



RICE

# *Human Subjects Research & the Common Rule*

John M. Cornwell, Ph.D.

IRB Chair

Rice University

October 29, 2015



RICE

Values

## *Rice's Values*

**R**esponsibility

**I**ntegrity

**C**ommunity

**E**xcellence





### Respect for Persons

Individuals should be treated as autonomous agents

Individuals with diminished autonomy are entitled to protections

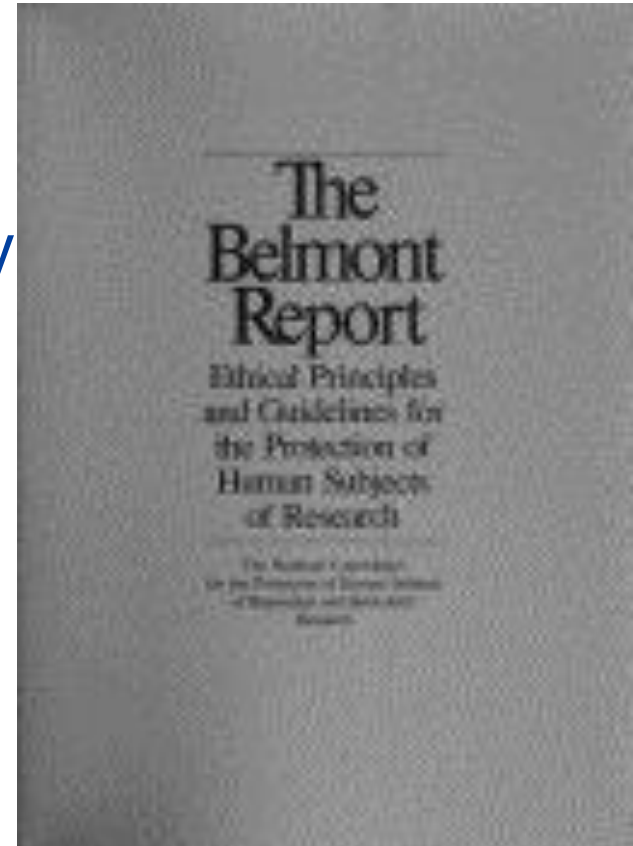
### Beneficence

Do not harm

Maximum possible benefits, and minimize potential harms

### Justice

Fair distribution of burdens and benefits of research





- ✓ Common Rule – broadly applicable & IRB oversight/review is value-added
  - Methodology is not the same as risk
  - Exclusion & self-determined exemption is problematic
  - Institution's Values encourage oversight



- ✓ Single IRB overview is sufficient for multiple site projects





### ✓ Posting of Informed Consent Forms could have severe, unintended consequences:

- Intellectual property rights of researchers
- Marketing targeted at researchers
- Protests and harassment
- Security & safety issues
- New reporting requirement





- ✓ Common Rule – broadly applicable & IRB oversight/review is value-added
- ✓ Single IRB overview is sufficient for multiple site projects
- ✓ Posting of Informed Consent Forms could have severe, unintended consequences