UNIVERSITY OF TORONTO
FACULTY OF MEDICINE

astellas

2016/2017Astellas Prostate Cancer Innovation Fund Terms of Reference

I. Table of Contents

II. Background

Astellas Pharma Canada, Inc. ("Astellas") is continuing their ongoing commitment to research and development within the Urologic Oncology community through a research grant program with The University of Toronto (UofT), first established in 2015. The *Astellas Prostate Cancer Innovation Fund* at the University of Toronto aims to support investigator sponsored research in prostate cancer, with recipients subject to internal academic peer review. Astellas will provide the funding for the Program. The University of Toronto will provide the receipt, processing, evaluation and decision-making infrastructure for the Program, and will administer the funds to the selected Grant recipient(s).

III. Key Dates

Competition Launch	September 12, 2016
Application deadline	December 2, 2016
Notification Date	January 16, 2017
Funding Start Date	February 1, 2017
Study update submitted to the University of Toronto	12 Months from Grant Receipt

IV. Objectives and Scope

The objective of the *Astellas Prostate Cancer Innovation Fund* is to support peer-reviewed research that addresses barriers in the field of Urologic Oncology, with the ultimate goal of advancing long-term health outcomes and quality of life for Canadian prostate cancer patients.

The primary focus of the Program is to support research in the field of prostate cancer – in the Departments of Surgery, Medicine, Laboratory Medicine & Pathobiology, Radiation Oncology, and Medical Imaging – across the UofT health sciences network with preference given to collaborative and interdisciplinary proposals.

Grant recipients are expected to demonstrate improved understanding of the specific research area and/or contribute to improving patient care. Grants will be awarded to the successful applicant(s). It is anticipated that 3 grants of $50,000 will be provided.

V. Eligibility

The University of Toronto shall receive and process applications, and shall evaluate the submitted proposals. Proposals will be deemed eligible based on the following:

A. Eligible Applicants

The Applicant must:

- Have an academic appointment at the University of Toronto, in one of the following Departments: Surgery, Medicine, Laboratory Medicine & Pathobiology, Medical Imaging, or Radiation Oncology
- If successful, agree to have their application shared in confidence with Astellas for internal documentation and auditing purposes
- If successful, agree to provide progress reports to the University of Toronto

B. Eligible Research Proposals

In the 2016/2017 academic year, the research proposals being considered will be those addressing the area of prostate cancer.

C. Review Criteria

All proposals will be reviewed and assessed by January 16, 2017.

Research proposals will be evaluated based on the following criteria:

1. Significance

- Scientific merit (validity, integrity, originality)
- Contribution to advancement of scientific knowledge in the field of prostate cancer
- Clinical relevance or potential clinical value and applicability

2. Feasibility

- Feasibility of study design, methodology, analysis
- Adequate power and sample size
- Study Budget & Proposed timelines

VI. Guidelines for Application Submission

The research proposal should be novel and previously unpublished.

The University of Toronto must receive the completed application no later than *December 2, 2016*. The magnitude of the project should match the size of the award; the award is not intended to supplement a major grant, however it is anticipated that this funding may be used to produce data to apply for larger/national level grant funding.

Documentation received after the submission deadline will not be reviewed. The applicant is responsible for ensuring completeness of the application and incomplete applications will not be considered. Applicants may submit their application electronically to *urology.admin@utoronto.ca*.

The following are suggestions for preparation of the research proposal. The headings suggested include 1) Statement of Objective(s), 2) Recent relevant research by applicant, 3) Brief review of literature and background information, 4) Hypothesis(es), 5) Design and Methodology, 6) Analysis of Data, 7) Anticipated Timeline, 8) Impact, Future research plans and Knowledge Translation, and 9) Budget.

VII. Conditions of the Astellas Prostate Cancer Innovation Fund

A. Research Ethics Board approval:

The successful applicant must provide evidence of appropriate Ethics Committee approval along with consent forms where human subjects are involved in the study, before the funding is released.

B. Financial Considerations

The amount of each Grant is intended to cover costs associated with the study, including direct costs (labour and study costs), study drug costs (if applicable), and indirect costs (publications, congress presentations, and software license fees).

C. Research Grant Administration

1. Progress Reports

The Grant recipient must provide a progress report to the University of Toronto within 12 months of receipt of the Grant summarizing work completed, including any publications, as well as an accounting for funds.

2. Publications

Grant recipients are expected to present their findings at scientific meetings and/or to submit their work for publication in peer-reviewed journals. The University of Toronto shall require a copy of all proposed publications upon submission for publication or other public disclosure and shall provide said information to Astellas forthwith. All publications and presentations that result from a project supported by the Astellas Prostate Cancer Innovation Fund should carry the following acknowledgement: *"This research was supported by the Astellas Prostate Cancer Innovation Fund provided by Astellas Pharma Canada, Inc. and jointly established by Astellas Pharma Canada, Inc. and The University of Toronto".*

D. Grant Recipient Responsibilities

The following responsibilities must be assumed and carried out by the Grant recipient:

- Review and execution of study
- Research Ethics Board submission and approval (if applicable)
- Health Canada Clinical Trial Application (CTA) submission and approval (if applicable)
- Compliance with all applicable laws, regulations or guidelines (e.g. ICH- GCP, etc.)
- Study-related activities such as data management, statistical analysis, medical writing, monitoring, etc.
- Registration and posting of study results on http://prsinfo.clinicaltrials.gov
- Safety Reporting to Health Canada, the research ethics board (as per local requirements), and if a drug product is involved, the Product Safety/Pharmacovigilance group for the appropriate company. Please refer to the Serious Adverse Events and Lack of Therapeutic Efficacy Reporting Section.
- Communication of progress updates to the University of Toronto
- Forward copy of abstract(s)/manuscripts(s) to the University of Toronto upon submission to congress/journal

VIII. Notification of Decision for the Astellas Prostate Cancer Innovation Fund

Grant recipients will be notified of the decision regarding funding around January 16, 2017. Both successful and unsuccessful applicants will receive a notification and a constructive critique from the University of Toronto.

A. Address for Submissions

Please send completed submissions electronically, no later than December 2, 2016

urology.admin@utoronto.ca
Kim Moffat
Division of Urology
Department of Surgery, University of Toronto

IX. Serious Adverse Events (SAE) and Lack of Therapeutic Efficacy

1. As sponsor of the study, the grant recipient is responsible for reporting SAEs and Lack of Therapeutic Efficacy directly to **Health Canada** (pursuant to the Canadian *Food and Drug Regulations*) and to the local REB, as required.

2. If a drug product is involved, the Grant recipient is also required to notify the Product Safety/Pharmacovigilance group for the appropriate company.[1]

A ***Serious Adverse Event*** is any untoward adverse event/adverse drug reaction that at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, is a congenital anomaly/birth defect, or results in other medically important events.

Lack of Therapeutic Efficacy – If a health product fails to produce the expected intended effect, there may be an adverse outcome for the patient, including an exacerbation of the condition for which the health product is being used. Clinical judgment should be exercised by a qualified health care professional to determine if the problem reported is related to the product itself, rather than one of treatment selection or disease progression since health products cannot be expected to be effective in 100% of the patients.

[1] If the research involves a drug product marketed by Astellas Pharma Canada, Inc., the Grant recipient is required to notify **Astellas Pharma Global Development – Global Pharmacovigilance (GPV)** at fax: 1-847-317-1241 or Email: Safety-us@astellas.com within twenty-four (24) hours of receiving a SAE or Lack of Therapeutic Efficacy report or any of the Product Safety Information as listed below.

Product Safety Information ***("PSI")*** including but not necessarily limited to:

1. *Death (always considered serious)*
2. Abuse/Misuse/Overdose
3. Medication Errors (in prescribing, dispensing, or administration)
4. Drug Exposure during impregnation, pregnancy, breastfeeding or as a result of one's occupation
5. AEs reported in association with suspected or confirmed quality defects or counterfeit reports
6. Suspected transmission of an infectious agent