

Title: Severe Emotional Disturbance Studies

Author: James M. DuBois (based on several cases reported in Hoagwood, Jensen, and Fisher, *Ethical Issues in Mental Health Research with Children and Adolescents*, Lawrence Erlbaum, 1996)

Description: Dr. Randall has proposed two studies involving children with severe emotional disturbance (SED), one involving a control group and the other random assignment into foster care.

Headings: Study Design and Risk-Benefit Analysis; Experimental designs (randomization, clinical trials); Minors (children, adolescents); Mental health disorders, participants with (including addictive disorders and developmental disabilities)

Case Type: Decision making

Severe Emotional Disturbance Studies

Study I: Psychoeducational Intervention with Parents

Dr. Randall proposed to the ERB a program designed to develop and assess a psychoeducational intervention for parents of children with severe emotional disturbance (SED). The principal investigator (PI) directs a local agency that provides most of the social and mental health services delivered to children with SED and their families. The program was to consist of 15 educational sessions at weekly intervals with 6 months of follow up. In order to test the efficacy of the program, the PI would like to use a randomized experimental design. Ideally, he would like a control group consisting of half of the participants, who would be placed on a wait list. They would eventually receive the same services as the experimental group, but by being on a wait list during the nine months of intervention they would provide baseline data. However, as a mental health provider the PI is aware that any delay in the provision of services to children with SED could be detrimental to the child and the child's family. There are no other agencies in the area serving children with SED, thus increasing the burden of a wait list control, even while increasing the validity of the study (by reducing the likelihood of confounding mental health interventions).

Participant Description

Jaime is a 16-year-old in his freshman year of high school. He repeated 7th grade after missing excessive days. He has received state-sponsored services for most of the past 3 years for serious emotional disturbance (SED). He developed a series of emotional and behavioral problems shortly after his parents separated. His father was verbally abusive to the whole family and physically abusive to Jaime's mother. Nevertheless, the separation was extremely stressful for Jaime. At 13 he was diagnosed with depression and was treated for a time with medications. However, he did not think they helped and he went off the medication after about 6 months. At 14 he attempted suicide by overdosing on Tylenol. After a period of inpatient therapy and resuming medication, he appeared to be doing well and his level of support services was decreased. He continued to do well throughout 8th grade. However, recently he has started acting out in class. When he is reprimanded, he screams and curses at his teacher. This past week he hit his math teacher when she insisted that he stop screaming at her. Jaime has also begun to be verbally abusive toward his mother and has shaken her several

times in the past month. His counselor has recommended that he be placed into foster care. His mother is not happy about this, but she accepted a referral because she did not know how else to help Jaime. Jaime is upset because he thinks his mother needs him. He sometimes babysits his two younger siblings and cooks when she needs to work late.

As an ERB member, would you approve the study as initially proposed, or would you recommend changes to the PI? Would you consider Jaime's mother to be an appropriate participant in this study?

Study 2: Therapeutic Foster Case Program Evaluation

Two years later, Dr. Randall was PI of another initiative. This program was designed to compare the outcomes of a therapeutic foster care program to those of an enhanced home-based intensive case management program for children with SED. The study was meant to assess the influence of several variables: provider behavioral (e.g., the services provided), family outcomes (e.g., family adaptability and cohesion), child outcomes (e.g., home, school and community functioning), and systems outcomes (e.g., costs and service system changes). Children between 6 and 16 years old were to be randomly assigned to one of the two treatment conditions. However, this raised concerns because the researchers would be randomly removing half of the children from their homes.

As a member of the ERB, would you approve this study as is, or encourage a different study design or recruitment strategy? As a member of the ERB, would you require only parents to give informed consent? Should the study also require that the minors give their assent?