

INTEGRATED SAFEGUARDS DATA SHEET

IDENTIFICATION / CONCEPT STAGE

Report No.: ISDSC19597

Date ISDS Prepared/Updated: 17-Aug-2016

I. BASIC INFORMATION

A. Basic Project Data

Country:	World	Project ID:	P161232
Project Name:	Support to Research and Development at the International AIDS Vaccine Initiative		
Team Leader(s):	Robert Oelrichs		
Estimated Date of Approval:	03-Oct-2016		
Managing Unit:	GHN05	Lending Instrument:	IPF
Financing (in USD Million)			
Total Project Cost:	2	Total Bank Financing:	0
Financing Gap:	0		
Financing Source			Amount
Free-standing TFs for HDNVP			2
Environment Category:	B - Partial Assessment		

B. Project Development Objective(s)

To support the International AIDS Vaccine Initiative (IAVI) in the development of a novel HIV vaccine candidate through a program of fundamental translational research and product development.

C. Project Description

The project will entail further research to optimize the replicating vector platform. The applied research required to optimize vaccine vector design to ensure efficacy and safety of a vaccine for wide-scale usage is considerable. Informed by the studies conducted as part of the project P119051 using Sendai virus vector candidate, the research in the current project will include iterative design and the systematic investigation of modified vectors and vaccination regimens in order to identify the most practical effective route and dose, mainly in a series of monkey studies. The research will help identify and characterize the immunologic mechanisms that provide protection, which will inform improvements in the HIV vaccine candidates as well as direct how the vector can be used to develop vaccine candidates against pathogens of poverty. The project might consider clinical trials in humans at a later stage.

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

New York City, USA and other laboratories in USA and Europe

E. 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 of IAVI's financial management, procurement, and safeguard capacity was undertaken during the project P119051, which concluded that IAVI has adequate rules and procedures, staff, and systems. All safeguard and Fiduciary indicators were assessed as satisfactory during project preparation, supervision and ICR. The organization overall had not only a good financial management system, but strong systems in fiduciary risk management. The initial review of IAVI also highlighted the technical know-how, experience, and procurement capacity to undertake the procurement activities under the Trust Fund TF071457. Environmental due diligence note was prepared for P119051 that stated that IAVI works exclusively with certified and accredited research and manufacturing organizations and laboratories that meet GLP and GMP requirements. The risks and mitigation measures from the due diligence note are reflected in the ISDS for the project. IAVI is familiar with safeguard policies of the World Bank and has demonstrated effective safeguard management during ongoing partnership with the World Bank.

F. Environmental and Social Safeguards Specialists on the Team

Africa Eshogba Olojoba (GEN05)

II. SAFEGUARD POLICIES THAT MIGHT APPLY

Safeguard Policies	Triggered?	Explanation (Optional)
Environmental Assessment OP/ BP 4.01	Yes	<p>The proposed Safeguards Instrument for the project is an Environmental Management Plan (EMP) which will draw upon a due diligence document prepared for the previous project P119051. The EMP will identify risks, measures to mitigate those risks, and indicate how implementation of the measures will be monitored. This is appropriate because activities and conditions of the current project are the same. Although the project is not anticipating clinical trials in humans, the EMP will include appropriate provisions to reflect the risks associated with human trials and propose relevant mitigation measures. The EMP will be disclosed prior to Appraisal. Given the nature of this project, no public consultation is required beyond disclosure on website with a mechanism for people to ask questions or make comments for the team's consideration and/or response.</p> <p>Adverse environmental health impacts may occur from improper biosafety measures during vaccine construction and characterization, or virulence and/or toxicological studies at AIDS research laboratories; or during AIDS vaccine</p>

		<p>manufacturing at manufacturing facilities; or at clinics during AIDS vaccine tests on humans. The risk - which is high - is associated with the 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. The exposure may be 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 risk is associated with the management of wastes from project activities. Handling of animals during testing and disposal of animal carcasses are also areas that require special attention. Despite the above-mentioned risks, the project is not expected to have any large-scale, significant and/or irreversible impacts as appropriate mitigation measures will be taken.</p>
Natural Habitats OP/BP 4.04	No	The project will not affect any protected areas, known natural habitats, or established or proposed critical natural habitats.
Forests OP/BP 4.36	No	The project will not involve commercial logging operations in primary tropical moist forests, purchase of logging equipment for use in primary tropical moist forests, or production or trade in wood or other forestry products from unmanaged forests.
Pest Management OP 4.09	No	The project will not procure any pesticides nor will it result in an increased use of pesticides.
Physical Cultural Resources OP/BP 4.11	No	The project will not affect sites with archeological, paleontological, historical, religious, or unique natural values.
Indigenous Peoples OP/BP 4.10	No	The project will not affect indigenous people.
Involuntary Resettlement OP/BP 4.12	No	Involuntary resettlement would not be triggered.
Safety of Dams OP/BP 4.37	No	The project will not involve construction or rehabilitation of dams, nor will it rely on the performance of any dam.
Projects on International Waterways OP/BP 7.50	No	There are no project activities involving international waterways as defined in the policy.
	No	

Projects in Disputed Areas OP/BP 7.60		The project is not located in any known area of territorial disputes defined in the policy.
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III. SAFEGUARD PREPARATION PLAN

Appraisal stage ISDS required?: No

IV. APPROVALS

Team Leader(s):	Name: Robert Oelrichs	
<i>Approved By:</i>		
Safeguards Advisor:	Name: Agnes I. Kiss (SA)	Date: 17-Aug-2016
Practice Manager/ Manager:	Name: Ernest E. Massiah (PMGR)	Date: 17-Aug-2016

¹ Reminder: The Bank's Disclosure Policy requires that safeguard-related documents be disclosed before appraisal (i) at the InfoShop and (ii) in country, at publicly accessible locations and in a form and language that are accessible to potentially affected persons.