

# HIV Vaccine Trials Network

## US Community Educators/Recruiters Conference Call

Tuesday, Dec. 21, 2010 9 a.m. Pacific

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### Participants:

Carneka Grant – LA	Annet Davis Vogel – Philadelphia
Michael Haymer - LA	Brooke Willis – Cleveland
Keith Barsky - Orlando	Bob Bucklew – Cleveland
Maggie White – Houston	Teress Votto – Boston
Dan Eide - Denver	Coco Alinsug – Boston
Christopher Foote - Rochester	Kim Louis – Seattle
Jason Roberts - Rochester	Ro Yoon – Seattle
Patrick Fisher - Rochester	Erica Avant – Atlanta
Alex Hannan - Rochester	Borris Powell – HANC Legacy Project
Jim Carey – Chicago	Carrie Schonwald – HVTN Core
David Garcia – NYC	Genevieve Meyer – HVTN Core
John Bonelli – NYC	Niles Eaton – HVTN Core
Casey Braddy – Nashville	Gail Broder – HVTN Core
Vic Sorrell – Nashville	Magda Sobieszczyk – HVTN 505 co-chair
Gavin Morrow-Hall – San Francisco	

### MINUTES

Introduction	<p>Gail Broder: Thank you to everyone for allowing us to take over the agenda for today's call. A slide set and backgrounder were included in the conference call announcement. We at the HVTN and a subset of the HVTN 505 Protocol Team is keenly interested in what the iPrEx results mean to you and to HVTN 505. Magda will be reviewing the iPrEx results and answering your questions about the results, and then we'll open up for any comments you have about what the results mean for HVTN 505.</p>
	<p>Magda Sobieszczyk: Will quickly review the slides we sent, and our purpose here today is:</p> <ul style="list-style-type: none"><li>• To make you are aware of the iPrEx results;</li><li>• To let you know the HVTN 505 study team is working to understand what the results mean to 505;</li><li>• To ask:<ul style="list-style-type: none"><li>• What do these results mean to you?</li><li>• What do these results mean to your communities?</li><li>• What do you think the results mean for HVTN 505?</li></ul></li></ul>

	<p>We are starting on page 3 of the slide set, just to move things along quickly so that we might move onto your questions sooner.</p> <p>Please see slide set here: <a href="http://www.hvtn.org/community/SWGiprexpresentation.pdf">http://www.hvtn.org/community/SWGiprexpresentation.pdf</a>  For background information, click here:  <a href="http://www.hvtn.org/community/iprexbackground.pdf">http://www.hvtn.org/community/iprexbackground.pdf</a></p> <p>11 sites in six countries  2,499 participants  MSM and transgender- received truvada or placebo  Took it once a day and came to clinic once a month for adherence, risk reduction and sti counseling  Majority were in SAmer- only 9% in us</p> <p>No major side effects- nausea in the first 4 weeks of the study in ?%</p>
<p>Questions?</p>	<p>Ro Yoon wonders whether the results have been broken out at all by country. As their staff shares the results with 505 participants, they feel it would be helpful to have some context about the American study participants. Magda: The data has not been presented in this manner yet, but it is possible that more detail of this sort will become available over time. She agrees that it would be helpful to have this country-specific information.</p> <p>Erica Avant wonders whether there has been a breakdown of the data between MSM and transwomen. Magda: I haven't seen this yet, but I agree it would be very interesting to know. It is possible that it will be part of future presentations. I believe the next release of data is expected to happen at the CROI conference in Boston in February, 2011. Gail: Yes, it is important to note that only the initial publication has come out so far, and we can expect to see further analysis for some time. By comparison, HVTN just presented its final analysis from the Step Study and that study was stopped in 2007.</p> <p>Brooke —is high level of alcohol intake statistically significant?  Magda- we don't yet- they will look at that in further analyses.  Did they releas anything about the use of these meds in a preventive capacity in long term use.  No, but they will be following participants for a much longer time than was originally planned (another 18 ms). More info about adherence, etc.</p>
<p>What do the iPrEx results mean to you, your communities and HVTN</p>	<p>Ro is interested in knowing what participants think about PrEP, whether they would be interested in using it, or if they have been using it already. Magda: Yes, this is the sort of informal analysis that could be incorporated into 505.</p> <p>Gail: Magda, could you explain a little more about what you mean by informal or formal analysis, so that those terms are clear?</p>

505?	<p>Magda: Informal would mean things like asking about PrEP use, and documenting this information for each participant. It could mean adding questions to our behavioral surveys, or concomitant medications forms. Formal would involve things like monitoring drug levels. It could also mean making PrEP available to 505 participants and analyzing and comparing people’s immune responses.</p>
	<p>Keith: Wouldn’t that impact our ability to tell what the vaccine is doing? How could you tell the difference?</p> <p>Magda: Yes, that’s exactly the challenge. We might need to add arms to the study, or increase the sample size to account for the change in incidence. These are all things the protocol team must consider.</p>
	<p>Gavin would be interested in adding an arm to the study that receives PrEP. He feels that since the US enrollment in iPrEx was such a small percentage of the overall study, 505 would offer an opportunity to give PrEP to a larger cohort and get country-specific data. This would allow us to look at adherence, attitudes about taking PrEP daily versus being vaccinated, whether PrEP is something people would choose to use for HIV prevention, etc. Magda: Yes, this is a unique point in time, so if we wanted to look at these kinds of questions, there is a limited period for us to make changes.</p>
	<p>Borris: If PrEP were added to 505, would the protocol be changed to offer STI screening? I feel that this was a very important component of the iPrEx trial. Magda: Yes, this was important, and it is a very good suggestion.</p>
	<p>Gail Broder: Further questions or comments? We will be posting all of the minutes of these calls on the public HVTN website, to keep this process as transparent as possible. These will be uploaded as they are completed. There is also an e-mail address where you can send any additional comments to the protocol team for their consideration.</p> <p>Niles: Decisions about how this information will impact 505 are likely to be made in early 2011. The protocol team would like to be able to state the HVTN’s position at the CROI meeting.</p>