



CAB Retreat 2005 All I can say is, 'Wow!'

by Mark Kornegay, New York CAB

First of all, I have to say that it felt good, especially after the grueling plane ride, to be greeted by other folks who were attending the Global CAB meeting. The actual familiarization process started in the airport. In the morning is when work — and I mean work started.

All I can say is, 'Wow!' That reaction is encompassing of the whole HVTN Seattle experience. It was like being at the U.N. of Vaccines; I felt honored to actually be sitting in one room with people interested in doing the work from all around the world. The exchanging of ideas and meeting of the minds that occurred was incredible. Also incredible were the presentations, given by both noted doctors and experts in the field as well as fellow CAB members. Admittedly, it was very encouraging that my fellow CAB members did some of the presenting!

I gained a lot of new knowledge especially about where the HVTN lies in the government hierarchy, the inner workings of the HVTN, and the different levels that one can become involved in as you increase your level of volunteer participation, which I plan on doing. I was really inspired which will definitely help our CAB. I will sit with Denise Goodman, our Community Educator, and go over what

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In this issue

The recent CAB Retreat brought CAB members from all but one site to Seattle for trainings on a variety of topics about HVTN work. In that spirit, this issue of the CAB Bulletin brings you an overview of work currently being done at Core and at the HVTUs.

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An update on the Network from Dr. Larry Corey

Over the past year, the HVTN has undertaken several activities that have given us a chance to reflect on the progress and goals of the Network, and to articulate our intentions as we move forward. This fall, the HVTN Full Group Meeting will be focused more on the Network's own operations than reviews of the field of HIV vaccines. This meeting will provide an opportunity for us to share with each other key information about HVTN trials and accomplishments from our sites.

As we take stock of the Network, it has been clear that the most important current challenge we are facing is recruitment for two new exciting HIV vaccine concepts that we have just

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CAB members at the Retreat take a last moment to say goodbye to each other. From left is Joann Williams (Philadelphia CAB), Dave Crawford (Chicago CAB), Mark Kornegay (New York CAB), Michael Flint (Baltimore CAB), and Frank Phiri (Blantyre CAB).

My experiences at the CAB Retreat

by Phineas Malahlela, CAB member, Soweto, South Africa

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trainings I will do for the CAB.

I keep pondering the following questions, and since I've left Seattle I ponder them more and more: Who is the community of the CAB? Who is the community? Is it those infected and affected by HIV? Is it people we are targeting for a specific study? Is it HIV negative people? Since the Retreat, I am on a never-ending quest for answers.

Love you guys!!
Peace (really the operative word now)
Mark Kornegay

The objective of the CAB Retreat was to train participants in information that they can then take back to their sites and offer training on. As a prospective trainer, I learned how to make presentations and formulate an appropriate message. I also learned that vaccinology, immunology and epidemiology are inter-related in the process of developing an HIV vaccine.

According to the needs of my local cab, I will prioritize my trainings for them as follows: protocol reading/protocol review; ethics training; public speaking. Other training sessions will be done as need arises using training material from HVTN.

As I talked to other CAB members at the Retreat, I sensed dedication in the way that other CABs conduct their activities. They carefully plan events, HIV/AIDS vaccine awareness days and workshops around the process of developments in HIV vaccine research.

I think the CAB Retreat will help our CABs because the number of trained CAB members will multiply at each site. Gatherings such as the Retreat help CABs because one learns what worked best for other CABs, gets to know other CAB members, understands CAB diversity in the HVTN and learns new techniques of doing things.



Presenting to CAB members: Just like a cocktail party discussion

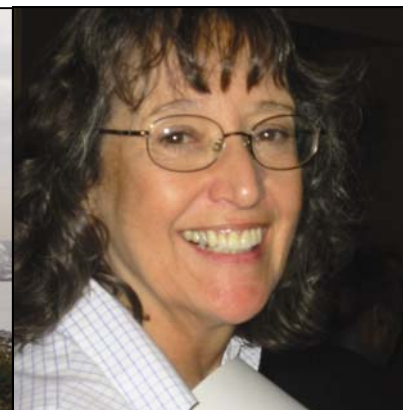
By John Hural, Quality Assurance Project Manager, HVTN Lab Unit

When Andy Lambert and Lisa Bull asked me to put together a group of scientists to explain our assays at the CAB retreat I thought about how often I describe what I do at cocktail parties and the like. What we find when discussing scientific issues with a random cross-section of the population is that everyone has a different level of background information, and we just need to be prepared with a range of terms and analogies to help bring everyone into the discussion. Some scientists are, of course, more social than others, and are therefore more practiced at varying the terms we use.

I think each of us who participated in the assay workshop embraced this chance to interact with the community members and provide them with information that would be useful. We found the participants to be engaged and truly interested in understanding how we evaluate the immune response to vaccines. They asked pertinent questions that indicated they were following the presentations and expanding their knowledge of immunology and immunological assays. It was a rewarding experience to see the community members passing on this information to each other in the smaller groups. Their presentations were impressive, particularly considering the short descriptions that they received from us. I think I can speak for all of us in saying we would all welcome the chance to interact with the community members more and to learn more about the techniques they use when conducting their work.



The CAB Retreat Assay Workshop proved to be very popular. John Hural, from the HVTN Laboratory Unit, gave an introduction of lab assays (tests used to determine immune system reactions). Everyone then divided into groups and talked with a lab scientist about one particular assay. Finally, one person from each of the four assay discussion groups joined together, and the CAB members explained to each other what they had just learned. It was a very dynamic session.. Above, left to right: Helen Horton answers a question from Richard Sarkis (Rochester). Phineas Malahlela (Soweto) explains his assay. John Hural. Paula Chirinos (Lima), Rubens Duda (Sao Paulo) and Mauro Nunes (Rio de Janeiro) bridge the language gap while discussing a protocol.



CAB members get a view of Seattle, left. Above, Linda Sawin, Seattle CAB member, is feeling pretty relieved after successfully presenting to her peers on 'How to read a protocol.'

HVTN CAB Retreat 2005: A worthwhile learning experience

by Frank Phiri, CAB member, Blantyre, Malawi

This year's HIV Vaccine Trials Network (HVTN) Community Advisory Board (CAB) conference in Seattle, Washington (September 28-October 1), definitely did not disappoint and provided fresh insight into the scope of my work as a community volunteer for my site in Blantyre. The Retreat evidenced the unflinching devotion that communities and scientists have invested in the search for a vaccine that will one day prevent infection by HIV.

Rigorous, but at most times flexible, sessions of academic work and truly candid talk about challenges that researchers and communities face through the various phases of vaccine trials filled the three-day retreat. For a number of board members like myself, this was our first experience at a Network meeting, and our first chance to talk with a team of more experienced CAB members. Most importantly, it was an opportunity to get under the spell of research doctors and learn new things related to the trials, and this helped make the third annual CAB Retreat worthwhile. It was most inspiring that, despite their

experience in the HVTN family, old-time CAB members like Richard Sarkis from New York were ever more eager to learn from first-time retreat participants like myself. Through the Retreat's discussions, I admired the work and milestones that other sites have accomplished.

I am happy to have learned a lot of new things, most of which I only had a vague idea of previously. This was not a media event, but as a journalist the massive tomes of information we received made me think again about better approaches to coverage of HIV vaccine trials that I believe most media organisations in Africa are missing.

My biggest task now is to make my CAB more acceptable in the eyes of stakeholders and the often-cynical public. That way, we will give our research staff and PI's peace of mind to concentrate on their laboratory work. In all medical research trials that use humans, including HIV vaccine trials, gaining public acceptance

and understanding presents its own tall challenges. Yet from my brief experience in Seattle, it became clear to me that the HVTN is not doing badly in dealing with most of these challenges.

One of my key assignments upon my return from this successful retreat is to train my CAB on some of the specifics of the science of HIV vaccine development. As my site is currently in the second stage of Phase I of a vaccine trial, after successfully completing the initial safety phase, I believe that learning a broader base of the science could help develop the understanding by the CAB of what goes on in the bodies of our trial participants.

Finally, I would like to publish a newsletter for my CAB. I heard about other newsletters and websites that HVTUs have, and I would like my site to have this advantage for communication.

started: the Step Study (HVTN 502) and HVTN 204. The Step Study is a Phase IIB trial and is the HVTN's first efficacy trial, and it's the largest trial to date (3,000 persons). It is being done in collaboration with Merck, in a true collaboration, integrating sites, costs, and work, of which we should be proud.

Evaluating the efficacy of a vaccine is a real milestone for both the vaccine developer and the HVTN. Many resources, people, and hard work were needed to carry us this far, and we are at the brink of defining whether the scientific community will have achieved a breakthrough in HIV vaccine development. The immune responses we have produced with the Step Study vaccine concept is greater than any other study vaccine we have tested in our network. We think the study vaccine is generating the type and quantity of immune responses we feel will be necessary to impact an infection like HIV. The purpose of the STEP trial is to determine if the vector will actually reduce the acquisition rate or rate of progression of HIV.

The next milestone is the opening of HVTN 204, the Phase II evaluation of the DNA and Ad5 vaccine developed by the Dale and Betty Bumpers Vaccine Research Center. The VRC vaccine is an exciting and complementary approach to the Step Study vaccine. It is actually a mixture of 10 separate study vaccines, mixed into two vials. One vial contains six separate DNA study vaccines and the other a mixture of 4 separate adenovirus vector study vaccines. The genes carried in the VRC vaccine cover the genes that we feel will produce immune responses to a wide variety of HIV isolates worldwide. Thus, while these two vaccine concepts have some similar components, they are also quite different and offer exciting approaches to vaccine design and development.

Evaluating these vaccines thoroughly and well are challenges for us and for the global community involved in de-

veloping an HIV vaccine. It is important for us to meet this challenge. As a Network, we are now building on our potential and drawing on our dedication toward developing a useful HIV vaccine. We have arrived at the brink of what we have all dreamed about. It is now time to turn this dream into reality. The trials will require many participants and visits, which, while no small task, is one we must meet.

As we develop our recruitment for the Step Study and HVTN 204, the HVTN will also continue to move new study vaccines into Phase I trials. We will focus on raising awareness of vaccine research among the communities most affected by the epidemic. And we will continue to

build effective relationships between the community and the researchers.

This is an exciting time in the Network. I want to thank all of you for the work you are doing both to reach out into your communities and to build stronger relationships with HVTN team members in the clinics. We face an important task in the upcoming months and years, and we thank you for the critical roles you play in the HVTN.

Cordially,

Larry Corey,
HIV Vaccine Trials Network
Principal Investigator

The HVTN 066 protocol team at work. It is important to remember that very few people in the room understand every piece of the protocol — there are many areas of specialty, and it takes everyone working together to make the most useful document possible.



Once the work is over, everyone can enjoy the sense of accomplishment and camaraderie. Phineas Malablela, CAB member from Soweto, stands in the center with the HVTN 066 sign.



Community Educators join protocol teams

CAB representatives have always been a part of HVTN protocol teams, but recently the HVTN added Community Educators to the teams as well. Each protocol team now has one Community Educator and two community representatives. The CER and one of the CAB members attends each face-to-face protocol meeting, and all may join in on the protocol team conference calls and through email correspondence. Sometimes both community members participate in all meetings, and sometimes they alternate attendance. Below are some thoughts from recent CER protocol team representatives on what they have gained from participating in the protocol process.

Diving right in

Being on the HVTN 064 Protocol Team has been a very rewarding experience. In preparation for the face-to-face (F2F) protocol meeting in January 2005, I met with local CAB member Florette Ruggiero, who is also a team member but who was not at the F2F meeting. Over the next two weeks, she and I each raised questions about the protocol and then submitted these to Core prior to the F2F meeting. Most of these questions addressed the informed consent.

At the F2F meeting in Seattle, Nilda Altamirano (CAB Protocol Team member from Lima, Peru) and I were members of the Team's Informed Consent working group. Out of approximately 100 changes that the Team suggested for the entire protocol, almost 50 were for the informed consent. For example, although the draft protocol included information about the use of PVP (Polyvinylpyrrolidone- the adjuvant mixed with the experimental DNA vaccine in this study) in experimental DNA vaccines, it was unclear whether or not PVP had been approved as a vaccine adjuvant. We clarified that PVP is being used safely in many FDA-approved drugs such as antibiotics and eye drops.

Being on a Protocol Team has greatly increased my understanding of protocols and my ability to explain the protocol development process to our CAB and other community members. I can better articulate why the research and development process takes so long, while expressing my confidence in a Protocol Team's many responsibilities.

—*Sydney Montstream-Quas,*
Providence Community Educator

Learning from each other

The CAB representative I worked with on the HVTN 065 protocol team, Rick Church, was helpful in providing a fresh perspective into the community. As CER staff, we become so saturated with protocols it can be difficult to see things from an unsullied point of view. He helped me recognize that what we CER may take for granted, some of our potential participants may not fully comprehend.

On the other side of the fence, I feel I was able to make Rick aware that informed consent is not just a piece of paper, it is a process. In that process we insure that participants are fully educated as to trial purpose, length, possible risks including social harms, and benefits to them.

We were able to work together as a team (CAB, CER, and CEU) to merge both the CAB and CER sides into what we felt was a strong consent form that would be easy to understand, yet

stressed the main issues central to the vaccine trials.

—*Cortni Romaine, St. Louis Recruiter/Retention Specialist*

Speaking from experience

I am frequently asked about protocol development. Now, I have hands on knowledge of the process. Although it has been explained to me many times, there is nothing like actually experiencing it, and my ability to explain how protocols are developed and who contributes has improved tenfold. Going over the protocol line by line with the team, hearing the different perspectives, and having all of my questions answered has given me an added confidence. The diversity of people working together as equals, trying to reach a common goal, has reignited my belief in the process. The community perspective (CER and CAB) was highly valued and respected. Seeing this increased the magnitude of my voice in the community. Many times in the past, I have been accused of blindly rubber stamping the effort, but now I can discuss what actually happens. A lot of work went into the development of the protocol draft (066), and, collectively, the team banded together to produce a working document. I am taking that experience with me into the community.

—*Theron Scott, Johns Hopkins Educator*

Andrew Lambert, HVTN Community Education International Projects Manager, Theron Scott, Hopkins (Baltimore) Community Educator, and Phineas Malablela, Soweto CAB member, prepare community comments for the HVTN 066 face-to-face meeting in Seattle. During these meetings, the community team discusses the protocol draft, raises concerns, and prepares comments and questions for the face-to-face. The community team usually focuses on the informed consent document, although they may comment on any part of the protocol.



Multi-site CAB Retreat hosted in Nashville

By Shawn McCormick, Vanderbilt CAB co-chair

This summer, the Vanderbilt University CAB hosted a retreat in Nashville for HIV-research-focused CAB members (from both HVTN and non-HVTN CABs) that are in the middle of the country. Representatives from CABs in Tennessee, Alabama, and Missouri met July 22 and 23 to discuss the fight against HIV and AIDS taking place in between the two coasts.

Attending was a broad spectrum of activists and volunteers, not only from the world of HIV vaccine studies, but also from areas of prevention and treatment advocacy. The primary objective was to find common ground: the challenges we each face, our shared goals, and the ways we can work together to reach those goals.

We started Friday night with a Welcome Event and a celebration of the release of the second edition of the AIDS Vaccine Advocacy Coalition's AIDS Vaccine Handbook. Representatives of the local GLBT press asked questions, and best of all, the arriving CAB members met and started the dialog that was to continue throughout the conference.

Bright and early the next day, Vanderbilt HVTU CAB co-chairs Keri Adams and Shawn McCormick and Vanderbilt HIV Vaccine Program Community Educator and CAB Liaison Josh Barnes welcomed all and stressed that the conference was to be an interactive opportunity for group dialog. Diverse opinions were welcome, and attendees were encouraged to share their personal experiences.

To emphasize the feeling of shared community, the first workshop focused on the history and growth of community involvement in HIV/AIDS. Next up was a Civil Society Forum, featuring a panel of experts from the worlds of HIV prevention, treatment, and vaccine research. The panel discussed and answered questions about the different priorities each group had, conflicts that can arise, common challenges, and areas for collabora-



Unfortunately, the photos from the Nashville CAB were destroyed, but Josh Barnes, Vanderbilt Community Educator, was willing to send in a photo of himself modeling the Retreat T-shirt, with the Nashville skyline in the distance.

tion. Edd Lee of AVAC delivered the keynote address, "Social Justice and Community Involvement in HIV/AIDS," which provoked a great deal of discussion.

In the planning stages, attendees expressed an overwhelming interest in the ethics involved in HIV/AIDS research, leading to a workshop focused on the community's role in ethical HIV/AIDS research. This was facilitated by Carolyn Szetela, Ph.D., Meharry Medical College, and Butch McKay, Birmingham CAB member and member of the HVTN Ethics Working Group. CAB member Mark Hubbard then led the group in a workshop on working with the entire community that brought the day's many chains of discussion together. This discussion focused on concrete ways that different CABs can work together.

The conference's scope was ambitious, but it was clear that these CAB members had a common impulse to take action. Feedback was positive, and many of us came away with new ideas for reaching out to our communities through work with other CABs. We shared successful strategies for keeping our members engaged and energized,

and for communicating with the diverse social and ethnic groups that we serve. Many attendees were buoyed by a renewed awareness of their own vital role in a larger force fighting HIV and AIDS, and we were all humbled by the enormous, unflagging dedication and passion that these CAB members possess.

Perhaps most remarkable about the conference was the way it came into being through the efforts of CAB members reaching out to each other. The conference attendees proved that CABs have rich resources in their members, and it was exciting to expand on the attendees' knowledge.

In addition to the willingness of so many CAB members to give of their time in attending, an enormous amount of work went in to planning and executing the Cross-CAB Conference. We were extremely gratified by the many people who helped us plan and host this event. Find out more about our spirited Cross-CAB Conference at www.crosscabconf.com.

Community Education and Recruitment Posters from 2005

As education and recruitment work continues to develop at the HVTUs, sites are evaluating and communicating information about their work. Below are excerpts from several of the posters presented by HVTU staff at conferences in the last year.

University of Maryland presented "Recruitment of African American Volunteers in Preventive HIV Vaccine Trials" at AIDS Vaccine 2005. Included here is their abstract, which gives an overview of their work:

Background: Recruitment for preventive HIV vaccine trials in an inner city population that is 64 percent African American is challenged by distrust of government research and the legacy of Tuskegee.

Methods: Social marketing (radio and print advertisements), and community outreach (health fairs, flyering) are employed to recruit volunteers to contact the site's toll free number. Screening triage is employed for early identification of volunteers who do not meet eligibility criteria. The Project BRAVE Volunteer Recruitment Tracking Database monitors enrollment efficiency and referral source in real time to guide recruitment and enrollment processes.

Results: In the first quarter of 2005, the impact of different recruitment strategies was monitored. The leading source of calls was via a "Q-munity" radio station targeting an African American audience with trial eligible demographics. When tracking demonstrated a decline in call volume, ramp up of radio advertisement units increased call volume and allowed the site to achieve 200 % of enrollment target for the quarter with African Americans comprising 100% of newly recruited volunteers. Men and women responded almost equally to recruitment approaches but women were less likely to complete or to be successfully enrolled. These new approaches resulted in the development of an appropriate cohort of volunteers, reflected in the fact that 61 percent of those who completed a clinic screening visit met eligibility criteria for enrollment, an improvement over our previous record of 45 percent. As a consequence, the labor intense process of screening to enrollment was reduced from a ratio of 4:1 to 2:1.

Conclusion: Targeted social marketing is successful in achieving high levels of African American enrollment. However, barriers to enrollment of African American women need to be addressed.

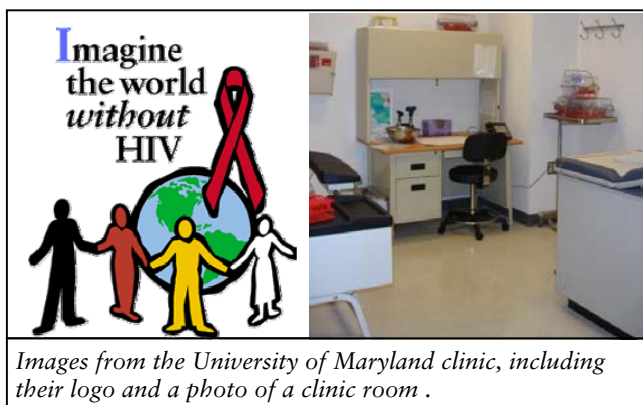
San Francisco's AIDS Vaccine 2005 poster, "A comparison of recruitment strategies at a U.S. HIV vaccine trials unit," listed the conclusions from a comparison of three recruitment strategies: print, internet and TV-based advertisements.

Conclusions

- Participant refusal and ineligibility excluded 85% of original contacts.
 - Significant effort is required to pre-screen participants, emphasizing the need to identify efficient recruitment methods.
- Internet-based recruitment was a successful, inexpensive strategy for recruitment.
 - At our site, internet advertising using craigslist.com was 15% the cost of print and TV strategies, yet generated a comparable number of office screens.
- While TV yielded half as many initial contacts than print ads, a higher proportion came for office screens.
 - This also held true among persons of color who contacted the HVTU.
- Further development of TV advertising is warranted as a method to reach a racially/ethnically diverse U.S. population.
 - Optimizing ad placement and minimizing development costs may improve TV's cost effectiveness.

Future Recommendations

- Because communities of color in the U.S. are disproportionately affected by HIV/AIDS, further targeted strategies are needed to enhance recruitment of diverse populations.
- Pooling recruitment data across trial sites will provide greater power and generalizability to identify the most efficient methods to recruit diverse cohorts.
- Systems to closely track recruitment methods for individuals at high risk for HIV infection are also needed to ensure rapid accrual into ongoing and future efficacy trials.



In Seattle, the staff put together a poster detailing work they did to assess and improve participation in and satisfaction with the CAB. Their conclusions led them to the following changes:

Post Assessment

- Adjusted staff/CAB ratio at meetings
- Redefined roles and responsibilities; created volunteer agreements and new recruitment materials
- Formed committees and working groups
- Organized orientation/retreat
- Involved CAB members throughout the process

AIDS Vaccines 2005 Conference in Montreal

by Dan Kuninsky, Community Educator/Recruiter, Nashville HVTU

Going to Montreal for the 2005 AIDS Vaccine Conference was certainly an opportunity I appreciated in my role as a Community Educator/Recruiter for the Vanderbilt HVTU. In one trip I felt like a scientific collaborator, a community outreach worker, an advocate, and an explorer.

Each day of the conference was packed with various presentations, poster sessions, and round-table discussions. This was my first scientific conference as a Community Educator. What I gathered from the meetings most of all was actually a sense of urgency and optimism. There were a broad array of HIV/AIDS research groups represented, but the two presentations that hit home for me most were from HVTN leaders. Dr. Judy Wasserheit, HVTN Director, gave a concise overview of the state of the field, while Dr. Larry Corey, HVTN Principal Investigator, summarized the changing face of HIV Vaccine clinical trials. Together, these presentations gave me a global perspective on our mission. In the day-to-day work of a CER it is sometimes easy to lose sight of what we are accomplishing in the effort to fight HIV/AIDS.

There was much discussed about the Global HIV Vaccine Enterprise. This virtual organization aims to create a solid alliance with various entities to invigorate and intensify the search for a successful HIV vaccine. Through funding from the Gates Foundation, this group will be a source of advocacy and help to aid collaboration in HIV vaccine research.

Next year's conference is in the Netherlands so anyone planning to submit a paper should get started now. While there was one primary session devoted to community education/recruitment at the '05 meeting, it would be great to see that portion of the conference grow and gain increased attention.



Dan Kuninsky, Nashville Educator/Recruiter, on the streets of Montreal

ALMOST 2 DECADES OF HIV VACCINE RESEARCH

- MORE THAN 30 PRODUCTS TESTED
- MORE THAN 85 TRIALS CONDUCTED
- THOUSANDS OF VOLUNTEERS, INVESTIGATORS & STAFF FROM OVER 25 NATIONS PARTICIPATED IN CLINICAL TRIALS
- MORE THAN \$3 BILLION INVESTED

Conferences and Announcements

The next Full Group Meeting will be held November 7-9 in Seattle, Washington. The GCAB call that will be held in the week following the Full Group Meeting will be open to all CAB members who attended the 2005 CAB Retreat or the November 2005 Full Group Meeting. On this call we will answer any follow-up questions from these meetings and address any topics of concern. ☘



Calendar of Events



CAB Protocol Working Group Conference Call:

Friday, November 4th, 8 a.m. PST/11 a.m. EST

Friday, December 2nd, 8 a.m. PST/11 a.m. EST

Global GCAB Conference Call (note Nov. change):

Thursday, November 17th, 8 a.m. PST/11 a.m. EST

Thursday, December 8th, 8 a.m. PST/11 a.m. EST

Global Ethics Working Group Call (note change):

November call canceled and December call rescheduled:

Thursday, December 1st, 9 a.m. PST/12 p.m. EST

Community Education/Recruitment Coordination Call:

Tuesday, November 15th, 9 a.m. PST/12 p.m. EST

Tuesday, December 20th, 9 a.m. PST/12 p.m. EST

Community Advisory Boards (CABs) are one way that the HVTN involves community in the research process. CABs consist of volunteers from diverse backgrounds who work with local research units and advise the site from a community perspective. Community input has been invaluable to the broad community education efforts, as well as the development of this bulletin.

Send suggestions, questions, and article submissions to:
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