



LETTER OF INTENT FORM

From the

Government of Canada

(Canadian International Development Agency, Public
Health Agency of Canada and Industry Canada)

and

the Bill & Melinda Gates Foundation

on behalf of the

Canadian HIV Vaccine Initiative

for a

Pilot Scale HIV Vaccine Manufacturing Facility in Canada for Clinical Trial Lots

April 15, 2008

DEADLINE:

June 10, 2008, 4:00 p.m. Eastern Standard Time

DISCLAIMER

The Government of Canada and the Bill & Melinda Gates Foundation are under no obligation to provide funding, or enter into Funding Agreements as a result of this *Invitation to Submit Applications*.

THE GOVERNMENT OF CANADA AND THE BILL & MELINDA GATES FOUNDATION ALSO RESERVE THE RIGHT TO:

- **reject any or all applications received in response to this *Invitation to Submit Applications*;**
- **accept any application as a whole or in part; and**
- **cancel and/or re-issue this *Invitation to Submit Applications*.**

Please note that the Government of Canada or the Bill & Melinda Gates Foundation will not reimburse an Applicant for costs incurred in the preparation and/or submission of a *Letter of Intent*.

NOTES TO APPLICANTS

- Ce document est disponible en français.
- This Letter of Intent (LOI) is open to **Not-for-Profit Corporations** (see details in the *Invitation to Submit Applications* document).
- This *LOI Form* is available electronically in WordPerfect and MS Word Formats. To receive an electronic version of this *LOI Form*, please email the contact person identified below.
- This *LOI Form* is the first stage in the application process for funding for the Pilot Scale HIV Vaccine Manufacturing Facility in Canada for Clinical Trial Lots. Completed *LOI Forms* submitted by June 10, 2008, 4:00 p.m. Eastern Standard Time deadline will be reviewed by Government of Canada and the Bill & Melinda Gates Foundation staff as well as a review committee. Following this review, selected Applicants will be invited to complete and submit a full *Application Form* which will be due late October, 2008. **Only those Applicants who have successfully completed the LOI process will be sent the full Application Form and invited to submit an Application.**
- Please answer all questions and complete all tables fully in each *LOI Form* section. **Incomplete LOI Forms and completed LOI Forms that do not adhere to the LOI Form format may not be considered.**
- All *LOI Forms* must be submitted to the contact person identified below.
- *LOI Forms* may be submitted in either official language of Canada.
- All monetary amounts in the completed *LOI Form* are to be shown in Canadian dollars.
- The *LOI Form* should include a cover letter and be typed in a font size of 12 point black ink on white paper, one sided and letter size only (8.5" x 11"). Please ensure your pages are numbered. Supporting documents - with the exception of relevant corporate brochures and marketing literature that may be provided - should be photo reduced if larger than (8.5" x 11").
- Completed *LOI Forms* should be submitted in six (6) copies, in hard-copy paper format, please ensure one (1) copy is unbound. *LOI Forms* submitted electronically or by fax will not be accepted. Only *LOI Forms* post-marked by the deadline date will be accepted.

- Prior to completing and submitting this *LOI Form*, please ensure you have reviewed the Pilot Scale HIV Vaccine Manufacturing Facility in Canada for Clinical Trial Lots *Invitation to Submit Applications for Funding* document available at www.chvi-icvv.gc.ca. For any additional questions please contact the contact person identified below.
- Recent amendments to the Lobbyists Registration Act and Regulations (Canada) broaden the definition of lobbying. We would encourage you and/or your organization to review the revised Act and Regulations to ensure that you/they are in compliance with any obligations you/they may have. For more information, you may wish to visit the Office of the Registrar of Lobbyists website at www.orl-bdl.gc.ca or contact the Office of the Registrar of Lobbyists directly.
- Any questions or requests for clarification of this document must be submitted in writing by email to the contact person identified below. All questions and requests, along with the associated responses, will be posted anonymously on a “Questions, Answers and Corrections” website page on www.chvi-icvv.gc.ca. Any corrections to the *Letter of Intent Form* will also be posted on the “Questions, Answers and Corrections” website page on www.chvi-icvv.gc.ca. Applicants to the Pilot Scale HIV Vaccine Manufacturing Facility in Canada for Clinical Trial Lots initiative are encouraged to check this website page regularly to keep up-to-date with any posted questions, answers and corrections. Questions and requests for clarifications will be answered if received at least seven (7) calendar days prior to the date stipulated for submission of completed *Letter of Intent Forms*.
- Applicants are strongly encouraged to direct all inquiries relating to this *Invitation to Submit Applications* ONLY to the contact person named below. The information gained from all other contacts may be factually incorrect, may not necessarily reflect the opinions of the Government of Canada or the Bill & Melinda Gates Foundation as related to this project and should not be used for the basis of completing any element of a Letter of Intent or Application. Only the information contained in this *Invitation to Submit Applications*, accompanying *Letter of Intent Form* and *Application Form* and subsequent written information posted on www.chvi-icvv.gc.ca should be considered to accurately reflect the intent of the Government of Canada and the Bill & Melinda Gates Foundation as related to this project.

- **Contact person:**

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Acting Director
Office of HIV Vaccines
Public Health Agency of Canada
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www.chvi-icvv.gc.ca

The Public Health Agency of Canada collects the information for the purpose of evaluating Applicants' proposals for grants and contributions. Information contained in these proposals, such as the objectives and activities of the organizations, number of staff and financial data may be accessible under the provisions of the Access to Information Act. All personal information will be protected in accordance with the Privacy Act. Instructions for making requests pursuant to the Acts are located in Info Source, which is available at www.infosource.gc.ca

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1. APPLICANT INFORMATION

1.1 Information about the Applicant:

Legal Name of Corporation:
Executive Director:
Street Address:

City, Province*/State:
Country:
Postal Code/Zip Code:
Telephone: ()
Fax: ()
E-mail:
Web Site (if available):

Mailing Address (if different from above):

City, Province*/State:
Country:
Postal Code/Zip Code:
Telephone: ()
Fax: ()
E-mail:

* An organization in Quebec whose operations are partially or fully funded by the province of Quebec may be subject to *An Act Respecting the Conseil exécutif* (L.R.Q., chapter —30).

Headquarters of Corporation if different from Mailing Address above:

City, Province*/State:
Country:
Postal Code/Zip Code:
Telephone: ()
Fax: ()
E-mail:
Web Site (if available):

1.2 Contact Information for individual responsible for completing this LOI Form (should further information be required):

Name:

Title (e.g., Executive Director/Board Chair/President/Program Coordinator):

Telephone: ()

Fax: ()

E-mail:

1.3 Incorporation/Registration Information:

a. Is your organization a registered Not-for-Profit Corporation (NPC)?

Yes _____

No _____

To be eligible, the Applicant must be a Not-for-Profit Corporation.

If yes, date of incorporation/registration as a non-profit corporation:

b. Incorporation/registration number:

c. Attach a notarized copy of the corporation's constating documents (e.g., Articles of Incorporation, Letters Patent, By-laws, etc.).

1.4 Structure and Description of Applicant. Applicants will provide the following:

- its corporate background and general corporate description. (This information should illustrate the capability and capacity of the NPC to successfully meet the objectives of this project. If the Applicant wishes to include corporate brochures and other supporting documentation with its Application, provided they are relevant and significant they will be attached as an appendix.);
- a brief description of their NPC's current overall (total) programs, activities and/or other initiatives;
- three brief examples of successfully completed programs, activities and/or initiatives; and
- their corporate organization chart.

1.5 Values and Principles of the Applicant. Applicants will demonstrate that their corporation's established track record reflects values and principles similar in scope and nature to those of the Global HIV Vaccine Enterprise, the Canadian HIV Vaccine Initiative and the facility by providing appropriate indicators such as:

- copies of corporate mission and vision statements, corporate priorities and objectives and statement of ethics (or specifically referencing where they can be found in the corporation's constating documents which were provided in accordance with paragraph 1.3); and
- copies of corporate resolution(s) supporting principles and values such as strategic coordination and integration with appropriate world-wide initiatives, multi-sectoral collaboration and engagement, promotion of human rights and Global Access and accountability and transparency.

1.6 The Applicant must have an Elected, Volunteer Board of Directors:

- a. Provide the formally defined roles and responsibilities for the Board of Directors of the NPC as contained in pre-existing corporate statues and by-laws.
- b. Provide a list of the current board members and officers of the corporation with their titles and responsibilities.
- c. Provide the backgrounds of the members of Board of Directors and/or key corporate executives and officers showing their individual involvement in similar enterprises/initiatives.
- d. Please provide the date of and numbers attending the most recent Annual General meeting of the NPC.

1.7. Appendix A - Corporate Literature (at the discretion of Applicants). Applicants may provide any relevant corporate brochures and marketing literature from their NPC.

2. PARTNER INFORMATION (if applicable)

2.1 General. Applicants may enlist the support of one or more Partners to assist in the project. Partners are those who formally combine their money, property, knowledge, skills, time, personnel and/or other resources under a formal agreement with the Applicant to specifically assist in the establishment, operation and/or maintenance of a pilot scale HIV vaccine manufacturing facility in Canada for clinical lot trials.

2.2 Information about Partners:

Legal Name of Partner who is an Individual :
Street Address:

City, Province/State:
Country:
Postal Code/Zip Code:
Telephone: ()
Fax: ()
E-mail:
Web Site (if available):

Area of Expertise:
Contribution to the Applicant's effort:

Repeat as necessary

and/or

Legal Name of Partner that is a Company/Corporation:
Executive Director:
Street Address:

City, Province/State:
Country:
Postal Code/Zip Code:
Telephone: ()
Fax: ()
E-mail:
Web Site (if available):

Area of Expertise:
Contribution to Applicant's effort:

Repeat as necessary

- 2.3 **Background.** Provide a brief description of the background of any corporate and individual Partners. This information should illustrate the capability and capacity of the corporation(s) and individual(s) to successfully undertake the project activities.
- 2.4 **Roles and Responsibilities.** Provide detailed roles and responsibilities of all Partners and explain why their participation strengthens your Application. Describe the nature of the relationship between the Applicant and each Partner.
- 2.5 **Organization Chart.** Provide an organization chart linking the Applicant and its Partner(s) indicating major areas of functional responsibility.
- 2.6 **Formal Agreement(s).** Provide a copy of each Partner's formal agreement with the Applicant.
- 2.7 **Appendix B - Corporate Literature** (at the discretion of Applicant). Applicants may provide any relevant corporate brochures and marketing literature from its Partner(s).

3. ADMINISTRATIVE DETAILS

3.1 **What is your preferred language of correspondence?**

Please check one of the following:

- English
- French

The Applicant/Partners must have an ability to communicate with the public in both official Canadian languages (i.e., in English and French).

Describe the Applicant's/Partner's(s') ability, policies and/or procedures to communicate in both French and English.

As funding is provided for a project that is supported by the Government of Canada and may include dealings with vaccine Discoverers/Developers of both linguistic communities, Applicants must ensure that:

- announcements to the public concerning the project are in both official languages of Canada;
- services offered to members of the public are available in both official languages;
- documents relating to the project for the general public are made available in both official languages; and
- activities are organized, when appropriate, in such a manner as to meet the needs of the two linguistic communities.

Please visit the following website for more information:

http://publ-service.tbs-sct.gc.ca/pubs_pol/hrpubs/offlang/chap1_4-1_e.asp#national

3.2 Sources of Funding

- a. Describe any federal funding the Applicant and its Partner(s) is currently receiving. Please provide the following details:

Table 3.2A - Federal Funding Sources

Name of the Department and Funding Program	
Name of who is receiving the funding	
Contact Person in the Department <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/> Other	Provide project information below Start date: yy/mm/dd
Name:	End date: yy/mm/dd
Title:	Amount
Telephone number: () Ext	Project Title
E-Mail Address	

Repeat as necessary

- b. Describe any funding the Applicant and Partner(s) is currently receiving from the Bill & Melinda Gates Foundation (Gates Foundation). Please provide the following details:

Table 3.2B - Gates Foundation Funding Sources

Name of the Gates Foundation Funding Program	
Name of who is receiving the funding	
Contact Person at the Gates Foundation <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/> Other	Provide project information below Start date: yy/mm/dd
Name:	End date: yy/mm/dd
Title:	Amount
Telephone number: () Ext	Project Title
E-Mail Address	

Repeat as necessary

c. Describe other source(s) of funding the Applicant is currently receiving.

Table 3.3B - Other Funding Sources

Name of Other Funding Source	Duration of Funding	Amount, Type of Funding	Brief description

3.3 Does the Applicant or its Partner(s) owe any amounts to the federal government under legislation or previous funding agreements?

Yes _____ No _____

If yes, please indicate which legislation and/or provide the funding program name, project reference number and departmental contact name.

3.4 Conflict of Interest¹

Applicants and recipients of funding must respect and comply with the Conflict of Interest Act, the Conflict of Interest and Post-Employment Code for the Public Service and the Values and Ethics Code for the Public Service. Where an Applicant or Partner employs either a current or former (in the last twelve months) public office holder or public servant in the federal government, compliance with the Act and Code(s) must be demonstrated. Please contact the contact person identified in the Notes to Applicants section of this LOI Form if you require further information.

Has the Applicant or its Partner(s), in the last 12 months, employed a former Public Servant or a Public Office Holder who is subject to the *Conflict of Interest Act* and/or the *Conflict of Interest and Post-Employment Code for Public Services Employees*? (The same requirement applies to members of the Board of Directors).

Yes _____ No _____

(If yes, please contact the Contact Person identified in the Notes to Applicants section of this LOI Form.)

¹ These references are to Government of Canada legislation and policies.

Does the Applicant or its Partner(s) have links to or any involvement with other government programs?

Yes _____

No _____

(If yes, please contact the Contact Person identified in the Notes to Applicants section of this LOI Form.)

Does the Applicant or its Partner(s) have links to or any involvement with the Gates Foundation?

Yes _____

No _____

(If yes, please contact the Contact Person identified in the Notes to Applicants section of this LOI Form.)

4. UNDERSTANDING OF OBJECTIVES

4.1 Understanding of the Key Objectives

Applicants will:

- identify and describe in their own words the goals and objectives of the project as they understand them;
- identify and describe some of the issues, challenges and opportunities related to carrying out this project;
- discuss the key factors which should be considered in order to successfully address these issues, challenges and opportunities; and
- describe the scope of the proposed project as they understand it.

5. COMMITMENT TO PRINCIPLES

5.1 Commitment to Principles

Applicants will:

- a. briefly describe in their own words the importance of the objectives of the Global HIV Vaccine Enterprise, the general principles of the Canadian HIV Vaccine Initiative and the specific principles of the facility;
- b. briefly describe in their own words what Global Access means, what elements and parties it encompasses and how they plan to successfully manufacture HIV vaccine for clinical trials lots while respecting it:
 - (1). provide a statement committing to Global Access as they have described it;
- c. briefly describe in their own words an overview of how facility operations and maintenance will be self-sustainable for a 20-year period following the facility's establishment:
 - (1). provide a statement committing to facility self-sustainability as they have described it;
- d. briefly describe their ability to operate and maintain the facility in a self-sustainable manner while ensuring the principles of Global Access are adhered to;
- e. briefly describe in their own words what Universal Candidacy means, what elements and parties it encompasses and how they plan to attract the best HIV vaccine candidates while respecting it:
 - (1). provide a statement committing to Universal Candidacy as they have described it;
- f. briefly describe in their own words what benefits their operation of the facility will provide to low- and middle-income countries (LMICs);
- g. briefly describe their ability to successfully participate in a global initiative and provide specific examples of relevant current and past experience (within the last two years); and
- h. provide a statement committing to assume and maintain ownership of the facility until its final disposition.

6. APPLICANT/PARTNER EXPERIENCE & CAPABILITY

6.1 General

Applicants should provide sufficient detail to adequately showcase their experiences and capabilities such that they can be differentiated from other Applicants.

6.2 Previous Commercial Vaccine Development and Manufacturing Experience

- a. describe the Applicant’s and/or its Partner’s(s’) proven experience and expertise in commercial vaccine development and manufacturing including details on the vaccines and types of technologies employed.
- b. complete Table 6.2A by listing three previous vaccine development and/or vaccine manufacturing projects/activities performed by the Applicant and/or its Partner(s) (where the Applicant and/or its Partner(s) were materially involved) and specifically identify who was involved.

Table 6.2A - List of Similar Vaccine Projects/Activities

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/or Partner(s)	Project/Activity Value
1				
2				
3				

- c. complete Table 6.2B by listing two other similar projects/activities undertaken within the last five years by the Applicant and/or its Partner(s).

Table 6.2B - List of Other Relevant Projects/Activities

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/ or Partner(s)	Project/Activity Value
1				
2				

- d. complete Template 6.1 for each project/activity listed in Tables 6.2A and 6.2B providing in a narrative format a brief description of the project/activity objectives and its approach and methodology, the Applicant’s and/or its Partner’s(s’) responsibility and the relevance of this experience to this project.

Demonstrate that the projects/activities offered as examples are linked to the key personnel proposed as part of the Applicant’s proposed team to establish the facility. Describe the nature of the contributions of the proposed establishment team personnel in the relevant projects/activities listed. References may be contacted by the Crown.

6.3 Previous HIV/AIDS Research Experience

- a. describe the Applicant’s and/or its Partner’s(s’) proven experience and expertise in HIV/AIDS research.
- b. complete Table 6.3A by listing three previous HIV/AIDS research projects/activities performed by the Applicant and/or its Partner(s) (where the Applicant and/or its Partner(s) were materially involved) and specifically identify who was involved.

Table 6.3A - List of Similar Research Projects/Activities

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/ or Partner(s)	Project/Activity Value
1				
2				
3				

- c. complete Table 6.3B by listing two other similar projects/activities undertaken within the last five years by the Applicant and/or its Partner(s) that are relevant to this project.

Table 6.3B - List of Other Relevant Projects/Activities

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/or Partner(s)	Project/Activity Value
1				
2				

- d. complete Template 6.1 for each project/activity listed in Tables 6.3A and 6.3B providing in a narrative format a brief description of the project/activity objectives and its approach and methodology, the Applicant’s and/or its Partner’s(s’) responsibility and the relevance of this experience to this project. Demonstrate that the projects/activities offered as examples are linked to the key

personnel proposed as part of the Applicant’s proposed team to establish the facility. Describe the nature of the contributions of the proposed establishment team personnel in the relevant projects/activities listed. References may be contacted by the Crown.

6.4 Previous LMIC Experience

- a. describe the Applicant’s and/or its Partner’s(s’) proven experience and expertise working with LMICs in the area of scientific research (preferably HIV/AIDS-related) or vaccine development and manufacturing.
- b. complete Table 6.4A by listing three previous scientific research or vaccine development and manufacturing projects/activities performed by the Applicant and/or its Partner(s) (where the Applicant and/or its Partner(s) were materially involved) that involved significant interaction with personnel, organizations and/or governments of LMICs. Identify whether the Applicant and/or its Partner(s) were involved.

Table 6.4A - List of Similar LMIC Projects/Activities

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/or Partner(s)	Project/Activity Value
1				
2				
3				

- c. complete Table 6.4B by listing two other similar projects/activities undertaken within the last five years by the Applicant and/or its Partner(s) that are relevant to this project.

Table 6.4B - List of Other Relevant Projects/Activities

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/or Partner(s)	Project/Activity Value
1				
2				

- d. complete Template 6.1 for each project/activity listed in Tables 6.4A and 6.4B providing in a narrative format a brief description of the project/activity objectives and its approach and methodology, the Applicant’s and/or its Partner’s(s’) responsibility and the relevance of this experience to this project.

Demonstrate that the projects/activities offered as examples are linked to the key personnel proposed as part of the Applicant’s proposed team to establish the facility. Describe the nature of the contributions of the proposed establishment team personnel in the relevant projects/activities listed. References may be contacted by the Crown.

6.5 Previous Experience Creating Synergy

- a. describe the Applicant’s and/or its Partner’s(s’) proven experience and expertise in bringing together disparate activities and talents to create a result that would not have been otherwise achievable. The example could include (but is not limited to) bringing together:
 - not-for-profit and private sector expertise;
 - research and manufacturing expertise;
 - researchers from LMICs and Canada; or
 - researchers from one field of study with researchers from another field.
- b. complete Table 6.5A by listing two previous projects/activities wherein synergy was created by the Applicant and/or its Partner(s) (where the Applicant and/or its Partner(s) were materially involved) and specifically identify who was involved.

Table 6.5A - List of Similar Synergetic Projects/Activities

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/or Partner(s)	Project/Activity Value
1				
2				

- c. complete Table 6.5B by listing one other similar project/activity undertaken within the last five years by the Applicant and/or its Partner(s) that are relevant to this project..

Table 6.5B - List of Other Relevant Projects/Activities

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/or Partner(s)	Project/Activity Value
1				

- d. complete Template 6.1 for each project/activity listed in Tables 6.5A and 6.5B providing in a narrative format a brief description of the project/activity objectives and its approach and methodology, the Applicant’s and/or its

Partner's(s') responsibility and the relevance of this experience to this project. Demonstrate that the projects/activities offered as examples are linked to the key personnel proposed as part of the Applicant's proposed team to establish the facility. Describe the nature of the contributions of the proposed establishment team personnel in the relevant projects/activities listed. References may be contacted by the Crown.

6.6 Previous Experience with Regulatory Approval Processes

- a. describe the Applicant's and/or its Partner's(s') proven experience and expertise with regulatory approval processes (e.g., Good Manufacturing Practices (GMPs), bio-safety level 3 (BSL 3) licensing, etc. as applicable) in Canada and in foreign locations where clinical trials can be expected to be conducted.
- b. complete Table 6.6A by listing three previous projects/activities involving regulatory processes wherein the Applicant and/or its Partner(s) (where the Applicant and/or its Partner(s) were materially involved) and specifically identify who was involved.

Table 6.6A - List of Similar Projects/Activities Involving Regulatory Approval Processes

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/or Partner(s)	Project/Activity Value
1				
2				
3				

- c. complete Table 6.6B by listing two other similar projects/activities undertaken within the last five years by the Applicant and/or its Partner(s) that are relevant to this project.

Table 6.6B - List of Other Relevant Projects/Activities

#	Project/Activity Name	Project/Activity Start/End Dates	Indicate Involvement by Applicant &/or Partner(s)	Project/Activity Value
1				
2				

- d. complete Template 6.1 for each project/activity listed in Tables 6.6A and 6.6B providing in a narrative format a brief description of the project/activity

objectives and its approach and methodology, the Applicant's and/or its Partner's(s') responsibility and the relevance of this experience to this project. Demonstrate that the projects/activities offered as examples are linked to the key personnel proposed as part of the Applicant's proposed team to establish the facility. Describe the nature of the contributions of the proposed establishment team personnel in the relevant projects/activities listed. References may be contacted by the Crown.

Template 6.1
Project Information Synopsis Sheet

Project/Activity Name & Location:	Point of Contact (Reference) Name and Contact Information:
Description of Project/Activity Objectives:	
Approach and Methodology:	
Applicant/Partner's Responsibility (specify which):	
Contribution of Proposed Personnel Resources:	
Outcome of the Project/Activity:	
Relevance of the Project/Activity to this Project:	

6.7 Summary (maximum of 350 words in total)

- a. The mandate of the Applicant (i.e., Not-for-Profit Corporation) is.....
- b. The Partner(s) with whom the Applicant will work is/are.....
- c. The objectives of the project are.....
- d. The activities the Applicant and its Partner(s) will undertake to meet the objectives are.....
- e. The expected results are.....
- f. The initiative will be considered a success if
- g. Success will be measured by.....

7. PRELIMINARY BUDGET INFORMATION

7.1 Preliminary Budget Estimate²

- a. Provide a preliminary (rough order of magnitude) estimate of the cost of establishing the facility by fiscal year of expenditure (i.e., 1 April Year X to 31 March Year X + 1) including but not limited to, work activities such as the following:

Table 7.1A - Cost Estimate to Establish Facility³

Work Activity	Preliminary Budget			
	FY 2009/10	FY 2010/11	FY 2011/12	FY 2012/13
Design				
Land				
Environmental Review/ Assessment				
Construction/Retrofit				
Office Equipment				
Laboratory Equipment				
Manufacturing Equipment				
Computer Equipment				
Other Furnishings/Equipment				
Licensing				
Certification				
Annual Sub-Totals				
Total Cost				

² Show all monetary amounts in this LOI Form in Canadian dollars.

³ Costs to establish the facility are eligible expenses as stated in the Invitation to Submit Applications document.

- b. Provide a preliminary (rough order of magnitude) estimate of the one-time start-up costs associated with establishing the facility by fiscal year of expenditure (i.e., 1 April Year X to 31 March Year X + 1) including but not limited to, work activities such as the following:

Table 7.1B - Start-up Cost Estimate for the Facility⁴

Work Activity	Preliminary Budget			
	FY 2009/10	FY 2010/11	FY 2011/12	FY 2012/13
Initial Hiring/Recruitment				
Initial Training				
Training Supplies and Materials				
Annual Sub-Totals				
Total One-Time Start-up Cost				

- c. Provide a preliminary (rough order of magnitude) estimate of the annual cost of operating and maintaining the facility including but not limited to, work activities such as the following:

⁴ The Government of Canada cannot fund start-up costs but start-up costs are eligible expenses for funding from the Gates Foundation as stated in the Invitation to Submit Applications document.

Table 7.1C - Cost Estimate to Operate/Maintain Facility⁵

Work Activity	Preliminary Budget
Governance	
Utilities	
Rent	
Hiring/Recruitment	
Personnel (Salaries and Benefits)	
Travel	
Materials	
Reconfiguration of internal space for new vaccine candidates	
Repairs	
Evaluation, Audit and Reporting	
Total Annual Cost	

- d. Provide a preliminary indication of the planned funding sources and/or in-kind contributions for the work activities to establish, start-up and operate/maintain the facility:

Table 7.1D - Planned Funding Sources

Work Activity	Planned Funding Sources		Planned Sources for In-Kind Contributions	
	Source	Amount	Source	Amount
Establishment				
Design				
Land				

⁵ Facility operations and maintenance costs are ineligible expenses as stated in the Invitation to Submit Applications document.

Work Activity	Planned Funding Sources		Planned Sources for In-Kind Contributions	
	Source	Amount	Source	Amount
Environmental Review/ Assessment				
Construction/Retrofit				
Office Equipment				
Laboratory Equipment				
Manufacturing Equipment				
Computer Equipment				
Other Furnishings/Equipment				
Licensing				
Certification				
Sub-Total				
Start-up Costs				
Initial Hiring/Recruitment				
Initial Training				
Training Supplies and Materials				
Sub-Total				
Operations & Maintenance				
Governance				
Utilities				
Rent				
Hiring/Recruitment				
Personnel (Salaries and Benefits)				

Work Activity	Planned Funding Sources		Planned Sources for In-Kind Contributions	
	Source	Amount	Source	Amount
Travel				
Materials				
Reconfiguration of internal space for new vaccine candidates				
Repairs				
Evaluation, Audit and Reporting				
Annual Sub-Total				

e. Provide a brief description of other costs, if any.

8. AUTHORIZATION

8.1 Certification by the Applicant:

By my signature, I declare that

- all the information provided in this completed LOI Form is accurate and complete;
- no current or former public office holder or public servant subject to the Conflict of Interest Act or to whom the Conflict of Interest and Post-Employment Code for the Public Service or Values and Ethics Code for Public Service of Canada applies, shall derive any direct benefits from these Funding Agreements unless the provision and receipt of such benefits is in compliance with the Codes or applicable Canadian legislation; and
- the application is made on behalf of the Applicant and Partner(s) named on Sections 1 and 2 with their full knowledge and consent.

Name (please print):

Title:

Signature:

Date:

I am authorized to bind the corporation.

8.2 Authorization by Chair/President of the Applicant's Board of Directors:

By my signature, I declare that

- all the information provided in this completed LOI Form is accurate and complete;
- no current or former public office holder or public servant subject to the Conflict of Interest Act or to whom the Conflict of Interest and Post-Employment Code for the Public Service or Values and Ethics Code for Public Service of Canada applies, shall derive any direct benefits from these Funding Agreements unless the provision and receipt of such benefits is in compliance with the Codes or applicable Canadian legislation; and
- the application is made on behalf of the Applicant and Partner(s) named on Sections 1 and 2 with their full knowledge and consent.

Name (please print):

Title:

Contact Information:

Signature:

Date:

Witnessed By (please print name):

Signature: