

## UCSD Research Ethics Program

### TOUGH CASES – A lunch time ethics discussion series

#### Placebo Trials of Medications for Psychiatric Disorders

Tuesday, January 27, 12:00pm – 1:30pm  
UCSD School of Medicine, Stein Bldg. Room #148

**Moderator:** Mary Devereaux, Ph.D., Research Ethics Program

**Presenter:** Mary Devereaux, Ph.D., and Mani Akhtari, MS II

### January's Tough Cases

#### **Introduction:**

The use of placebo controls in clinical trials for patients with mood disorders such as depression is one of the most controversial topics within psychiatric research today. January's Tough Cases will discuss the ethics of placebo controls in clinical trials that test the effectiveness of new psychiatric drugs. The National Depressive and Manic-Depressive Association (NDMDA) issued a consensus statement in 2002 approving the use of placebos in trials of new drugs involving patients with mood-disorders "if the sample population is effectively monitored, controlled, and screened for serious adverse events, such as suicidal ideation." This month's case asks how these guidelines are applied in practice.

#### **Case:**

As an Internist at the local VA Hospital in 2002, you are asked to help enroll patients for a new study to evaluate Prazosin efficacy for nightmares and sleep disturbances in patients with PTSD. Prazosin (trade names Minipress, Vasoflex, Hypovase) is a sympatholytic drug used to treat high blood pressure. Previous studies demonstrate its effectiveness in treating nightmares and PTSD in children. For the new study, twenty Vietnam combat veterans with chronic PTSD and severe trauma-related nightmares are to be enrolled in a 20 week double-blind crossover protocol. You have several patients who meet the enrollment criteria and are interested in participating. All are on current medications, but with varying outcomes. None are free of nightmares and sleep disturbances.

#### **QUESTIONS FOR DISCUSSION:**

- a) What ethical issues does the use of placebo in this trial raise?
- b) Under what conditions, if any, would you recommend that your patients enroll in this study?
- c) What guidelines and procedures would you want to see in place to protect the welfare of your patients?