

Responsible Conduct of Research

Daneng Li, MD
Assistant Clinical Professor
City of Hope

NIH Award 1R25CA183723-01A1



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



Human Subjects Research



- Responsibilities of research investigator
- Collaborative 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

- Quality improvement exercises
- Typical educational practices
- Educational tests, surveys, interview, or observation of public behavior

- Would advice to check with your IRB
- Consider whether or not you want to publish results

Research Vs. QI

- ***Quality Improvement***: QI is the systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product
- ***Research***: Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research Vs. QI

	Research	Quality Improvement
Intent	Develop new knowledge; involves a study plan	Improve a practice/process
Design	Draw conclusions; may involve controls or randomization	May review literature to compare or design programs
Dissemination	Intent to publish new knowledge	Publication intent is suggest an effective model; footnote that this is QI
Effect	Not intended to affect institution; may influence future process	Expected to directly affect institutional practices
Benefit	May not benefit directly	Participants expected to benefit
Deviation from practice	May deviate significantly from standard practice	Unlikely to deviate significantly from standard practice

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



