Regional/National Clinical Research Initiatives (RHF-CRI)
Joint CFI/CIHR Call for Project Outlines

BACKGROUND AND OBJECTIVES:

The revolution in fundamental health research has created unprecedented opportunities for translating new insights of human biological diseases into clinical applications. However, there is a growing gap in the application of this new science to humans. Clinical Research[1] has not been able to keep pace with the rapid advances in fundamental scientific discovery. This gap is impeding important advances in our understanding and control of human disease and in the design and execution of clinical trials of new drugs, or new health care interventions. As in other countries, including the US and the UK, the causes of this gap are due to a number of factors including:

- Rapid development of new technologies and infrastructure meaning that existing infrastructure is obsolete;
- Severe career disincentives creating a growing shortage of appropriately trained clinician scientists; and,
- Competing demands of the health care system where the emphasis is towards services, rather than research.

Recognizing the need and opportunity to strengthen clinical research in Canada, the Canada Foundation for Innovation (CFI) and the Canadian Institutes of Health Research (CIHR) are working in partnership to foster collaboration across institutions, regions, and various research sectors. The agencies are coordinating their efforts and resources to achieve enhanced national impact, increased value for resources deployed, and efficiencies in the application process for institutions, investigators and referees.

CALL FOR PROJECT OUTLINES:

The CFI and CIHR jointly invite proposals for Regional/National Clinical Research Initiatives (RHF-CRI) with a major focus on building the excellence, national capacity and critical mass required to allow Canada to become an international leader in clinical research that leads to a better health care system, improved health and a stronger economy. The CFI will provide funding for research infrastructure under the Research Hospital Fund and CIHR will provide funding for high quality research, research personnel, and training and research program operations.

Under the RHF-CRI, CIHR and the CFI challenge institutions and their investigators to consider non-traditional models and/or combinations of traditional/non-traditional models to best meet the overall objective of enhancing clinical research through multidisciplinary and collaborative approaches. Multidisciplinary research teams focused on high impact, clinically relevant health problems, training programs in clinical research, formal knowledge translation programs and a strong underlying ethics framework, should be integral components of the proposals. It is expected that the infrastructure requests will take advantage of new genomic, proteomic, and informatics tools, innovative clinical trials methodologies and integration with the health care system.

[1] Clinical research is that part of the continuum of health research which is conducted on human subjects or on materials, specimens, or data derived from human subjects or populations and with a focus on: **Mechanisms** of human health and disease; **Bench to bedside** research; Experimental and observational **Clinical Trials** of prevention and therapy; and **Clinical Epidemiological** studies. In addition, clinical research may utilize the methods of Health care services/systems research and Population health research as they relate to clinical encounters.

Annex A provides some examples of potential models. The CFI and CIHR wish to maximize the likelihood of capitalizing on innovation and opportunity as conceptualized by investigators, hospitals, and provinces. Accordingly, CIHR and the CFI will consider all proposals that are consistent with the objectives of this initiative.

WHAT ARE THE OBJECTIVES?

The ultimate objective of the Regional/National Clinical Research Initiatives is to contribute to improved health for Canadians, a sustainable health care system, and a stronger economy through a focus on solving high-impact, clinically-relevant health problems. In order to achieve this overarching objective, the initiative aims to:

- support high-quality research programs with potentially high-impact, clinically relevant health problems ;
- support outstanding teams of talented and experienced researchers;
- improve the national infrastructure for clinical research;
- increase operational funding for clinical research;
- provide superior training and mentorship environments in order to sustain Canadian talent and leadership in clinical research; and,
- ensure that discoveries made in Canada are evaluated, further developed and implemented in Canada, maximizing health and economic benefits.

WHO IS ELIGIBLE TO APPLY?

Only research hospitals eligible to access the Research Hospital Fund can submit combined applications for the CRI. The eligibility criteria for a research hospital are the same as those for the Large-Scale Institutional Endeavours. For more details, please consult the "Large Scale Institutional Endeavours". Institutions or organizations that do not qualify as eligible institutions to receive CFI funding can participate as collaborators or partners of eligible institutions.

Eligible research hospitals are not limited to participation in one RHF-CRI application.

In deciding whether to submit a proposal, hospitals should take into consideration that the CFI will expect institutions to start the construction/renovation component of a project within **18 months** of the award announcement. This means that contracts for construction or renovation must have been finalized, and the construction/renovation work begun.

The time to put in place requested infrastructure should not be a limiting factor to implement the research program. It is **mandatory** that the research programs begin within **12 months** of the official decision announcement.

Both above requirements speak to the need for mature projects.

*For hospitals and teams of researchers wishing to apply to the CRI **for CIHR funding only**, without an infrastructure request, please refer to www.cihr-irsc.gc.ca for the more information*.

Eligibility criteria for all CIHR research funding (grant) programs apply. The business office of the institution of an eligible Nominated Principal Applicant generally administers CIHR funds. Please refer to the Eligibility Requirements for CIHR Grants and Awards regarding the eligibility requirements for individuals and institutions.

Each application must designate a Project Leader. In order to be eligible for this role, the individual must fulfill the eligibility criteria of CIHR's Nominated Principal Applicant. The Project Leader must be a researcher with proven leadership capabilities and experience who will assume administrative responsibility for the RHF-CRI. Eligibility criteria for all CIHR research funding programs apply. Please refer to the Eligibility Requirements for CIHR Grants and Awards regarding the eligibility requirements for individuals and institutions.

Randomized Controlled Trials (RCTs) will be considered under this Call for Project Outlines only if necessary background research or preliminary studies have been completed in order to justify the need for a RCT. Applicants who are considering submitting a Randomized Controlled Trial application in response to this Request for Applications MUST consult the CIHR RCT staff listed in Contact Information and are advised to familiarize themselves with the RCT specific guidelines and instructions, which are fully described in Randomized Control Trials.

HOW MUCH FUNDING IS AVAILABLE?

CIHR:
At least $50 million will be available over 5 years from CIHR to support high quality research, research personnel, training and research program operations, for applications for either both RHF-CRI or for CRI only. For each proposal, a maximum of $2 million per year over five years will be awarded by CIHR. Although CIHR strongly encourages applicants to leverage these funds by seeking partnership support for these components, it is not a requirement.

CFI:
The CFI will contribute **up to** $100M for the infrastructure component of the RHF-CRI, i.e. a contribution of up to 40% of the total cost of the infrastructure. The CFI will entertain proposals requesting a CFI contribution between $2 to $10 million. Clinical infrastructure needs requiring a CFI contribution greater than $10M should be submitted under the Large-Scale Endeavour component of the RHF. In addition, the CFI will provide an amount equivalent to 30% of the CFI funding awarded towards the operation and maintenance costs **of the infrastructure**.

HOW DO PROJECTS FIT INTO THE HOSPITAL STRATEGIC RESEARCH PLAN?

Each research hospital submitting a proposal under the RHF-CRI must provide a Strategic Research Plan (SRP) summary of no more than 3 pages that must include:

- An outline of the major research themes of strategic importance to the hospital, focusing on those themes for which support is requested in the proposal;
- A description of how the hospital will support these priority areas (e.g. institutional resources to capitalize on the infrastructure, creation of new academic staff positions, research chairs, etc.);
- A description of the hospital's current and projected research space requirements for the next five years;
- An explanation of how this infrastructure project will help build capacity in the hospital's strategic research priority areas, including:
    1. how it will enhance the attraction and retention of highly qualified researchers;
    2. how this investment will enhance the hospital's capacity to support research, training and knowledge translation; and,

3. how this support will build regional or national capacity for innovation and increase international competitiveness in these areas; and,

- A description of the planning and approval process for the SRP at the hospital.

HOW SHOULD HOSPITALS ENGAGE THEIR KEY PARTNERS, IN PARTICULAR THEIR PROVINCES?

Hospitals are required to provide evidence that key partners, in particular their provinces, are engaged in the planning of the project. Provinces are recognized to be key stakeholders in research infrastructure projects in hospitals. As such, there must be close interactions between the institutions and their provincial government from the beginning of the process to take into consideration provincial priorities and opportunities.

Hospitals are therefore required to demonstrate that they have discussed their proposed initiative upfront with their respective provinces, including their business plan. At the **full application stage,** institutions will be required to provide evidence of provincial support in the form of a letter, signed by the appropriate provincial authority such as a deputy minister or assistant deputy minister, indicating that the proposed project is aligned with provincial health strategy(ies) and will be feasible once appropriate partner support is found.

Other partnerships and collaborations

Proposals that represent active partnerships between community organizations and research teams based in institutions (including universities, colleges, hospitals, and affiliated research institutions) are encouraged.

For community-focused proposals, the guiding principle for participation is that community groups are active, influential and ongoing participants in the research, training, mentoring and knowledge translation activities, and that their roles have been formally agreed upon in the spirit of ensuring equity and mutual benefits from the partnership.

It is expected that the partners will contribute to the Knowledge Translation of the CRI through:

- Project Design (formulating research agendas; providing input into the development of research and training projects); and,
- Dissemination (synthesizing and disseminating findings; applying the research findings to inform policies, programs and/or practices, and in some cases, conducting the research).

WHAT ARE ELIGIBLE COSTS?

CFI

The CFI will provide funding for up to 40% of the eligible infrastructure costs of a project. Partner contributions and cash expenditures by the institution themselves must have taken place after **February 19, 2003**. Eligible costs for the CFI under the Regional/National Clinical Research Initiatives call will be the same as it is for the Large-Scale Institutional Endeavours, with an emphasis on space.

CIHR

CIHR funding will support high quality research, research personnel, training and research program operations.

To guide applicants with respect to allowable costs and activities under the Regional/National Clinical Research Initiative, applicants should review:

1. Use of Grant Funds
2. Guidelines for Awards.

In the context of this initiative, CIHR funding can be used to support the following:

- Research operating costs for the proposed collaborative research program, which must be distinct in its objectives from those for which team members currently receive funding;
- Costs of data collection, database development and maintenance of information holdings directly related to the clinical research program;
- Costs of regional, national and international networking activities, including collaboration, planning, and knowledge exchange activities, directly related to the clinical research program;
- Salaries of research assistants, technicians, methodologists and other highly qualified personnel who will enhance the capacity, quality and productivity of the clinical research program;
- Support of research trainees, at the rate specified by CIHR for trainees paid from research grants. All clinical research programs are expected to integrate necessary components to support an exceptional training environment;
- Salary of a professional coordinator and/or administrative assistant;
- Release time payments to enable employees of community partners to participate in the research program, limited to 50% of salary costs, and an overall maximum of $100,000 per year;
- A maximum of $20,000 annually for a release time stipend for the project leader;
- Establishment funds and salary for new investigators joining the team (new investigators are within the first five years of their independent research careers). Salary contributions paid for by the Grant must not exceed the stipend paid to CIHR New Investigators ($60,000 per annum including fringe benefits). Those paid from the Grant cannot also hold a Canada Research Chair or another salary award. Note that new investigators paid from the grant can not be listed as co-applicants on the grant application. Similarly, they can not be listed as co-investigators on the grant after it is approved; however they can be considered members of the team;
- Costs involved in linkage with and dissemination of research findings to those who use the results, as appropriate for the research program, (including other researchers, the public, practitioners and policy communities, and the industrial sector); and,
- Costs involving website development, office supplies, and education and development costs in good clinical research practice.

With the exception of co-applicants who are trainees or research associates, co-applicants may not receive a salary, stipend, or honorarium from CIHR grants on which they are a co-applicant (as described in Participant Applicant Categories for CIHR Grants). The only exception is the release time stipends for the team leader and employees of community partners as described.

The full application must provide a detailed justification of all costs.

WHAT IS THE APPLICATION PROCESS?

The CFI and CIHR expect institutions to closely work with one another to ensure that a coordinated approach is followed when submitting project outlines for Regional/National Clinical Research Initiatives. As mentioned previously, a few models are provided as examples, but CIHR and the CFI also encourage institutions to explore different approaches from those three models described in

Annex A, taking into account the goals of the Regional/National Clinical Research Initiative and the Research Hospital Fund and the evaluation criteria outlined below.

It is important to note that proposals to the RHF-CRI and to the CRI have the **same deadlines** and will undergo the **same review process**. They will be **evaluated by the same Assessment Committee**.

Eligible applicants will submit:

By April 16, 2007: 12 paper copies of the Project Outline to CIHR, accompanied by the hospital's Strategic Research Plan summary, and the signed following forms: CFI's "Collection, Use and Disclosure of Personal Information" and CIHR's "Applicant Consent Form for Use and Disclosure of Personal Information Provided to CIHR for Peer Review".

If invited to submit a full application:

- **By October 9, 2007**: a complete electronic application, as well as complete paper copies (number to be determined at invitation) of the application, including floor plans for construction. In addition, the applicant must provide a letter of support, signed by the appropriate provincial authority, indicating that the proposed project is aligned with provincial health strategy(ies) and will be feasible with appropriate partner support. In this regard, letters from partners confirming their partner contributions to the project are also required.

See Annex B for full competition schedule and RCT deadline requirements.

Project Outline

The Project Outline will consist of a maximum of **eight (8)** pages of written text, in which the following points **must be addressed**:

- the key elements of the clinical research program, its innovative and multi-disciplinary nature and planned activities, and the anticipated impact of the program on the health of Canadians and other socio-economic benefits to Canada;
- justifications about why this proposal is essential and will bring added value to the Canadian clinical research enterprise and how the objectives cannot be met otherwise;
- a short description of the requested and/or the existing infrastructure;
- an explanation of how this clinical infrastructure will build on and complement other investments already made at the regional, national and international levels, and allow for new and different activities to advance and enhance the achievements of the research program, and how this resource will be made available to researchers, regionally, nationally and internationally, where appropriate;
- an overview of the training opportunities for clinical researchers and other highly qualified personnel (HQP) and, where appropriate, how training centres located in different places plan to interact/coordinate with one another;
- the nature and extent of the collaboration among investigators across the country, with the anticipated value added to the research program through the formation of this collaboration; and,
- the approach for the knowledge translation strategy to ensure the desired impact.

An additional 2 pages of diagrams or illustrations can also be included with the Project Outline. No other additional material will be accepted.

National/Regional Clinical Research Initiatives proposals including Randomized Controlled Trials (RCTs) as part of their proposal must indicate so in the cover letter.

The Project Outline must also be accompanied by a covering letter signed by the President/CEO (or his/her authorized signatorie) of the leading institution that will receive funding through the initiative, and by the designated project leader. The letter should also include all of the following:

1. the title of the Regional/National Clinical Research Initiative (RHF-CRI)
2. the name of the lead institution
3. the name of the project leader
4. the project leader's CFI PIN number[2]
5. the project leader's CIHR PIN number[3]
6. the estimated total project cost
7. the amount requested from the CFI
8. the amount requested from CIHR
9. five (5) keywords describing the project
10. if an RCT will be part of the application

The Project Outline must follow the following formatting guidelines:

Attached documents may be prepared in the word processing software package of your choice, printed and included with the application form. Failure to follow these guidelines may result in the administrative withdrawal of the Project Outline.

- Documents can be prepared with the word processing software of your choice, using only letter size (21.25 X 27.5 cm / 8.5" X 11") white paper for all attachments
- Print on one side of the paper only. A font size of 12 point, black ink. Six lines per inch. No condensed type or spacing.
- A minimum margin of 2 cm (3/4 inch) around the page is mandatory.
- Observe page limitations, additional pages may NOT be added unless specified.
- Photocopies must be single-sided.

***Access to Information Act and Privacy Act*, and the *Personal Information Protection and Electronic Documents Act* (PIPEDA)**

---

[2] To obtain a **CFI PIN** the project leader must register on the CFI web-site (https://www2.innovation.ca/pls/fci/FCIEN.base). A researcher may only have one PIN in the CFI database. If you already have a PIN, then you should use it. If you have ever been part of a previous application to the CFI or the Canada Research Chairs, then you probably already have a PIN. If you wish to find out if you are already registered, you can contact the CFI (*pin.nip@innovation.ca)* with your name, research institution and department. We will respond to the query by the next business day.

[3] To obtain a CIHR PIN, the principal applicant must register on CIHR web site at https://cihr-irsc.fcar.qc.ca/pls/crm/CRMEN.inscrip . You will have to login to the PIN form screen to request a PIN and create a password. This is an on-line submission. You will be notified by e-mail within one working day of submission when CIHR has granted you access to web forms. If you are an existing CIHR client, you will have to enter your PIN, and your password.

Your PIN is your unique identifier, and remains active for the duration of your association with CIHR. One working day is typically required to process PIN requests; however, longer processing times may be required during peak periods. If you previously registered and have forgotten your PIN or Password do not re-register. Instead, refer to the Search for PIN or Password page or contact the CIHR Information Desk for assistance at 1-888-603-4178 (option 1) or by e-mail at pin-nip@cihr-irsc.gc.ca.

Each time you wish to log into the system, you will need your CIHR PIN as well as the password you have created. We suggest that you write down your PIN and password and keep them in a safe place. (Please note: the system is case sensitive).

All personal information collected by CIHR and the CFI about applicants is used to review applications, to recruit reviewers, to administer and monitor grants and awards, to compile statistics, and to promote and support health research in Canada. Consistent with these purposes, applicants should also expect that information collected by CIHR may be shared as described in Use and Disclosure of Personal Information Provided to CIHR for Peer Review and in CFI's "Collection, Use and Disclosure of Personal Information".

CIHR and the CFI are subject to the Access to Information Act and the Privacy Act, therefore the requirements of these two statutes will apply to all information under CIHR's and CFI's control including, without limitation, cost-sharing agreements related to this Call for Project Outlines and all matters pertaining thereto.

Send the completed Project Outline package by courier to:

RE: "National/Regional Clinical Research Initiatives - Joint CFI/CIHR Call for Project Outlines"
Clinical Research Initiative
Canadian Institutes of Health Research
Room 97, 160 Elgin Street
Address locator: 4809A
Ottawa, Ontario K1A 0W9

Contact Information

For questions on this initiative, contact:

Julie Senécal
Clinical Research Initiative
Canadian Institutes of Health Research
Telephone: (613) 941-0057
Fax: (613) 954-1800
Email: cri-irc@cihr-irsc.gc.ca

What is the Review Process for Project Outlines?

Assessment Criteria

In reviewing the project outlines, the CFI and CIHR will apply the following three criteria:

1. **Quality of Research and Need for the Requested Infrastructure and/or Appropriateness of the Existing Infrastructure**
   - Quality, innovation and transformative potential of the research that could not be performed under existing programs;
   - Feasibility and sustainability of the proposed research plan and how it has the potential to generate valid, reliable and useful knowledge;
   - Evidence of the expertise, talent, and experience of the team in conducting high quality clinical research;
   - Where applicable to the type of research proposed, evidence that the proposal takes into account the social, ethical, cultural and environmental factors surrounding the research problem;

- Appropriateness, effectiveness and efficiency of the requested and/or existing infrastructure in supporting the proposed research, housing equipment, or bringing researchers and highly qualified personnel together;
- If there is construction involved, the likelihood that the construction of the facility will start within 18 months of the official decision announcement;
- Evidence that the infrastructure requests is not a limiting factor to implement the research program and that the research programs can begin within 12 months of the official decision announcement.

2. Contribution to Strengthening the Capacity for Innovation

- Build regional or national capacity for innovation and excellence in clinical research and for international competitiveness;
- Create stimulating and enriched environment for training clinical researchers and other highly qualified personnel and to support high quality clinician-scientists;
- Strengthen multidisciplinary approaches, collaborations among clinician-researchers, and collaborations or partnerships with other institutions and sectors to allow for better research, knowledge translation, and technology development, and for a more effective and efficient use of available resources.

3. Potential for Impact - Benefits of the Research to Canada

- Importance of the health problem being addressed;
- Generate knowledge that can be translated into improved health for Canadians, more effective Canadian health services and products, and a better Canadian health care system;
- Contribute to job creation and economic growth in Canada.

To be invited, a proposal must satisfy all three criteria to a degree appropriate to the size and complexity of the proposal.

Review Process for the Project Outlines

CIHR and the CFI will undertake a joint review of the project outlines to select those that show the most promise, and invite full proposals. To do this review, the agencies will convene an International Assessment Committee, with broad expertise in clinical research and clinical research management. In addition, the CFI and CIHR will strive to achieve a balanced representation of gender, region and research sector. Collectively, the Committee will be competent to review applications in both official languages.

In order to maximize the opportunity for the creation of national/regional clinical research infrastructure across the country and range of health issues, and to encourage promising applications in common research areas to collaborate together, it is possible that consultations with individual institutions will be initiated following the review of the Project Outlines.

The institution and project leader will be informed of the outcome of the review process.

Full Proposals

The requirements for the full proposal will be similar but more detailed than the evaluation criteria described in the project outline. The following additional evaluation criteria are provided as they can influence decisions to apply:

1. Evidence of alignment with the hospital Strategic Research Plan;

2. Partnership Support, including provincial support;
3. The sustainability of the clinical research infrastructure reflected in a business plan; and,
4. Randomized Controlled Trial (RCT) requirements: For each RCT, a project outline shall be submitted to CIHR on August 1st 2007 (consult the Competition Deadline Schedule for Randomized Controlled Trials Program).

All further details regarding the full applications will be found in the electronic form and in the accompanying instructions.

Institutions that submit applications to both this Call for proposals and the Large-Scale Institutional Endeavours component of the Research Hospital Fund will be asked to reference their Large-Scale Institutional Endeavours in a specific section of the application form for Regional/National Clinical Research Initiatives (RHF-CRI) and vice versa.

What is the Review Process for the Full Proposals?

Assessment Criteria

In reviewing the full proposals, the CFI and CIHR will apply the following three criteria:

1. **Quality of the Research and Need for the Requested Infrastructure and/or Appropriateness of the Existing Infrastructure**
   - The quality, innovativeness and transformative nature of the proposed clinical research research;
   - Where applicable to the type of research proposed, evidence that the proposal takes into account the social, ethical, cultural and environmental factors surrounding the research problem;
   - Evidence of the expertise, talent, and experience of the team in conducting high quality clinical research;
   - Appropriateness, efficiency and effectiveness of the requested and/or existing infrastructure for the proposed research, and for the development of enhanced integrated facilities;
   - If there is construction involved, the likelihood that the construction of the facility will start within 18 months of the official decision announcement;
   - Evidence that the infrastructure request is not a limiting factor to implement the research program and that the research programs can begin within 12 months of the official decision announcement.

2. **Contribution to Strengthening the Capacity for Innovation**
   - The project's potential for building regional or national capacity for innovation and for international competitiveness in health research along with expected increased needs for additional clinical research funding;
   - The potential of the project to create a stimulating and enriched environment for training researchers in clinical research and other highly qualified personnel, and to support high quality researchers in clinical research;
   - The research excellence of the Mentors, and their success in training researchers in clinical research;
   - The project's potential for raising the national standard for best practices in training and dissemination of curriculum materials in clinical research;
   - The capacity of the project to strengthen multidisciplinary collaborations among clinician-researchers, and collaborations or partnerships with other institutions and sectors to

allow for better research, knowledge translation, and technology development, and for a more effective and efficient use of available resources;
- The effectiveness of the management, operation and maintenance of the clinical research infrastructure on an ongoing basis;
- The sustainability of the clinical research infrastructure reflected in a business plan.

3. Potential Benefits of the Research to Canada

- Importance of the health problem being addressed
- The project's potential for translating research results into improvements to the health and quality of life of Canadians, including the creation of policies and practices, more effective health services and products and a better health care system;
- The project's potential for contributing to job creation and economic growth.

To be funded, a proposal must satisfy all three criteria to a degree appropriate to the size and complexity of the proposal.

Review Process

The CFI and CIHR will undertake a joint review of full proposals. A core of members of the original international Assessment Committee that reviewed the project outlines will review the full proposals. New members will be added to the Committee to ensure that its expertise is appropriate and complete.

As mentioned above, the Assessment Committee will also take into account the following factors in its evaluation of the proposals

1. the Strategic Research Plan of the institution;
2. evidence of support from partners, including provinces;
3. the sustainability of the clinical research infrastructure reflected in a business plan; and,
4. CIHR Randomized Controlled Trial (RCT) project outline peer review committee recommendations.

The Assessment Committee recommendations will transmit a single recommendation on each proposal to the CFI and CIHR.

How Will the Decisions Be Made?

The CFI Board of Directors and CIHR Governing Council will make the final decision for each proposal. The final decision could be for full funding, partial funding or no funding.

Summary comments will be provided to the institutions for all proposals.

Please refer to Annex C for CIHR Conditions of Funding.

ANNEX A

The CFI and CIHR challenge institutions and their investigators to consider non-traditional models and/or combinations of traditional/non-traditional models to best meet the overall objective of enhancing clinical research through multidisciplinary and collaborative approaches.

Following extensive consultation by CIHR, some types of infrastructure have been identified by the clinical research community and are provided below. However, it is recognized that the required infrastructure needs may potentially be addressed by other models and/or combinations of those outlined below. The CFI and CIHR wish to maximize the likelihood of capitalizing on innovation and opportunity as conceptualized by investigators, hospitals, and provinces. Accordingly the CFI and CIHR will consider proposals for clinical research infrastructure that are different from those outlined below, as long as they are consistent with the principles of the initiative.

1) Clinical Research Networks

A well defined multicentre interdisciplinary Network focused on a specific disease area hosted at a specific Institution and lead by an outstanding researcher with collaborators across a region or across Canada. This Network would focus on the development of innovative diagnostic suites, taking advantage of accumulating biobanks, to be used in evaluating new therapies and patient responsiveness. This Network would incorporate innovative training programs for future leaders in clinical research and would develop new biostatistical methodologies.

2) Clinical Research Centres
Nationally/regionally networked centres that will be located within research hospitals and that will have the capacity for excellent clinical research, including all phases of clinical trial development, training, and knowledge translation.

These centres will have the necessary infrastructure and critical mass of clinical researchers to enable leading-edge advances of national and international impact. Depending upon regional strengths and opportunities, some centres with strong basic biomedical research will focus on translational research, facilitating Phase 1 and 2 clinical trials. Others will have close interactions with health care systems/services and population health research. Regional hub-and-spoke relationships will broaden the reach and influence of each centre, which will be networked with other clinical research centres across the country.

This Canadian model will incorporate some of the philosophy of the US' National Institutes of Health (NIH) General Clinical Research Centres and specialty clinical research centres, but will be more oriented to the future of clinical research (multidisciplinarity: crossing all 4 themes of biomedical, clinical, health systems/policy and population health; and engagement of the community and referring centres) and its interactions will extend regionally and nationally. A key feature of these research centres will be technologically and organizationally state-of-the-art networking which links the centres and dramatically increases the critical mass of Canada's clinical research endeavour. CIHR will support the new Leaders in clinical research in each centre. There will be a requirement for programs of knowledge translation as an important part of the mission of each Centre.

3) Clinical Research Technology Platforms

Examples of such Platforms include clinical trials methods centres and cutting edge tissue/databanks with linked molecular and imaging platforms which position Canada to become a global leader in clinical research. These platforms would offer technology support to research

projects funded by CIHR and others on a cost-recovery basis. Formal networking, clinical research training, and knowledge translation would be integral to these technology platforms. The salary support of highly qualified personnel (e.g., biostatisicians for clinical trial method centres) will be available through this model. At least two general types of technology platforms are needed:

- **Methods centres** provide clinical trials support (protocol development, case report forms, data management, reports and analysis, regulatory advice, and management);
- **Wet and dry human data banks** are concerned with the collection, curation, and management of secure, high-quality, ethically appropriate, and readily available data. These platforms would provide tissue and serum repositories with standard collection and storage procedures, and modern analytical and diagnostic capabilities. The establishment of such infrastructure is at a very preliminary stage in Canada and yet the availability of standardized human biologicals and other data is vital to modern clinical research.

Annex B

Schedule for the two RHF competitions

Call for Proposals
(Clinical Research Initiatives + Large-Scale Institutional Endeavours)

Mid-February, 2007

Clinical Research Initiatives	**Large-Scale Institutional Endeavours**
Project Outlines ***April 16, 2007***	
Review by AC ***Week of May 28, 2007***	
Invitations for full proposals ***By middle of June 2007***	
Randomized Controlled Trials (RCT) *Outline submission to CIHR* *August 1, 2007*	Notifications of Intent ***April 20, 2007***
	Full proposals ***September 11, 2007***
Full proposals ***Week of October 9, 2007***	
RCT Outline CIHR Peer Review *December 2007*	Expert Review ***Oct. to Dec. 2007***
CIHR/CFI AC ***Week of January 28, 2008***	
	IAC ***Week of February 11, 2008***
CIHR Governing Council and CFI Board decisions ***Early March 2008***	
Announcement of results ***March 2008***	
RCT Registration Deadline to CIHR *August 1, 2008*	
RCT Full applications to CIHR *September 1, 2008*	
RCT Notification of Decision by CIHR	

ANNEX C

CIHR Conditions of Funding

All conditions specified in CIHR General Grants and Awards Policies shall apply to applications funded through this competition. Conditions cover areas such as Applicant and Institutional Responsibilities, Ethics, Official Language Policy, Access to Information and Privacy Acts, and Acknowledgement of CIHR Support. Successful applicants will be informed of any special financial conditions prior to the release of funds or when they receive CIHR's Authorization for Funding (AFF) document.

Access to Information Act and Privacy Act, and the *Personal Information Protection and Electronic Documents Act* (PIPEDA)

All personal information collected by CIHR about applicants is used to review applications, to recruit reviewers, to administer and monitor grants and awards, to compile statistics, and to promote and support health research in Canada. Consistent with these purposes, applicants should also expect that information collected by CIHR may be shared as described in Use and Disclosure of Personal Information Provided to CIHR for Peer Review.

CIHR as a federal entity is subject to the Access to Information Act and the Privacy Act, therefore the requirements of these two statutes will apply to all information located in CIHR's premises including, without limitation, cost-sharing agreements related to this Request for Applications and all matters pertaining thereto.

While respecting the application of the Privacy Act to federal entities, all signing parties involved in a collaborative agreement will also be bound by the Personal Information Protection and Electronic Documents Act (PIPEDA). All personal information (as identified by the PIPEDA) collected, used or disclosed in the course of any commercial activity under collaborative agreements related to the Request for Applications will be collected, used and disclosed in compliance with the PIPEDA.

Communications Requirements

In addition to following the policies relating to the Acknowledgment of CIHR's Support, National/Regional Clinical Research Initiatives (RHF-CRI) grant recipients will also be required to adhere to special branding requirements as a condition of receiving a National/Regional Clinical Research Initiative (RHF-CRI). The official name is "CFI-CIHR Clinical Research Initiative in (area of research)." In cases where there is another major funding partner a shared title should be considered. The format of a shared title is " CFI-CIHR/(partner name) Clinical Research Initiative in." The name must be used in all communication and promotion relating to the National/Regional Clinical Research Initiatives (RHF-CRI). A team name must be proposed as part of the application for a National/Regional Clinical Research (RHF-CRI). Successful applicants and their host institutions will be required to agree in writing to proper use of the name as well as the CIHR and CFI logos on appropriate communications materials such as brochures, letterhead, publications and media materials. Recognition guidelines, including instructions on logo use, will be provided to successful applicants as part of the approval package.

Monitoring, Performance Measurement and Evaluation

CIHR is committed to demonstrating results to Canadians for the money invested in health research. Therefore, processes for monitoring progress and appropriate use of funds, as well as for performance measurement and program evaluation are in place. As a result, grant recipients must:

- adhere **CIHR's** reporting requirements and provide required information in a timely fashion. **Grantees are required to submit an annual Progress Report describing the progress made since the start of the grant.** CIHR will cancel the last 12 months of the grant if the progress is unacceptable and will cancel the final two years of the grant if it does not receive a report by the dates requested. **Details about the Progress Reports will be provided to the grant recipients along with their Notification of Award.**
- 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;
- encourage their associates, trainees and administration to participate in the monitoring, review and evaluation of CIHR's programs, policies and processes as required.