

Responsible Conduct of Research

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Ethical Concerns in Research

- Plagiarism
- Misuse of Privileged Information
- Data
 - Integrity of data
 - Use and misuse of data/misconduct
 - Ownership of and Access to Data
 - Storage and Retention of Data



Authorship and Other Publication Issues

- Criteria for authorship
- Order of authors
- Self-Citations
- Duplicate Publication
- Accessibility of Publications
- Early Release of information about to be published



Other Ethical Issues

- Interference
- Obligation to Report
- Curriculum Vitae
- Conflict of Interest





- Responsibilities of Research Investigator
- Collaborative research
- Responsibilities of Funding Agencies
- Human Subject Research

Historical Background

- Nuremberg NAZI Doctors Trial (46-47)
- Led to the Nuremberg Code
- Declaration of Helsinki (World Medical Association), 1964



Tuskegee Study and Other Unethical Studies



- **National Commission Reports (DHEW)**
- **Belmont Report, 1979**
 - Justice
 - Respect for Persons
 - Beneficence

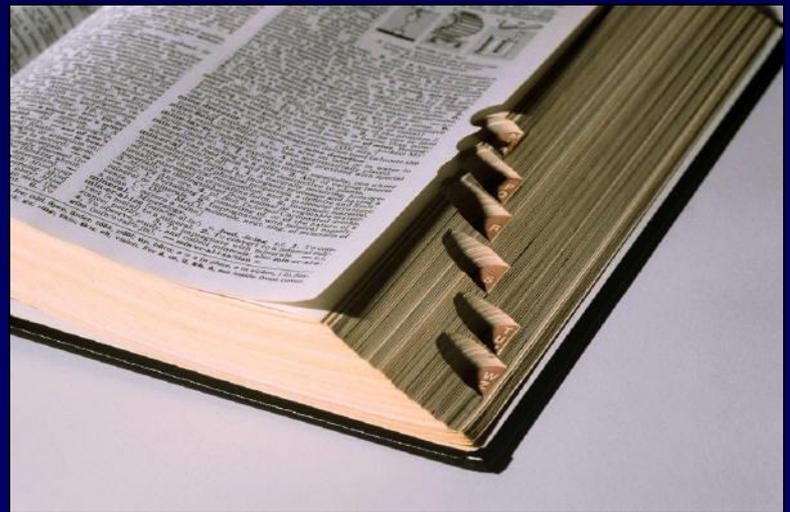
Institutional Review Board (IRB)

- **Institutional Policies**
- **Protection of Vulnerable Human Subjects**
 - Pregnant women, fetuses
 - Prisoners
 - Children



Definition of Research

- Research means a systematic investigation involving a human subject (living individual), including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge



Exempt Research-determined by individual institution

- Typical educational practices
- Educational tests, surveys, interview, or observation of public behavior
- Research with elected public officials
- Existing data, documents, pt. specimens, if publicly available or anonymized
- Evaluation of public benefit service programs
- Taste and food quality evaluation and consumer acceptance studies

Expedited Review

- Involves no more than minimal risk
- Determined by the IRB office



Full Board Review

- Forms are determined by the institution
- Includes both scientific and ethical review





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