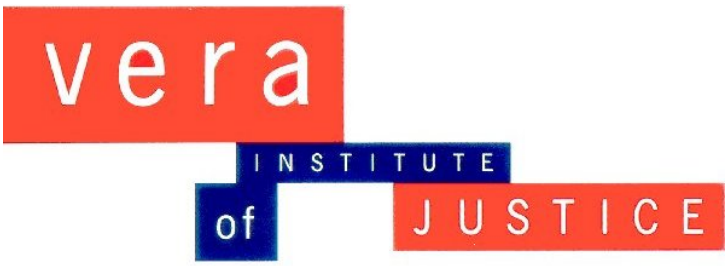

Clinical Trials Project: Progress Report 3

Vera Institute of Justice
April 2006

This report is the third 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 January 1, 2006, to March 31, 2006. The current report describes:

- Implementation of the document review,
- Policies to prevent disclosure of confidential information,
- Vera Advisory Board activity,
- Institutional Review Board (IRB) developments,
- Outreach activities, and
- Next steps.

This report also contains an appendix describing our confidentiality protocol.

Summary: In January, Vera staff began executing the document review: a six-person team is now reviewing case management and case planning files, and two other teams—a second team of document reviewers and a team of medical record reviewers—are being recruited. We have also finalized our confidentiality protocols (minimizing the risk of releasing confidential information), completed recruitment for the Clinical Trials Advisory Board, and presented plans for Phase I of the project—focusing on the file review and interviews with key respondents—to Vera's IRB. Finally, we continued our outreach activities (meeting with community-based service providers, children's advocates, AIDS activists, and pediatricians) and our analysis of administrative data.

Section 1. Implementing the review

After substantial planning, preparation, and training, the document review team began its formal review of the files. This review process is expected to reveal why children who participated in trials came into care, how medical decisions were made for the children, the consent process for clinical trials, and the child welfare outcomes for children and families.

We expect to be able to use this information and other data that we collect to determine whether the clinical trials' consent procedures, initial enrollment criteria, and monitoring during enrollment were consistent with the New York City Administration for Children's Services' (Children's Services) policies and with enrollment criteria and monitoring requirements established by the National Institutes of Health (NIH). Examples of what we expect to document include:

[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.

- The HIV status of each child enrolled in a clinical trial and how the HIV status was determined and confirmed prior to enrollment,
- The clinical and immunological status of each child prior to and following completion of a clinical trial,
- Any adverse events suffered by children while they were enrolled in a clinical trial and the actions taken to address these occurrences,
- Immediate and long-term clinical outcomes for these children,
- The determinations that were made as to who had the legal right to consent to enrollment and whether consents were properly secured, and
- The trajectory of the children through foster care including their placement histories and discharge outcomes.

Collecting child welfare data. To address the complexity of the cases we are reviewing, we are collecting some standard data for each case. These data are collected using a standardized data abstraction instrument developed and tested by our clinical trials team. The instrument surveys over 200 items related to the reason the child entered care, the HIV and child welfare status of siblings and parents, and the existence and nature of diligent search processes. In addition, a narrative is written about each child to capture unique aspects of each case. A portion of cases reviewed by our document reviewers will be reviewed again by a senior member of the team for quality assurance purposes.

Recruitment for the document review staff began in January. Out of more than 400 candidates, we hired six reviewers with diverse experiences and backgrounds. After training the group, we had each member read, review and code the same set of cases. This allowed us to improve our data collection instrument and help ensure that different reviewers would code the same file in the same way.

Much of our work over the next several months will involve reviewing files at Children's Services and at the voluntary agencies. To speed this task, we will hire and train additional reviewers.

Collecting medical data. Our medical data collection instrument, which has been reviewed by members of Vera's advisory board as well as by Dr. Robert Johnson, the dean of the University of New Jersey's School of Medicine and Dentistry, relies heavily on lab data and chart notes. Much of this information is contained in existing files, especially the case planning files maintained at the nonprofit agencies that provide most foster care in New York City. To supplement these data, Children's Services plans to request clinical trial progress notes and IRB minutes from the medical centers where the trials were conducted.

We are currently in the process of hiring staff to review the medical documents. Like our document reviewers, the medical reviewers must meet a set of conflict-of-interest criteria that will exclude candidates who worked on HIV/AIDS clinical trials while employed at a medical center, pharmaceutical companies that manufacture HIV/AIDS-related drugs, or the New York City Administration for Children's Services. This is a smaller pool of candidates, and we expect it will take us longer to fully staff these positions.

Section 2. Preventing disclosures

The clinical trials team is committed to ensuring the confidentiality of the names and other identifiable information of the children who participated in the trials and their caregivers. In other contexts, disclosures of HIV status have had devastating consequences, including loss of health insurance, housing, and social supports. Disclosing someone's HIV or foster care status without his or her permission is also illegal. Unauthorized disclosure of a person's HIV status, for example, is punishable by up to a $5,000 fine and a year in jail for each disclosure.

Our completed confidentiality protocols (Appendix I) were developed in consultation with many experts, including professionals in electronic network security and HIV surveillance personnel working with state and federal governments. Vera has worked with confidential data throughout its 45-year existence, and to our knowledge the Institute has never disclosed individually identifiable sensitive data. These protocols will help us keep that record.

Section 3. IRB 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. 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 is being done in two phases: the first review concerns the interviews of key respondents, and the second review concerns interviews of children and their caregivers.

The key respondents we plan to interview in phase I include:

- Medical researchers,
- Medical research staff,
- Independent advocates assigned to some of the clinical trials,
- Members of the ACS Medical Advisory Panel that reviewed the clinical trials and provided recommendations to the commissioner,
- Past and present employees of nonprofit agencies that provide most foster care in New York City,
- Community and advocacy organization staff,
- Funding, regulatory, and monitoring staff, including staff at the National Institutes of Health, and
- Past and present Children's Services employees.

We made our first presentation to the IRB on February 9, 2006. We continue to work with them on phase I procedures and consent forms. Vera policy and the federal

guidelines mandate that the interviews themselves cannot begin until the IRB has approved our procedures. A follow-up IRB meeting is scheduled for April 12.[2]

Section 4. Advisory board

As discussed in our last update, Vera has been assembling an independent advisory board to provide guidance on methodology for the review, issues related to child welfare and medicine, community engagement, and bioethics. In January, Vera finished recruiting the advisory board. The seven board members' biographical summaries appear below.

Vera Clinical Trials Advisory Board

Richard G. Dudley, M.D. (**Chair)**—Vera trustee. Dr. Dudley has a private practice in psychiatry that includes a clinical practice, a forensic practice, and consultation/education. He is a former deputy commissioner of the New York City Department of Mental Health, Mental Retardation, and Alcoholism Services and an original member of the National Black Leadership Commission on AIDS. Dr. Dudley has also served as the medical director of 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.

Michael Arsham, M.S.W.—executive director of the Child Welfare Organizing Project (since 1998); former director of social service policy for the New York State Council of Family and Child Caring Agencies (COFCCA). He also served Rheedlen Centers for Children and Families (now known as the Harlem Children's Zone) for 13 years, staffing, developing, and directing preventive service programs in Central Harlem, Manhattan Valley, and Hell's Kitchen.

Kevin W. Concannon, M.S.W.—director of Iowa Department of Human Services (since 2003); formerly commissioner of Maine's Department of Health and Human Services (1995-2003), director of the Oregon Department of Human Services (1987-1995), and commissioner of the Maine Department of Mental Health and Mental Retardation (1980-1987). He has also served as president of the American Public Welfare Association (APWA) and been a member of the boards of directors of APWA and the American Public Human Services Association. He is past president of the National Association of State Mental Health Program Directors.

Errol A. Harvey, B.D.—rector of St. Augustine's Church since 1983; currently serves as a member of the board of directors of Housing Works, Inc., and has served as the president of the Lower East Side Needle Exchange and as convener of the Episcopal Black Caucus of the Diocese of New York.

[2] Legally, federal human subjects guidelines must be followed only on federally funded projects. It is Vera's policy, however, to subject all research projects to IRB review using the federal guidelines.

Luz Amarilis Lugo, M.D.—assistant program director of internal medicine at Saint Vincent Catholic Medical Center, New York, NY; attending physician at the Comprehensive HIV Center of St. Vincent's; assistant professor at New York Medical College; board-certified in internal medicine and infectious diseases.

Karen Porter, J.D.—executive director of the Center for Health, Science and Public Policy at Brooklyn Law School and an adjunct instructor of clinical law, teaching on law and medicine, and AIDS and the law; former senior policy analyst and staff counsel to the National Commission on AIDS.

Marjorie Speers, Ph.D.—executive director of the Association for the Accreditation of Human Research Protection Programs (AAHRPP). She formerly served as acting executive director of the National Bioethics Advisory Commission (NBAC) and as deputy associate director for science at the Centers for Disease Control and Prevention (CDC), as well as director of the Division of Chronic Disease Control and Community Intervention at CDC.

In February and March, we held one group conference call and seven individual conference calls with board members. The participants in the individual conference calls included Dr. Dudley, one of Vera's principal investigators on the project (either Tim Ross or Anne Lifflander), and each of the other advisory board members. The calls covered a range of topics, including how best to engage families and caregivers in a sensitive manner, issues related to requesting medical records, whether Vera or an outside organization should conduct the review of the medical records, and how to deal with issues of consent and assent. The team has continued to seek advice from the advisory board members in their areas of expertise and plans to convene the group in June.

Section 5. 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.

In January, February, and March, we met several times 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, chief executive officer and president of the National Black Leadership Commission on AIDS (NBLCA). We will attend the next meeting of this group, scheduled in May.

We also discussed this project with pediatricians engaged in HIV/AIDS clinical trials in New Jersey—a state that does not allow foster children to participate in such trials.

On March 14, Vera staff made a presentation to approximately 40 representatives from the voluntary agencies that Children's Services contracts with to provide foster care. The presentation explained the study and the cooperation that Vera will need from the agencies to complete the study.

We continue to have regular discussions with Dr. Robert Johnson, chair of the Children's Services Medical Oversight Committee, and with key Children's Services staff to discuss issues related to case management, case planning and Pediatric AIDS Unit files, 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.

Section 6. Next steps

Unless otherwise noted, we have completed each of the "next steps" identified in our last progress report.

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

- Continue analyzing administrative data,
- Continue the document review already underway and begin preliminary analysis,
- Hire and train additional staff for the document review,
- At the request of the City Council and Children's Services, we will comment on drafts of Children's Services' new clinical trials policy,
- Hold a meeting of Vera Clinical Trial Advisory Board members,
- Begin interviews with key respondents,
- Obtain IRB approval for phase I of the project, and
- Present our plan for phase II of the Key Respondent Interviews (interview children and caregivers) to Vera's IRB, the Vera Clinical Trials Advisory Board, and Children's Services' HIV/AIDS Health Care Advisory Board.

Appendix I: Confidentiality Protocols

- Vera document reviewers have completed the Collaborative IRB Training Initiative (CITI) course that discusses the importance of confidentiality in the context of research ethics.
- All Vera personnel who work with confidential data must sign a confidentiality agreement.
- Vera staff directing and implementing this project attended training conducted by the Legal Action Center on Article 27-F of the public health law (pertaining to the confidentiality of HIV status information). In accordance with Article 27-F, we have developed a need-to-know list of people with access to confidential HIV-related information. The list includes our clinical trials team, legal staff, Vera staff who share immediate office space with clinical trials team members, and information technology professionals who manage our network and will help us construct and maintain our databases.
- Children's Services case management files from the contract agencies that provide foster care will be reviewed at the contract agencies, in secured environments. Pediatric AIDS Unit case files will be reviewed in a secure file room at Children's Services' headquarters at 150 William Street. Policy documents, some of which may contain individually identifiable information related to HIV/AIDS or foster care status, will be reviewed at both Children's Services and Vera.
- All electronic media (discs and CDs) containing identifying data are stored in a locked box in a locked filing cabinet at Vera. Keys to the locked box and locked filing cabinets are kept in different locations, are under observation during working hours, and are stored in locked drawers.
- All paper documents containing identifiable data at Vera are stored in a locked filing cabinet that contains only Clinical Trials Project files and is accessible only to staff assigned to this project.
- Electronic files stored on Vera's network related to this project are stored in folders that are accessible only to project staff. Anyone entering Vera's network must supply a valid user name and password. Computers of all clinical trials team staff are set to lock automatically after five minutes of non-use.
- Transcripts and audiotapes of interviews will be numbered and will have no identifiable data. Consent forms, the only link between participants and the information they give, will be maintained in a locked filing cabinet at Vera separate from the interview transcript and tape.
- Document reviewers collect data from the field on paper and on laptop computers, both of which are kept in locked briefcases while in transit. The laptops are password protected at start-up and require an additional user name and password after start up. The laptop can connect only to Vera's network; all other methods of moving data off the laptops (printer ports, floppy disks, CD writers, etc.) have been disabled. Only Vera's Information Technology staff can change these settings. The laptops are set to lock automatically after five minutes of non-use. When a case is completed, electronic and paper files are removed from the brief cases. This is done each evening. All laptops are returned to Vera and stored in locked filing cabinets at the end of the work day.
- People entering Vera must pass through two security check points—one upon entering the building, the other upon entering Vera's space.