

Ministry of Health and Long-Term Care Drug Innovation Fund

Request for Letters of Intent For The 2008/2009 Review Cycle

Key Milestone Dates	
May 15, 2008	Anticipated Posting of Call for Letters of Intent (LOI)
June 30, 2008	Letter of Intent must be received by this date.
September 2008	First Peer Review Panel Meeting to Discuss LOI Evaluations & Funding Recommendations
Mid October 2008	Anticipated Notification Letters Sent to Researchers re LOI Decision
December 1, 2008	Full Research Applications Must be Received by This Date.
February 2009	Peer Review Panel Meeting to Discuss Full Research Proposal Evaluations & Funding Recommendations
Beginning of March 2009	Anticipated Notification of Final Funding Decisions to Researchers
Before End of March 2009	Anticipated Funding Start Date.
Background	
<p>In 2007, the Ministry of Health and Long-Term Care has established the Drug Innovation Fund - an annual fund of \$5 million dollars to provide Ontario researchers (including patient groups, employers and professional associations) with stable, long-term funding needed to perform systems outcomes research and prove the value of medicines in delivering expected health outcomes.</p> <p>Funding will be provided to Ontario researchers and relevant organizations through the Drug Innovation Fund to perform evidence-based research that will demonstrate the impact of drugs on patient outcomes and health system outcomes (i.e. non-drug expenditures) within Ontario's health care system. It is intended that the research support drug policy decision making in the province.</p> <p>To inform evidence-based policy making, improved "real-world," population-based evidence is needed on the impact of drug utilization on costs and outcomes. Greater evidence is required with regard to the impact of the use of new drugs (those recently approved for marketing and sale) on both patient and health system outcomes related to the treatment of a particular condition within a patient population. Innovative methodologies are needed to conduct such evaluations and greater use of public, administrative and private data sources is required.</p> <p>Short-term and multi-year funding for literature reviews, environmental scans, short and multi-year projects, will be provided to eligible researchers and organizations in Ontario to support evidence-based research on the impact of drugs on patient outcomes and health system outcomes (including non-drug expenditures) in Ontario in order to support drug policy decision making in the province. Capacity building and knowledge transfer are also important objectives of the Fund.</p> <p>In an effort to drive innovation, the ministry has not defined funding ceilings for an initiative but the project terms are flexible but should not exceed 3 years. Renewal opportunities may be available.</p>	
Purpose	
<p>Through the <i>Transparent Drug System for Patients Act</i> (formerly known as Bill 102), the Ontario Government has committed to provide annual funding for innovative health system research through the establishment of the Drug Innovation Fund.</p>	

The mandate of the Drug Innovation Fund is to:

- Generate strong, high-quality, independent scientific evidence on the impact and value of new and existing drugs across the healthcare system, by linking drug interventions to health or system outcomes.
- Support linkages between researchers, clinicians and drug policy decision makers to ensure the timely and effective application of relevant evidence-based scientific information and to support the objectives and priorities of the Ontario Public Drug Programs.
- Support and develop research capacity in the area of drugs and health outcomes in Ontario.

The scope of the Drug Innovation Fund is to:

- Provide funding for targeted drug-related research projects.
- Provide stable, long-term funding to Ontario researchers/academics and other relevant organizations (including but not limited to patient groups, professional associations, etc.) to perform research into the impact of drugs on patient outcomes and/or non-drug health expenditures (inpatient hospital expenditures, ambulatory care, physician visits, etc.), as a tool to evaluate the potential costs of funding new drugs and programs.

Research Themes

Areas of focus to determine the impact of drugs on health outcomes, non-drug health system outcomes and costs could include:

Impact of Drug Access and Utilization

- Assess the association between the use of drugs, and health outcomes, health system outcomes (including non-drug expenditures).
- Assess the impact of the use of newer drugs (for a particular health condition) on:
 - patient health outcomes (e.g., reduced risk of complications, improved survival)
 - health system outcomes (e.g., inpatient hospital stays, ambulatory care, home care and associated costs)
 - cost (i.e., the impact on the overall cost of treating a given disease)
 - cost effectiveness / cost benefit (i.e., a comparison of drug costs to outcomes or potential cost savings in other parts of the healthcare system)
- Assess the relationship between the number of drugs a patient has access to and drug age (the length of time a drug has been on the market since approval) on health outcomes and other (non-drug) health expenditures, including hospital costs.
- Evaluate health outcomes and costs among those with differential access to newer drugs through private and public drug plans or for those with no drug coverage.
- Evaluate the impact of drugs compared to other non-drug approaches such as multi-disciplinary care, best supportive care, etc.

Optimal Use of Drugs

- Determine the factors that impact on safe, appropriate, and effective drug use.
- Assess the infrastructure and organizational influences on optimal drug use.
- Determine effective ways to improve prescribing and patient safety related to prescription drugs, including physical, procedural, behavioural, technical and system innovations.
- Develop methods for uptake of best practices among healthcare providers.
- Identify key sources of influence in patients' decisions to seek a prescription drug, including the influence of direct marketing efforts such as direct-to-consumer advertising, toll-free lines, patient forums and patient support groups, free equipment (pens, monitoring devices, etc.), third-party support for accessing public or private coverage, etc.
- Assess the impact of disease management programs (e.g., for asthma, hypertension or diabetes) and/or direct pharmacist involvement in drug therapy on patient and system outcomes and other (non-drug) expenditures.

Drug Adherence

- Evaluate adherence among those with differential access to prescription medications.
- Assess the impact of financial barriers on drug adherence.
- Assess the impact of drug non-adherence on healthcare costs and health outcomes – including disease-related work-day absences and disabilities – and on other healthcare-related expenditures.
- Assess the causes of poor adherence in the treatment of chronic conditions, including the impact of limited access to certain drugs, side effects, ineffective therapy.

Eligibility

Applicant(s) must be a permanent resident(s) and Canadian citizen(s) with an appointment at, or affiliation with an Ontario post-secondary institution.

To be eligible to receive a research grant, an organization must fall into one of the following categories:

- An *Ontario post-secondary institution or an affiliated institution (including hospitals and research institutes);
- *Ontario non-governmental not-for-profit health sector organisations (including community or charitable organisations) with a mandate that clearly includes knowledge transfer;
- Any other not-for-profit corporation, municipality, Indian Band and agency board or commission if their research or research-related activities are consistent with the goals of the ministry.

The ministry does not provide funding to private or for-profit corporations or organizations except in the following circumstances:

- The corporation or organization is part of a team that includes at least one Ontario non-profit organization or academic researcher.
- The corporation or organization provides matching funds.
- Sponsoring organization must be an eligible institution as outlined above.

*Note: At least one primary investigator must be affiliated with an Ontario institution/organization.

Allowable Costs

Category	Eligible Costs	Ineligible Costs
Personnel Services	<ul style="list-style-type: none">• Direct salaries and wages of researchers• Direct salaries and wages of secretarial, administrative and technical support staff• Benefits equivalent to levels at sponsoring organisation <p><u>Note:</u></p> <ol style="list-style-type: none">1) Personnel costs must be deemed necessary to further the objectives of the research.2) Salary requests should parallel those paid to similarly classified persons at the sponsoring organisation.3) Personnel paid from the grant are not employees of the ministry.	<ul style="list-style-type: none">• Salary & benefit costs of the principal investigator• faculty release time

<p>Supplies and Services</p>	<p>Operating costs such as:</p> <ul style="list-style-type: none"> • Stationery • Postage/ courier expenses • Telephone/ fax charges • Printing/ photocopy charges • Cell phone charges (where necessary for data collection) • Repair and maintenance costs of computers (e.g. annual maintenance contracts) • Compensation for overhead or indirect costs (sometimes referred to as 'Facilities and Administrative/ Service Costs' which are the costs of providing facilities and infrastructure required to perform research), up to 20 percent. <p><u>Note:</u></p> <ol style="list-style-type: none"> 1) Supplies and services must be reasonable and deemed necessary to further the objectives of the research. 2) Supplies and services shall be acquired through a competitive process, determined by the recipient and sponsor that ensure the best value for funds expended. 3) It is the expectation of the ministry that overhead or indirect costs will be the responsibility and considered the contribution of the sponsoring organisation. 	<ul style="list-style-type: none"> • Costs associated with maintaining and operating physical facilities e.g. rent for office/ laboratory space, heat, light/ electrical power utilities etc • Support Facility costs such as libraries, computer networks • Project administration costs such as accounting, technology transfer offices
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<p>Equipment</p>	<p>Capital expenditure on minor research related equipment such as:</p> <ul style="list-style-type: none"> • Office equipment directly required for the project which are not provided by the sponsoring organisation. These may include purchase costs or lease rental costs whichever is more cost effective. Example fax machine, photocopier, printer, telephone, etc • Software and software development costs if directly required for the project • Hardware costs such as purchase/ lease of desktops or laptops required directly for the project which are not provided by the sponsoring organisation <p><u>Note:</u></p> <ol style="list-style-type: none"> 1) Equipment & computers shall be acquired through a competitive process, determined by the recipient and sponsor that ensure the best value for funds expended. 2) Assets acquired with ministry funds for the purposes of conducting research belong to the sponsor. 3) At the end of the funding period the sponsor retains ownership of the asset provided the asset continues to be used to further approved research within the sponsoring organisation. If the sponsor sells the asset, the resulting funds must be reinvested in approved research-related activities. 4) During the funding period the recipient and sponsor shall not, without the ministry's prior written consent sell, lease or otherwise dispose of any assets purchased with the funds, the net book value of which exceeds \$5,000. 	<ul style="list-style-type: none"> • Renovations • Office Furniture • Capital expenditures
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Travel	<p>Travel costs such as:</p> <ul style="list-style-type: none"> • Road/ rail/ air travel for off-site conferences • Field work travel • Accommodation and meal costs for off-site travel <p><u>Note:</u></p> <ol style="list-style-type: none"> 1) Travel expenses must be reasonable and deemed necessary to further the objectives of the research. 2) Travel must be claimed at the lowest rate available not to exceed full fare economy. <p>Good judgement must be exercised while selecting hotel/ motel accommodation and incurring meal expenses.</p>	
Other	<p>Details of other necessary expenditures not captured by the above categories such as:</p> <ul style="list-style-type: none"> • Research dissemination costs (e.g. article dissemination, workshops, seminars, newsletters, website etc.) • Legal fees directly related to the project • Audit costs • Consulting and other services • Honoraria (e.g. guest lecturers) <p><u>Note:</u></p> <ol style="list-style-type: none"> 1) 'Other' expenses must be reasonable and deemed necessary to further the objectives of the research. 2) Honoraria should not exceed the limits as specified in the ministry's guidelines on 'Government Appointees'. 	Entertainment & hospitality costs.

Please complete a proposed budget using the ministry's template, which can be found at: http://www.health.gov.on.ca/english/providers/ministry/grants/hrp_07/gen_templates.html

Review Process and Evaluation Criteria

Eligible Letter of Intent (LOI's) and full applications will be evaluated by a specifically-constituted, multidisciplinary, independent and impartial Peer Review Panel designed specifically to review proposals for research received under the Drug Innovation Fund. Presently, the Joint Academic and Relevance Review Panel consists of 9 members (including the Chair). These members include experts in the drug therapy, pharmaceutical field, researchers/decision makers, as well as industry and a patient representative.

When the review of LOI's will be completed, selected applicants will be notified in writing to submit a full application by the deadline date.

Terms and Conditions

The ministry will provide the successful candidates with funds to support expenses for the award period in accordance with the following conditions:

All material produced by successful candidates and all copyright and other intellectual property rights in that material shall belong to the award recipient and the sponsoring organization.

The award recipient and the sponsoring organization grant to the Ministry of Health and Long-Term Care and to each and every Local Health Integration Network (LHIN), the right to use, for government purposes, without cost, any and all material of any kind produced by grant, including the right to copy and distribute such material as the Ministry and each LHIN respectively, considers appropriate, and to post such Material on a website accessible by the Ministry and by each and every LHIN.

The award recipient and the sponsoring organization shall notify the Ministry of the anticipated date of publication of any material at least 30 days before such material is published.

The award recipient and the sponsoring organization shall acknowledge the support of the Ministry of Health and Long-Term Care in all reports and materials and in all advertising and publicity relating to the grant, in a format approved by the Ministry.

The award recipient and the sponsoring organization shall ensure the acknowledgement in any report or materials indicates that the views expressed in the report or materials are the views of the award recipient and the sponsoring organization and do not necessarily reflect those of the Ministry of Health and Long-Term Care.

The Ministry shall be entitled to disclose the name of the award recipient and the sponsoring organization any general information about the grant in Ministry forums and publications.

The award recipient and the sponsoring organization will be required to make a full disclosure of all funding being received from other sources (e.g., foundations, private sector organizations, non-profit organizations, etc.) and academic/professional affiliations.

Monitoring, Performance Measurement and Evaluation

The Ministry of Health and Long-Term Care is committed to demonstrating results to Ontarians 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.

Application Process

The application process is comprised of two steps: 1. Letter of Intent (LOI) and 2. Full Application.

1. Letter of Intent (LOI):

In the first stage of the application process, the nominated principal applicant is required to email an electronic copy (MS WORD format) of the LOI, and mail the original Letter of Intent along with 14 copies (double sided, stapled and three-hole punched) by courier, to:

Orest Sporniak
Senior Program Analyst
Ontario Public Drug Programs
9th Floor, Hepburn Block
80 Grosvenor St., Queen's Park
Toronto ON M7A 1R3

General Format

- Times New Roman 12 point font must be used. Condensed type is not acceptable.
- Text must be single-spaced, with no more than six lines per inch. Margins must be at least 1-inch.
- Funding amounts should be in Canadian dollars, with no cents.
 - Observe all restrictions on the amount of information or number of pages indicated in the relevant sections of the Application Form.
- Use clear language and avoid technical jargon.

The LOI must include:

a) The Investigator/Institution Information

- Research Funding Project Title
- Primary Investigator(s) name(s), title(s) and contact information
- Applicants/Co-Applicants name(s), title(s) and contact information
- Sponsoring Institution information
- Name and contact information of institutions signatory(s)

b) Plain language Summary

Using no more than 250 words, describe your research; state the issue that your research addresses; how will your research address these issues; and how this research will benefit the Ontario health care system.

c) Proposal:

In a maximum of five pages (not including references). Provide a detailed but concise description of the proposed research. Describe the purpose of the proposed research, outlining your research direction and objectives within the context of the current state of knowledge in the field. Describe your proposed research activities, outlining your plans and methodological approaches.

Also include:

- The nature of the PI and extent of collaboration between investigators, with an explanation of the anticipated value added to the research program through the synergy of the PI (why this cannot be funded through one or more operating grants).
- The capacity of the PI to carry out the program of research proposed.
- The preliminary plan for the research program and schedule of work.
- The nature and extent of the host institutions' financial and other forms of long-term commitment to the PI's research, and to ensuring a favourable environment for carrying out the research activities.
- A brief description of the importance and novelty of hypotheses or questions to be addresses and expected findings.
- The plan, including proposed organizational structures for engaging and linking with those who will ultimately use the research findings.
- The research training and mentoring environment that will provide a superior experience for undergraduate, graduate and/or post-doctoral trainees, including those with a health professional background.

If the PI's team involves partners:

- The proposed roles of partners in the planning and execution of the research program and the dissemination and utilization of the research results.

d) Attachment:

- A brief curriculum vitae (maximum two pages per applicant) for a maximum of five of the key applicants, including the PI(s). This must include information on grants held (source, type, title, amount/yr, duration), relevant publications from the last five years, and 5-10 expertise keywords. Full CV s will not be considered.
- A one-page request must be submitted with the LOI, outlining the activities for which the development grant will be used, plus a one-page budget description.
- Reference list

Please email an electronic MS WORD file of the LOI to Orest.Sporniak@ontario.ca, and mail the original Letter of Intent along with 14 copies (double sided, stapled and three-hole punched) by courier to:

Orest Sporniak
Senior Program Analyst
Ontario Public Drug Programs
9th Floor, Hepburn Block
80 Grosvenor St., Queen's Park
Toronto ON M7A 1R3

2. Full Application:

Selected applicants will be invited to submit a full application. Details of the application procedure will be provided to those invited to apply. Information required will include a description of the individual components making up the Principal Investigator's research program, as well as the justification for supporting the synergistic aspects of the entire proposal. The review process may involve external reviews and/or a meeting of the PI(s) with sub-sets of the review committee, as appropriate.

For further information please contact:

Orest Sporniak
Senior Program Analyst
Ontario Public Drug Programs
9th Floor, Hepburn Block
80 Grosvenor St., Queen's Park
Toronto ON M7A 1R3
(416) 326-3141
Orest.Sporniak@ontario.ca

or

Esther Turner
Research Analyst
Research Unit
1075 Bay Street, suite 300
Toronto ON M5S 2X4
(416) 327-8365
Esther.Turner@ontario.ca