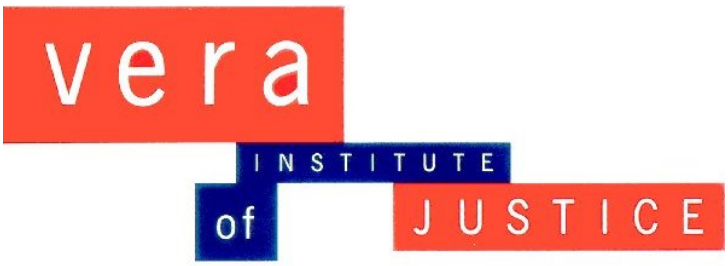

Clinical Trials Project: Progress Report 4

Vera Institute of Justice
July 2006

This report is the fourth 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.[1] It covers the quarter running from April 1, 2006, to June 30, 2006. The current report describes:

- Implementation of the research design,
- Institutional Review Board review of key respondent interviews,
- Activities of Vera's Advisory Board,
- Outreach, and
- Next steps.

Summary: During this quarter we hired and trained additional staff. By the end of June, the file review staff included eight reviewers of child welfare documents and three reviewers of medical documents. We also hired two summer interns to conduct background research and literature reviews. Officials from New York City's Administration for Children's Services (Children's Services) believe that approximately 465 children participated in clinical trials. As of the end of this quarter, we have reviewed 167 child welfare case management files, 75 child welfare case planning files, 52 medical case management files, and 77 medical case planning files. Vera's Clinical Trials Advisory Board met in May. That same month, project staff informally briefed the City Council. Throughout the quarter, project staff continued working with Children's Services' HIV/AIDS Health Care Advisory Board to refine the agency's current policy for enrolling and monitoring foster children in clinical trials.

Section 1. Implementing the research design

The research team continued its formal file review, begun earlier this year. This process is expected to reveal why children came into care, how medical decisions were made for them, the consent process for participating in clinical trials, and the child welfare outcomes for these children and their families. For more information, see Progress Report 3.

More than 30 nonprofit agencies were under contract to New York City's child welfare agency to provide case planning and foster care services to foster children participating in the clinical trials. Three agencies—Saint Vincent's Services, Leake and Watts Services, and Catholic Home Bureau (now merged with Catholic Guardian Society)—provided services to nearly half of the children. Each of these three agencies had a specific program to address the special needs of children who tested positive for HIV. Vera began its file review process by reviewing the case management and case planning files of the children who received services from these agencies. Over the next several months, the document review process at these and other agencies should continue to make up the bulk of our work.

In April, we hired several additional file reviewers—some to review child welfare files and some to review medical information. Our professionally and demographically diverse child welfare

[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.

document review team now consists of eight full-time employees, including four reviewers with master's degree-level education. Our medical reviewer team consists of a nurse and two physicians with Master of Public Health degrees. All reviewers completed comprehensive training in protection of human research subjects and were screened for conflict of interest.

By the end of this quarter, the child welfare document reviewers had completed 165 case management files, which are housed at Children's Services, and 75 case planning files, which are retrieved by storage companies for each contract agency and reviewed by Vera staff at the agencies themselves.[2] As of the end of this quarter, our medical document reviewers had completed 52 case management files and 77 case planning files. As discussed in previous progress reports, the medical file review requires staff with specialized knowledge. Because of the additional time it takes to recruit for this task, we expect the medical review to lag behind the child welfare review throughout the course of this project. To minimize this lag, the child welfare reviewers flag all medically-related information. This lets the specialized medical team work more efficiently.

We have further refined our data collection instruments, which document reviewers fill out when reviewing a case, and we have written guidelines explaining how reviewers should answer each question on the instruments. We are also in the process of updating the database that will store the information collected during this project. Collecting, entering, and analyzing the data will take many more months. To provide a full and fair assessment of the information we collect, Vera will limit the release of preliminary analysis until we have a complete data set.

Our experience with the document review process to date suggests that our work would benefit from a review of additional types of documents. We have consulted with Children's Services, the Children's Services' HIV/AIDS Health Care Advisory Board, the Vera Clinical Trials Advisory Board, and the chair of Children's Services' Medical Oversight Committee, Dr. Robert Johnson, on ways to access medical and research records of the children who participated in clinical trials. These files normally include informed consents and progress notes on the clinical condition of the children who participated in the trials.

Section 2. Institutional Review Board review of key respondent interviews

Because this project involves human beings as research subjects, it is being reviewed by Vera's Institutional Review Board (IRB), which is composed of people trained in the rules and ethics of research protocols. We have submitted our protocols to Vera's IRB for our interviews with key respondents.[3] On April 12, the IRB reviewed and approved the process for conducting interviews with people in these groups (for a list see Progress Report 3), pending some wording changes in the consent forms and interview guides, which have since been revised and finalized. We anticipate that the IRB will review the protocols for interviewing clinical trial participants and caregivers (bioparents, foster parents, and kinship parents) in September.

[2] The large volume of case planning files made copying and storing files at Children's Services impractical due to the cost of duplication, risks to confidentiality in the copying process, and limits on space at Children's Services.
[3] Some examples of the key respondents are medical researchers, medical research staff, and independent advocates assigned to some clinics. For a complete list of key respondent categories, see Progress Report 3.

Section 3. Advisory Board

As discussed in our previous update, Vera has assembled an independent Clinical Trials Advisory Board to provide project staff with guidance on research methods, issues related to child welfare and medicine, community engagement, and bioethics. A list of board members and their backgrounds is posted on our web site, www.vera.org/clinicaltrials.

At its first meeting, in May, the advisory board reviewed the structure of the project, the project's aims, and the progress thus far. The board provided a wealth of useful advice and suggestions from a range of perspectives—research, administration, advocacy, community, medicine, mental health, law, and ethics. The board agreed to meet again to discuss the structure of the final report and the project's findings. Outside of such formal meetings, the board continues to serve as a resource to the research team by answering questions, arranging meetings, and providing advice on a range of issues.

Section 4. Outreach

There are a range of views on what happened when children were enrolled in clinical trials in the past and on how the child welfare system should handle similar circumstances 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. Below are highlights of our outreach efforts during this quarter.

- In April, May, and June, we met several times with Children's Services' HIV/AIDS Health Care Advisory Board, which is composed of community-based health service providers and advocates and chaired by Debra Fraser-Howze, chief executive officer and president of the National Black Leadership Commission on AIDS. The Health Care Advisory Board meetings focused on discussions of Children's Services' draft policy for enrolling foster children in clinical trials as well as Vera's progress on this project. We expect to attend the next meeting of this group, scheduled for July 13.

- In May, Vera staff briefed members of the City Council's General Welfare Committee and Children's Services managers on the progress made on the project.

- We continue to have regular discussions with Dr. Robert Johnson, chair of Children's Services' Medical Oversight Committee. 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.

Section 5. Next steps

Time devoted to recruiting, training, and supervising new staff prevented us from completing two of the next steps listed in our last progress report: starting interviews with key respondents and presenting our plan for interviewing children and caregivers to Vera's IRB.

In the next quarter, we plan to do the following activities:

- Continue analyzing administrative data,
- Continue the document review,
- Finish construction of the database that will store the data collected on this project,
- At the request of the City Council and Children's Services, continue our participation in the development of Children's Services' new clinical trials policy,
- Begin key respondent interviews, and
- Present our plan for interviews with children and caregivers to Vera's IRB