Dr. Seth Berkley  
President and CEO  
International AIDS Vaccine Initiative  
110 William Street  
New York, NY 10038-3901

Grant Agreement between the International AIDS Vaccine Initiative and the International Bank for Reconstruction and Development and the International Development Association concerning the Support to IAVI-Sendai Vector Single-Donor Trust Fund (TF097822)

Dear Dr. Berkley:

In response to the request for financial assistance made on behalf of the International AIDS Vaccine Initiative (“Recipient”), I am pleased to inform you that the International Bank for Reconstruction and Development/International Development Association (“World Bank”), acting as administrator of grant funds provided by the Japan Ministry of Finance (“the Donor”), under the IAVI-Sendai Vector Single-Donor Trust Fund (TF071457), proposes to extend to the Recipient a grant in an amount not to exceed nine million two hundred sixty thousand two hundred fifty six United States Dollars (US$9,260,256) (“Grant”) on the terms and conditions set forth or referred to in this letter agreement (“Agreement”), which includes the attached Annex, to assist in the financing of the project described in the Annex (“Project”). This Grant is funded out of the abovementioned trust fund for which the World Bank receives periodic contributions. In accordance with Section 3.02 of the Standard Conditions (as defined in the Annex to this Agreement), the Recipient may withdraw the Grant proceeds subject to the availability of such funds.

The Recipient represents, by confirming its agreement below, that it is authorized to enter into this Agreement and to carry out the Project in accordance with the terms and conditions set forth or referred to in this Agreement.

Please confirm the Recipient’s agreement to the foregoing by having an authorized official of the Recipient sign and date the enclosed copy of this Agreement, and returning it to the World Bank. Upon receipt by the World Bank of this countersigned copy, this Agreement shall become effective as of the date of the countersignature; provided, however, that the offer of this Agreement shall be deemed withdrawn if the World Bank has not received the countersigned copy of this Agreement within 15 days after the date of signature of this Agreement by the World Bank, unless the World Bank shall have established a later date for such purpose.
Very truly yours,

INTERNATIONAL BANK FOR
RECONSTRUCTION AND DEVELOPMENT
INTERNATIONAL DEVELOPMENT ASSOCIATION

/s/ Cristian Baeza
Sector Director
Health, Nutrition and Population Team
Human Development Network

AGREED:

International AIDS Vaccine Initiative (IAVI)

By /s/ Seth F. Berkley
Authorized Representative

Name: Seth F. Berkley
Title: President and CEO
Date: March 16, 2011

Enclosures:

(1) Standard Conditions for Grants Made by the World Bank Out of Various Funds, dated July 1, 2010
(2) Disbursement Letter of even date, together with World Bank Disbursement Guidelines for Projects, dated May 1, 2006
IAVI-Sendai Vector Trust Fund Grant No. TF097822
ANNEX

Article I
Standard Conditions; Definitions

1.01. **Standard Conditions.** The Standard Conditions for Grants Made by the World Bank out of Various Funds dated July 1, 2010 ("Standard Conditions") with the modifications set forth in the Appendix to this Agreement constitute an integral part of this Agreement.

1.02. **Definitions.** Unless the context requires otherwise, the capitalized terms used in this Agreement have the meanings ascribed to them in the Standard Conditions or in this Agreement.

Article II
Project Execution

2.01. **Project Objectives and Description.** The objective of the Project is to support the International AIDS Vaccine Initiative (IAVI) in the development of a novel HIV vaccine candidate that is based on the Sendai virus Vector, as a Global Public Good through a program of transitional research, product development and clinical trials.

   (i) The Project consists of the following components - all **Recipient-Executed Trust Fund Activities**

   A. Development and clinical trials of HIV vaccine candidates based on Sendai virus Vector (SeV): virulence and preclinical safety studies, manufacturing, and the first phase of clinical trials (regulatory, ethical and biosafety clearances) through:

      (1) Construction of vaccine candidates using SeV as a vector encoding different HIV genes, or antigens.

      (2) Conduct of virulence and preclinical safety studies in animals with the newly constructed candidates for suitability in advancement into clinical trials in humans.

      (3) Development of manufacturing processes for the production of vaccine material at a scale and standard suitable for clinical trial.

      (4) Conducting the first stage of clinical trials (Phase I) of the SeV-based HIV vaccine candidates in humans, alone as well as coupled in a prime-boost regimen (with SeV-based HIV vaccine as a prime or as a boost), to assess vaccine safety, elicited immune responses and "proof of concept" studies.

   B. Administration of research program, including reporting, management of compliance requirements and the selection and management of the out-sourced contracts.
(ii) **World Bank’s role:**

A. Grant supervision: Supervise Grant for Research program of development and trial of novel HIV vaccine/s based on Sendai virus Vector, including independent evaluations of the work.

B. Administration of Trust Fund (TF) to support research program: monitoring TF, internal and external TF reporting, maintenance of TF account and ensuring compliance with audit requirements.

C. The Bank will not be responsible for any of the activities implemented by the Recipient as a result of this Grant Agreement, nor will the Bank be liable for any costs incurred by the Recipient in terminating the engagement of any employee of the Recipient connected with the implementation of the Grant activities. Additionally, it is agreed and understood that the Bank will in no way be liable for any adverse results of the development and clinical trials associated with the activities financed by this Grant; such as (but not limited to) disputes over licensing, patents, trademarks, copyrights or other intellectual property; non compliance with legal requirements to conduct clinical trials; personal injuries, damaged reputations etc. The Recipient hereby confirms that it has adequately taken the appropriate measures to protect itself from the risks mentioned above (among others).

2.02. **Project Execution Generally.** The Recipient declares its commitment to the objectives of the Project. To this end, the Recipient shall carry out the Project in accordance with the provisions of: (a) Article II of the Standard Conditions; (b) the “Guidelines on Preventing and Combating Fraud and Corruption in Projects Financed by IBRD Loans and IDA Credits and Grants”, dated October 15, 2006 (“Anti-Corruption Guidelines”) with the modifications set forth in the Appendix to this Agreement; and (c) this Article II.

2.03. **Donor Visibility and Visit.** (a) The Recipient shall take or cause to be taken all such measures as the World Bank may reasonably request to identify publicly the Donor’s support for the Project; and (b) for the purposes of Section 2.09 of the Standard Conditions, the Recipient shall, upon the World Bank’s request, take all measures required on its part to enable the representatives of the Donor to visit any of the Recipient’s operations for purposes related to the Project.

2.04 **Intellectual Property Rights.** In developing a vaccine candidate as a Global Public Good in accordance with Section 2.01, the Recipient shall take measures to ensure that Intellectual Property Rights claimed over potential vaccine candidates, as well as Project related agreements and any licensing arrangements with sub-contractors and collaborators, allow for a commercialization strategy to make any resulting successful vaccine accessible widely and at affordable prices in developing countries. The Recipient shall consult with the World Bank and the Donor on the commercialization strategy prior to its implementation.

2.05. **Project Monitoring, Reporting and Evaluation.** (a) The Recipient shall monitor and evaluate the progress of the Project and prepare Project Reports in accordance with the provisions of Section 2.06 of the Standard Conditions and on the basis of indicators listed in Annex I attached hereto.

(i) Progress reports shall cover the period of one calendar year, and shall be furnished to the Bank not later than one month after the end of the period covered by such report. The reports shall cover all activities undertaken by the Recipient.
towards the Project objectives that have been financed under the Recipient Executed Trust Fund activities. The reports should include the milestone reports detailed in 2.05 (ii) contained within the same calendar year. For the last Project year, the annual progress report will be replaced by the Completion Report described below.

(ii) Milestone reports shall be submitted no later than one month after the end of the quarter of scheduled completion of specific activity milestones, detailed as indicators in Annex 1. These reports should comprise a brief description of the milestone and a report of its completion.

(iii) On the World Bank’s request, the Recipient will participate in annual technical briefings to the Donor in Tokyo, at which progress in the work supported under the Trust Fund will be presented by IAVI and its consultants and contractors. These meetings will be attended by the representatives of the World Bank and expert consultants in the field of HIV/AIDS vaccinology and clinical research, appointed by the World Bank (and agreed to by IAVI), to provide it with independent technical assessment and evaluation of the progress of the Project. The Recipient will provide these experts with any additional briefing they require for the purposes of their confidential assessment and evaluation.

(b) The Recipient shall prepare the Completion Report in accordance with the provisions of Section 2.06 of the Standard Conditions. The Completion Report shall be furnished to the World Bank not later than six months after the Closing Date.

2.06. Financial Management. (a) The Recipient shall ensure that a financial management system is maintained in accordance with the provisions of Section 2.07 of the Standard Conditions.

(b) The Recipient shall ensure that interim unaudited financial reports for the Project are prepared and furnished to the World Bank not later than sixty (60) days after the end of each six (6) month period, covering the six (6) months, in form and substance satisfactory to the World Bank.

(c) The Recipient shall have its Financial Statements audited in accordance with the provisions of Section 2.07 (b) of the Standard Conditions. Such audit of the Financial Statements shall cover the period of one fiscal year of the Recipient. The audited Financial Statements for such period shall be furnished to the World Bank not later than six months after the end of such period.

2.07. Procurement

(a) General. All services required for the Project and to be financed out of the proceeds of the Grant (Category 1 of Article III, para 3.01) shall be procured in accordance with the requirements set forth or referred to in “Guidelines: Selection and Employment of Consultants by World Bank Borrowers” published by the World Bank in May 2004 and revised in October 2006, and May 2010 (“Consultant Guidelines”).

(b) Definitions. The capitalized terms used in the following paragraphs of this Section to describe particular procurement methods or methods of review by the World Bank of particular contracts, refer to the corresponding method described in the Consultant Guidelines, as the case may be.
(c) Particular Methods of Procurement of Services

(i) Procurement of consultants’ services, including procurement of related goods items under the same contract, shall be carried out on in accordance with the requirements set forth in paragraph 3.14 – (Commercial Practices) of the Consultant Guidelines.

(d) Review by the World Bank of Procurement Decisions. Except as the World Bank shall otherwise determine by notice to the Recipient, all contracts financed under Category 1 of Article III, para 3.01 shall be subject to Prior Review by the World Bank.

Article III
Withdrawal of Grant Proceeds

3.01. Eligible Expenditures. The Recipient may withdraw the proceeds of the Grant in accordance with the provisions of: (a) the Standard Conditions; (b) this Section; and (c) such additional instructions as the World Bank may specify by notice to the Recipient (including the “World Bank Disbursement Guidelines for Projects” dated May 2006, as revised from time to time by the World Bank and as made applicable to this Agreement pursuant to such instructions), to finance Eligible Expenditures as set forth in the following table. The table specifies the categories of Eligible Expenditures that may be financed out of the proceeds of the Grant (“Category”), the allocations of the amounts of the Grant to each Category, and the percentage of expenditures to be financed for Eligible Expenditures in each Category:

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount of the Grant Allocated (expressed in USD)</th>
<th>Percentage of Expenditures to be Financed (inclusive of Taxes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Services, including consultants’ services and related goods under the Project</td>
<td>5,556,154</td>
<td>100%</td>
</tr>
<tr>
<td>(2) Operational Costs*</td>
<td>3,704,102</td>
<td>100%</td>
</tr>
<tr>
<td>TOTAL AMOUNT</td>
<td>9,260,256</td>
<td></td>
</tr>
</tbody>
</table>

*For purposes of this Grant the term “Operational Costs” includes the Recipient’s technical services and gross salaries of in-house staff for project management, regulatory and other services such as human resources, accounting, executive office, budgeting, Information Technology (IT), contract management, and related overheads.

3.02. Withdrawal Conditions. Notwithstanding the provisions of Section 3.01 of this Agreement, no withdrawal shall be made for payments on expenditures made prior to the date of countersignature of this Agreement by the Recipient except that withdrawals up to an aggregate amount not to exceed one million
United States dollars (US$1,000,000) equivalent may be made for payments on expenditures made prior to this date but on or after July 1, 2010, for Eligible Expenditures under Category 3.01.

3.03. Withdrawal Period. The Closing Date referred to in Section 3.06 (c) of the Standard Conditions is June 30, 2015 or five years after the date of countersignature of this Agreement by the Recipient, whichever is sooner.

**Article IV**

**Recipient’s Representative; Addresses**

4.01. **Recipient’s Representative.** The Recipient’s Representative referred to in Section 7.02 of the Standard Conditions is President and Chief Executive Officer.

4.02. **Recipient’s Address.** The Recipient’s Address referred to in Section 7.01 of the Standard Conditions is:

110 William Street, 27th Floor,
New York, NY 10038, USA

Telephone: +1-212-847-1111
Facsimile: +1-212-847-1112

4.03. **World Bank’s Address.** The World Bank’s Address referred to in Section 7.01 of the Standard Conditions is:

International Bank for Reconstruction and Development
1818 H Street, N.W.
Washington, D.C. 20433
United States of America

Cable: INTBAFRAD
Telex: 248423 (MCI) or 64145 (MCI)
Facsimile: 1-202-477-6391
Section I. The modifications to the Anti-Corruption Guidelines are as follows:

1. Section 5 is re-numbered as Section 5(a) and a new Section 5(b) is added to read as follows:

   “(b) These Guidelines also provide for the sanctions and related actions to be imposed by the Bank on Borrowers (other than the Member Country) and all other individuals or entities who are recipients of Loan proceeds, in the event that the Borrower or the individual or entity has been debarred by another financier as a result of a determination by such financier that the Borrower or the individual or entity has engaged in fraudulent, corrupt, coercive or collusive practices in connection with the use of the proceeds of a financing made by such financier.”

2. Section 11(a) is modified to read as follows:

   “… (a) sanction in accordance with prevailing Bank’s sanctions policies and procedures (fn13) a Borrower (other than a Member Country) (fn 14) or an individual or entity, including (but not limited to) declaring such Borrower, individual or entity ineligible publicly, either indefinitely or for a stated period of time: (i) to be awarded a Bank-financed contract; (ii) to benefit from a Bank-financed contract, financially or otherwise, for example as a sub-contractor; and (iii) to otherwise participate in the preparation or implementation of the project or any other project financed, in whole or in part, by the Bank, if at any time the Bank determines (fn 15) that such Borrower, individual or entity has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in connection with the use of loan proceeds, or if another financier with which the Bank has entered into an agreement for the mutual enforcement of debarment decisions has declared such person or entity ineligible to receive proceeds of financings made by such financier or otherwise to participate in the preparation or implementation of any project financed in whole or in part by such financier as a result of a determination by such financier that the Borrower or the individual or entity has engaged in fraudulent, corrupt, coercive or collusive practices in connection with the use of the proceeds of a financing made by such financier.”

Footnotes:

“13. An individual or entity may be declared ineligible to be awarded a Bank financed contract upon completion of sanctions proceedings pursuant to the Bank’s sanctions policies and procedures, or under the procedures of temporary suspension or early temporary suspension in connection with an ongoing sanctions proceeding, or following a sanction by another financier with whom the Bank has entered into a cross debarment agreement, as a result of a determination by such financier that the firm or individual has engaged in fraudulent, corrupt, coercive or collusive practices in connection with the use of the proceeds of a financing made by such financier.”

“14. Member Country includes officials and employees of the national government or of any of its political or administrative subdivisions, and government owned enterprises and agencies that are not eligible to bid under paragraph 1.8(b) of the Procurement Guidelines or participate under paragraph 1.11(c) of the Consultant Guidelines.”

“15. The Bank has established a Sanctions Board, and related procedures, for the purpose of making such determinations. The procedures of the Sanctions Board sets forth the full set of sanctions available to the Bank. In addition, the Bank has adopted an internal protocol outlining the process to be followed in implementing debarments by other financiers, and explaining how cross-debarments will be posted on the Bank’s website and otherwise be made known to staff and other stakeholders.”
# ANNEX I

## Performance monitoring sheet

<table>
<thead>
<tr>
<th>Objective</th>
<th>To construct vaccine candidates using SeV as vector encoding HIV immunogens</th>
<th>Completion Calendar year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator</td>
<td>Have constructed vaccine candidate using SeV as vector that express the HIV Gag appropriately.</td>
<td>Done 2Q10</td>
</tr>
<tr>
<td>Indicator</td>
<td>Have achieved genetic stability evaluation of the SeV Gag vaccine candidate.</td>
<td>4Q10</td>
</tr>
<tr>
<td>Indicator</td>
<td>In parallel, have constructed vaccine candidate using SeV as vector that express the additional HIV immunogens appropriately and have completed Genetic Stability assessment.</td>
<td>1Q12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objective</th>
<th>To conduct virulence and pre-clinical safety studies in animals with newly constructed SeV Gag and HIV-immunogens candidate to assure that it will be suitable for advancement into clinical trials in humans.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator</td>
<td>Have conducted virulence studies in suitable animal model with SeV-Gag.</td>
</tr>
<tr>
<td>Indicator</td>
<td>Have conducted preliminary virulence studies in suitable animal model with SeV-HIV Immunogens</td>
</tr>
<tr>
<td>Indicator</td>
<td>Have conducted immunogenicity studies in suitable animal model demonstrating that SeV-Gag vaccine elicits immune response to HIV when administered at safe dose ranges.</td>
</tr>
<tr>
<td>Indicator</td>
<td>Have conducted immunogenicity studies in suitable animal model demonstrating that SeV-HIV-Immunogens vaccine elicits immune response to HIV when administered at safe dose ranges.</td>
</tr>
<tr>
<td>Indicator</td>
<td>Have conducted toxicity in selected animal model with SeV-Gag vaccine to establish safe starting dose for clinical trials and no significant toxicology findings.</td>
</tr>
<tr>
<td>Indicator</td>
<td>Have conducted toxicity and Virulence studies in selected animal model with SeV-HIV immunogens vaccine to establish safe starting dose for clinical trials and no significant toxicology findings.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objective</th>
<th>To obtain approval from Ethical and Regulatory Bodies</th>
</tr>
</thead>
</table>
| Indicator | Have prepared and submitted clinical trial application to regulatory, ethics and biosafety committees for SeV-Gag vaccine candidate as required to obtain:  
  - Approval by the National Regulatory Agency (FDA or similar)  
  - Approval by Ethics committee (IRB or similar)  
  - Approval by Biosafety committee (if appropriate) | 3Q12 |
| Indicator | Have prepared and submitted clinical trial application to regulatory, ethics and biosafety committees for SeV-HIV-immunogens vaccine candidates as required to obtain:  
  - Approval by the National Regulatory Agency (FDA or similar)  
  - Approval by Ethics committee (IRB or similar)  
  - Approval by Biosafety committee (if appropriate) | 2Q15 |

<table>
<thead>
<tr>
<th>Objective</th>
<th>To develop manufacturing process for large scale production of clinical trial material of SeV Gag and SeV-HIV-Immunogens candidate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator</td>
<td>Process developed to support SeV-Gag vaccine manufacturing at clinical trial scale.</td>
</tr>
<tr>
<td>Indicator</td>
<td>Process developed to support SeV-Immunogens vaccine manufacturing at clinical trial scale.</td>
</tr>
<tr>
<td>Indicator</td>
<td>SeV-Gag Vector GMP material for Toxicity studies released</td>
</tr>
<tr>
<td>Indicator</td>
<td>SeV-Gag Vector clinical trial material released</td>
</tr>
<tr>
<td>Indicator</td>
<td>SeV-HIV-Immunogens Vector clinical trial material released</td>
</tr>
<tr>
<td>Objective</td>
<td>Indicator</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>To conduct the Phase I clinical trial in humans to assess SeV-Gag and SeV-HIV-immunogens vaccine safety as well as immune responses against candidate vaccines.</td>
<td>To have begun a Phase I safety and immunogenicity dose escalation clinical trials with SeV-Gag.</td>
</tr>
<tr>
<td>Indicator</td>
<td>Second dosage completed</td>
</tr>
<tr>
<td>Indicator</td>
<td>Third dosage completed</td>
</tr>
<tr>
<td>Indicator</td>
<td>To have completed SeV Gag dose escalation trial (with one administration, four dosages) and acquired interim safety data</td>
</tr>
<tr>
<td>Indicator</td>
<td>SeV-Gag study Phase I in a Prime-Boost Regimen (0, 3 months) initiated (post safety data report from second dosage)</td>
</tr>
<tr>
<td>Indicator</td>
<td>SeV-Gag study Phase I in a Prime-Boost Regimen: Enrolled</td>
</tr>
<tr>
<td>Indicator</td>
<td>SeV-Gag study Phase I in a Prime-Boost Regimen (0, 3 months): Vaccination completed</td>
</tr>
<tr>
<td>Indicator</td>
<td>To have completed SeV Gag in a Prime: Boost regimen (with one administration of each at 0, 3 month SeV-Gag as prime or as boost) trial and acquired safety and preliminary immunogenicity data</td>
</tr>
<tr>
<td>Indicator</td>
<td>Have conducted 1 year follow-up post last –Gag vaccine candidate (dose escalation)- LVLV</td>
</tr>
<tr>
<td>Indicator</td>
<td>Have conducted 1 year follow-up post last vaccination in the Prime-Boost study- LVLV</td>
</tr>
</tbody>
</table>