



Report on the Influenza Research Network Application Development Workshop

**February 26, 2008
Ottawa, Ontario**



CIHR IRSC

Institut des maladies
infectieuses et immunitaires
Institute of Infection and Immunity

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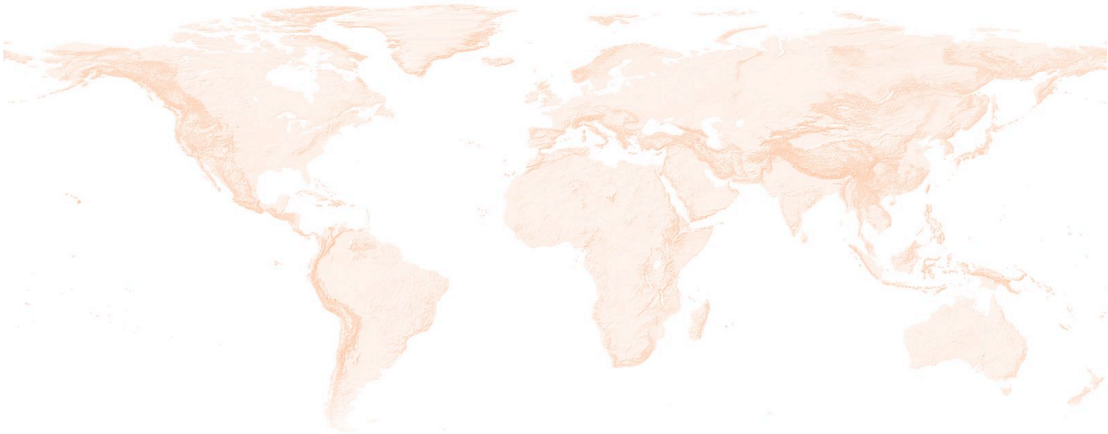
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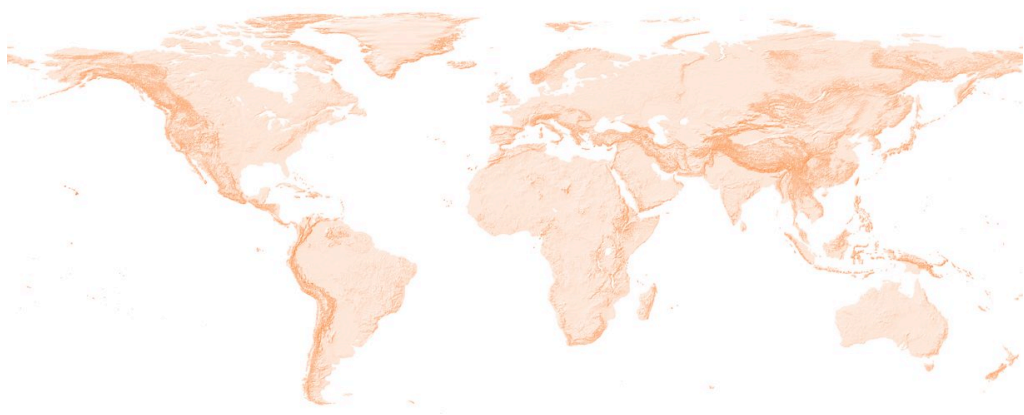
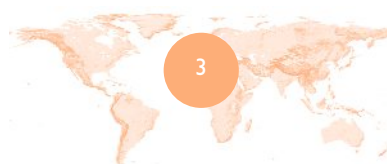


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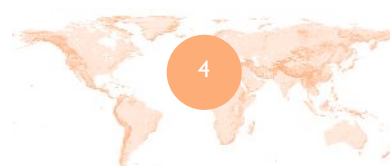
Executive Summary

Influenza is an infectious disease that causes several thousand deaths each year worldwide. New viral strains occasionally emerge to cause an influenza pandemic that, in the past, has resulted in several million deaths. There is growing concern amongst infectious disease experts that an influenza pandemic is overdue. A pandemic would have severe health, economic and social consequences, and experts believe more research is required to prevent its occurrence and/or reduce its impact on society.

In response to the need for pre-pandemic preparation and the essential evaluation of pandemic vaccines, the Public Health Agency of Canada (PHAC) Centre for Immunization and Respiratory Infectious Diseases (CIRID) and the Canadian Institutes of Health Research Institute of Infection and Immunity (CIHR-III) launched a funding opportunity to support the establishment of the Influenza Research Network (IRN). The goal of the IRN is to establish a Canada-wide network of individuals and groups who will conduct applied public health research to develop and test methods to rapidly evaluate the safety and effectiveness of vaccines in persons of all ages before and after release for general use. The IRN is expected to consolidate existing expertise in vaccine evaluation, and to create and strengthen links and knowledge exchange amongst researchers and between researchers and decision makers. The Network will focus on five relevant research areas: (1) Rapid evaluation of candidate vaccines for safety and immunogenicity in persons of all ages; (2) Population-based methods to evaluate vaccine effectiveness and safety following release for general use; (3) Rapid implementation of pandemic vaccine programs; (4) Vaccine coverage including isolated communities and cohorts of concern; and (5) Adverse events following immunization.

On February 26, 2008, CIRID and CIHR-III hosted an application development workshop for researchers with an interest in applying to the IRN Funding Opportunity. Over 20 individuals, including researchers with expertise in influenza and vaccine evaluation, participated in the Workshop. The purpose of the workshop was to assist researchers in gaining an understanding of the application process and the key components of the application. The workshop also enabled researchers who are interested in applying for funding to meet each other, exchange information and begin preparation of an application. Participants were introduced to the CIRID and its Pandemic and Avian Influenza Preparedness and Response Portfolio and then were given an overview of the Pandemic Preparedness Strategic Research Initiative led by CIHR-III. A detailed review of the IRN Funding Opportunity was presented with discussions focusing on the objectives, expectations and the five relevant research areas. Representatives from CIHR reviewed eligibility requirements, the two-stage grant application process and conditions for funding. Because of the scope of the research areas and the requirement to have nation-wide representation, participants were encouraged to submit one single application.

The second part of the workshop focused on assisting participants in developing the Letter of Intent (LOI) for the IRN application. Participants gathered in small groups to discuss the research areas outlined in the funding opportunity in more detail and to identify the expertise that will be needed to achieve the IRN objectives.



Participants agreed it would be most effective to focus on a single application that included interested researchers and support personnel from across Canada. To develop a preliminary plan for the Network

and to aid in the writing of the LOI, participants nominated a tentative principal applicant/Network leader to oversee the application as well as leaders to prepare the application portion in the five relevant research areas. This will include developing research questions and work plans and identifying and contacting additional contributors. Leaders in the areas of laboratory support, data management and statistical support, financial and administration management and training were also nominated.

Participants and organizers agreed that the workshop had achieved its objectives. Participants stated that the meeting was effective in enhancing linkages between researchers and helping the researchers begin to plan an application.

Background

Each year several thousand individuals worldwide die due to influenza infections. Occasionally, new viral strains of influenza emerge to cause a pandemic that, in the past, has resulted in several million deaths. Most infectious disease experts agree that the next pandemic is overdue. There are concerns that a highly pathogenic strain of influenza A virus (H5N1) that has emerged in south-east Asia in recent years could be the next pandemic strain, but this is not certain.

An influenza pandemic would have severe health, social and economic consequences. The Public Health Agency of Canada (PHAC) has estimated that 4.5 to 10.6 million Canadians will become clinically ill, 2 to 5 million will require outpatient care, 34,000 to 138,000 will require hospitalization and that 11,000 to 58,000 will die. The World Health Organization has suggested that worldwide between 2 million and 7.4 million people could die from a global influenza pandemic.

Canada was one of the first countries to develop a strategy to prepare and respond to a potential pandemic in the form of the Canadian Pandemic Influenza Plan. This plan was developed by the PHAC and was established to assist with developing strategies in surveillance, vaccine programs, antiviral use, health services, emergency services, public health measures and communications.

The PHAC has also played a leadership role in identifying priorities in pandemic influenza research in the area of public health and in supporting related research. For example, in September 2005, PHAC organized and sponsored an Influenza Priorities Workshop in partnership with Canadian Institutes of Health Research Institute of Infection and Immunity (CIHR-III). Critical knowledge gaps and research priorities in pandemic preparedness in Canada were identified by the researchers and clinicians in attendance. These priorities helped shape the Pandemic Preparedness Strategic Research Initiative led by CIHR-III in partnership with PHAC. The priorities also formed the basis of a CIRID Pandemic Influenza Research Portfolio Consultation held in June 2007. At the



Consultation, a multi-year research agenda for the Pandemic Influenza Research Portfolio of CIRID was established. One of the priorities discussed was support for and the establishment of an influenza research network with a focus on pandemic vaccines.

In the event of a pandemic, vaccination will play a critical role in preventing the spread of disease. Canada will need to rapidly test and evaluate a new vaccine produced by its domestic manufacturer during a pandemic. Recognizing the need to develop and test appropriate methodologies to rapidly evaluate candidate vaccines for safety, immunogenicity, and effectiveness, PHAC in collaboration with CIHR-III announced it will help to establish and fund an Influenza Research Network (IRN). The IRN will consolidate existing expertise in vaccine evaluation and create and strengthen links amongst researchers and between researchers and decision makers. The IRN will take advantage of the pre-pandemic period to develop and ensure appropriate methods are in place to rapidly evaluate vaccines during an outbreak.

To support pandemic preparedness, the Government of Canada announced in its 2006 Federal Budget \$1 billion (\$600 million over 5 years and \$400 million contingency) for avian and pandemic influenza preparedness. The funds are being managed by PHAC, CIHR, the Canadian Food Inspection Agency and Health Canada and are being used to support the Pandemic and Avian Influenza Preparedness and Response Portfolio of CIRID and the Pandemic Preparedness Strategic Research Initiative of CIHR-III.

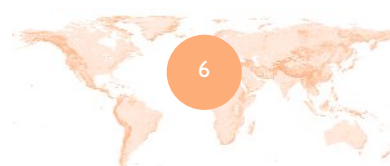
Workshop Overview

On February 26, 2008, CIRID and CIHR-III hosted an Application Development Workshop in Ottawa for researchers with an interest in applying to their IRN funding opportunity. See Appendix 1 for a list of funding partner representatives and Appendix 2 for a list of participants. The main objective of the workshop was to assist researchers in gaining an understanding of the application process and requirements. The Workshop was designed to enable researchers to meet one another, exchange information and begin preparation of an application. Over 20 individuals with expertise in influenza, immunization and vaccine evaluation attended the Workshop. See Appendix 3 for the Workshop agenda.

Welcoming Remarks and Overview of the Pandemic and Avian Influenza Preparedness and Response Portfolio

Arlene King, Director General, CIRID

Dr. Arlene King welcomed all participants. She then gave an overview of CIRID's Pandemic and Avian Influenza Preparedness and Response Portfolio. The Portfolio maintains the Canadian Pandemic Influenza Plan; develops and ensures domestic pandemic vaccine production capacity; oversees the production and testing of prototype pandemic vaccines; procures adequate reserves of antiviral medication; monitors, detects, and reports unusual respiratory illnesses; strengthens collaboration with provincial, territorial and international governments; supports pandemic influenza research; provides technical support and expertise on human health issues related to avian influenza; and develops partnerships with national and international organizations to strengthen surveillance, laboratory capacity, emergency preparedness and communications. CIRID is committed to developing priority



driven pandemic influenza research and in conjunction with CIHR is establishing the IRN and will support its activities.

Overview of the Pandemic Preparedness Strategic Research Initiative

Carol Richardson, Acting Assistant Director, CIHR-III

CIHR-III established the Pandemic Preparedness Strategic Research Initiative (PPSRI) in May 2006 to develop and support influenza research that focuses on improving Canada's preparedness to prevent and/or respond to an influenza pandemic. The focus of the PPSRI is to build research capacity and support strategic research that will form the basis of informed decision making. Activities of PPSRI are led by the PPSRI Task Group, which in consultation with stakeholders, identified four strategic priority areas to focus research efforts. These are: 1) Vaccines and immunization programs; 2) Biology of the influenza virus; 3) Prevention and treatment; and 4) Ethics, legal and social research.

In the first two years of the PPSRI, CIHR and partners including PHAC funded both team and operating grants to support research in the areas of disease control, prevention measures and preparedness of healthcare systems. Recognizing the need to establish research teams and methods that can be deployed in the event of a pandemic and to enable the research community to act immediately in an outbreak, CIHR-III and PHAC launched the IRN and other funding opportunities in December 2007. To further support influenza research in Canada, CIHR-III and partners are organizing an annual meeting of pandemic influenza researchers and knowledge users. The inaugural meeting will be held in Winnipeg on November 7-8, 2008.

Review of the Influenza Research Network Funding Opportunity

Goals and Objectives — *Arlene King, CIRID*

The primary objective of the IRN funding opportunity is to take advantage of the pre-pandemic period to conduct applied public health research in the development of methodologies to evaluate the safety and effectiveness of candidate pandemic vaccines in persons of all ages. This will include programs and mechanisms for rapid data collection, and the analysis and evaluation of vaccine effectiveness and safety before and after the release of the vaccine for general use. With these objectives in mind, the IRN will assemble existing research experience and talent in vaccine evaluation, coordinate the efforts of individual researchers and research centres across the nation and build on core competencies and collective expertise. It will create and strengthen links and facilitate two-way knowledge exchange both amongst researchers and between researchers and decision makers. The IRN will focus on five research areas: 1) Rapid evaluation of candidate vaccines for safety and immunogenicity in persons of all ages; 2) Population-based methods to evaluate vaccine effectiveness and safety following release for general use; 3) Rapid implementation of pandemic vaccine programs; 4) Vaccine coverage including isolated communities and cohorts of concern; and 5) Adverse events following immunization.

Eligibility and Review Process — *Carol Richardson and Allison Jackson, CIHR*

The IRN must capitalize on existing nation-wide expertise including promising new investigators and must address all five research areas. Because of these requirements, participants were encouraged to submit one single application. An eligible application will include a Network leader who will act as



director of the IRN and will assume administrative responsibility for the grant. The Network leader must be a researcher with proven leadership capabilities and experience. The Network must consist of at least five additional principal applicants who are independent investigators and have an established research track record in areas related to the Network.

The application will be comprised of two stages: the Letter of Intent (LOI) and the full application. The deadlines are: May 1, 2008 for the LOI and December 1, 2008 for the full application. The LOI will undergo both relevance review and peer review. The relevance review, conducted by representatives from PHAC and CIHR-III, will assess whether the LOI describes research that meets the objectives and encompasses all five areas outlined in the funding opportunity. If the application proposal is not relevant, it will not be peer reviewed.

The primary consideration of the peer review of the LOI will be to assess whether the applicants have outlined a clear plan to involve applicants from across the nation with the necessary research expertise to develop a full application. In addition to a preliminary research plan and schedule of work, an overview of the organizational structure of the Network and the process for establishing and managing a complex multidisciplinary, multi-institutional research program must be clearly described.

The full application will be peer reviewed, and the committee will evaluate the research proposed; the Network membership, which must include relevant stakeholders; and the proposed management of the network. If only one application is received, the application could be funded as submitted or funded with revisions. Alternatively, the review committee could decide that the application is not fundable. If more than one application is received, then only the top-ranked application will be considered for funding and will be deemed fundable as submitted or fundable with revisions. In the full application, a detailed justification for all costs must be provided. Applicants are referred to the “How to Apply” directions in the funding opportunity for complete details on completing the application.

PHAC and CIHR will fund one Network over a period of three years. In addition to having to meet standard CIHR funding guidelines and conditions, the IRN must also have a PHAC employee appointed as an ex-officio member of the management committee of the Network. It must forward proceedings of workshops/consensus activities for posting on both CIHR and PHAC websites; submit an annual progress report; and submit a final performance report summarizing results and describing how the funds were used.

In the question period the following points were made:

- There are a minimum number of applicants required for the application; however, there is no maximum number.
- Industry partners may be included in the application, but are not mandatory. CIHR has a number of cross-appointed industry partners. Testing pre-pandemic vaccines will likely require industry input.
- Isolated communities refer to both geographically remote areas of the country as well as isolated cohorts such as cultural groups or populations within a community (e.g. drug abusers, the homeless, the elderly).



- There needs to be a balance between the planning and hypothetical approaches and the actual implementation of projects that will be evaluated at the end of the funding opportunity. A good part of the research will be in designing and developing methodologies in the relevant research areas; however, it is also important to do preliminary testing of the methods to ensure the plans will work in the event of a pandemic.
- It is expected that the IRN will include all of the expertise and infrastructure that will be needed during a pandemic. It is important to establish these links before an outbreak to ensure the necessary experts have been identified and can work well together as a group. Generally, any pilot studies will need to be publishable in order to benefit the applicants.
- Applicants must meet CIHR eligibility requirements. If an individual does not meet these requirements, he or she can be added as a collaborator. For example, frontline healthcare workers or community organizations may not meet the eligibility requirements, but may be essential for the research described in the application.
- Only relevant applicants should be included in the application and roles in the project should be clearly defined. If an applicant does not appear to be integral or actively involved in the project, he or she may be pulled from the application.
- It is anticipated that there will be only one application for this funding opportunity, because Canada does not have sufficient expertise in all of the specified research areas to allow for more than one complete application.

IRN Development Session

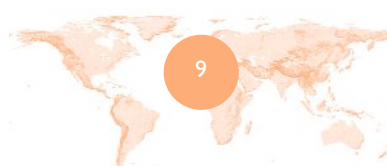
Preparation of the Letter of Intent, small group sessions

This session of the workshop focused on assisting participants in developing the LOI for the IRN application. Participants gathered in small groups to discuss the expertise required to address the relevant research areas and the opportunities and challenges of the Network application. This exercise gave researchers an opportunity to start networking with peers from across the country, exchange information, and discuss in more detail the IRN application.

During this session, participants agreed it would be most effective to focus on a single application that included interested researchers and support personnel from across Canada. A tentative list of principal applicants was developed by the participants (Appendix 4).

Summary

The organizing committee and participants were pleased with the discussions and outcomes of the Workshop. Participants felt the Workshop provided a good networking opportunity to enhance linkages among influenza researchers and helped them identify a team of lead applicants to prepare the LOI for the application. Participants said the dialogue with PHAC and CIHR representatives was particularly helpful in clarifying the objectives and expectations of the funding opportunity. See Appendix 5 for a summary of responses to a questionnaire soliciting feedback on the Workshop from participants.



Appendix I: Funding Partner Representatives

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Appendix 2: List of Workshop Participants

Name	Affiliation
Gordean Bjornson	Canadian Association for Immunization Research and Evaluation (CAIRE)
Mark Cameron	University Health Network
Curtis Cooper	University of Ottawa
Terry Cyr	Health Canada
Gaston De Serres	Institut national de santé publique du Québec
Scott Halperin	Dalhousie University
David Kelvin	University Health Network
Lisan Kwindt	University of British Columbia, BC Centre for Disease Control
Jeff Kwong	Institute for Clinical Evaluative Sciences
Craig Laferriere	CANVAX
Anne McCarthy	The Ottawa Hospital, University of Ottawa, Ottawa Health Research Institute
Allison McGeer	Mount Sinai Hospital
Thomas Rowe	University Health Network
Petra Rykers	Clinical Trials Research Center, Canadian Center for Vaccinology
David Scheifele	BC Children's Hospital, University of British Columbia, CAIRE
Danuta Skowronski	University of British Columbia/BC Centre for Disease Control
Jane Sutherland	The Ottawa Hospital, OHRI
Dat Tran	The Hospital for Sick Children
Brian Ward	McGill University



Appendix 3: Workshop Agenda

INFLUENZA RESEARCH NETWORK APPLICATION DEVELOPMENT WORKSHOP

February 26, 2008
Constitution Square, Tower 3
W. David Hopper Auditorium
150 Kent St., Ottawa

PURPOSE OF THE WORKSHOP

Welcoming Remarks and Introductions

*Dr. Arlene King
Director General, CIRID*

CIHR'S PANDEMIC PREPAREDNESS STRATEGIC RESEARCH INITIATIVE (PPSRI)

Overview of CIHR's PPSRI

*Carol Richardson
A/Assistant Director, CIHR*

REVIEW OF THE INFLUENZA RESEARCH NETWORK (IRN) FUNDING OPPORTUNITY

Review of the IRN Funding Opportunity
Goals and Objectives

Dr. Arlene King

BREAK

Review of the IRN Funding Opportunity
Eligibility and Review Process

*Carol Richardson &
Allison Jackson,
Deputy Director, CIHR*

Highlights of Expertise Relevant to the IRN

All

LUNCH

IRN DEVELOPMENT SESSION

Preparation of Letter of Intent (LOI)

Small Group Session

Report Back

All

BREAK

IRN Development

All

Evaluation of Workshop



Appendix 4: List of Nominees to be Lead Applicants

A preliminary list of lead applicants was developed by the participants at the Workshop. The tentative leads for each research area are listed below.

Principle Applicant/Network Leader:

Lead: Scott Halperin

Team Leaders for Relevant Research Areas:

Rapid evaluation of candidate vaccines for safety and immunogenicity in persons of all ages

Lead: David Sheifele

Population-based methods to evaluate vaccine effectiveness and safety following release for general use

Lead: Danuta Skowronski

Vaccine coverage including isolated communities and cohorts of concern

Leads: Jeff Kwong and Anne McCarthy

Adverse events following immunization

Lead: Gaston De Serres

Rapid implementation of pandemic vaccine programs

No lead was identified, however, the nominees listed below will be asked if they would like to take on the role of lead and/or participate in the application.

Nominees: Maryse Guay, Reka Gustafson, Marsha Johnson, Elizabeth Rea, Margaret Russell, Ross Upshur

Leaders for Relevant Supporting Areas:

Laboratory Support

Lead: Brian Ward

Financial and Administration Management Lead

Lead: Gordean Bjornson

Data Management/Statistical Support

No lead was identified, however, nominees listed below will be asked if they would like to take on the role of lead and/or participate in the application.

Nominees: David Buckeridge, Jean-Paul Collet, David U

Training and Education

No lead was identified, however, nominees listed below will be asked if they would like to take on the role of lead and/or participate in the application.

Nominees: Bob Bortoloussi, Shelly McNeil



Appendix 5: Workshop Evaluation

Participants rated the overall effectiveness/usefulness/interest of each session:

Poor	Fair	Good	Very Good	Excellent
1	2	3	4	5

n = 17; average: 4

The presentation was effective in clarifying the Goals and Objectives of the IRN Funding Opportunity — unanimous agreement

- “Good discussion.”
- “Very helpful.”
- “Unusual case because of desire for single request of national nature.”

The presentations were effective in helping you to understand Eligibility Requirements and the Review Process for the IRN — yes: 16, no: 1

- “Needs some fine tuning.”
- “It would have been good to know that the idea was developing a network right from the start.”

The Workshop was effective in enhancing the linkages among researchers — unanimous agreement

- “Very much so; this in my mind is a big benefit of a network.”
- “Yes, made several new acquaintances.”
- “Would have been helpful to have more of the objectives prior to the workshop. Concerned that more might have attended if knew that a tentative team was to be formed.”
- “Absolutely. Linkages went beyond those pre-existing.”
- “I was able to meet at least one person face-to-face for the first time in 2-3 years of collaboration.”
- “Good networking opportunity.”

The workshop assisted you to prepare the Letter of Intent for the IRN — unanimous agreement

- “Roles clarified well.”
- “Group proposal accepted as goal.”

The Institute of Infection and Immunity and PHAC should hold a similar workshop in the future — unanimous agreement

- “Served its purpose.”
- “Very helpful-good value for CIHR, I think.”
- “This is such a large group (by necessity), that this kind of workshop is particularly important.”
- “Important to interface with CIHR administration.”



Areas that should be emphasized at future events of this type

- “HIV, vaccine, infectious diseases.”
- “Need to work on finding out what else is going on around the country/other investigators.”

General comments on the workshop

- “I was not clear about the objectives or process at this workshop before I arrived. A little more advanced information would have helped”
- “Need to put address/site in multiple areas”
- “Great day, thanks”





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