

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 (HEREINAFTER REFERRED TO AS GOVERNMENT OF CANADA)

AND

**THE BILL & MELINDA GATES
FOUNDATION**

**August 2006
Toronto, Canada**

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

1. *Background*

The Government of Canada and the Bill & Melinda Gates Foundation (“Gates Foundation”) have a history of collaborating on HIV-related vaccine research initiatives.

2. *Mission of respective organizations*

The Government of Canada, through Health Canada and the Public Health Agency of Canada, aims to promote and preserve the physical, mental and social well-being of the people of Canada and to protect them against the spread of diseases. The Canadian Institutes of Health Research aims to excel in the creation of new health knowledge and to translate that knowledge from the research setting into real world applications. Over the years, this has resulted in an improvement to the health of Canadians, the delivery of more effective health services and products and the strengthening of the Canadian health care system. The Canadian International Development Agency supports sustainable development in developing countries in order to reduce poverty and to contribute to a more secure, equitable, and prosperous world. The domestic and global responses to HIV/AIDS are an important priority for the Government of Canada.

The Bill & Melinda Gates Foundation is an independent, privately endowed charitable foundation which 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 Gates Foundation is supporting a number of HIV vaccine research projects aligned with the Scientific Strategic Plan of the Global HIV Vaccine Enterprise, which is dedicated to accelerating the development of a preventive HIV vaccine by implementing a strategic plan for HIV vaccine research; mobilizing significant new funding; and promoting more efficient, faster ways for researchers to share information.

3. *Objective*

The objective of this MOU is to formalize a collaboration of the Government of Canada and the Gates Foundation 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. The Government of Canada and the Gates Foundation will develop a separate agreement(s) to outline their respective roles and responsibilities related to the specific project(s) to be identified jointly by them.

4. *Areas of Collaborative Activity*

The Parties will provide financial support for projects in line with the Scientific Strategic Plan of the Global HIV Vaccine Enterprise as follows. The Government of Canada is currently prepared, in principle, to contribute up to \$85M (CDN) of newly allocated funds. The Gates Foundation is currently prepared, in principle, to contribute up to \$28M (CDN), and to contribute up to \$40M (US) total. The difference between the \$28M (CDN) and the \$40M (US), however, will be provided on the same 3:1 matching basis for any additional newly allocated funds above the \$85M (CDN) identified by the Government of Canada and which are committed for funding of the HIV vaccine projects. Initial proposed financial allocations for the collaboration are presented in Appendix 1. Any additional future contributions by the Gates Foundation, up to the specified maximum of \$40M (US), will be allocated by mutual agreement between the parties.

Key aspects of this collaboration include support for production capacity for manufacturing of HIV vaccine pilot lots, clinical trials capacity and discovery research. Appendix 2 describes the potential project areas in greater detail, with the understanding that actual funding by the Gates Foundation will be based upon the execution of individual grant agreements that will specify the terms of payment, required reporting obligations and other applicable provisions.

The Parties will collaborate to secure private sector partners to implement specific initiatives, in particular on manufacturing and production of vaccines.

5. *Coming into Force/Duration/Amendment*

This MOU comes into force, for a five-year period, on the day of signature by the parties. Either party may terminate the MOU with a 90-day written notice. This document may be executed in counterparts, each of which will be deemed an original.

The parties may amend this MOU by mutual consent and in writing.

6. *Monitoring/Follow-up*

To implement the MOU, the parties will engage in ongoing communication, such as conference calls, meetings, and attendance at key activities through their respective officials.

The specific mechanisms through which this collaboration will be developed and implemented are to be defined by both parties.

7. *French and English versions*

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

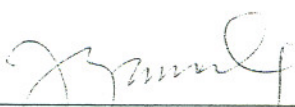
8. *Non-Binding at Law*

This MOU does not create legally binding obligations between the parties.

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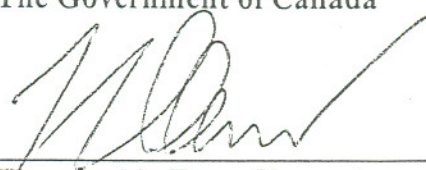
Signed at Toronto, Ontario on August 17, 2006

For the Bill & Melinda Gates Foundation

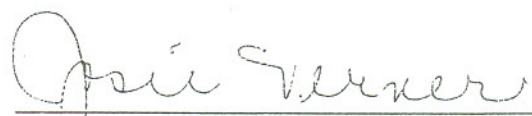


Tadataka Yamada, M.D.
President, Global Health Program

For The Government of Canada



The Honourable Tony Clement
Minister of Health



The Honourable Josée Verner
Minister for International Cooperation

Appendix 2: Description of Activities

The overall goal of the collaboration is to create a coordinated national effort to develop HIV vaccines as a contribution to the Global HIV Vaccine Enterprise. Our intent is to mobilize private/public/philanthropic partnerships and expertise to contribute to the Global HIV Vaccine Enterprise. The Initiative is designed to address some key priorities in the Enterprise's Scientific Strategic plan, to build on key strengths and prior investments by the Government of Canada and to mobilize private/public/philanthropic partnerships and expertise.

The following sets out the areas of collaboration and potential activities within each area:

- **Discovery research and capacity:** including antigen, adjuvant and vector discovery, discovery of protective mucosal immune responses, induction of mucosal immune responses in humans and core support for a level 3 non-human primate facility for preclinical work (this facility has been constructed in Quebec with partial funding by the Canada Foundation for Innovation);
- **Clinical trials and networks:** including support to the Canadian Clinical Trials Network in order to build clinical trial capacity in developing countries and conduct early phase clinical trials of candidate HIV vaccines in Canada;
- **Production capacity:** including construction of a globally accessible level 3 pilot lot HIV vaccine manufacturing facility in Canada (the facility would be also useable for other infectious agents in an emergency);
- **Policy and regulatory:** including assistance to developing countries in vaccine policy, ensuring appropriate market incentives for HIV vaccines are in place, capacity building for vaccine regulation in developing countries;
- **Community and social dimensions:** including community based and social science research on HIV vaccine research issues as well as building capacity for community involvement and social science research in developing countries including ethical aspects; and
- **Planning, Coordination and Evaluation of activities described above:** including development of scientific strategic plans, operational support for non-profit entities and program evaluation.

Appendix 1: Indicative Financial Allocations for the Collaboration

CIAHV Priority Areas	Government of Canada (existing)	Government of Canada (new)*	Gates Contribution	Total Funds Available
Discovery Research and Capacity	\$10M	\$12M		\$22M
Clinical Trials and Networks		\$16M		\$16M
Production Capacity	\$5M	\$55M	\$28M	\$88M
Policy and Regulatory	\$4M			\$4M
Community and Social Dimensions	\$5M	\$2M		\$7M
Planning Coordination and Evaluation	\$2M			\$2M
Total Costs	\$26M	\$85M	\$28M	\$139M

* New funds eligible for 3:1 matching from Gates Foundation (3 Canadian Government: 1 Gates Foundation)

Note: All figures in Canadian dollars