Canadian Immunization Research Network

6-A: "Sponsors"

The Canadian Institutes of Health Research Institute of Infection and Immunity (CIHR-III) in partnership with the Public Health Agency of Canada (PHAC)

6-C: "Description"

Through the current 3 year grant awarded to the Canadian Immunization Research Network (CIRN), PHAC and CIHR supported the formation and function of a national research network. This Network has provided policy makers and program administrators with the opportunity to assess the actual impact of immunization programs more rapidly and to assess innovative approaches to scheduling and program delivery.

CIRN is a national network of vaccine and immunization researchers who develop and test methodologies related to the evaluation of vaccines and immunization in regard to safety, immunogenicity and effectiveness, and program implementation and evaluation.

The Network undertakes coordinated, collaborative, and multi-disciplinary vaccine and immunization-related research. This includes examining various biomedical research questions and aspects of the vaccine life cycle including safety, short- and long-term effectiveness and protection, as well as social issues like hesitancy and uptake. The Network has established capacity for timely evaluation of vaccines for a variety of infectious diseases, seeks to continue to improve immunization programs and coverage nationwide, and has built strong links between the research community and key decision makers. The Network is seen to be a Canadian clinical trials resource for vaccine-preventable diseases and has research capacity that is at times rapidly mobilized and used in the event of an infectious disease outbreak.

The Network is comprised of a set of research teams, led by Team Leaders, which are linked and are each comprised of researchers spanning CIHR's four themes (biomedical; clinical; health systems and services; social, cultural, environmental and population health). Although each team focuses on a separate aspect of vaccine and immunization research, their activities are coordinated to form a larger, concerted research strategy. The Network has an existing formal governance structure which provides guidance and direction to the research teams, and promotes knowledge sharing.

The Network will involve the training and mentoring of personnel across the full continuum of training (Masters, Doctoral, Post-Doctoral and Clinical Fellows) including establishing a competitive process to support the research of at least one New Investigator in each of the first three fiscal years. New Investigators must be identified as not having previously been involved in the Network.

Included in the Network design is a structure for conducting essential emerging pathogens or outbreak research projects that are deemed a matter of public importance. Research on the Ebola virus is a recent example. Should an outbreak of an emerging or re-emerging infectious disease occur, team leaders can submit a more detailed research plan, which undergoes an expedited review and funding process related to the circumstances of any such outbreak. The Network can provide additional support to these mobilized research teams during public health events of concern.

The next phase funding of CIRN will strengthen Canada's research capacity, evidence base, and expertise in the field of immunization and vaccines for vaccine-preventable diseases, and complements previous investments made by the Government of Canada.

Funds Available

CIHR and partner(s) financial contributions for this initiative are subject to availability of funds. Should CIHR or partner(s) funding levels not be available or are decreased due to unforeseen circumstances,

CIHR and partner(s) reserve the right to <u>reduce</u>, <u>defer or suspend financial contributions</u> to grants received as a result of this funding opportunity.

The maximum amount available for this single grant is \$10,083,334 over a 55 month period between 2017-18 to 2021-22, The funding distribution will be as follow: \$1,833,334 in year one, \$2,200,000 per annum in years two to four and \$1,650,000 in the last seven months.

Of this amount, at least \$2,000,000 of the overall funding must be dedicated for research interventions to improve vaccine acceptance and uptake (research area # 3).

Additional funds may be provided to the Network by PHAC to expedite the development and implementation of rapid response research focused on an event of public health importance. These funds will be made available through an expedited funding process launched when needed, and are solely dedicated for rapid response research.

6-D: "Objectives"

The goal of this funding opportunity is to support the next phase funding for CIRN over a four years and seven months period using a directed grant mechanism.

The specific objectives of this funding opportunity are:

- 1. Support a formal organizational infrastructure to facilitate collaborative research amongst vaccine and immunization researchers, clinicians, public health professionals, and policy makers to:
 - a. Develop methodologies to test vaccines in areas such as safety, short- and long-term effectiveness and protection, and adverse reactions;
 - b. Evaluate current immunization programs for coverage and effectiveness;
 - c. Improve immunization coverage rates in Canada;
 - d. Train the next generation of vaccine and immunization researchers; and
 - e. Improve knowledge exchange mechanisms between the stakeholders.
- 2. Support a rapid response research capacity.

Relevant Research Areas

Applicants are expected to address the following research areas:

- 1. Rapid evaluation of candidate vaccines for safety and immunogenicity in persons of all ages including sex;
- 2. Population based methods to evaluate vaccine effectiveness and safety following release for general use (including adverse events following immunization);
- 3. Research on interventions that can help to improve vaccine acceptance and uptake including consideration of priority research projects to inform current and future policy; and
- 4. Vaccine modeling and economic analysis work.

The Network must also address the following areas:

Sex and gender considerations in methodologies.

- Research on Indigenous populations.
- Official Languages Minority Communities (where appropriate).
- Ethical, legal, and social implications (ELSI) such as recruitment of study subjects from vulnerable populations or information sharing with public health organizations.
- Importance of leveraging a wide range of existing immunization clinical trials and utilizing a variety of methodologies inclusive of other clinical trials (i.e. comparative/effectiveness trials).

CIRN will continue to be ready to support pandemic situations and utilize a rapid response research mechanism to assist with other public health events that could be a risk to Canadians.

6-E: "Eligibility"

Eligibility criteria for all CIHR research funding programs apply. The business office of the institution of an eligible Nominated Principal Applicant generally administers CIHR funds. Refer to the Individual Eligibility Requirements regarding the eligibility requirements for individuals and institutions.

Eligibility to Apply

For your application to be eligible:

- 1. This is a directed funding opportunity to the PHAC-CIHR Canadian Immunization Research Network (CIRN).
- The Nominated Principal Applicant must be an <u>independent researcher</u> appointed at an eligible institution (See <u>Institutional Eligibility Requirements</u> for eligibility process and associated timelines). This individual will act as Network Leader.
- 3. At least four other Principal Applicants must be <u>independent researchers</u> called **Team**Leaders who will lead research teams.
- 4. The Network must be national in scope, with Team Leaders from primary institutions based in at least four (4) different provinces.
- 5. Each research team must include researchers from at least three (3) different provinces.

6-F: "Guidelines"

General CIHR Guidelines

This funding opportunity will comply fully with the policies and guidelines as outlined in CIHR's Funding Policies. CIHR policies reflect areas of importance such as (but not limited to): Gender and Sex-Based Analysis, Knowledge Translation, Open Access, Global Health Research and International Collaborations. Policies and guidelines also cover areas such as applicant responsibilities, Official Languages policy, Access to Information Act, Privacy Act, Tri-Agency Open Access Policy on Publications and Communication Requirements. Information collected by CIHR may be shared as described in the Conflict of Interest and Confidentiality Policy of the Federal Research Funding Organizations.

Allowable Costs

Recipients should review the <u>Use of Grant Funds</u> section of the Tri-Agency (CIHR, NSERC and SSHRC) Financial Administration Guide for a complete listing and description of allowable costs and activities.

The following expenditures will be considered eligible for funding received through this funding opportunity:

- Maintenance costs for an administrative/coordinating centre, which may be a physical centre or a
 virtual network, and includes office supplies and the salary of Network support coordinator(s). No
 more than 10% of the annual funds per year can be invested in the support of the administrative
 structure.
- Costs of regional, national and international networking activities, including collaboration, planning, and knowledge exchange activities directly related to the Network, such as funds for an annual scientific/networking meeting to support a website for the Network - not to exceed 10% of the annual funds.
- Salaries of program coordinators.

Conditions of Funding

Successful applicants funded through this funding opportunity and any other persons working on the project must comply fully with the <u>CIHR Funding Policies</u>. Policies and guidelines cover areas such as Applicant Responsibilities, Official Languages policy, Access to Information and Privacy Acts, and Acknowledgement of CIHR's Support. Successful applicants will be informed of any special financial requirements prior to the release of funds or when they receive CIHR's Authorization for Funding (AFF) document.

In addition to CIHR standard guidelines and requirements, the following special requirements shall apply:

- A grant agreement will be put in place between the successful organization and CIHR and PHAC to lay out the roles and responsibilities of the grant.
- A competitive process must be established in order to support the research conducted by at least one
 <u>New Investigator</u> in each of the first three fiscal years. New Investigators must be identified as not
 having previously been involved in the Network.
- CIHR and PHAC staff will participate in an ex-officio capacity on the CIRN Management Committee.
- CIHR and PHAC staff will participate in the CIRN Annual General Meeting.

6-G: "Performance Measurement"

CIHR is committed to collecting and disseminating information on the outputs and impacts of the research it funds. This information is an important part of CIHR accountability within the Federal Government and to Canadians. If successful within this funding opportunity:

- The Nominated Principal Applicant will be required to submit an annual progress report to CIHR and PHAC, documenting the advances made in the previous year. CIHR and PHAC staff, along with the CIHR-Institute of Infection and Immunity Scientific Director, will meet annually to review these reports and will provide feedback to the Network.
- The Nominated Principal Applicant will be required to submit an electronic Final Report to CIHR. This online report will be made available to the Nominated Principal Applicant on ResearchNet at the beginning of the grant funding period and can be filled in as the research progresses. The report will be shared with PHAC.
- The Nominated Principal Applicant will be required to contribute to the monitoring, review and
 evaluation of CIHR's programs, policies and processes by participating in evaluation studies, surveys,
 workshops, audits and providing data or reports as required for the purpose of collecting information
 to assess progress and results.
- The Nominated Principal Applicant will be required to encourage their associates, trainees and administration to participate in the monitoring, review and evaluation of CIHR's programs, policies and processes as required.

6-H: "Review Process and Evaluation"

Review Committee

A CIHR review committee will evaluate the full applications. The committee will be created specifically for this funding opportunity. Committee members are selected based on suggestions from many sources including the institute(s)/ branch(es) and partner(s), following the <u>Conflict of Interest and Confidentiality Policy of the Federal Research Funding Organizations</u>. Network members may be invited to address the review committee questions in order to complete their evaluation.

For information on CIHR's peer review principles, see the <u>Peer Review: Overview</u> section of CIHR's website.

Evaluation Criteria

To support the strategic objectives of this funding opportunity, the following evaluation criteria will be used.

1. Approach

- a. The extent to which the Network's vision and programming addresses the specific objectives and research areas of this funding opportunity.
- b. Appropriateness of the proposed program of activities for achieving the Network's vision.
- c. Quality of the design and rigorousness of the research projects.
- d. Originality of the proposed research, in terms of the hypotheses/research questions addressed, novel technology/methodology, and/or novel applications of current technology/methodology.
- e. Appropriateness of the research methodologies to test vaccines in areas such as safety, short- and long-term effectiveness and protection, and adverse reactions.
- f. Appropriateness of the research methods, including consideration for ethical, legal, and social implications, sex and gender, Indigenous populations and official languages minority communities.
- g. Feasibility of the research approaches (including: recruitment of subjects, project timeline; preliminary data where appropriate; consideration of social, cultural and environmental factors surrounding the research problem).
- h. Appropriateness of the plans to evaluate current immunization programs for coverage and effectiveness.
- Appropriateness of the plans to leverage a wide range of existing immunization clinical trials and utilizing a variety of methodologies inclusive of other clinical trials (i.e. comparative/effectiveness trials)
- j. Appropriateness of the mechanism(s) for rapid research response and for quick implementation of research protocols in the event of a pandemic outbreak.
- k. Anticipation of difficulties that may be encountered in the research and plans for management.
- Appropriateness of the plan to leverage additional research funding from outside the Government of Canada.

2. Governance and Network Function

- a. Appropriateness of the Network's governance plan, including structure and functioning to achieve defined goals, as well as clear identification of the roles and responsibilities of partners.
- b. Appropriateness of processes to ensure accountability, shared strategic leadership, priority setting and transparency in decision-making.
- c. The extent to which the Network is pan-Canadian in scope, including appropriate use of existing Canadian infrastructure and resources to enable national improvement.

- d. The extent to which the proposal addresses an evaluation plan with specific outcome indicators.
- e. Appropriateness of the scope of Network activities within the proposed budget.
- f. Appropriateness of the conflict resolution strategy.
- g. Effectiveness of proposed internal and external communication strategies.
- h. The extent to which the Network optimizes the utilization of resources, including the sharing of equipment, facilities and expertise.

3. Applicant(s)

- a. Qualifications of the applicants, including training, experience and independence (relative to career stage).
- b. Experience of the applicants in the proposed area of research and with the proposed methodology.
- c. Expertise of the applicants, as demonstrated by scientific productivity over the past five years (publications, books, grants held, etc.). Productivity should be considered in the context of the norms for the research area, applicant experience, and total research funding of the applicant.
- d. Ability to successfully and appropriately disseminate research findings, as demonstrated by knowledge translation activities (publications, conference presentations, briefings, media engagements, etc.).
- e. Appropriateness of the Network members to carry out the proposed research, in terms of complementarity of expertise and synergistic potential.
- f. The extent to which Network members have demonstrated the importance of their contributions to the Network as a whole.

4. Environment for the Research

- Availability and accessibility of personnel, facilities, and infrastructure required to conduct the research.
- b. Suitability of the environment to conduct the proposed research.
- c. Suitability of the environment (milieu, project, and mentors) for the training and mentoring of personnel across the full continuum of training (masters, doctoral, post-doctoral and clinical fellows) including establishing a competitive process to support the research of at least one New Investigator in each of the first three fiscal years. New Investigators must be identified as not having previously been involved in the Network.

5. Impact of the Research

- a. The extent to which the Network clearly demonstrates how members will achieve greater impact through collaboration.
- b. The extent to which the Network will increase knowledge related to vaccines and immunization.
- c. The extent to which the Network will improve immunization coverage rates in Canada.
- d. The extent to which the applicants will facilitate collaborative research amongst vaccine and immunization researchers, clinicians, public health professionals, and policy makers that will contribute to the larger functioning of the Network.
- e. The extent to which the Network will improve communication between stakeholders.
- f. The extent to which the activities of the Network will support the training of the next generation of vaccine and immunization researchers.

- g. The extent to which the Network will contribute to a rapid research response for vaccinepreventable diseases.
- h. Appropriateness of the proposed strategies for Knowledge Translation.

Funding Decision

Upon completion of peer review, the CIHR and the Public Health Agency of Canada will receive a formal funding recommendation from the committee on whether or not the application is recommended for funding. The application will be given a pass or fail grade by the review committee. A single network will be funded through this funding opportunity.

6-I: "How to Apply"

Important: Please read all instructions to familiarize yourself with the application process before applying. For new applicants or for those wanting a reminder of the main application procedures, an overview of CIHR's application processes can be found under <u>Application Process</u>. Note that these are general instructions only as the specific application instructions for this funding opportunity are located below.

The application process for this funding opportunity is comprised of one step: Application.

To complete your Application, follow the instructions in the <u>Team Grants / Emerging Team Grants – ResearchNet "Application" Phase Instructions Checklist</u> along with any additional instructions found below under "Specific Instructions".

Reminder to applicants: Please ensure that your application is <u>complete</u> (includes all required signatures) and is submitted on time to CIHR.

Submission Requirements

Your Application must be submitted using <u>ResearchNet</u>. Scan and upload **the signed signature pages** including the routing slip in the Print/Upload Signature Pages task in ResearchNet prior to submitting your application.

Specific Instructions

Step 1 - Application:

Task: Identify Participants

- List all participants involved in the Network, including collaborators.
- Applicants will enter their Common CV Confirmation number in this task. CVs are required for the Nominated Principal Applicant and all Principal Applicants. Co-Applicants, Knowledge Users and Collaborators do not need to submit a CV.

Task: Enter Proposal Information

- Summary of Progress: In a maximum of four (4) pages, summarize progress under the current grant.
- Research Proposal: In a maximum of twenty (20) pages (not including references, charts, tables, figures, and photographs), address each of the elements below:

1. Approach

- a. Description of the network's vision and programming and how it addresses the specific objectives and research areas of this funding opportunity.
- b. Description of the proposed program of activities to achieve the Network's vision.
- c. Explanation of the design and rigorousness of the research projects.

- d. Explanation of the originality of the proposed research, in terms of the hypotheses/research questions addressed, novel technology/methodology, and/or novel applications of current technology/methodology.
- e. Description of the research methodologies to test vaccines in areas such as safety, short- and long-term effectiveness and protection, and adverse reactions.
- f. Explanation of the appropriateness of the research methods, including consideration for ethical, legal, and social implications, sex and gender, Indigenous populations and official languages minority communities.
- g. Explanation of the feasibility of the research approaches (including: recruitment of subjects, project timeline; preliminary data where appropriate; consideration of social, cultural and environmental factors surrounding the research problem).
- h. Description of the plans to evaluate current immunization programs for coverage and effectiveness.
- Description of the plans to leverage a wide range of existing immunization clinical trials and utilizing a variety of methodologies inclusive of other clinical trials (i.e. comparative/effectiveness trials)
- j. Explanation of the mechanism(s) for rapid research response and for quick implementation of research protocols in the event of a pandemic outbreak.
- k. Description of anticipated difficulties that may be encountered in the research and plans for management.
- Description of the plan to leverage additional research funding from outside the Government of Canada.

2. Governance and Network Function

- Description of the Network's governance plan, including structure and functioning to achieve defined goals, as well as clear identification of the roles and responsibilities of partners.
- b. Description of processes to ensure accountability, shared strategic leadership, priority setting and transparency in decision-making.
- c. Description of the pan-Canadian scope of the Network, including appropriate use of existing Canadian infrastructure and resources to enable national improvement.
- d. Description of an evaluation plan with specific outcome indicators.
- e. Explanation of the appropriateness of the scope of Network activities within the proposed budget.
- f. Description of the conflict resolution strategy.
- g. Description of the proposed internal and external communication strategies.
- h. Explanation of the extent to which the Network optimizes the utilization of resources, including the sharing of equipment, facilities and expertise.

3. Applicant(s)

- a. Description of the qualifications of the applicants, including training, experience and independence (relative to career stage).
- b. Description of the experience of the applicants in the proposed area of research and with the proposed methodology.
- c. Description of the expertise of the applicants, as demonstrated by scientific productivity over the past five years (publications, books, grants held, etc.).

- Productivity should be considered in the context of the norms for the research area, applicant experience, and total research funding of the applicant.
- d. Description of the ability to successfully and appropriately disseminate research findings, as demonstrated by knowledge translation activities (publications, conference presentations, briefings, media engagements, etc.).
- e. Explanation of the appropriateness of the Network members to carry out the proposed research, in terms of complementarity of expertise and synergistic potential.
- f. Explanation of the importance of the contributions of the Network members to the Network as a whole.

4. Environment for the Research

- a. Description of the availability and accessibility of personnel, facilities, and infrastructure required to conduct the research.
- b. Description of the suitability of the environment to conduct the proposed research.
- c. Description of the suitability of the environment (milieu, project, and mentors) for the training and mentoring of personnel across the full continuum of training (masters, doctoral, post-doctoral and clinical fellows) including establishing a competitive process to support the research of at least one New Investigator in each of the first three fiscal years. New Investigators must be identified as not having previously been involved in the Network.

5. Impact of the Research

- a. Explanation of how members will achieve greater impact through collaboration.
- b. Description of how the Network will increase knowledge related to vaccines and immunization.
- c. Description of how the Network will improve immunization coverage rates in Canada.
- d. Description of how the applicants will facilitate collaborative research amongst vaccine and immunization researchers, clinicians, public health professionals, and policy makers that will contribute to the larger functioning of the Network.
- e. Explanation of how the Network will improve communication between stakeholders.
- f. Explanation of how the activities of the Network will support the training of the next generation of vaccine and immunization researchers.
- g. Explanation of how the Network will contribute to a rapid research response for vaccine-preventable diseases.
- h. Description of strategies for Knowledge Translation (KT plan).
- Attach any documents supporting the proposal (e.g., references, charts, tables, figures, photographs, etc.) in the Research Proposal Appendix.

Task: Enter Budget Information and Supporting Documents

- Under the Financial Assistance Requested section insert funds requested for the entire Network.
- Under the Budget Attachment section, (for the Financial Assistance Requested Details documents) provide budgets itemized justifications for the core Network and each research project (identify each table with the research project title).
- For each of these individual budgets clearly justify all budget items (including cash and in-kind contributions, if relevant).

Clearly highlight the amount of funding allocated to the research area #3 (see <u>Relevant Research</u>
<u>Areas</u>).

Task: Attach Other Application Materials

- Publications:
 - A listing of no more than ten (10) publications from the 5 past years relevant to the proposal (optional).
- Upload these documents as "Other":
 - o Applicant table:
 - In a table format, name all Network members with their **affiliation**, **province**, **role** on the application (Network Leader, Team Leader, etc.), **relevant expertise**, **stakeholder group** (i.e. researchers, clinicians, policy makers, knowledge users, etc.) they are representing and a **short description of their contribution** to the Network.
 - o Organizational chart showing the Network's management structure and governance.

Task: Print/Upload Signature Pages

- o Required Signatures:
 - Signatures must be included for individuals submitting a Canadian Common CV and individual(s) with signing authority from the Canadian Institution Paid. The Institution Paid will administrate the grant funds.
 - Original signatures are not required. The scanned signed signature pages and the Routing Slip must be uploaded in the Print/Upload Signature Pages task in ResearchNet prior to submitting.

6-J: "Contact Information"

For all inquiries please contact:

CIHR Contact Center Telephone: 613-954-1968 Toll Free: 1-888-603-4178 Email: support@cihr-irsc.gc.ca

6-K: "Sponsor Description"

Partners

The Public Health Agency of Canada (PHAC)

The Public Health Agency of Canada has been created to deliver on the Government of Canada's commitment to help protect the health and safety of all Canadians. Its activities focus on preventing chronic diseases, like cancer and heart disease, preventing injuries and responding to public health emergencies and infectious disease outbreaks.

Internal Collaborators

Canadian Institutes of Health Research (CIHR)

The Canadian Institutes of Health Research (CIHR)is the Government of Canada's health research investment agency. CIHR's mission is to create new scientific knowledge and to enable its translation into improved health, more effective health services and products, and a strengthened health care system for Canadians. Composed of 13 Institutes, CIHR provides leadership and support to more than 13,000 health researchers and trainees across Canada.