

# JERHRE NOTES

*Skills for Solving Ethical Problems in Human Research*

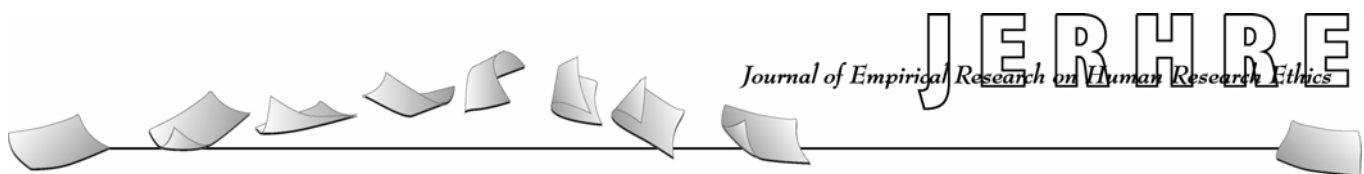
## Evaluating Vulnerability in Research Participants

The preconceptions that we hold regarding subpopulations of research participants impact our judgments about their need for protection. Thus, we may *assume* that a particular age 15 child has less decisional capability than her parents, although her capabilities may be superior to theirs. Similarly, some frail elderly and marginally demented persons may be more competent than their next of kin to make their medical decisions. Adequate risk assessment requires looking beyond simple labels to the specific circumstances and capabilities of individuals.

Psychiatric patients have been identified as vulnerable and requiring special protections from research risk beyond those needed by participants in medical research. However, when IRB committee members read vignettes describing research protocols involving patients with psychiatric and medical diagnoses, they viewed psychiatric subjects as having greater vulnerability to coercion and less decisional capacity than medical subjects. Further, this relationship held *even when* the medical illness was of high severity, such that it was likely to engender psychiatric comorbidities and when the psychiatric illness was of such a low severity that it was unlikely to impact decisional capacity.

Instead of assuming limited decisional capacity, investigators should focus on managing the consent process to augment the decisional capacities of vulnerable subjects. They should also recognize that decisional capacities may be compromised by various medical disorders that commonly have psychiatric co-morbidities, including cancer, acute trauma, myocardial infarction, diabetes and severe pain.

Luebbert, R., et al. (2008). IRB Member Judgments of Decisional Capacity, Coercion, and Risk in Medical and Psychiatric Studies. *JERHRE*, 3(1), 15-24.



To find JERHRE Notes on other topics, or in other languages, please go to [www.csueastbay.edu/JERHRE/notes](http://www.csueastbay.edu/JERHRE/notes).  
To see abstracts of other "Jerry" articles, purchase this entire issue, or subscribe to JERHRE, see <http://caliber.ucpress.net/loi/jer>.  
Subscriptions are affordable because JERHRE is published by non-profit U.C.Press and by editors who serve on a voluntary basis.