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Respect for Persons and Informed Consent

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Framework for Ethical Analysis

- ◆ Respect for persons
 - Moral requirements
 - Acknowledge autonomy
 - Protect those with diminished autonomy
 - Practical applications
 - Informed consent
 - Informational privacy/confidentiality

Topics to Be Covered

- ◆ Principle of autonomy
- ◆ Introduction to informed consent
 - Legal, medical, and research history
- ◆ Basics of informed consent
 - Theoretical and practical
- ◆ Barriers to informed consent
 - Personal and procedural



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Section A

Principle of Autonomy

Principle of Autonomy

- ◆ Autonomy
 - Self-rule
 - Free from controlling influence

Principle of Autonomy

- ◆ Conditions for autonomy
 - Agency
 - Liberty
- ◆ Autonomous action
- ◆ Respect for autonomy

Principle of Autonomy

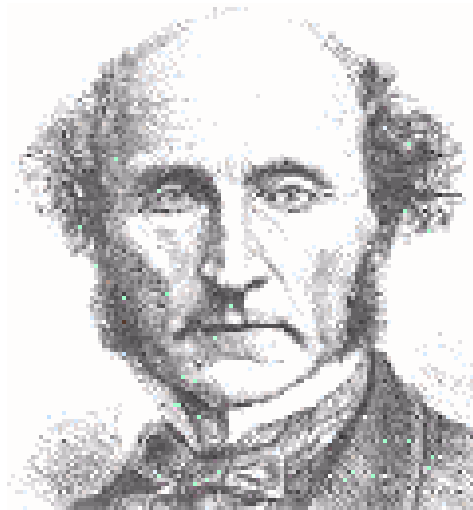
- ◆ Autonomous action
 - Intentional
 - With understanding
 - Without controlling influence

Principle of Autonomy

- ◆ Respect for autonomy
 - Right to hold views, make choices, take actions
 - Obligations to build capacity

Principle of Autonomy

- ◆ Philosophical roots
 - Kant
 - Mill



John Stuart Mill



Kant

Principle of Autonomy

- ◆ Obligations
 - Negative
 - Positive

Introduction to Informed Consent

- ◆ Threads of influence
 - Legal precedent
 - Medical practice
 - Research standards



Landmark Cases

- ◆ Legal precedent
 - Non-consensual/offensive touching
 - Consent has to be “informed”
 - Professional negligence regarding disclosure of information
 - Reasonable patient standard

Landmark Cases

- ◆ Non-consensual/offensive touching
 - Mohr v. Williams (1905)
 - Ear surgery
 - Scholendorf v. Society of New York Hospitals (1914)
 - Examination only

Landmark Cases

- ◆ Non-consensual/offensive touching
 - “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable.”

Landmark Cases

- ◆ Consent has to be “informed”
 - Salgo v. Leland Stanford Jr. University Board of Trustees (1957)
 - Back surgery

Landmark Cases

- ◆ Professional negligence regarding disclosure of information
 - Natanson v. Kline (1960)
 - Radiation treatment

Landmark Cases

- ◆ Physicians obligated “to disclose and explain to the patient, in language as simple as necessary to the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body.”

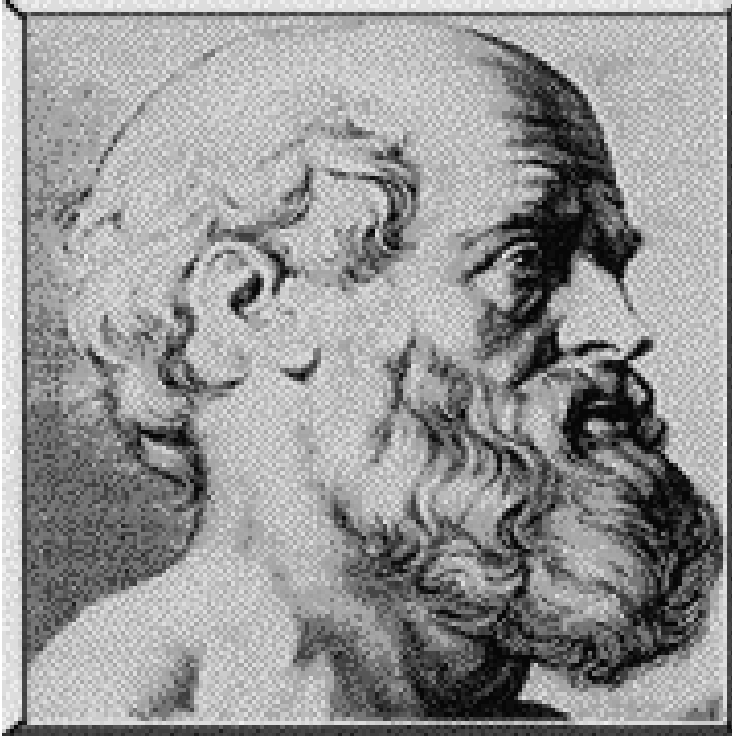
Landmark Cases

- ◆ Reasonable patient standard
 - Canterbury v. Spence (1972)
 - Back surgery, fall
 - Truman v. Thomas (1980)
 - Pap smear

Landmark Cases

- ◆ Recent cases in the research setting
 - Gelsinger v. Trustees of University of Pennsylvania, et al.
 - Gene therapy
 - Robertson, et al. v. Oklahoma University Health Science center in Tulsa, et al.
 - Melanoma

Physician-Patient Relationship

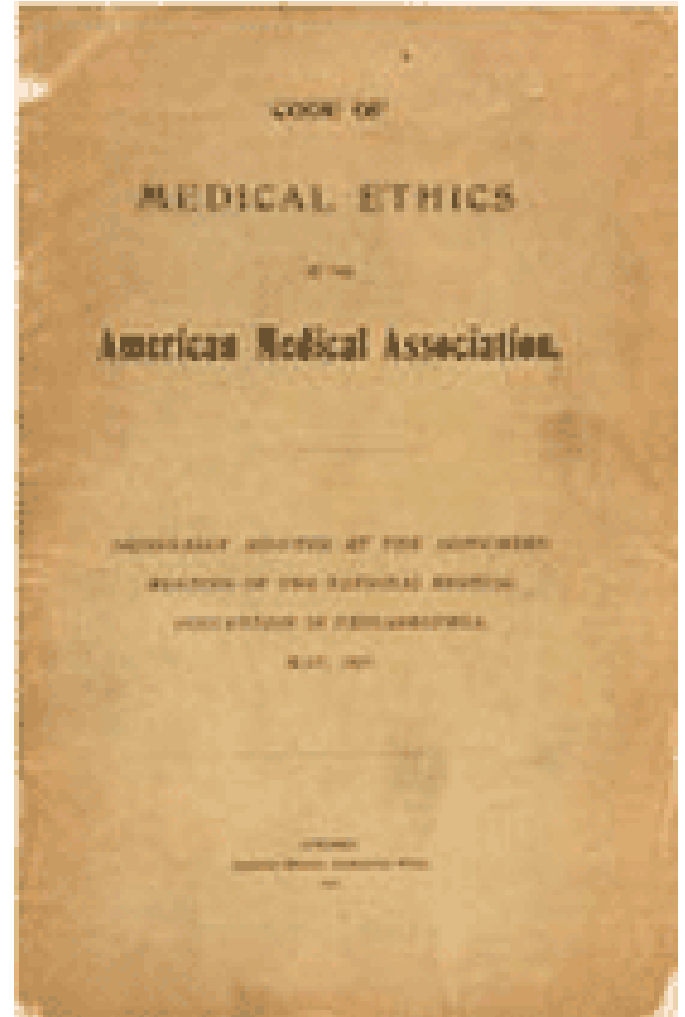


Hippocrates

- ◆ Hippocratic oath
- ◆ Withholding of information justified

Physician-Patient Relationship

- ◆ Truth-telling
 - Medical Ethics (1803)
 - AMA Code (1847)



Physician-Patient Relationship

- ◆ Modern medicine
 - Empirical evidence



Louis Pasteur

Physician-Patient Relationship

- ◆ Advances in research setting
 - National Commission

History of Research Ethics

- ◆ Yellow fever
 - First documented case of consent for research
- ◆ Nuremberg
 - Voluntary consent of human subject is absolutely essential

History of Research Ethics

- Declaration of Helsinki
 - Non-therapeutic v. therapeutic research
- Research in international setting
 - Alternative modes of decision making



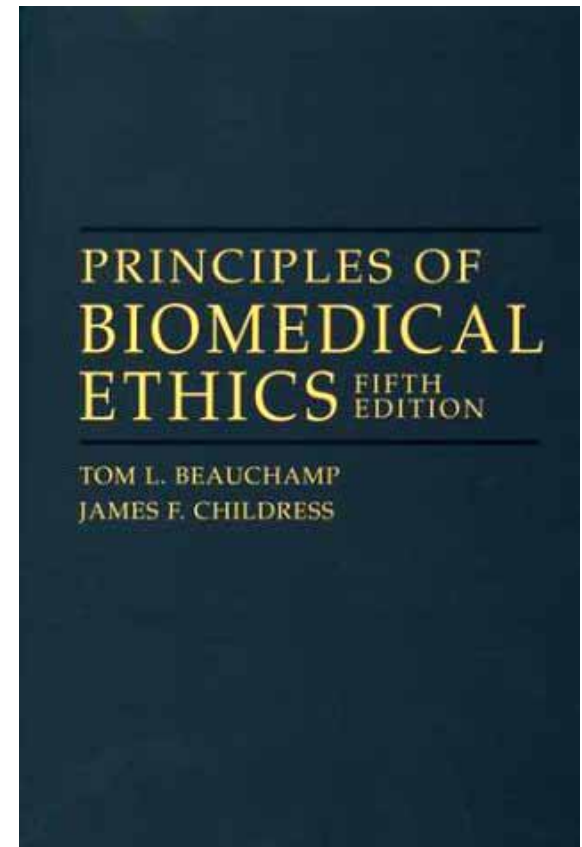
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Section B

Basics of Informed Consent

Basics of Informed Consent

- ◆ Theoretical (Beauchamp & Childress)
 - Threshold
 - Competence
 - Voluntariness
 - Informational
 - Disclosure
 - Plan
 - Understanding



Theoretical (Beauchamp & Childress)

- ◆ Consent
 - Decision
 - Authorization

Practical Application to Research

- ◆ Threshold
 1. Competence
 2. Voluntariness
- ◆ Informational
 3. Disclosure
 4. Understanding
- ◆ Consent
 5. Decision

Threshold Element

- ◆ Competence
 - Ability to perform task
 - Criteria may vary by task
 - Intermittent

Threshold Element

- ◆ Competence?
 - Careful review
 - Surrogate decision maker
 - Assent

Threshold Element

- ◆ Competence
 - Sliding scale

Threshold Element

- ◆ Voluntariness
 - Persuasion
 - Coercion
 - Manipulation

Threshold Element

- ◆ Voluntariness
 - Persuasion
 - Influence based on facts

Threshold Element

- ◆ Voluntariness
 - Coercion
 - Credible threat (Willowbrook)
 - Undue inducement (person with HIV)

Threshold Element

- ◆ Voluntariness
 - Manipulation
 - Informational
 - Of options

Information Elements

- ◆ Disclosure
 - Reasonable patient standard
 - Subjective standard

As Required by the Common Rule

- ◆ Description of study
- ◆ Reasonable risks and discomforts
- ◆ Reasonable benefits to individual or to others
- ◆ Alternatives to participation

As Required by the Common Rule

- ◆ Confidentiality protections
- ◆ Compensation for injuries, if any
- ◆ Point(s) of contact
- ◆ Participation is voluntary

As Required by the Common Rule

- ◆ Unforeseeable risk
- ◆ Termination of enrollment
- ◆ Additional costs
- ◆ Consequences of withdrawal
- ◆ Notification of new findings
- ◆ Number to be included

Other Suggestions for Disclosure

- ◆ Invitation to participate
- ◆ Explanation as to why approached
- ◆ Recommendation to consult others
- ◆ Source of funding
- ◆ Potential conflicts of interest

Information Element

- ◆ Understanding
 - Substantial v. complete

Consent Element

- ◆ Decision
- ◆ Autonomous authorization
 - Informed
 - Understanding
 - Absence of control
 - Intentionality
 - Authorization
 - Legally effective

Consent Element

- ◆ “Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator obtained the legally effective informed consent of the subject or the subject’s legally authorized representative ...

Consent Element

...“An investigator shall seek consent only under circumstances that provide the prospective subject of the representative *sufficient* opportunity to consider whether or not to participate and that minimize the possibility of coercion and undue influence. The information that is given to the prospective subject or the representative shall be in language *understandable* to the subject or the representative.”

Basics of Informed Consent

- ◆ Obtaining informed consent is a process—
not an event



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Section C

Barriers to Informed Consent

Barriers to Informed Consent

- ◆ Patient-centered
 - Age
 - Education
 - Illness

Patient-Centered

- ◆ Illness
 - Physician-patient relationship
 - Dependency
 - Passive role in decision making

Patient-Centered

- ◆ Illness
 - Enrollment in research for treatment
 - Blurring of line
 - Last hope

Patient-Centered

- ◆ Illness
 - Overestimation of medical benefit
 - False belief?

Patient-Centered

- ◆ Illness
 - Summary
 - Reassurance
 - Honest accounting of benefit
 - Patient hope

Patient-Centered

- ◆ Other
 - Review of form
 - Legal formality

Process-Centered

- ◆ Timing of discussion
 - Opportunity to digest information

Process-Centered

- ◆ Time allocated to decision making and questions about protocol
 - Engage subject in conversation

Process-Centered

- ◆ Readability of consent form
 - Assess literacy
 - Simplify text
 - Supplement form
 - Potential subject review

Process-Centered

- ◆ Content of consent form
 - Ask explicit questions

Process-Centered

- ◆ The process selects my best treatment (14%)
- ◆ Each patient has exactly the same chance of receiving the drug, or not receiving the drug, as any other participating patient (68%)
- ◆ One treatment is given one time, another is given another time (0%)
- ◆ The doctor decides which treatment is the right one for me (18%)

Summary

- ◆ **Potential subjects deserve respect**
- ◆ Obligations of investigators
 - Information sharing
 - Assessment of understanding
- ◆ Consent is a **process**

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