

## A Matter of Justice: Foster Children as Human Subjects

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*Voices in Bioethics*  
Winter 2014

In April of 2001, I visited Emmanuel A. at the Incarnation Children's Center ("ICC"). Emmanuel was one of my first clients.<sup>1</sup> He had come into foster care at birth. His mother was young, a recent immigrant, addicted to heroin, and living in poverty. Her first two sons were born in Nigeria, full-term healthy babies. Emmanuel was born eight weeks premature, addicted to heroin and HIV positive. His two older brothers lived with the children's maternal aunt; Emmanuel's home was the Incarnation Children's Center, a nursing home for children with AIDS. In 2002, Emmanuel was adopted by his aunt, and I shipped his file to offsite storage. Emmanuel's was not a remarkable case.

A decade later I am pursuing a master's in bioethics. For the past three years I have been a member of the Institutional Review Board (IRB) at a large teaching hospital, and I have entered my second decade as an attorney representing children in foster care. My head is clouded with images of foster children and clinical trials, vulnerable subjects, and ethical valuations. And suddenly I remember Emmanuel and ICC. I remember arriving at the brick building on Audubon Avenue and being ushered upstairs to a large recreation room. The floor was littered with brightly colored toys, the walls camouflaged in children's art. I had never met a child with AIDS. The childcare worker who had escorted me to the floor identified Emmanuel for me. He was a smaller-than-average four-year-old who was throwing himself over furniture like a miniature pro-wrestler. I remember thinking, "He can't be Emmanuel." I had studied his records before coming. My Emmanuel had a gastronomy tube and was sick with AIDS. He did and he was. But his feeding tube, I learned, would connect to a port that was invisible under his striped polo shirt, and having AIDS, I learned, doesn't mean you can't play. Emmanuel and I talked a little and played a little. I remember that. I also remember fighting for his discharge from ICC. The Commissioner of Social Services, to whom Emmanuel's care and custody had been committed, and the staff at ICC did not believe that his aunt could care for him at home. They claimed his medications were too involved and his illness too progressed for home care. During the winter of 2001, Emmanuel was discharged to his aunt's care and was adopted sometime the following year.

I remember and now I wonder: Was Emmanuel among the roughly 486 foster children enrolled in HIV/AIDS clinical trials in New York City between 1977 and 2001? What was being delivered through his G-tube? Enteral nutrition? Experimental drugs? Why did we have to fight so hard to get him home? Sickness? Fear of losing a human subject? Could I have known? Was there anything to know?

In the 1980s, AIDS tore through this city and left behind children like Emmanuel. There were thousands of them; between 1977 and 2006 nearly 4 thousand New York City children were born HIV positive.<sup>2</sup> The *New York Times* reported that of these children "who were born HIV positive, as many as one in five...were dying before the age of two and up to 50 percent were dead by four."<sup>3</sup> Almost 40 percent of the city's HIV-positive children were

in foster care. Children were dying, families and physicians were desperate for options, and the available treatments had never been tested in a pediatric population. Human subjects were needed to test the safety and efficacy of anti-retroviral drugs, but the subjects had to be small. Very small. And the Incarnation Children's Center was brimming with them.

In the winter of 2004, the red brick building on Audubon Avenue became a symbol of devastating human rights violations. In February of that year, self-proclaimed conspiracy realist Liam Scheff web-published an article titled "The House that AIDS Built." In his exposé, Scheff excoriates the Incarnation Children's Center and its affiliates, Columbia Presbyterian and Catholic Charities. He alleged that AIDS-infected children living at Incarnation were used as test animals—plied with drugs such as AZT and Nevirapine, drugs that were not approved for children. These children, Scheff said, fell ill from the medications and were left to die. Scheff spoke to relatives of the children at Incarnation. They reported that their sons, sisters, nieces, and nephews were forced into surgeries to insert gastrostomy tubes because they refused to take medication that made them sick. The families reported that these surgeries, which were performed at Columbia Presbyterian, were done without familial consent. Scheff alleged that the gastrostomy ports were left in children, untended, for years at a time. The *New York Post* quickly picked up Scheff's story, and in July 2004 a *New York Press* headline screamed: "Abandoned kids are force-fed experimental AIDS drugs at a Catholic children's home in Washington Heights. And the city wants it that way." On November 30, 2004, the BBC aired the documentary *Guinea Pig Kids* based on Scheff's investigation. The opening image: an IV being inserted into the arm of a toddler, arms flailing, as she is being fed into the gaping mouth of an MRI machine. By the dawn of 2005, Scheff's murmur had grown to an international chorus of outrage.

On April 22, 2005, the Administration for Children's Services (ACS) issued a press release acknowledging that "approximately 465 children likely participated in [clinical] trials between 1988 and 2001." They announced a new contract with the Vera Institute of Justice. Vera would conduct an "independent review of ACS policy and practice regarding the enrollment of HIV-positive children in foster care in clinical drug trials during the late 1980s and 1990s." Among the concerns that the Vera Institute would investigate were whether the research conducted was "based on sound medical knowledge," whether proper consent was obtained, and whether the children who were enrolled were monitored diligently and in accordance with the current ACS protocols.<sup>4</sup>

Accountability was demanded from Incarnation and ACS, as well as the sponsors of the trials and the hospitals that had participated. Following Scheff's exposé, the Alliance for Human Research Protection (AHRP) filed an official complaint with the Office for Human Research Protections (OHRP) against Columbia University Medical Center (CUMC). After a lengthy investigation, OHRP found that CUMC had failed to meet regulatory compliance pursuant to 45 CFR §46.111(a) and (b). The statute places upon IRBs the responsibility of making specific determinations prior to approving research and demands they be particularly cognizant of the special problems of research involving vulnerable populations. According to OHRP, the CUMC IRB failed to meet regulatory requirements because, *inter alia*, they had not obtained sufficient information regarding safeguards required by statute to protect wards of the state and had failed to obtain sufficient information regarding the

selection of wards of the state and foster children as research subjects. Additionally, OHRP found that the CUMC “records demonstrate[d] a failure...to obtain sufficient information regarding the process for obtaining permission of parents and guardians for wards of the state or foster children.”<sup>5</sup>

Although some of the most sensational allegations lobbed against the Incarnation Children’s Center, ACS, and CUMC remain unverified or discredited, the Vera Institute’s final report published in 2009 found serious regulatory and policy violations. Among their findings: Twenty-one children participated in clinical trials despite ACS’s Medical Advisory Panel (MAP) recommending otherwise; 64 children participated in trials without the MAP reviewing their cases; there were no signed informed consent documents in the case files of 21 percent of the children enrolled in clinical trials; in some cases where consent was obtained, it was not obtained from a legally authorized person; and in at least 16 cases ACS never approved or consented to children in their custody being enrolled in a clinical trial. Ultimately, investigative journalism, internal reviews, and the Vera Institute’s findings confirmed the perpetration of serious human rights violations against children in foster care.

It has been just under nine years since Scheff’s exposé. Today, when I mention the prospect of children in foster care participating in clinical research, the responses I receive range from visible shudders to colorful indignation. But I persist. I recently spoke with the director of a leading New York City adolescent health center that routinely provides standard of care treatment to adolescents in foster care. Despite frequent applications to IRBs for research approval, the center rarely requests approval to enroll wards of the state. When I asked the director why such a large portion of her patient population was so underrepresented in clinical research, her response was short and telling: they’ve never been able to obtain IRB approval, so they’ve stopped trying. Next, I approached the chair of an IRB and asked why research involving wards of the state is rarely (never?) approved. The answer: it’s just too dicey. Regulatory compliance is stressful enough without adding controversial research into the mix.

In the three years I sat on an IRB, I was involved in the review of over 200 studies and only once saw a submission that allowed for the inclusion of children in foster care. The study was approved, but the approval was conditioned upon the principal investigator amending the research protocol to exclude wards of the state.

A fair question is, why should I care? What’s the big deal if children in foster care are excluded from research? In fact, as an attorney for children in care, shouldn’t I find their inclusion as human subjects troublesome, if not offensive? It is precisely because of my decade of representing these children that I balk at a *per se* exclusion of foster children from clinical research. The child welfare system frequently treats dignity as a disposable commodity. Self-respect and clothing are carried in garbage bags from foster home to foster home. For children in care it is meaningful to be allowed to participate, but allowance without opportunity is just a hypothetical construct, another castle in the air.<sup>4,5</sup> CFR §46.409 explicitly allows for the participation of wards of state in human subject research.<sup>6</sup> The statute is clearly drafted with the intent to provide deserved protection to a vulnerable class. Had the legislative intent been to exclude the mentally ill, or children, or

prisoners, or any of the other protected groups, then “thou shalt not perform research on any vulnerable classes” would have been a better choice. Why isn’t that what the legislature chose? Isn’t it the safer, more prudent course, the course that will keep us from repeating the horrors of Holocaust research, the seed from which human subject protection sprouted and grew wild?

Children in foster care share the same fate, perhaps to a greater extreme, as other vulnerable classes. Overprotection results from the following formula: at some point in recent history, a class was egregiously and offensively experimented upon—the examples are many--the children at Willowbrook, prisoners in Alabama state penitentiaries, the syphilitic men of Tuskegee all provide damning tales of physical and psychological abuse perpetrated on figuratively and literally captive audiences. And from these experiments regulations were born. These regulations present strict parameters, sometimes seemingly unattainable standards, which have had the practical effect of repelling research. But even more unforgiving than the regulations is public memory. The memory of Tuskegee and the Holocaust victims, Willowbrook, and foster children with AIDS, crowds and clouds the public perception of human subject research. Collective memory is a difficult thing to change. The media doesn’t cover uneventful research—who would read that story?

While societal response to human rights violations is a vital and often accurate barometer of current ethical culture, public opinion, or fear of it, should not be the final arbiter of what constitutes ethical research. A thoughtful investigator pondering the choice of who to include or exclude from research should reflect upon public opinion, but also upon ethical guidelines and extant legislation. The researcher does not need to look further than the Belmont Report to learn that the inclusion of vulnerable classes is not just permissible but demanded by the principle of justice. Belmont’s foundational question of justice is, “Who ought to receive the benefits of research and bear its burdens?” The principle of justice demands that those engaged in human subject research carefully weigh its benefits and burdens and ask themselves if their selection of subjects is fair. Are the burdens proportionately allocated? Were the burdens accepted knowingly in the spirit of respect for persons? Thoughtful research that embodies the spirit of justice takes into account not just who but why. Have subjects been selected because they are easy targets without capacity or voice to object? Or were they selected because they are representative of the population being studied? Are they excluded because to include them would be to exploit their vulnerability or because their inclusion would be an administrative nightmare? The principle of justice stands for children in foster care having the right to be proportionately included within human subject research. They should have the right to reap its benefits and shoulder its burdens.

There are many areas of research where participation of children in foster care may provide opportunity for direct benefit to the individual subjects and/or the foster care population, generally. An example is asthma research. Inner-city children are disproportionately represented in the pool of asthmatic children, as well as the pool of children in foster care.<sup>7</sup> Often these children are over-treated and undermonitored.<sup>8</sup> Pediatric asthma studies abound. An example is a study funded by the National Institute of Allergies and Infectious Diseases (NIAID), whose study population comprised inner-city

children suffering from chronic asthma. Among the list of exclusion criteria: living with a foster parent. Despite their over-representation in the research population, foster children were excluded. They were deprived of the possibility of direct benefit from the study drug and the inherent benefit in continued close monitoring of their asthma.

A second example is the plethora of studies currently being conducted around therapeutic interventions for post-traumatic stress disorder (PTSD). Frequently children in foster care are misdiagnosed with attention deficit hyperactive disorder (ADHD) and oppositional defiant disorder (ODD). They present with hyper-arousal and documented cognitive difficulties and are forthwith prescribed psychotropic medication at a rate four times greater than their peers who are not in care.<sup>9</sup> Trauma-focused cognitive behavioral therapy (TF-CBT) has emerged as a promising treatment modality for PTSD. Randomized controlled trials of TF-CBT rarely include foster children, despite the marked prevalence of PTSD in the foster care population. Participation in TF-CBT trials has the potential for direct benefit for these children, should they be allowed to participate. Not only would it provide them with the possibility of receiving a highly regarded treatment intervention, but the control group in these trials receive consistent standard of care mental health treatment, a service that children in care wait for indefinitely. Additionally, the knowledge gained from this type of research would undoubtedly benefit the foster care population as a whole.

Opponents may argue that the fact that children in care were over-represented in the AIDS population situated them perfectly for exploitation. I don't disagree. They may argue that ACS struggles to monitor the health and well-being of its wards without the added level of scrutiny required for those involved in research. I don't disagree. They may argue that children in foster care frequently lack a parent or caregiver who can monitor the effects of study drugs or advocate for study termination. I don't disagree. But the proper response to these arguments is caution, deliberateness, and accountability, not paternalistic overprotection.

Today, the legacy of the Incarnation scandal is a *de facto* barring of a foster children from human subject research. This blanket exclusionism is injustice hiding behind the mask of ethical research. For far too long we have allowed ourselves to be blinded by history rather than guided by it. As a research community, we have the responsibility as well as the power to rewrite this legacy. The time has come to renew our commitment to the principle of justice. "To each person an equal share."<sup>10</sup>

#### References:

1 Names and identifying information altered to protect privacy.

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4 The Administration for Children's Services: Press Office, 2005, *ACS Contracts with Vera Institute of Justice to Conduct Historical Review of Enrollment of Foster Children in Clinical Trials for Aids Treatments*. [Press Release].

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5 Department of Health and Human Services, "Letter to Harvey R. Colten, M.D. and Laura L. Forese, M.D. Columbia University Medical Center," May 23, 2005.

[http://www.hhs.gov/ohrp/detrm\\_lettrs/YR05/may05c.pdf](http://www.hhs.gov/ohrp/detrm_lettrs/YR05/may05c.pdf).

6 Title 45 of the Code of Federal Regulations: §46.409 Wards. (a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is: (1) Related to their status as wards; or (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. (b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

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