

**MEMORANDUM OF UNDERSTANDING**

**BETWEEN**

**THE MINISTER OF HEALTH, ON BEHALF OF THE  
DEPARTMENT OF HEALTH, THE PUBLIC HEALTH  
AGENCY OF CANADA, THE CANADIAN INSTITUTES OF  
HEALTH RESEARCH AND THE MINISTER FOR  
INTERNATIONAL COOPERATION, ON BEHALF OF THE  
CANADIAN INTERNATIONAL DEVELOPMENT  
AGENCY, AND THE MINISTER OF INDUSTRY, ON  
BEHALF OF INDUSTRY CANADA**

**(HEREINAFTER REFERRED TO AS  
THE GOVERNMENT OF CANADA)**

**AND**

**THE BILL & MELINDA GATES  
FOUNDATION**

**July 2010**

**MEMORANDUM OF UNDERSTANDING BETWEEN  
THE GOVERNMENT OF CANADA AND  
THE BILL & MELINDA GATES FOUNDATION**

***1. Preamble***

The Government of Canada (GoC) and the Bill & Melinda Gates Foundation (BMGF) signed a Memorandum of Understanding (MOU) on August 17, 2006. The objective of the MOU was to formalize a collaboration to further strengthen global efforts to accelerate the development of HIV vaccines and to contribute to the achievement of the Global HIV Vaccine Enterprise's Scientific Strategic Plan (SSP). The Canadian HIV Vaccine Initiative (CHVI) was established by the Government of Canada to serve as the vehicle for implementing the MOU. The GoC and the BMGF are collectively referred to as the Participants.

There have been significant recent developments in the HIV vaccines domain including recent proof of concept demonstrated by the RV144 HIV vaccine trial in Thailand and the 2010 update of the Global HIV Vaccine Enterprise's SSP. These developments provide a greater impetus for global HIV vaccine development efforts, which are essential for stopping the HIV epidemic worldwide. At the same time, there remains a need to support existing prevention interventions among those most affected, particularly in low-and-middle income countries (LMICs). Through this MOU, the GoC and the BMGF wish to identify new areas of focus for the collaboration. This MOU replaces the 2006 MOU.

***2. The Participants***

Government of Canada

The GoC participants in this MOU are the Canadian International Development Agency (CIDA), Public Health Agency of Canada (PHAC), Industry Canada (IC), Canadian Institutes of Health research (CIHR) and Health Canada (HC). PHAC provides horizontal coordination for activities undertaken by the GoC under the MOU.

Bill & Melinda Gates Foundation

The BMGF is an independent, privately endowed charitable foundation that is located in Seattle, Washington U.S.A., which has as one of its missions the reduction of global health inequities by accelerating the development, deployment and sustainability of health interventions that will save lives and dramatically reduce the disease burden in developing countries. The BMGF, through its Global Health Program, supports a number of HIV/AIDS-related projects and aligns its HIV vaccine activities with the SSP of the Global HIV Vaccine Enterprise.

### *3. Objectives*

The objective of this MOU is to renew the collaboration between the GoC and the BMGF. The collaboration represents a key component of Canada's comprehensive approach to HIV prevention in Canada and internationally. The collaboration aligns with GoC approach to HIV prevention as well as that of the BMGF.

Building on the recent results from the RV144 vaccine clinical trial, the primary objective of the collaboration is to accelerate the development of a safe and effective HIV vaccine by building on Canada's scientific excellence for the benefit of those most in need in LMICs (particularly in Africa) but also in Canada. This represents a significant contribution to the achievement of the Global HIV Vaccine Enterprise's SSP.

In addition to supporting these joint HIV vaccine development efforts, the MOU also includes GoC activities that will seek to improve the efficacy and effectiveness of available interventions, specifically the prevention of mother-to-child transmission (PMTCT) of HIV in LMICs. The GoC and the BMGF recognize the need to slow the spread of HIV by strengthening existing prevention interventions, while the development of an HIV vaccine is actively pursued.

### *4. Key Areas of Focus*

Harnessing and capitalizing on Canadian leadership and expertise where applicable, the MOU will include activities in two key areas of focus.

**For HIV Vaccine Research and Development**, funding will be provided by the GoC and the BMGF to support activities that span the continuum of HIV vaccine research and development efforts in the private and public sectors including academic institutions. This includes: advancing the basic science of HIV vaccines in Canada and in LMICs focussing on discovery and social research; translating the basic science of HIV vaccines into clinical trials in humans in LMICs including technology development; and addressing the enabling conditions in Canada and in LMICs for HIV vaccine research and development with a focus on strengthening the capacity of LMIC national regulatory authorities and ethical review.

The GoC and the BMGF will provide funding for the establishment of a Canada-based Alliance for HIV vaccine research and development, comprised of a network of public and private sector organizations with expertise in HIV/AIDS and vaccines fields, to serve as the focal point for Canadian research, product development and technical expertise related to HIV vaccines (the Alliance). The Alliance will be linked to LMIC research institutions particularly in Africa to leverage local expertise and knowledge, build on cooperative research and policy initiatives, and expand needed local capacity. Funding will be provided by the GoC to establish the CHVI Research & Development Alliance Coordinating Office (ACO) to support the development and maintenance of the Alliance. The ACO will report to PHAC as per the terms and conditions of its funding agreement. The ACO will be selected based on pre-established eligibility criteria through an open and transparent call for applications.

**For HIV Prevention**, funding will be provided by the GoC under this MOU to enhance access, quality and uptake of services to prevent mother to child transmission (PMTCT) of HIV, by determining innovative and effective implementation strategies and programmatic solutions to overcome existing barriers and bottlenecks and to enhance PMTCT service delivery. Opportunities for synergies will be explored in countries where other CHVI activities are being implemented. The Participants recognize that the BMGF is highly supportive of these activities and provides funding for similar and related initiatives outside the implementation of this MOU. The BMGF will not be providing funding for PMTCT under this MOU but will collaborate with the GoC.

The GoC and the BMGF will work together to further define the specific initiatives to be supported by the MOU. Once identified, these specific initiatives will be described in a separate appendix to be added to this MOU.

### ***5. Financial Contributions***

The total initial contribution available through the collaboration is up to \$139M plus additional potential contributions as described below.

The GoC total contribution of \$111M includes \$26M of previously existing funding plus \$85M of newly allocated funds. The BMGF is prepared, in principle, to contribute up to \$28M, representing a 1:3 match of newly allocated Canadian funding. A notional breakdown of the funds to be allocated to each focus area is presented in Appendix 1.

Of the GoC contribution, \$51M has already been disbursed or committed to support HIV vaccine activities pursuant to the MOU of 2006 (See Appendix 2). The GoC is prepared, in principle, to provide the remaining of up to \$60M in additional funding to support activities in the two key areas of focus outlined in the MOU. The Participants may agree to modify these allocations.

In addition, the BMGF is prepared to contribute up to an additional \$12 million, for a total maximum contribution by the BMGF of up to \$40 million should new sources of funding be identified by the GoC. The additional contribution will be determined based on the same 1:3 matching formula whereby the BMGF will provide \$1 dollar for every \$3 additional new dollars invested by the GoC in the collaboration. Any additional future contribution to be provided by the BMGF and the GoC will be allocated among areas of focus by mutual agreement of the Participants.

It is understood that the provision of funding for any initiative or project is subject to the respective Participant's internal review and approval procedures, and the signing of individual funding agreement(s) between the funding organization (GoC or BMGF) and the recipient(s).

It is understood that the Participants' activities will be structured and implemented in a manner consistent with applicable laws and policies, as well as in a manner consistent with Canada's international obligations.

## **6. Governance**

The GoC and the BMGF will establish an Advisory Board to oversee the implementation of the MOU and to provide recommendations to CHVI Ministers and the BMGF on projects to be funded that are aligned with the MOU's *Key Areas of Focus*. Final decisions regarding projects to be funded rest with responsible CHVI Ministers and the BMGF, subject to their respective internal review and approval procedures. The GoC and the BMGF will also seek advice from the Advisory Board on the selection of the ACO which will play a critical role in identifying specific HIV vaccine projects and in coordinating the activities of the Alliance.

The GoC and the BMGF will develop formal terms of reference for the Board. The terms of reference will address, among other things, the following:

- Mandate, role and responsibilities;
- Membership;
- Frequency and method of meetings;
- Sub-committees;
- Secretariat support; and
- Communications.

## **7. Separate Agreements**

The GoC and the BMGF may develop separate agreements outlining their respective roles and responsibilities in relation to specific programs, initiatives or projects that they agree to support under this MOU. These agreements may cover such things as funding levels, delivery, administration and monitoring procedures, as well as activities associated with program evaluation and review.

## **8. Planning, Monitoring and Reporting**

Semi-annual progress reports will be reviewed by the GoC and the BMGF on activities covered in this MOU for planning and monitoring purposes.

## **9. Communication and Consultations**

Communications with stakeholders will be conducted in a coordinated and timely manner, and the GoC and the BMGF will work together to ensure consistency in all communications. When appropriate, a senior-level communications committee will be convened with representatives from all participants under this MOU.

Consultations with stakeholders will strive to be inclusive, transparent and use existing opportunities for engagement where possible.

Stakeholder and expert consultations will be held within 180 days of the signing of the MOU to seek input on potential initiatives. The GoC and the BMGF may consider providing annual updates on progress to key domestic and international stakeholders through such vehicles as the respective GoC & BMGF websites, and conferences.

Neither Participant shall use the other Participant's name or identifiers without prior consent of the Participant in each case.

***10. Coming into Force/Duration/Amendment***

This MOU comes into force, for a five-year period, on the day of signature by the Participants. Either Participant may terminate this MOU with a 90-day written notice. This document may be executed in counterparts, each of which will be deemed an original. The Participants may amend this MOU by mutual consent and in writing.

***11. French and English versions***

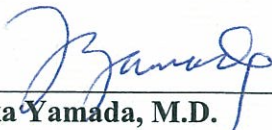
Both the English and French versions of this MOU are equally authoritative and each reflects the intention of the Participants.

***12. Non-Binding at Law; Non-Exclusive***

This MOU does not create legally binding obligations between the parties. This MOU is entered into a non-exclusive basis, such that neither Participant shall be restricted from making any arrangements or agreements with any third party for direct or indirect support of or contribution to any activities that are similar to those described in this MOU.

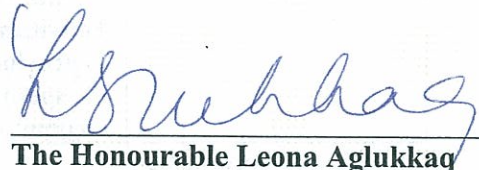
13. Counterparts

**For the Bill & Melinda Gates Foundation**


  
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**Tadataka Yamada, M.D.**  
**President, Global Health Program**

7/8/10  
\_\_\_\_\_  
**Date**


**For the Government of Canada**

  
\_\_\_\_\_  
**The Honourable Leona Aglukkaq**  
**Minister of Health**

JUL 13 2010  
\_\_\_\_\_  
**Date**

  
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**The Honourable Beverley J. Oda**  
**Minister for International Cooperation**

JUL 12 2010  
\_\_\_\_\_  
**Date**

  
\_\_\_\_\_  
**The Honourable Tony Clement**  
**Minister of Industry**

JUL 15 2010  
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**Date**

### Appendix 1: Funding Allocations

Key Areas of Focus		GoC			BMGF	Total
		Current Activities(funds previously spent or committed)	New Activities* To be funded	Total		
HIV Vaccines	Advancing Basic Science	\$22M	\$5M	\$27M	\$7M	\$34M
	Translating Research into Clinical Trials	\$16M	\$18M	\$34M	\$14M	\$48M
	Addressing the Enabling Conditions	\$9M	\$4M	\$13M	\$7M	\$20M
Prevention of Mother to Child Transmission of HIV		\$0M	\$30M	\$30M	\$0M	\$30M
Supporting a Coordinated Approach (GoC and Alliance)		\$4M	\$3M	\$7M	\$0M	\$7M
Total		\$51M	\$60M	\$111M	\$28M	\$139M

\* Funding allocations for new activities are notional only and may be adjusted by mutual agreement of GoC and BMGF

## Appendix 2: Current CHVI Activities

Current CHVI activities being funded by the GoC are focused on:

- **Advancing the Basic Science of HIV Vaccines** (approximately \$22M) by supporting multiple discovery and social research grant programs to support the creativity of individual investigators and collaborative teams in academic institutions in Canada and in Low-and-Middle Income Countries.
- **Translating the Basic Science of HIV Vaccines into Clinical Trials** (approximately \$16M) by strengthening the capacity of researchers and research institutions to conduct high-quality clinical trials and to build site capacity to undertake clinical trials of HIV vaccines and other preventive technologies in Low-and-Middle Income Countries.
- **Addressing the Enabling Conditions** (approximately \$9M) by supporting the involvement of domestic and international stakeholders in addressing HIV vaccines policy issues, building capacity and promoting global harmonization of regulatory pathways, and improving community preparedness.
- **Supporting (Governmental) Coordinated Efforts** (approximately \$4M) by ensuring strategic planning, scientific oversight, coordination and evaluation and responsiveness to emerging HIV priorities.