



Ethics Committee Training in Africa

In this issue

Ethical concerns in HIV vaccine work are challenging and often have no clear solutions. It is important that we continue to revisit the issues to make sure that we are doing as much as we can. This Bulletin highlights some recent ethics-related HVTN activities.

CONDUCTING ETHICAL RESEARCH IN DEVELOPING COUNTRIES

Summary of a recent key ethics article Page 2

SAAVI PARTNERS WITH THE NELSON MANDELA FOUNDATION

Foundation to work on HIV vaccine issues, with a focus on adolescent concerns Page 4

AN OVERVIEW OF HVTN 502

The HVTN is soon to begin a Phase IIB trial. Find out more Page 5

In the past, the bulk of clinical trials were carried out in the most developed countries. Now, however, clinical trials are undertaken in countries around the world. As developing countries build their research infrastructure, they are also working to institute a parallel formal ethical structure that guides the research. Last year, HVTN Core staff members Renee Holt and Danna Flood participated in a grant for a project to develop human subjects protection resources in developing countries. The following is Renee's story of their recent experience in Africa.

By Renee Holt — Last June I participated in a highly successful new experience that allowed us to train ethics committee members in Southern Africa. The training was made possible through a U.S. National Institutes of Health (NIH) grant, which awards a U.S. institution funds for projects that will strengthen human subject protections. When I became aware of the grant application, I saw an ideal opportunity to develop skills in human subjects protections for, and ethical review of, HVTN research conducted in low-resource settings. I presented the idea to Danna Flood, the HVTN Training Director, and Karen



Photo by Karen Hansen

Dr. B.C. Didia, a participant from Nigeria, during a break in the training held in Malawi.

Hansen, the Fred Hutchinson Cancer Research Center Institutional Review Office Director, and they were as excited as I was.

Our project focuses on four ethics committees at four HVTN locations internationally. We chose ethics committees that were located near each other: two in the Caribbean and two in Southern Africa. The project involves three phases:

Phase 1: Fly ethics committee members from each of the selected sites to a major U.S. ethics meeting — the annual meeting of PRIMR (Public Responsibility in Medicine and Research) and ARENA (Applied Research Ethics National Association). This happened on December 3, 2003, with much success. The participants, by articulating

Continued on page 2



Photo by Andrew Lambert

The HVTN Community Education Unit would like to welcome to the Network the new Community Education and Recruiter team from Cape Town, South Africa. The group completed a five-day HVTN community educator and recruiter training in August, and are ready and eager to begin working in their community. Photo (from left to right) top row: Nmandla Tomsana, Fezeka Mboleka, Nonkululeko Ntalabati; bottom row: Pozna Gomomo, Marra Mbarane, Zukiswa Mazula, Mirriam Spondo

their international perspective, possibly contributed more to the meeting than they gained, although they expressed much gratitude for the opportunity to attend.

Phase 2: Conduct regional ethics committee trainings (currently ongoing, and the subject of this article.)

Phase 3: Upon request, conduct an audit or assessment of individual ethics committees using FDA audit guidelines.

As we planned for phase 2, so many people at the Division of AIDS and PRIMR were interested that they offered to join the effort in Southern Africa by working with us to host a larger regional training. The Division of AIDS (DAIDS, a part of the NIH) became very involved with supporting the meeting. The planning committee, including me, Karen, Danna, and many others, spent months holding weekly conference calls to develop the agenda and identify speakers. We wanted more than half of these speakers to be African. Through the help of Joseph Mfutso-Bengo, the head of the University of Malawi College of Medicine's research-ethics committee, and contacts through the Fogarty Training Program, we succeeded. Dr. Mfutso-Bengo chaired the conference, and was a great help to us.

Our first training was a focused, on-site training in Gabarone, Botswana. This was followed by the larger conference in

The challenge for ethics-committee members in developing countries is to take the U.S.-mandated ethical principles and interpret them in a meaningful way in their own culture. This will help ensure research is conducted in harmony with local ethical standards. — Danna Flood

Malawi, which was attended by research ethics committee members from 12 countries in sub-Saharan Africa. At the Botswana training, Karen Hansen brought her expertise in running an institutional review office, and withstanding about five audits. I was very happy to learn, and to

This conference went a long way toward helping the U.S. attendees better understand African perspectives on research and ways that U.S. research partners can enhance their collaboration with African ethics committees.
— Danna Flood

get Karen coffee when she needed it! We then moved on to the Malawi conference, called PEHRP (Partnership for Enhancing Human Research Protections) and I am telling you the conference was truly remarkable! We had many attendees and presenters from all over Africa, including the countries of Kenya, Ethiopia, Tanzania, Botswana, South Africa, and Ghana, to name a few. Afterwards, e-mail from attendees thanked their colleagues and the sponsors for a job well done. To quote one attendee, "... and to the sponsors, thank you for doing it our way." This, to me, is the best evaluation we could get; it means we listened to the needs of the attendees, respected their cultures, and let them speak. We are gathering ourselves up now and planning for the next training, which will be in the Dominican Republic and Haiti in October. ☘

Conducting Ethical Research in Developing Countries

By Dr. George Counts, HVTN
Senior Advisor on Special Populations, retired

Since the HVTN has expanded to nearly 15 sites in the developing world, it is more critical than ever that we ensure ethical standards in HVTN research. Historically, the debate on ethics in resource-poor settings has centered on three issues: standards of care, availability of interventions that are proven useful, and the quality of informed consent. To address some of these issues, an article was recently published by a group of bioethicists from the National Institutes of Health, who proposed eight specific and practical principles to guide researchers and ethics committees.¹ The views expressed are the authors' own beliefs and should not be misinterpreted as government policy. The following is intended to summarize the main ideas from this article.

Most agree that a single, universal, absolute ethical principle would be too general and not useful. Thus, a more complex system may be more appropriate, but this inevitably requires these benchmarks to compete and be balanced. Regardless of the standard, it is critical that they be

Continued on page 3



Photo by Karen Hansen

Malawi training participants, including Rose Kingamkono of Tanzania and Ames Dhai of South Africa in the front row.

specified *before* the beginning of a trial.

Collaborative Partnership

The first principle is the need for a partnership between researchers, host country sponsors, policy makers, and communities. This type of collaboration increases the chances that the research is responsive to the community's health concerns. If the local community is not involved, the study is not likely to have a lasting impact. If the political leaders are ignored, it is doubtful that results will influence health policy makers. In defining a collaborative partnership, there must be representation from all sides in the decision-making process, mutual respect for distinctive values, and a fair distribution of the tangible and intangible rewards of research among partners, such as a sharing of intellectual property rights and royalties.

Social Value

Ethical research must have social value; otherwise, research would expose participants to risks without good cause. It is difficult, however, to always translate research, especially basic research, into immediate health improvements. Nevertheless, the article describes several benchmarks that ensure social value. The research should specify who will benefit, and the value of the research should be enhanced through information dissemination in the local language and/or health system improvements. Lastly, the research must not undermine the community's existing health-care services but rather supplement the current structure.

Scientific Validity

Studies must be designed so that the results will be useful in the context of the health problems in the developing country. The design cannot deny health-care services to which the community is entitled, nor require services that are not able to be delivered in the host country's current structure. The design must also be feasible given the social, political, and cultural environment in which the study is being conducted. This may require infrastructure building or personnel training.

Fair Subject Selection

It has always been a challenge for research in developing countries to have a fair selection process while trying to balance the need for participation from diverse populations.

Clearly, participants should be selected to ensure valid science, which may include certain high-risk populations. In this case, it is critical that risks be minimized, which may mean selecting certain communities that are more amenable to research. This also means that researchers must take into consideration factors such as familial coercion, social marginalization, political powerlessness, and economic deprivation to determine a community's vulnerability. If a scientifically appropriate population appears to be rather vulnerable, special safeguards should be put in place.

Favorable Risk-Benefit Ratio

While all research should offer participants a favorable risk-benefit ratio, there are two issues that are unique to research in developing countries. **First, the risk-benefit ratio for the individual must be favorable in the context in which the participant lives.** This means that it would not be ethical to do a study on smallpox vaccines in populations where the risk for smallpox was minuscule. **Second, the risk-benefit ratio must also be favorable to the community.** The benefits must be specified before the beginning of the trial. Benefits could include services provided to participants or healthcare improvements in the community.

Independent Review

Transparency is critical in multinational research in order to minimize researchers' conflicts of interests and to ensure public accountability. Supplementary reviews by local community groups, non-governmental agencies, or ministries of health may be appropriate depending on the particular study.

Informed Consent

Informed consent has long been recognized as essential to clinical research.

However, differences in culture and traditions make the issue of informed consent complicated when conducting multinational research. **The local community must be consulted and assist in establishing recruitment procedures and incentives for participants that are consistent with cultural norms.** Dissemination of information should not only be done in the local language but also through the common local avenues for spreading information. It is important to recognize that certain communities may be required to consent before an individual can make his/her decision. With few exceptions, it is unacceptable not to get individual informed consent.

Respect for Participants and Study Communities

Researchers have on-going obligations even after informed consent has been obtained. Updated scientific information must be given to enrolled participants in a timely fashion. Research-related injury must be addressed before the study begins and care should be comparable to existing local norms at a minimum. Mass dissemination of results is critical so that the larger community can reap the potential benefits of the study.

Summary

The principles and benchmarks set forth in the article provide an ethical framework that is intended to justify research in developing countries. Differences in health, economic, social, and cultural aspects of a given community will inherently affect the application of the framework. The required "balancing" of the different benchmarks will change according to the situation in which the framework is applied. This balancing act will inevitably stir disagreement, yet this does not necessarily make one side ethical and the other unethical. Instead, this framework could perhaps allow for these discussions to happen in a more organized and productive manner. ☘

¹ Emanuel EJ, et al. What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *Journal of Infectious Diseases* 2004;189:930-937.

SAAVI Partners with the Nelson Mandela Foundation

By Lisabeth Bull, Administrative Assistant

The South African AIDS Vaccine Initiative (SAAVI) and the Nelson Mandela Foundation have announced a partnership aimed at fighting AIDS in South Africa. Nelson Mandela spoke out personally in October, 2003 to endorse the first South African HIV vaccine trial, HVTN 040. In doing so, he gave visibility and approachability to the HIV vaccine message (see the November/December 2003 CAB Bulletin, Vol. 4 Issue 6). Now, with the support of the Nelson Mandela Foundation, SAAVI has a very powerful partner as they work to communicate and advance HIV/AIDS vaccine issues.

An exciting aspect of this partnership is its focus on the issue of adolescent involvement in HIV vaccine trials. Including adolescents in HIV vaccine trials is a scientifically important, emotionally

charged, and ethically complicated undertaking. With SAAVI leadership, the HVTN and SAAVI have been collaborating with others through the Adolescent Working Group to address the barriers to conducting adolescent HIV vaccine trials. The support of the Nelson Mandela Foundation will support this work and allow for new avenues of development.

In the press release issued by both organizations, several specifics about the partnership were listed, as follows:

- The Nelson Mandela Foundation will offer support to SAAVI in its aim of developing an effective HIV vaccine for South Africa, and will endeavour to show leadership in gaining further support for HIV vaccines.
- SAAVI will support the Nelson Mandela Foundation in its endeavours to make a significant impact on the HIV epidemic through its research and development activities, as well as through support of Foundation activities.
- The Foundation will be involved in existing SAAVI structures, such as the Childhood and Adolescent Working Group, a multidisciplinary group that examines the complex clinical, human rights and ethical issues involved in preparing adolescents, their families and communities for appropriate participation in AIDS vaccine clinical trials.

- The furthering of a strategy and implementation programme to drive adolescent HIV vaccine preparation and trial support.
- The organising of an international consultative meeting of appropriate continental and international experts in adolescent work to advance the issues on continental and international levels.
- Ongoing advocacy work by both organisations to encourage parents and adolescents to participate in HIV/AIDS vaccine development in appropriate ways.
- Downstream funding by the Foundation of SAAVI's activities.

Dr. Tim Tucker, Director of SAAVI, com-

mented that "both organisations have youth as one of their key constituencies. As a result, the focus of this partnership between SAAVI and the Nelson Mandela Foundation will be the expansion of our adolescent-friendly HIV vaccine community activities and the responsible involvement of adolescents in HIV vaccine trials," he continued. "SAAVI is committed to the long-term involvement of fully informed adolescents in HIV vaccine research and development, and in the speedy roll-out of a successful vaccine to this target group. Preparing for this work is a cornerstone of the partnership, as a successful HIV vaccine that is effective in adolescents would be a huge step forward in protecting future generations."

SAAVI is a South African public-private partnership that coordinates HIV/AIDS vaccine research, development and testing in South Africa. Created in 1999, SAAVI is housed at the Medical Research Council (MRC) of South Africa. The HVTN has an on-going collaboration with SAAVI.

The Nelson Mandela Foundation seeks to expand Nelson Mandela's work by creating opportunities to support and expand democracy and freedom, with an emphasis on social change and human development. One of the central goals of the Foundation is generating and facilitating relationships that further the fight against AIDS. ☘



The SAAVI/Nelson Mandela partnership was announced at the Johannesburg premiere of *Yesterday*, the first movie made in the isiZulu language. The movie portrays a mother who finds out she has AIDS and struggles to live long enough to see her young daughter go to school. *Yesterday* is this year's South African entry for the Academy Awards' Best Foreign Language Picture. Described as an eloquent, unsentimental yet hopeful film, *Yesterday* takes place against the beautiful, harsh landscape of eastern KwaZulu-Natal. As many as one in four women from KwaZulu-Natal province are thought to be HIV positive.

UBUNTU

The Nelson Mandela Foundation seeks to embody the spirit of ubuntu, also called botho. The concept is explained below in an excerpt from Desmond Tutu's book No Future Without Forgiveness.

"Ubuntu is very difficult to render into a Western language. It speaks of the very essence of being human. When we want to give high praise to someone we say "Yu, u nobuntu"; "Hey, so-

Continued on page 5

An Overview of HVTN 502

By Derrick Mapp, CAB member, San Francisco

The Concept

This Phase IIB trial is the first ever HIV vaccine ‘proof of concept’ trial and will be sponsored by a partnership between Merck, the HVTN, and DAIDS (Division of AIDS). ‘Phase IIB’ is a study midway between Phase II and Phase III trials. The Phase IIB trial is planned to collect efficacy data as well as safety data, while limiting costs, time and other resources — such as participants — in comparison to a Phase III trial. Phase IIB trials evaluate more efficacy data than a Phase II trial, but they do not use the same number of participants as a Phase III trial.

There is strong data behind the Phase IIB concept, and the NIH (National Institutes of Health) and some community advocacy groups, as well as the HVTN External Advisory Committee, have stated support for continued development of the concept. This initial Phase IIB study will evaluate the safety and efficacy of Merck’s Ad-5 product, described below.

The Product

The study vaccine being evaluated is Merck’s modified adenovirus serotype 5 prototype. The adenovirus is a family of double DNA viruses that is very common in the human population and causes a range of mild infections, such as the common cold. Merck’s modified adenovirus serotype 5 is a sterilized, non-replicating (not disease-causing) virus with HIV genes inserted into it. The inserted HIV

genes, which are also non-replicating, include gag, pol and nef, each of which affect the HIV virus’ ability to shield itself against the body’s immune system.

This vaccine uses genes from the HIV Clade B virus, and is therefore being tested in locations where Clade B is prevalent. Additionally, along with a focus on the Clade B version of HIV, the study’s vaccine product is expected to be most effective in persons with low Ad-5 titers (levels in the blood).

The Study

The study will be an international, multi-site trial to include HVTN sites in the US, the Caribbean and South America. Merck has identified appropriate additional sites globally to participate in the study through their own clinical network. The trial will be double-blinded, placebo-controlled and randomized, and will test a 3-dose regimen of the vaccine product. It will evaluate the vaccine’s safety, tolerance and efficacy in high-risk HIV-negative adults. The primary objectives are to evaluate whether the vaccine product can block HIV infection, and if not, then to determine whether the vaccine product delays HIV disease progression and/or time to development of AIDS. Secondary objectives include evaluating immune responses that may be connected to vaccine efficacy, and the possibility of causing an effect on rates of infection.

This is an event-driven study — there will be study analyses triggered at predetermined events in the life of the study (an interim and final analysis). In this study the ‘event’ will be the number of participants seroconverting (becoming HIV positive) after receiving the vaccine. HVTN 502 will continue until the number of HIV-positive participants reaches its predetermined maximum number of people. Once this number is reached, the study will be continued for the trial’s HIV-positive participants. This part of the trial will include observation. The HIV negative participants’ data will be evaluated at one final visit. For this reason, unlike most other studies, participants and researchers will be unable to predict the

HVTN 502

WHERE

HVTN sites will be in the US, the Caribbean, and South America

WHAT:

Phase IIB ‘proof of concept’ trial

WHEN:

Anticipated start date is December, 2004

DURATION:

Approximately four years per participant

PRODUCT:

Merck’s adenovirus-5 (Ad-5) product

SCIENTIFIC GOAL:

To gather safety and efficacy data. To determine if the study vaccine is very effective or ineffective at preventing or controlling HIV infection. If it produces results that fall in between, efficacy rates will have to be determined with a Phase III trial.

Ubuntu, continued from page 4

and-so has *ubuntu*.” Then you are generous, you are hospitable, you are friendly and caring and compassionate. You share what you have. It is to say, “My humanity is caught up, is inextricably bound, in yours.” We belong in a bundle of life. We say, “A person is a person through other persons.” It is not “I think therefore I am.” It says rather: “I am human because I belong. I participate, I share.” ☞

exact time frame during which the study may be concluded, although the trial is planned to take less than four years for all participants.

It is expected that 1500 volunteers will be enrolled at HVTN sites. The inclusion/exclusion criteria target high risk participants. It is advanced in its strong focus on recruitment of women and people of color.

The study is scheduled to begin in December 2004 and is expected to be concluded by its fourth year, in either late 2008 or early 2009. ☞

Update from AIDS Vaccines 2004 International Conference

Developments from the annual conference

By Steve Wakefield, Associate Director of Community Education and Relations

Over 800 scientists, coming from more than 50 countries and representing every element of HIV vaccine research, gathered in Lausanne, Switzerland on August 30th for the annual AIDS Vaccine 2004 International Conference. In general, the focus was on the meeting's theme, "global commitment." Discussions about collaborative efforts and the sharing of information across networks offered more opportunity for optimism than the science itself.

The Enterprise

Dr. Helene Gayle gave an update on the progress of the Global HIV Vaccine Enterprise. The Enterprise was announced a year ago, and has been in development since then, under the auspices of the Bill & Melinda Gates Foundation. In the last year over 60 people have participated, representing a range of institutions and organizations worldwide. This summer, the Enterprise was endorsed by the leaders of the G8 group of influential industrial countries.

The Enterprise intends to build on past advances and bring a new level of planning, resources and collaboration to the world of HIV vaccine research. Importantly, the Enterprise is not creating anything new, but rather working as an alliance of independent partners, who view themselves as a community dedicated to coordinating activities. New participation in the Enterprise will continue to be welcome as the undertaking grows. It is expected that other public and private funders

will join forces with the Gates Foundation to help support the Enterprise in the future.

Other Collaborations

In other news on collaborative developments, Dr. Anthony Fauci introduced the Center for HIV/AIDS Immunology, or CHAVI. This is to be a leadership center that will coordinate strategic plans around key research issues in HIV vaccine design and immunology research. The CHAVI consortium will coordinate with the Global HIV Vaccine Enterprise.

The European AIDS vaccine consortium, Eurovacc, announced that it will be undertaking a shared clinical project with the HVTN.

The Science Update

At every conference one hopes to hear that the scientists have found the magic bullet. Unfortunately, once again there were no announcements of that sort. There was, however, a spirit of cooperation and easy sharing of data, especially as relates to the conduct of clinical trials. Huntly Collins, Director of Science and Information for the AIDS Vaccine Advocacy Coalition and a Hopkins CAB member, noted that key issues discussed "include[d] the use of hard data to make go/no-go decisions for advancement of products into large human trials; the development of better assays (tests) and

their standardization so they can be used across groups for head-to-head comparisons of products and approaches; more transparency, including the public sharing of negative trial results; and a rational use of data from monkeys."

Data presented by IAVI (International AIDS Vaccine Initiative) indicates that their DNA/MVA product is not producing immune responses that would take it into future trials. IAVI noted that they will wait until the completion of current trials to make a decision about this strategy, but barring radically different data over the next year, it is expected that the MVA approach would need to be re-worked to move forward. Interestingly, the DNA prime in the IAVI DNA/MVA product did not seem to have any effect.

In a separate session, Dr. Larry Corey commented generally that "DNA vectors are being found to require high milligram doses; significant immune responses to them are in a minority of volunteers and are not persistent."

The majority of trials currently in progress test products geared to stimulate cellular immunity, but as was once again clear at this conference, the trend is moving back to neutralizing antibody approaches, and especially to the possibility of combining antibody and cellular approaches.

Cont. on page 7



Two sites have recently worked with pro-bono (free!) professionals to produce advertisements for their site. On the left is one of Seattle's three ads, which are currently running in newspapers, on buses, and as posters. On the right is an image from San Francisco's new TV ad. Stay tuned for information about how successful these campaigns are!

In Their Own Words

Two CAB members talk about the University of Miami ethics training

International Conference, cont.

Another agreement at the conference is that work is needed to develop a wider array of standardized tools in order to interpret data in a meaningful and comparative way. The HVTN has made important advances, but more needs to be done.

The challenge of using animal data effectively remains; results from animal trials often does not correspond with immune responses in humans. Researchers are wrestling with ways to test vaccines in monkeys in order to establish the most useful safety and immunological data to inform trials in humans.

Recruitment and Retention

Several presentations considered the issues around recruitment and retention, with the focus on the challenges ahead. In IAVI's trial in Uganda and Kenya there were low rates of retention among women, but this was not true in South Africa and Europe. A study among Rwandan couples recruiting for joint testing and counseling had 1600 discordant couples show interest out of 8000 invitations issued. Only 400 of these 1600 couples were eligible. In Thailand, a recent study indicates that only 13-16% of the population seem willing to participate in an HIV vaccine trial, and the majority of these people would be considered low risk.

One session at the conference was devoted to addressing the barriers to conducting HIV vaccine trials for adolescents and children, and development of those vaccines to be used to prevent mother-to-child transmission.

Accomplishments

The pace of clinical HIV vaccine trials has increased significantly. There are currently 30 trials of vaccine candidates in 19 countries, with a total of about 5000 participants to be enrolled in approximately the years between 2003-2005, excluding the current Phase III trial in Thailand. There is important new information about conducting trials, and next year's budget for HIV vaccine research from the U.S.'s National Institutes of Health is \$410 million.

The work continues. ☘

By Butch McKay, CAB member, Birmingham HVTU

I was hesitant to log on to the CITI Course at first, fearing it might be too technical. I found just the opposite to be true. The biggest hassle in the beginning was just logging onto the site. If you have problems logging on, refer to the instructions provided on the next page.

The site provides a link to the Belmont Report, which you are to study prior to taking the course. Please take time to study it closely as it will provide a helpful background for understanding the different modules and exams. Each module gives you a brief description and an outline of what you are expected to know upon completion. They will also give you an estimate of the time it will take you to complete each module. I found that because I took the course at the office and encountered interruptions, it took me a little longer on some modules. I suggest that you try to find uninterrupted time to take the course. Each module is only about 15-20 minutes on the average. I took the course over a two-day period and in total spent only a few hours.

I found the course easy to follow and extremely informative, and unlike exams in school you are allowed to retake any exam to improve your overall score. I went back and printed all the modules so I would have them for a future reference. I encourage everyone to take advantage of this opportunity.

Good Luck!



*Butch McKay,
Birmingham, AL
CAB Member*



*Tom Gibson,
Denver, CO
GCAB co-chair*

By Tom Gibson, GCAB co-chair, CAB member-at-large, Denver, CO

Wow! My first online course - what a great experience. I strongly encourage all CAB members — in all countries — to take the course. It is easy to get started, extremely educational, and the course keeps your attention.

The "Basic Course" consists of an introduction, seven modules, and some notes on the HVTN. Don't be alarmed when you see that the first couple of modules are fairly lengthy and you need to pay close attention while reading the module. The modules get shorter as you go. You don't have to take the modules all at once — I spread them out over several weeks.

At the end of each module is a short quiz. AGAIN, DON'T BE ALARMED — you're going to miss an answer or two on most of the quizzes — I did. But you can go back and re-take the quizzes. After each quiz, you are automatically graded, and as part of the process the correct answer and an explanation is given. After reading the explanation, you can go back and re-take the quiz.

Even though many of us have taken other ethics courses (including courses offered through the HVTN), you'll find this course full of new information and very interesting. What I really liked about it was the links to other websites and to information — so that when I was really interested in something, I could get more information on the topic.

I think the course will help local CAB members learn about and discuss potential ethical issues. Overall, I know that I learned a lot. I'm sure that the training will make me a more productive member of the Global CAB and the Ethics Working Group — and will help me to recognize ethical issues in protocols and trial designs.

So, when you have a break from work, I strongly encourage you to work on the course! ☘

Course instructions on Page 8

INSTRUCTIONS FOR LOGIN TO THE UNIVERSITY OF MIAMI/CITI COURSE IN HUMAN SUBJECTS PROTECTION

Go to the website <http://www.citiprogram.org/> and click on the text [Register for the CITI Course](#).

At the page headed "Select your organization" go to the fourth box, "All Others," and click on the drop-down arrow. Scroll down and select HIV Vaccine Trials Network, then click "submit."

You will be asked to select your user name, password (and then verify your password), and to provide a phrase that will help you if you forget your password (If you forget your password in the future, they will give you this phrase to help you remember it). Once you have provided all of the information, click "submit."

On the registration page complete all of the fields except for the "Employee Number" field, which you can leave blank. For "Department", you can use anything you wish, including "community education." For "Role in Human Subjects Research," select "OTHER" from the drop-down list. When you have completed all of the information, click "submit."

When you get to the "Select Group" screen: Step 1 – click on the link "information from your institution." This will take you to a page which shows you the seven modules required by the HVTN (blue shading), as well as the other modules, which are optional. When you close this page you will return to the "Select Group" page. In Step 2, click in the circle for "All Investigators and Key Personnel," then click "submit." When asked "have you completed the course before?" click "no."

You will next be taken to the "Learner's Menu." Click on the first line for "Basic Course," and then you'll be taken to the "Grade Book" screen. You will see the required modules listed first, and then the optional modules listed below. Your grades should be blank, and it will indicate that you have not yet completed any of the modules. Click on "Introduction" to begin. You can also click on any of the other navigation buttons on the top or on the left for more information.

Upcoming Conferences

The 8th annual United States Conference on AIDS (USCA) will be held in Philadelphia, Pennsylvania from October 21–24, 2004. USCA is the country's largest AIDS-related gathering and includes over 3,000 service providers, people living with HIV/AIDS, policymakers, and public health officials in search of the latest tools and solutions for the challenges posed by this epidemic. Vaccine-related presentations will include confronting myths and misperceptions, information about the HVTN's minority outreach effort called The Legacy Project, learning about HIV vaccine research, and combining HIV vaccine information with treatment advocacy. For more information on this conference, please visit www.nmac.org and click on "conferences."

HVTN Full Group Meeting

The October Full Group Meeting is just around the corner. Make sure the CAB representative for your site has the information he or she needs to best represent your CAB at the meeting. ☘



Calendar of Events



CAB Protocol Working Group Conference Call:
Friday, November 5, 2004, 11 a.m. E.T./ 8 a.m. P.T.

Global Ethics Working Group Call:
Thursday, November 18th, 2004, 12 p.m. ET/ 9 a.m. PT

Global GCAB Conference Call:
Thursday, October 7, 2004, 11 a.m. E.T./ 8 a.m. P.T.
Thurs., November 11, 2004, 11 a.m. E.T./ 8 a.m. P.T.

Community Education/Recruitment Coordination Call:
Tuesday, October 19, 2004, 12 p.m. E.T./ 9 a.m. P.T.
Tuesday, November 16, 2004, 12 p.m. E.T./ 9 a.m. P.T.

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.

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