Case 5c: IRB Review of a Needle Exchange Program Evaluation Study

Needle exchange programs, in which intravenous drug users trade used needles for free, sterile ones, are generally thought to reduce the spread of HIV infection, hepatitis, and other blood-borne contagious conditions. It is possible, however, that part of the success of such programs is the result of self selection by drug users who are already inclined to repair their lives and are more likely to participate in the exchange program.

To examine these issues, a study was proposed that would randomize 600 intravenous drug users into two groups: one group could exchange used needles for sterile ones; the other group could not, but would be told where to acquire clean needles inexpensively and legally. All participants would be referred to treatment programs if desired.

The protocol was approved by a local IRB and by the federal Office of Protection from Research Risks. Nevertheless, the proposed study has generated considerable controversy.

Opponents of the study contend that it would unnecessarily expose members of the second group to increased risk of disease and constitute the withholding of a lifesaving device. Others argue that careful studies are still needed to acquire important data about the self-selection hypothesis and that the availability of cheap needles and treatment programs for the second group would reduce their risk to acceptable levels.

Questions for Discussion

1. Suppose an IRB of which you were a member was evaluating this study: What position would you take, and why?
2. Assume that members of the second group would, in fact, face an increased risk of disease. Does the information that would be gained by this study provide sufficient justification for placing individuals at increased risk of serious disease? Does it matter that all of the participants will have given their informed consent?
3. Although several observational (nonrandomized) studies have already shown the utility of needle exchange programs, the United States Government does not provide funding for such programs, which are politically controversial. How much financial support should be provided for evaluating controversial public health programs such as needle exchange programs, condom giveaways, and so forth?

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Suggestions for Further Reading

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