

Cumming School of Medicine Clinical Research Fund – Terms of Reference

Goal

To increase the number of University of Calgary (UCalgary) investigator-initiated clinical research studies that result in Tri-Council peer reviewed funding, industry partnerships and/or changes in health care delivery.

Opportunity

UCalgary and Alberta Health Services (AHS) have entered into a Memorandum of Understanding (MOU) for joint management of clinical research overhead funds. These will be managed entirely by the Calgary Centre for Clinical Research (CCCR). Administrative costs of both organizations (AHS and UCalgary) will be paid first and the remaining funds will be re-invested into research that informs clinical practice.

This document outlines the terms of reference for the use of these funds.

Objectives

To promote the *Eyes High* vision of leadership in high impact clinical research at UCalgary and to promote the objectives of AHS strategy for research innovation and analytics through

- a. Enhancing the quality of our clinical research and its implementation to support improved patient outcomes,
- b. Increasing our number of submitted and funded Tri-Council clinical research studies,
- c. Increasing the number of high impact clinical research publications from UCalgary
- d. Enhancing the number and quality of UCalgary investigator-initiated clinical research studies,
- e. Increasing the implementation of evidence informed practice to improve health outcomes,
- f. Increasing the number of our investigator-initiated, industry-partner clinical research studies,
- g. Broadening the scope of research that informs clinical practice to encompass implementation science, knowledge translation and practice change

These will be accomplished by

a. Enhanced education in clinical research and enhanced hands on research opportunities within AHS SCNs for

- i. Students / Trainees
- ii. Investigators
- iii. Supporting Personnel, including AHS staff
- Additional methodological support for clinical research through partnerships with AHS, Research, Innovation and Analytics (RIA), and Strategy for Patient Oriented Research (SPOR) platform teams
 - i. Statistical expertise
 - ii. Design and execution expertise
 - iii. Regulatory expertise
 - iv. Database support
- c. Establishing a competition funding certain types of clinical research, including drug trials (see below)
- d. Exploring the development of a phase 1 clinical trials facility that would be available on a cost-recovery model to other researchers external to the UCalgary.

Description of the Opportunity

- 1. Funds will be available annually for re-investment into research related to clinical practice/clinical trials.
- 2. Funds will be applied to clinical research projects led by PI's appointed at UCalgary that are anticipated to result in peer reviewed funding and/or industry investment in investigator-initiated clinical research or in changes in practice(s) to improve the health of Albertans.
- 3. The CRF will not offer a Major Grant in 2020. Applications for other types of grant (see below) will continue to be processed twice yearly (seed grants) or year-round (pre-submission, planning, and data collection grants). A review committee will assess applications.
- 4. Funds from the CRF may be requested as cash, as credit to be used towards work done in a CSM clinical research facility (Clinical Research Unit [CRU] or Heritage Medical Research Clinic [HMRC], or a combination of cash and credit.
- 5. See FAQ for additional details.

Types of Awards and Eligibility

- A. Major Grants this program is being redesigned. The CRF will not offer a Major Grant in 2020.
- **B. Seed Grants** (up to \$50,000 per team). Proposals may include requests for up to \$25,000 in cash; the remainder (i.e. up to the maximum of \$50,000) may be used to pay for work done in a CSM

clinical research facility (Clinical Research Unit [CRU] or Heritage Medical Research Clinic [HMRC]).

These are designed to seed new ideas for investigation, with the expectation that such data and collaborations will result in the submission of one or more peer-reviewed clinical research applications or the securing of industry support for clinical research. These will be available to support clinical research, including studies of therapies, diagnostic tools, pharmaceuticals and prevention strategies in humans, as well as comparative evaluations of those interventions against each other and against existing practices. Basic research related to identifiable human tissues, retrospective analyses, surveys, and other types of CIHR pillar 1 research are not eligible for funding by the CRF."

Accepting a seed grant from the UCalgary Clinical Research Fund constitutes a commitment that results will be used as the basis for an application to a Tri-Council agency within two years. Applications for seed grants will be accepted twice yearly (deadlines July 15, December 15).

C. Pre-submission, Planning or Data Collection Grants (up to \$10,000 per team)

These are designed to set up new projects or to perform pre-submission activities that are expected to result in the submission of a peer-reviewed clinical research application or securing industry support for a clinical research study. These will be available to support clinical research, including studies of therapies, diagnostic tools, pharmaceuticals and prevention strategies in humans, as well as comparative evaluations of those interventions against each other and against existing practices. Basic research related to identifiable human tissues, retrospective analyses, surveys, and other types of CIHR pillar 1 research are not eligible for funding by the CRF.

Applications for presubmission, planning or data collection grants are available on an ongoing basis and applications will be accepted at any time.

Principles

- Cancer-related applications are not eligible as there is a separate fund available for these applications administered through Alberta Cancer Clinical Trials.http://www.albertacancerclinicaltrials.ca/researchers/funding-for-trials/
 - Seed Grants and Pre-submission Grants be available to support clinical research, including studies of therapies, diagnostic tools, pharmaceuticals and prevention strategies in humans, as well as comparative evaluations of those interventions against each other and against existing practices. Basic research related to identifiable human tissues, retrospective analyses, surveys, and other types of CIHR pillar 1 research are not eligible for funding by the CRF.
- 2. These awards are available to all UCalgary faculty or researchers who hold an academic appointment.

- 3. Priority will be given to pre-submission applications that request a greater proportion of funds to be used to pay for work done in a CSM clinical research facility (Clinical Research Unit [CRU] or Heritage Medical Research Clinic [HMRC]) rather than cash.
- 4. Budgets must be well justified and requests may be made for amounts smaller than the maximum.
- 5. Investigators must hold and manage the funds through accounts at UCalgary; therefore, they must have adequate privileges and permissions through UCalgary.
- 6. Allowable Costs: UCalgary policies will apply for expenditures related to the project and approved by the CRF committee.
- 7. Independent peer review process:
 - Reviewers will be drawn from UC scientists, the Scientific Directors, Senior Medical Directors or operational SCN leads, and prior recipients of CRF funding
- 8. Applications will be assessed using the following guidelines:
 - The review process will follow the CIHR framework for RCTs or open operating grants, as appropriate.
 - Funding of applications will be based according to rank.
- 9. Applicants must demonstrate that there is no conceptual overlap with other funded projects to the satisfaction of the reviewers.
- 10. Grant recipients will be required to provide CCCR an annual progress report and statement of expenditures through the online review system.
- 11. All unspent funds will be returned to CCCR. A researcher has the following time frame to expend CRF funds during which time the grant will be counted toward the limits in #14 below:
 - Pre-submission 1 year
 - Seed grant 2 years

Extensions may be granted at the discretion of the ACT committee. Please email ccr@ucalgary.ca if you require an extension.

- 12. Successful applicants and their co-investigators are expected to participate in the review of future CRF grants. Failure to participate in reviews may lead to cancellation or suspension of an existing reward, or to ineligibility to apply to the CRF.
- 13. No more than two grants (one of each type) (pre-submission, seed or major) can be held by a given principal investigator at any one time. A maximum of 1 application per year (either a seed grant or presubmission grant, but not both) to the CRF is permitted per calendar year (January 1 December 31). Grants are considered to be held by the principal investigator for the durations listed in #12. For example, a principal investigator would be considered to hold a seed grant for 2 years

from the date of award. Successful applicants of the major award may not apply again for three years from the date of receipt.

Contact Information

For further information on the Clinical Research Fund, please contact:

Calgary Centre for Clinical Centre (CCCR)

(403) 210-6730

cccr@ucalgary.ca