Passage from "Guinea Pig Kids: Myth or Modern Tuskegees?" *by Valerie Leiter & Sarah Herman published in Sociological Spectrum · December 2014:*
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Lead Paint Abatement Repair and Maintenance Study

An article in The Baltimore Afro-American in September of 1993 warned parents of the ''ever present menace'' of lead poisoning, which is credited as the ''number one environmental public health problem affecting young children'' (Battle 1993:A10). In the very next sentence, the Kennedy Krieger Institute (KKI) in Baltimore is described as leading ''the effort to rid society of lead poisoning.'' Doctors at the center, including ''an international expert in lead poisoning'' were cited, as was a mother who sang praises of the Institute. Her three young children had been treated for lead poisoning and the Institute was trying to help her find a lead-free home in which to live. ''Ms. Reedy considers the institute very special to her family. ''My son Thomas wasn't really talking, and they got him into a speech program, said Reedy. He's also in a toddler program. They really do help you here and they really care about the children,'' she said. The Public Relations director of the Institute wraps up the article, stating that ''With this 20 year reputation, and a dedicated and loving staff, we can help many, many, children. We will continue on the road to stamp out lead poisoning once and for all,'' he concluded.

This article is remarkable not just for its earnest and wholehearted endorsement of the KKI, but because it was printed when the KKI was conducting a lead abatement experiment on Baltimore children and seems designed to create trust within the African American community in that city. The international expert who was cited in the article was one of the key researchers behind the lead experiment, which ran from 1993 to 1995. The KKI's study placed children into 108 homes in 5 groups: 3 treatment groups with varying degrees of lead abatement (ranging from minimal in which peeling paint was repaired, to more extensive painting and use of floor covering and plasterboard to encapsulate lead, to all of the above plus window replacement), and 2 comparison groups (Farfel and Chisholm 1991). KKI recruited children who were living in inner city housing into the study; an estimated 40–50% of children living in these high-risk areas had ''moderate'' blood lead levels (Pollak 2002). The children were predominantly African American (Farfel and Chisholm 1991; Pollak 2004; Williams 2011). By design, some children were meant to live in housing with incomplete lead removal, to test the effectiveness of various levels of lead abatement, while their blood levels were tested periodically to measure the effect of partial abatement. The Environmental Protection Agency (EPA) funded and approved the abatement and the study, which was reviewed by the Joint Committee on Clinical Investigation of the Johns Hopkins University School of Medicine and the Johns Hopkins Hospital (Kopelman, 2002).

The families of Ericka Grimes and Myron Higgins, two of the children in the study, pursued the researchers in court, saying that the researchers did not inform them fully of the risks of participation and should have shared the results of the periodic blood-lead tests with them so that they could have taken action and prevented further harm to their children. These cases were dismissed in trial court, but the families pursued their cases to the appeals level. At the appeals level, the researchers argued that they had no duty of care to ''an institutional volunteer'' (Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 832 (Md. 2001). However, the informed consent form contradicted that position. It stated, ''We are also doing free blood-lead testing of children aged 6 months to 7 years, up to 8 or 9 times over the next two years.'' Under ''benefits,'' the informed

consent form stated that, ‘‘We would provide you with specific blood-lead results. We would contact you to discuss a summary of house tests results and steps that you could take to reduce any risks of exposure’’ (Grimes v. Kennedy Krieger Institute, Inc.). These statements implied that KKI was monitoring the children, with the aim of reducing exposure.

In August 2001, the Court of Appeals overturned the earlier decision, Grimes v. Kennedy Krieger Institute, Inc., finding for the families. In a scathing opinion, the court mentioned the Nazis' experiments on Jews during the Holocaust and said that this study ‘‘presents similar problems as those in the Tuskegee Syphilis Study conducted from 1932 until 1972 . . . the intentional exposure of soldiers to radiation in the 1940s and 50s . . . the tests involving the exposure of Navajo minors to radiation . . . the secret administration of LSD to soldiers by the CIA and the Army in the 1950s and 60s . . . and notorious use of ‘‘plague bombs’’ by the Japanese military in World War II.’’ The Court concluded, ‘‘It is clear to this Court that the scientific and medical communities cannot be permitted to assume sole authority to determine ultimately what is right and appropriate in respect to research projects involving young children free of the limitations and consequences of the application of Maryland law. The Institutional Review Boards, IRBs, are, primarily, in-house organs.’’ In this instance, the Court said that the IRB ‘‘abdicated its responsibility’’ to protect human subjects, by encouraging the researchers to misrepresent the study as therapeutic so that it would be subject to a lower standard of regulation.

In the conclusion of the Grimes decision, the court stated that ‘‘We hold that in Maryland a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject.’’ This statement seemed to prohibit any nontherapeutic research involving children, that is, research that would not benefit child participants directly. The Association of American Medical Colleges, the Association of American Universities, Johns Hopkins University, and the University of Maryland all asked the Court of Appeals to reconsider its decision because the decision seemed to eliminate research on individuals who could not legally consent to participation (who are described as having a ‘‘legal disability’’). Their letter said that ‘‘A rule prohibiting nontherapeutic research or studies in which there is any risk of injury would prohibit virtually all medical and public health research involving children and other persons under a legal disability’’ (Kopelman 2002:41). The court rephrased its decision later to state that nontherapeutic studies with more than minimal risk could not be conducted (Kopelman 2006). In this instance, the Court did not consider the children who might get lead poisoning to have a ‘‘condition,’’ deeming the project to be nontherapeutic.

KKI eventually settled the suit out of court (Kopelman 2006), but the case lives on as a contemporary classic example of tension between the goals of increasing knowledge and protecting human subjects (Glantz 2002). In 2002, the Office of Human Research Protections (OHRP) found that the Johns Hopkins University IRB had improperly reviewed the abatement study as an expedited review when the study involved more than minimal risk. In this regard, the IRB did not adequately address respect for persons through the use of informed consent, as required under federal guidelines for human subjects research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). The IRB was required to take corrective action, by changing ‘‘its procedures to require strict adherence to the requirements for expedited review of protocols,’’ creating new IRB application forms that contain additional information on consent, and requiring that the IRB include at least one pediatrician as a member (Office of Human Research Protections 2002).