

Ethical Principles for Human Subjects Research

Principles versus standards:

- principles are goals for behavior; these may conflict
- standards are rules for behavior; these can be thought of as the way that we put principles into practice
- NIH and various professional organizations set standards for professional researchers
- *Institutional Review Boards* follow these standards in administering and monitoring research at universities and other organizations
- professors are responsible for setting these standards for student research (UNCG's IRB has delegated this authority to professors)

A little history...

- formal concern for the ethics for human subjects research is relatively recent (last 60 years)
- Nuremberg war trials after World War II included charges against doctors who performed experiments on prisoners of war
- trials resulted in the Nuremberg Code, which focused on the need for informed consent and for scientifically useful and socially beneficial research

- in the 1960s, more concern given to rights of subjects and more attention given to deceitful practices; these concerns led to the Helsinki Recommendations by the World Health Organization
- in the 1970s, several unethical and harmful experiments came to light—most notably, the Tuskegee Syphilis Study (systematic denial of penicillin to black syphilis patients); these led the government to develop procedures
- in 1979, a government committee issued *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*
- government also developed formal procedures (Title 45, Code of Federal Regulations, Part 46), which remain in effect today

Three Principles of the *Belmont Report*

- Respect for Persons
 - o must respect the dignity and decision-making ability of people
 - o basis for informed consent
 - o recognizes that some people—children, prisoners, mentally challenged, severely ill—are less able to make independent decisions
- Beneficence (doing good)
 - o minimize harms and risks to subjects
 - o maximize social and scientific benefits
- Justice

- people should be fairly chosen as subjects unless there are scientific reasons for focusing on a particular group
- subjects should come from groups that are likely to benefit from research
- These principles underlie current regulations at all levels

University research

- Human subjects research at most universities, including UNCG, is regulated by an Institutional Review Board (IRB)
 - universities agree to this as a condition of receiving grant money from the Department of Health and Human Services and other government agencies
 - IRB covers all human subjects research, not just funded research
- Plans need to be submitted to the IRB if they involve:
 - research (systematic investigation intended to contribute to generalizable knowledge, i.e., possible publication or dissemination)
 - human subjects
- Research can be shut down if investigators don't follow the rules
- First step is getting training; several organizations, including the Collaborative Institutional Training

Initiative <http://www.citiprogram.org/default.asp>, offer on-line training

- Any application to study human subjects will require proof of training (can also put this on your resume)

Applicability to Economic Research

- Economic researchers sometimes interact directly with human subjects
 - o most frequently occurs in survey/interview research
 - o economists sometimes conduct experiments
- Economists also indirectly rely on human subjects when they use *secondary* data
 - o regulations involving secondary data are evolving (UNCG has its own regulations)
 - o researchers must realize that there are potential risks from disclosure of certain data—
confidentiality risks
 - o analyses of secondary data may be treated as human subjects research if subjects can be identified and the information covers sensitive topics

References:

National Institutes of Health, Office of Human Subjects Research, Regulations and Ethical Guidelines webpage <http://ohsr.od.nih.gov/guidelines/index.html> .