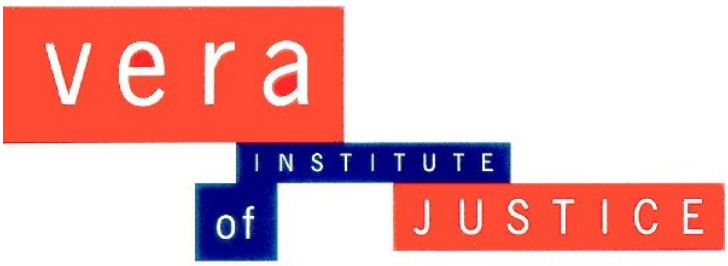


Clinical Trials Project: Progress Report 1

Vera Institute of Justice
October 2005

This report is the first 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 July 1, 2005, to September 30, 2005. The current report describes:

- Efforts to gain access to necessary information,
- Outreach activities,
- Preliminary planning to establish our methodology,
- The recruitment of an independent advisory board, and
- Next steps.

Summary: In July and August, Vera began recruiting staff and advisory board members, gathered background materials to gain a better understanding of the issues involved in conducting the study, and worked with government agencies to ensure that the review is conducted legally and ethically. In September, the New York State Office of Children and Family Services (OCFS) approved the request from New York City's Administration for Children's Services (Children's Services) that Vera review case files and administrative data, in essence officially granting Vera permission to conduct the review. Also in September, Vera's Institutional Review Board approved the process that Vera staff proposed for the stages of the review, including an initial planning stage followed by subsequent IRB meetings to review the more detailed study design. That planning process is now underway.

Section 1. Gaining access to data and people

Projects that involve sensitive or private information are regularly reviewed by legal staff at Vera and government agencies to ensure that regulations and laws about disclosing such information are followed. The children and youth involved in this project represent an exceptionally vulnerable group. We are paying careful attention to ensure that this project adheres to all legal requirements governing information about individuals' HIV or foster care status.[2]

Vera routinely trains its staff on appropriate ways to ask if people want to participate in research, how to handle confidential information, and other issues related to protecting research participants. In this case, we have arranged for additional training on regulations regarding health-related inquiries and data. All project staff will be required to pass the Collaborative IRB Training Institute's web-based course on the protection of human

[1] In spring 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 26, 2005.

[2] Article 27-F of New York State's public health law regulates the disclosure of HIV status and other health information.

subjects in scientific and biomedical research.[3] Also, we are consulting with experts and community advocates to help us conduct this review as sensitively as possible. Finally, we have added additional security to our electronic network.

Projects that involve human beings as research subjects are usually reviewed by an Institutional Review Board (IRB) composed of people trained in the rules and ethical concerns of research protocols.[4] Project staff met with Vera's IRB in September to assess a two-stage IRB review process for developing our protocol. That process calls for examining a sample of records to help us plan the project. After completing this task, we plan to solicit formal IRB approval of a detailed plan for reviewing all of the records and administrative data. We will return to the IRB a second time when we have written the interview questions and consent procedures that we hope to use. [For more about this process, see section 3, The Planning Process.] When polled, the IRB members agreed to this process. Because of the sensitive nature of this project, our IRB has asked that they receive regular updates on our plans.

Section 2. 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 the different opinions people have so that we can take these perspectives into consideration as we do our work.

Vera staff attended committee hearings held by the New York City Council on May 5, 2005, and the New York State Assembly on September 8, 2005. Both hearings concerned the enrollment of HIV-infected and -exposed foster children in clinical trials. At these hearings, we heard the views of advocates, parents, lawyers, researchers, doctors, child welfare providers, and government officials. In September, we met with Children's Services' HIV/AIDS Health Care Advisory Board—a group of community health service providers that is chaired by Debra Fraser-Howze, the CEO and President of the National Black Leadership Commission on AIDS (NBLCA). In October, we plan to attend 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 part of the federal government's National Institutes of Health. We have also had discussions with Dr. Robert Johnson, chair of Children's Services' Medical Oversight Committee, and met with the New York City Department of Investigation to discuss their concerns.

[3] Since its founding in 2000, the Collaborative IRB Training Institute (CITI) has provided web-based training to more than 400 institutions and facilities around the world. For more information on CITI, visit www.citiprogram.org/citidocuments/aboutus.htm.

[4] Vera policy mandates that all of its research projects, broadly defined, follow federal IRB guidelines concerning the ethical treatment of human subjects. Vera's standing IRB is chaired by Charles Bleiberg. The other members are Lowell Johnston, Jerome McElroy, Geri Ferrara, and Karen Goldstein. Ms. Goldstein, Vera's general counsel, was previously employed by the New York City Human Resources Administration, which oversaw child welfare during part of the time period that Vera is examining. Consequently, she has recused herself—she will not be involved in the project in any way.

3. The Planning Process

This is a complex project. It requires an understanding of government operations at the intersection of child welfare, medicine, and clinical research in the local, state, and national contexts. Also, there are many types of files to review, and a range of people to interview.

As mentioned in section 1, the planning process involves reviewing files of between thirty and fifty of the children who were involved in clinical trials. From this review, begun as soon as we got access to the files in September, we are learning about the type and quality of information in the case files and the amount of time it takes to review a case. This file review is taking place in a locked room at Children's Services main office, where files from Children's Services archives and the Children's Services Pediatric AIDS Unit have been assembled. We plan to review additional files at the contract agencies that provide most of New York City's foster care services.

The actual file review process—which will begin upon approval from Vera's IRB—is expected to be lengthy: the files housed at Children's Services alone fill approximately sixty lateral file drawers. This does not include files kept by the contract agencies, the Pediatric AIDS Unit, or the medical centers that provided most of the medical care the children received. The few cases we have reviewed so far suggest that it can take hours to review a single file, though other files take much less time. Consequently, even though we are eager to provide information about the many questions that prompted this review, the completion of a quality analysis will take time. In addition, Vera may need to locate and obtain permission from the youth themselves or their guardians to access certain files. If this occurs, additional time will be added to complete the review.

As part of our planning process we are reviewing medical information about the clinical trials in which the children participated. To that end, we have begun to collect and review articles that medical researchers wrote to describe the drugs studied, the methods used in the study, and the results of the trials (including discussions of the positive and negative effects of the drugs). This information will be summarized in our final report.

4. Vera's Independent Advisory Board

As part of this project, Vera decided to create an independent advisory board to provide guidance on research methods, issues related to child welfare and medicine, and bioethics. The advisory board will be composed of approximately five highly regarded experts. Throughout July and August, Vera staff developed guidelines for selecting advisory board members which minimize the possibility of conflict of interest. For example, people who worked for Children's Services (or its predecessor agencies) during the period when the clinical trials took place cannot serve on Vera's advisory board.

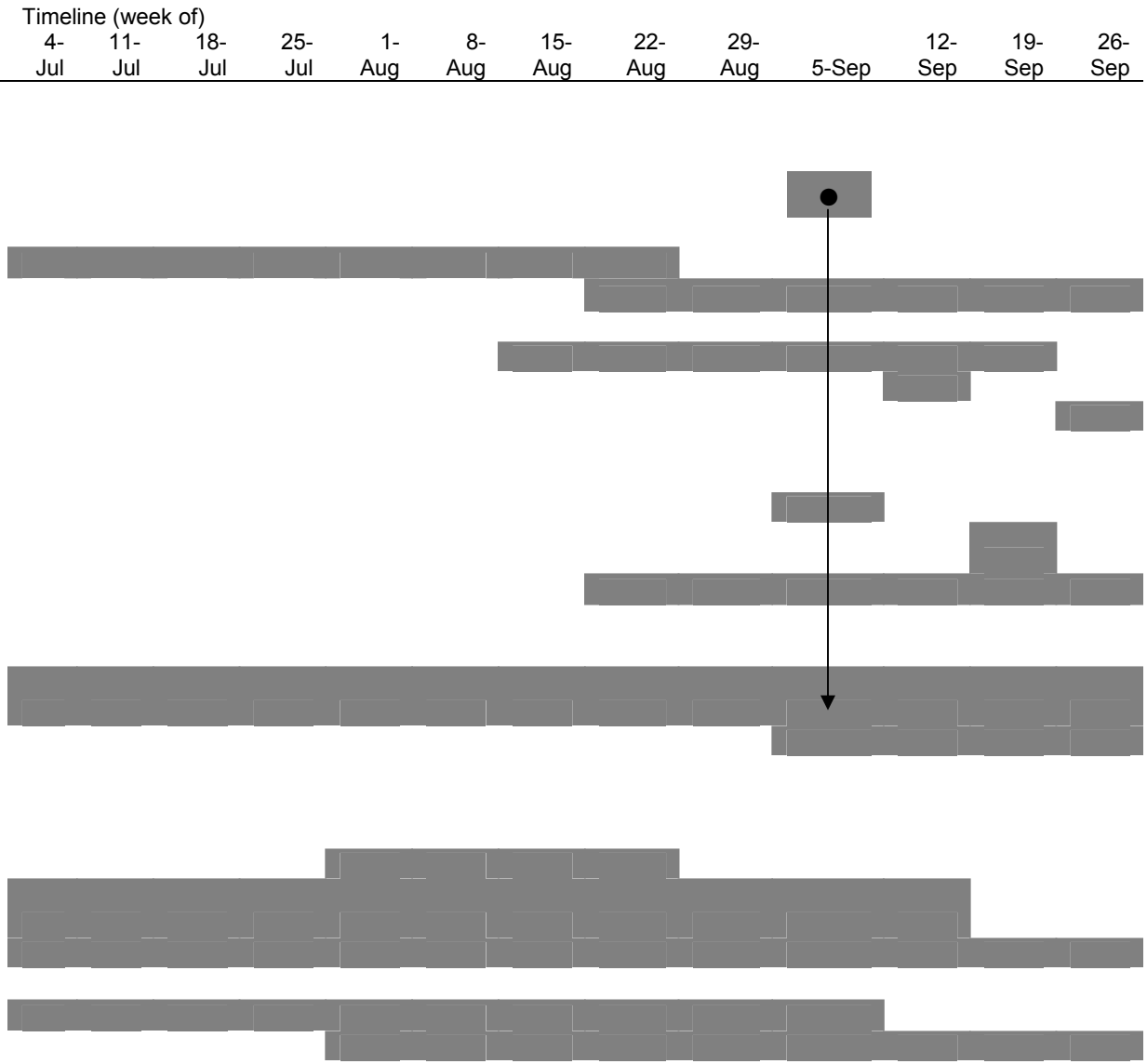
In September, Richard G. Dudley, M.D., agreed to serve as the chair of the advisory board. Dr. Dudley, a Vera board member, divides his work between a clinical practice focused primarily on the evaluation and treatment of African-American men, and a forensic practice. As a forensic psychiatrist, Dr. Dudley is frequently called 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 and a board member of Gay Men's Health Crisis. 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.

5. Next Steps

Vera staff will draft a formal protocol for reviewing files. This protocol will be presented to our Institutional Review Board. Once the protocol is approved, we will start the full file review. In addition, we will continue our outreach and staff recruitment activities.

Our next progress report will cover the period from October 1, 2005 to December 31, 2005. We plan for the report to describe the flow of children who were involved in clinical trials through foster care and will include information on when children came into care, how old they were, how long they stayed in care, and how they left care. This will provide a better understanding of the context for the children's enrollment in clinical trials. In addition, we plan to identify the clinical trials in which the children participated, the duration of those trials, and the drugs tested in those trials.


Timeline (week of)
Activity
4-Jul
11-Jul
18-Jul
25-Jul
1-Aug
8-Aug
15-Aug
22-Aug
29-Aug
5-Sep
12-Sep
19-Sep
26-Sep
Gaining access to data and people
OCFS approval for data access
Issues of disclosure
Review of legal requirements around disclosure
Consultation with experts and community advocates
Additional security and protections
IRB preliminary review
Greater security added to electronic network
Enrollment in CITI training on protection of human subjects
Outreach
State Assembly Hearing
Meeting with Children's Services' HIV/AIDS Health Care Advisory Board
Conversations with medical experts and community advocates
Planning process
Review of background literature and medical information on specific trials
Preliminary review of Children's Services files
Recruitment
Independent Advisory Board
Creation of selection guidelines
Advisory board chair recruitment (Dr. Richard G. Dudley accepts position as chair)
Recruitment of other advisors
Staff
Recruitment of senior research staff with medical expertise
Recruitment of research analyst