



TARGETED RFA IN PROSTATE CANCER RESEARCH
Advanced imaging to improve treatment planning
and patient outcomes for patients with advanced prostate cancer

Part 1: Overview Information

Participating Organization(s)	Prostate Cancer Canada
Funding Opportunity Title	Movember Translation Acceleration Grant to improve patient outcomes and treatment planning with advanced imaging
Description	<p>With this funding opportunity announcement, Prostate Cancer Canada (PCC) invites members of the prostate cancer research community to collaboratively participate in a multi-stage process to submit one (1) application for an investigator-initiated Translational Acceleration Grant (TAG).</p> <p>New imaging modalities are increasing our ability to detect low volume prostate cancer metastases. The project funded by this mechanism will explore how advanced imaging such as PET, CT and mpMRI, together with appropriate treatment for men with advanced prostate cancer can lead to better outcomes.</p> <p>This request for applications (RFA) will be a two-step process:</p> <ol style="list-style-type: none"> 1) Individuals submit an Expression of Interest to participate in developing a proposal. Selected individuals will be brought together with the intention of collaborating. 2) As a team, submit an application that will have the greatest potential to demonstrate the value of incorporating advanced imaging modalities into prostate cancer management in Canada and abroad by designing and carrying out a prospective clinical trial that evaluates patient outcomes following image-guided treatment planning. <p>This mechanism will not consider applications that are primarily focused on developing new imaging modalities or probes or on improving detection or staging of low volume metastatic prostate cancer as a means in itself. Projects that focus on diagnosis alone will not be considered.</p>

	A multidisciplinary approach is required and the Movember TAG application will consist of independent investigators based in multiple institutions. PCC will only consider a project that is completely focused on prostate cancer.
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Application Process

This is multi-stage process:

- Expression of Interest (EOI) letters submitted by individuals
- Invited individuals attend proposal planning meeting
 - The planning meeting will be supported financially by Prostate Cancer Canada.
 - Attendance will be by invitation from submitted EOIs, and will represent key expertise and knowledge of this area in Canada.
- TAG application registration general information
- TAG full application submitted
- TAG applicant team representatives present to the peer review panel

It is critical that the applicants follow the instructions outlined in the **Application Process** section of this document (**Part 2: Section IV**). **An application that does not comply with these instructions may not be accepted for review.**

Important Dates

Program launch	May 2019
Solicit Expressions of Interest (EOIs) from individuals in the Canadian research community	May-June
EOI submission deadline	June 27, 2019
Invitations extended to attend planning meeting	July 12, 2019
Planning meeting; invited individuals meet to plan TAG proposal; <u>SAVE THE DATE</u>	September 23, 2019
TAG application registration general information deadline (list all participants, grant title, keywords, etc.)	November 27, 2019
TAG full application deadline	January 29, 2020
Peer review	February-March 2020
Peer review panel meeting; applicant team representatives present to review panel	TBD late Feb-March 2020
Anticipated award notification date	March 2020
Earliest start date	April 1, 2020

Part 2: Full Announcement

Section I. Funding Opportunity Description

Background

Accurately understanding the stage of prostate cancer is critical to inform treatment decision making. Recent advances in imaging have significantly improved our ability to detect low volume metastatic prostate cancer. However, while this has great potential it is not fully clear whether new and improved imaging modalities lead to better outcomes. Prospective clinical trials that evaluate patient outcomes with robust health economic analyses would be important additions to the field, both in Canada and internationally.

Description

This funding opportunity aims to elucidate the value of imaging modalities in improving outcomes for men with metastatic prostate cancer, building upon previous work conducted in Canada and around the world in programs such as the Movember GAP 2 project. Using the multi-step process outlined, Prostate Cancer Canada (PCC) will invite one group to submit an application for an investigator-initiated Movember Translational Acceleration Grant (TAG) designing and conducting prospective clinical trials that evaluate patient outcomes following a therapeutic intervention that has been informed by imaging modalities such as multi-parametric Magnetic Resonance Imaging (mpMRI), computed tomography (CT) or positron-emission tomography (PET). In addition, a health economic/health services assessment of the imaging modality is required.

The project funded through this mechanism cannot be focussed primarily on:

- developing novel imaging modalities or probes
- improving detection or staging of disease as a means in itself
- diagnosis

The proposal should utilize existing and validated technology with a primary focus on the impact on patient outcomes. In addition, there is an expectation that an imaging biobank will be created to enable sharing of annotated imaging datasets openly with other researchers in the field to accelerate progress.

A multidisciplinary approach is required and the Movember TAG application will consist of independent investigators based in multiple institutions. **PCC will only consider a project that is completely focused on prostate cancer.**

The intent of this program is not to support new discovery. Rather the proposal should leverage existing knowledge and capabilities to accelerate impact without overlapping currently funded Prostate Cancer Canada and Movember initiatives. However, a proposal that leverages the funding provided through these programs and other funding mechanisms is encouraged.

Note: PCC will allow an eligible proposal with a budget greater than that available from this competition. In such a case, PCC’s funding will be contingent upon the acquisition of funds for the entire project.

Objectives

The primary objective of this RFA is to support research into the application of existing knowledge with the potential to greatly impact prostate cancer management in the short term.

Additional objectives of the program are:

- to support a multidisciplinary group of prostate cancer researchers;
- to support high quality research;
- to support a program of significant impact, where the group research environment will maximize the chances of success;
- to train highly qualified individuals;
- to support the translation of research findings into improvements in the health of Canadians and the Canadian cancer care system.

This opportunity is awarded by Prostate Cancer Canada and proudly funded by the Movember Foundation.



Section II. Award Information

Funding Instrument	Grant
Application Types Allowed	New
Funds Available and Anticipated Number of Awards	The amount available for this funding opportunity is approximately \$3M.
Award Budget	The applicant may request a budget of up to \$3M total (direct costs).
Award Project Period	The maximum period is 3 years.

**The amount available for this program is subject to funds raised. Should funding levels decrease, PCC reserves the right to reduce, defer or suspend financial contributions to grants received as a result of this funding opportunity.*

Section III. Eligibility Information

Eligibility to Apply

The **Leadership Team** will oversee the project and be composed of multiple Principal Investigators, with multidisciplinary expertise. The leadership team must have experience in the following areas: developing radionuclides, translational research, clinical trials, and strong prostate cancer knowledge.

However, the application must have:

1. A single **Program Director/Principal Investigator** who is an **independent investigator**;
2. At least 2 other applicants (**Co-Principal Investigators**) who are independent investigators from different institutions from the Program Director;
3. The **Program Director/Principal Investigator** and **Co-Principal Investigators** must each be formally affiliated with **eligible institutions**;
4. The proposal must consist of at least 3 highly-integrated projects.

The **Program Director/Principal Investigator** is an independent investigator who will:

- be responsible for the direction of the proposed activities;
- assume the administrative and financial oversight for the entire award;
- assume the financial responsibility for his/her own portion of the award at his/her own institution; and,
- receive all related correspondence from PCC.

An **independent investigator** is an individual who:

- has an academic or research appointment which:
 - must commence by the effective date of funding; and
 - allows the individual to pursue the proposed research project, to engage in independent research activities for the entire duration of the funding, to supervise trainees, and to publish the research results; and
 - obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees, and the employment conditions of staff paid with PCC funding.
- will assume financial responsibility for his/her portion of the award at his/her own institution and will be responsible for reporting this information back to the Program Director as well as to PCC.

Co-Principal Investigators and **Co-Investigators** are also independent investigators at eligible Canadian institutions and are part of the team contributing to the grant.

Section IV. Application Process

Please read all instructions before applying.

The application and review process for this funding opportunity is comprised of multiple steps:

- 1 - Expressions of Interest (submitted by email) from individuals interested in participating on this application
- 2 – Planning meeting
- 3 – Submit Registration General Information
- 4 – Submit Full Application
- 5 –Peer Review Panel Meeting with Reverse Site Visit

Phase 1 – Expression of Interest (EOI) Letters

EOI letters from individuals must be submitted by email to joanne.reynolds@prostatecancer.ca by **5:00 PM (ET) June 27, 2019**.

Cover letter (2-page maximum) to include:

- Name
- Email address
- Institution/Department that you represent (one representative per Institution, or Department where appropriate)
- Your current position
- How your area of expertise and experience is relevant (i.e. why should you be selected to attend the proposal planning meeting)
- If you cannot attend, the person you would nominate to attend in your place
- Identify additional personnel or expertise who you feel need to be represented at the planning meeting/ on the applicant team for the proposal

Funding and publications (1-page maximum):

- Selected related funding and publications

PCC staff will review the EOI submissions and select candidates who will be invited to attend the application planning meeting. Successful candidates will be notified by July 12, 2019; SAVE the date for the Planning Meeting – September 23, 2019.

Phase 2 – Planning Meeting – September 23, 2019

Convened by Prostate Cancer Canada, invited participants will be expected to take the lead and use the opportunity to plan how they will proceed with completing an application for this competition. Following the planning meeting, a nominated Program Director and key team members must be identified for the application. The online application form for completing Phases 3 and 4 will be made available to the Program Director(s) at: <https://pccgrants.smartsimple.ca>.

Phase 3 – Registration General Information Requirements

The **Registration General Information** section must be completed by **November 27, 2019** so that PCC staff can screen reviewers for conflicts; however, no attachments (CVs etc.) are required until the full application is submitted.

Registration General Information

1. Participant info:

- **Program Director/Principal Investigator (PI)**
 - **The leadership team will be composed of several Co-Principal Investigators, but one individual must be responsible for being the main contact PI.**
- **Co-Principal Investigators (Co-PI)**
- **Co-Investigators (Co-I)**

(Note: Collaborators are identified at the full application stage).

NOTE: Each investigator is linked to the application using a PIN obtained from registering at the link above.

Each named participant in these categories must qualify as an **independent investigator**:

- An individual who has an academic or research appointment which:
 - Must commence by the effective day of funding; and
 - Allows the individual to pursue the proposed research project, to engage in independent research activities for the entire duration of the funding, to supervise trainees, and to publish the research results; and
 - Obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees and the employment conditions for staff paid with PCC funding
- Will assume financial responsibility for his/her portion of the award at his/her own institution and will be responsible for reporting this information back to PCC.

*Attachment: (to be attached only at the **Full Application**):*

Abbreviated **CVs** for PI, each Co-PI and Co-I:

Include the following information:

- Training and education
- Degrees
- Positions and honours
- Relevant publications (past 5 years)
- Research Support, ongoing and completed (past 5 years)

2. Project Title

3. Area of Research

4. Keywords (5-10 required)

5. Applicant Table

List all applicants with their affiliations and expertise keywords. Identify approximate percentage of investigator work time allocated to work on this grant.

6. Dean of Faculty/Head of Division or Vice President/Director, Research

7. Financial Officer

8. Reviewer Recommendations (5 required) International recommendations preferred. For each, list:

- Name
- Institution
- Contact info including e-mail address
- Area of expertise

9. Reviewer exclusions (optional): For each, list:

- Name
- Institution
- Reason for exclusion

Note that assigned reviewers will have access to this information.

Phase 4 - Full Application

The full application must be submitted online by **5:00 PM (ET) on January 29, 2020**.

10. List of collaborators: A Collaborator can be: an independent investigator (inside or outside Canada), a graduate student, a postdoctoral fellow, a research associate or technical support staff who contributes to the project. List all collaborators by name and institution.
Attachment: Letters of Collaboration (optional)

11. Case for Support (maximum 250 words): Using everyday language, tell us why this is the most important project to fund. How would you describe to a prospective donor how the project will advance the field of prostate cancer research and improve the lives of prostate cancer patients or their caregivers?

12. Scientific Abstract (maximum 250 words): Provide a summary of the proposed research, indicating specific aims, methodology of the proposed research, intended outcomes and potential significance to prostate cancer.

13. Goal and Specific Aims (maximum 400 words)

State the areas to be studied. State the overall objective and extent of innovation of the research program. State the specific aims and goals of the program as a whole. Summarize the expected outcomes and impact of the results; significance of the research on our understanding of prostate cancer. List and label each individual project/core numerically.

14. Proposal Overview (maximum 800 words)

List overall significance, overall innovation, overall approach and preliminary studies.
Attachment: References for this section

15. Research Proposal (maximum 10,000 words, not including Attachments)

Each project/core must have a single theme, a designated project leader and a budget. For each project/core detail the goals and specific aims and the significance of the problem. Describe the strategy, methodology and analyses to be used, along with potential problems, alternative strategies, expected outcomes and impact that the results will have on that area of research. Details about sample size including calculations, assumptions and other factors that may impact on successfully powering the trial should be included. Identify the milestones in this project and the appropriate timeline for meeting them.

Additional notes:

- The feasibility of the implementation of the project at the clinical or population level must also be described in detail. A health economics evaluation of the intervention being studied must be included in the proposal.

Attachments: Related tables/figures

References

16. Leadership, Management and Synergy Plan (maximum 800 words)

In the text box (supported by the accompanying attached table or diagram):

- Describe the leadership capabilities of the Program Director/Principal Investigator.
- Explain how the projects and cores will together address the overall goals and aims and how they will be more effective than if done independently.
- Address the capacity of the research team to carry out the program of research proposed and how information, reagents, personnel, equipment etc. will be shared between the proposed projects and shared cores to create synergy within the program.
- Explain plans for organizational and administrative management of the program.
- Describe the chain of authority for decision-making and administration.
- Explain how coordination and communication will be achieved among the projects and cores.
- Explain methods for monitoring and assessing progress and effective use of resources within the research projects.
- Identify strategies for engaging and linking with stakeholders who will ultimately use the research findings.

Attachment: Attach table or diagram showing all proposed projects and shared resources and their relationship within the proposed program.

17. Training and Education Component (maximum 800 words)

Describe the environment and suitability for training and mentoring of students and fellows and how, given the nature of this program, it is unique from a regular research grant. **The TAG8 application must include a description of how it will leverage training in their institution(s) for clinical research fellows.**

18. Improving quality of life in the short term (maximum 400 words)

Identify your strategy and knowledge translation plan to ensure that the funded research will meet the goal to improve treatment planning and patient outcomes for patients with advanced prostate cancer.

19. Certificates required: Identify institution(s) for each type of certificate required:

- Biohazard/Biosafety
- Animal Care
- Ethics
- Stem Cells

20. Current and Pending Funding (PI and Co-PIs)

Using the categories: 1) Active Grants and 2) Pending Grants, provide one consolidated list that includes all current and pending grants for the **Program Director/Principal Investigator** and **Co-Principal Investigators**. **List each grant only once**, clearly indicating all of the applicants that are affiliated with the grant. The following format is to be used:

- Title of Grant
- Source
- Grant #
- Dollars Awarded
- Dates of Approved Project (start/end)
- Name of PI, % of time PI will devote to the work of the listed grant
- List of Co-investigators, % of time each Co-I will devote to the work of the listed grant
- The major goals of this project
- % Overlap with current application

For **Co-investigators with overlap**, list current and pending funding information where there is a % overlap with the current application. Use categories as noted above.

Attachment: For PIs, Co-PIs, Co-Is, abstracts must be attached for each grant or pending grant listed. Ensure that the title of the project/grant is clearly indicated on the abstract.

21. Publications, Reprints, Pre-prints or Abstracts (attach up to 5 relevant publications)

22. Detailed Budget with Justification:

Note: PCC will allow an application that forms a component of a larger multi-funder initiative; however, PCC's approval will be contingent upon funding approval for the larger initiative. In such a case, provide budget details for the larger initiative as an attachment.

There is no yearly maximum; however, the complete budget must not exceed \$3M over 3 years. Overall total and year by year totals must match detailed budget figures. Show consolidated budget for the PCC contribution year by year:

- Salaries
 - Salaries of research staff
 - Stipends to trainees
- Small equipment (maximum 5% of total budget)
- Research materials and supplies
- Services
- Data collection, database management
- Regional, national and international networking activities
- Research knowledge translation (KT) activities
 - Travel to conferences when presenting results from the funded research grant/award (maximum of 1% of budget)
 - Publication costs relating to the funded research
 - Other knowledge dissemination activities
- Other expenses

Provide full justification for all budget elements

Attachment: Budget support documents; include a breakdown for each project, shown year by year, using the categories listed.

23. Signature Page – download form, sign and attach. Signed by Principal Investigator, all Co-Principal Investigators, Co-Investigators, Host Institution Dean of Faculty/Head of Department/VP Research, Host Institution Financial Officer.

Attachments to Full Application:

All attachments must be provided in PDF format.

1. CVs for each Principal Investigator, Co-Principal Investigators and Co-investigator. Include:

- Training and education
- Degrees
- Positions and honours
- Relevant publications (past 5 years)
- Research Support, ongoing and completed (past 5 years)

2. **Letters of Collaboration**
Attach Letters of Collaboration as appropriate.
3. **References for Proposal Overview**
4. **References for the Research Proposal**
5. **Tables/Figures** related to the Research Proposal
6. **Current and Pending Funding Abstracts** (PI and Co-PIs, Co-Is)
Abstracts must be attached for each grant or pending grant listed for the PI, Co-PIs and Co-Is, ensuring that the title of the project is clearly indicated on the abstract.
7. **Publications, Reprints, Preprints, Abstracts:** maximum 5 documents relevant to the application.
8. **Budget Support Documents:** If this submission is part of a larger multi-funder initiative, provide budget details for the larger initiative as an attachment. Include individual project/core budget figures showing year by year breakdown. Documents may also include quotes for equipment, services, etc.
9. **Signature Pages** – Multiple pages may be scanned and attached. Signed by Principal Investigator, all Co-Principal Investigators, Co-Investigators, Host Institution Dean of Faculty/Head of Department/VP Research, Host Institution Financial Officer.

Phase 5 – Panel Meeting and Reverse Site Visit

Representatives of the applicant team(s) will be invited to a Reverse Site Visit with the review panel in Toronto in late February-March 2020 (Date to be confirmed).

Section V. Guidelines and Review Process

General PCC Guidelines

PCC policies and guidelines, as outlined on the PCC website, will apply to the application submitted and award made in response to this RFA. PCC reserves the right to amend the review process at any time. Any changes that are made to the process will not adversely affect the rigor and equity of the process. Every effort will be made to inform applicants of changes in a timely manner.

Review

An expert review panel will be established to evaluate the proposal submitted to this RFA. The review panel will make recommendations to PCC if the submitted proposal should be funded based on the following criteria:

1. Overall objective and potential to improve patient care
2. Significance/relevance of the research
3. Feasibility of the clinical implementation of the project
4. Leadership capabilities and track record of the Principal Investigator
5. Capacity of the research team to carry out the program of research proposed

6. Institutional support for the program
7. How the proposal complements and builds upon existing projects in this area

The review panel may choose: 1) to fund the program as is, 2) fund the program pending recommended changes, or 3) not to fund the proposal.

Depending on the result of the initial evaluation, the applicant team may be required to submit further information to clarify or refine the proposed project before a final funding decision is made.

Allowable Costs

Note: PCC will allow an eligible proposal with a budget greater than that available from this competition. In such a case, PCC's funding will be contingent upon the acquisition of funds for the entire project.

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

Research operating costs for the proposed research program, which must be distinct in its objectives from those for which group members currently receive funding:

- Salaries:
 - Salaries of research assistants, technicians, program coordinator and other personnel who will enhance the collaborative research productivity of the program team
 - Stipends paid to trainees (e.g., undergraduate, graduate students, postdoctoral fellows) shall be in accordance with departmental guidelines. At funding, the Host Institution must provide to PCC a letter to verify departmental stipend requirements for students and fellows relevant to trainees indicated in the proposed budget.
- Purchase of small equipment and maintenance contracts for common services and shared infrastructure essential to the proposed research program (maximum 5% of budget)
- Research materials and supplies
- Services
- Costs of data collection, database and maintenance of information holdings directly related to the proposed research program
- Costs of regional, national and international networking activities, including collaboration, planning, and knowledge exchange activities, directly related to the proposed research program
- Knowledge translation activities
 - Travel to conferences when presenting results from the funded research grant/award (maximum of 1% of budget)
 - Publication costs relating to the funded research
 - Other knowledge dissemination activities
- Other expenses

Non-Allowable Costs

The following expenditures are NOT eligible for funding received through this funding opportunity:

- Indirect costs* associated with the conduct of research
- Salary or honoraria for PIs and Co-Investigators
- Fringe benefits for students, postdoctoral fellows and clinical research fellows

- Conference travel (except where noted above)
- Entertainment and hospitality costs
- Membership fees, union dues

***Indirect Costs**

PCC supports only the direct costs of research. Indirect costs refer to the operational costs that underpin an institution's research activities (e.g., heating, lighting, ethics reviews, facilities for animals used in research, management of intellectual property, environmental assessment and safety compliance). The services that give rise to indirect costs are institutionally-based, and are not specific to individual research projects. PCC fully recognizes that indirect costs are a legitimate part of the total cost of conducting research. However, in full accord with the other members of the Health Charities Coalition of Canada, PCC believes such costs are the responsibility of the institutions where research is performed, or the governments that support those institutions, and that such costs should not be borne by charitable donations to Prostate Cancer Canada.

Conditions of Funding

Successful applicants funded through this funding opportunity must fully comply with the following conditions:

- Acknowledgment of PCC and the Movember Foundation's support in all publications and presentations that result from the funded research. **In addition, PCC staff must be notified prior to publication of a research paper (i.e. upon acceptance of a research paper).**
- The PI will be required to submit to PCC annual written progress reports that include a list of all publications resulting in whole or in part from this grant, as well as lay summaries for each publication.
- Financial statements must be submitted to PCC annually no later than 45 days after the end of each grant year by the PI receiving funds from PCC.
- The PI will be required to submit to PCC a final written report with a final financial statement.

Performance Indicators

Performance indicators will be developed in order to evaluate the success of the Targeted RFA Grants.

Questions and Contact Information

For questions relating to this RFA, please refer to our Frequently Asked Questions (FAQs) document available on the website.

Contacts:

Joanne Reynolds
Manager, Research Operations
416 441-2131, Ext. 226
joanne.reynolds@prostatecancer.ca

For more information on this funding opportunity, visit prostatecancer.ca.

For more information on Movember, visit www.movember.com.