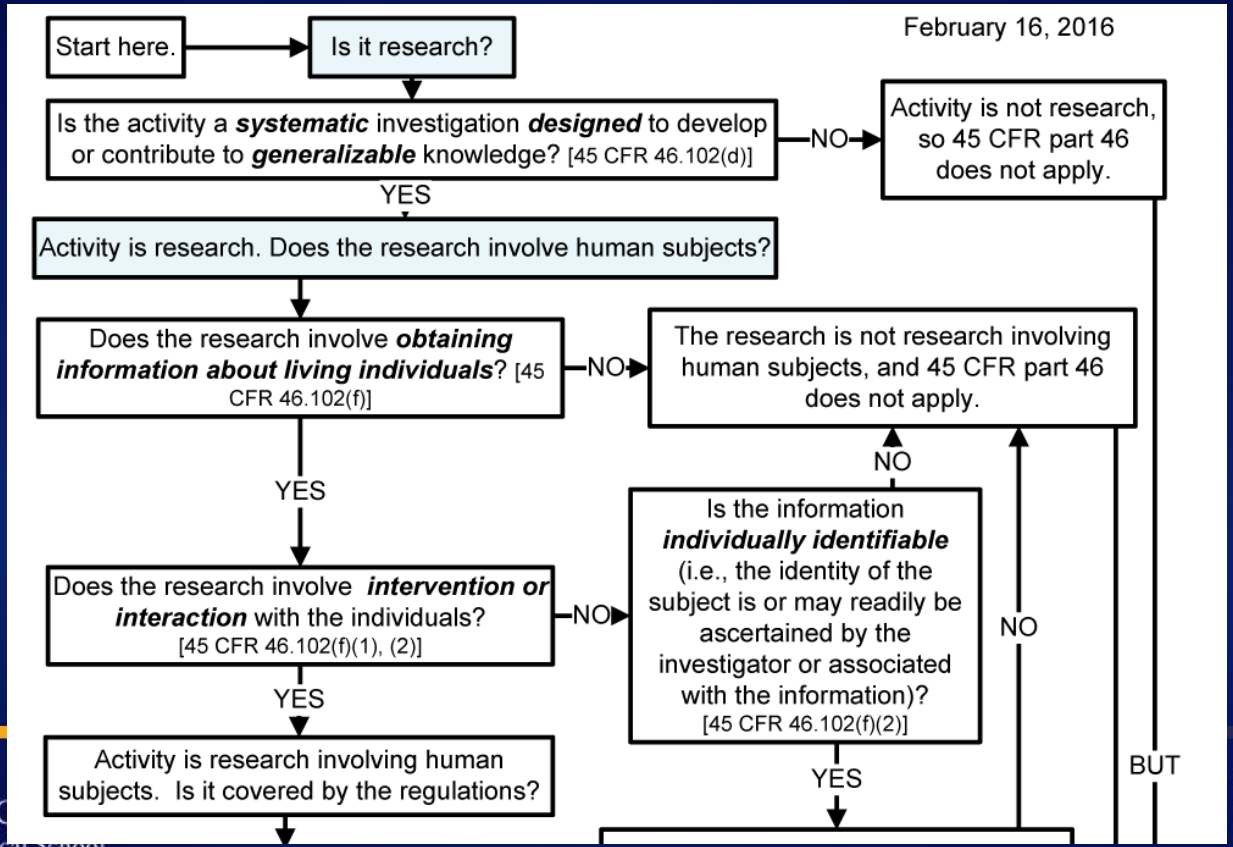
- Demystifying the Institutional Review Board
- Human Subjects Research
- Exempt studies
- Expedited Review
- Full IRB review
- Informed Consent

Demystifying the Institutional Review Board

- Composed of individuals from different backgrounds
- The primary duty of an IRB is to protect patients
- The degree to which your study will be scrutinized is directly related to the risk the study poses to its participants

- Recommendation: go sit in on IRB meetings and listen to their discussions

Human Subjects Research



After Submission

- Assessment regarding how to review study
- Three general categories
  - Exempt studies
  - Expedited review
  - Full IRB review

Exempt Studies

- Established data sets
  - If individual patients are not identifiable
  - NTDB, NSQIP, National Cancer Data Base
- Some educational settings
- Some surveys, qualitative studies

More info:
https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c3

Expedited Review

- Research presents no more than minimal risk to participants
- Participants or their responses does not place them at risk of liability (criminal, civil, insurability, employability, reputation, financial) and privacy risks are minimized
- Research is not classified
- Certain other requirements, including but not limited to:
  - No IND/IDE; noninvasive biologic specimen collections; data already collected in normal clinical practice

Full IRB Review and Approval

- Most other studies requires full IRB review
- Approval requires:
  - Risks are minimized and reasonable in relation to benefits
  - Equitable participant selection
  - Informed consent
  - Privacy protections

Informed Consent

- Statement that the study involves research
- Description of risks/discomforts
- Description of benefits
- Disclosure of alternative treatments
- Confidentiality disclosures
- Compensation availbaility
- Contact info for questions
- Statement that participation is volunary

Waiver of Consent

- No more than minimal risk to participants
- Waiver will not adversely affect the rights of participants
- Research could not practicably be carried out without waiver
- When appropriate, subjects notified after participation
- Not subject to FDA regulation

Exception from Informed Consent (EFIC)

- Life threatening situation necessitating urgent intervention
- Available treatments are unproven or unsatisfactory
- Evidence is necessary to determine safety/effectiveness of intervention
- Obtaining informed consent is not feasible due to condition
- Intervention must be given prior to LAR availability
- No reasonable manner to prospectively identify subjects
- Research holds direct benefit to subjects
- Study could not practicably be carried out without waiver

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