IMPACT - Child Health Award - Fall 2015

Full Application Guidelines and Submission Form

Background
Congratulations on the success of your LOI. This document describes the process by which to submit full IMPACT - Child Health Award proposals. In this form, applicants are asked to provide more detail about their research study including collaboration with and between Ontario Child Health SUPPORT Unit (OCHSU) and Ontario SPOR SUPPORT Unit (OSSU) Research Centres, patient engagement, study methods, and the budget.

IMPACT is an acronym for:
- Innovative
- Measurable
- Patient-oriented
- Appropriate
- Collaborative
- Transformative

IMPACT - Child Health Award is a new competition for patient-oriented child health research projects. This strategic award, directly aligned with Ontario’s Action Plan for Health Care, will support patient-oriented research projects and bring together diverse stakeholders – patients, clinicians, researchers, policy makers, knowledge users, industry and other health sector participants – to develop and implement research activities that improve child health outcomes and advance the health system. 

Note: the term “patient” is understood to include patients, caregivers, families and health consumers.

The purpose of the IMPACT - Child Health Award is to catalyze collaboration between researchers, patients, clinicians, policy makers, health system administrators, knowledge users, industry decision makers, and the OSSU Research Centres. Projects are expected to mobilize diverse groups in order to develop and implement interventions, programs, policies, or processes that have the potential to lead to large health impacts at both the individual and health system level.

General Guidelines

1. Projects must involve OCHSU and at least two other OSSU Research Centres. For information on OCHSU go to: http://www.ochsu.ca/. For information on OSSU Research Centres go to: http://ossu.ca/about-us/research-centres/ or see table on page 14 of this document.
2. Applicants must demonstrate the potential to conduct research that is patient-centred and has the potential to lead to improved patient health outcomes and health system functioning within a reasonable time period.

3. Patients must be involved in a meaningful way in the planning and conduct of the project. Applicants must describe how they plan to do this. The proposal must also highlight other stakeholder engagement, including knowledge users and industry partners where applicable. Stakeholder participation should reflect the social, cultural, linguistic and geographic diversity of Ontario.

4. Preference will be given to rigorous comparative research employing pragmatic trials or well controlled observational designs.

5. In planning their projects, applicants should consider the implications for equity in health system access and delivery.

6. Proposed budgets should be a maximum of $300,000 CAD total over 2 years. Research funds must be spent in Ontario.

Submission Format
The following format must be followed for all submitted applications – excess text will be deleted and not considered in the review process.

- 1-inch margins on all sides, letter sized paper (8.5” x 11”), in portrait format
- 12-point Times New Roman font with standard (non-compressed) character spacing
- Single line spacing
- Page numbers and last name of Principal Investigator in the footer for each page
- To reduce the amount of paper used in the review process, use the boxes provided and delete instructions in blue bold italic font and the first four background pages of this document prior to submission.

Full Application Submission Deadline
Applications must be submitted electronically to Impact.ChildHealth@sickkids.ca by 5:00 pm EST on February 29, 2016. Applicants will receive confirmation of receipt of their submission by the next business day.

Important Dates

<table>
<thead>
<tr>
<th>Event</th>
<th>Action</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification to proceed to full</td>
<td>Selected applicants receive notification via email</td>
<td>January 11, 2016</td>
</tr>
<tr>
<td>application</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strengthening Workshop</td>
<td>Applicants meet with OSSU Research Centres to formalize their</td>
<td>February 5, 2016</td>
</tr>
<tr>
<td></td>
<td>support</td>
<td></td>
</tr>
<tr>
<td>Full Proposal Submission Deadline</td>
<td>Applicants submit full application by email to: <a href="mailto:Impact.ChildHealth@sickkids.ca">Impact.ChildHealth@sickkids.ca</a></td>
<td>5pm EST; February 29, 2016</td>
</tr>
<tr>
<td>Review of Full Applications</td>
<td>International Panel of experts review applications</td>
<td></td>
</tr>
<tr>
<td>Award winners notified</td>
<td>Successful PIs notified by email</td>
<td>March 31, 2016</td>
</tr>
</tbody>
</table>
IMPACT - Child Health Award Review Criteria

Applications will be reviewed by an international expert panel. Evaluation of IMPACT - Child Health applications will be based on:

**Scientific Rigor:**
- Scientific excellence, whether quantitative, qualitative or mixed methods are employed. Applicants are encouraged to consult methodologists who are expert in the relevant fields.
- Demonstration of sufficient scientific merit to ensure that the study goals will be met, including a clear research plan with scientific methods guided (as appropriate) by input from OCHSU, Institute for Clinical Evaluative Sciences (ICES), Clinical Trials Ontario (CTO), Ottawa Methods Centre and Population Health Research Institute (PHRI) or other OSSU Research Centres.
- Quality of the research team based on experience, expertise, and productivity.
- An appropriate research environment sufficient to support the conduct of the project.
- Proposals submitted for pragmatic trials must meet the OSSU/ Pragmatic Trials Working Group requirements:
  - Overall, trials seeking support should be designed as pragmatic trials to inform decision-making and address existing knowledge gaps. These trials should answer important clinical, public health, or policy questions.
  - Trials will usually need to be multicenter, involving multiple recruitment sites in order to obtain sufficiently large numbers of units or participants to obtain reliable results and to enhance the applicability of the results.
  - Applications must engage OCHSU and a minimum of two other OSSU Research Centres.
  - Where appropriate, study proposals must discuss plans to foster broad stakeholder or community involvement in the project (from research, health systems, patient, decision-maker and stakeholder communities).

**Patient-centeredness and Patient Engagement:**
- Patients should be involved at all stages of the design and conduct of the projects, including:
  - As project planning team members involved in bringing forward priority issues for research and having input into values and ethical considerations.
  - In designing recruitment strategies (where relevant).
  - In the planning and delivery of knowledge translation and exchange activities.
  - In evaluating the success of the project upon completion.


**Relevance and Potential for Large Health Impacts:**
- Does the research question address an important gap in current knowledge and clinical practice?
- Has the outcome and intervention been identified as important by patients (including families, caregivers, health consumers)?
• Is the research likely to improve care and patient outcomes?
• Does the condition create a substantial burden by virtue of its frequency and/or severity?
• Does the evidence indicate the potential for a substantial benefit of the intervention relative to current practice at both the individual and population level?

**High Health System Impact:**
• What is the potential impact this research on current practice in the Ontario healthcare system?
• Could it result in a major change in current policy, thus improving practice and patient outcomes?
• Could widespread implementation result in significant cost savings?

**Knowledge to Action:**
• The extent to which IMPACT - Child Health Award projects would build on and support the knowledge translation and exchange of existing high quality evidence.
• The project should mobilize and promote direct involvement of diverse partners, including patients, clinicians, policy makers, health system administrators, and/or industry decision makers as true partners in its design and undertaking.
• The project should demonstrate that people representing the population of interest will suggest plans for knowledge translation and implementation activities.

**Potential for High Return on Research Investment:**
• Opportunities to leverage and capitalize on the OSSU platform and expertise of the 12 OSSU centres/networks and other groups with expertise across Ontario by including OCHSU and at least two other OSSU Research Centres. Where appropriate, studies should use ICES data (or other administrative datasets) for outcome determination.
• Consideration of health economic issues, where relevant. Research teams are strongly encouraged to include meaningful engagement with health economists.

**Contact Information**

For additional information or questions about the IMPACT - Child Health Awards, contact:

Donna Wilkes, MSc
Project Manager, Clinical Research Services
5262 Black Wing, The Hospital for Sick Children
Toronto, ON Canada. M5G 1X8
416 813 7654 ext 203390
donna.wilkes@sickkids.ca
1) Submission Registration Number (this is the number assigned to your LOI):

2) Descriptive title of IMPACT Award project (Use the exact title provided in the original LOI application)

   The title should include the innovation or intervention under study, the comparator, the populations and conditions being studied, and the methods employed.

3) Relevant Priority Area (select one)¹

   □ Prevention: focus on comparative studies of interventions designed to prevent serious illnesses and/or their complications, including the complications of treatment. The conditions selected should have significant impact on children and youth, their families and health systems.

   □ High burden child health care in the hospital, community and at home: focus on the effectiveness of different methods (including policies) of improving delivery and/or outcomes of care of children with high burden of illness including those requiring complex care. Targeted and integrated interventions should improve health outcomes, reduce the burden of caregiving on families, and decrease health care expenditures.

   □ Child health system integration, sustainability and patient safety: focus on comparative studies to better integrate the various components of the health system, reduce inappropriate health care and improve patient safety. Inappropriateness is present when there is a gap between evidence and practice – leading to over/under diagnosis and/or over/under treatment of disease.

4) Details of Applicants

Names and affiliation of Principal Investigator (PI) and Co-PI(s)

Note: The PI, and Co-PIs where applicable, must be from an eligible Ontario research institution; the PI must be affiliated with an Ontario institution that is eligible to receive funds from CIHR, such as an Ontario-based university, college, research-hospital or research institute.

¹ These priority areas have been established to align with provincial health priorities, as articulated in Ontario’s Action Plan for Health. http://www.health.gov.on.ca/en/ms/ecfa/healthy_change/. The priorities should be examined with recognition of the social, cultural, linguistic and geographic diversity of Ontario.
<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-PIs (if applicable)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a) Additional team members and co-investigators
   
   *Note: Additional team members and co-investigators can include individuals working inside or outside Canada; however, funds must be spent in Ontario. Insert additional rows if required. In this section, PIs should only list individuals who plan to work on the project at least weekly.*

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
<th>Contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5) Lay Summary

*In 400 words or less, provide a lay summary of the proposed research in non-technical terms. This must be written in plain language and should be tested for understanding by patients, families or caregivers prior to submission.*

6) Involvement of OCHSU and other OSSU Research Centres

*Projects must involve OCHSU and a minimum of two or more OSSU Research Centres (list of Centres and website URLs on page 14 of this document) in a meaningful way. The IMPACT – Child Health Award is intended to demonstrate the value of linking independent Research Centres and gaining synergies from their collaborative efforts. Indicate here which Centres you have approached and the nature of their involvement. At various points in this document you will be asked to show how OCHSU and the other OSSU Research Centres have been consulted and will be engaged in the planning and conduct of different aspects of this project.*
7) Engaging Patients

*In 400 words or less, applicants must state their commitment to patient engagement.*

**Note: the term “patient” is understood to include patients, caregivers, families and health consumers.**

Provide a description of the plan for engaging patients, families and caregivers over the course of the project.

*We ask that you build on the details presented in the LOI by providing a clear and concise justification of both the types of patients, caregivers and stakeholders that will be engaged and how those individuals will contribute to the research. This could include, for example, acting as project planning team members involved in bringing forward priority issues for research. They could be involved in: 1) choice of study design and selection of patient-relevant outcomes; 2) having input into values and ethical considerations; 3) designing recruitment strategies (where relevant); 4) the interpretation of the study results; 5) planning and delivery of knowledge translation and exchange activities; and 6) evaluating the overall success of the project upon completion and the need for further research. Refer to the section on Review Criteria of this document for examples of patient engagement frameworks.*

*You should consider patient involvement at each stage of your project. We appreciate that this will vary by the type of project and may not always be feasible. We ask if you could provide a clear justification for not including patients and other stakeholders at any applicable stage(s) of your project.*
8) Background and Main Project Summary

This section will be used to assess the clarity of the submission and the potential impact of the proposed project. It is very important that applicants provide thorough responses to the items below. In 1000 words or less, applicants should provide a compelling case for conducting the project:

- Summarize the contemporary evidence (literature and Ontario data) to identify knowledge and/or practice/policy gaps.
- Why is this project important and why now? Justify the project in terms of the topic being studied. Does the study have the potential to have a large impact – for example a substantial improvement in survival and/or quality of life for individual patients? Does the project have a potentially large public/health system benefit – for example evidence that the target condition(s) are common and create a significant burden, or that the intervention addresses an important gap or issue for vulnerable or special health needs sub-populations.
- Use the Population, Interventions, Comparisons, Outcomes and Time Frame (PICOT) framework to define your research question.
- Justify your selection of research design (See Methods section below).
- In what ways does the proposed research reflect the social, cultural, linguistic and geographic diversity of Ontario?

9) Methods

In 1500 words or less, describe and justify the study methods including:

- Show how the partnering OCHSU and other OSSU Research Centres have been engaged in the planning of the study.
- IMPACT - Child Health Award applicants should develop plans to foster broad stakeholder or community involvement (from patients, decision-makers and other stakeholders) in designing their studies.
- Study design and methods:
  - In the case of controlled observational studies, provide details of how you selected the study groups for comparison. Note that the study populations should be as inclusive as possible and reflect the social, cultural, linguistic and geographic diversity of Ontario.
  - Justify the choice of interventions /comparators (the two or more options being compared).
  - Justify the study outcomes, how they will be measured and show why they are important to patients and families (e.g. study design includes patient-
specified outcome measures).

- In the case of controlled observational designs, show how you intend to adjust for bias and confounding.

- In the case of pragmatic trials consider the following:
  - Trials will usually need to be multicentre, involving multiple recruitment sites in Ontario, to obtain sufficiently large numbers of units or participants, leading to valid, reliable, and applicable results.
  - Be clear about whether the unit of randomization is a single patient or some form of cluster (e.g. a family health team).
  - Be clear about the unit of analysis - is it the same as the unit of randomization?
  - Efficient designs should be considered (e.g. factorials).
  - Where possible, studies should use data from the Institute for Clinical Evaluative Sciences [ICES] (or other administrative datasets) for outcome determination.

- Provide the estimated sample size, along with a rationale for this, including underlying assumptions and any adjustments for clustering.

- Describe analytic plan and any pre-specified subgroup analyses.

10) Feasibility and Scalability

In 400 words or less address the following:

- Show that the intervention is feasible – in other words, if effective, it could be implemented within the Ontario health care system at reasonable cost.
- Show that the intervention is scalable – in other words, if successful, it can be delivered to the majority of patients who have the capacity to benefit.

11) Addressing Inequities

In 400 words or less, provide details of how the project will address inequities and how they will be addressed in the project. Potential topics to address include sex and gender; racial/ethnic groups; individuals with low socioeconomic status; individuals with limited English proficiency; lesbian, gay, bisexual, and transgender persons; residents of rural areas; and individuals with disabilities.

Applicants should identify major expected differences in prevention, or treatment effectiveness or in preferred outcomes across different patient populations and the Ontario healthcare system.
Applicants should also consider inequities in access to, and capacity to benefit from, public health and healthcare interventions. Applicants are invited to consult the CIHR's Gender, Sex and Health resource and the Ontario ministry's Health Equity Impact Assessment when developing sex and gender-based analysis in their proposals. If a sex and gender based analysis is not included in the project, applicants should provide a rationale as to why this is not applicable.

12) Working with Aboriginal Communities and Organizations

Work with Aboriginal communities, within the framework of the IMPACT-Child Health Award project, is encouraged. If relevant to your project, please show how you have consulted with the communities and/or representative organizations prior to submission of your application. Your proposed research must comply with the Tri-Council Policy Statement (TCPS 2) http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf and, in the case of First Nations, must respect the principles of Ownership, Control, Access and Possession (O CAP http://fnigc.ca/). It is preferred that communities are part of the research team. If this is not possible, it is important that the communities are involved and engaged in the project.

Note that access to First Nations and Métis identifiers on ICES data-sets is subject to special governance procedures. Any planned use of linked administrative data with First Nations or Métis identifiers must first be discussed with the organizations that oversee the governance arrangements (Chiefs of Ontario and Métis Nation of Ontario).

13) Ethics


14) Implementation Research and Knowledge Translation and Exchange

A major goal of IMPACT - Child Health Award projects is the promotion of research findings to all potential knowledge users and, where appropriate, to advance the science of implementation research and knowledge translation and exchange.

In 500 words or less, provide information regarding:

- How the project will include relevant stakeholders (including patients and families, clinicians, policy makers, health system administrators, all knowledge users and/or industry decision makers) as partners in the project. In the case of
patients, please also provide detailed answers under section 7.

- How you will engage with policy leads/decision makers within the sector.
- Whether your project will employ innovative methods to change provider practice/policy or patient behavior.
- The end of project knowledge translation plan, which must include health system, stakeholders and patients in particular.
- The names of any non-research organizations that plan to participate in the project.

15) Contribution to Capacity Building and Training

**In 400 words or less, provide detail regarding:**

- How the project will enhance knowledge and skills of researchers and their ability to work with other researchers with complementary expertise.
- How the project will enhance the knowledge and skills of researchers to work with patients and policy makers in the design and conduct of the proposed IMPACT-Child Health Award project.
- How the project will provide appropriate research training (particularly the ability to understand research rather than conduct it) to patients, health professionals and policy-makers.
- Any funds that will be allocated to graduate students or post-doctoral fellowships, noting that a minimum of two of these positions should be included in project budgets.

16) Prior Experience of PI and, Where Applicable, Co-PIs

*In 400 words or less, provide any relevant information about management of large research projects.*

17) Summary of Recent Research Performance of PI and, Where Applicable, Co-PIs

Provide links to accessible summary citation databases for the PI and Co-PIs (e.g. Google Scholar and/or ResearchGate).

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>[insert link]</td>
</tr>
<tr>
<td>Co-PIs (if applicable)</td>
<td>[insert link]</td>
</tr>
</tbody>
</table>

18) Budget
Provide the following details:

- The total direct costs and duration of the proposed project.
- Details of funding partnerships, including governments, non-governmental non-profit organizations and private for-profit industry.
- The names of any organizations or institutions that the applicants plan to list as subcontractors and/or partners on the project.

19) Leveraging Other Sources of Funding

In 100 words or less indicate:

- If there is intention to request funding for this project from other organizations.
- If external funding has already been obtained, please provide details (note justification in Section 18).

20) Timelines and Milestones

Provide:

- All planned timelines and perceived milestones/deliverables for the IMPACT-Child Health Award project.

21) Instructions for Letters of Support

Provide letters of support:

1. One letter of support from OCHSU and letters from at least two other OSSU Research Centres that you will collaborate with, detailing the support they will provide and how it will benefit the proposed project.
2. A fourth letter must come from the home institution of the nominated PI describing the support that will be provided to project (e.g. in-kind/financial support).

Letters of support must be signed and provided on the letterhead of the sponsor's organization. The information in the letters will be used to assess the extent to which the project objectives and identified activities will have an impact by addressing an important gap, need or opportunity related to the priority areas identified, as well as the extent to which the project will have a substantive and sustainable impact on health outcomes, practice, programs and/or policy within that priority area. And most importantly, they should demonstrate the value of linking appropriate independent research centres and gaining synergies from their collaborative efforts.
Signature of Principal Investigator

Date

Signature of Institutional VP Research (or equivalent)

Date
List of OSSU Research Centres and Contact Details:
OSCHU and a minimum of two OSSU Research Centres must be involved in the IMPACT - Child Health Award Project. Below are listed OSSU Research Centres and their respective websites for further information.

<table>
<thead>
<tr>
<th>OSSU Research Centre</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre for Rural and Northern Health Research</td>
<td><a href="http://www.cranhr.ca/">http://www.cranhr.ca/</a></td>
</tr>
<tr>
<td>Health System Performance Research Network</td>
<td><a href="http://www.hsprn.ca/">http://www.hsprn.ca/</a></td>
</tr>
<tr>
<td>Institute for Clinical Evaluative Sciences</td>
<td><a href="http://www.ices.on.ca/">http://www.ices.on.ca/</a></td>
</tr>
<tr>
<td>Ontario Brain Institute</td>
<td><a href="http://www.braininstitute.ca/">http://www.braininstitute.ca/</a></td>
</tr>
<tr>
<td>Ontario Child Health SUPPORT Unit</td>
<td><a href="http://www.ochsu.ca/">http://www.ochsu.ca/</a></td>
</tr>
<tr>
<td>Ottawa Methods Centre and Provincial KTE Network</td>
<td><a href="http://www.ohri.ca/programs/clinical_epidemiology/MethodsCentre/">http://www.ohri.ca/programs/clinical_epidemiology/MethodsCentre/</a></td>
</tr>
<tr>
<td>Population Health Research Institute</td>
<td><a href="http://www.phri.ca/">http://www.phri.ca/</a></td>
</tr>
<tr>
<td>Women’s College Hospital: Women’s Xchange</td>
<td><a href="http://womensxchange.womensresearch.ca/">http://womensxchange.womensresea</a></td>
</tr>
</tbody>
</table>