



Paint It Gray:

The Ethical Review Process and Research Involving People with Intellectual Disabilities

Continuing Education for USM's Institutional Review Board

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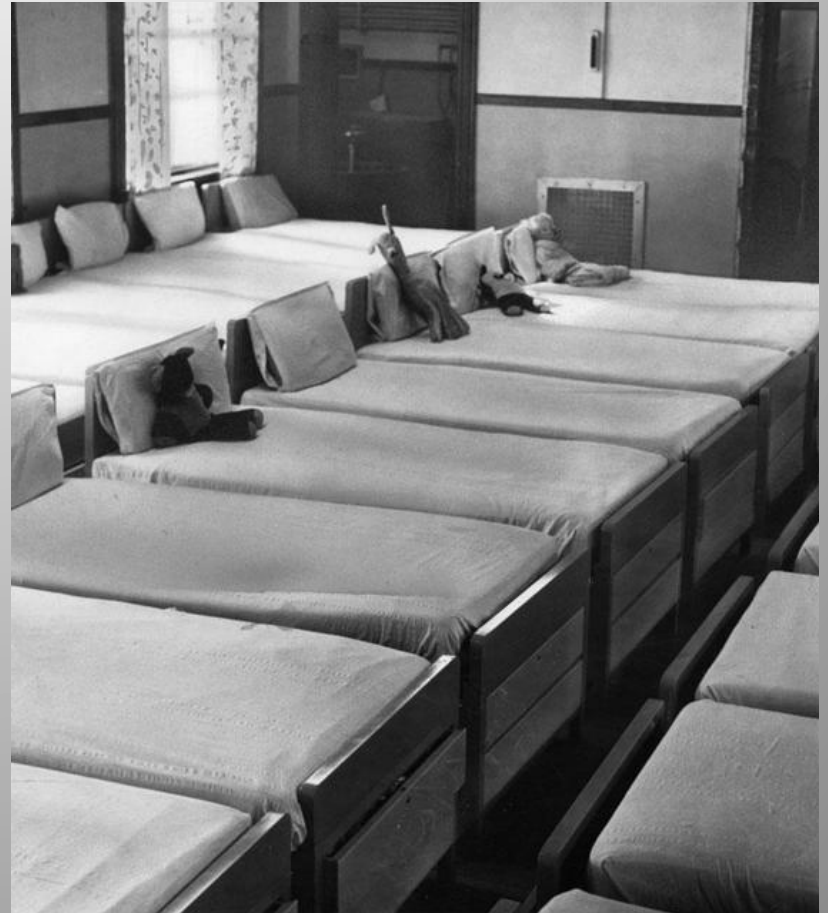
Willowbrook Hepatitis Study

Starting in 1958 the Willowbrook Study involved a group of children diagnosed with mental retardation, who lived at the State Hospital in Staten Island, New York. These children were deliberately infected with the hepatitis virus; early subjects were fed extracts of stools from infected individuals and later subjects received injections of more purified virus preparations. Investigators defended the injections by pointing out that the rate of infection in the hospital for hepatitis B was nearly 100% and that the patients' parents had consented.

Willowbrook



Willowbrook



Letter to Parents

November 15, 1958
Willowbrook Study
Staten Island, New York

Dear Mrs. _____:

We are studying the possibility of preventing epidemics of hepatitis on a new principle. Virus is introduced and gamma globulin given later to some, so that either no attack or only a mild attack of hepatitis is expected to follow.

This may give the children immunity against this disease for life. We should like to give your child this new form of prevention with the hope that it will afford protection. Permission form is enclosed for your consideration. If you wish to have your children given the benefit of this new preventive, will you so signify by signing the form.

Unethical Research

“The Willowbrook hepatitis experiment” is one of the medical studies like Tuskegee that has come to be known for its grossly unethical use of vulnerable subjects and lack of informed consent. The Willowbrook study specifically utilized children with MR as subjects, today these children would be covered as a special population under ethical research standards. What about adults?

Charlie

Charlie is 18 and quite proud of it. He often tells his parents that he can now make his own decisions.

Charlie's parents know him to be a young man who likes to follow rules and laws. They hope this will keep him out of trouble. Charlie has an intellectual disability (ID) as a result of Down's Syndrome, and he is his own guardian.

Katie

Katie is in her 20's and lives independently. Her parents have worked very hard advocating for services for her as she is diagnosed with autism and a borderline IQ. Recently, they have discovered that Katie has been lending money and credit to people who have taken advantage of her. She must now apply for bankruptcy.

Inclusion (Justice) or Protection (Benevolence)

The ethical issues related to the inclusion of adults with ID in research studies is complicated and for the most part painted gray. There is not one common consensus what best ethical practice looks like, and a number of concerns to be addressed. In addition IRBs have had a tendency toward “protection,” while researchers who may be aligned with disability rights activists lean toward “inclusion.”

Risks/Ethical Questions

- Are adults with ID able to make free informed choice about participation? What is their capacity to understand?
- Are adults with ID at greater risk for coercion? Noted in the literature are the following risk factors: communication barriers, lack of experience with decision-making, coercive social contexts and isolation.
- Will adults with ID disclose sensitive personal information without understanding the consequences to them?
- What about confidentiality? Is it particularly problematic?
- What happens when the research is over and the “research” relationship with the new found “friend” ends? Disappointment, rejection and loss have been noted.

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Psychological Harm: embarrassment, emotional distress, performance anxiety, and general discomfort.

- High -risk studies require the most vigilance and protection, but it should be noted that assessing psychological risk even in lower risk studies is complicated: For non-disabled adults, IRBs consider the features of the study in assessing risk.
- For adults with ID, psychological risk is also attributed to emotional vulnerability as it is known that these adults:
 - ✓ Are more easily traumatized by sensitive information
 - ✓ Can be easily influenced by others
 - ✓ Often lack coping skills to manage and regulate their distress. (McDonald, K.E. et al, 2009).
 - ✓ May downplay their disability appearing to be competent when they actually do not understand.

Safeguards in the Informed Consent Process: Shades of Gray?

- For all adults with ID presence of an advocate as well as a family member during the consent process.
 - ◆ What about **coercion**?
- For adults with ID who have been judged to require a guardian, a group decision including family members, staff and advocates. This may be particularly important when the guardian has little contact with the person.
 - ◆ What is the **plan**?

Assessment of Capacity

- Inclusion of psychological testing or consultation with a psychologist, medical practitioner, educational specialist or lawyer familiar with persons with ID.
- **Considerations for determining capacity:**
 - ✓ Ability to retain and comprehend information
 - ✓ Ability to appreciate that the information is of personal relevance
 - ✓ Ability to weigh information to reach a decision vs tendency to “please others”
 - ✓ Ability to communicate the decision

Potential Guidelines

For Researchers:

1. Even in low-risk studies with persons with ID the research design must be sound. Specific attention should be paid to student research.
2. Researchers should demonstrate within the proposal awareness of and preparation for the capacity to give consent. This is different than research with other adult populations where capacity is assumed.
3. Researchers should also demonstrate within the proposal that they are aware of the particular risks of including this population within even low-risk studies. Provisions should be made for addressing these risks.
4. The role of the researcher(s) must be clearly spelled out in the informed consent.

Potential Guidelines

For the IRB

5. Inclusion of at least one member on the IRB (could be a community member) designated to review proposals involving participants with ID. This IRB member should be familiar with available ethics guidelines regarding the population like those of the IASSID (International Association for the Scientific Study of Disabilities.)
6. When the person with ID has been judged incapable of consent, provision should be made to assess the guardian's relationship to the person. In cases where the relationship is distant an additional advocate or advocates should be included in the consent process.
7. As in all research proposals, consent should be a process that is reviewed on an on-going basis. This is particularly important with this population as they may have difficulty retaining information. The plan for on-going consent should be included in the proposal.
8. An invitation to report back to the IRB should be extended to all researchers who have approved studies that include adults with ID. In this way the IRB can gain greater ethical clarity in an area that is widely judged to be complex and "gray."

Resources:

Aman, M.G. and Handen, B. (2006). Reactions to “Ethical challenges and complexities of including people with intellectual disability as participants in research by Terea Iacono, Journal of Intellectual and Developmental Disability, 31(3), 180-182.

Dalton, A.J. and McVilly, K.R. (2004). Ethics guidelines for international multicenter research involving people with intellectual disabilities. Journal of Policy and Practice in Intellectual Disabilities, 1(2), 57-70.

Ellem, K. Wilson, J., Wing Hong Chui, Knox, M. (2013). Ethical challenges of life story research with ex-prisoners with intellectual disability. Disability and Society, 23(5), 497-509.

Feudtner, C. and Brosco, J.P. (2011). Do people with intellectual disability require special human subjects research protections? The interplay of history, ethics and policy. Developmental Disabilities, 17, 52-56.

Hays, S-J. and Murphy, G. (2003). Gaining ethical approval for research into sensitive topics: ‘two strikes and you’re out.’ British Journal of Learning Disabilities, 31, 181-189.

Iacono, T. (2006). Ethical challenges and complexities of including people with intellectual disability as participants in research. Journal of Intellectual and Developmental Disability, 31(3), 173-179.

Resources continued:

Iacono, T. (2006). Further comments on the researched, researchers and ethics committees: A response. Journal of Intellectual and Developmental Disability, 31(3), 189-191.

Lai, R., Elliott, D. and Oulette-Kuntz, H. (2006). Attitudes of research ethics committee members toward individuals with intellectual disabilities: The need for more research. Journal of Policy and Practice in Intellectual Disabilities, 3(2), 114-118.

McDonald, K.E. and Kidney, C.A. (2012). What is right? Ethics in intellectual disability research. Journal of Policy and Practice in Intellectual Disabilities, 9(1), 27-39

McDonald, K.E., Kidney, C.A. et al. (2009). Including adults with disabilities in research: Scientists' perceptions of risks and protections. Journal of Policy and Practice in Intellectual Disabilities, 6(4), 244-252.

McDonald, K. and Patka, M. (2012). "There is no black or white": Scientific community views on ethics in intellectual disability research. Journal of Policy and Practice in Intellectual Disabilities, 9(3), 206-214.