

Protecting Subjects from Coercion

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Respect for Persons

- ◆ ...respect for persons demands that subjects enter into the research voluntarily and with adequate information.

The Belmont Report
Ethical Principles and Guidelines for the Protection of Human
Subjects of Research

April 18, 1979

Coerce = to compel with force

- ◆ *Cum* - with
- ◆ *Arcere* - to confine or restrain

i.e., Not Voluntary

COI ≠ Coercion

- ◆ Conflicts of interest may lead to coercive situations
- ◆ Conflicts of interest are not necessarily coercive
- ◆ Coercion can arise without any conflict of interest

Who Are the Coercers?

- ◆ Researcher
 - As investigator/inventor/investor
 - As care provider
 - As boss
- ◆ Family members
- ◆ Research subject himself (toughest to detect)

Coercive Factors in Research

- ◆ Reward (money, etc.)
- ◆ Desire to please
- ◆ Fear of reprisal
- ◆ Hope for cure
- ◆ Good of society

Vulnerable populations

Coercive Acronyms

- The Greatest Treatment for Heart Failure Trial
- The Last Diabetes Trial You'll Ever Need

◆ CURE, HOPE, HELP, IMPROVED, LIFE, RESCUE, MIRACL (sic), SAVED, or ALIVE

Orlowski JP, Christensen JA.
The potentially coercive nature of some clinical research trial acronyms.

Chest. 2002 Jun;121(6):2023-8.

Who applies what pressure?

	Researcher	Family	Subject
Reward	■	■	■
Desire to please	■	■	■
Fear of reprisal	■	■	■
Hope for cure	■	■	■
Good of society	■	■	■

Coercion's Subtle Clues

- ◆ I know this is important to you, doctor.
- ◆ So there isn't any risk, right?
- ◆ My family really wants me to do this.
- ◆ It's my last chance for a cure.
- ◆ The money will help us.
- ◆ It will give me a chance to get out of my cell more.

Reducing Coercion

- ◆ Create Rules (the moral floor) like:
 - Investigator who is also care provider can't obtain consent
 - Employees/trainees can't be subjects
 - Define COIs and manage them
- ◆ Create Culture of Conscience (behave ethically)
 - Investigators understand coercion and accept responsibility for avoiding coercive situations