



Project Information Document/ Integrated Safeguards Data Sheet (PID/ISDS)

Concept Stage | Date Prepared/Updated: 29-Aug-2018 | Report No: PIDISDSC24535



BASIC INFORMATION

A. Basic Project Data

Country World	Project ID P167064	Parent Project ID (if any)	Project Name HIV Vaccine Research and Development (P167064)
Region OTHER	Estimated Appraisal Date Oct 01, 2018	Estimated Board Date Jan 30, 2019	Practice Area (Lead) Health, Nutrition & Population
Financing Instrument Investment Project Financing	Borrower(s) International AIDS Vaccine Initiative	Implementing Agency International AIDS Vaccine Initiative	

Proposed Development Objective(s)

To develop and characterize viable HIV vaccine candidate(s) and other potential viral vectors as basic research for new technologies against infectious diseases of poverty.

PROJECT FINANCING DATA (US\$, Millions)

SUMMARY

Total Project Cost	5.75
Total Financing	5.75
of which IBRD/IDA	0.00
Financing Gap	0.00

DETAILS

Non-World Bank Group Financing

Trust Funds	5.75
Free-standing TFs for HDNVP	5.75

Environmental Assessment Category
B - Partial Assessment

Concept Review Decision
Track I-The review did authorize the preparation to continue



Other Decision (as needed)

B. Introduction and Context

(1) Country Context

The project is not country-specific, hence not applicable.

(2) Sectoral and Institutional Context

1. **The need for a vaccine against Human Immunodeficiency Virus (HIV) remains urgent**, with the epidemic contributing to reversals in health, food security, education and other measures of prosperity and stability. Approximately 5,753 people become newly infected with HIV each day. The pandemic is still outpacing current treatment and prevention efforts in many countries. There is no cure for HIV infection. However, effective (but costly) antiretroviral medicines can control the virus and help prevent transmission so that people with HIV, and those at substantial risk, can enjoy healthy and productive lives. Another hope is that a vaccine can be developed against the virus. Its introduction will improve millions of lives around the world. Even though no vaccination is 100% effective, overall, immunization has proved to be one of the most cost-effective means to prevent vaccine-preventable diseases.
2. **Global investment in the research and development (R&D) of a preventive vaccine for HIV should continue.** More than 30 candidate vaccines have been developed and only a few have been tested for efficacy in people. None of them have proven efficacious enough in long-term protection to be introduced into clinical practice. A series of failures and the absence of prospects of a fully effective vaccine in the near future seems to discourage the pharmaceutical industry to further invest into vaccine R&D against HIV and pathogens of poverty.
3. **The technical basis for further investments in HIV vaccine research is strong.** While immune correlates for protection against HIV infection are currently unknown, it is generally hypothesized that antibodies, cell-mediated immune responses and mucosal immunity may all be needed in an effective preventive HIV vaccine. Among the goals for an efficacious vaccine is eliciting protective mechanisms at the primary interface for HIV infection, the mucosa. Although there is demonstration that parenterally administered vaccines could provide such protection, it will may require mucosal administration of vaccines to achieve optimal protection at those surfaces. Further, there is great interest in the potential for replicating vectors to elicit optimal responses, in terms of profile and magnitude.
4. **Rationale for creating a new Trust Fund.**
 - a. The Trustee account TF071457 “Support to International AIDS Vaccine Initiative Trust Fund” was established June 24, 2010. Several contributions totaling \$10 million from the Japan Ministry of Finance were made according to a contribution schedule (prior to FY13 - \$6M; FY14 - \$2M; FY15 - \$2M). The objective of the trust fund was to develop a new candidate HIV vaccine. The trust fund supported the IAVI



in the development and trial of a novel vaccine candidate - the *Sendai Vector*, with a work program of 5 years. A Trustee account TF072627, parallel to TF071457, was established June 13, 2016 to take account of an updated cost recovery policy of the World Bank. The contribution was made by the same donor in the amount of \$4 million (FY16 - \$2M; FY18 - \$2M). Since 2010, the original account TF071457 has been extended twice and for more than two years, which warranted the approval from senior Bank management.

- b. A new trust fund will support a new program of research, not related to the Sendai Virus technology, and will have different objectives.

(3) Relationship to CPF

The project is not country-specific, hence not applicable.

C. Proposed Development Objective(s)

To develop and characterize viable HIV vaccine candidate(s) and other potential viral vectors as basic research for new technologies against infectious diseases of poverty.

Key Results (From PCN)

- (1) VSV-G vector fully characterized including in immunological, genetic and cellular propagation aspects
- (2) Two further novel vectors (VSV(NJ) and a novel VSV-like vector) constructed and characterized
- (3) GMP compliant cell line for use in manufacturing of VSV-based HIV vaccine vectors produced
- (4) Joint learning events and meeting outputs developed with global partners in R&D for potential epidemic diseases and diseases of poverty

D. Concept Description

The Project consists of Bank Executed (BE) activities as well as Recipient Executed (RE) activities.

5. The BE activities are supervision of the implementation of the Project as well as Management and administration. Management and Administration activities for the Trust Fund, including but not limited to, supporting Trust Fund related meetings; planning and executing work plans and budgets; managing communications and conducting outreach; disseminating lessons learned; reporting on progress; and monitoring and evaluating the activities.
6. The RE of this Project consists of R&D components and non-R&D components in order to achieve the proposed development objectives.

R&D component

7. Under the R&D component, activities that support the development of HIV vaccine candidate including vector optimization and development of a related viral presentation platform are planned. The Project will entail further research on the transcriptomic and immunological response to the VSV-vectored HIV vaccine candidates and applied research to address optimization of methods related to effective vaccine production. The Project



will also include activities to establish a VSV vector platform for development of vaccines against variety of infectious diseases.

Pillar I. Detailed immunologic and transcriptomics analysis on samples collected from studies funded by IAVI and other collaborating partners

Detailed immunologic and transcriptomic analysis on samples will be implemented.

Pillar II. Applied research aimed at developing a cell line that will support GMP-manufacturing of G-pseudotyped VSVDG-Env.BG505

Under the past IAVI/WB/Japan Partnership Program, some initial work on modifying the Vero cell line to express the VSV G glycoprotein along with the human CD4 and CCR5 coreceptors needed to propagate VSVDG-Env.BG505 was done. Although the results were not very satisfactory, they provided evidence that a G-pseudotyping cell line was feasible with further development and innovation. Hence, this pillar addresses optimization of methods related to effective vaccine production.

Pillar III. Construction and characterization of two VSV-like vectors

This work aims at advancing development of additional VSV-like vaccine vectors to enable broader application of the chimeric virus vaccine platform to other viral diseases.

Non-R&D component

8. Under the non-R&D component, the following activities are planned in order to strengthen the coordination among key stakeholders, namely IAVI, Coalition for Epidemic Preparedness Innovations (CEPI) and Global Health Innovative Technology Fund (GHIT), to promote further engagements from the global scientific community, private sector and other stakeholders.

Pillar I. Regular scientific stakeholder meeting co-organized by IAVI/CEPI/GHIT

Pillar II. Development of communication material

Pillar III. Field visits to IAVI Clinical Research Centers

SAFEGUARDS

A. Project location and salient physical characteristics relevant to the safeguard analysis (if known)

Administrative offices located in Manhattan, New York City, USA and laboratory located in Brooklyn, New York City, USA.



B. Borrower’s Institutional Capacity for Safeguard Policies

IAVI is one of the leading institutions in this field of HIV vaccine research and is well positioned to carry forward the replication-competent vector platform. This capacity is demonstrated in its current related work in the development of VSV-based vaccines. A comprehensive assessment by the World Bank of IAVI's safeguard capacity was undertaken during prior projects (P119051 and P161232), which concluded that IAVI has appropriate rules and procedures, staff, and systems to comply with the legal requirements of the United States and State of New York, as well as safeguards requirements of the World Bank. IAVI is familiar with safeguard policies of the World Bank and has demonstrated effective safeguard management during ongoing partnership with the World Bank. Safeguards performance in P161232 has been assessed as highly satisfactory.

C. Environmental and Social Safeguards Specialists on the Team

Jun Zeng, Social Specialist
Brandon Enrique Carter, Environmental Specialist

D. Policies that might apply

Safeguard Policies	Triggered?	Explanation (Optional)
Environmental Assessment OP/BP 4.01	Yes	<p>The Project will involve no physical works. Key environmental and social risks and impacts are expected related to HIV/AIDS vaccine development to be supported by the Project, including: biosafety; occupational health and safety, including exposure to hazardous materials and biohazards; management of hazardous materials; and storage and disposal of hazardous waste and biohazardous/medical waste. The Project is Category B, as these risks and impacts are few in number and readily mitigated.</p> <p>Biosafety risks are high, relating to exposure of AIDS culture by researchers, AIDS vaccine prototype by production facility personnel, or HIV infected blood by such personnel at the clinics as nurses, physicians, laboratory analysts, technicians, and other health workers. These exposures may result through an intact or broken skin, or a puncture wound, or through the eyes or other mucous membranes such as nose and mouth. Sharps or broken glass contribute to injuries leading to human exposure. Another area of biosafety risk is associated with the handling of animals subjects, including non-human primates (NHPs), during testing and disposal of animal carcasses.</p>



The Project will not support vaccine tests on human subjects or procurement of NHPs. However, closely related research in vector optimization development supported from other sources may include testing on animal subjects, including NHPs. In conducting research on animal subjects, including NHPs, IAVI complies with all relevant laws of the United States (the Animal Welfare Act) and the State of New York, as well as maintaining animal welfare accreditations from the US Department of Agriculture and AAALAC International, the latter being a voluntary third-party animal welfare accreditation standard for use of animals in scientific research.

An Environmental Management Plan (EMP) was prepared under P161232 to meet OP 4.01 requirements. The EMP integrated IAVI's existing, robust and documented Standard Operating Procedures (SOPs) and management plans, including a chemical hygiene plan, a biosafety and security plan, a biosafety manual, a safety SOP, a safety audit checklist, a post exposure plan, and biosafety objectives, among others. The program is managed by a safety committee comprised of twelve members with representatives from each of the laboratory research teams that meets monthly and is responsible for training, recording and monitoring of incidents and revisions to SOPs.

During preparation, the Bank will assess whether there have been any changes or revisions to the management plans, SOPs or IAVI's health and safety program that would necessitate updating the EMP.

Performance Standards for Private Sector Activities OP/BP 4.03	No	
Natural Habitats OP/BP 4.04	No	The Project does not involve any activities which will trigger this policy.
Forests OP/BP 4.36	No	The Project does not involve any activities which will trigger this policy.
Pest Management OP 4.09	No	The Project does not involve any activities which will trigger this policy.
Physical Cultural Resources OP/BP 4.11	No	The Project does not involve any activities which will trigger this policy.
Indigenous Peoples OP/BP 4.10	No	The Project does not involve any activities which will trigger this policy.



Involuntary Resettlement OP/BP 4.12	No	The Project does not involve any activities which will trigger this policy.
Safety of Dams OP/BP 4.37	No	The Project does not involve any activities which will trigger this policy.
Projects on International Waterways OP/BP 7.50	No	The Project does not involve any activities which will trigger this policy.
Projects in Disputed Areas OP/BP 7.60	No	N/A.

E. Safeguard Preparation Plan

Tentative target date for preparing the Appraisal Stage PID/ISDS

Apr 27, 2018

Time frame for launching and completing the safeguard-related studies that may be needed. The specific studies and their timing should be specified in the Appraisal Stage PID/ISDS

The EMP will be updated (if needed) and redisclosed on the Bank’s website prior to Appraisal. Given the nature of this Project, no public consultation is required beyond external disclosure on Bank’s website.

CONTACT POINT

World Bank

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Borrower/Client/Recipient

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Implementing Agencies

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APPROVAL

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