



The Well Project Women's Research Initiative on HIV / AIDS
Annual Meeting
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Amelia Island, Florida

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The Well Project Mission and the Women's Research Initiative on HIV/AIDS

The Well Project (TWP) is committed to changing the course of the AIDS pandemic through a unique and comprehensive focus on women. Given the increasing impact of the pandemic on women, TWP believes that a comprehensive focus on women must address prevention, treatment, and care. TWP's strategy as an organization is to focus our efforts on overcoming the three most significant barriers to accelerating progress:

- Research on women is inadequate, inefficient, and uncoordinated
- Communication of medical information on women is limited and not accessible to the patients and treaters who need it most
- Communities and care-givers most impacted by HIV lack capacity

The Well Project's Women's Research Initiative on HIV / AIDS (WRI) is the focal point of our efforts to accelerate research on women.

This report documents the 4th annual meeting of the WRI, our significant progress to date, and the major action plans we have identified for 2007.

The WRI mission

The mission of the WRI is to encourage expedience and efficiency in research about HIV disease in women by producing a coordinated effort across disciplines and organizations. *Our aim is to enable more, better, and faster research that yields improved prevention, treatment, and care for women.*

Overall, the ongoing WRI body is made up of nearly seventy-five experts across disciplines and sectors. This group of experts, representing research institutions, clinics, government agencies, advocacy organizations, and pharmaceutical companies, has committed thousands of hours of volunteer time to this effort. We are most grateful for their significant contributions of time and talent.

The 4th annual meeting of The Well Project's Women's Research Initiative on HIV / AIDS (WRI) convened September 14-17, 2006 in Amelia Island, Florida. This year, the meeting participants included thirty individuals from the broader WRI body.

Evolution of the WRI: Significant accomplishments to date

The WRI has evolved over the past several years from a one-time Think Tank to a year-round initiative and a powerful force for change in the HIV / AIDS arena. Through the efforts of the WRI working groups, significant progress has been made in key areas. Highlights of these accomplishments include:

- Created a comprehensive, prioritized list of research needs on women and HIV
- Reviewed the National Centers of Excellence in Women's Health program as sponsored by the Office of Women's Health in the US Department of Health and Human Services to determine its impact on HIV care for women
- Partnered with amfAR to launch the Women HIV and AIDS Coalition (WHAC)
- Completed a comprehensive review of HIV antiretroviral (ARV) drug labels and started an ongoing dialogue with FDA on recommendations to improve access to data on clinical trials experience in women
- Encouraged FDA to perform a meta analysis of their database to analyze information specific to women in order to accelerate the development of future research – a project which is now underway
- Worked with Boehringer-Ingelheim (BI) to launch a national survey on women's experiences and information needs at HIV diagnosis and for three years following diagnosis
- Partnered to develop novel strategies for engaging and enrolling women in clinical trials that has contributed to the innovative "GRACE" study design, a women-focused clinical trial currently underway sponsored by Tibotec Therapeutics
- Developed a plan to launch a multi-phased research study using surveys to learn about women's knowledge and barriers to participating in clinical trials

2006 Meeting Focus: Breaking the constraints to progress

Building on the growing momentum of recent WRI accomplishments, this year's meeting focused on two key concepts: first, identifying the most critical constraints to accelerating progress in research and second, focusing our efforts only on those specific constraints within our direct sphere of influence. This approach helped the WRI to zero in on a few key initiatives for the coming year.

These initiatives can be broadly described as addressing two basic questions:

1. What things do we *not* know that, if known, could significantly impact the course of the epidemic?
2. What things *do* we know which, if broadly disseminated, could significantly impact the course of the epidemic?

What we don't know: Our aim here is to *enable more, better and faster research*. To accomplish this, the WRI identified initiatives in three areas:

- Research "policies, practices, and priorities": The major constraints to research progress are policies and practices which create barriers to research participation for women. Identifying and removing these policy and practice barriers will accelerate research progress significantly. With these barriers relieved, we

propose identifying the top three to five research priorities which have the potential for meaningful breakthroughs over a three to five year period.

- Clinical Trial Network Accountability: With the framework for research “policies, practices, and priorities” developed, we will have a significant tool to hold the Clinical Trial Networks accountable for their focus on enrollment of women in clinical research. The timing of this work is critical as the clinical trial networks are undergoing a reorganization based on the recent NIH reauthorization.
- Community engagement and leadership development: Through a national survey of HIV-positive women and through the National Positive Women’s Training Initiative – we will engage the community of positive women in research, education, and advocacy. This effort will further inform the policies, practices, and priorities as we move forward.

While there is much we don’t know, there is much that we do know. Our aim here is to *yield improved prevention, treatment, and care for women*. To accomplish this, the WRI identified initiatives in a few key areas to put information into practice:

- Label review dissemination: Identify mechanisms to disseminate the findings from the label review analysis of the WRI. A number of tactics and actions were identified.
- Community, patient & provider education: Identify mechanisms to disseminate important HIV research findings and integrate them into broader women’s health care.

The detailed action plans for 2007 in each of these areas are addressed in the next section.

WRI Key Actions for 2007

Action 1: Research Priorities, Policies, and Practices

Initially, our discussions launched from last year's work were focused on creating a "Living Research Agenda". We discussed creating a dynamic process for the WRI to assess research progress and to publish an updated agenda on a regular basis to reflect the most current priorities. As the discussions progressed however, the group realized that the major constraint is not the lack of questions to ask, but rather, systemic obstacles to women's participation in research. These obstacles are often created by both policies and practices which prevent researchers from succeeding in finding the answers to the ever growing list of important questions. By developing a framework document on "Research Priorities, Policies, and Practices" the WRI believes we will create an important advocacy tool to advance research progress.

For example, as policy, there are no current requirements that companies seeking ARV drug approval need to demonstrate safety and efficacy in a population which is, by race and gender, representative of the population in which the drugs are intended to be used. Identifying and relieving these policy and practice barriers will accelerate research progress significantly.

Additionally, with these practical barriers addressed, we also propose identifying the top three to five research priorities which have the potential for meaningful breakthroughs over a three to five year period. The WRI suggested reviewing all of the available research agendas that focus on or include women and girls. This review will streamline our efforts to identify the common areas of focus as well as identify any missing components necessary to develop the WRI list of *Essential Research for Women and Girls with HIV* which we will disseminate broadly. We will use this list to focus our advocacy efforts with all stakeholders in HIV research.

Next steps:

- Convene working group of WRI to develop draft document on research policy and practices
- Convene working group of WRI to develop the WRI list of *Essential Research for Women and Girls with HIV*

Action 2: Clinical Trial Network Review

During the meeting, a strong consensus emerged that the WRI should pursue a review of the AIDS Clinical Trial Networks (e.g. VTN, MTN, PTN, IMPAACT, INSIGHT, ACTG) and funding mechanisms (e.g. DAIDS) to assess their efforts, policies, and practices regarding women's participation in research on HIV/AIDS. The timing of this work is critical as the clinical trial networks are undergoing reorganization over the next year with opportunities to develop new detailed plans and requirements from the NIH and DAIDS as a result of the recent reauthorization. This reorganization should provide the opportunity for external input and a thoughtful review of both priorities and practices that will impact the work of these networks specifically as it pertains to research on and including women and girls with HIV.

It was decided at the meeting that this will be an initiative of TWP and does not require a WRI working group.

A review of the clinical trial networks would assess, at minimum:

- Who is including women and girls on their agenda?
- What are they asking?
- How are they asking it?
- In all studies, how many women are enrolled? Are there enough to provide statistical analysis of sex and gender differences?
- Do study sites provide primary care?

The group identified several potential action steps for TWP to take:

- Assess efforts in similar areas (e.g. Microbicides Trials Networks) to determine how they were successful in advancing their agenda.
- Review the OAR research agenda and funding mechanisms. How are the clinical trial networks accomplishing the stated goals for women and girls by the NIH and OAR?
- Partner with the Congressional Black Caucus and others who accurately reflect the population of women most affected by HIV/AIDS in the US.
- Based on the review, request appropriate reprioritization of budgets to address agenda for women and girls.
- Ensure third party independent review of the clinical trial networks.

Action 3: Community Engagement Working Group

The WRI believes that improving community engagement and leadership capacity is critical to furthering research, prevention, treatment and care. A working group of the WRI was formed to better engage women in two key areas: first, understanding research needs and barriers through a national survey and second, increasing the leadership capacity of HIV-positive women through a national peer support program. By engaging the community of positive women in research, education, and advocacy, we will further inform the policies, practices, and priorities of research as we move forward.

Background

Across the United States, HIV / AIDS is disproportionately impacting the lives of women in low-income communities, particularly women of color. Between the years 2001-2004, African American women accounted for 68% of HIV / AIDS diagnoses among women in the 33 states with confidential name-based HIV reporting. Latina women account for 18% of all new infections even though they represent less than 5% of the total population. More than three-fourths of those cases were attributed to heterosexual contact. In 2004, the rate of AIDS diagnoses among African American women was 23 times higher than that of their white female counterparts.¹

Although much of the crisis mentality about AIDS in the United States has waned, HIV is still a crisis among women in this country. Women infected with HIV are further disadvantaged by having limited, if any, access to local social support programs where they can talk with one another about treatment, care, and the every day stresses and impact of HIV on a woman's life. As the number of women infected with HIV continues to rise, there must be a reciprocal increase in peer health education programs to address and support the unique needs of women living with HIV. Decades of research has shown that social support reduces individuals' vulnerabilities while serving as a psychosocial "protective factor" to the harmful effects of stress on health.²

HIV-positive women are also disproportionately under-represented in leadership roles in their communities. As the numbers of positive women are increasing, the roles and voices of these women should be reflected in their communities, on planning councils, and on advisory boards. The leadership and advocacy of HIV-positive women, particularly women of color, is important to address the specific and different realities for women living with HIV. As more HIV-positive women choose to become involved in their communities, social networks form that enhance information dissemination, psychosocial support, and the reduction of stigma. HIV-positive women, who have access to training and mentoring, have increased leadership competency and are better prepared to undertake leadership roles in their communities, such as on the Ryan White Title I and Title II Planning Councils and Consumer Advisory Groups. Additionally, increasing women's participation in HIV research requires the active involvement of HIV-positive women in all levels of clinical trial design and implementation.

As of 2004, women comprised approximately 27% of persons living with HIV infection in the 35 states with HIV reporting. Yet, historically, women have been underrepresented in

¹ Centers for Disease Control and Prevention (2006). Fact sheet: HIV / AIDS among African Americans. Retrieved March 2006 from <http://www.cdc.gov/hiv/topics/aa/resources/factsheets/aa.htm>

² Heaney, C. A. and Israel, B. A. (1997). *Social Networks and Social Support* in Health Behavior and Health Education. Glantz, Lewis, and Rimer, eds. p. 182.

HIV clinical research. Although women have been shown to have differences in HIV viral load, selected drug-related toxicities, and pharmacokinetics compared with men, there is little information about most of our antiretroviral therapies to make rational decisions about choice of therapies and dosing by gender. It is critical, therefore, that women be included in clinical trials in large enough numbers to be able to understand how best to use antiretroviral therapies in their treatment.

Working group goals

The WRI community engagement working group is focused on how to better engage women in community leadership and research. Two goals were identified:

Goal #1: Launch the National Positive Women's Training Initiative

The National Positive Women's Training Initiative (NPWTI) will demonstrate that bringing HIV-positive women together enhances social networks, develops untapped competencies for leadership and growth, and helps to destigmatize HIV disease. NPWTI will build a network of well-trained HIV-positive women peer health educators to improve access to treatment information, increase social support in communities, and improve the lives of women living with HIV.

The Well Project strategy for the National Positive Women's Training Initiative is to locate, interview, convene, and update a group of women across the United States originally trained to organize local peer-based treatment education programs in the late 1990's through a program called the National HIV-U Training Program. The National HIV-U Training Program was a train-the-trainer program designed to provide women around the US with the skills, tools, and resources necessary to design peer health education programs tailored to the needs of HIV-positive women in their respective communities. Over a four-year period (1997-2000), 80 women from 40 communities around the US participated in an intensive five-day training program. This program encompassed components of a possible peer-based treatment education program while providing significant additional training on community organizing, program design and implementation, and follow-up mentoring for guidance and issue resolution.

Although the National HIV-U Training Program lasted only 4 years, we estimate that many of the women trained between 1997 and 2000 remain actively engaged in their communities as peer advocates, educators, or community leaders as a direct result of their participation in the program. We believe that with proper evaluation, the resounding impact of the National HIV-U Training Program will be proven and key learnings may then be applied to the development of new programs and services for HIV-positive women. In the last six years there have been no successful programs implemented at the national level designed to build capacity and increase social support in communities, improve access to treatment information, and foster a national network of HIV-positive women advocates. Tapping into the loose network of former program graduates will enable us to develop the National Positive Women's Training Initiative with efficiency and expedience.

The National Positive Women's Training Initiative will work on three fronts:

- 1) Conduct a needs assessment with the former graduates of the four National HIV-U Trainings that will lead to a tailored and needs-specific update training, as well as inform the design and development of the second phase of this project.
- 2) Using lessons learned from phase 1, a new group of HIV-positive women will go through the revised and enhanced national peer education training program.

- 3) Support, capacity building, and technical assistance will be provided for both groups in order to sustain their local efforts and develop long-range plans. In the third year of the project we will develop a national HIV-positive woman's support, advocacy, and educational network called the Positive Women's Leadership Institute (PWLI).

The timetable for this project is January 1, 2007 – December 31, 2009.

The Well Project believes that this peer-health education program will:

- Improve health and access to care of HIV-positive women by increasing the number of peer-led health education programs in their communities established by HIV-positive women graduates of the National Positive Women's Training Initiative
- Increase the leadership roles of HIV-positive women in their local, regional, and state HIV planning and advisory groups by providing skills training, capacity-building, technical assistance, and a network of support
- Strengthen relationships among positive women in the U.S. and launch a national HIV-positive women's support, advocacy and educational network: the Positive Women's Leadership Institute (PWLI)

Goal 2: Conduct a national survey of HIV-positive women regarding access to treatment, care, and their involvement in research.

As discussed in the background section, women comprised approximately 27% of persons living with HIV infection in the 35 states with HIV reporting in 2004. Yet, historically, women have been underrepresented in HIV clinical research. Although women have been shown to have differences in HIV viral load, selected drug-related toxicities, and pharmacokinetics compared with men, there is little information about most of our antiretroviral therapies to make rational decisions about choice of therapies and dosing by gender. It is critical, therefore, that women be included in clinical trials in large enough numbers to be able to understand how best to use antiretroviral therapies in the management of their HIV disease.

There is great speculation, but little is truly known about why women do not enroll in clinical trials on HIV in larger numbers. Addressing classic issues such as childcare and transportation needs at diverse study sites across the U.S. has not resulted in substantial changes in enrollment numbers. Researchers are often asked why women do not enroll in trials, but HIV-infected women themselves are rarely asked.

The goal of this project is to design and implement a national survey of HIV-infected women in order to better understand the barriers that keep them from participating in clinical research. The key steps and timeline are as follows:

1. Secure funding for focus group surveys to define parameters of a national survey
2. Conduct the focus groups
3. Define requirements and seek funding for a national survey
4. Conduct the national survey
5. Timeline:
 - a. Develop initial proposal for focus groups by January 2007
 - b. Secure multi-company funding for first phase of survey study design by February 2007
 - c. Conduct Focus groups and Expert Advisory Board by Spring 2007

- d. Develop and submit an abstract for presentation for the International AIDS Conference in Sydney and for the YWCA World Conference on Women and AIDS in summer 2007 to generate interest and financial support for National Survey to be conducted in 2008

Action 4: Information Dissemination to Providers and Patients

At the 2004 meeting, a working group called “Standards of Care” was established to help enhance research participation of women. Over the past two years, this group has made significant progress in several areas:

- Completed a comprehensive review of ARV drug labels and started (ongoing) dialogue with FDA on recommendations to improve access to data on clinical trials experience in women
- Encouraged FDA to perform a meta analysis of data including women in their HIV therapeutics database which is now underway

At the 2006 meeting, the major focus turned to how to disseminate the findings of the label review efforts so that providers and patients are aware of the latest information. To accomplish this, the WRI identified initiatives in a few key areas to put information into practice:

- Label review dissemination: Identify mechanisms to disseminate findings from the label review analysis of the WRI. A number of tactics and actions were identified.
- Community, patient & provider education: Identify mechanisms to disseminate research findings and integrate them into broader women’s health care.

As a first step, the group identified action steps to complete and validate the label review effort:

- Complete reviews of remaining drugs (Darunivir and Atripla)
- Review final spreadsheet with industry and FDA by Q4 - 06
- Develop a list of gaps and recommendations Q4 - 06 and meet in person at CROI in February 2007
- Produce white paper, abstract, position paper for broad publication in Q1 - 07
- Design marketing plan for broad distribution of TWP content derived from this analysis of on and off label treatment information Q1 - 07

To support the dissemination of this information, the group identified key principles of this education effort:

- Information must be very simple for use in clinical settings
- Information must be presented in standardized language and in technically accessible formats (e.g. XML) to encourage broadest possible dissemination
- To encourage adoption, information must be accessible via the most common existing mechanisms used by healthcare professionals (e.g. Medline, TWP website, eprocrates, pocket guides, conference sessions).
- Continuing education credits should be offered to encourage provider adoption.

With these principles identified, the group agreed on several next steps to develop the plan:

- Investigate web links and publication options for the updates and expanded information (e.g. epocrates, NIH sites, etc.)
- Consider producing a pocket guide for distribution (2007)
- Produce a CE program in 2007 for presentation at appropriate venues

Appendices

Appendix A: Women's Research Initiative 2006 Meeting Design and Agenda

Meeting Background

Since 2003, The Women's Research Initiative on HIV and AIDS has involved more than 75 of the top thought leaders across disciplines of research, treatment, and care of women with HIV disease. The WRI has identified the gaps and controversies in research on women and HIV and developed a prioritized research agenda. It has designed and launched an action plan for coordinating a multi-disciplinary effort to develop, track, and enhance research on HIV disease in women and worked to accelerate the pace at which this is implemented across sectors.

Meeting Intent

The intent of the 2006 Women's Research Initiative annual meeting is to assess the overall WRI strategy, share learnings from recent working group activities, and reconstitute working groups to pursue key activities for 2007. We anticipate full group working sessions and/or breakout groups in the following areas:

1. Constraints – Identifying solutions to critical barriers to accelerating research on women and HIV
2. Community Engagement -- Developing networks of HIV-positive women to influence and enhance all aspects of research, treatment, and care
3. Research Agenda – Assessing the current state of scientific research and prioritizing critical needs
4. Standards of Treatment and Care – Improving the clarity and accessibility of ARV use in women information

Meeting Agenda

Thursday, September 14, 2006

- 10:00 am – 7:00 pm Optional pre-meeting activities (hike, swim, spa, massage, etc)
6:45 pm Shuttle from Villas to Welcome Reception (shuttles run until 10:30)
7:00 pm – 10:00 pm Welcome Reception and Dinner *Marchet Burette*

Friday, September 15, 2005

- 6:45 am – 8:00 am Shuttles from Villas to Racquet Park Complex
7:00 am – 8:00 am Breakfast *Verandah Restaurant*
8:00 am – 8:45 am Welcome, introductions, and meeting overview *Heron Room*
8:45 am – 9:45 am TWP Organizational & Strategy Update *Heron Room*
9:45 am – 10:00 am Break
10:00 am – 12:00 pm Identifying constraints in the HIV/AIDS epidemic *Heron Room*
12:00 pm – 1:15 pm Lunch & Break *Verandah Restaurant*
1:15 pm – 3:00 pm Living Research Agenda *Heron Room*
3:00 pm – 3:15 pm Break
3:15 pm – 4:30 pm FDA Meta-analysis Update & Discussion *Heron Room*
4:30 pm – 6:45 pm Free time; Shuttle to Villas
6:45 pm – 7:15 pm Shuttle to Walkers Landing
7:00 pm – 10:00 pm Dinner *Walkers Landing*
9:00 pm -- 10:00 pm Shuttle to Villas

Saturday, September 16, 2006

- 6:45 am – 8:00 am Shuttles from Villas to Racquet Park Complex
7:00 am – 8:00 am Breakfast *Verandah Restaurant*
8:00 am – 8:30 am Day 2 kickoff session *Heron Room*
8:30 am – 10:15 am Improving Provider Information (Standards of Care) *Heron Room*
10:15 am – 10:30 am Break
10:30 am – 12:15 pm Community Engagement *Heron Room*
12:15 pm – 1:30 pm Lunch & Break *Verandah Restaurant*
1:30 pm – 3:00 pm Working Group Sessions *Heron Room*
3:00- 3:30 pm Shuttle to Villas
3:30 pm – 6:00 pm Rest, reflect, re-energize
4:30 pm Early bus option to Fernandina Beach (near dinner location)
6:00 pm Bus to dinner
6:30 pm Reception *Brett's Waterway Cafe*
7:30 pm – 9:00 pm Dinner *Brett's Waterway Cafe*
9:00 pm Bus to Villas

Sunday, September 17, 2005

- 6:45 am – 8:00 am Shuttles from Villas to Racquet Park Complex
7:00 am – 8:00 am Breakfast *Verandah Restaurant*
9:00 am – 10:15 am Working Group Action planning *Heron Room*
10:15 am – 10:30 am Break
10:30 am – 11:30 am Presenting Action Plans *Heron Room*
11:30 am – 12:00 pm Meeting Close *Heron Room*
12:00 pm Box Lunch, Shuttle to Villas
12:30 pm – 3:00 pm Depart

Appendix B: 2006 WRI 2006 Annual Meeting Participants

Richard Averitt
The Well Project
483 Edgewood Drive
Nellysford, VA 22958
W: 434-361-0015 F: 434-361-1001
raveritt@thewellproject.org

Julie Barroso
Duke University School of Nursing
DUMC 3322
Durham, NC 27710
W: 919-684-9341 F: 919-1-8899
julie.barroso@duke.edu

Dawn Averitt Bridge
The Well Project
483 Edgewood Drive
Nellysford, VA 22958
W: 434-361-0015 F: 434-361-1001
daveritt@thewellproject.org

Rebecca Clark, MD
LSU HSC
136 S. Roman St.
New Orleans, LA 70112
W: 504-903-7302 F: 504-903-5313
rclark@lsuhsc.edu

Elizabeth Connick, MD
Associate Professor of Medicine
University of Colorado at Denver and Health
Sciences Center
4200 E. Ninth Avenue, Box B168, MS1813
Denver, CO 80262
W: 303-315-0906 F: 303-315-8681
liz.connick@uchsc.edu

Terri Creagh, PhD
Director of Research
Clinical and Epidemiologic Research
3825 South Roxboro St., Suite 136-244
Durham, NC 27713
W: 919-403-5550 F: 919-403-1134
Cec1@mindspring.com

Jane Hitti, MD
Associate Director
University of Washington Medical Center
Dept. Ob/Gyn
Box 356460
Seattle, WA 98195
W: 206-543-9867 F: 206-616-9479
jhitti@u.washington.edu

Katherine Hollinger, DVM, MPH
FDA / Office of Women's Health
5600 Fisher's Lane, HF-8
Rockville, MD 20857
W: 301-827-0935 F: 301-827-0935
Katherine.hollinger@fda.hhs.gov

Ben Kozub
Boehringer Ingelheim
900 Ridgebury Road
Ridgefield, CT 06877
W: 203-798-5413 F: 203-791-5926
bkozub@rdg.boehringer-ingelheim.com

Meagan Lyon, MPH
Senior Research Assistant
Forum for Collaborative HIV Research
2175 L. Street NW, Suite 799

Gina Brown, MD
Maternal-Fetal Specialist
New York city Department of Health and Mental
Hygiene
2 Lafayette Street 18th Floor NC-34A
New York, NY 10007
W: 212-442-1771 F: 212-442-1789
Gbrown@health.nyc.gov
Susan Ellen Cohn, MD, MPH
Associate Professor of Medicine
University of Rochester
601 Elmwood Avenue, Box 689
Rochester, NY 14642
W: 585-275-2590 F: 585-273-1055
Susan_cohn@urmc.rochester.edu
Robert W. Coombs, MD, PhD, FRCPC
Professor, Laboratory Medicine & Medicine
University of Washington
Box 359690, 325-9th Avenue
Seattle, WA 98104-2420
W: 206-341-5200 F: 206-341-5203
bcoombs@u.washington.edu

Kristy Grimm
Associate Director, Virology Medical Strategy
Bristol-Myers Squibb
777 Scudders Mill Road
Plainsboro, NJ 08536
W: 609-897-3544 F: 609-897-6068
kristy.grimm@bms.com
Sally L. Hodder, MD
University of Medicine & Dentistry of New
Jersey
MSB-I506
185 South Orange
Newark, NJ 07101
W: 973-972-3846 F: 973-972-2122
hoddessa@umdnj.edu
Rowena Johnston, PhD
Director, Research
AmfAR – The Foundation for AIDS Research
120 Wall St. 13th Floor
New York, NY 10005
W: 212-806-1605 F: 212-806-1601
Rowena.Johnston@amfar.org

Sharon Lee
Director
Family Health Care
340 Southwest Boulevard
Kansas City, KS 66103
W: 913-722-3100 F: 913-722-2542
slee2@kumc.edu

Cathy Olufs
Education Director
The Center for Health Justice (formerly
CorrectHELP)

Washington, DC 20037
W: 202-416-0090 F: 202-416-0433
mlyon@gwu.edu

Andrew Pavia, MD
Professor and Chief, Division of Pediatric
Infectious Disease
University of Utah
30 N, 1900 E; Room 2A152
Salt Lake City, UT 84132
W: 801-581-6791 F: 801-585-3789
andy.pavia@hsc.utah.edu

Claire Rappaport
Community Liaison
International Network for Strategic Initiative in
Global HIV Trials (INSIGHT)
10 Inyo Street
Brisbane, CA 94005
W: 415-476-9554 x319 F: 415-476-6948
crappoport@php.ucsf.edu
Wendy Rhein
Executive Director
The Well Project
112 Krog Street NE, Suite 23
Atlanta, GA 30307
W: 404-474-3152 F: 404-474-4235
wrhein@thewellproject.org

Yolanda Rodriguez-Escobar
Executive Director
Mujeres Unidas Corba el SIDA
307 E. Evergreen
San Antonio, TX 78212

Stephen P. Storfer, MD
Senior Associate Director, Virology
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Rd.
Corp Center G3220
Ridgefield, CT 06877
W: 203-798-4011
ssstorfer@rdg.boehringer-ingelheim.com

8235 Santa Monica Blvd., Suite 207
West Hollywood, CA 90046
W: 323-822-3830 x13 F: 323-822-3838
cathylufs@earthlink.net

Martell Randolph
Community Educator
AIDS Research Alliance
621-A North San Vincent Boulevard
West Hollywood, CA 90069
W: 301-360-3871 F: 310-357-2431
mrandolph@aidsresearch.org

Patricia Reichelderfer
NIH/NICHHD
6100 Exec Blvd. 8B13D
Rockville, MD 20852
W: 301-435-6991 F: 301-480-1972
crappoport@php.ucsf.edu

Alex Rinehart
Associate Medical Director
Tibotec Therapeutics
2505 Meridian Parkway, Suite 350
Durham, NC 27713
W: 919-313-2665 F: 919-313-2670
arineha2@tttus.jnj.com

Ellie Schoenbaum, MD
Director of AIDS Research Program
Montefiore Medical Center
111 E. 210 Street
Bronx, NY 10467
W: 718-655-1809 F: 718-231-8655
eschoenb@montefiore.org

Kimberly Struble, PharmD
Medical Team Leader
Food and Drug Administration, Division of
Antiviral Products
4704 15th Street NW
Washington, DC 20011
W: 301-796-0819 F: 301-796-9338
Kimberly.struble@fda.hhs.gov

Melanie Thompson, MD
Principal Investigator
AIDS Research Consortium of Atlanta
131 Ponce de Leon Ave, Suite 130
Atlanta, GA 30306
W: 404-876-2317 x338 F: 404-872-1701
drmt@mindspring.com

Fulvia Veronese, PhD
Chair, HIV/AIDS Etiology and Pathogenesis
Coordinating Committee
NIH, Office of AIDS Research
5635 Fishers Lane, Suite 4023
Rockville, MD 20892-9310
W: 301-496-3677 F: 301-480-4742
Fx10@nih.gov

Ron Wilder
President
Aligned Action, Inc.
3434-135 Kildaire Farm Road, Suite 143
Cary, NC 2518
919-362-0679
ron@alignedaction.com