



THE REBECCA PROJECT FOR HUMAN RIGHTS

Health Safety and Dignity for Vulnerable Families

Unethical Medical Research on Black and Hispanic Foster Children

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Study identification	
Study name:	<p>Multiple studies utilized Black and Hispanic foster children. An investigation of HIV-related research on foster children in New York City during 1986-2005 lists 88 studies, including 41 medication trials sponsored by NIH, 16 medication trials sponsored by pharmaceutical companies, and 31 other studies (appendix 10, Ross 2009).</p> <p>Note: Although this list includes only studies that recruited 1 or more foster children in New York City during 1986-2005, many listed studies were multi-center studies that recruited other children as well, including foster children elsewhere in the US.</p> <p>Note: I have not been able to find a list or account of medical research studies: (a) on foster children outside New York City; (b) on topics unrelated to HIV/AIDS; or (c) on HIV/AIDS research on foster children in New York after 2005.</p>
US research organization:	<p>At least 27 health and/or research institutions, including Columbia University, Johns Hopkins and University of Chicago. During 2005 and 2006, the Office for Human Research Protections (OHRP) sent Determination Letters to 27 medical research organizations concerning HIV-related research on children. Most of these letters mentioned concerns about how the institutions protected wards of the state (OHRP 2005; OHRP 2006).</p>
US funders:	NIH, pharmaceutical companies, others
Study ID number:	Many (for an incomplete list, focusing only on HIV/AIDS trials that enrolled 1 or more foster children in New York City during 1986-2005, see appendix 10, Ross 2009)
Study synopsis	
<p>Most of the studies tested drugs to treat children with HIV, including anti-retroviral drugs and drugs to treat opportunistic infections. Some of the most dangerous trials for the children were Phase I and II trials designed to determine optimum doses; very likely some children received dangerously high doses of some drugs (some information relevant to assess risks for children may be in papers published in medical journals; but a lot of relevant information may never have been published). Studies helped to establish treatment regimens that reduced HIV-related deaths in children, especially after 1996.</p> <p>Other trials were observational trials, with no interventions.</p>	
Ethical issues	
Alleged offenses	Relevant DoH, CFR clause

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Not determining the degree of risk and benefit to children involved in the research, which is relevant to whether or not the Common Rule (45 CFR 46) requires institutional review boards to appoint advocates for foster children (OHRP 2005; OHRP 2006).	CFR 46.404 through CFR 46.409
Not protecting vulnerable children (wards of the state); not appointing a legal advocate for each child in research with more than minimal risk (see pp. 226-257, Ross 2009; OHRP 2005; OHRP 2006).	CFR 46.409(b), CFR 46.111
Not obtaining informed consent from parents or, if parents are absent or have lost parental rights, from persons legally authorized to give consent (see pp. 226-257, Ross 2009).	DoH 9, 27; CFR 46.408
Public criticism, investigation, litigation	
2004	
In January 2004, journalist Liam Scheff published a criticism of HIV-related research on foster children at the Incarnation Children's Center in New York city, alleging that trials tested dangerous drugs that harmed children. Although Scheff is a denialist (believing that HIV does not cause AIDS) some of his claims have been verified by independent reporters.	
In 10 March 2004, the Alliance for Human Research Protection, a private organization, filed complaints with FDA and OHRP alleging that Columbia University Medical Center had conducted unethical Phase I and Phase II drug trials on foster children (see Statement of Vera Hassner Sharav in Subcommittee on Human Resources 2004).	
On 16 March and 16 December 2004, OHRP sent letters to Columbia University Medical Center and New York Presbyterian Hospital raising questions about risk assessment and protections for foster children in several ongoing HIV-related research studies. OHRP's communications with these organizations continued into 2005 (OHRP 2005).	
In November 2004, the British Broadcasting Corporation aired Guinea Pig Kids, based in part on Scheff's allegations.	
2005	
On 4 May, Associated Press distributed an article by John Solomon that expanded the story beyond New York City. Charges include: in Chicago, none of almost 200 foster children got independent monitors; children in trials of dapsone (proposed to prevent pneumonia in HIV-positive children) suffered drug toxicity, and those taking the drug daily had higher death rates (Solomon 2005).	
On 18 May 2005, the Subcommittee on Human Resources, Committee on Ways and Means, US House of Representatives, held hearings on Protection of Children Enrolled in Clinical Trials (Subcommittee on Human Resources 2004). None of the foster children involved in HIV-related research or their parents testified. The Alliance for Human Research Protection provided the only critical testimony directly linked to HIV-related research on foster children (see Statement of Vera Hassner Sharav in Subcommittee on Human Resources 2004).	
New York City contracts with VERA Institute for Justice to investigate possible abuse of foster children in HIV-related research during 1986-2005; VERA reported the results from its investigation in 2009 (see discussion of VERA's 2009 report, below).	
On 21 May, the General Welfare Committee of the New York City Council held a public hearing on foster children in medical research.	
On 8 September, the New York State Assembly Standing Committees on Health and on Children and Families held joint hearings on foster children in medical research.	
2006	

	During 2006 OHRP sent letters to several dozen institutions raising questions about HIV-related research on children. Most of the letters noted concerns with protections for foster children (OHRP 2006).
	2009
	<p>In January 2009, the VERA Institute for Justice issued a 506-page report summarizing its investigation of HIV-related research on foster children in New York City during 1986-2005. VERA began its investigation in 2005 at the request of the New York City Administration for Children’s Services. From a review of records, VERA identified 532 foster children who participated in one or more of 88 HIV-related studies during 1986-2005. The investigation found deficiencies in processes – eg, not asking for informed consent; enrolling children in trials which not approved according to the City’s established policies (see pp. 226-257, Ross 2009). The investigation did not find evidence that research harmed children, or that HIV-negative children were mistakenly included in trials intended for HIV-positive children.</p> <p>However, VERA did not contact any of the children who had been involved in the trials, did not get access to any of their medical records, and interviewed only two care-givers. Considering that NIH, drug companies, and medical research teams had been able to find and work with hundreds of HIV-positive children in New York City, it is puzzling that VERA was unable to do so as well. It is also puzzling that medical files would be unavailable to a team contracted to investigate the charge that research had damaged children’s health. VERA’s investigation did not do what was required to determine if errors in procedures and/or deficiencies in regulations harmed the health of foster children.</p>
	2011
	Rebecca Project (2011) noted lack of any legal penalties for those involved in unethical and illegal research on foster children, despite OHRP’s complaints and 2005 Congressional hearings on the matter.
	2011
	Kwame Fosu, Policy Director for the Rebecca Project, states: “There has been a deep callousness and racism regarding Black people being exploited and harmed as human subjects. Foster children are the most vulnerable of vulnerable populations, and therefore should NEVER be recruited for research except under the watchful scrutiny of legal child advocates, and only for the most compelling and rational reasons to save their lives. The Rebecca Project does not believe that recruitment of so many Black and Hispanic foster children for HIV-related research is a simple a coincidence. Similar to the victims of syphilis research in Tuskegee and Guatemala (60 years ago), these new victims have to be compensated for being unethically and often illegally exploited in human experiments, at times without informed consent.”
	References
	Office for Human Research Protections. 2005 Determination Letter to Columbia University Medical School/New York Presbyterian Hospital on 5 May. Available at: http://www.hhs.gov/ohrp/detrm_lettrs/YR05/may05c.pdf (accessed 8 March 2012). [This letter refers to previous OHRP letters to the two institutions on 16 March and 16 December 2004.]
	Office for Human Research Protections. 2006 Determination Letters. Available at: http://www.hhs.gov/ohrp/compliance/letters/2006.html (accessed 7 March 2012). All letters during 2006 dealing with HIV-related research on children are listed below, with links. Most but not all of these letters raise concerns about protections for foster children (wards of the state): February <ul style="list-style-type: none"> • February 17, 2006 Bellevue Hospital Center • February 17, 2006 Bronx-Lebanon Hospital Center • February 17, 2006 Children’s Hospital - Denver • February 17, 2006 Children’s Hospital - Oakland

<ul style="list-style-type: none"> • February 17, 2006 Children's Hospital - Philadelphia • February 17, 2006 Children's Hospital & Regional Medical Center • February 17, 2006 Columbia University Medical Center/New York Presbyterian Hospital • February 17, 2006 Cook County Bureau of Health Services • February 17, 2006 Harbor-UCLA Medical Center • February 17, 2006 Johns Hopkins Health System • February 17, 2006 North Shore-Long Island Jewish Health System • February 17, 2006 SUNY Stony Brook • February 17, 2006 SUNY Upstate Medical University • February 17, 2006 University of Chicago • February 17, 2006 University of Maryland Baltimore Professional Schools • February 17, 2006 University of Medicine and Dentistry New Jersey/New Brunswick <p>June</p> <ul style="list-style-type: none"> • June 19, 2006 Bronx-Lebanon Hospital Center • June 19, 2006 Universidad Central del Caribe • June 19, 2006 Children's Hospital of the King's Daughters • June 19, 2006 Children's Hospital and Research Center at Oakland • June 19, 2006 University of Medicine and Dentistry of New Jersey • June 19, 2006 Bellevue Hospital Center • June 19, 2006 Children's Hospital and Regional Medical Center • June 19, 2006 SUNY Upstate Medical University • June 19, 2006 Drexel University College of Medicine • June 19, 2006 Cook County Bureau of Health Services • June 19, 2006 Children's Hospital of Philadelphia • June 19, 2006 Duke University School of Medicine • June 19, 2006 University of Miami • June 19, 2006 University of Chicago • June 19, 2006 Children's Hospital of Orange County • June 19, 2006 Children's Memorial Hospital • June 19, 2006 San Juan City Hospital • June 19, 2006 University of California, San Francisco • June 26, 2006 University of Maryland Baltimore School of Medicine <p>July</p> <ul style="list-style-type: none"> • July 21, 2006 San Juan City Hospital <p>August</p> <ul style="list-style-type: none"> • August 15, 2006 Children's Hospital of Philadelphia • August 28, 2006 Cook County Bureau of Health Services • August 28, 2006 Drexel University College of Medicine
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