

**Forum for Collaborative HIV Research
2009 Update on Rethinking Approaches to Expanded Access Programs**

**Sofitel Washington DC Lafayette Square
806 15th Street, NW Washington DC 20005**

November 18, 2009

DRAFT AGENDA (version date: 09 November 2009)

8:00 - 9:00 a.m.		
<i>Breakfast and Registration</i>		
9:00 - 9:15 a.m.	Welcome and Introductions	Veronica Miller
9:15 - 9:30 a.m.	Recap of 2007 FCHR Expanded Access Meeting	Linda Onaga
9:35 - 10:05 a.m.	Expanded Access for Patients with Limited Treatment Options - Background and Survey Results	Nelson Vergel
10:05 - 10:45 a.m.	Lessons Learned from Recent EAPs and TINDs	Brian Woodfall Tibotec Hernan Valdez Pfizer
10:45 - 11:00 a.m.		
<i>Break</i>		
11:00 - 11:30 a.m.	Regulatory Perspective: FDA New Regulations on Access to Investigational Agents	Jeff Murray and FDA colleagues
11:30 - 11:45 a.m.	Academic Perspective	Kate Squires
11:45 a.m. - 12:00 p.m.	Private Practice Perspective	Jay Lalezari (by phone)
12:00 p.m. - 12:15 p.m.	Advocacy/community perspective	Lynda Dee; Bob Huff
12:15 - 1:00 p.m.	Discussion: What should future access programs look like? *Ideas and Recommendation on an EAP with 2 or 3 drugs sponsored by different companies	Moderator: Trip Gulick Discussants: Pablo Tebas; Nelson Vergel; Stanley Lewis; Garret Nichols; Linda Lewis
1:00 - 1:20 p.m.	<i>short break to get lunch and bring back to the table</i>	
1:20-1:50 p.m.		
WORKING LUNCH Continuation of Discussion		
Moderator: Trip Gulick		
1:50- 2:35 p.m.	Discussion: Where do we go from here? What are the recommendations and action items	Moderator: Dan Kuritzkes
2:35 - 3:00 p.m.	Wrap Up	Linda Onaga; Veronica Miller
3:00 p.m.		
<i>Adjourn</i>		