

Title: Heightened Protections in Clinical Trials

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Description: A researcher recommends additional protections for participants in clinical trials that pose any risk of severe decline or relapse.

Headings: Study Design and Risk-Benefit Analysis; Placebo; Community and consumer representation; Mental health disorders, participants with (including addictive disorders and developmental disabilities)

Case Type: Decision making

Heightened Protections in Clinical Trials

Sam Tenenbaum, PhD, is a psychiatric researcher at a university hospital. His main area of research is the quality of life of patients diagnosed with severe mental disorders. Over the years, he has heard many stories from patients who have participated in clinical trials at his hospital. Two scenarios have come up more than once and caused him great discomfort. First, some patients reported relapsing or severely declining during a trial. They failed to go to their scheduled follow up visits, effectively dropping out of the study. Because of this, they received no monitoring or follow up treatment. One patient said his friend actually tried to kill himself when he was “off everyone’s radar screen.” Second, some patients who relapsed reported that they suffered severe consequences. Some lost their jobs and subsequently their housing. One patient in particular reported how he lost his job as an accountant and ended up living on the streets for 3 months until his ex-wife found him and brought him into treatment.

Dr. Tenenbaum is a member of his hospital’s institutional review board (IRB). At one meeting when the IRB was reviewing a placebo-controlled trial of a new anti-psychotic medication, he recommended that the IRB adopt two new protections for patients with severe mental disorders who enter into any clinical trial that includes a risk of relapse (thus any trial that involves washout, placebo controls, or switching medications).

1. The informed consent form and discussion should disclose not only the risks of relapse, but also the possible consequences of relapse including: loss of employment and housing, stigma, and difficulty becoming re-stabilized.
2. All outpatient enrollment should require the consent of the participant to contact a third party (friend, family member, or other who provides social support) in case the participant misses two consecutive follow up visits or leaves the study. The purpose would be to facilitate follow up care for individuals, who will no longer be monitored by the researchers and may need treatment. The third party would be required to sign an agreement stating that he or she is willing to be contacted by the researchers and is willing to try to locate the participant and assist the participant in finding treatment if necessary.

Most of his colleagues in psychiatry are upset by this proposal because they think it exaggerates risks and will unnecessarily and unfairly exclude patients from participating if they lack the same support system that others have. They note that people might be reluctant to be a contact person if they are asked to sign something, which could put them at legal risk.

As a member of the IRB, would you vote to support the routine use of either or both of these additional protections? Why or why not?