Epidemiology -- Research – or Not Research?

Medical Research Summit

March 2002 -- Tom Puglisi, PhD

P w C

Historical Overview

- National Research Act - 1974
  - National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- Belmont Report - 1979
  - Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Historical Overview

The Belmont Report -- 1979

- Respect for Persons => Informed Consent
  => Capacity to Consent
- Beneficience => Do No Harm
  => Maximize Benefit
- Justice => Equitable Selection of Subjects
  => Equitable Burdens and Benefits

Federal Regulations for the Protection of Human Subjects

- HHS Regulations -- 1974 -- Revised 1981
  - 45 CFR Part 46
  - Core Protections => Subpart A
  - Special Protections => Subparts B, C, C
- The Federal Policy (Common Rule) -- 1991
  - 45 CFR 46 Subpart A

Other Human Subject Research

- 17 Federal Agencies Codified the Common Rule
- Some Agencies Required Additional Protections
  - VA => Compensation for Research - Related Injuries
- Some Agencies Do Not Require
  Informed Consent or IRB Review
  - Department of Labor - Miners and Coal Dust
  - Appalachian Regional Commission - Telemedicine
  - Department of Transportation - Sleepy Truck Drivers
- No Federal Regulation for Research Not Covered Under The Common Rule or FDA Regulations

Current Issues in Epidemiology Research Involving Human Subjects

P w C

Issues for Epidemiology Researchers

- My Work is NOT Research!!
- My IRB is Unreasonable!!

- When is IRB Review Required?
- When is Informed Consent Required?
- When is Written Documentation Required?
- Who is an Adult?
- What about Vulnerable Populations?

“It’s NOT Research” -- The Unreasonable IRB

- Understanding of Epidemiology Research
  - Regulations Require that the IRB have the Scientific and Professional Competence to Understand the Research that It Reviews
- Understanding of Regulatory Requirements
- SOMETIMES THE IRB IS RIGHT!

Definition of Research

- “Research” means
  - -- a systematic investigation
  - -- designed to develop or contribute to generalizable knowledge
- Research includes
  - -- research development, testing, evaluation -- ie, pilot studies

Definition of Human Subject

- Human subject means
- a living individual about whom an investigator…conducting research obtains
- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.

Definition of Human Subject

- “Private Information” means
- (1) information about behavior in a context in which an individual can reasonable expect that no observation or recording is taking place
- (2) information, provided for specific purposes, that the individual can reasonably expect will not be made public (e.g., a medical record)

Human Subject Research -- Levels of Review

- Verification of Exemption
- Expedited Review
- Convened (Full) Review
- Continuing Review

Six Exemptions: Exemption 2

- (2) Research involving the use of
  - educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior

  UNLESS

  - information is recorded in an (directly or indirectly) identifiable manner (**NOTE**: Coded = identifiable)

  AND

  - disclosure would place subject at risk of criminal or civil liability or be damaging to financial standing, employability, or reputation

Six Exemptions: Exemption 4

- (4) Research involving the collection or study of
  - **existing** data, documents, records, specimens

  IF

  - the sources are publicly available

  or

  - the information is **recorded** by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

  NOTE: Even brief recording of identifiers or codes disqualifies the exemption

Expedited Review 45 CFR 46.110

- Conducted by Chair or IRB member designed by Chair.
- Only minimal risk research.
- Must fit into a category on November 1998 list.
- All other provisions and requirements apply.
- Can only approve research -- cannot disapprove.
- Must be reported to full IRB.
- 45 CFR 46.110 (b)(2) allows for expedited review of **MINOR** changes in previously approved research, **during** the established approval period,

Expedited Review 45 CFR 46.110: 10 Categories

- Categories Possibly Applicable to Epidemiology Research

(5) Research involving materials (data, documents, records, or specimens) that
-- have been collected
-- will be collected for non-research purposes

(7) Research on individual or group behavior or characteristics -- cognition, motivation, identity, language, communication, cultural beliefs/practices, social behavior; survey, interview, oral history, focus group, program evaluation, human factor, quality assurance methodologies.

Research Involving Existing Data Sets

- Use of data sets containing identifiable private information requires IRB review
- Original informed consent provisions may apply
- Waiver criteria may be applicable
- “Anonymization” of data may be possible
- Use of publicly available data sets is exempt
- Use of data sets containing only non-coded, non-identifiable information is exempt

Informed Consent

P w C

Legitimacy of Data Access

-- Investigator must have legitimate access to identifiable private information

-- Waiver criteria at 45 CFR 46.116(d) may be applicable

Informed Consent

- Legally effective informed consent
  (age of majority determined by State Law
- No coercion or undue influence (recruitment)
- Language understandable to the subject
  (obligation is continuous)
- No exculpatory language
- Eight required elements

Informed Consent Generally

- There is no such thing as “passive consent”
  - -- consent is required unless formally waived
  - -- documentation is required unless formally waived
- “Non-Target” Family Members
  - -- if an investigator obtains “identifiable private information” about a living individual, the individual is a human subject, regardless of the source family

Waiver of Informed Consent

- Minimal risk research
- Waiver or alteration will not adversely affect the rights and welfare of the subjects
- Research could not practicably be carried out without the waiver or alteration
- Subjects will be provided with additional pertinent information -- Usually not applicable to Epidemology Research

Waiver of Documentation of Informed Consent

- Minimal Risk Research Involving Procedures That Do Not Require Written Consent in Non-Research Context
- Research Where Breach of Confidentiality is the Principal Risk and the Signed Informed Consent Document Constitutes the Only Link to the Subject's Identity
- IRB May Require a Subject Information Sheet

HIPPA

The Health Insurance Portability Act of 1997

P w C

HIPPA

- ***Protected health information*** => individually identifiable health information
- ***Covered entity*** means =>
  - A health plan
  - A health care clearinghouse
  - A health care provider

HIPPA

- Research =

  a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

HIPPA -- Research Uses of Protected Health Information

Prior Authorization Is Required Unless--

- Use is necessary to prepare a research protocol
- Use involves only decedants' information
- IRB or Privacy Board Approves Waiver of Authorization

HIPPA -- Research Uses of Protected Health Information

Waiver (or Alteration) Criteria

- **(A) The research involves no more than minimal risk to the individuals;**
- **(B) The alteration or waiver will not adversely affect the rights and welfare of the indiiduals;**
- **(C) The research could not practicably be conducted without the waiver (or alteration);**

[note Common Rule Waiver Criteria at Section 46.116(d)]

HIPPA -- Research Uses of Protected Health Information

Waiver (or Alteration) Criteria

- **(D) The research could not practicably be conducted without access to and use of the protected health information;**
- **(E) The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;**
- **(F) There is an adequate plan to protect the identifiers from improper use and disclosure;**

HIPPA -- Research Uses of Protected Health Information

Waiver (or Alteration) Criteria

- **(G) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and**
- **(H) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity**

HIPPA

- **Effective -- April, 2003**

p w c

Your worlds Our people