

Selected Topics Communications and Mobile Computing (Smart Health)

TU Graz

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Ethical vs. Unethical Studies

- Ethical studies protect subjects and are carried out using scientific principles
- Unethical research includes:
 - Scientific misconduct
 - Fraud, research protocol violations
 - Fabrication, falsification, forging of data
 - Plagiarism
 - Putting subjects at risk without consent

Elements of Ethical Research

- Protecting human rights
- Understanding informed consent
- Understanding institutional review of research
- Balancing benefits and risks in a study

Landmark Unethical Research Studies?

- Nazi medical experiments
- Tuskegee syphilis study
- Willowbrook study
- Jewish chronic disease hospital study

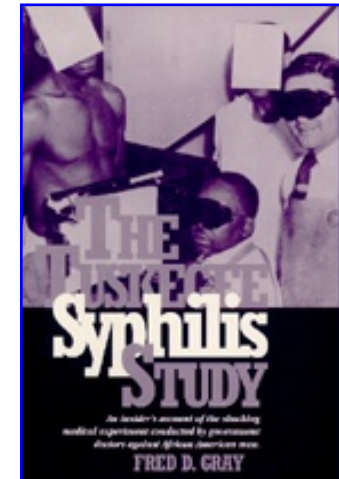
Nazi Medical Experiments

- World War II
- Purpose: To conduct extreme experiments
- Subjects: Concentration camp prisoners
- Problems: Too numerous to list!
- Led to Nuremberg Trial (1947)



Tuskegee Syphilis Study

- 1932-1972 (US Public Health Service)
- Purpose: To determine natural course of syphilis over time
- Subjects: Poor African-American men
- Problems:
 - Deception, vulnerable population
 - Appropriate treatment withheld



Willowbrook School Study

- 1956-1970s
- Purpose: To study effects of hepatitis
- Subjects: Mentally delayed children
- Problems:
 - Vulnerable population
 - Injected with hepatitis virus



Jewish Chronic Disease Hospital

- 1960s
- Purpose: To determine patients response to injection of live cancer cells
- Subjects: Elderly patients
- Problem:
 - Vulnerable population
 - Subjects not informed
 - Risk of disease



History of Ethical Codes and Regulations

- Nuremberg Code (1949)
- Declaration of Helsinki (1964)
- Department of Health, Education and Welfare (DHEW) regulations (1973)
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978)

Declaration of Helsinki

- Right to self-determination and the right to make informed decisions
- Subject's welfare must always take precedence over the interests of science and society
- Ethical considerations must always take precedence over laws and regulations
- Recognition of the increased vulnerability of individuals and groups (surrogate consent)
- Careful assessment of risks and benefits

National Commission for the Protection of Human Subjects Guidelines

- Ethical principles:
 - Principle of respect for persons
 - Principle of beneficence
 - Principle of justice

Respect for Persons

- Self-determination (participation and withdrawing)
- No coercion (e.g., coercion could be large incentives)
- Full disclosure, no deception
 - Covert data collection
 - Misinforming participants about true purpose of study
- Provide ALL information about the study
- Voluntary consent
- Persons with diminished autonomy have special protections

Beneficence

- Freedom from harm
- Freedom from exploitation
- Risk/benefit ratios
 - High anticipated benefit may balance high risks

Categories of Harm

1. No anticipated effects
2. Temporary discomfort
3. Unusual levels of temporary discomfort
4. Risk permanent damage
5. Certainty of permanent damage

Protection from Exploitation

- Researcher will not use information against participants
- Examples:
 - Illicit drug use
 - HIV status
- Researcher-participant relationship should remain professional

Justice

- Fair treatment (even if the person chooses not to participate)
- Those who undertake the burdens of research must be likely to benefit from the research
- Right to privacy
 - Anonymity
 - Confidentiality

Title 45 Part 46: Protection of Human Subjects Regulations

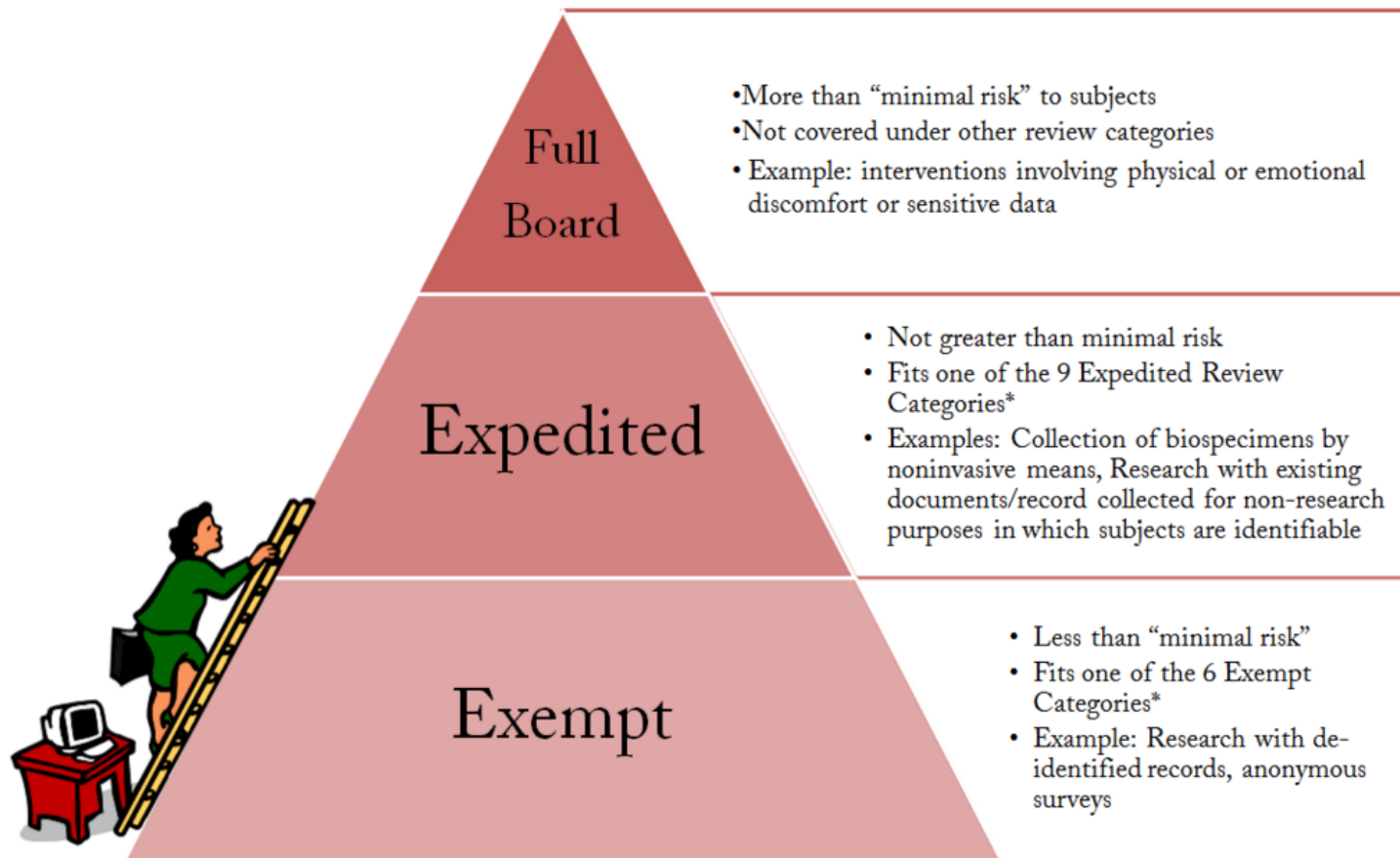
- Protection of human subjects in research
 - Additional protection for pregnant women, human fetuses, neonates, children, and prisoners
- Documentation of informed consent
- Implementation of the IRB process

Institutional Review Board

- Any board formally designed by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

IRB Reviews

Levels of IRB Review



*Defined by federal regulation (45 CFR 46)

Additional Government Protections

- U.S. Food and Drug Administration (FDA)—regarding clinical investigations with human subjects involving products
- Animal studies also included
- Clinical trials for drug investigations must comply with FDA regulations

What is HIPAA?

- Also known as: Public Law 104-191
- Implemented in 2003 to protect individuals' private health information
- HIPAA privacy rules are very strict
- Affects research studies by requiring patient consent to use private health information

IIHI

- Individually identifiable health information: Any data that can be correlated with an individual
 - Also called protected health information (PHI)
- Consent (in context of privacy): Written or verbal permission to allow use of your individually identifiable health information

HIPAA Privacy Rule

- Protects individually identifiable health information
- De-identifying protected health information is allowed only if the following are removed:
 - Names, geographic information, dates, phone numbers (+fax/e-mail), social security numbers, medical record numbers, certificate numbers, vehicle identifiers, device identifiers, URLs, IP addresses, fingerprints/voiceprints, full-face photos, all identifying numbers

HIPAA Privacy Rule

- Data use agreement—must be included in the consent
- Covered entities
 - Health care providers
 - Health care plans
 - Employers
 - Health care clearinghouses

Right to Anonymity and Confidentiality

- Confidentiality: researcher refrains from sharing information with others
 - Breach of confidentiality: unauthorized access to raw data
- Anonymity: no one, not even the researcher, knows the identity of the subjects

Informed Consent

- Essential information for consent
- Comprehension of consent information
- Competence to give consent
- Voluntary consent

Essential Information for Informed Consent

1. Introduction of research activities
2. Statement of research purpose
3. Selection of research subjects
4. Explanation of procedures
5. Description of risks and discomforts
6. Description of benefits
7. Disclosure of alternatives
8. Assurance of anonymity and confidentiality

Essential Information for Informed Consent

9. Offer to answer questions
10. Voluntary participation
11. Option to withdraw
12. Consent to incomplete disclosure

European Union General Data Protection Regulation

- The General Data Protection Regulation (GDPR) imposes new rules on organizations that offer goods and services to people in the European Union (EU), or that collect and analyze data tied to EU residents, no matter where they are located.
- Enforced on May 25, 2018

GDPR Data Definitions Regardless of Nationality or EU Residence



Personal Data (from GDPR)

“...means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.”

Examples:

- Name
- Identification number (e.g., Social Security number)
- Location data (e.g., home address)
- Online identifier (e.g., e-mail address, screen names, IP address, device IDs)
- Genetic data (e.g., biological samples from an individual)
- Biometric data (e.g., fingerprints, facial recognition)

“The GDPR also requires compliance from non-EU organizations that offer goods or services to EU residents or monitor the behavior of EU residents.”

Source: *Brief: You Need An Action Plan For The GDPR*; Forrester Research; October 2016

GDPR Basics

- Provide notification to data subjects, in clear and plain language
- Request and obtain the data subject's affirmative and granular consent
- Discontinue with processing activities if the data subject denies consent
- Provide a mechanism for data subjects to withdraw consent
- Obtain affirmative consent from a child's (under the age of 16) parent or guardian

De-Identification

- 87 percent of the U.S. population can be uniquely identified by five-digit ZIP code, gender, and date of birth
- Genomic data can aid in re-identification in clinical research studies
- Social security numbers can be predicted from public data

Governor Weld

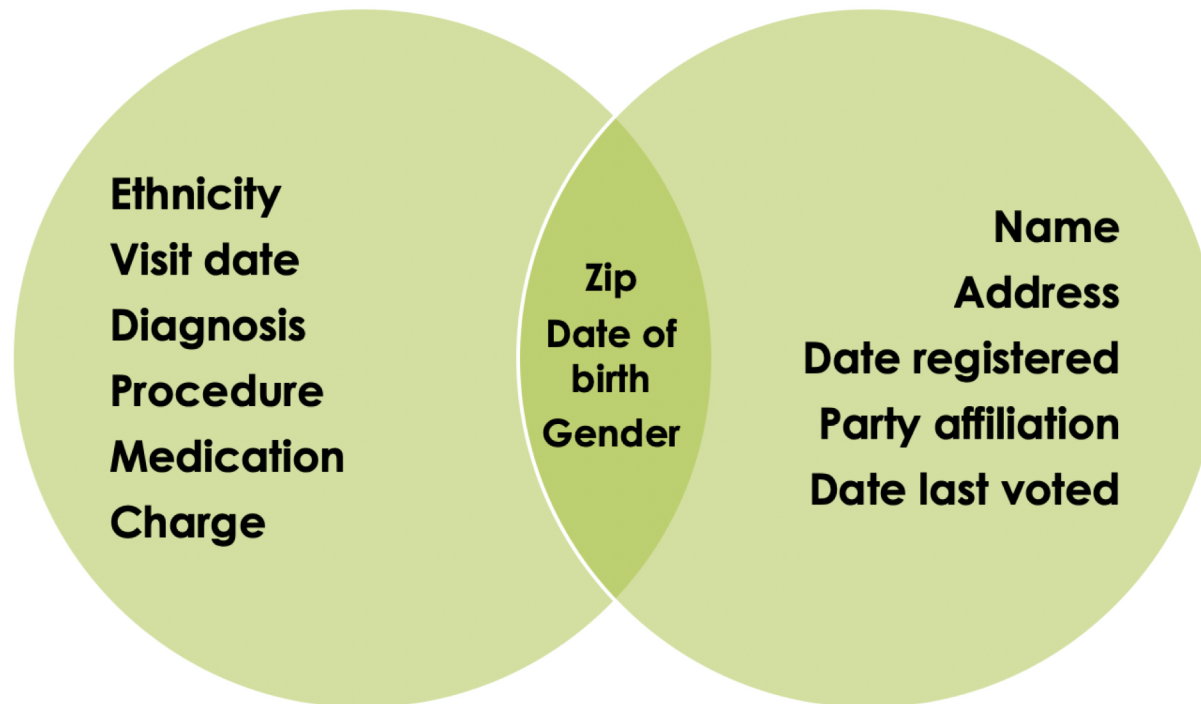


Figure: The overlapping data enabled identification of the governor.
(Adapted from Sweeney, 1997)

Flow of Information in Healthcare

