



Public Health  
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Health  
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**DRAFT – For Consultation Purposes**

**Invitation to Submit Applications**

**Canadian HIV Vaccine Initiative (CHVI)**

**[www.chvi-icvv.gc.ca](http://www.chvi-icvv.gc.ca)**



**Community Initiatives Fund**

**June 2008**

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## BACKGROUND

### Vaccines and HIV/AIDS

One of the greatest public health interventions in the past 100 years has been the discovery and widespread use of vaccines. More than 30 common infectious diseases are preventable with vaccines, and one of the most deadly, smallpox, was eliminated from human populations in 1979. The cost to eradicate smallpox was US\$300 million, whereas the benefit has been estimated at US\$27 billion over 20 years. Vaccines are one of the most cost-effective public health interventions available.

In the absence of a vaccine or cure, HIV/AIDS continues to spread at an alarming rate, devastating individuals and communities around the world. The Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) estimate that approximately 33.2 million people worldwide were living with HIV in 2007 – 4.2 million more than in 2001. An estimated 2.5 million people became newly infected with HIV in 2007. The burden of HIV/AIDS is greatest in low- and middle-income countries (LMICs), particularly in sub-Saharan Africa, which is home to more than two-thirds of all people living with HIV.

The number of persons living with HIV in Canada is also increasing. The Public Health Agency of Canada estimates that 58,000 people were living with HIV infection in Canada at the end of 2005 – a 16 per cent increase from the 2002 estimate of 50,000.

Safe, effective, affordable and globally accessible preventative HIV vaccines represent the most promising breakthrough needed to reverse the devastating inequalities that have been exacerbated by HIV/AIDS especially in the developing world.

### Global HIV Vaccine Enterprise

The Global HIV Vaccine Enterprise (the Enterprise), first proposed in 2003, was developed as an alliance of independent organizations around the world dedicated to accelerating the development of a preventive HIV vaccine through:

- ***A Shared Scientific Strategic Plan (SSP)***: Implementing a strategic plan for HIV vaccine research that spans vaccine discovery, product development and manufacturing, and clinical trials;
- ***Increased resources***: Mobilizing significant new funding to achieve the scientific plan; and
- ***Greater collaboration***: Promoting more efficient, faster ways for researchers to share successes and failures and avoid unnecessary duplication of efforts.

The SSP of the Enterprise, published in February 2005, describes the major challenges facing the field and makes recommendations in six priority areas: vaccine discovery, laboratory standardization, product development and manufacturing, clinical trials capacity, regulatory issues and intellectual property issues. An update on these activities can be found in *The Enterprise Report of Activities 2005-2007* <http://www.hivvaccineenterprise.org/plan/index.aspx> published in August 2007.

### **The Canadian HIV Vaccine Initiative (CHVI)**

In February 2007, the Prime Minister of Canada and Bill Gates jointly announced a new collaboration between the Government of Canada and the Bill & Melinda Gates Foundation (Gates Foundation) to support the Canadian HIV Vaccine Initiative (CHVI). The overall goal of the CHVI is to coordinate HIV vaccine research, development and access activities with international efforts in support of the Enterprise.

The Government of Canada is committed to a collaborative approach in responding to HIV/AIDS by working with all levels of government, international organizations, local non-governmental organizations, community groups, health professionals, researchers and people living with, and affected by, HIV/AIDS. To support this approach, the CHVI has been developed with the following objectives:

- strengthen HIV vaccine discovery and social research capacity;
- strengthen clinical trial capacity and networks, particularly in LMICs;
- increase pilot scale manufacturing capacity for HIV vaccine clinical trial lots;
- strengthen policy and regulatory approaches for HIV vaccines, particularly in LMICs;
- promote the community and social aspects of HIV vaccine research and delivery; and
- ensure horizontal collaboration within the CHVI and with domestic and international collaborators.

The CHVI is guided by the following principles:

- **Strategic Coordination and Integration:** The CHVI's ongoing alignment with the Global Enterprise will focus Canadian public and private sector expertise on addressing critical areas that will contribute towards achieving the objectives of the Global Enterprise's Scientific Strategic Plan.
- **Multi-Sectoral Collaboration and Engagement:** The CHVI will promote active involvement and collaboration among governments, the private sector, academics, non-governmental organizations, civil society, people living with HIV/AIDS and other relevant stakeholders. It will strengthen domestic and international linkages to foster collaboration among researchers, policy makers, regulators, communities, the private sector, funders, and other countries and initiatives, and will promote use of the most appropriate and up-to-date

technologies. The CHVI will explore new collaborations and mechanisms for leveraging additional investments.

- **Promotion of Human Rights and Global Access:** The CHVI will ensure that all activities are consistent with established international principles and best practices to promote and protect human rights; support the meaningful involvement of people living with HIV/AIDS; focus on evidence-based interventions; support the principles of social justice and gender equality; and support the principles of global access, striving to ensure benefits from the initiative are relevant and accessible to all, especially those in LMICs, where the burden of HIV/AIDS is the highest and the needs are the greatest.
- **Accountability and Transparency:** Recognizing the multi-sectoral nature of this initiative and the scope of the projects to be undertaken, the CHVI will be implemented through open, integrated, and transparent processes with regular, publicly available progress reports.

The CHVI is closely aligned with the goals of the Federal Initiative to Address HIV/AIDS in Canada and with the Canadian International Development Agency's support of research-based solutions addressing the health needs of developing countries.

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## CHVI COMMUNITY INITIATIVES (CI) FUND

### INTRODUCTION

The CHVI CI Fund is a joint Public Health Agency of Canada (PHAC) - Health Canada grants and contributions funding program.

PHAC is mandated to promote and protect the health of Canadians through leadership, partnership, innovation and action in public health by ensuring healthy Canadians and communities in a healthier world. In terms of the CHVI, PHAC contributes its public health scientific, policy and program expertise, building on past HIV/AIDS and vaccines initiatives, and houses the CHVI Secretariat.

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. In terms of the CHVI, Health Canada contributes expertise in vaccine-related policy, regulations and protocols; and facilitates networks of specialists to enhance international collaborations.

The development of the funding program has been guided by [“The Canadian HIV Vaccines Plan: Towards a World Without AIDS”](#) completed in Spring 2006 as well as input received at the [February 10-12, 2008 CHVI Consultation on Funding Programs](#).

In order to streamline the application, review and approval processes; the CI Fund will be administered jointly by PHAC and Health Canada.

PHAC projects will be established as contribution agreements and Health Canada funded projects will be established as grant agreements. The activity, duration, amount and review process will determine the type of agreement allocated.

### CI GOAL

In keeping with the overall objectives and guiding principles of the CHVI, the main goal of the CI fund is to strengthen Canada’s contribution to global HIV vaccines-related policy development and community-engagement efforts.

### ELIGIBLE ACTIVITY AREAS

#### 1. Policy Development:

Projects will undertake analysis on the full spectrum of issues related to HIV vaccines from research and development, manufacturing, clinical trials, regulatory review through to eventual distribution and uptake. Projects may explore intellectual property issues and other potential barriers to global access, as well explore economic, social and other incentives for an affordable, equitable and globally accessible vaccine. Projects may also examine best practices related to health systems infrastructure and delivery of HIV vaccines and other HIV prevention technologies.

## **2. Legal, Ethical and Human Rights Analysis:**

Projects will explore critical issues regarding the legal, ethical and human rights dimensions of HIV vaccines development and clinical trials, delivery and access. Issues may include informed consent and the involvement of vulnerable populations in clinical trials. Projects may also promote and enhance the application of UNAIDS/WHO documents on Ethical considerations and Good participatory practice guidelines related to biomedical HIV prevention trials.

## **3. Community Awareness and Preparedness:**

Projects will build knowledge, capacity and tools to support the engagement of Canadian organizations in HIV vaccines research and clinical trials, delivery and access. Examples of activities include the development of resources for training and awareness programs, capacity building for Community Advisory Boards, communication plans, and twinning projects with organizations in LMICs.

## **FUNDING PARAMETERS:**

Applicants must clearly demonstrate that they meet the **goal and eligible activity area(s) of this ISA (as outlined in the logic model - Appendix B), as well as the overall objectives and guiding principles of the CHVI.**

To be considered for funding from PHAC and Health Canada, applications must clearly demonstrate the following:

- the main focus is on HIV vaccines with relevant linkages to other HIV prevention technologies and efforts;
- a domestic and global component to the project – as a minimum, a global dissemination plan that supports global access (e.g., sharing of results with international organizations by participating in international fora).
- strengthened and/or new collaborations, partnerships or networks between Canadian and international organization(s) involved in the global response to HIV vaccines is a requirement for Health Canada funding.

Only one application per organization will be accepted however, one application may include several eligible activity areas.

### **WHO IS ELIGIBLE TO APPLY?**

Canadian not-for-profit voluntary, educational, health, medical, social policy and research organizations, institutions, agencies with demonstrated experience in HIV/AIDS and/or vaccines and other HIV prevention technologies.

### **WHAT ARE THE ELIGIBLE COSTS?**

Funding will cover costs, in accordance with Treasury Board of Canada Guidelines, directly related to the activities of the proposed activity.

In general, eligible expenses include:

- Personnel and related costs directly associated with the initiatives;
- Reporting costs;
- Travel and accommodation to meetings by organizers and honoraria for speakers;
- Costs for producing and disseminating records of decision, abstracts, proceedings, etc.;
- Supplies and services (e.g. administration, facilitation, translation);
- Event-related communications (postage, telephone, fax, internet, etc.);
- Hospitality;
- Evaluation (up to 10%); and
- Other costs that are time limited in support of the initiatives and consistent with the objectives of the fund.

The costs for facilities and other overheads are eligible for PHAC contribution funding however, these costs are not eligible for Health Canada grant funding and must be absorbed by the host institution.

### **HOW MUCH FUNDING CAN A APPLICATION RECEIVE?**

This initiative will provide support to a maximum of \$200,000 for each successful application.

## **HOW LONG CAN THE PROJECT LAST?**

The anticipated start date of activities is October 01, 2008, and projects receiving funds can operate until September 30, 2010 (maximum of a 2 year duration).

## **HOW WILL APPLICATIONS BE REVIEWED?**

All applications will be subject to an initial screening by PHAC and Health Canada officials to verify completeness, conformity and eligibility. Applications that do not meet these mandatory requirements will be rejected without further review.

Eligible applications will be reviewed against the criteria outlined herein by a review committee comprised of representatives from the CHVI Participating Departments/Agencies, and domestic and international experts who are familiar with the relevant issues, represent a range of stakeholder interests, and are able to contribute to the assessment of applications and awarding of funds. The committee will make recommendations to the PHAC and Health Canada.

PHAC and Health Canada are under no obligation to provide funding or to enter into a contribution and/or grant agreement as a result of this ISA, of the funding applications submitted, or as a result of existing or previous funding agreements with an organization. Additionally, PHAC and Health Canada reserve the right to:

- reject any or all applications received in response to this ISA;
- accept any application in whole or in part;
- cancel, modify or re-issue this ISA at any time;
- verify any or all information provided by an organization as part of their application.

## **APPLICATION REVIEW CRITERIA**

### **Organizational Capacity:**

- The organization demonstrates experience and abilities to achieve results in the area of HIV/AIDS and/or vaccines and other HIV prevention technologies.
- The organization has the infrastructure necessary to successfully carry out the proposed activities.

### **Strategic Partnerships (for Health Canada funding only):**

- The organization has provided evidence of appropriate partnership support and

collaboration with an international organization(s) engaged in similar work that supports the global response to HIV/AIDS. This evidence gives clear indications of what the partner(s) will contribute to the project.

**Objectives/Guiding Principles:**

- The project supports the overall objectives and guiding principles of the CHVI.
- The project increases capacity of Canadians and/or Canadian organizations to engage more effectively in global HIV vaccine efforts.

**Proposed Work plan:**

- The proposed activities are consistent with the goal and the eligible activity areas of the CI Fund.
- There are clear linkages between activities, time-lines, outputs, expected short-term outcomes (as defined in the CI logic model - Appendix B) and personnel responsible.
- The evidence used to justify the need for the project activities is clearly outlined and based on the best available and most appropriate sources.
- The proposed activities can be accomplished within the proposed time frame
- The job descriptions for responsible personnel are included and appropriate.

**Evaluation and Accountability:**

- The project has budgeted up to 10% of its total budget to evaluation activities.
- The dissemination plan to share project resources, materials, final/evaluation report is adequate, in-line with the project activities and supports Global Access.

**Budget:**

- The budget demonstrates the in-kind donations from both the applicant organization and the project partner(s).
- The proposed budget is understandable and feasible to support the proposed activities.
- The budget demonstrates value for money.

**AUDIT PROCESS (if application is funded)**

Contribution agreements under the CHVI are subject to a Risk-Based Audit Framework, which identifies the audit process to ensure that the expenditure of public funds is exercised with

appropriate diligence. The CHVI manager will monitor projects and determine which should be audited on the basis of risk.

Audits are planned and conducted to ensure that expenditures were made in accordance with terms and conditions of the contribution agreements, that specific non-financial terms and conditions are met, that the recipients were efficient in managing the agreement, and that the Crown received value for money. Audit arrangements, including coverage and scope, will be determined by PHAC. In general, auditors will be appointed by the Agency unless other arrangements are stipulated in the agreement.

## **INTELLECTUAL PROPERTY**

Agreements supporting successful applications under this ISA will incorporate the following provision, in relation to intellectual property rights:

*Any documentation produced by the recipient or third party in carrying out the obligations under the agreement shall vest in and remain the property of the recipient or the third party, unless otherwise agreed to. The Minister may require the recipient or third party to provide documents, if any, that have been produced under the contribution.*

*The Minister will have a non-commercial, non-exclusive, irrevocable, worldwide, fully-paid, and royalty-free license to use the intellectual property as he/she deems fit, including copying, translating, producing or further developing all documents for publication or for any other purpose, except sale or licensing in commercial competition with the recipient (and/or third party). The Minister's license also includes the right to disclose the components to other organizations for information purposes only.*

## **INFORMATION SHARING AND KNOWLEDGE EXCHANGE**

In line with the CHVI principles and the mission of the Global HIV Vaccine Enterprise, applicants will be expected to share project information throughout the project life cycle with CHVI stakeholders and other international organizations working under the umbrella of the Global HIV Vaccine Enterprise.

PHAC, Health Canada and other CHVI participating departments and agencies are currently developing meetings/fora and other mechanisms to support information sharing and knowledge exchange across the CHVI. Recipients will be expected to actively participate in these fora and mechanisms once established.

## OFFICIAL LANGUAGES ACT

It is the responsibility of the applicant to ensure that the proposed project respects the spirit and intent of the *Official Languages Act* (<http://laws.justice.gc.ca/en/showtdm/cs/O-3.01//20070205>). The applicant should also include the costs related to official languages requirements in their budget. For further information, please refer to Canada's *Official Languages Act* ().

## APPLICATION REQUIREMENTS

The application must be submitted in hardcopy, provide all the relevant information requested on the application form and adhere to specified format and requirements.

## ADMINISTRATIVE AND REPORTING REQUIREMENTS (if application is funded)

Administrative requirements, such as financial and narrative reporting as well as other monitoring activities, will be established in a formal agreement between PHAC or Health Canada and the successful applicants. For all contribution agreements, there is a requirement to:

- Submit quarterly activity and cash flow reports;
- Submit a final report; (give details and include evaluation)
- Participate in on-site visits as required.

Specific details of the accountability and reporting requirements will be outlined in the agreement.

## APPLICATION AND SUBMISSION DETAILS

Please refer to the Application Form that is attached with this ISA and submit to the address shown below. To be considered for funding, eligible applicants must provide all of the requested information as indicated.

The deadline for applications is **XXX XX, 2008 at 4:00PM EDT**. Only applications post-marked by the deadline will be accepted. It is the applicant's responsibility to ensure that the application is received on time.

**For further information please contact:**

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