

**Title:** Placebo Trials with Prevalent but Unproven Treatments

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**Description:** At a residential treatment center for persons with mental retardation, lithium is frequently used to treat aggressive and self-injurious adolescents. However, this use of the drug has never been systematically tested on this population. Investigators propose a placebo-control experimental design but some staff members believe this is depriving patients of an established treatment.

**Headings:** Special Populations and Cultural Competence; Institutionalized populations; Mental health disorders, participants with; Study Design and Risk-Benefit Analysis; Experimental designs; Placebo

**Case Type:** Decision making

### **Placebo Trials with Prevalent but Unproven Treatments**

The positive effect of lithium in the treatment of children and adolescents with aggressive behavior has been proven through clinical investigation. However, no published studies have included children with mental retardation. Investigators plan to conduct a two-arm parallel group study at a residential treatment facility for persons with mental retardation. Participants will be randomized to treatment with lithium or placebo.

Many staff members at the treatment facility have already been using lithium to treat aggressive behavior of person with mental retardation. The institutional review board (IRB) approved the study, but many staff members continue to believe that using placebo would be withholding of an effective, established treatment.

**What measures do you recommend the investigators take to increase cooperation and compliance from treatment facility staff members?**

*See Hoagwood et al. (1996) for a discussion of how this case was addressed by the researchers.*