

IRBs and Ethical Issues in Psychiatric Research

Project Staff: Joe Catania

Project Description: The proposed study will

- (a) conduct an initial "screener" survey of 500 Institutional Review Boards (IRBs) with Federal Assurances, and screen these on gender and ethnicity of their IRB Chairs and on their total review volume and
- (b) present case scenarios to and interview a subsample of 175 IRB Chairs composed of an oversample of IRB Chairs of color and female chairs.

We will study how IRB Chairs would respond to scenarios that depict controversial issues in research ethics, such as drug withdrawal studies and research on persons with questionable decision-making capacity. Based on qualitative in depth and semi structured interviews, this work will

- (a) characterize the human participant concerns that IRB Chairs consider significant in these scenarios,
- (b) characterize the suggestions IRB Chairs make to address these human participant concerns,
- (c) characterize how IRB Chairs would communicate their concerns and protocol modifications to investigators who are skeptical of IRB review and
- (d) produce updated statistics on IRB work volume and IRB Chair demographics based on our screener survey.

Significance: Some research that promises important knowledge about mental health and psychiatric illness also raises difficult human participants concerns. This project is significant because IRB Chairs may identify human participants concerns that need further discussion, suggest best practices that other IRBs might adopt, provide feedback on strategies suggested in the literature, and suggest how to overcome the skepticism of researchers regarding IRB review.

Project End Date: 2006