CUASF-CMSHC Grant 2021

Terms of Reference

Background

The CUASF-CMSHC Research Competition was initiated by Canadian Men's Sexual Health Council (CMSHC) to support scientific discovery and innovation in andrology in Canada. The CUASF-CMSHC Grant Program has been established to support investigator-sponsored research in andrology in Canada that will be peer reviewed by the CUASF. The funding for the grant will be provided by the CMSHC. The CUASF 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	**March 1, 2021**
Notification Date	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-CMSHC Grant Program is to support peer-reviewed research that promotes excellence in andrology research with the ultimate goal of improving patient care. The primary focus of the Program is to support research in the area of male factor infertility, erectile dysfunction, ejaculatory dysfunction, and Peyronie's disease and hormone replacement therapy. Proposals in other areas of urological research will not be considered. Research projects can be clinical, translational or basic science studies. Grant recipients are expected to demonstrate improved understanding of the specific research area and/or contribute to improving patient care in andrology. Grants will be awarded to the successful applicant (or applicant's institution on behalf of the applicant, if applicable). It is anticipated that up to one (1) grant of $50,000 CDN will be awarded each year for up to eight years. The grant is intended to be used over a 12-month period follow receipt.

Eligibility

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

Eligible Applicants

- All CUA members
- 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.

Eligible Research Proposals

In 2021, the research proposals being considered will be in areas of male factor infertility, erectile dysfunction, ejaculatory dysfunction, and Peyronies disease and hormone replacement therapy.

Preference will be given to junior investigators and to new/pilot projects that have not been previously funded.

The research proposal may belong to 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 be considered. The proposed application should include a 'standalone' 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 in excess of $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-CMSHC Grant proposals will be reviewed and approved by the CUASF-CMSHC Review Panel. Review members will be those individuals chosen/recommended by the CMSHC and by the recommendation from 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 applicability

Feasibility:

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

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. 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 March 1, 2021. Each applicant must arrange for a letter of support from the Chair of the University Department/Division affiliated with the research. The letter should indicate the level of support and commitment by the University and/or affiliated institution for the application.

Documentation received after the submission deadline will be returned to the applicant. Incomplete applications 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) Brief review of literature and background information, 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 application: 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, and 5)A list of all current grants and submitted grant applications in the past 3 years (maximum of 1-2 pages) with the title of the grant, granting

agency and amount of the grant. Incomplete applications will be disqualified.

Conditions of the CUASF-CMSHC Research Grant Program

Financial Considerations

The amount of each Grant should include direct costs (labor and study costs), institutional overhead costs (if any), study drug costs (if applicable), and indirect costs (publication, software license fees, and REB fees). Each payment will be made in installments according to milestones, with a maximum of 50% of the funding delivered at the beginning of the project. Institutions are expected to waive overhead fees that might otherwise apply to industry-funded research.

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

The Grant recipient must 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

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-CMSHC Grant should carry the following acknowledgement:

> "This research was supported by the *CUASF-CMSHC 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-CMSHC 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
Anil Kapoor, MD, FRCSC Chair, Scientific Council
c/o Ms. Marfisa Defrancesco
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