Association of University Radiologists
60th Annual Meeting

Ethics and Professionalism in Radiology Education, Research, and Practice

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Ethics in Educational Research

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To paraphrase bioethicist George Annas:

... good ethics begins where the law ends.
Disclosure

Physician Payment Sunshine Act

*HHS has issued a Proposed Rule to implement Title VI § 6002 of the Patient Protection and Affordable Care Act (PPACA)

Amends Title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP. Manufacturers and group purchasing organizations are to report all payments made in aggregate in excess of $100.00 to physicians.
Disclosure

Neither I nor my immediate family members have a financial relationship with a commercial organization that may have a direct or indirect interest in the content of this presentation.
Disclosure

Licensed in
Washington
Massachusetts
Federal

Cited cases or legal opinions do not necessarily reflect the policies of the University of Washington.
Objectives

Address and identify ethical principles relevant to research in education study design notwithstanding;

Improve the likelihood that your IRB/Human Subject Divisions will approve your educational research activities
It’s all about risk.

Educational and social science research activities are governed by the same principles and regulations as other human subjects research such as clinical trials.

The level of risk to participants determines the level of protection subjects should be accorded by researchers.

The Institutional Review Board (IRB) has the authority to assess the level of risk as defined by statute.

45 CFR 46.107: Public Welfare
Human Subjects of Research Protections
Federal Statutory*

Title 45, Code of Federal Regulations, Part 46
Protection of Human Subjects

US DHHS: Office for Human Research Protections
http://www.hhs.gov/ohrp/policy/

US OCR: Office of Civil Rights
http://www.hhs.gov/ocr/privacy/

*not exclusive
Professional Associations*

American Board of Radiology
American College of Radiology
American Medical Association
Principles and Codes of Medical Ethics
American Educational Research Association
Code of Ethics
British Educational Research Associations
Ethical Guidelines

*Not exclusive
State Regulatory Sources


RCW 70.02. *Medical Records and Health Care Information Access and Disclosure*

Institutional Regulations
Human Subjects Research

Nuremberg Code of 1947

National Research Act (Pub. L. 93-348) 1974

The Belmont Report  (Common Rule)

The Helsinki Declaration of 1964 (revised in 1975)

Ethical principles and guidelines for the protection of human subjects of research
(1979) DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014
Basic Ethical Principles: respect

Respect for participants

1) each person is autonomous

2) those incapable of self-determination are entitled to protection
   children
   disabled
   prisoners
Informed Consent

Disclosure to participants:

risks
potential benefits
potential compensation
subject comprehension
absence of coercion
ability to withhold or withdraw consent
A. CONSENT PROCESS

"Informed consent is a process, not a piece of paper"

Who is providing consent?

Is the patient a minor?

Is the patient capable of consent?

Who is providing consent?

Is the patient capable of consent?

Is a surrogate available?*

Is there an emergency?

Is the treatment one to which minors may consent?

Obtain & document consent**

Explain what you would want your family member to know!

Obtain & document consent from surrogate***

1) Guardian
2) Other court-appointed person
3) Parent(s)
4) Authorization holder
5) Relative

1) Legal guardian
2) DPOA holder
3) Spouse or registered domestic partner
4) Adult children
5) Parents
6) Adult siblings

Emancipated minor, STD (14), reproductive care (no specific age), mental health (13), substance abuse & (13)

SURrogates MAY NOT CONSENT TO MENTAL HEALTH TX (unless there is a MH advance directive), sterilization, or ECT

** See Part B (page 2) regarding required documentation (the "piece of paper")

***If a surrogate is needed, consult the minor surrogate list unless the minor is emancipated
Basic Ethical Principles: beneficence

Beneficence: safeguard welfare of participants

Do no harm

Maximize benefits to subjects
Basic Ethical Principles: Justice

Distributive justice

who gains benefits

who bears burdens

fair, equitable, appropriate treatment between and among different groups of subjects
Medical Education Settings

Pre-medical students
Medical students
Residents
Fellows & Acting Faculty
Adjunct Faculty
Faculty
Non-academic venues
It’s all relative: vulnerability

Control over research interaction
Power of researchers as perceived by subjects
Control over the research setting
Context of the research setting
Access to power
Secrecy and confidentiality
The question . . .

Do I need an approval from the IRB for my activity?

Analysis

1. Is this activity research?

2. Is this human subjects research?
What is research?

Systematic investigation designed to develop or contribute to generalizable knowledge, including

- research development
- testing
- evaluation

Some demonstration and service projects or programs may contain research activities

45 CFR 46 § F 1.1
Is this research?

Two scenarios:
1. A medical educator modifies her pedagogical strategy in her small group tutorial and routinely evaluates in order to assess efficacy and make further modifications. She also wishes to examine the data to elucidate something enduring about learners or the learning process.
2. Residency programs systematically collect data to assess candidates. Later, however, an investigator intends to explore factors that predict success in a residency program and reanalyzes the data using methods designed to produce generalizable results.

- Is the activity a systematic investigation?
  - No: Not research
  - Yes: Is the intent to generalize findings?
    - No: Not research
    - Yes: Research

Scenario:
Residents are routinely evaluated during various rotations using standard assessment forms. The activity involves a systematic collection of data, and may employ scientific methods, but the intent is to inform the local programs.

Johansson, Anna; Durning, Steven; Gruppen, Larry; Olson, Marianne; RN, PhD; Schwartzstein, Richard; Higgins, Patricia; RN, PhD
DOI: 10.1097/ACM.0b013e31821d6c4c

Is this human subjects research?

A living individual about whom a professional or student investigator conducting research obtains

1. data through an interaction or intervention with the individual, or

2. identifiable private information

HIPAA

45 CFR 46 § F 1
Is this human subjects research?

Perspective: Medical Education Research and the Institutional Review Board: Reexamining the Process. Johansson, Anna; Durning, Steven; Gruppen, Larry; Olson, Marianne; RN, PhD; Schwartzstein, Richard; Higgins, Patricia; RN, PhD

Academic Medicine. 86(7):809-817, July 2011. DOI: 10.1097/ACM.0b013e31821d6c4c

What category?

Minimal Risk

Exempt*

Expedited*

Full committee
Research Design in Educational Research

Experimental

Quasi-experimental

Descriptive
  Phenomenological
  Ethnographic
  Case Study
  Grounded Theory
Web-based Research

Confidentiality
Identification
Security of transmitted data
Data storage
Recruitment, sampling, diversity
Tracking
Bias
Results/debrief
Dishonesty
Web-based Research

Respect: dignity, privacy

Communication about enrollment
Enrollment/inclusion and exclusion
**Guaranteed informed consent
Identity verification
Web-based Research

Beneficence

Benefits: sample size, ease of application, analysis can be simplified by proprietary survey software

Risks:
  protect from unauthorized access or publication thereby violating privacy and confidentiality

Limit usage, *i.e.*, guard against search engines, data mining
Web-based Research

Justice

fair and equitable
inclusion and exclusion criteria
access to coordinators
ability to stop or withdraw consent
Educational Research and the Internet

Cedfelt AS, Bower EA, Grady-Weliky TA, et al:

A Comparison Between Physicians and Demographically Similar Peers in Accessing Personal Health Care

Academic Medicine, March 2012, 87:327-331
Beyond Belmont
From 1947-1949 U.S. Health Service performed inoculation studies designed to expose subjects – Guatemalans – to STDs.

“ETHICALLY IMPOSSIBLE”
STD Research in Guatemala from 1946 to 1948

Presidential Commission
for the Study of Bioethical Issues

September 2011
Among findings: harmonize standards and practices internationally, accounting for cultural and normative differences.

Informed consent is among the main issues.
In 2010 U.S. funded approximately 55,000 experiments on human subjects worldwide which include social and educational studies. No centralized repository or safeguards.

Recommended 14 changes to current practices to improve human subjects protections, accountability & tracking of research funded by U.S. tax-payers:

- Compensation for harms caused by research
- Assessment of current regulations to enhance protections and informed consent for subjects
- Creation of a public data base all federally funded human research studies
Proposed Changes

Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators: DHHS (ANPRM)

Re: Educational Research

ANPRM proposes to (1) reduce administrative burden having little to protect subjects, particularly in those studies with little or no physical or psychological risk; (2) enhance and focus oversight on higher-risk research studies and extend protections to human subjects research not currently required to comply.

**Recommendations include reduction of paperwork for minimal-risk studies, and ‘exempt’ studies may become ‘excused’ from IRB review but subject to increased data security and protection from informational harm.**
SAVE THE DATE

March 26-28, 2012

Oral Arguments at the U.S. Supreme Court on the constitutionality of the PPACA:

http://www.supremecourt.gov/docket/PPAACA.aspx
Selected References*

ACCME: Standard for Commercial Support
http://www.accme.org/education-and-support

American College of Radiology

American Educational Research Association

American Medical Association
http://www.acaai.org/about/pages/code-of-ethics.aspx

British Educational Research Association

*All web-based citations accessed March 19, 2012
Selected References*

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html


Johnson B, Christensen L. Educational Research (3rd ed) 2008


Panter and Sonya K. Sterba, eds. Handbook of Ethics in Quantitative Methodology. (2011)

President’s Bioethics Commission for the Study of Bioethical Issues  
http://bioethics.gov/cms/node/559