# Global HIV Vaccine Enterprise Council Meeting Minutes

**Tuesday, April 14, 2009**  
7:00 AM to 3:00 PM  
Global HIV Vaccine Enterprise Offices

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In attendance:

**Enterprise Council Members:**
- Dr. Seth Berkley (Principal representing the International AIDS Vaccine Initiative/IAVI)
- Dr. José Esparza (Alternate representing the Bill & Melinda Gates Foundation)
- Ms. Cynthia Hallenbeck, Enterprise Board Secretary Treasurer
- Dr. Catherine Hankins (Alternate representing WHO-UNAIDS)
- Mme Jeannette Kagame, First Lady of Rwanda
- Dr. Yves Levy (Alternate representing ANRS)
- Dr. Malegapuru (William) Makgoba (University of KwaZulu-Natal)
- Dr. Peter Piot (President of the Board)
- Dr. Manuel Romaris (Alternate representing the European Commission)
- Mr. Mitchell Warren (AIDS Vaccine Advocacy Coalition/AVAC)

**Council members joined by phone:**
- Dr. Rafi Ahmed (Emory University; representing the Enterprise Science Committee)
- Dr. Helene Gayle (CARE)

**Enterprise Secretariat:**
- Dr. Alan Bernstein, Executive Director (ex-officio Council member)
- Ms. Juliana Hawawini, Operations Manager
- Dr. Amapola Manrique, Science Officer
- Ms. Myra Ozaeta, Director of External Relations
- Ms. Candace Rosen, Director of Operations
- Dr. Yegor Voronin, Science Officer

**Invited Guests:**
- Dr. Agnes Binagwaho, Government of Rwanda
- Ms. Diana Mpyisi, Government of Rwanda

**Enterprise Council and Board Members unable to participate:**
- Dr. Jean François Delfraissy (Principal representing French National Agency for Research on AIDS and Viral Hepatitis/ANRS)
- Dr. Ruxandra Draghia-Akli (Principal representing the European Commission)
- Dr. Anthony Fauci [Principal representing the National Institutes of Health, US Department of Health and Human Services (NIH/NIAID)]
- Mr. Peter Kim (Merck Research Laboratories)
- Ms. Daisy Mafubelu (Principal representing WHO-UNAIDS)
- Dr. Mark Walport (Principal representing the Wellcome Trust)
- Dr. Tachi Yamada (Principal representing the Bill & Melinda Gates Foundation)

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**1. Introductions**

Council did a brief round of introductions.

**2. Resolution ratifying new Council Appointments**

Council unanimously approved the following resolution, which had previously been passed electronically, ratifying new Council appointments:

"**RESOLVED:** That Council hereby ratifies and affirms the appointment of Cynthia Hallenbeck and Peter Kim to be members of the Global HIV Vaccine Enterprise Council, effective April 13th, such appointments to be renewed at the discretion of the Council; and

**FURTHER RESOLVED:** That Council hereby ratifies and affirms the appointment of Dr. Ruxandra Draghia-Akli (Principal representing the European Commission) and Ms. Daisy Mafubelu (Principal representing WHO-UNAIDS) to be members of the Global HIV Vaccine Enterprise Council, effective April 13th, such appointments to be renewed at the discretion of the Council; and"
FURTHER RESOLVED: That Council hereby ratifies and affirms the nomination of Cynthia Hallenbeck to serve as a member of the Board of Directors of the Global HIV Vaccine Enterprise.

3. Endorsement of Council Charter

Director of Operations Mr. Silvers presented the revised Council Charter for review and approval by Council. He explained specific changes to the Council including:

- Addition of a term for Council Members
- List of new members appointed
- Inclusion of a mission statement for the Enterprise
- Clarification of purpose for Council
- Expansion of number of Council members to no more than two times plus three the number of key stakeholder organizations
- Addition of clause clarifying non-compensation for Council service
- Addition of alternative venues for a meeting by phone or email
- Amendment to repeal of charter

Council members reviewed the changes and discussed whether membership was attributable to an organization or an individual. Following discussion, they agreed that it is a hybrid of the two: i.e. - some Council members are representatives of their organization while some are representing themselves. Further clarification was sought regarding Council size limits. Dr. Bernstein reminded Council that at their previous meeting Council had agreed that it was important to keep the body inclusive while, at the same time, keeping it as small as possible.

Council discussed the implementation of staggered terms for Council members to ensure continuity. Council decided a limited term must first be established and asked the Enterprise Secretariat to bring forward a proposal for discussion at the next Council meeting. It was also agreed that Council establish a Nominating Committee. Council Chair Peter Piot asked that volunteers for the nominating committee contact Dr. Bernstein so that, at the next Council meeting, Council can decide how to move forward.

Council discussed representation from all continents on the Enterprise Council. It also agreed that industry representation on Council, reflected in Dr. Peter Kim’s appointment, was important.

Council then approved the Charter as amended. See Exhibit A for the charter as approved and the resolution below.

“RESOLVED: That the Charter of the Global HIV Vaccine Enterprise Council (the “Council”), in substantially the form attached hereto as Exhibit A, is hereby approved and adopted as the Charter of the Council.

FURTHER RESOLVED: That the following individuals, who already have been appointed by the Global HIV Vaccine Enterprise (the “Enterprise”) Board as the initial members of the Council, shall serve until the Council’s September 2011 meeting or until their successors are appointed:

1. Dr. Rafi Ahmed (Emory University, representing the Enterprise Science Committee)
2. Dr. Seth Berkley (Principal representing the International AIDS Vaccine Initiative/IAVI)
   a. (Alternate representing IAVI: none selected)
3. Dr. Jean François Delfraissy [Principal representing the French National Agency for Research on AIDS and Viral Hepatitis (ANRS)]
   a. (Alternate representing ANRS: Dr. Yves Lévy)
4. Dr. Anthony Fauci [Principal representing National Institutes of Health, US Department of Health and Human Services (NIH/NIAID)]
   a. (Alternate representing NIH/NIAID: Dr. Margaret [Peggy] Johnston)
5. Dr. Catherine Hankins (Alternate representing WHO-UNAIDS)
6. Madame Jeannette Kagame (First Lady of Rwanda)
7. Dr. Helene Gayle (CARE)
8. Dr. Malegapuru (William) Makgoba (University of KwaZulu-Natal)
9. Dr. Manuel Romaris (Alternate representing the European Commission)
10. Dr. Mark Walport (Principal representing the Wellcome Trust)
    a. (Alternate representing Wellcome Trust: none selected)
11. Mr. Mitchell Warren [AIDS Vaccine Advocacy Coalition (AVAC)]
12. Dr. Tachi Yamada (Principal representing the Bill & Melinda Gates Foundation)
a. (Alternate representing the Bill & Melinda Gates Foundation: Dr. José Esparza)

13. Dr. Alan Bernstein (Executive Director of the Global HIV Vaccine Enterprise, ex-officio Council member)

FURTHER RESOLVED: That the following individuals are hereby appointed to the Council to serve until the Council’s September 2011 meeting or until their successors are elected and appointed:

1. Dr. Ruxandra Draghia-Akli (Principal representing the European Commission)
2. Ms. Cynthia Hallenbeck (Enterprise Board Secretary-Treasurer)
3. Dr. Peter Kim (Merck Research Laboratories)
4. Ms. Daisy Mafubelu (Principal representing WHO-UNAIDS)
5. Dr. Peter Piot (Enterprise Board President)

4. Council Member roundtable on Enterprise related activities

Council members shared information regarding their individual organizations’ current and planned Enterprise-related activities:

- The Bill & Melinda Gates Foundation (BMGF) noted that the original Enterprise Scientific Strategic Plan (SSP) inspired the Collaboration for AIDS Vaccine Discovery (CAVD) that is supporting 21 research consortia with over $350 million over 5 years. The first round of funding for CAVD is set to end in July 2011 and the BMGF is considering options on how to move forward with the CAVD. They are also anticipating that the discussion that will take place during the updating of the Enterprise SSP will inform the process for the CAVD. The BMGF believes the SSP should be developed in very close collaboration with funders and others to ensure that it reflects a broad perspective in the field and remain relevant to all.

- The AIDS Vaccine Advocacy Coalition (AVAC) is publishing its annual report which will include an assessment of the Enterprise. The report is looking at where the Enterprise is and where it could go. The report will be published in May 2009 as part of World AIDS Vaccine Day. Mitchell Warren, Executive Director of AVAC, chairs the communications working group on behalf of the Enterprise. The group is now planning for organized communication and discussion the release of Thai vaccine trial results. AVAC is also tracking key indicators in the field as part of a resource tracking tool in partnership with IAVI and UNAIDS. The annual report is due out in July 2009.

- The National Institutes of Health/National Institute of Allergy and Infectious Diseases (NIH/NIAID) created the Center for HIV/AIDS Vaccine Immunology (CHAVI) in response to the original Enterprise SSP. Funded at $48-50 million a year, CHAVI focuses on describing and understanding early events in the host immune response to HIV and the strategy that the infecting virus employs to escape or evade the host’s immune system. Now in the 4th year, CHAVI scientists have made a number of important observations, including a deeper understanding of the role of host genetics in HIV transmission and disease progression, genotypic and phenotypic characterization of transmitted/founder virus and its progeny, creating the clearest picture to date of events in early infection and immune responses, elucidating the structure of the envelope trimer, and developing inserts that produce broad immune responses. CHAVI is moving first candidates into clinical testing with sanofi pasteur. CHAVI’s last year of funding is 2011. The NIH/NIAID is laying the groundwork now for a decision they will have to make next year on CHAVI’s future. As a result, they are also looking to the SSP for input on what they should be thinking about in a new CHAVI. NIH/NIAID also supports HIV vaccine discovery through an additional $22 million for 45 investigator initiated grants. Other potential new grants from the recent stimulus bill are possible. The basic vaccine discovery initiative will be continued in 2010 for $10 million. The innate immune receptors and adjuvant discovery program as well as other programs will also continue. Various workshops were held in 2008, including workshops on B cell immunology, NHPs, systems biology, acute infection and assay standardization. Two initiatives aim to increase involvement of B-cell immunologists and systems biologists in HIV vaccine research. The Human Vaccine Trial Network (HVTN) will be up for renewal in 2013 and NIH will also initiate discussions on the optimal way for them to support clinical trials. Supporting research in resource-poor settings and reexamination of models used for domestic and international research support will be examined. NIH support for early and new investigators includes an early stage and new investigators portal, an increased funding “payline” at 25%, and supplements to several programs as a result of the stimulus package.
The International AIDS Vaccine Initiative (IAVI) presentation summarized some highlights of a recent review of IAVI. IAVI recently opened the Brooklyn design lab. The purpose of the lab is three-fold: 1) design of replication-competent viral vectors; 2) validation of assays used in NHP research; 3) large-scale preparation of reagents for the community such as generating antibodies for the Neutralizing Antibodies Consortium (NAC). Currently the lab has a staff of 32 scientists but there is considerable space available for future expansion. IAVI is interested in the lab’s best use for the field and is looking at the possibility of inviting senior scientists to the facility. Additionally, the NAC at Scripps is opening in September 2009. While IAVI specializes in AIDS vaccines, they have excess site capacity for other potential prevention activities including a small trial for PrEP. IAVI is looking to start PrEP trials at two sites in the next few months.

The French National Agency for Research on AIDS and Viral Hepatitis (ANRS) oversees several programs whose total annual amount is Euro7.5M. Among these programs, the ANRS is developing vectors through collaboration (Eurovacc, others) but also looking for new vectors. Cellular immune responses to vectors containing fusion antibodies against dendritic cells (DC) and HIV are being explored in proof of concept studies in non-human primates. The ANRS is looking at Phase 1 trials and then manufacture at the end of 2009. Six trial sites in France will be extended to ten by the end of the year with over 70 volunteers. An ANRS therapeutic trial is based on passive immunization of HIV infected patients with autologous DCs and subsequent cessation of ARV treatment, success of the trial will be measured by control of viral load. The NHP program of the ANRS is being used not as a gatekeeper for human trials, but as a model system to answer basic questions in vector/insert design. The ANRS basic science program aims to bring new collaborators to the field. Cross platform collaboration continues with Eurovacc to share tools across programs. The ANRS is doing a Phase 1 trial in France for further collaboration with partners. The CAVD/Eurovacc Phase 2 trial is in preparation.

The European Commission (EC) is focusing on finalizing Requests for Proposals (RFPs). The 2010 RFP will be published in July 2009. The EC is undecided if the RFP will be specific for HIV vaccines. The EC continues to work on European policy regarding HIV vaccines coordination and funding coordination to avoid gaps in funding provided by different countries. An updated SSP is a very important part of this process. A 2003-2008 evaluation of activities is underway. The report is scheduled for the end of 2009 and is part of the consideration in the EDCTP renewal process. The report will have specific recommendations for the future. If the review is positive, a new EDCTP might focus on other continents. Any redesigned program would start in 2010 and run through 2015.

WHO - UNAIDS has conducted several training workshops on several topics, including ethical considerations in trial design, African AIDS Vaccine Program (AAVP) and AVAC communications, evolving standards of prevention, and updated good participatory practices for clinical trials. Another current focus is injecting drug users (IDUs) in Thailand. Additional topics (AAVP, AVAN) were to be discussed later on the agenda, so were not discussed during this segment of the meeting.

Madame Kagame spoke as a representative of AAVP. She advocated for civil society as a way to reinforce what governments are doing.

Dr. Bernstein pointed out that all efforts by Council member organizations towards a vaccine are an integral part of both the vision and SSP for the Enterprise. As such, he recommended that Council members consider including the Enterprise logo on all their communications related to HIV vaccine research. The presence of the Enterprise logo serves as a compelling symbol of a global commitment to work together, collaboratively and effectively, to speed up the search for an HIV vaccine. The Council chair suggested a future discussion on use of the Enterprise logo.

5. Update from the Executive Director

Dr. Bernstein began his Update with an overview of the Enterprise mission: drafting and implementing a shared scientific plan, increasing resources for the field, and facilitating greater collaboration. The update focused on greater collaboration as the SSP was elsewhere on the agenda. He highlighted regional collaboration efforts involving the Enterprise secretariat, including the African AIDS Vaccine Program (AAVP) and Madame Kagame’s role as AAVP’s High Representative, the proposed AIDS Vaccine Asian Network (AVAN), and the recently established Chinese AIDS Vaccine Initiative (CAVI).

Dr. Bernstein briefly outlined plans for HIV Vaccine Awareness Day and the preparations for the Thai trial results. He also mentioned the work that the Secretariat has done in organizing systems biology meetings.

a) Operations at the Secretariat (Brant Silvers)
Mr. Silvers, Director of Operations, gave a staffing update. Since the last Council meeting the Enterprise Secretariat has hired four new staff: Myra Ozaeta (Director of External Relations), Yegor Voronin and Amapola Manrique (Science Officers) and Juliana Hawawini (Operations Manager). In response to a request from Council, Mr. Silvers undertook to present to Council a staffing plan for the next 2-3 years. The Council asked about the length of the office space lease and was informed that is seven years.

Dr. Bernstein noted that the Enterprise Secretariat is still looking for a Director of Science and asked for candidate recommendations. The individual should have a reputation in the field, a broad perspective, and be knowledgeable about HIV vaccine research. If the Enterprise cannot identify a suitable candidate, an alternative could be to have a sabbatical opportunity for individuals on a rotating basis. There are some pros and cons to that strategy: but one of the big pros are it gains engagement of the scientific community. The disadvantage is continuity issues. The sabbatical term would be 6 months or more. The Council chair asked the Enterprise Secretariat to send a position description to Council members. One Council member suggested considering someone early in their career or to ask a local scientist in New York City if they could incorporate it into their regular responsibilities. Dr. Bernstein responded that he is looking for such opportunities in the New York community but feels that individuals in an early stage of their career is already well represented with Amapola Manrique and Yegor Voronin on staff.

b) New Minds, New Ideas Initiative (Candace Rosen)

Ms. Rosen, Senior Advisor for Strategic Planning and Policy Development, explained that the Enterprise launched the New Minds, New Ideas Initiative to address one of the key challenges facing the field of HIV vaccine research and development: the urgent need to attract new scientific talent, bringing with it innovative ideas, fresh ways of thinking, and novel approaches to developing an HIV vaccine. The recent efforts by the NIAID attract B cell immunologists to HIV vaccine research is a good example of where an Enterprise partner is reaching out to attract new talent. Also as part of this initiative, at the International AIDS Conference in Mexico City in August 2008 and at the AIDS Vaccine Conference in Cape Town in October 2008, the Enterprise hosted satellite sessions titled “New Minds, New Ideas: Attracting the Next Generation of Investigators to HIV Vaccine Research.” The satellite sessions brought together leading HIV vaccine researchers and young and early career investigators (YECI) to discuss the barriers facing YECI in HIV vaccine research and to propose constructive strategies to enhance YECI visibility and participation in the field.

Key to the success of the Enterprise’s New Minds, New Ideas Initiative is the engagement and empowerment of YECIs to articulate the obstacles and solutions facing YECI as contributors to the search for an HIV vaccine. To that end, the Enterprise has launched its YECI Committee to provide recommendations to the Enterprise on these issues. Co-Chaired by Drs. Dan Barouch, Associate Professor of Medicine at Beth Israel Deaconess Medical Center, Harvard Medical School and Dr. Thumbi Ndung’u, Associate Professor of Medicine at the University of KwaZulu Natal, the YECI Committee is comprised of scientific investigators who are age 40 or younger or who are within 10 years of receiving their terminal degree or related clinical training. The YECI committee currently consists of 12 members from around the world.

c) Regional Initiatives [AAVP, AVAN] (Candace Rosen)

Ms. Rosen reviewed the involvement of the Enterprise Secretariat in regional HIV vaccine research and development initiatives, including the AAVP (currently supported by WHO and UNAIDS), and the recently proposed AVAN. The Enterprise has entered into a memorandum of intent with WHO/UNAIDS to establish an effective basis for cooperation and to harmonize efforts with respect to engaging in consultations to evaluate options for a future operating framework for the AAVP. The Enterprise - WHO/UNAIDS cooperation includes expediting the transition of the AAVP Secretariat from WHO/Geneva to Africa. As a member of the AAVP Transition Committee (ATAP), the Enterprise Secretariat has taken an active role in developing, distributing, and reviewing the Request for Applications inviting African institutions/organizations to serve as the host of the AAVP Secretariat in Africa. The Enterprise Secretariat will help ATAP select the AAVP host. On February 11 and 12, 2009, the Enterprise Secretariat and IAVI hosted the AAVP Advocacy Strategy & Communications Meeting in the Secretariat’s offices and IAVI’s Design Lab in New York. The meeting covered topics such as the establishment of a task force to prioritize AAVP’s advocacy initiatives, the development of a communications strategy, and how to leverage media opportunities. Finally, Ms. Rosen and Mitchell Warren will represent the Enterprise on the International Organizing Committee of the 5th AAVP forum, helping to draft the agenda.

The Enterprise Secretariat is collaborating with the WHO/UNAIDS to establish the regional coordination and collaboration of HIV vaccine research and development activities in Asia through AVAN. From February 22 to 24, 2009, the Enterprise and WHO/UNAIDS co-hosted a consultation in Beijing: “Expanding AIDS Vaccine Research
Council discussed the Enterprise’s investment of time and resources into the formation of the AVAN Task Force and AVAN, noting that it was critical for the countries in the region to take ownership of the process of development. Council also discussed the need for AVAN countries to have balanced representation on the Task Force and on AVAN and proposed to have a revolving chair for AVAN. Dr. Bernstein suggested that a model is AAVP. In AAVP, the role of WHO, UNAIDS, and the Enterprise is to act in an ex-officio capacity, providing technical input and supporting secretariat needs. Council also noted the difficulty in certain countries with being able to test vaccines and the lack of regulatory harmonization in the region, creating additional challenges to the formation of a regional clinical trials network. Council signaled that this should not take precedence over other programs at the Secretariat. Ms. Rosen discussed baseline training as an incremental step to form a basis of cooperation.

5. Updating Scientific Strategic Plan

a) Overview (Alan Bernstein)

Dr. Bernstein discussed the updating of the SSP by reminding Council members that the plan will be the product of collaborative efforts of all Key Stakeholders. Council members and organizations need to provide input and align their activities with the Plan if it is to have traction. The role of the Enterprise is to collect this input and promote the exchange of ideas through both formal and informal communication with the Stakeholders.

Dr. Bernstein explained that the SSP update process has several components. The Enterprise will convene targeted working groups that will address specific issues in HIV vaccine research and development. The plan will be divided into two major sections:

- A review of goals and achievements of the previous plan. Did the original 2005 SSP guide the resource allocation decisions of funders? Did those decisions align with the original SSP and did they advance HIV vaccine development?
- Discussion of current challenges and future priorities. The largest part of this section will discuss the mechanisms necessary to most effectively address current scientific challenges in the field. The second part will address the problem of attracting new scientists to HIV vaccine research. Finally, the last part will deal with general issues surrounding the scientific questions, e.g., ethical considerations of trial design, intellectual property, and regulatory challenges.

b) Scientific Working Groups (Rafi Ahmed)

Chair of the Science Committee Dr. Rafi Ahmed gave a summary of the inaugural Science Committee (SC) meeting. The SC had several areas of overall agreement at the end of the day. The following proposed working groups were proposed:

- **Immunogens and Antigen Processing WG**: will focus on rational design of the components of an HIV vaccine, such as inserts, vectors, and adjuvants, and their effects on antigen processing and presentation to T and B cells. Ralph Steinman agreed to chair, looking for a co-chair outside SC. The chair and co-chair will populate the working group.
- **Host Genetics and HIV Diversity WG**: will focus on the host genetic factors influencing adaptive and innate immunity. The group will consider novel approaches to limit viral escape from host immune responses, taking into account the extraordinary genetic diversity of the virus. Andrew McMichael has agreed to chair.
- **Novel Approaches, including Systems Biology, to HIV Vaccine Research and Development WG**: will focus on the development and application of new or existing tools and technologies, including systems biology, to HIV vaccine research. The group will also consider non-conventional approaches to vaccine design and lessons learned from vaccines against other pathogens. (Suggested Chairs: Alan Aderem and Rino Rappuoli)
- **Translational and Clinical Research WG**: will focus on developing an iterative and rapid process for translating concepts and sharing results between pre-clinical and clinical research. (Chair: Larry Corey)
- **Non-Human Primate Research and Clinical Studies WG**: will focus on bridging non-human primate research to clinical studies of the human immune response to HIV. (Suggested Chair: Louis Picker)

Dr. Ahmed assured the Council that the SC will not work in isolation from Council and stakeholders. The Council had several main areas for feedback on the SSP update process:

i. **WG Composition – Openness, transparency and buy-in.** The process of selecting working group (WG) members should be transparent to Council. It is important to ensure strong representation from industry and from young and early career investigators (YECIs). The selection process should strive to achieve both diversity and scientific excellence of its members. It is critical that Council members not only have the opportunity to vet the SSP as it moves forward but also that the Council be fully engaged in developing the SSP. In the fullest sense, the SSP has to be ‘owned’ by all Enterprise partners.

The Enterprise Secretariat agreed and will circulate to Council the list of potential WG members. The Secretariat will ask Council Members to review the proposed members and to nominate additional candidates for the WGs. Industry representatives and YECIs will be included in each WG. The Enterprise Secretariat and WG Chairs will put significant effort into ensuring that each WG is both scientifically strong and diverse. The Secretariat trusts that Council understands the inevitable comprises that result from developing lists in this manner, with multiple inputs and multiple factors that need to be taken into account. Council will have multiple opportunities to comment on the WG reports, and the organizations represented on Council will be included in the WGs.

ii. **Broad input from scientific community.** Council stated that WGs should seek input from the HIV vaccine field and the broader scientific community. International conferences (e.g., IAS, AIDS Vaccine 2009, and AAVP Forum) are ideal opportunities to seek broad input from the HIV research community.

The terms of reference for each WG include the requirement for consultations with scientists in the field. The Secretariat is also planning to seek input on completed reports from prominent scientists outside the HIV field. The suggestion to use upcoming international meetings as opportunities for consultation is an excellent one, and the Secretariat will incorporate this idea into our work plan (we are not sure about the utility or timing of the IAS meeting in July in Cape Town - it may be too early and there are very few vaccine researchers at that meeting - but the Paris and Kampala meetings are both excellent opportunities for consultation).

iii. **Cohesiveness of the final report.** Council stressed that the Enterprise needs to develop a process for integrating the WG reports into the final document to create one coherent SSP. Hiring a professional writer should be considered. Creating a separate WG (consisting of WG Chairs and some other scientists) to oversee the writing of the final report should be considered.

The Secretariat plans to develop a process for writing the final report and has already requested the credentials and portfolio samples of several science writers. Additional recommendations of good science writers are welcome.

iv. **Innovation in the updated SSP.** Council felt that the five WG topics are not innovative and have been discussed previously. Innovation and “out-of-the-box” ideas are not highlighted. Systems Biology may not yet be ready for prime time.

Several responses were discussed during the meeting. Innovation doesn’t happen in a vacuum but rather during the course of trying to solve a significant problem. Innovation comes from having the right people around the table. Innovation can’t be legislated. The mandates of all the WGs will encourage innovative thinking. Two of the six WGs address innovation and “out-of-the box” thinking. The “Novel Approaches” WG explicitly request its members to consider new tools and technologies as well as non-conventional approaches to vaccine design. The creation of the New Minds, New Ideas Initiative
reflects data suggesting that paradigm shifts and innovative thinking is highest amongst young people. Furthermore, to encourage true innovation, we need to attract established investigators from other fields of science. Hence, the emphasis on young people in the SSP (YECI) should be viewed as a key, proven strategy for achieving innovation.

During the discussion, it was pointed out that the complexity of the mammalian immune system and the multiple immunological interactions between HIV and its human host has so far eluded classical approaches. As was noted at the Council meeting, after 26 years, we are still at the very beginning of understanding the correlates of protective immunity. It is clear we need all the tools at our disposal. Systems Biology is now a standard tool and way of thinking in other areas of biomedical research, including cancer research, cardiovascular disease, neurobiology, and other areas of infectious disease research. HIV vaccine research has been notably slow in incorporating this powerful way of understanding the molecular architecture that underlies complex biological processes.

Lastly, Council emphasized that the key value of the SSP is the “How” not the “What.” Clearly, the updated SSP needs to address the issue of innovation by thinking about new ways of encouraging new minds, ideas, tools, and technologies to enter the field.

v. The WG Terms of Reference. Council suggested modifications in the Terms of reference of the WGs to ensure that the WGs: 1) provide advice to Key Stakeholders on the best ways to align their activities with SSP, 2) inform on issues where no consensus was achieved by WG members, and 3) compile the estimated costs into an “investment menu” that can be used by funders. The Secretariat agreed and will include these issues in the Terms of Reference.

c) Young and Early Career Investigator (YECI) Working Group (Candace Rosen)

As noted in the “New Minds, New Ideas” section of the minutes, the initial charge of the YECI Committee is to contribute to the updating of the SSP by serving in a WG that will draft a section of the SSP devoted to the challenges affecting YECI engagement in HIV vaccine research and development. Ms. Rosen described the rationale for including a separate YECI section in the SSP: An HIV vaccine is urgently needed and there is no vaccine on the horizon. There is a need to renew the field with a diversity of ideas and approaches, and young minds are unfettered by prevailing scientific thinking. Historically, paradigm shifts and new ideas come from young and early career investigators. Therefore the future of the field depends on the creativity, passion, lack of bias, naiveté, and energy of the global community of YECI. As such, it was important to address the obstacles hindering YECI career development. There was a discussion among Council members whether the SSP should have a section on YECI challenges or whether it was more appropriate to include YECIs on each Scientific WG to present the “voice” of YECIs in the larger scientific discussion. Ms. Rosen explained that in addition to the YECI WG, which was comprised of the YECI Committee members, each Scientific WG would have YECI representation.

The YECI Committee hosted an informal meeting at the Keystone conference on HIV Immunobiology and Prevention of HIV/ AIDS, where YECI WG members could publicize the efforts of the YECI Committee and the Enterprise’s “New Minds, New Ideas Initiative,” interact with the larger YECI community, and seek preliminary input on the challenges and solutions proposed for the report. At Keystone, members of the YECI WG and Enterprise Secretariat staff moderated a dynamic brainstorming session and designed and distributed a short survey to attendees of the Keystone conference requesting demographic information on gender, age, career stage, country of origin and residence, and provided space for attendees to describe challenges and potential solutions. More than 90 of the 100+ attendees who participated in the brainstorming session also completed the survey and requested to continue participating in the activities led by the YECI Committee. The Enterprise Secretariat will compile the results of the survey and work with the YECI Committee to design a more comprehensive survey and strategy for its dissemination to the greater YECI community in the field of HIV vaccine research and development. These efforts will serve to ensure that the YECI WG addresses the global landscape of challenges and solutions.

Next, Ms. Rosen described the process by which the YECI WG will develop and draft its report. The YECI WG has met twice by teleconference and once in person at the offices of the Enterprise secretariat and will follow a process similar to the other WGs including engaging stakeholders early in the process, undergoing consultations with funders, community members, and pre-eminent scientists, and presenting an early draft to Council for input. The YECI WG will present its report at a Satellite Session at AIDS Vaccine 2009.

7. External Relations
Ms. Ozaeta, Director of External Relations, summarized activities of the Secretariat to prepare for the release of the results from the ‘Thai’ trial. She stressed that Enterprise activities are being closely coordinated with the trial sponsors through sanofi pasteur and the United States Military HIV Research Program. She provided some background on the Enterprise Coordinating Group to Prepare for Release of HIV Vaccine Efficacy Trial Results (Coordinating Group) which was convened originally in 2007 in preparation for the release of the STEP trial results. The Coordinating Group developed a critical path for all clinical trials use. The sponsors of the Thai Trial have developed their own critical path document to address prospective outcomes of the trial. The Coordinating Group will meet and initiate a series of discussions with the sponsors to ensure that Enterprise stakeholders are informed and can each prepare for the release of the Thai Trial results. The Secretariat will convene a meeting of the Coordinating Group and Thai Trial sponsors in May 2009. A separate meeting involving Enterprise stakeholder communications staff (the Enterprise Communications Sub-group) and sponsor organizations communications staff will also take place in May 2009.

Council members discussed the above process. The STEP trial finished prematurely and, thus, caught the Enterprise by surprise. Despite this challenge and what was perceived to be disappointing trial results, messaging from throughout the Enterprise was very consistent. The Thai trial sponsors have already started to develop a communications strategy. Council emphasized that this plan needs to be shared with the Enterprise. Timing is critical, so it makes sense to support the Thai Trial sponsors as the lead in this process. Council held that this is not only a challenge but an opportunity. World press attention will be on this topic, and the field needs to be well prepared.

b) AIDS Vaccine Conferences

Ms. Ozaeta deferred discussion of the AIDS Vaccine 2009 Conference for Dr. Lévy to cover in his presentation. She discussed current topics for the AIDS Vaccine 2010, including the dates of the conference (September 28 to October 1, 2010), regularly scheduled planning teleconferences, and the prototype logo design. Ms. Ozaeta also updated Council on AIDS Vaccine 2011. She informed Council that the AIDS Vaccine Conference Steering Group (Steering Group) met by teleconference on March 30, 2009. On the agenda for this teleconference was the site selection for AIDS Vaccine 2011. Ms. Ozaeta reported that the Steering Group agreed to greater transparency in the site selection process. The Steering Group agreed that the Enterprise Secretariat will use an updated version of the Local Host application form to solicit interest from prospective Local Hosts. The Enterprise Secretariat will post the application form on the Enterprise web site, and Dr. Bernstein will contact prospective Local Hosts who have expressed interest or who have been recommended by Steering Group members to ascertain their interest.

Council discussed the option of hosting the AIDS Vaccine conference every other year. An additional complication lies in the need to balance the timing of the AIDS Vaccine conference with the Keystone and IAS meetings. Some Council members noted that timing drives researchers’ conference selections. Researchers will present their data at the most opportune venue. The Council chair recommended that Council table the discussion in favor of a more informed conversation about conference timing at a later date. The Enterprise Secretariat agreed to prepare a list of pros and cons on conferences every year versus every other year for discussion at the next Council meeting.

c) HIV Vaccine Awareness Day

Ms. Ozaeta informed Council that on May 18, 2009, HIV Vaccine Awareness Day, the Enterprise Secretariat will co-host a forum (official title TBD) that will bring together scientists and representatives from the advocacy community. AVAC, the Enterprise Secretariat, and the Treatment Action Group (TAG) are co-organizing the event which will be held at TAG’s headquarters in New York. The forum will focus on future directions for HIV vaccine research, development, and advocacy in the context of a comprehensive prevention effort.

8. AIDS Vaccine Conference 2009 (Yves Lévy)

Dr. Lévy represented the ANRS and reviewed important dates for the AIDS Vaccine 2009 Conference. He also presented the Local Organizing Committee list, the Enterprise Science Committee working group for AV 2009 and International Science Committee. Dr. Lévy also reviewed the scientific program and schedule for Council. Council members were excited about the program and agenda for the Conference.
and thanked Dr. Lévy and his colleagues for their ongoing efforts to make this year’s conference a success. Some suggestions were made for additional speakers, pending replies from some of the invited speakers.

9. Meeting sponsorship criteria

Ms. Ozaeta led this discussion. The Enterprise Secretariat receives many requests for sponsorships and management would like Secretariat decisions to reflect the mandate of the Enterprise. The Secretariat requested Council input on the best way to review these applications. Three options were discussed.

During the discussion that followed, Council agreed that the decision of which meetings to support should be made by the Secretariat and not, for example, by a sub-committee of Council. Some Council members described the double dipping phenomenon of one meeting organizer going to multiple funders. Council suggested that the Enterprise set a limit of the maximum amount that would be allocated to any one meeting.

An alternative suggestion was to not fund any meetings. In other words, the message should be sent that the Enterprise is not there to simply sponsor meetings. Rather, the message should be that the Enterprise has a mandate to carry out and will only support those meetings that advance the Enterprise mission and which are so aligned with the current Enterprise priorities that the Secretariat is not only prepared to allocate funds but also staff resources to assist in developing the meeting more broadly, including program, venue, etc. Specifically, Council suggested requirements for meetings as follows:

- Normally, meetings should be international or regional, not national
- Enterprise Secretariat should be involved in the development of the meeting agenda
- Enterprise logo use should be required

10. Other business

Council members requested more regular updates.

11. Dates for future meetings

Council discussed both the timing and the site for the next and future meetings. Madame Kagame generously offered to host a future Council meeting in Kigali. The possibility of timing the next meeting in Paris just before or after the AIDS Vaccine conference in October was discussed but it was pointed out afterwards that this idea would not be practical because of the Satellite meetings that are taking place before and after the Conference. The Secretariat will share a number of possibilities with Council shortly.

With no further business, Council adjourned.
I) **Global HIV Vaccine Enterprise Mission:** The Global HIV Vaccine Enterprise is an alliance of independent organizations around the world dedicated to accelerating the development of a safe and effective preventive HIV vaccine by: (1) **A shared scientific plan:** Implementing a strategic plan for HIV vaccine research that spans vaccine discovery, product development and manufacturing, and clinical trials; (2) **Increased resources:** Mobilizing significant new funding to achieve the scientific plan; (3) **Greater collaboration:** Promoting more efficient, faster ways for researchers to share successes and failures and avoid duplication of efforts.

II) **Global HIV Vaccine Enterprise Council Purpose:** The Global HIV Vaccine Enterprise Council (the “Council”) is established as the senior advisory body of the Global HIV Vaccine Enterprise (the “Enterprise”) to provide advice and recommendations regarding (i) the mission, objectives and policies of the Enterprise; (ii) possible areas of collaboration and interaction for stakeholder organizations to support and implement the Enterprise’s Scientific Strategic Plan (iii) nominees to serve as directors and officers of the Enterprise; and (iv) such other matters as the Executive Director or the Board of Directors of the Enterprise (the “Board”) may request from time to time. The Council shall have neither the power to bind the Enterprise nor the authority to act on behalf of the Enterprise.

III) **Membership:**

A. **Qualifications.**

1. **General.** The Council membership shall include individuals from organizations, government institutions and corporations that support the development of a preventive vaccine for HIV/AIDS, as well as from outside the field based on expertise and influence, and who have such other qualifications as the Council may determine from time to time.

2. **Key Stakeholder Organizations.** One Council membership seat shall be reserved for an individual drawn from each organization designated by the Council as a “key stakeholder organization”. Initially, the key stakeholder organizations shall be as follows: (i) Bill & Melinda Gates Foundation; (ii) European Commission; (iii) French National Agency for Research on AIDS and Viral Hepatitis (ANRS); (iv) International AIDS Vaccine Initiative; (v) National Institutes of Health, US Department of Health and Human Services (NIH/NIAID); (vi) Wellcome Trust; and (vii) WHO-UNAIDS HIV Vaccine Initiative. The Council may, from time to time, add or remove key stakeholder organizations by amending this Charter.

B. **Number.** The Council shall normally consist of at least four (4) and not more than fourteen (14) members. The Council shall endeavor to ensure that the total number of Council members in office at any time is not more than two times plus three (3) the number of key stakeholder organizations.

C. **Appointment.** The Board shall designate and appoint the initial Council members. Successor members shall be appointed by the Council. In appointing members to occupy the Council seats reserved for key stakeholder organizations, the Council shall, as appropriate, consult with and/or seek input from the respective key stakeholder organizations.

D. **Stakeholder Alternates.** Each key stakeholder organization may designate one alternate Council member; provided that, the designation and appointment of such alternate shall be approved in advance by the Chair of the Council. Alternate members shall receive notice of and have the right to attend Council meetings but shall not count for quorum purposes or have the power to vote. Notwithstanding the foregoing, an alternate member shall count for quorum purposes and have the right to vote if the Council member who normally occupies the seat of the key stakeholder organization that designated such alternate member is absent. An alternate member shall hold office until he or she resigns or is removed by the key stakeholder organization that appointed such alternate or by the Council.

E. **Term.** Each initial Council member shall serve the term specified by the Board in the resolution appointing such individual. Thereafter, each Council member shall serve a three (3) year term and shall serve until his or her successor is appointed or until his or her death, resignation or removal. Members may be elected to successive terms without any limitation on the number of terms.
F. **Vacancies.** The Council may appoint an individual to fill a vacancy in the position of Council member at any meeting of the Council by the affirmative vote of a majority of the remaining Council members, even if less than a quorum of the Council is present at the meeting. Any vacancy in a key stakeholder organization Council seat shall be filled with an individual drawn from such key stakeholder organization unless the Council has removed such organization from the list of designated key stakeholder organizations.

G. **Resignation or Removal of Council Member.** A Council member may resign at any time by delivering notice thereof in writing or by email to the Chair or by giving such notice at any meeting of the Council. Any such resignation shall take effect at the time specified therein, or if the time is not specified, upon delivery thereof. The Council, by resolution adopted by a majority of the members, may remove from office any member of the Council, with or without cause. Without limiting the generality of the foregoing, if a member who occupies a key stakeholder organization ceases to be affiliated with such organization, this shall be cause for removal.

H. **Ex Officio Member.** The Executive Director of the Enterprise shall be an ex officio, non-voting member of the Council.

I. **Compensation.** Council members shall not receive compensation for their services as such, although the reasonable expenses of Council members for attendance at Council meetings may be paid or reimbursed by the Enterprise.

IV) **Chair:** The President of the Enterprise shall serve as the Chair of the Council.

V) **Operations:**

A. **Meetings.** The Council shall meet at least annually. Additional meetings may occur as the Council Chair deems advisable or necessary. The Council Chair shall preside at all meetings, cause adequate minutes of Council proceedings to be kept, and regularly report the actions and activities of the Council to the Board.

B. **Participation by Telephone.** Members of the Council may participate in a Council meeting by means of a telephone or similar communications.

C. **Electronic Voting in Lieu of Meeting.** Unless otherwise provided in the Articles of Incorporation, Bylaws, this Charter, or by the laws of the state of Washington, any action required or permitted to be taken by the Council may be taken without a meeting by written or email consent. Unless a more restrictive voting requirement is specified in this Charter, an affirmative vote of a two-thirds (2/3) of all the voting members of the Council shall be required to approve any action by such written or email consent. The results of the vote shall be sent to Council members promptly in writing or by electronic transmission. The written and/or email consents shall be filed with the minutes of the proceedings of the Council.

D. **Quorum.** Unless a greater portion is required in the Articles of Incorporation, Bylaws, this Charter, or by the laws of the state of Washington, a majority of Council members shall constitute a quorum for the transaction of business or any particular item of business at any Council meeting, but in no event shall a quorum consist of less than one-third of the total number of Council members. If a quorum is not present at a meeting, a majority of the Council members may adjourn the meeting and set a date and time for the meeting to reconvene.

VI) **Nominating Committee.** The Council may have a nominating committee that consists of Council members drawn from the key stakeholder organizations (the “Nominating Committee”). The initial Nominating Committee members shall be appointed by the Board. Their successors shall be appointed by the Council. The Nominating Committee shall be responsible for identifying and vetting candidates to serve as directors and officers of the Enterprise, and recommending nominees to the Council. Nominees approved by the Council shall be passed on by the Council to the Board. Notwithstanding the foregoing, the initial Nominating Committee shall have the power to recommend directly to the Board nominees to serve as the First Permanent Board of the Enterprise (as defined in the Enterprise Bylaws), without Council approval. The Nominating Committee may elect a chair from amongst its members to preside at Committee meetings, report to the Council on Committee activities and undertake such other responsibilities as the Committee may determine.

VII) **Amendment or Repeal of Charter.** This Charter may be amended or repealed by the affirmative vote of a majority of the Council at any meeting of the Council.

VIII) **Authority and Responsibilities:** The Council shall have the authority and responsibility to:

A. Provide advice and recommendations to the Executive Director and the Board regarding the Enterprise's mission, objectives, and policies.
B. Recommend nominees to serve as directors and officers of the Enterprise, pursuant to such nominations process as the Board may approve from time to time.

C. Ensure that the Board is informed regarding Council activities.

D. Review this Charter and amend it as the Council deems necessary or appropriate, provided that this Charter is consistent with and subject to Article 7 ("Global HIV Vaccine Enterprise Council") of the Enterprise Bylaws.

Endorsed this 14th day of April, 2009