

RESPECT FOR PERSONS
AND ELEMENTS OF
CONSENT

INFORMED CONSENT



WE BEGIN HERE
(SORT OF)



THE BELMONT REPORT

- **Respect for Persons**

- 1) Individuals should be treated as autonomous agents,
- 2) Persons with diminished autonomy are entitled to protection.

- **Beneficence**

- 1) Protecting the individual subjects against **risk** of harm
- 2) Consideration of not only the **benefits** for the *individual*, but also the *societal* benefits that might be gained for research

- **Justice**

- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved."

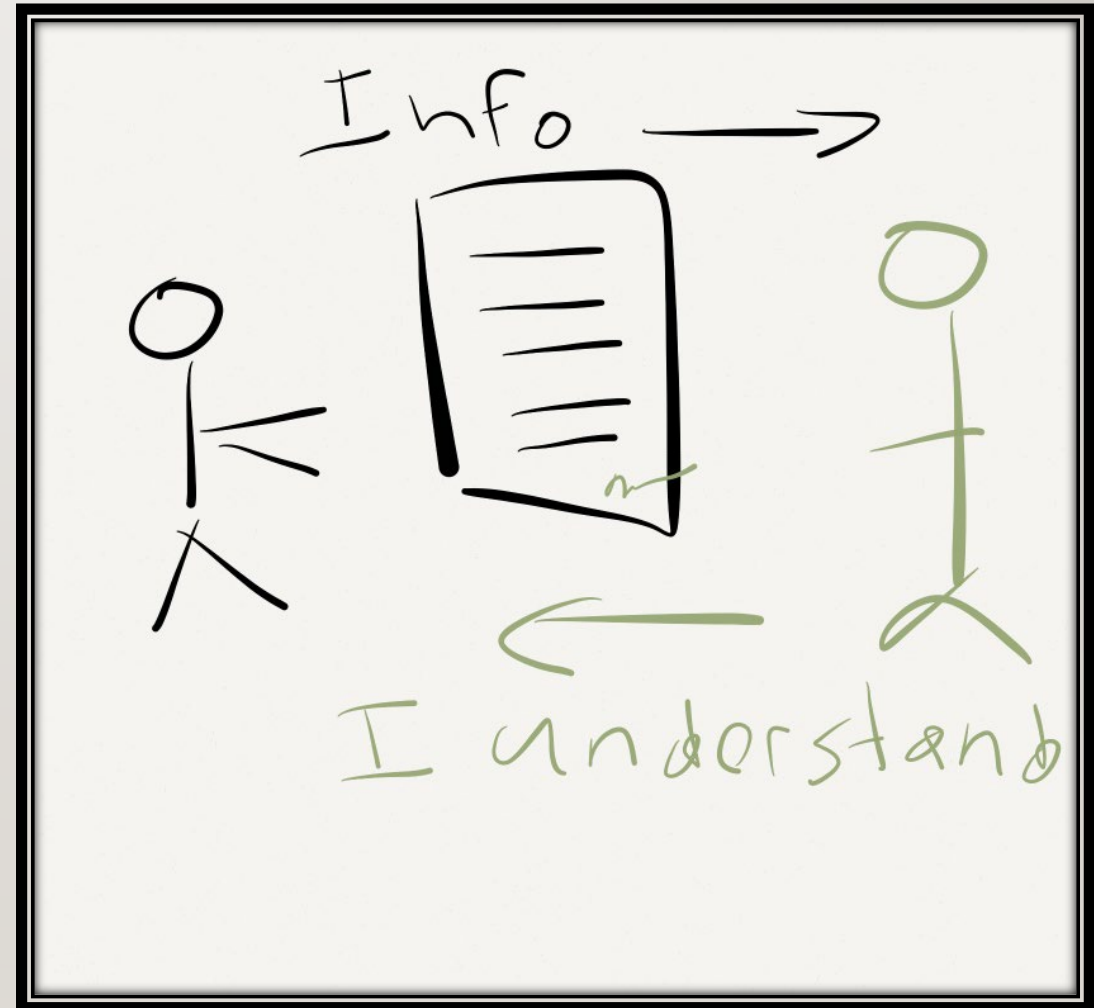
RESPECT FOR PERSONS

1) Individuals should be treated as autonomous agents

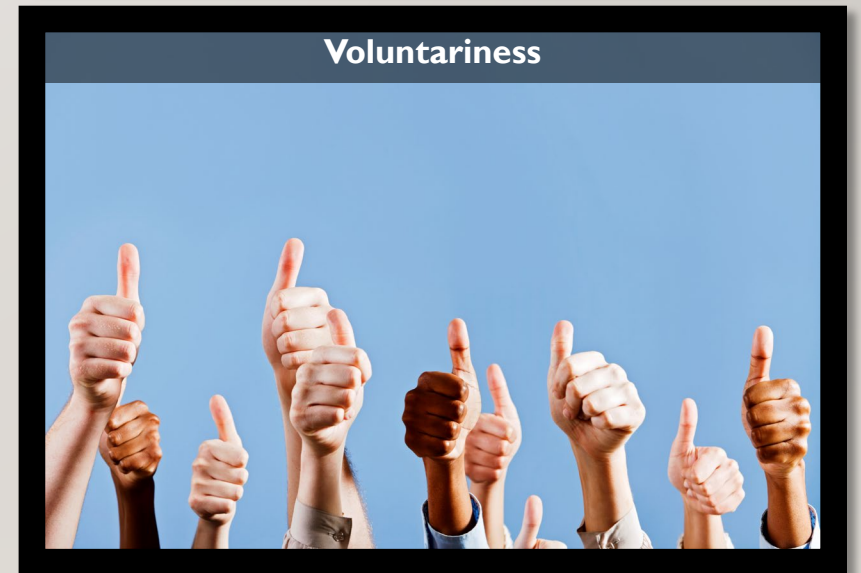
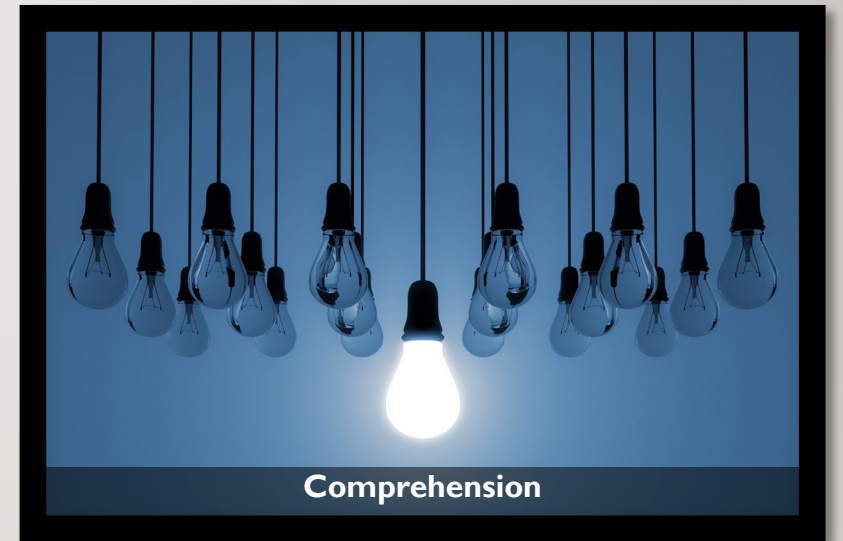
- Deliberation about person goals
- Respecting and not obstructing

2) Persons with diminished autonomy are entitled to protection

- Capacity matures and changes



PRINCIPLES APPLIED





FROM
PRINCIPLES TO
(COMMON)
RULE

- Apply Common Rule (45 CFR 46)
- Criteria for approval (§46.111)
- Regarding informed consent:
 - Consent is obtained (§46.116)
 - Consent is documented (§46.117)

CONSENT IS OBTAINED (§46.116)



Before research, obtain consent from participant or representative



Appropriate circumstances, free from coercion or undue influence



Understandable language



“Reasonable person” standard



Key Information and organization



No exculpatory language

ELEMENTS OF CONSENT

- Involves research
- Purpose and procedures, including duration
- Risks/discomforts and benefits
- Confidentiality provisions
- Participation is voluntary
- No penalty or loss of benefits if do not participate or withdraw
- Future use of participant data
- Contact information x2

