

ETHICAL FRAMEWORKS FOR RESEARCH INVOLVING VULNERABLE POPULATIONS

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What principles guide human subjects research?

- Autonomy
- Beneficence
- Non-maleficence
- Justice
- Relationality

All express respect for different aspects of human beings
(DuBois, Ethics in mental health research, Oxford, 2008)

Current practices in research with vulnerable practices are skewed toward non-maleficence

- Begin with consideration of special populations
- More protections are better; play it safe
- Safeguards based on hunches or stereotypes
- Institutional review boards, researchers, and ethicists are the best people to determine which protections are needed
- Assess decisional capacity to exclude people
- Special safeguards required only for vulnerable groups

Objectives

- Identify regulatory requirements for research with vulnerable populations
- Examine two frameworks for understanding vulnerability
- Evaluate:
 - When additional protections are indicated
 - How additional protections are selected
 - Who receives additional protections

Common Rule

“When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.”

45CFR46.111(b)

What are examples of “additional protections?”

- What do you think of these?
- What do participants think of these?

Participants Often Don't Want Some Additional Protections

- How do we deal with tensions between:
 - respect for participant preferences,
 - concern about voluntary informed consent, &
 - IRB / Regulatory requirements?

DuBois JM, Callahan O'Leary C, Cottler LB. "The attitudes of females in drug court toward additional safeguards in HIV prevention research." *Prevention Science* 2009;10:345-52.

What is Vulnerability?

Being “susceptible to physical or emotional attack or harm.”

- New Oxford American Dictionary

The Belmont Report expands on list of harms:

- “risks of psychological harm, physical harm, legal harm, social harm and economic harm ...” (C.2)

NBAC's 5 Kinds of Vulnerability

| Kinds of Vulnerability | Sample Vulnerable Population |
|-------------------------------|---|
| Cognitive or communicative | Children, fetuses, decisionally impaired, seriously ill |
| Institutional or deferential | Prisoners, students, employees |
| Medical | Terminally or incurably ill patients |
| Economic | Impoverished populations |
| Social | Racial, ethnic, sexuality minorities |

How Vulnerabilities May Compromise Consent

| Kinds of Vulnerability | <u>Possible</u> Threat to Consent |
|-------------------------------|---|
| Cognitive or communicative | Lack of understanding, appreciation or reasoning with consent information |
| Institutional or deferential | Difficulty saying no |
| Medical | May be desperate for a cure and use biased reasoning; cognitive deficits |
| Economic | May be unduly influenced |
| Social | May less information due to bias among IRBs or researchers; language barriers |

Four Elements of Decisional Capacity

- Understanding
 - Ability to understand consent info such as study design, duration, risks, benefits
- Appreciation
 - Ability to believe and relate pertinent information to one's own life and values
- Reasoning
 - Ability to reason with consent info, e.g., to weigh risks and benefits in light of personal situation
- Expressing a Choice
 - Ability to agree to or decline participation in a relatively clear and stable manner

What Is Screening for Capacity?

UCSD Brief Assessment of Capacity to Consent (UBACC)

1. What is the purpose of the study that was just described to you?

Response (2 = Study investigational drug for memory)

Score

0

1

2

2. What makes you want to consider participating in this study?

Response (2 = Improve memory and attention, help others)

Score

0

1

2

3. Do you believe this is primarily research or primarily treatment?

Response (2 = Research)

Score

0

1

2

4. Do you have to be in this study if you do not want to participate?

Response (2 = No)

Score

0

1

2

5. If you withdraw from this study, will you still be able to receive regular treatment?

Response (2 = Yes)

Score

0

1

2

What Populations are Commonly Targeted for Screening?

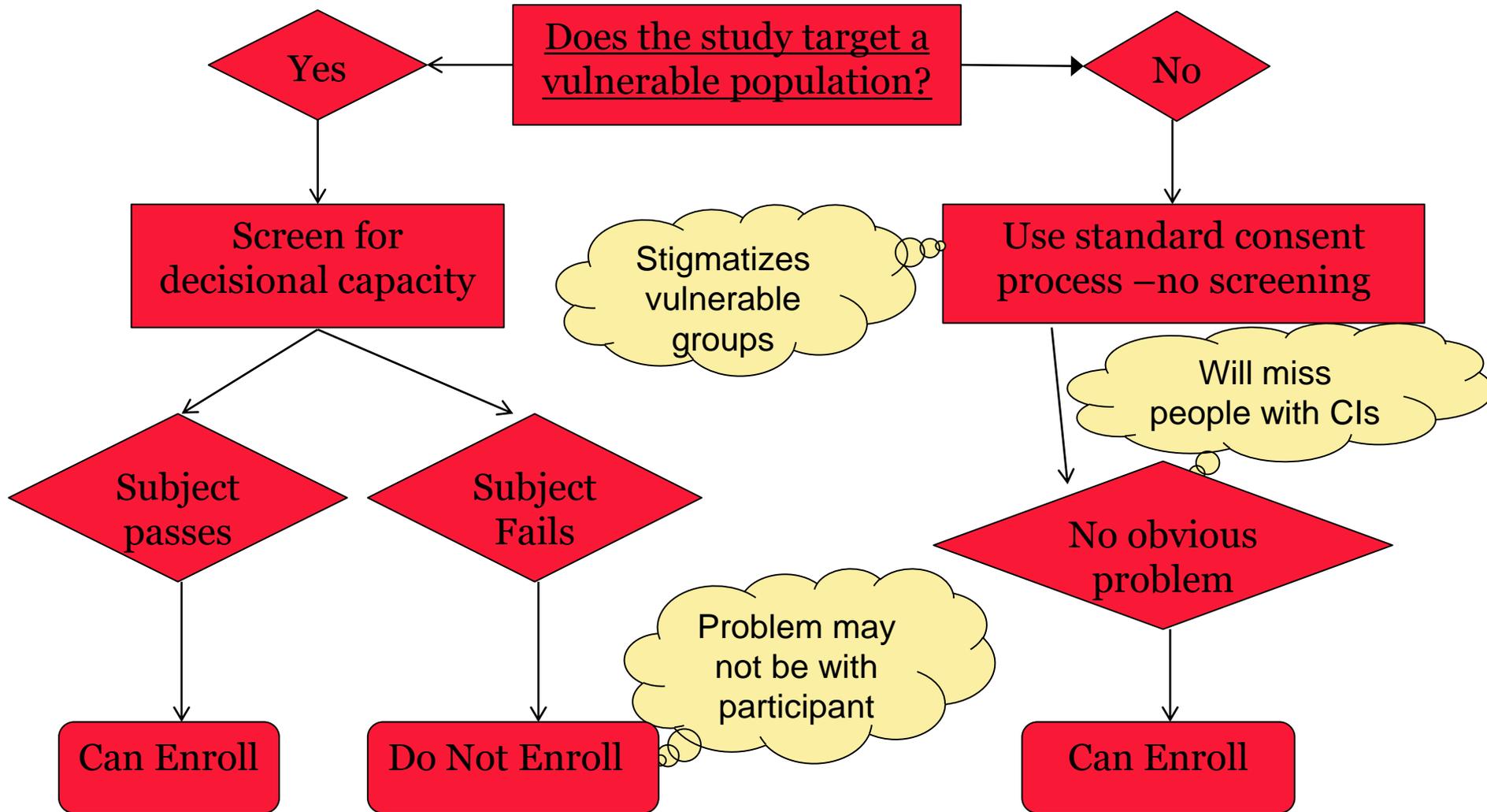
| Common Rule-Enumerated | Common Rule-Unenumerated |
|-------------------------------|---------------------------------|
| Children | Low education |
| Pregnant women, fetuses | Cognitively impaired |
| Prisoners | Poverty |

Key Questions

**When should we screen
for decisional capacity?**

**Should risk level or population drive our
decision?**

Population-based screening



The Problem of Stigma

- People often know when they are being treated differently due to stereotypes
- Stigma associated with mental disorders and with Alzheimer's can lead to shame, a sense of isolation, and a fear of coercion that prevents individuals from seeking care.

Corrigan PW. *On the stigma of mental illness*. Washington, DC: American Psychological Association; 2005.

Werner P, Heinik J. Stigma by association and Alzheimer's disease. *Aging & mental health*. 2008;12(1):92-99.

There are MANY Risk Factors for Cognitive Impairments

| Psychiatric | Medical |
|---------------------|---------------|
| Schizophrenia | Heart disease |
| Bipolar | Cancer |
| Opioid use disorder | Diabetes |
| PTSD | Advanced age |

1. Screening only when at risk populations are being targeted fails to ensure adequate consent from **individuals** who belong to these other groups.
2. Stereotyping leads IRBs to requiring screening primarily for psychiatric studies (Luebbert et al 2008)

There are MANY Reasons Why Outcomes of a Consent Process May Be Poor

| Individual Factors | Communication Factors |
|---------------------------|-------------------------------------|
| Neurocognitive functions | Complexity of information |
| Education/Health literacy | Timing of communication |
| Language fluency | Use of communication best practices |

Blaming participants' lack of capacity may be easier than creating a consent documents and processes using best practices, which are proven to enhance participant understanding. (Iltis et al 2013; Dunn et al 2001)

Restoring Balance (DuBois et al 2012)

| Status Quo | Balanced Practices and Attitudes | Benefits |
|--|---|---|
| - Begin with consideration of special populations | - <i>Begin with consideration of risk level posed by study design</i> | - Avoid unnecessary burdens on valuable research |
| - More protections are better—play it safe | - <i>As many protections as necessary, as few as possible—too many protections cause harm</i> | - Avoid harms due to overprotection |
| - Safeguards based upon hunches or stereotypes | - <i>Safeguards based upon dialogue with relevant communities</i> | - Avoid unfair stereotyping |
| - IRBs, researchers, and ethicists are the experts on which protections need to be offered | - <i>Participant communities have unique expertise on many issues of ethics—benefits, risks, privacy, autonomy, etc</i> | - Provide a voice to those most affected by the research |
| - Focus on decisional capacity of participants | - <i>Focus on the success of the consent process</i> | - Address system problems while avoiding a focus on individual deficits |
| - Special safeguards required only for “vulnerable” groups | - <i>Universally apply safeguards when needed</i> | - Avoid stigmatization while protecting all groups when justified by risk level |

References

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4. Luebbert R, Tait RC, Chibnall JT, Deshields TL. IRB Member Judgments of Decisional Capacity, Coercion, and Risk in Medical and Psychiatric Studies. *Journal of Empirical Research on Human Research Ethics*. 2008;3(1):15-24.
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