

FUNDING GUIDELINES

Health Research

Clinical Research,
Medical Education Research,
& Health Systems Research

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OVERVIEW

The PSI Foundation was established in 1970 by the physicians of Ontario with the original capital of Physicians Services Incorporated, the doctor-sponsored prepaid medical care plan. The Foundation was established with the mission of improving the "health of Ontarians." Physicians from across Ontario remain involved as members of the Foundation's House of Delegates as well as part of the governing board of directors for the Foundation.

PSI's granting interests are in two areas: education of practising physicians and health research with an emphasis on research relevant to patient care. The Foundation's support of health research is offered in the following four areas:

- Clinical research
- Medical education research at the post M.D. level
- Health systems research
- Healthcare research by community physicians (see separate guidelines and application form)

This document serves as the funding guidelines for the Health Research funding program offered by PSI in the areas of Clinical, Medical Education, and Health Systems research.

For the funding guidelines and applications for the Healthcare Research by Community Physicians or Resident Research funding programs, please visit the PSI website at https://www.psifoundation.org/funding-programs/

CONTACT INFORMATION

Please contact us at 416.226.6323 or by email at psif@psifoundation.org to discuss any questions you may have about submitting an application for funding.

Follow us on Twitter <a>@PSIFoundation and check our website at <a>www.psifoundation.org for the latest news and updates, such as updated application forms and policy revisions.



ELIGIBILITY OF APPLICATIONS

ELIGIBLE TYPES OF RESEARCH

- **Clinical Research** which is of direct relevance to patient care. Studies involving animals will be considered only if the animals are required as an immediate patient surrogate, which must be demonstrated in the written application.
- Medical Education Research which focuses on projects designed to assess through research in the post M.D. educational environment, such as curricula, methods and teaching resources. The Foundation recognizes that research within this area may involve teams that include non-medical researchers and consultants. Please note:
 - This funding stream is intended to support hypothesis driven research proposals; therefore, applications will only be considered for projects that evaluate curriculum, methods and teaching resources. Projects intended to create and/or develop curriculum, educational programs or tools will not be considered. Also, any costs attributed to the creation and/or development of curriculum, educational programs or tools will not be considered.
 - Research participants must be at the post M.D. level (e.g. residents) and cannot include undergraduate medical school students.
- Health Systems Research which focuses on projects of a special nature within the healthcare system, such as preventative medicine, care of the elderly, communications within the system, underserviced regions and ways of enhancing the effectiveness of medical practice.

Please note: Since PSI funds hypothesis-driven research, applications focusing on developing a tool or application must contain a strong research component. Applications lacking a strong research component may be deemed ineligible and not receive full peer and committee review.

INELIGIBLE APPLICATIONS

AREAS OF NON-SUPPORT & FUNDING EXCLUSIONS

Listed below are the areas and items which will not be accepted for consideration by the Foundation:

- Applications under PSI's areas of non-support:
 - PSI will not consider applications that focus on problems associated with cancer, heart & stroke, or pharmaceutical drug development studies. Rather, PSI allocates research funding to areas that may not have funding opportunities to the same extent as the areas listed above.
- Systematic reviews and meta-analyses
- Fund-raising campaigns
- Building funds or other capital cost campaigns
- Operating costs of any organization or department
- Budget deficits
- Membership fees
- Entertainment / hospitality costs
- Service programs
- Ongoing research
 - o PSI may consider/approve studies where very preliminary activities have started
- Major equipment, unless required for a research project being supported by the Foundation



- Projects where the Principal Investigator is located and/or the research is being completed outside the province of Ontario
- Films, books and journals

If you are unsure if a potential project falls into one of the above areas and items, then please contact the Foundation for guidance on how to proceed.

RESUBMISSION OF PREVIOUSLY DECLINED APPLICATIONS

Declined applications may be resubmitted to the Foundation one time only and must include a letter detailing how the external reviewer comments to the previously declined application have been responded to in the revised resubmission.

PSI's Grants Committee expects resubmitted protocols to be enhanced based on the feedback from the external peer review process and/or Grants Committee's comments.



ELIGIBILITY OF INVESTIGATORS

PRINCIPAL INVESTIGATORS/APPLICANTS

ELIGIBLE

The principal investigator/applicant for a research grant must be either:

• A College of Physicians and Surgeons of Ontario licensed M.D. with an academic appointment and therefore eligible to apply for their own research grants as an independent investigator.

OR

- A fellow who is a College of Physicians and Surgeons of Ontario licensed M.D. and who has a
 supervising co-Principal Investigator for the research project. The supervising co-Principal
 Investigator, who is a College of Physicians and Surgeons of Ontario licensed M.D. with an
 academic appointment, will therefore provide the necessary research supervision and
 infrastructure (including administering the grant at their sponsoring institution).
 - O Please note: Fellows must include with their application a letter of support from the supervising co-Principal Investigator. If the fellow's training is scheduled to end before the projected end date of their research study, then the supervisor must confirm that they will take over the fellow's responsibilities in the event where the fellow may not be able to complete the project as the PI.

PSI will consider and support only one project per Principal Investigator at any given time. If an investigator is currently being supported by PSI as the Principal Investigator, the Foundation will not consider an application for a new project until the end of the current granting period as agreed to by the PI and PSI. Also, applicants must not submit more than one application as Principal Investigator per grant cycle.

INELIGIBLE

Applications will not be considered from the following Principal Investigators:

- Residents (must apply through the Foundation's Resident Research Grant stream)
- Principal Investigators who hold a Ph.D but not an M.D.
- Graduate students or trainees
- Investigators based outside of Ontario

CO-PRINCIPAL INVESTIGATOR/CO-INVESTIGATORS/COLLABORATORS

ELIGIBLE

Examples of co-Principal Investigator, co-investigators, and collaborators including but not limited to:

- Faculty members who hold a Ph.D but not an M.D.
- Healthcare professionals who do not have an academic appointment

Collaborators can be anyone who is not a co-investigator but assisting with the project in some way; i.e. providing lab space, samples, expertise, etc.

INELIGIBLE

Applicants must not name the following as co-Principal Investigator/co-investigators/collaborators:



- Residents
- Students (including undergraduate, graduate/Ph.D, and medical school students)
- Individuals whose personnel costs are included in the grant budget (see <u>Project Budget Use of Funding section</u> for more details)



APPLICATION POLICY & REQUIREMENTS

SPONSORING INSTITUTION

All applications must have a sponsoring institution which is registered with Revenue Canada as carrying on charitable activities.

Eligible institutions must:

- Be located in the Province of Ontario
- Be a registered charity
- Have its own, independent research ethics board*
- Be eligible to hold Canadian Institute of Health Research grants. The list can be found at http://www.cihr-irsc.gc.ca/e/36374.html.

The sponsoring institution must provide the necessary infrastructure for the research project: including, but not limited to, accounting and reporting of grant funds as well as ensuring the research is carried out according to the institution's policies and procedures and accepted research standards in Canada. In addition, Research Ethics Board (REB) approval must come from the sponsoring institution.

*For institutions who do not have an internal REB, they may access an existing REB at another institution. The REB approval must clearly state where the research is taking place, who the primary investigators are, and have a matching title to the PSI approved study.

AMOUNT AND DURATION OF FUNDING

Up to \$250,000 for a maximum of three years (maximum \$100,000 in any one year).

PROJECT BUDGET - USE OF FUNDING

The proposed budget must include a detailed budget narrative within the application (including quantities and rates/prices) to explain how amounts were determined. A detailed breakdown and justification of costs is required for projects involving the Institute of Clinical and Evaluative Studies (ICES), specifically the number of hours an analyst is dedicating to a project and their hourly rate.

Ineligible or unjustified budget items will be removed from the budget. The eligible budget items are outlined as below:

ELIGIBLE BUDGET ITEMS

PERSONNEL

- Salaries for technicians, technologists, research assistants and other similar persons required for the successful completion of the project and who are not assigned to the project for the purpose of receiving training.
- Salaries for personnel must be in accordance with those paid to similarly qualified persons at the institution where the project is undertaken.
- The Foundation will not provide salary support at a level greater than the experience required for the work to be undertaken on a project.
- The employer's cost of project staff benefits may be included in the budget proportional to hours of employee time directed to project.
- Salaries for trainees and students, including medical students and fellows.



- Personnel costs may not include any individuals named on the application (Principal Investigator/co-Principal Investigator/co-Investigators/collaborator) or salaries/stipends for residents.
- Secretarial assistance is also excluded.

EQUIPMENT

- Equipment necessary for carrying out the project activities is to be included in this budget category.
- The Foundation is unable to support items such as the cost of computers, furniture, tape recorders, photographic equipment, and calculators. Service contracts on equipment will also not be covered.
- Ineligible costs also include fees charged by the investigator's institution for IT support (Internet/web connections, software licenses, network components, etc.).

MATERIAL AND SUPPLIES

- Direct project related material and supplies.
- The cost of purchasing animals and the maintenance thereof is an allowable expense.

PUBLICATION COSTS

 Publication costs including open-access fee and the cost to purchase a reasonable number of reprints.

CONFERENCE PRESENTATIONS

Costs associated with attending scientific meetings to present papers on a project.

OTHER EXPENSES

 Direct project related items that may not fit within the categories above (such as research activity travel costs) that are necessary for completion of the project activities and requested with detailed justification is provided.

ADDITIONAL PROJECT BUDGET REQUIREMENTS

- PSI funds may be used outside of Ontario only in exceptional circumstances, which will be reviewed on a case-by-case basis. Any such funds must flow through the sponsoring institution as PSI will not send such funds directly to any institution outside of Ontario.
- It is expected that the institution at which the project will be undertaken will provide research and office space.
- Overhead and indirect costs are ineligible expenses.
- PSI funds cannot be used for expenses pre-dating the date of funding approval.
- Funds awarded will be deposited with the institution where the project will be undertaken, to be administered by the appropriate officer.
- PSI understands that the amount allocated in the approved PSI budget for publications and conference travel may be used after the end of the studies' granting period; therefore, PSI will accept a final accounting statement showing a balance of the amount allocated in the approved PSI budget for publications and conference travel and recognize the account being closed.



EQUITY, DIVERSITY, AND INCLUSION

PSI FOUNDATION STATEMENT ON RESEARCH WITH INDIGENOUS PEOPLES, EQUITY, DIVERSITY AND INCLUSION, AND SEX AND GENDER-BASED ANALYSIS

The PSI Foundation mandate is to improve the health of Ontarians through physician-led research. As a foundation we are committed to improving the health of ALL Ontarians regardless of race, gender, ability, rurality, sexual orientation, education level or socioeconomic status.

Going forward, all grant applications will need to include a discussion of how the grant will address the following areas in terms of representation on the research team and incorporation into the grant methodology, data analysis, and interpretation of results where applicable:

- Research with Indigenous Peoples
- Equity, Diversity and Inclusion
- Sex and Gender-based Analysis

RESEARCH WITH INDIGENOUS PEOPLES

The PSI Foundation recognizes the harms caused to Indigenous peoples through research. As a foundation, we are committed to walking on a path towards reconciliation as guided by the Truth and Reconciliation
Commission Calls to Action and the United Nations Declaration on the Rights of Indigenous Peoples.

For projects that explicitly include Indigenous peoples, and for projects that may include data from Indigenous peoples, describe how the project will:

- Engage with Indigenous stakeholders, knowledge keepers and knowledge users
- Adhere to the principles outlined in the <u>Tri-council Policy Statement 2, Chapter 9</u>
- Incorporate the best practices for research set forth by
 - First Nations Information Governance Committee: <u>OCAP® Principles</u> (Ownership, Control, Access, Possession)
 - Inuit Tapiriit Kanatami and Nunavut Research Institute: <u>Negotiating Research Relationships with</u> Inuit Communities, A Guide for Researchers
 - Métis Centre at the National Aboriginal Health Organization: <u>Principles of Ethical Métis</u> <u>Research</u>

Refer to the <u>CIHR Indigenous Health Research</u> webpage for more guidance in this area.

EQUITY, DIVERSITY AND INCLUSION (EDI)

Describe how EDI has been incorporated in both your team and research study. Groups may include but are not limited to women, indigenous peoples, persons with disabilities, members of visible minorities/racialized groups, and members of LGBTQ2+ communities.

Refer to the Ministry of Health <u>Health Equity Impact Assessment (HEIA) Tool Template</u> and the <u>CIHR Equity</u>, <u>Diversity and Inclusion in the Research System</u> webpage for more guidance in this area.

SEX AND GENDER-BASED ANALYSIS (SGBA)

Describe how sex and gender will be incorporated into your methodology, data analysis, and interpretation of results.

Refer to the CIHR Sex and Gender in Health Research webpage for more guidance in this area.



FUNDING CRITERIA

ORDER OF PRIORITY

Research applications will be assessed on an equal weighting basis of scientific merit and clinical relevance.

NEW INVESTIGATORS

In establishing priorities among applications submitted, when scientific merit and clinical relevance are equal, preference will be given to the new investigator over the established investigator.

LEVERAGED FUNDING/CO-FUNDING OPPORTUNITIES

PSI is open to considering co-funding opportunities.

QUESTIONS TO CONSIDER

The following questions represent the criteria that will be considered by the Grants Committee in assessing an application (as applicable to the specifics of the research). Please consider these questions with respect to your research proposal fully before completing an application for funding to PSI:

- Is the proposal within the interests and objectives of the Foundation, or is it a proposal which is more appropriate for support by another granting agency?
- Does the proposed study represent truly innovative work?
- Will the proposal add significantly to the state of knowledge?
- Is there a strong knowledge translation component/plan?
- Is the investigator fully aware of the present state of knowledge in the area to be investigated?
 Does the application demonstrate a comprehensive literature review was carried out?
- To what extent could the research project findings strengthen clinical care and improve the health outcomes of patients in Ontario?
- Are the aims of the project feasible and can they be achieved realistically within the timeframe outlined in the application? Are the objectives of the project testable and, if the objectives are stated in the form of a hypothesis, is the time reference reasonable with respect to the realization of the testing of this hypothesis?
- Are the research methods appropriate for the objectives of the study? Is the methodology of the proposal sound? The application must include sufficient detail to provide a full understanding of the steps / protocols. Is the sample size statistically justified and feasible?
- Is the principal investigator qualified and is the environment in which they work satisfactory to carry out the project?



- Are the personnel and equipment proposed adequate to carry out the project? Are all budget items sufficiently justified in the application? Is the budget feasible in relation to the objectives of the study?
- Will the project have any impact on reducing health costs?
- What is the relevance of the project to the provincial health context?
- Are there alternative ways to address the clinical problem being addressed by the research?



APPLICATION PROCESS

HOW TO APPLY

All requests for funding must be submitted using PSI's online application system. Please refer to the online application form for specific information in regards to documents required, page limits, signatures, etc. for the grant proposal.

To be eligible for consideration, applications must contain all requested information in full. PSI is unable to consider incomplete applications.

All applicants are required to complete the PSI application submission survey. The link is available in the online application form.

Please do not upload scanned documents to the online system, with the exception of letters of support with signatures and the completed signature page

Please note: all applications received by the Foundation through the online system are acknowledged automatically. You will receive a second notification of acceptance within a few weeks.

Applications submitted will be reviewed for completeness and eligibility. PSI will notify you through the online grants management system if we require clarification or additional information. Failure to respond in a timely manner may result in your application's review being delayed or your application being declined.

Once completeness and eligibility are confirmed, the application will be sent for external peer review by experts in the research focus area.

SUBMISSION DEADLINE & APPLICATION TIMELINE

The PSI Foundation no longer has deadlines. You may submit an application at any time.

PSI's internal review committee will consider your application at its next meeting following the peer review process. You will generally receive a decision within six months. Since PSI does not fund ongoing research, applicants are required to wait for a funding decision from PSI to begin their research project.

EXTERNAL PEER REVIEW PROCESS

Applicants are asked to suggest potential reviewers with appropriate expertise to assess their proposal.

PEER REVIEWER LOCATION

Each suggested reviewer should be from a different hospital/academic institution. Reviewers can be from anywhere in the world as long as they can complete the review in English.

EXCLUDED INDIVIDUALS

Suggested reviewers must not have a potential, real or perceived conflict of interest in reviewing the proposal. As such, applicants must not suggest the following as potential expert peer reviewers (research team includes all named investigators):

- A person who has a family / personal relationship with any member of the research team
- A person who is in a position to gain or lose financially or materially from the funding of this application



- A person with whom anyone on the research team has regular interactions within their department, institution, organization, or other
- A person who has within the last 5 years:
 - Been a colleague at any member of the research team's clinical and/or academic institution
 - Been a supervisor or trainee of any member of the research team
 - Has collaborated or published with any member of the research team, or intends to in the near future

OTHER INFORMATION

Your application will be reviewed by the PSI Grants Committee once the peer review process is completed. In cases where PSI has difficulty obtaining sufficient peer reviews, applicants will be asked to suggest additional potential reviewers.

The external peer review process represents the most time-sensitive aspect of the application review process, so we ask that you take care to suggest appropriate peer reviewers to increase the likelihood of avoiding unnecessary delays in reviewing your application.

DECISION PROCESS

The Grants Committee will review the full applications and external reviews prior to their meeting. At the Grants Committee meeting each application will be discussed and a consensus funding decision will be reached based on overall scientific merit and clinical relevance. All applicants will be notified of the Committee's funding decisions and receive unattributed external reviewer comments within 15 business days.



GRANT RECIPIENT REQUIREMENTS

If funding is awarded, the following requirements are a condition of funding:

CONDITIONS OF RELEASING THE INITIAL PAYMENT

- The Principal Investigator (PI) is to provide a start and end date for the project, which will also represent the start and end date of the granting period. Please note: PSI will use this date to determine when the sponsoring institution will close the research account and when to expect interim and final reports from the grant recipient.
- The first payment of funding is conditional upon receipt of all applicable approval certificates and registrations. These applicable ethics and research standard approvals and registrations must have the same title as that of the application approved by PSI.
- The project must start within six months of the date of the letter from PSI offering funding and be completed within the approved time period. In conjunction with the Principal Investigator, PSI will establish a granting period for every award. This granting period represents the timeframe for which the grantee has to complete the study.

REPORTING & CONDITIONS OF RELEASING FUNDS

- Subsequent payments of funding are conditional upon verification of valid approval certificates and registrations. Upon expiry, approval certificates must be renewed and provided promptly to PSI for funding to continue.
- Projects of duration longer than twelve months are to provide an interim report of one to two pages on the progress to date of research activities, as well as a financial accounting statement of disbursement of the funds awarded at the end of each twelve-month period. Scheduled payments will be subject to receipt and satisfactory review of both annual research progress and accounting reports.
- PSI will withhold 10% of the value of the grant (i.e. 10% holdback payment) until the Principal Investigator submits a final report, which must include a final accounting statement from the sponsoring institution (with any unused funds returned) and a completed PSI Results of Research form. This material must be submitted within three months of the granting period's end date as a condition of funding.
- External Peer Review represents a core component of PSI's robust grants review process. PSI continues to find it difficult obtaining external peer reviews, similar to other funders and journals. We believe our grantees represent part of the solution of this ongoing issue; therefore, PSI has included the expectation that all currently funded grantees provide one (1) external peer review per year of support as a condition of receiving the 10% holdback payment. PSI will attempt to limit one (1) request per year; however, PSI may exceed this number under extreme circumstances. We are keen to receive reviews of varying levels of expertise, so please consider your ability to comment on general methods and relevance if fully within your area of expertise.
- The Principal Investigator must report the results of the project, including publications and
 presentations, so PSI can track the outcomes of all funded projects. Subsequent applications will
 not be considered unless the previously funded research project has met all reporting
 requirements.



CHANGES TO THE ORIGINAL PROTOCOL, BUDGET, & FUNDING PERIOD

- The Principal Investigator and/or the sponsoring institution are responsible for notifying PSI of any significant changes to the project, including but not limited to methodology, budget or personnel prior to the changes being implemented to ensure all aspects of the project continue to meet PSI's funding criteria.
- The Principal Investigator must notify PSI of any leave to be taken, apart from ordinary vacation, in order to make adjustments as applicable to the status of the study and to the payment of the funds. PSI must be notified before the leave starts. In the case of maternity/paternity leaves, the Principal Investigator may request an extension to the granting period of up to one year. The request for an extension must be endorsed by the appropriate institution officials, in order for adjustments to be made to the granting period and reporting and payment schedule. During the absence of the principal investigator, another investigator with an academic appointment at the same university (or institute) as the Principal Investigator may be given the responsibility of monitoring the project, supervising the personnel working on the project, as well as act as signing authority for the grant. Please note that the arrangement must be outlined in writing to PSI from the original Principal Investigator, the replacement Principal Investigator and the sponsoring institution.
- Grant funds must be used according to the approved project budget; however, PSI understands
 that the Principal Investigator is the best judge of the use of the funds awarded and may propose a
 change in the use of the grant funds, except where the Foundation has specifically excluded an
 expense item from its funding. Please note: the Principal Investigator must notify PSI of any
 significant changes in the project budget before the change is made to ensure the proposed
 changes meet PSI's eligibility criteria.
- If the project is delayed for any reason that will result in the project duration exceeding beyond the scheduled end date, please email your request for an extension to PSI before the original scheduled project end date. The request for extension must explain in detail the reason for the project timeline extension, a budget update and the state of the progress of the project to date and a revised project end date. Please note that such extension requests cannot contain a request for additional funding of the same project.

UNUSED FUNDS

- The institution to which a grant is paid must immediately notify and return unused funds to PSI if a
 grantee is unable, for any reason, to carry out or complete the research for which the grant is
 given.
- Within three months of the end of the granting period, the research account must be closed and all
 unused funds remaining in the account must be returned to PSI along with a final accounting
 statement for how funds were used.
- When work is completed or cannot be continued for any reason, unused funds must be immediately returned to PSI.

ACKNOWLEDGING PSI FOUNDATION

• All publications, presentations, public messages, or media coverage arising from the funded project are to include acknowledgement of funding from "PSI Foundation." Grant recipients are encouraged to connect with us prior to any media announcements. Furthermore, PSI's logo should be included whenever possible. An electronic file of the logo is available on the website.



• Where papers are published or presented, reprints or copies must be submitted to PSI. Please note that you may send electronic copies by email rather than paper copies.

OTHER REQUIREMENTS

• PSI requires that all funded research projects adhere to the sponsoring institution's policies and procedures as well as accepted research standards.