CUASF SCHOLARSHIP FUND – BLADDER CANCER CANADA RESEARCH GRANT

Terms of Reference 2024

BACKGROUND

The CUASF-BCC Research Competition was initiated by Bladder Cancer Canada (BCC) to support scientific discovery and innovation for bladder cancer in Canada. The objective of the CUASF is to provide financial support for urologic research conducted in Canada. The three main objectives of BCC are funding bladder cancer research, providing support and information to bladder cancer patients and raising awareness of this disease. The CUASF-BCC Research Grant Program has been established to support investigator-sponsored research that will be peer reviewed by the CUASF, members of the BCC Medical Research Board or other qualified reviewers. The funding for the grant will be provided jointly by BCC and the CUASF. The CUASF in partnership with BCC will provide the receipt, processing, evaluation, and decision-making infrastructure for the Program and will administer the funds and enter into investigator-initiated study agreements with the selected grant recipients.

KEY DATES

Application deadline	**April 15, 2024**
Notification Date	2024 Annual Meeting of the CUA
Study update submitted to CUASF	Within 6 months of receipt of the Grant

OBJECTIVES AND SCOPE

The objective of the CUASF-BCC Grant Program is to support peer-reviewed research that promotes excellence in bladder cancer research with the ultimate goal of improving patient care and understanding the biology of bladder cancer. Proposals may include basic science, translational or clinical research. Proposals in other areas of urological research exclusive of bladder cancer will not be considered. Grant recipients are expected to demonstrate improved

understanding of the specific research area and/or contribute to improving patient care in bladder cancer. It is anticipated that there will be two grants of $50,000 and four grants of $25,000. The grant funding should be used for operational expenses. The funding is not to be used for salary support. The funding is non-renewable.

ELIGIBILITY

The CUASF shall receive, process, and evaluate the submitted proposals. Proposals will receive Grants based on the following:

Eligible Applicants

- All CUA members
- Faculty members at a recognised university, health care institution and voluntary health sector organizations or research institutes. Trainees are not eligible.
- M.D. or Ph.D. trained individuals.
- Agrees to execute an Investigator-Initiated Study Agreement with the CUASF
- Agrees to provide a progress report, including publication/congress plan, to the CUASF for dissemination of study results.
- Agree to participate in writing newsletter articles or submit photos to BCC as it relates to the research being conducted.

Eligible Research Proposals

In 2024, the research proposals being considered will be in all areas of bladder cancer.

The research proposal may belong to any one of the following categories:

- Clinical, translational, interventional studies
- Basic research, genetic studies
- Epidemiology, health outcomes, and quality of life studies

The study must be completed within 12 months of receipt of funding; no renewals will normally be considered. The proposed application should include a 'stand alone' project. The current Grant is not meant to complete funding for larger projects.

Non-eligible Research Proposals

The following types of proposals will not be eligible:

- Proposals for projects that have received funding from another source, including government or industry sponsors.
- Proposal budgets more than $50,000 CDN will not be considered unless there are available matching funds from the applicant's institution.
- Proposals for pharmaceutical product development (including studies on non-approved indications for drugs) and/or product comparison, or product promotion will not be considered.

Review Criteria

The CUASF-BCC Grant proposals will be reviewed and approved by the CUASF-BCC Committee. Review members will be those individuals chosen/recommended by the BCC and the Chair of the Scientific Council.

Research proposals will be evaluated based on the following criteria:

Significance:

- Scientific merit (validity, integrity, originality)
- Contribution to advancement of scientific knowledge in relevant therapeutic field
- Clinical relevance or potential clinical value and applicabilityOriginality of the research plan

Feasibility:

- Feasibility of study design, methodology, analysis
- Ability of investigator to conduct the research in his/her research environment
- Adequate power and sample size
- Study budget
- Proposed timelines.

Scoring:

- Applications will be ranked on a scale of 1 to 10 based on the above evaluation criteria. The minimum score required to fund a grant will be 7.5.

- Any overlap of the application with current grants or pending applications will be considered in funding decisions.

Guidelines for Application Submission

The research proposal, including the budget and references, should not exceed five (5) pages and should be in the standard 12 font (not including Lay Summary). Hard copies are no longer accepted as our granting program has moved to an electronic submission only format. The completed application must be received at the Office of the Chair of the CUASF no later than April 15, 2024.

Incomplete applications and documentation received after the submission deadline will be returned to the applicant. Applicants must submit their applications electronically to the CUASF office via www.cuasf.org.

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) Background, 4) Hypothesis(es), 5) Design and Methodology, 6) Analysis of Data, 7) Anticipated Timeline, 8) Impact, 9) Budget and 10) References.

In addition, the following must accompany the research proposal: 1) Completed Application form, 2) Research proposal, 3) Evidence of appropriate Ethics Committee approval or application for approval along with consent forms where human subjects are involved in the study, 4) Letter of support and commitment from the Chair of the Department/Division indicating the level of institutional and/or university support, 5) A list of all current grants and submitted grant applications in the past 3 years (maximum of 2 pages) with the title of the grant, granting agency and amount of the grant. Incomplete applications will be disqualified, and 6) A brief lay summary (maximum of 250 words).
A letter of reference may be submitted (optional) for junior investigators (within 5 years of first faculty appointment).

Conditions of the CUASF-BCC Research Grant Program

Financial Considerations

The amount of each Grant should include direct costs (labour and study costs) and study drug costs (if applicable). Indirect costs are not eligible under this grant. Each payment will be made in a lump sum. Institutions are required to waive overhead fees.

Contract Administration

A copy of the Template Grant Agreement signed by the Grant recipient and the Grant recipient's affiliated institution (if applicable) must be returned to the CUASF prior to disbursement of Grant funds. Studies must be designed to be completed within 12 months after receipt of funding, yielding results that would merit submission as an abstract to a scientific meeting and subsequent publication in a peer-reviewed journal.

Progress Reports

If requested, the Grant recipient must agree to provide a progress report to the Chair of the Scientific Council within 6 months of receipt of the Grant. If the Scientific Council deems that the recipient has not made sufficient progress, further payment/installments may be withheld.

Publications

Publication suggested in CUAJ, and if published elsewhere, then mandatory synopsis published in CUAJ under 'CUASF Awards' within 4-6 weeks of the publication elsewhere.

Grant recipients are expected to present their findings at the CUA Annual Meeting as well as other scientific meetings, and to submit their work for publication in peer-reviewed journals. All publications that result from a project supported by the CUASF-BCC Grant should carry the following acknowledgement:

"This research was supported by the *CUASF-BCC Research Grant Program*."

Grant Recipient Responsibilities

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

- Study contract review and execution
- Research Ethics Board submission and approval (if applicable)
- Health Canada Clinical Trial Application (CTA) submission and approval (if applicable)
- 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. Please refer to the Serious

Adverse Events Reporting section.

- Communication of progress updates to the CUASF

Serious Adverse Events and other Product Safety Information Reporting

Required to be collected AND reported to Health Canada

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.

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.

Required to be collected by the Independent Investigator
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

Notification of CUASF-BCC Research Grant

Notification of the Grant will be made at the CUA Annual Meeting. Both

successful and unsuccessful applicants will receive a summary and a constructive critique from the Scientific Council of the CUASF.

Complete applications must be submitted online: www.cuasf.org

Questions should be directed to:

Canadian Urological Association Scholarship Foundation
Girish Kulkarni
Chair, Scientific Council
c/o Ms. Marfisa Defrancesco
marfisa.defrancesco@cua.org