

Title: Hepatitis Studies at the Willowbrook State School for Children with Mental Retardation

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Description: From 1956 through 1971, residents at the Willowbrook State School for Children with Mental Retardation were infected with live hepatitis in order to develop a vaccine. Parents gave permission for their children to participate in this study, often because it guaranteed acceptance into the overcrowded facility.

Headings: Classic Historical Cases

Case Type: Decision making

Hepatitis Studies at the Willowbrook State School for Children with Mental Retardation

Hepatitis studies were conducted at the Willowbrook State School for children with mental retardation from 1956 – 1971. Hepatitis was a major problem at Willowbrook. Given the unsanitary conditions that the children lived in, it was virtually inevitable that children would contract Hepatitis. This further added to stigmatization of the children, a good number of who became carriers (and later were reintegrated into public schools). Dr. Saul Krugman, the principal investigator, proposed research that appeared promising in distinguishing between strains of Hepatitis and in developing a vaccine. However, his study design involved feeding children local strains of live Hepatitis – i.e., deliberately infecting them.

Krugman argued that the development of a vaccine would outweigh the anticipated minor harms to these children. He also argued that they were bound to be exposed to the same strains under the natural conditions; they would be admitted to a special well-staffed unit where they would be isolated from exposure to other infectious diseases; they were likely to have only a sub-clinical infection followed by immunity to the particular hepatitis virus; and only children with parents who gave informed consent would be included.

However, critics of the study thought the parental permission letter down played the fact that the children would be intentionally infected with Hepatitis. Moreover, due to crowding and long wait lists for admission to the school, at times the only available rooms for children were on the experimental wing, thus influencing the decision of some parents who did not have the resources to care for their children.

As an IRB member, would you approve this study as designed? If not, why? Would you request changes to the study or simply urge that it be abandoned?