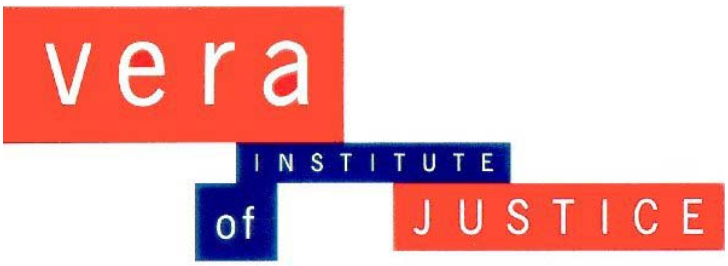



# Clinical Trials Project: Progress Report 2

Vera Institute of Justice
January 2006

This report is the second in a series of quarterly progress reports describing the Vera Institute of Justice's review of issues related to the enrollment of foster children in clinical trials of HIV and AIDS treatments during the late 1980s and 1990s.[1] It covers the quarter running from October 1, 2005 to December 30, 2005. The current report describes:

1. Lessons learned from the planning process.
2. Development of a research protocol and IRB submission,
3. Advisory Board and IRB member recruitment,
4. Outreach activities,
5. Testimony at City Council hearing, and
6. Next steps.

This report also contains two appendices: charts that describe some of the characteristics of the foster children believed to have enrolled in clinical trials and the testimony of Vera's director, Michael Jacobson, at a recent hearing before the New York City Council.

**Summary**: In October and November of 2005, Vera staff conducted a planning review of case management files from the Administration for Children's Services (Children's Services), case planning documents from agencies that contract with Children's Services, documents from the Pediatric AIDS Unit at Children's Services, and policy memoranda. This work led to the drafting in December of a detailed research protocol. This protocol includes interview questionnaires for key respondents, a data abstraction form that will guide our staff in reviewing the files of the children who were involved in clinical trials, and a memo to Vera's Institutional Review Board. We continue to reach out to people and groups involved in this issue, have neared completion of our advisory board, recruited an additional member to our Institutional Review Board (IRB), and testified at a hearing of the New York City Council's General Welfare Committee.

## 1. Lessons learned from the planning process

During the planning process, we reviewed approximately 20 cases of individual children who Children's Services believes participated in clinical trials. We also began analyzing the data contained in the Child Care Review Service (CCRS), an electronic database containing administrative data.

Below is a list of the file types that Vera staff reviewed and some of the lessons learned:

a. Children's Services case management files. Case management files are kept by Children's Services as part of their oversight responsibilities. A typical case

[1] In the spring of 2005, New York City's Administration for Children's Services asked Vera to explore issues related to the enrollment of approximately 465 foster children in clinical trials of HIV and AIDS treatments during the late 1980s and 1990s. In conducting this review, Vera staff will identify the established processes for enrolling and monitoring these children, determine whether those procedures were followed, and report on the condition of the children today. Vera signed the contract to do this work on June 28, 2005.

management file contains information on the investigation of child maltreatment that led to the child's placement in foster care; regular reviews that describe a child's experience in his or her foster care placement; notes on visits from parents and relatives; educational, psychological, and social work assessments of the child; and a range of other information. Case management files are family files and usually contain information about other siblings as well, making them time consuming to read through but also a source of extensive information about the case.

On average, it takes about three hours to read through each case management file. One of the lessons we learned is that it is not possible to pick out a few key papers in a document to get the information we need. Reading the whole case file, as time consuming as this may be, is the only way to ensure that all the information is properly reviewed.

b. Contract agency case planning files. These are files kept by private nonprofit agencies that Children's Services contracts with to provide most foster care in New York City. Because these files are stored at the agencies themselves and would cost many thousands of dollars to duplicate, we will review the files at the individual agencies after they have retrieved the files from storage. We reviewed fewer of these files compared to the case management files described in part a above, but those we did review contained detailed child care and medical information.

c. Pediatric AIDS Unit files. The Pediatric AIDS Unit (PAU) was originally set up as part of Children's Services' predecessor agency, the Child Welfare Administration, which was part of the Human Resources Administration. Files kept by the PAU contain correspondence between the medical researchers and the PAU, informed consents, correspondence about the situations of individual children, monitoring records, and some policy-related documents. Some files contain medical records as well. The PAU files were not well-organized when this study began. Some files were labeled with the names of individual children, some with the clinical trial number, and still others had no labels at all. The materials inside of the files often did not match the label; at times, they combined clinical trial level data, such as lists of children enrolled, with information related to the enrollment and monitoring of individual children.

   Children's Services has organized much of this information over the past several months. During this time, Children's Services also reconstructed some of the data lost when a computer that contained the PAU's electronic database of children in clinical trials and the results of HIV tests crashed in 1996. The agency is planning to develop a new database to store this information.

d. Policy Memoranda. Both the PAU and the Commissioner's Office maintained files related to the development and implementation of HIV testing and clinical trials policy. These files contain official policy bulletins and discussions of policy

development. In reviewing these files, we also did a preliminary review of meeting notes from the Medical Advisory Panel (MAP), a group of staff attorneys, medical personnel, and HIV/AIDS specialists that reviewed clinical trials to see if they were appropriate for foster children.

e. Child Care Review Service (CCRS). The CCRS is an electronic database containing administrative data such as information about a child's movements in the foster care system and changes in the permanency planning goals for the child. The charts in Appendix I are based on CCRS data and provide more detailed information on the approximately 465 children who Children's Services believes participated in clinical trials. *This analysis is preliminary.* As part of Vera's document review, we will confirm the participation of each child and also verify that children are not "double counted" for any reason, such as a change in their name. We expect any changes in the charts to be small and will explain any significant revisions.

   Our preliminary analysis of the CCRS suggests that most of the children who participated in clinical trials were born and entered care during the late 1980s and early 1990s. Most entered care before age two, and left care after an average stay of four years. Approximately 17 percent of the children died while in care, a rate far higher than typically seen among foster children and which reflects the increased risk faced by HIV infected children. Two-thirds of the children were adopted, about one in ten returned to their family, and one in twenty aged out of foster care. Few children had more than one spell in care and only a handful had more than two. Today, most of the surviving children are in their mid-teens, though some are as young as ten years old and others are in their 20s.

2. Development of a research protocol and IRB submission

During December, we neared completion of a research protocol, which is a more detailed plan that specifies the methods and data sources Vera will use to answer specific research questions. The research protocol will be reviewed by Vera's advisory board, chaired by Dr. Richard Dudley (see section 3 below); the Children's Services Medical Oversight Committee, chaired by Dr. Robert Johnson, dean of School of Medicine and Dentistry of New Jersey; and the Commissioner's HIV/AIDS Health Care Advisory Board, chaired by Debra Fraser-Howze, CEO and President of the National Black Leadership Commission on AIDS.

Because this is a project that involves human beings as research subjects, it will be reviewed by Vera's Institutional Review Board (IRB), which is composed of people trained in the rules and ethical concerns of research protocols. Before submitting a project for review, researchers need to explain to the IRB what they plan to do and how they plan to protect human subjects. The review will be done in two stages—and has changed slightly since our last progress report. The first IRB review, scheduled for February 9th, will cover the document review and interviews with people who know about the development and implementation of policy at Children's Services and its predecessor

agencies and people who know about how the clinical trials were conducted, such as researchers and National Institutes of Health officials. Our second IRB review will cover the most sensitive task in this project: interviewing children who participated in clinical trials and their caregivers. The IRB submission of this part of the study is still being developed in consultation with community advocates, HIV/AIDS service providers, and social science experts.

The IRB submission has many parts. It includes an assessment of risk to human subjects, how those risks will be minimized by Vera, and how this work adheres to federal guidelines. For all information, the IRB examines how we plan to protect the confidentiality of the data. It also includes the lists of questions we plan to ask each person we hope to interview. The submission contains informed consent forms that explain what types of questions we will ask in interviews and the risks and benefits of participating in the research. After discussing the informed consent form with Vera staff, each person we interview will decide if he or she wants to participate.

3. Advisory Board and IRB member recruitment

As discussed in our last update, Vera will have an independent advisory board to provide guidance on research methods, issues related to child welfare and medicine, community engagement, and bioethics. This board is chaired by Richard G. Dudley, MD. Dr. Dudley, a Vera trustee, divides his work between a clinical practice focused primarily on the evaluation and treatment of African-American men and a forensic practice. As a forensic psychiatrist, Dr. Dudley is frequently called upon to provide expert opinion and testimony in connection with both criminal and civil matters throughout the United States.

Earlier in his career, Dr. Dudley was Deputy Commissioner of the New York City Department of Mental Health, Mental Retardation, and Alcoholism Services. Dr. Dudley was also an original member of the National Black Leadership Commission on AIDS. Subsequently, he became Medical Director of the Washington Heights-West Harlem Community Mental Health Center. He currently teaches at New York University School of Law and at the City University of New York Medical School.

Vera has recruited several people to serve on the advisory board. We plan to announce the members of the board in January.

As part of its IRB process, Vera has recruited Dr. Fleda Mask Jackson, a professor at the Rollins School of Public Health at Emory University, to serve as the child advocate during the review process. Dr. Jackson is known for her research on stress and African-American women and will bring years of experience in participatory research involving families of color to the IRB process. We are grateful that Dr. Jackson has agreed to serve on our IRB for this project.

4. Outreach

There are a range of views on what happened when children were enrolled in clinical trials in the past and on what the child welfare system should do in the future. We feel it is important to hear and understand this range of opinions so that we can take diverse perspectives into consideration as we do our work. This work builds on the outreach activities described in our first progress report.

In October, we attended the annual meeting of the Pediatric AIDS Clinical Trials Group (PACTG). PACTG is a group of doctors and medical researchers working to improve treatment for pediatric HIV/AIDS and is an independent nationwide consortium funded through the federal government's National Institutes of Health. We also attended a meeting of a community advisory board of a current pediatric HIV/AIDS clinical trial. Often part of clinical trials processes, community advisory boards are composed of children, youth, caregivers, and clinical trial staff who meet to discuss issues and solicit input on specific clinical trials. We also met with one of the medical researchers who conducted pediatric clinical trials.

In December, we met with Children's Services' HIV/AIDS Health Care Advisory Board—a group of community-based health service providers and advocates chaired by Debra Fraser-Howze, CEO and President of the National Black Leadership Commission on AIDS (NBLCA). Future meetings of this group that we will attend are scheduled in January and February. We also met with community advocates who have testified at hearings or are otherwise involved in this issue.

To assist us in the research aspects of our study, we met with academics who have experience interviewing HIV-infected children and using questionnaires that assess a child's health and well-being. We also met with a veteran social work professor to discuss appropriate ways to interact with the children and to identify people who might help us with this study. In addition, we met with a senior law guardian to discuss the role of law guardians in the enrollment of children in clinical trials.

We have also had discussions with Dr. Robert Johnson, chair of Children's Services Medical Oversight Committee, and with staff of the Children's Services Policy and Planning division to discuss issues related to the Child Care Review Service database and the state central registry. We have also had meetings with Children's Services' Office of Child and Family Health to discuss the organization of the case files and the logistics of reviewing those files.

5. Testimony before the New York City Council

On December 20th, the New York City Council's General Welfare Committee, chaired by Councilmember Bill DiBlasio, held a hearing that included on the agenda the participation of foster children in clinical trials. Vera's director, Michael Jacobson, and

the project's principal and co-principal investigators, Timothy Ross and Anne Lifflander, testified at the hearing. Michael Jacobson's testimony is included in Appendix II.

6. Next Steps

In the next quarter, we plan the following activities:

a. Comment on the draft of Children's Services' new clinical trials policy as requested by the New York City Council,
b. Announce the members of Vera's Advisory Board,
c. Present the research protocol to the various advisory boards cited in section 2,
d. Research options and choose appropriate technology for safe data transportation and storage,
e. Present the first part of the study to the IRB,
f. Hire and train staff who will begin conducting the formal document review,
g. Start interviewing key respondents,
h. Meet with Children's Services' HIV/AIDS Health Care Advisory Board to discuss outreach to children and caregivers involved in clinical trials , and
i. Continue analyzing data from the Child Care Review Service described above.

Appendix I: The information that follows comes from our preliminary analyses of data from the Child Care Review Service, as discussed in section 1e of this report. The charts describe the approximately 465 children identified by the New York City Administration for Children's Services as having participated in HIV/AIDS-related clinical trials.

Chart 1:

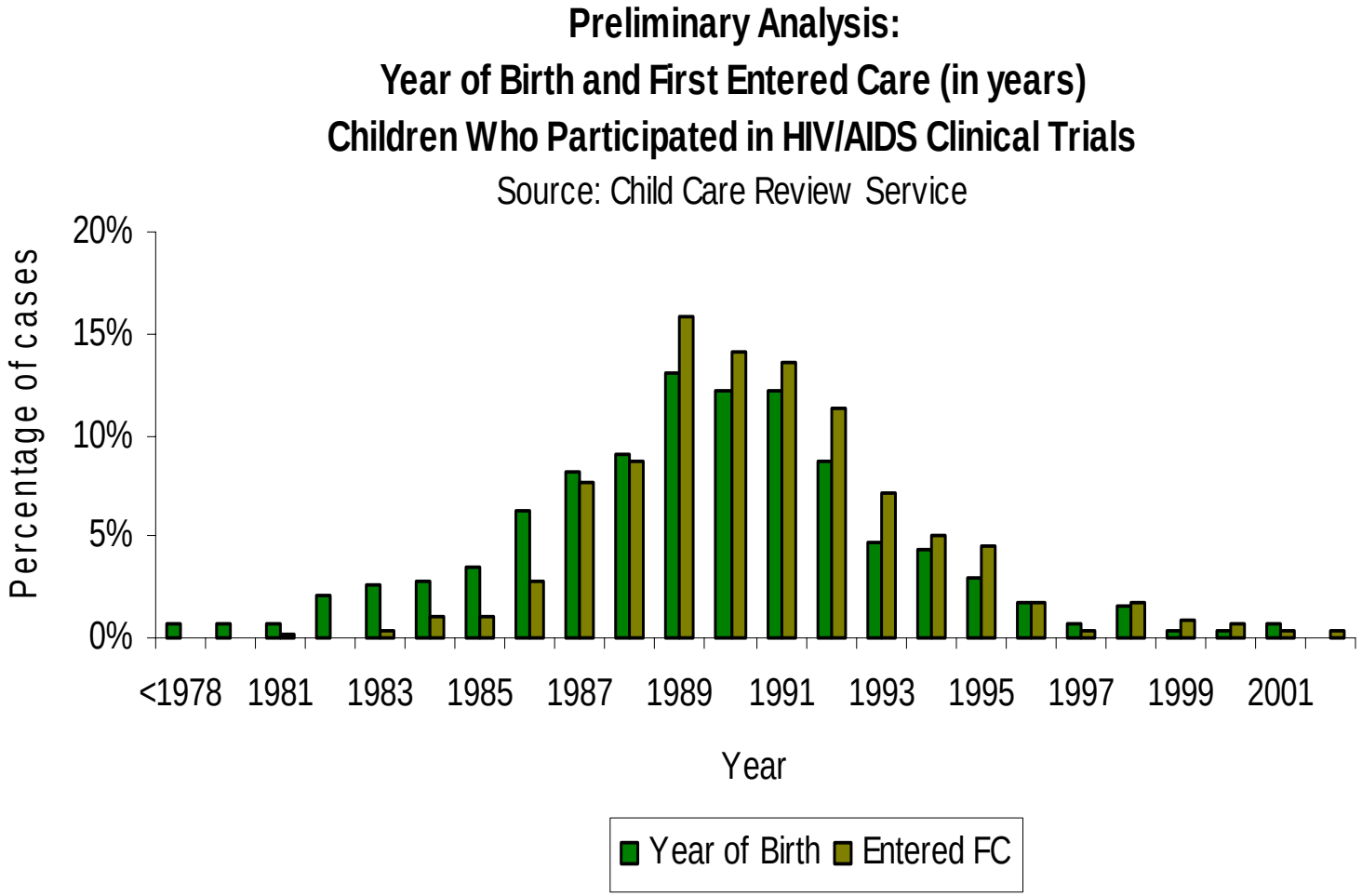
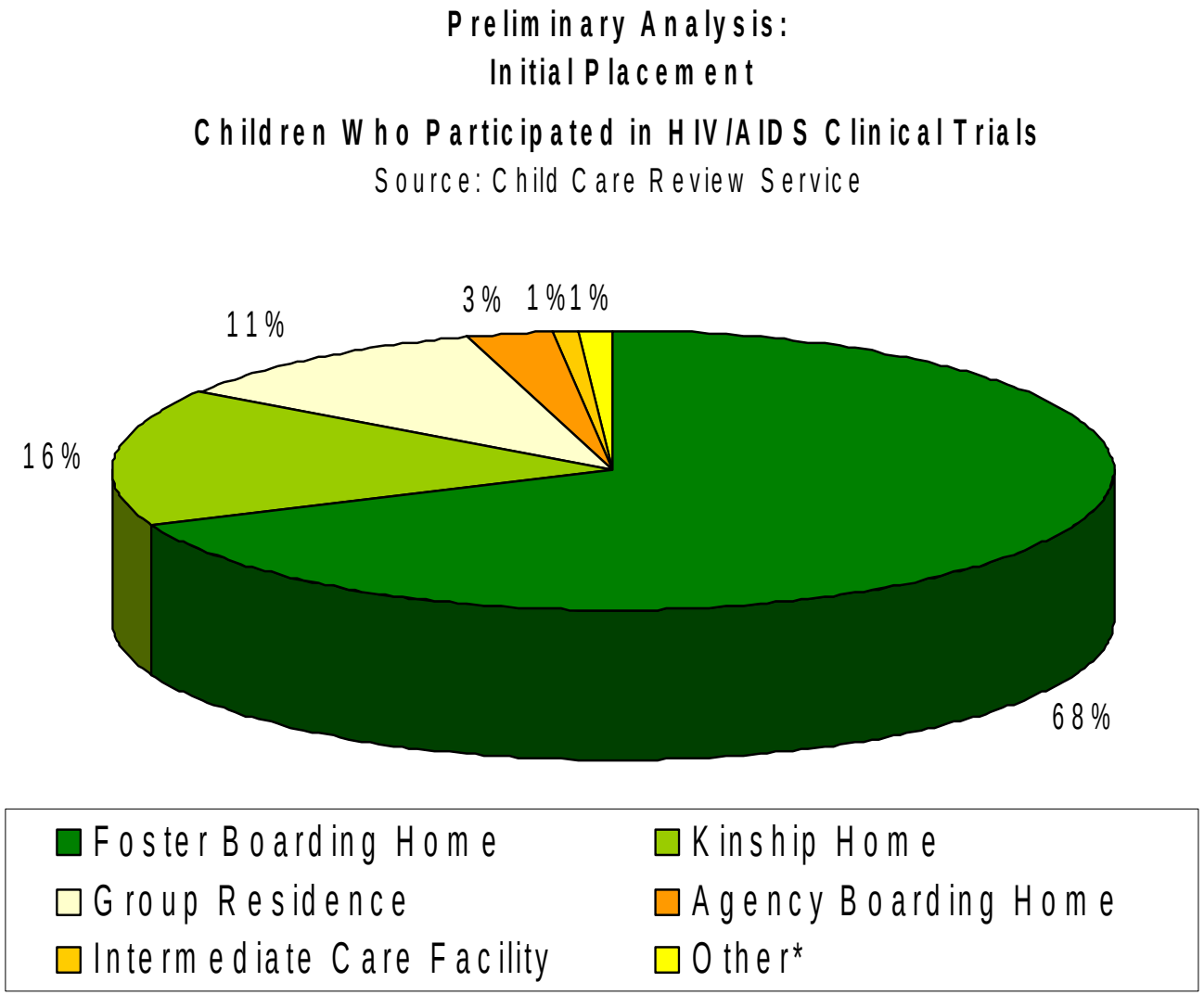


Chart 2:




**Includes group homes and institutions.*

Chart 3:

**Preliminary Analysis:**
**Length of Stay in Foster Care**
**Children Who Participated in HIV/AIDS Clinical Trials**
Source: Child Care Review Service

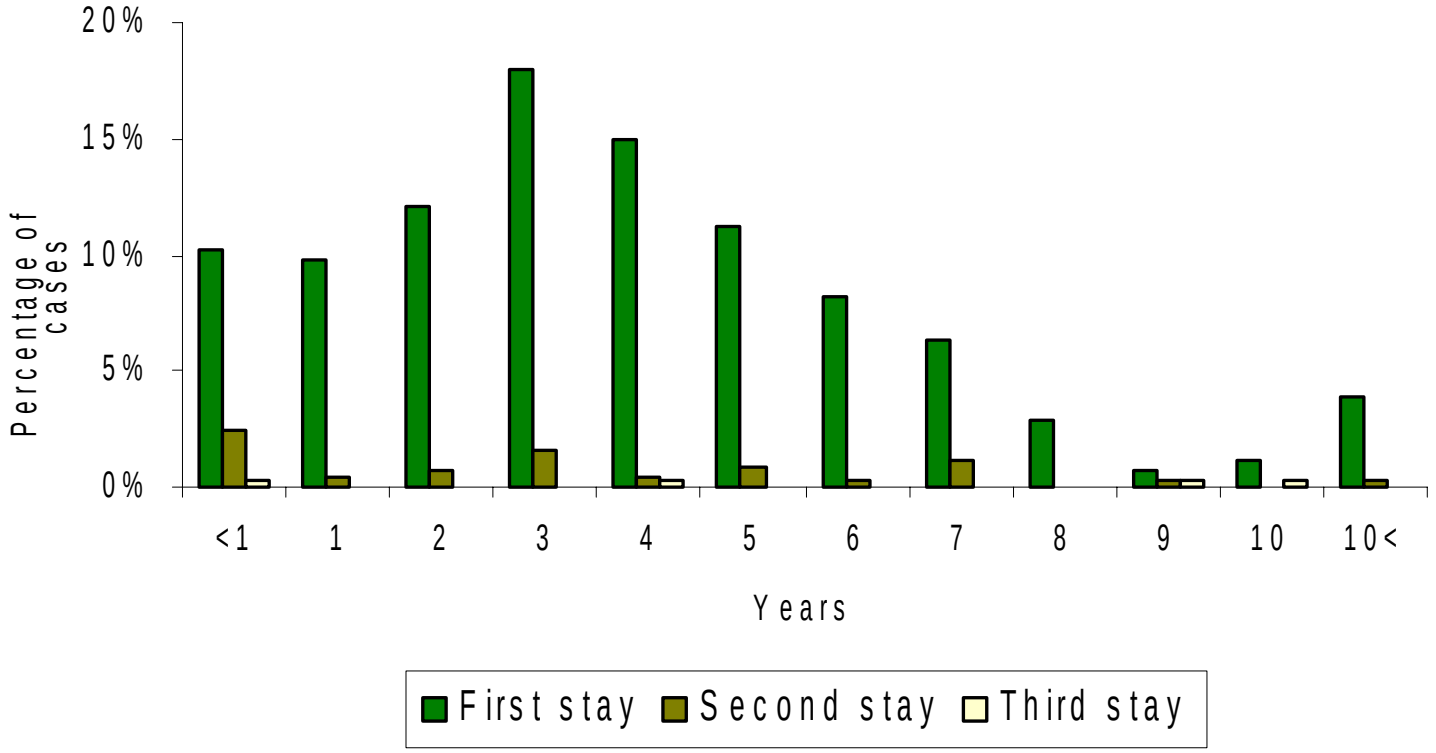
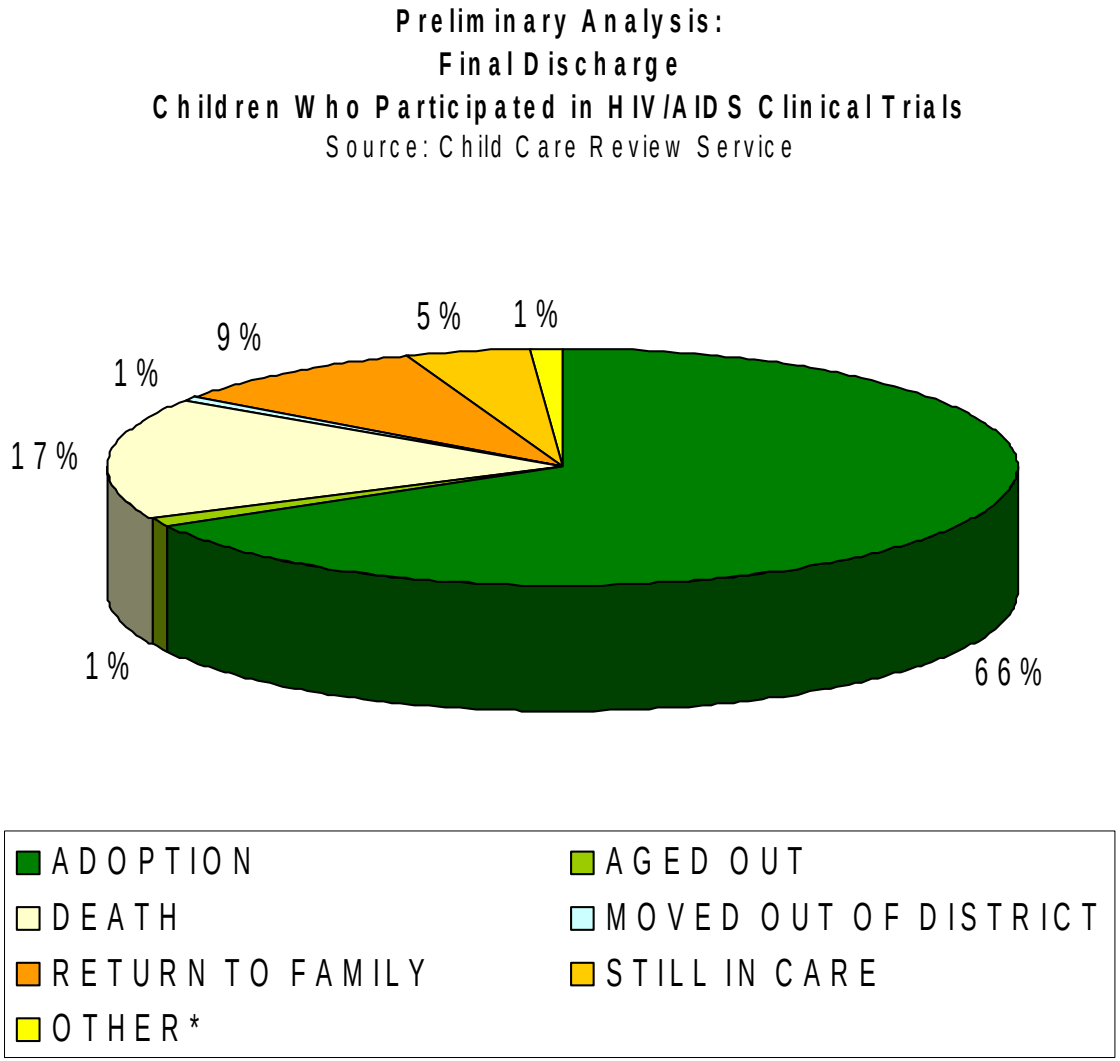


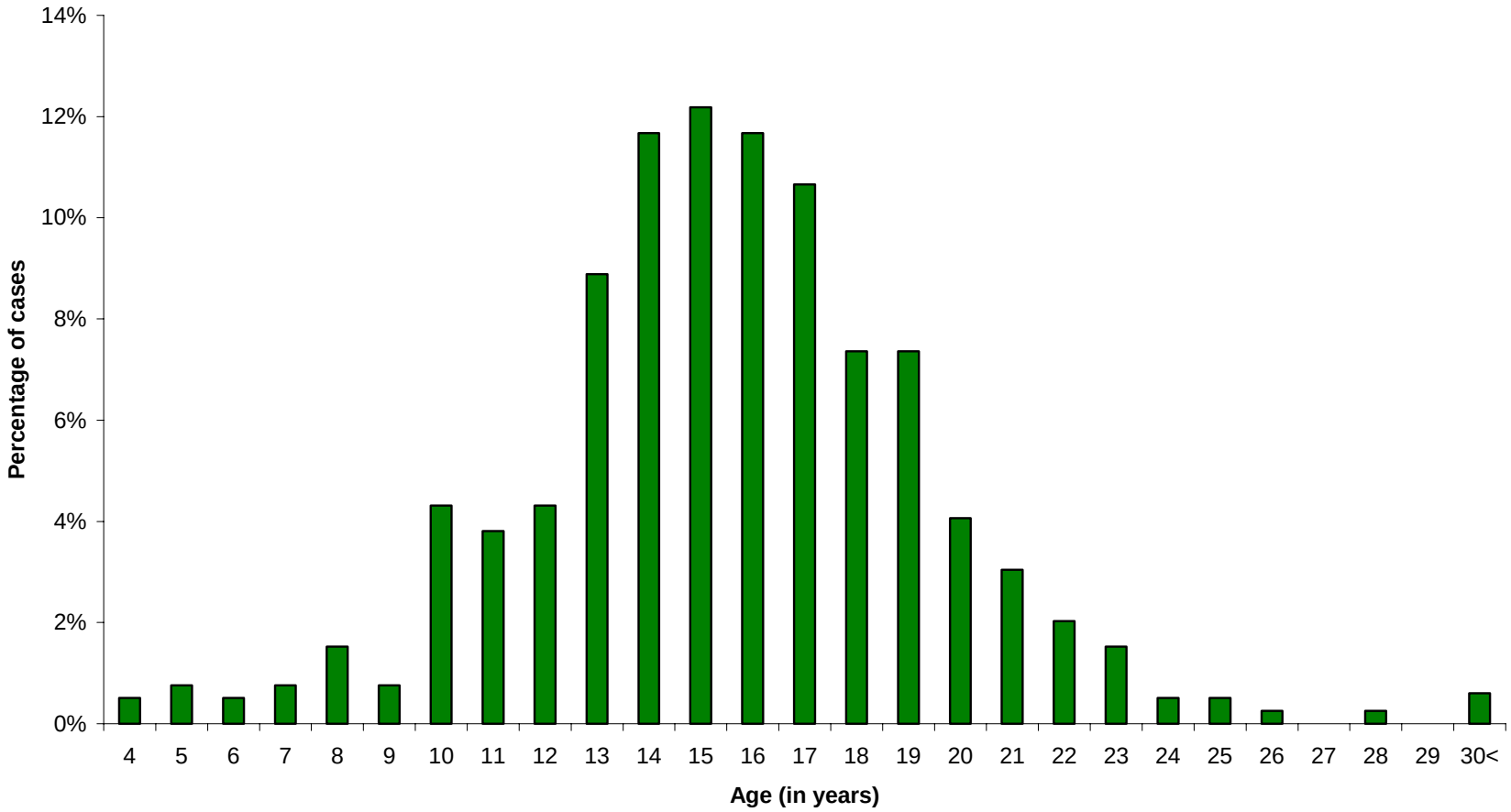
Chart 4:




**Includes administrative action, end of court ordered services, and services no longer needed—goal not achieved of preventing placement.*

Chart 5:

**Preliminary Analysis:**
**Age (in years) as of April 2006**
**Children Who Participated in HIV/AIDS Clinical Trials**
**Source: Child Care Review Service**



Appendix II:

Testimony for City Council Hearing
December 20, 2005

Submitted by Michael Jacobson
Director
Vera Institute of Justice

Members of the General Welfare Committee, thank you for the opportunity to testify today. I want to make three points in my testimony today. First, that AIDS has caused tremendous damage, especially in communities of color. Second, that how children in foster care were enrolled and monitored in clinical trials in New York and how these kids are today is a tremendously important issue to the people of this city and to the nation generally. Third, that Vera intends to do a thorough job, but to get the answers that we all want will take time.

***AIDS is a horrible disease that has caused incalculable harm especially in communities of color***

The Centers for Disease Control estimate that over half a million people in the United States have died of AIDS since the start of the epidemic, including over 5,000 children.[2] More Americans have died of AIDS in the United States than died in battles in World War I, World War II, Korea, Vietnam and the Gulf wars, *combined*.[3] The disease has taken an especially harsh toll on New Yorkers. Almost twenty percent of the people who have died of AIDS—100,000 people—lived in New York State, and most of those lived in New York City. Over 70,000 New Yorkers are living with HIV today.[4] Worldwide, the World Health Organization estimates that over three million people died from AIDS last year. The damage done by this illness is incalculable.[5]

AIDS has had an enormous and disproportionate impact on communities of color. In the United States, two-thirds of AIDS diagnoses since the epidemic began have been in people of color. In New York, the rate of HIV infection in 2004 for people of Hispanic origin was almost seven times that of whites and for African Americans almost eleven times the rate of infection for whites.[6] Fifty-seven percent of people who have died of AIDS in the US have been people of

[2] Table 7, HIV/AIDS Surveillance Report: Cases of HIV Infection and AIDS in the United States, 2004, Volume 16, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention, Department of Health and Human Services, 2005. Available at http://www.cdc.gov/hiv/stats/2004SurveillanceReport.pdf.
[3] Congressional Research Service, *American War and Military Operations Casualties: Lists and Statistics.* Updated July 13, 2005, Table 1. By Hannah Fischer, Knowledge Services Group. See http://www.fas.org/sgp/crs/natsec/RL32492.pdf.
[4] Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, Special Data Request, November 2005 (see http://www.statehealthfacts.org) and note 1, Table 12.
[5] UNAIDS/WHO AIDS Epidemic Update (December 2005).
[6] Centers for Disease Control and Prevention. *HIV/AIDS Surveillance Report, 2004.* Vol. 16. Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2005:[inclusive page numbers]. Also available at: http://www.cdc.gov/hiv/stats/hasrlink.htm. Table 5b.

color with African Americans accounting for 38 percent of all deaths. In communities of color hit the hardest by AIDS in our city, the rates of infection and the frequency of death are even higher and more devastating.

Adult and Adolescent Annual AIDS Case Rate per 100,000 Population by Race/Ethnicity, Reported in 2004

| | NY # | US # |
|---|---|---|
| White | 14.5 | 7.7 [1] |
| Black | 158.7 | 73.9 [1] |
| Hispanic | 93.7 | 26.8 [1] |
| Asian/Pacific Islander | 8.7 | 4.5 [1] |
| American Indian/Alaska Native | 20.7 | 10.8 [1] |

Definitions: A rate is a measure of an event, disease, or condition in relation to a unit of population, along with some specification of time. It is used as a method for standardizing and comparing the impact of the event, disease, or condition across different populations. The AIDS case rate is calculated by dividing the number of AIDS cases reported during the 12 months of the most recent year for which data are available by the population in that same year, multiplied by 100,000. Also see: http://www.cdc.gov/nchs/datawh/nchsdefs/rates.htm and http://www.cdc.gov/hiv/stats/2003SurveillanceReport/TechnicalNotes.htm.

Sources: Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, Special Data Request, November 2005.

HIV infection in a child is an especially heart-breaking event. Because most HIV+ children become infected because their mother is HIV positive, children with HIV must deal with both their own disease and that of their parent or parents. In the worst cases, AIDS has killed multiple members of the same family. Pediatric HIV infection has hit New York City particularly hard, with 3,812 children under the age of 13 diagnosed with HIV infection as of June of 2004. Thirty-seven percent of those children have died.[7]

The onset of the AIDS epidemic resulted in a massive investment in research in the 1980s and 1990s. In the past year alone, the National Institutes of Health spent close to $3 billion on AIDS research, and the cumulative investment is many times that number. Over the past several years, transmission of HIV to children has dropped dramatically and children infected with HIV are living longer lives. Despite these gains, AIDS continues to take a tremendous toll.

***Attention in many quarters (including advocates, the media, agencies responsible for monitoring trials, and ACS' Commissioner and staff) has focused on the processes for enrolling and monitoring HIV-positive and -exposed foster children into clinical trials which tested treatments for these conditions.***

Over the past two years, many concerns have been voiced about the enrollment and monitoring of foster children in clinical research that tested treatments for HIV and AIDS. Some community

[7] NYC Health, Pediatric & Adolescent HIV/AIDS Surveillance Update, New York City, December 2004

advocates and members of the media have leveled serious allegations about the conduct of this research. These allegations include forced participation of HIV-positive foster children in clinical trials, a lack of informed consent by the biological parents of foster children, suggestions that Children's Services benefited financially from enrolling children in clinical trials, a failure to monitor children in foster care while they were in the trials, and that children in care were disproportionately enrolled in clinical trials and were effectively used as guinea pigs. These are serious allegations.

The response to these allegations has come from many quarters. The doctors and medical researchers who led the trials claim that the allegations are false and that they worked hard to save the lives of HIV-positive children including foster children. Children's Services has said that efforts on the part of former officials helped foster children gain access to otherwise unavailable medications and that they have no evidence of wrong-doing with respect to the trials.

This debate has also taken place without the benefit of information that could advance public understanding of what happened during the period in question and lay the ground work for developing fair and just policies in the future. The public does not yet know how many biological parents of the foster children signed informed consents for their children to enter clinical trials and under what circumstances they gave consent, what the monitoring of the foster children looked like in practice, how long these children stayed in foster care, and where they went after they were discharged from care.

This is the kind of gritty, detailed research into government systems that Vera has done for the last 44 years. We have a long history of reviewing case files, analyzing administrative data, conducting interviews with vulnerable populations, including vulnerable populations from communities of color, and writing reports to inform public debate.

***Vera will address these concerns by conducting an extensive and thorough analysis of case records, administrative data, background materials, and interviews with people involved in this issue.***

What Vera will provide to the public, to the City Council, to the advocacy community, to child welfare officials, and to the medical community is a report containing the facts and knowledge that we will gain by reviewing case files, examining clinical trial protocols, reading published and unpublished research, analyzing administrative data, and conducting interviews. It is our goal to produce a report that spells out what happened, identifies past problems, and informs future policies.

In its simplest form, we will identify what the policy was for enrolling and monitoring children in clinical trials, find out how closely that policy was followed, and discover how the children are doing today. The issues involved in this project, however, are anything but simple. To properly fulfill our duty, we will need to answer a number of critical questions, including:

1. What was the historical, social and scientific context in which clinical trials of drugs to treat children with HIV-infection and AIDS were conducted between 1988 and 2001?

2. How did the development, dissemination, and enforcement of policies and practices related to HIV-infected and exposed foster children, including child welfare placement, medical care, enrollment in clinical trials, and monitoring during participation in clinical trials, take place in New York City?

3. What were the immediate outcomes of the participation of foster children in clinical trials including the scientific outcomes of the trials and the clinical and child welfare status of the children before, during and after enrollment?

4. What are the long-term outcomes of the participation of foster children in clinical trials and the clinical and child welfare status of the children today?

Answering these questions requires that we consider the impact of race and ethnicity on the questions that we ask and how we interpret the facts that we uncover. There are many studies that show that race and ethnicity have a persistent effect on decisions that are made in child welfare systems.[8] There is also a substantial literature on how a person's race and ethnicity influence their medical treatment, their access to care, and on the assumptions doctors make in their patient's likelihood of taking medications.[9]

To ensure that we have a range of perspectives, this study will have the benefit of three advisory groups. First, Vera has its own advisory group led by Dr. Richard Dudley—a Vera board member. Dr. Dudley, a child psychiatrist and child welfare specialist, was a founding member of the National Black Leadership Commission on AIDS. Second, we have met and will continue to meet with Children's Services' HIV/AIDS Healthcare Advisory Board chaired by Debra Fraser-Howze of the National Black Leadership Commission on AIDS. Third, Children's Services has appointed a Medical Oversight Committee chaired by Dr. Robert Johnson of the University of Medicine and Dentistry of New Jersey.

***We are actively working on this analysis, but it will take time to do the thorough job that this study demands***

This is a complex and complicated project. We have done a tremendous amount of work, but there is a huge amount of work left to do. I will summarize the main points here:

Vera signed the contract for this work on June 28th, 2005. The Comptroller's Office registered the contract in late August. After detailed discussions with the New York State Office of Family and Children's Services, the Administration for Children's Services received permission to have Vera conduct a management review of its files on September 8th.

[8] See, for example, Dennette M. Derezotes, John Poertner , Mark F. Testa, *Race Matters In Child Welfare: The Overrepresentation Of African American Children In The System*, CWLA Press (Child Welfare League of America, 2004.

[9] See, for example, Roberts, Dorothy, *Killing the Black Body, Race, Reproduction, and the Meaning of Liberty*. Vintage Books, New York City 1997

Since then, we have worked on a research protocol for Vera's Institutional Review Board, which reviews our research projects to make sure that they comply with federal regulations regarding the ethical treatment of human subjects. To design this protocol, we have reviewed a sample of ACS case files, files at the private agencies that provide foster care, records from the Pediatric AIDS Unit at ACS, and electronic administrative data from the Child Care Review Service database. We have reviewed some of the policy documents relating to the HIV testing and the development of clinical trials policy. We have also met with a wide range of people and groups, recruited most of our advisory board, and hired staff. We have reviewed an extensive bibliography of reports published in peer-reviewed medical journals on the outcomes of the clinical trials. We have read books that discuss the development and spread of AIDS in the Black Community, how race affects decision-making in child welfare, and the experiences of people of color in the medical system.

The bottom line is that it will take time to do this project correctly. There are thousands of documents that will need to be reviewed. There are potentially hundreds of interviews to conduct. And all of it must be done with the utmost care and sensitivity to the children who participated in the clinical trials. We are acutely aware that we only get one chance to do this and we intend to do it properly.

Along with Tim Ross, Anne Lifflander, and their research team, I am happy to answer any questions that you have.