Master 5.5 Answer Key
Willowbrook—Key Questions

(Fill out individually as homework.)

What is the ethical question?
Was the Willowbrook Study conducted ethically?

What are the relevant facts?

- Willowbrook State School was designed to house and care for mentally disabled children.
- Hepatitis A is a relatively mild disease affecting the liver.
- Hepatitis usually spreads from person to person when someone puts something in his or her mouth that is contaminated with the feces of an infected person.
- Krugman thought that if a child was infected with hepatitis after he or she had been injected with protective antibodies, a mild case of hepatitis would result, and the child would have long-lasting protection against future, potentially more serious, infections. He wanted to find the best ways to protect children from hepatitis.
- First studies: children in the experimental group were injected with protective antibodies and those in the control group were not; the degree of immunity to hepatitis was then observed. These studies used children already at the institution.
- Later studies: newly admitted children were isolated from the rest of the children in the facility, put in a special care unit, and given the protective antibodies. The children in the experimental group were then deliberately infected with hepatitis virus (isolated from sick children). The children who had received protective antibodies but were not deliberately infected served as the controls.
- The researchers noted that many children would become infected during their stay at Willowbrook, anyway. Krugman initially believed almost all new patients would contract hepatitis within their first year at Willowbrook (more recent estimates put the risk at 30 to 50 percent).
- Children who got hepatitis from other children had worse symptoms than those who got it from the study.
- The researchers obtained consent from the parents of each child involved in the study. Early on, information was provided to parents orally and in writing. Later in the process, parents were given the opportunity to meet the research staff, tour the facility, discuss the program with the staff and other parents, and speak with parents’ private physicians. Then, after several weeks, researchers asked for the parents’ consent.

Who or what could be affected by the way the question gets resolved?

- Children in the facility (with hepatitis and without)
- Incoming children
- Parents
- Adults at Willowbrook, including caregivers
- Other individuals with hepatitis
- Researchers
- Medical and regulatory communities
(Fill out with your partner.)

What are the **relevant ethical considerations**?

NOTE: Please see the case study and Master 5.4 for details and other possible answers.

**Pro:** The benefits outweighed the potential harms. Researchers did not expose the children to greater risks than those they would otherwise have been exposed to (there was no “excessive risk”).

1. The research provided valuable information about viral hepatitis and its treatment. It established that two types of hepatitis (A and B) occurred at Willowbrook and that injections of gamma globulin can have a protective effect against infection by hepatitis A virus.

2. In addition to this larger benefit to society, the research benefited the participants and everyone in the institution. The research reduced the amount of hepatitis among patients and employees by 80 to 85 percent because of better care. Many of the children who participated lived in a special facility where they were less likely to get sick from other diseases that were common at Willowbrook and their health could be monitored closely. Some children benefited from the vaccination as well as from the better health conditions in the special facility.

3. There was little additional risk of harm because there was so much hepatitis at Willowbrook—children were exposed to the same strain of hepatitis even if they were not in the study and had more serious symptoms if they got hepatitis naturally from other children. The researchers minimized risks by first observing the side effects of a low dose of virus.

**Con:** Respect for persons and fairness were violated. The study provided an undue inducement because students were given a coveted spot in Willowbrook in a newer part of the facility if they participated in the research. Parents and their children were not truly informed about the risks of the study. Also, it could have been done on the adults in the facility instead of the children.

1. Children in a mental health facility can’t fully understand the risks of a study they are participating in.

2. The methods by which children were recruited are also questionable. Parents were unduly induced to give their consent. For example, when the main school was closed to new admissions in 1964 due to overcrowding, parents were told there were openings in the hepatitis unit for children who could participate in the study. The public outcry over this case was largely due to the impression that parents had little choice over whether or not to participate in the research. Parents who wanted care for their children may not have had any other options.

3. There is no compelling reason to study viral hepatitis in children before studying it in adults; none of the 1,000 adults working at Willowbrook was enlisted for the study. Why wasn’t the research conducted on them first?

4. Hepatitis was present at high levels because of overcrowding and unsanitary conditions, which the healthcare professionals had a duty to improve. Instead, they took advantage of the situation to conduct an experiment.
(Fill out individually.)

Conclusions from Group Discussion

Agreement (if any)—After listening to both sides, did most people in your group agree on any points? If so, list those points here:

Answers will vary; students should justify their positions with facts from the case and reasons that relate to the ethical considerations.

Disagreement (if any)—Is there strong disagreement on any points? If so, list them here:

Answers will vary; students should justify their position with facts from the case and with reasons that relate to the ethical considerations.
(Fill out individually.)

Your Own Views

After listening to all the arguments, what are your own views on the Willowbrook Study?

- **Respect for Persons**
  Was this study respectful of the individuals involved? Why or why not?

  *Students should clearly demonstrate an understanding of the ethical consideration of respect for persons, as expressed through voluntary, informed consent. Students may also mention concern for vulnerable participants (institutionalized and mentally disabled children).*

- **Harms and Benefits**
  Did the benefits outweigh the risks (potential harms)? Why or why not?

  *Students should clearly demonstrate an understanding of the ethical consideration of harms and benefits, as expressed through the ideas of benefits to society and benefits and risks to participants.*

Do you think that researchers conducted the study ethically? Does it meet the guidelines for research that your class identified? If so, how? If not, why not?

*Students should justify their position by making specific reference to the guidelines for research the class identified.*