

IRB Issues in Medical Education Research – OHRP Perspective

American Association of Colleges of Osteopathic Medicine

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Panel Discussion



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Panelists

- Michael Carome, M.D., Associate Director for Regulatory Affairs, DHHS Office for Human Research Protections
- Jane Dumsha, M.S., CHES, Director of Academic Research Development, PCOM
- David Yens, Ph.D., Director, Educational Development Resource Unit, NYCOM





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OHRP Perspective

- Michael Carome, M.D.



Presentation Overview

- Department of Health and Human Services (HHS) regulations for the protection of human subjects
- Applicability of the HHS regulations
 - Definition of *research*
 - Definition of *human subjects*
 - Exemptions
- Informed Consent



Title 45

Code of Federal Regulations

Part 46

Protection of Human Subjects

(Last revised November 13, 2001)



Belmont Report

Basic Ethical Principles

- **Respect for Persons**
- **Beneficence**
- **Justice**

Fundamental Provisions of 45 CFR Part 46

- **IRB review**
- **Legally effective informed consent**
- **Assurance of Compliance**

Applicability of the HHS Regulations

- Research involving human subjects conducted or supported by HHS that is not otherwise exempt
- Non-exempt human subjects research conducted at an institution holding an applicable Assurance of Compliance

Applicability of the HHS Regulations

Research [45 CFR 46.102(d)]?



Human subjects [45 CFR 46.102(f)]?



Exempt [45 CFR 46.101(b)]?



Definition of Research (1)

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for [45 CFR 46.102(d)]



Definition of Research (2)

Activities which meet this definition constitute research for the purposes of [45 CFR part 46] whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

[45 CFR 46.102(d)]



Relationship Between Research and Other Activities



Research

- **Clinical Practice**
- **Public Health**
- **Program Eval.**
- **QI/QA**



Human Subject

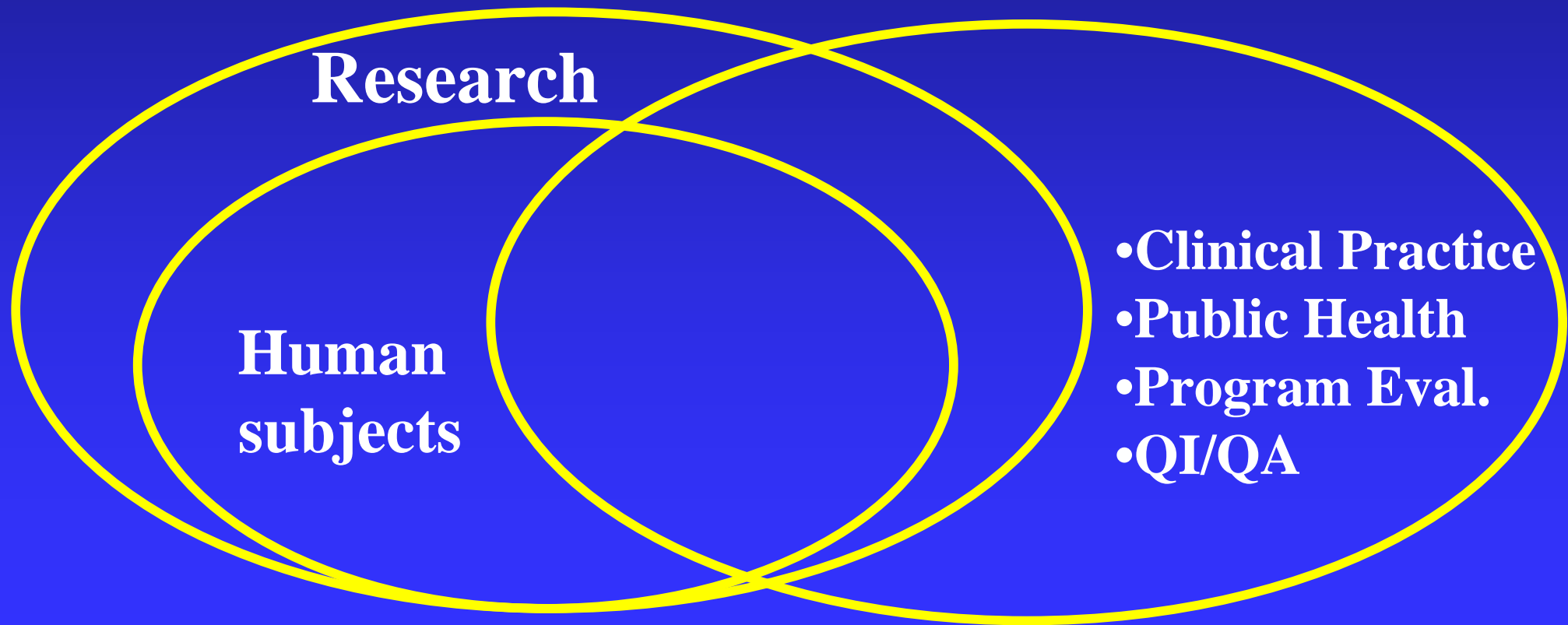
A living individual about whom an investigator conducting research obtains:

(1) Data through intervention or interaction with the individual; or

(2) Identifiable private information.

[45 CFR 46.102(f)]

Relationship Between Human Subjects Research and Public Health Activities





Exemption under 45 CFR 46.101(b)(1)

- **Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management method.**

Exemptions under 45 CFR 46.101(b)(2)

- **Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observations of public behavior, unless:**
 - (i) information is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subject; and**
 - (ii) any disclosure of the human subjects' response could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.**



Exemptions under 45 CFR 46.101(b)(3)

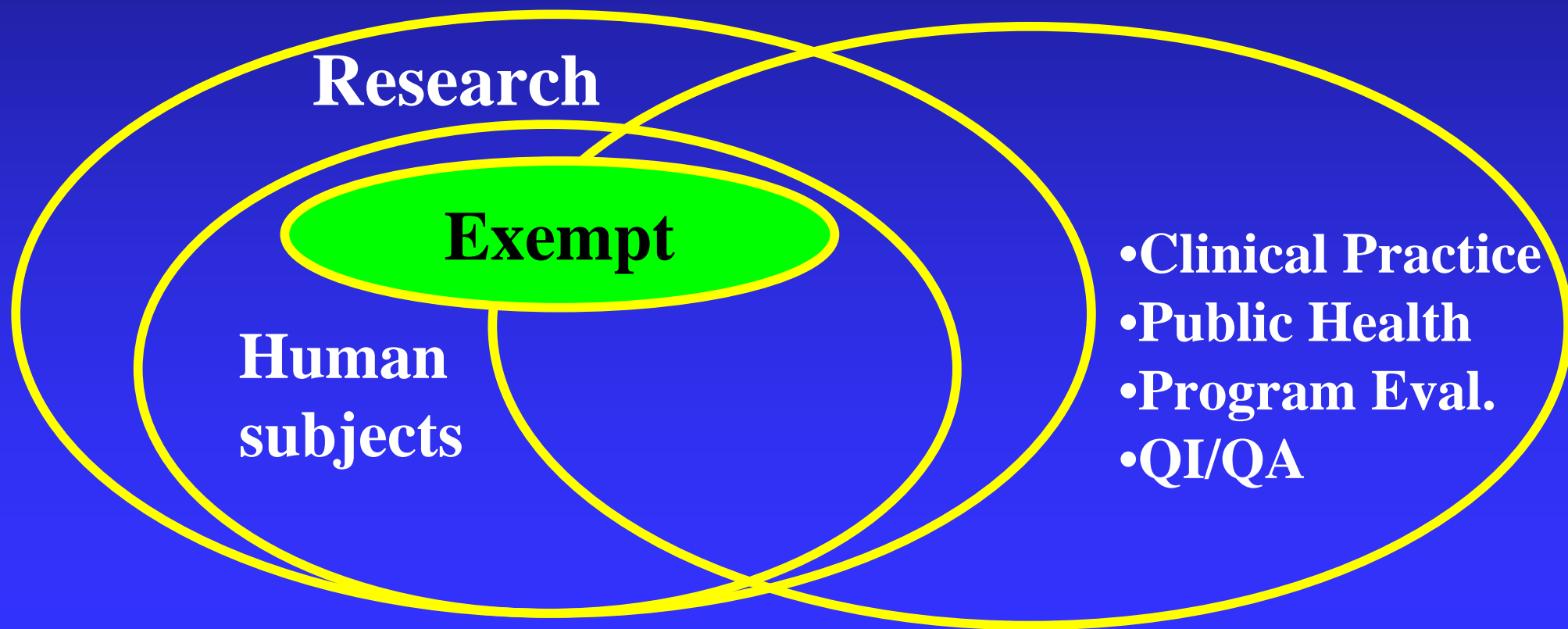
- **Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.**



Exemptions under 45 CFR 46.101(b)(5)

- **Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii)....**

Relationship Between Exempt Human Subjects Research and Public Health Activities





Exempt Research

- **OHRP recommends that someone other than the investigators make determinations about whether research is exempt.**
- **Institutional assurances must include a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at the institution, regardless of whether the research is subject to the Federal regulations [45 CFR 46.103(b)(1)].**

Informed Consent (1)

- **45 CFR 46.116**: “Except as provided elsewhere in this policy, no investigator may involve a human being in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.”



Informed Consent (2)

- **Required basic element listed at 45 CFR 46.116(a).**
- **Additional elements required when appropriate are listed at 45 CFR 46.116(b).**



Informed Consent (3)

- **Informed consent is an active, ongoing process, not a document.**
- **Informed consent requires full disclosure of appropriate information, adequate comprehension, and voluntary choice.**
- **“Blanket consent” and “passive consent” are concepts without basis in the regulations.**



Waiver or Alteration of Requirements to Obtain Informed Consent

- **The research involves no more than minimal risk to the subjects.**
- **The waiver or alteration will not adversely effect the rights and welfare of the subjects.**
- **The research could not practicably be carried without the waiver or alteration.**
- **Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**



Waiver or Alteration of Requirement to Document Informed Consent

- The only record linking the subject to the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.



Conclusions

- **Some medical education research is exempt.**
- **Medical education research that is not exempt must comply with the requirements of 45 CFR part 46, when applicable.**
- **Informed consent is an active, on-going process.**
- **For some medical education research, waiver of requirement to obtain informed consent or to document informed consent may be approvable by the IRB.**



The View from the Trenches

- Jane Dumsha, M.S., CHES, and
- David Yens, Ph.D.





Program Evaluation, Research or Both?

- Definitions
- Institutional policies & procedures
 - Exemption from informed consent requirements vs. exemption from IRB review requirements





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Disclosure and Risk

- How does an IRB (or an IRB administrator) define or quantify “reasonably”?
 - “...any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk...”
- Or do we err on the side of caution?
- Is erring on the side of caution creating needless burdens and/or barriers?





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Case Example

- Faculty conduct a course or program evaluation
- Later, they want to publish their results in a journal
- At what point do they need to obtain IRB review and approval?
- Is consent from students (evaluators) and/or other faculty (evaluees) required?





What Are Ethical Issues in Recruiting Students?

- Perceived or actual coercion
 - Announcements
 - “Brownie points”
- Hidden risks
 - Faculty blinding & bias
 - Future litigation (reasonable risk or far-fetched?)
- Equitable selection



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Survey Case Example

- Surveys about student study habits
 - Data on* small subset of students collected without identifiers
 - Data collected with identifiers to link to other data, such as grades, for individual students

*“on” could mean from students directly or from faculty e.g., advisors



What Are Ethical Issues in Obtaining Consent from Students?

- Privacy
- Confidentiality
- Perceived or actual coercion
- “Blanket” consent
- Anonymity, privacy & confidentiality and electronic data storage & retrieval



Existing Data Case Example A

- Use of non-anonymous data collected for non-research purposes
 - Videotapes
 - Other assessment tools, including exams





Existing Data Case Example B



- Linking previously unlinked data to identify predictors of individual performance
 - MCAT scores and Board scores





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Electronic Data Case Example

- Faculty use course management software to give quizzes and tests and record grades
 - Someone wants to do a study to see if performance predictors can be identified
 - If disclosure could reasonably place the subjects at risk, then
 - Informed consent and right to say no
 - How is data segregation handled for those who refuse?
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OHRP Input

- Gray areas
- Solutions to challenges
 - Student-created secret codes