STRATEGIC OPPORTUNITY

THE TERRY FOX RESEARCH INSTITUTE TRANSLATIONAL PROGRAM (2017)

Context

Since its creation as an Institute in 2007, the Terry Fox Research Institute (TFRI) has supported projects in translational cancer research based on excellence and impact. This targeted and applied research addresses the gap that exists between exponential growth in the pace of scientific discovery due to the development of new genomic and information technologies and the slow pace of translation of that knowledge into innovations (new diagnostic and therapeutic products and services) in the health system.

The reasons for the gap in translation of new knowledge into health outcomes are complex with no single element able to complete translation on its own. Partnerships and dialogue are required: basic researchers with their creativity and rigor are needed to discover new insights into cancer biology, clinical scientists in hospitals and the private sector are needed to develop innovative products that have therapeutic and analytic validity, clinical researchers are needed to test the clinical utility and validity of these innovations, and economists, epidemiologists and health systems researchers are needed to provide governments with data that show the potential of innovations to have an impact on cancer patients and their families. Patients and their families are also needed, as participants and advocates for improvements in health outcomes.

To advance translation, TFRI has adopted a model and strategy of collaboration and partnership on a Pan-Canadian basis for its translational programs. The TFRI model is predicated on Canadian researchers coming together – leaving personal agendas aside – to define the most important translational cancer research questions that can be addressed over a five-year period using a multi-centered, multi-disciplinary, milestone-driven team approach.

A translational project needs to define how it will make a measurable impact by (1) reducing the number of individuals diagnosed with cancer, or (2) improving the quality of life and/or survival of patients being treated for a particular cancer. Key characteristics of a project include:

- Projected measurable impacts and translational deliverables defined up front, with a rigorous method to monitor progress towards these deliverables
- Strong clinical and scientific leadership of interdisciplinary research teams
- A managed approach, with milestone-driven plans and GO/NO GO decision points
- Strong collaboration between research institutions and health centres including written commitments to share resources and data and to manage intellectual property appropriately
• Evidence of potential or existing partnerships with other organizations pursuing the same or closely related goals.

For the best ideas and teams, TFRI will commit up to $1 million per year, or $5 million over five years, in partnership with other funders interested in the same research.

Purpose

The purpose of this Strategic Opportunity (SO) is to accelerate development of clinically relevant discoveries, knowledge and innovation for adoption by cancer control systems in Canada and around the world.

Scope

To support collaborative clinical and scientific teams of excellence across Canada to target well-defined, integrated and transformative areas of clinically relevant cancer research and innovation, including tumour-site specific research, with potential to impact the health of cancer patients in the short to medium term. This SO supports the early stages of translation. It occupies the gap between scientific discovery and clinical trials. It also seeks to develop the evidence needed for innovation to be considered ready for adoption and implementation into the health system.

Secondary Program Goals include one or more of the following:

1. To build Pan-Canadian collaborative cancer research teams
2. To create translational resources for the cancer research community
3. To address specific cancers, i.e., rare and/or hard-to-treat cancers, for which collaboration and sharing is essential to improve outcomes
4. To accelerate the development of discoveries and innovation made by TFRI-funded researchers
5. To encourage co-investment with partners who share similar goals, and to create partnerships that increase the potential of uptake of the research results.

Support offered

This SO supports\(^1\) projects (networks and consortia) with teams of researchers (1) led by clinician scientist(s), or clinical and scientific co-leaders, and (2) consisting of three or more groups based in a minimum of three Canadian provinces or territories that have committed to collaboration in pursuit of translation of well-defined cancer research topics.

\(^1\) A list of eligible expense categories is provided below at Eligible Costs (page 5).
This SO supports *New Proposals*. *New Proposals* are defined as coming from a group of investigators seeking to advance translation of their research and may include expansion of component(s) of a Terry Fox Program Project Grant.

*New Proposals* can apply for up to $1,000,000 per annum from TFRI for a maximum of up to five (5) years commencing on July 1, 2017. Research groups are encouraged to contact TFRI before submitting an Expression of Interest to identify leveraging and matching opportunities. For additional information please see below on page 6.

*Extension Proposals* are defined as invited requests from an existing Terry Fox Translational Project within the last year of its support. Extensions will only be considered in exceptional circumstances (see below at page 7 for more detail).

**Funding Envelope**

The Terry Fox Foundation’s contribution to the amount available for this SO is subject to availability of funds raised by the Foundation. TFRI reserves the right to reduce, defer or suspend financial contributions to Terry Fox Translational Projects funded through this SO.

TFRI has committed up to $7.5 million over a five-year term to this SO, sufficient to fund one *New Application* and one *Extension*.

**Eligibility**

This SO is open to faculty-level scientific and clinical research groups at eligible Canadian institutions.

**Strategic Opportunity Process**

The multiple-step SO process is designed to select the best ideas of Canadian cancer research teams, and to create conditions for continuous improvement of those ideas. There are eight steps in the process:

1. Submission of an *Expression of Interest Letter* describing the concept for translation of a well-defined cancer research topic electronically to translation@tfri.ca by Monday June 6th, 2016
2. If invited, organization and holding of a Pan-Canadian *Scientific Workshop* by Monday September 19, 2016
3. Submission of a *Workshop Report* by the Scientific Workshop Organizing Committee two weeks after the Scientific Workshop is held

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2 Eligible Canadian institutions are a research-capable hospitals or institutes, or affiliated universities and foundations which have completed Memoranda of Understanding with the Terry Fox Research Institute.
4. Development of a **Project Outline** after completion of the Scientific Workshop by **Thursday October 6, 2016**

5. If invited, submission of a **Research & Development (R&D) Plan** by **Monday January 9, 2017**

6. If invited, a **Reverse Site Visit** by international peer reviewers (IPRs) by the middle of **March 2017**

7. **Project Approval** following International Peer Review of the R&D plan by **May 1, 2017**

8. If approved, **Project Start** to take place on **July 1, 2017**

These processes are described in greater detail below.

**Expression of Interest**

An Expression of Interest (EOI) must be submitted electronically to translation@tfri.ca by the applicants by 5:00 pm Pacific Time on Monday June 6th, 2016. The EOI template is provided at www.tfri.ca. The EOI must summarize (1) the initial translational cancer research question to be addressed, (2) the potential impact of such research upon the health outcomes of patients, (3) the unique strengths and resources that Canadian centres will bring to bear on the question, and must provide (4) an initial list of invitees, and (5) an initial agenda for a scientific workshop that will discuss and explore the concept presented in the EOI. Curricula Vitae of the applicants must be submitted using the TFRI CV form available at www.tfri.ca.

The applicants are expected to provide reasons why TFRI should consider supporting the EOI. EOIs will be reviewed and ranked by the TFRI Executive Committee with advice from the TFRI Scientific Advisory Committee. One or two EOIs will be selected to move to the next stage of the SO process – i.e., to organize a scientific workshop.

**Eligible Expressions of Interest**

The minimum requirements for an eligible EOI include:

1. The applicants must be Principal Investigators involved in the research idea to be pursued. The designated Project Leader(s) must have experience in leading multi-disciplinary research teams.

2. Active involvement of a minimum of three research groups located at eligible institutions in three Canadian provinces and/or territories. EOIs must be Pan-Canadian in scope and impact.

**Scientific Workshop**

The applicants of a successful EOI will be invited to organize a Pan-Canadian scientific workshop sponsored by TFRI and/or others by Monday, September 19, 2016. To encourage full participation of all interested Canadian researchers / organizations, a Scientific Workshop Organizing Committee including members of the TFRI Executive will draw up an invitation list of participants and international speakers (target 20 - 30 persons). Potential co-investing organizations will also be invited to attend the workshop at their own expense. TFRI will collaborate with the organizers to find potential partners for the Project. The Scientific Workshop Organizing Committee will prepare a Workshop Report within two weeks of the conclusion of the workshop based on a template report provided by TFRI. The Workshop Report will be
sent to all participants and to TFRI. The Workshop Report shall include a section on Next Steps including a list of individuals (the applicants) who will be responsible to submit a Project Outline.

**Project Outline**

A Project Outline (PO) must be submitted to translation@tfri.ca by the Project Leader(s) by 5:00 pm Pacific Time on Thursday October 6, 2016. A template for the Project Outline is provided at www.tfri.ca. The Project Outline must summarize 1) the health outcomes that will be targeted by the Project, 2) the background and rationale for the Project, 3) the components that will make up the Project (e.g., identifying people, assets and approaches to be used and how they will be integrated), 4) the Project’s deliverables and timelines, 5) the key questions / issues that will be addressed to translate the Project’s deliverables into innovations adopted by the health system, and how these will be addressed by the Project, 6) existing and potential partners, and 7) a high level budget proposal. The TFRI Executive will review the Workshop Report and Project Outline with the assistance of scientific peers to identify the Project to be invited to prepare full Research and Development Plans.

**Research & Development Plan**

A Research & Development Plan (R&D plan) must be submitted electronically to translation@tfri.ca by the Project Leader(s) by 5:00 pm Pacific Time on Monday January 9, 2017. A Guide to assist applicants complete the R&D Plan is available at www.tfri.ca. The R&D Plan should be the business plan for the Project, a living document with appendices which define how the Project will be carried out, progress monitored and milestones and deliverables recorded. The R&D Plan should include 1) identifying cover pages, 2) a contents page, 3) scientific executive summary (the why, what, how, when, where and who of the Project), 4) the project goals and components, 5) the team, 6) project management, 7) translational strategy and activities, 8) partnership plans and co-investors, 9) suggested names of qualified individuals to serve as members of the Scientific Advisory Committee (such names must include non-conflicted international peers and patient advocates of the project), 10) budget and justification, and 11) appendices (e.g., draft protocol(s), standard operating procedures, certificates, intellectual property, disclosures). Forms to be used as cover pages are provided by TFRI. Changes to the R&D Plan may be requested by TFRI Executive prior to the Plan being subjected to a reverse site-visit by international peer reviewers (IPRs). Changes may be requested to the Plan by the IPRs prior to recommendations being made to fund a R&D Plan.

**Eligible Costs**

Only the direct research costs of carrying out the Project will be considered eligible. Typically these costs will include:

1. Research operating costs for the proposed collaborative research program, which must not overlap with those for which Project team members currently receive funding
2. Salaries of coordinators, managers, research assistants, technicians and/or other personnel who will enhance the collaborative research productivity of the application. Projects are encouraged to include a program coordinator / manager among the salaries requested
3. Support for research trainees, at institution approved rates
4. Costs of data collection, database, maintenance of information holdings, and analysis directly related to the application
5. Costs for an external Scientific Advisory Committee for the Project to meet at least once a year
6. Travel, meetings and networking activities directly related to the Project, including costs of collaboration, planning and knowledge exchange activities, and costs to attend the TFRI Annual Scientific Meeting.

The following costs are not eligible:
7. Remuneration for Project Leader, Principal Investigators, Co-Investigators, Collaborators
8. Major equipment over $10,000 not included in the approved budget
9. Academic fees for students
10. Indirect costs such as overhead or infrastructure charges (e.g., institutional costs of research, building maintenance, rent, insurance, computer network charges, patenting costs)
11. Laboratory and office furniture
12. Entertainment or hospitality costs
13. Membership fees
14. Activities by researchers not part of the approved application.

Matching & Leveraged Funding

It is highly desirable for Pan-Canadian Projects to develop partnerships that include co-investment by other organizations (e.g., institutions, foundations, funding agencies and/or private philanthropy). Partnerships enable bigger and potentially more impactful projects. Applicants are expected to work collaboratively with TFRI to develop a realistic plan to secure such partnerships. The partnership plan must be in place when the R&D Plan is submitted. TFRI encourages potential partners to attend the planning workshop.

Evaluation

A general description of the multi-stage review process is outlined in the section above. R&D plans will be evaluated iteratively by the TFRI Executive Committee with the assistance of the TFRI Scientific Advisory Committee and an International Peer Review Committee based on the excellence and potential for impact of the Project. Applicants are required to provide names of potential non-conflicted reviewers. Criteria used by reviewers include, but are not limited to:

- Potential to impact healthcare (importance of problem and timeline for resolution)
- Potential for innovation (in terms of new interventions and changes to healthcare system)
- Strategy and detailed plans to achieve translation
- Strengths and weakness of the R&D plan
- Appropriateness of milestones, GO/NO GO decision points, and deliverables
- Training and track records of the Project team and its leadership
- The environment for the research
- The potential of the R&D plan to provide answers to the questions posed
• Whether or not the proposed budget is reasonable and realistic.

Extension of Funding

Translational Projects will only be extended in exceptional circumstances. Project leaders should speak to TFRI well in advance if they propose to request an extension. TFRI will offer 50% of the original funding, up to $500,000 per annum for up to four years, to extended projects – matched funding is required to move ahead with an extension application.

Teams are advised to arrange a meeting of the Project’s Scientific Advisory Committee at least six months before the end of the translational research project to obtain its opinion on the following:

• Is an extension essential for the Project to deliver and translate on its major goal(s)?
• Are the resources generated by the project essential for the benefit of qualified cancer research team / researchers?
• Have additional co-investment partners been secured to match the period of extension?
• Does the Scientific Advisory Committee support the extension?

A decision by TFRI to invite Project teams to submit a proposal for an extension will be based on the report of the appropriate Scientific Advisory Committee.

Conditions of Funding

Applicants and sponsoring Institutions are expected to observe TFRI’s Research Administration Policy, and depending on the nature of the research supported, will be required to complete a funding agreement and/or a collaborative research agreement. Standard conditions of funding include:

a. Certificates

Before funding is made available, the Applicants must obtain from the sponsoring Institution(s) all applicable certificates, including:

1. Biohazards. For projects involving use of biological material, a certificate guaranteeing that the project will be conducted under conditions which satisfy the Canadian Biosafety Standards (CBS) 2nd edition (2015) and associated handbook and guidelines (2016) (http://canadianbiosafetystandards.collaboration.gc.ca/).
2. Animal Care. For projects involving use of experimental animals, a certificate guaranteeing that all animals will be cared for and studied under conditions meeting the standards set forth in the Canadian Council on Animal Care’s “Guide to the Care and Use of Experimental Animals” Vol 1 (1993). (www.ccac.ca).
3. Human Studies. For projects involving human subjects, a certificate stating that the protocols and methods have been reviewed by the Institutional Research Ethics Board and found to be acceptable in accordance with current edition of the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada: ‘Tri-Council Policy Statement: Ethical Conduct for Research
Involving Humans’ (2014) (www.pre.ethics.gc.ca). If studies use investigational compounds, regulatory approval from Canada’s Health Protection Branch is also required.

4. **Use of Human and Biological Samples.** TFRI is committed to ensuring that high quality bio-specimens are used in research that it funds, as these yield high, reproducible quality data. For this reason, TFRI requires all applicants for funding to certify that (i) all prospective (new) bio-specimens included in the TFRI-funded research will be collected in accordance with the standards set by the Canadian Tissue Repository Network (https://www.ctrnet.ca/resources/operating-procedures) and/or the Clinical Laboratory Improvement Amendments Act (CLIA) of the United States (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html), and/or (ii) all retrospective (old) bio-specimens used in the TFRI-funded research have come from a CTRNet or CLIA-certified bio-repository. Links to the CTRNet certification program and registered biobanks can be found at http://www.biobanking.org/webs/certification. Applicants are required to submit evidence of current certification and participation in external quality assurance programs with the Project R&D Plan.

5. **Human Pluripotent Stem Cell Research.** TFRI endorses the guidelines set forward by the Canadian Institutes of Health Research on ‘Human Pluripotent Stem Cells’ now integrated into the ‘Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), Chapter 12. Section F (2nd edition) (http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/). Applicants are required to contact TFRI before submitting an application for support of cancer research requiring any use of human pluripotent stem cells.

b. **Reporting**

TFRI requires a funded team to submit an annual Research Metrics Report, six monthly Research Progress Reports and quarterly Financial Statements for the duration of the Project. Members of the team are expected to meet, usually by teleconference, with TFRI every six months and to meet, usually face-to-face, with the project’s Scientific Advisory Committee at least once every year. Team members and trainees are expected to attend the TFRI Annual Scientific Meeting during the term of the award.

c. **Project Title & Use of TFRI logo**

Funded Applications are to be called ‘The Terry Fox Translational Project in [short title of program] supported by the Terry Fox Foundation, Foundation Name’, etc. Applicants are expected to comply with TFRI’s Visual Identity Guidelines to be found at www.tfri.ca.
For inquiries, please contact:

**Russell Watkins**
Senior Programs Manager
Terry Fox Research Institute | l'Institut de recherche Terry Fox
675 West 10th Avenue
Vancouver, BC V5Z 1L3 CANADA
☎ Telephone: 1-604-675-8000 ext.7624
✉ Email: rwatkins@tfri.ca

*Date: April 18, 2016*