

Coercion and Undue Influence in Decisions to Participate in Psychiatric Research

Issues in Measurement

Why is this a problem

- Of the basic issues in informed consent, this is the least well defined
 - Measurement of ambiguous concepts is problematic
 - IRBs seem eager to regulate but confused
 - Hospitalized psychiatric research subjects may be at particular risk.

Substantive Issues: Incentives

- There has been considerable research on whether financial inducements are “undue”
 - What is undue is unclear

The Impact of Incentives

- Bentley and Thacker, Candilis et al, and Halpern et al. all suggest financial inducements encourage participation but do not affect perceptions of risk
- However Roberts et al. found that money was more important than doctors' or family recommendations in considering medication-free and placebo-controlled schizophrenia protocols

Context-free Measures?

Non-Western contexts

- Autonomy is a prized quality in Western culture
- Some other cultures accept more collective decision making
- Three different studies in Africa raise serious questions about the applicability of concepts of voluntariness.

Context-Free Measures? Detained Subjects

- Long tradition of suspicion about whether imprisoned or hospitalized subject are voluntary
- American IRB regulations have special provisions for them
- Do incentives have different meanings in long-term detention?
- Can individuals be thought of as voluntary subjects if they are involuntarily detained?

Context-Free Measures?

- Economically Deprived
- Addicted subjects
- Subjects desperate for health care

Pressures needing Assessment

- The status and authority of the individual gaining consent may intimidate
- Dependence on individual gaining consent (personal physician)
- Familial pressures

Methodological Issues

Diversity of Approaches

- Semi-structured interviews as a tool, e.g., Bennett et al.
- Scales - Gardner et al, Kjellin et al.
- Ethnographic interviewing - Lidz et al. 1984
- Perceived voluntariness vs. Objective evidence

Structured Scales - Advantages

- Produces a score
- Generally easy to use
 - either given to subjects or scored by objective data collector
- Can be easily entered into statistical analysis

Structured Scales - Limitations

- Can accommodate limited contextual differences
- Must decide on objectivity or subject's perspective
- Deceptive finality - the things it misses may be hidden from reader

Semi-structured Interviews - Advantages

- Allows greater inclusion of different factors in voluntariness
- If an interview, gives subject a voice
- More openness to unanticipated dimensions
- cultural and situational factors can be included

Semi-structured Interviews - Limitations

- Difficulty in producing a single score
- More time consuming to collect
- More time consuming to process
- Resources are likely to limit sample size

Ethnographic Observation - Advantages

- Best method for including context
- Best method for dealing with cultural differences
- provides a voice to subjects
- Openness to unexpected dimensions of voluntariness

Ethnographic Observation - Limitations

- Requires skilled personnel and thus expensive
- Time consuming and thus expensive
- Does not produce a score to include in quantitative analysis
- Interobserver reliability issues
- Limited by site access problems

Concluding with Questions

- What do we mean by a compromise of voluntariness?
 - What counts?
 - What are we measuring
- Can we have a single measure or must it be context dependent? Which contexts?
- Are the issues in psychiatric research different?