EMS Subspecialty Certification
Review Course

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

Updated: 7/2017

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

What is the “Common Rule?”
A. Institutional (university) regulations on the conduct of human subjects research
B. Federal regulations on the conduct of human subjects research
C. Principle that scientists must use common sense when conducting research
D. Laws governing conduct of research
Answer is B - Federal regulations on conduct of human subjects research

In 1991 all federal agencies involved in human research agreed on a common rule. The common rule provides for three levels of protection.

“Federal” refers to federal oversight of institutions conducting research. For example, institutions must apply for a Federal Wide Assurance (FWA) to conduct research.

“Institutional” refers to IRBs and their oversight over research activities at an institution.

“Investigator” refers to the responsibility of the researcher to obtain informed consent and protect the rights of the subject.

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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

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Until World War II, the ethics of human research were largely a concern of individual researchers. Prominent examples of unethical behavior drew attention to the ethical issues surrounding human medical research. Examples of unethical research abuses include:

- Experimentation on Nazi concentration camp prisoners
- Milgram study (in these studies, allegedly of learning and memory, the experimenter prompted the “teacher” to give escalating painful electrical shocks to a “student”)
- Thalidomide (the book refers to the use of thalidomide as related to research ethics, but there is no clear research ethics is related to Thalidomide.
- Tuskegee syphilis study (In this study, sponsored by the National Health Service, researchers knowingly did not provide treatment to subjects with ulcers and symptoms of syphilis in order to observe the natural course of the disease). In 1974, Congress passed the National Research Act, which required the development of federal regulations to govern human subjects research. The Act also highlighted the need for individual informed consent and spurred the development of Institutional Review Boards (IRBs).

As a result, the National Commission for the Protection of Human Subjects was established to address these needs.

In 1978, the commission published the Belmont Report, which presents the ethical standards upon which all federal research regulations are based.
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

“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)

Types of IRB Review

- Not Human Subjects Research
  - Example: CARES data base, 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
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

Tip #4

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

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)
    - This is different from a waiver of informed consent (although some references call it a waiver too)
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

This slide summarizes the conditions under which Exemption from informed consent can be applied.

The underlines highlight some of the salient points.
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

LAN = Legally Authorized Representative

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
A requirement of EFIC is the need for community consultation and public disclosure.

Community consultation refers to discussion of the study between investigators and community members
Public Disclosure refers to one-way transfer of information about the study to the community

Practically speaking, researchers achieve these goals through town-hall meetings, random-digit telephone dialing, news media and even social media

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Take-Home Points
• 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
• This topic is part of the EMS core content Quality Management and Research – 10% of the test