

**Title:** It's All the Same

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**Description:** A psychiatric researcher feels that a research coordinator recruiting patients for drug trials may be giving participants false hope about the experimental treatments being tested.

**Headings:** Voluntariness and Undue Influence in Recruitment; Other voluntariness or recruitment issues

**Case Type:** Decision making

### **It's All the Same**

Mary is a clinical research coordinator for a large psychiatric practice in New York that regularly participates in multi-site drug trials. Of the four research coordinators in the practice Mary has the highest participant enrollment rates – nearly twice as many as the rest. The director of the practice, Dr. Jalali, decides to observe her during the enrollment process to see whether the other coordinators might learn something from her approach. Indeed, he quickly discovers why she might be so effective. While consenting a 30-year old patient with bipolar disorder, the patient asked whether it would really wise to go off her medication and to risk receiving placebo or an unproven treatment. Mary replied, “Oh yes, there is no reason to believe that current treatments are any more effective than our experimental treatments. The Institutional Review Boards that approve our studies make sure of that. So your therapy should in no way be adversely affected.” Dr. Jalali was shocked. He confronted her and explained that research is not therapy and that she is wrong to lead patients to believe that the purpose of research is to give them the best treatment available. She replied that she is the one who presents their studies to IRBs, and that IRBs always ask about “clinical equipoise.” She said everything she’s telling patients is true and that the IRBs agree with her that there is no reason to believe that current therapies are superior to their experimental treatments or even placebo when that is used.

Dr. Jalali feels sure she’s wrong, but he’s not sure how to respond to her because he sat on an IRB for 3 years and he knows that they do indeed refuse to approve a study if there is no reason to believe that all treatment arms are possibly of equal value.

**What should he tell her?**