

**Title:** Students as Research Subjects

**Author:** William Timberlake, in *Research Ethics: Cases and Materials*, edited by Robin Levin Penslar, Indiana University Press, 1995

**Description:** A researcher recruits students to participate in study to test an experimental treatment for depression. Several students who are randomly assigned to the control group voice complaints about their lack of treatment.

**Headings:** Study Design and Risk-Benefit Analysis; Experimental designs (randomization, clinical trials); Voluntariness and Undue Influence in Recruitment; Financial incentives; Therapeutic misconception

**Case Type:** Decision making

### Students as Research Subjects

Dr. Z, a professor of clinical psychology at a medium-sized urban university, after receiving approval of the local IRB, ran an ad in the school newspaper seeking as paid subjects students who often felt depressed. After an extensive assessment battery and interview (for which all students were paid), 100 students were invited to sign up for a lengthy study that had to do with “the monitoring of depressive feelings.”

Based on his review of the literature, Dr. Z had developed the hypothesis that a combination of regular physical activity and cognitive therapy involving the repetition of affirmations would decrease the frequency of depressive feelings. The study, which was double-masked, contained four randomly assigned groups (A masked study is one in which either the investigator, the subject, or both do not know the identify of the treatment group to which the subject has been assigned. A double-masked study is one in which neither the investigator nor the subject knows the identity of the treatment group.):

- 1) a control group;
- 2) a group engaging in physical activity;
- 3) a group receiving cognitive therapy; and
- 4) a group both engaging in physical activity and receiving cognitive therapy.

Each student signed a consent form committing the student to two months of three half-hour sessions per week plus a follow-up session. The student would receive \$10 per hour of participation. Half of the money would be received at the end of the two months; the other half would be received after the six-month follow-up.

By the luck of the draw, three of the students were assigned to the control group. Control group members simply met and talked about their feelings. Over the course of several weeks, one of the students in the control group became increasingly more depressed and unhappy, and eventually stopped showing up, and withdrew from school. She subsequently filed a grievance with the university and with the APA arguing that she had signed up for the experiment with the hope that it would help her, but that instead it had harmed her.

A second student in the control group, after talking with a psychology graduate student, discovered that he was not receiving the treatment that was hypothesized to be most effective and demanded that he be given that treatment immediately. The investigator refused, and this student also filed a grievance insisting that his rights were being abrogated and his mental health endangered by the psychologist's refusal to treat him.

A third student argued that she should be released from the study because it wasn't helping her and, further, that she had been coerced into participating in the experiment by a lack of money and the unrealized hope of getting better. She argued that she should be paid for her time to date because she had been paid in previous psychology experiments in which she had declined to continue when given the opportunity either to stop or continue.

**How would you evaluate each of the students' claims?**

### **Questions for Further Reflection**

If each student's request or grievance is allowed, what are the implications for research related to therapy (e.g., clinical drug trials)?

Before consenting to participate in research, prospective subjects must be provided all informational material necessary to making a decision to participate. What information should participants in this study be given as part of the informed consent process? What, if anything, was missing in this case?

Is the design of the study – random assignment to control and treatment groups – justified?

Should the students have been informed about the structure of the design (i.e., that participants would be assigned to one of the four groups and that each group would receive a different experience that might affect the number and extent of depressive feelings)? Should the students have been allowed to choose the group they wished to be in? Why or why not?

Could Dr. Z have taken steps to avoid these difficulties?