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

Start here. Is it research?

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(d)]

Activity is research. Does the research involve human subjects?

Does the research involve obtaining information about living individuals? [45 CFR 46.102(f)]

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

Does the research involve intervention or interaction with the individuals? [45 CFR 46.102(f)(1), (2)]

Is the information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]

Activity is research involving human subjects. Is it covered by the regulations?
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 availability
• Contact info for questions
• Statement that participation is voluntary
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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