EMS Subspecialty Certification Review Course

Protection of Human Subjects
3.2.1 Informed Consent, "Final Rule,"
Exception from Informed Consent

2025

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Learning Objectives

- Upon the completion of this program participants will be able to:
  - Describe ethical principles of medical research
  - Describe the systems for protection of human subjects from risk of research
  - Describe the origins and purpose of informed consent
  - Describe the rationale and methods for Exception from Informed Consent

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What is the "Common Rule?"

a) **Institutional (university) regulations on conduct of human subjects research**
b) **Federal regulations on conduct of human subjects research**
c) **Principle that scientists must use common sense when conducting research**
d) **Laws governing conduct of research**

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Ethics in Research

- History of unethical experimentation
  - Nazi medical experimentation (1930s)
  - Milgram experiments (1960s)
  - (Use of Thalidomide)
  - Tuskegee syphilis study (1930-1972)
- 1974 – National Research Act
- 1979 – National Commission for the Protection of Human Subjects → Belmont Report

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Belmont Report (1979)

- Standards for US human subjects research
- **Three primary ethical principles**
  - 1) **Respect for persons**
    - Right of individuals to make informed free choice to participate in research
    - Persons with diminished autonomy have additional protections
  - 2) **Beneficence**
    - Risks of study should be kept to absolute minimum needed
  - 3) **Justice**
    - Risks of study not borne by one population while benefits go to another population

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The Common Rule

- Uniform federal regulations on conduct of human subjects research
  - Title 45 Part 45 Subpart A: "Basic HHS Policy for Protection of Human Research Subjects"
- Three levels of protection:
  - 1) Federal (Institutional Assurance of Compliance, Federal Wide Assurance (FWA))
  - 2) Institutional (Institutional Review Board (IRB))
  - 3) Investigator (Informed Consent)

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Types of IRB Review

- Not Human Subjects Research
  - Example: CARES database, Meta analysis
- Exempt Review
  - "Less than minimal risk"
  - Meets specific criteria
  - Example: de-identified records, anonymous surveys
- Expedited Review
  - "No greater than minimal risk"
  - Meets specific criteria
  - Example: Retrospective review of clinical data
- Full Review
  - More than minimal risk
  - Example: prospective clinical study

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Informed Consent

- Process of gaining permission from a subject for their participation in research
- Protected Groups
- Difficult in prehospital setting
- Waiver of informed consent
  - IRB may waive requirement for consent for low risk studies
  - Most important risks: 1) medical, 2) confidentiality
  - Example: Observational study of cardiac arrests treated by EMS

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Tip #5

Focus on content that is unique to Emergency Medical Services.
(this is not just another EM board exam)

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Exception From Informed Consent (EFIC)

- Not possible to obtain consent in emergency conditions
- 1979-1993 – various approaches to emergency consent
  - "Deferred", "implied", two-tiered consent
- 1993 – Federal moratorium on all studies without prospective informed consent
- 1996 – "Final Rule"
  - Provides mechanism for emergency research
  - **"Exception from Informed Consent" (EFIC)**
    - NOT waiver of informed consent

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Conditions Eligible for EFIC

- Life threatening condition
- Available treatment unproven
- Consent not feasible due to subject's medical condition
- Treatment must be given before possible to obtain consent from proxy
- No reasonable way to anticipate subject eligibility
- Risk/benefit must be reasonable
- Some prospect of direct benefit to subject

- Research could not be carried out without waiver of consent
- Attempts to contact LAR
- IRB approval of consent procedures
- Community consultation and public disclosure
- Independent data monitoring committee
- Early notification of subjects
- FDA approvals (IND, IDE)
- Disclosure of IRB disapprovals

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Community Consultation and Public Disclosure (Required for EFIC)

- CC: Refers to discussion between investigators and community members
- PD: One-way transfer of information about the study to the community
- Town hall meetings
- Random-digit dialing
- Newspaper, TV, internet ads
- Facebook, Twitter

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Take-Home Points

- Quality Management Research = 10% of test items
- Research subjects have rights and legal protections
- Researchers must respect and protect human rights
- Waiver of Informed Consent and Exception from Informed Consent are important tools for EMS research

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