# Request for Applications – Strategic Operating Grant for the Study of Medical Cannabis and Associated Cannabinoids

The Arthritis Society is pleased to announce a special call for research proposals on medical cannabis as part of our Strategic Operating Grants Competition (SOG) for the 2016-17 granting year.

#### DESCRIPTION

Two thirds of the Canadians currently accessing medical cannabis through Health Canada's Medical Marihuana Access Programme<sup>1</sup> are people living with arthritis. Recognizing the vital need for research into cannabinoids and medical cannabis, The Society has taken the lead in supporting research into herbal cannabis and the cannabinoid system. This special call will provide funds to support a research proposal aligned with the research priorities identified at the National Medical Cannabis Consensus Conference held in December 2015. In addition, all proposals must fit with at least one of The Society's Research Themes. The Society will be funding one (1) application. Applicants are strongly advised to read all program documentation as well as the Research Strategy. If you have any questions, please contact the research department at research@arthritis.ca.

#### The Arthritis Society's Research Themes are:

#### Strategic Theme I: Improving our understanding of arthritis and finding the cure

Research under this theme will seek to improve our understanding of the causes of arthritis in order to develop new approaches to alleviate the pain, prevent and/or slow the progression of disease, restore joint function, and eventually cure those affected by arthritis.

Research programs relevant to Strategic Theme I will have a main objective of:

- Understanding arthritis and arthritis pain pathophysiology and identifying therapeutic opportunities;
- Identifying and characterizing risk, and causal factors and/or development of arthritis and arthritis pain (including: biologic and endogenous factors; physical environment; and, psychological, social and economic factors);
- Discovering, developing and evaluating diagnostic (early detection), prognostic and predictive markers and technologies (such as imaging, diagnostic and other assessment tools) of disease (including: biomarker discovery and evaluation);
- Discovering, developing and evaluating potential therapeutic interventions in model systems and preclinical settings. (Including: pharmaceuticals; biologics; gene/cell/tissue therapies; medical devices; surgery (including joint replacement); and physical agents including physical therapy, radiotherapy, ultrasound, laser and phototherapy).

#### Strategic Theme II: Improving the care and management of arthritis

Research under this theme will seek to uncover new knowledge that will inform better ways to optimize the health of people with arthritis through improved treatment, management and self-care strategies.

<sup>&</sup>lt;sup>1</sup> As of April 1, 2014, the *Medical Marihuana Access Regulations* were repealed and the only way to access medical cannabis is through the process outlined in the new *Marihuana for Medical Purposes Regulations* (MMPR).

Research programs relevant to Strategic Theme II will include intervention research, observational studies and systematic reviews with a main objective of:

- Primary prevention of arthritis (including: individual characteristics, risk behaviours and influences, public policy and educational interventions/programs; environment; nutrition; and, vaccines);
- Treatment and disease management in clinical, community or population settings (including: pharmaceuticals; biologics; gene/cell/tissue therapies; medical devices; surgery; physical agents

   including radiotherapy, ultrasound, laser and phototherapy; physical, behavioural, and complementary therapies);
- Researching the individual's care (psychosocial impacts and economic consequences of disease, quality of life, management of pain and other symptoms, education), self-management (attitudes, beliefs and behaviours of health care providers; decision making; guidelines; education; and, work) of arthritis and its outcomes;
- Psychological, physical (PT/OT, exercise), lifestyle, coping (adaptations, accommodations) and complementary treatments, programs and interventions;
- Investigating influences and implementation issues related to screening;
- Evaluating the organization, governance and delivery of arthritis health care services, the impact of (local, regional and national) health policy and the economics of health care as well as studies into health care research design, measurement and methodologies.

# Research priorities identified at the December 2015 National Medical Cannabis Consensus Conference were:

#### **Basic Science**

- 1. Understanding the role of the endocannabinoid system (ECS) in arthritis.
  - Does cannabis or plant-derived cannabinoids increase or decrease the effectiveness of the ECS?
  - Can the ECS be harnessed therapeutically in disease?
- 2. Pathophysiology
  - What are the impacts of cannabis and plant-derived cannabinoids in pre-clinical disease models?
  - What are the impacts of the many components of cannabis on pain and inflammation?
- 3. Pharmacodynamics (PD) & Pharmacokinetics (PK)
  - Can cannabis or its ingredients be delivered effectively using topical, oral or others delivery strategies that do not require smoking?
    - PD cannabinoid absorption, distribution, metabolism, and excretion
    - PK The application of pharmacokinetic principles to safety and efficacy

#### **Clinical Science**

- 1. Safety
  - Adverse events
  - Clinical end points (response, disease management and quality of life)
  - Short and long term risks
  - Comparative risk with other treatments (*e.g.* NSAIDS)
- 2. Efficacy
  - Comparison of cannabis with standard treatment options
  - How does cannabis interact with other medications and treatments (including changes in lifestyle and diet)?
  - Measurement across the domains of pain, fatigue, mental health and functionality

- 3. Dosing
  - A guided framework to standardise the amounts of active ingredients
    - Dosing across different types of derivatives/strains
  - Validation of approaches to self-titration/individualized dosing research to optimise symptom management
- 4. Administration
  - Study the best route of administration and its relationship to dosing
    - Inhaled/vaporization and ingestions methods

#### Health Services & Policy Research

- 1. Study the implications of medical cannabis use on Canadian society as it relates to public, social and economic health.
- 2. The use of knowledge translation and exchange to provide evidence based data and better inform physicians, nurse practitioners, patients and the public.
- 3. How will medical use of cannabis be managed if and when cannabis is legalized?
- 4. How is the retail market for medical cannabis going to evolve?
- 5. How best to ensure access to medical cannabis is equitable and evolves in a non-discriminatory environment.

#### ELIGIBILITY

- Applications must be submitted by an eligible Nominated Principal Investigator (NPI) as defined by the Society;
- The roles and responsibilities of Nominated Principal Investigator, Co-Principal Investigator (CPIs) and Collaborator are defined in the Society's <u>Research and Training Program Guidelines</u> <u>and Policies</u>; and
- The roles and responsibilities of an Eligible Institution to receive and manage the Society's research and training funds are defined in the Society's <u>Research and Training Program</u> <u>Guidelines and Policies</u>.

#### AWARD AMOUNT AND TERM

The maximum award per application is \$120,000 annually for up to three years.

#### **COMPETITION TIMELINE**

Request for Applications published:	May 4, 2016
Research Application Portal open:	May 4, 2016
Letters of Intent (LOI) submission deadline:	3:00 pm (Eastern), June 3, 2016
Notification of decision:	Sep 2, 2016
Research Application Portal open:	Sep 2, 2016
Full Application submission deadline:	3:00 pm (Eastern), Oct 14, 2016
Notification of decision:	By Nov 30, 2016
Funding starts:	Jan 2017

#### LETTERS OF INTENT (LOI)

LOI must be submitted using the online form and include the following:

- i. Application Cover Page (signed by the institution, applicant and all CPIs)
- ii. Biographical Sketches of the NPI, all CPIs and consumer members of the research team
- iii. Project proposal
  - 1) Scientific Summary including approach (max. 700 words)
  - 2) Relevance of the proposal to the strategic theme(s) and medical cannabis research priorities
  - 3) (max. 700 words)
  - 4) Lay Summary (max. 350 words)

#### **LOI Review Process**

All LOI submissions will first be reviewed for eligibility and completeness. Applications that are deemed ineligible or incomplete will be triaged from the competition.

# It is the responsibility of the applicant to ensure that applications are complete at the time of submission. Incomplete or late applications will not be considered.

LOIs will then be assessed by a panel of peers including members of the Scientific Advisory Committee (SAC) and arthritis consumers:

- Quality of NPI and the research team
- Quality of research proposal
- Relevance of the proposal to the strategic theme(s) and medical cannabis research priorities

Each LOI will be scored out of 10 points plus Low or High for Relevance:

- a) Quality of NPI and the research team (5 points)
  - Qualifications of the applicant(s), including training, experience and independence (i.e. relative to career stage)
  - Experience of the applicant(s) in the proposed area of research and with the proposed methodology
  - Expertise of the applicant(s), as demonstrated by scientific productivity over the past five years (e.g. publications, books, grants held, etc.). Productivity should be considered in the context of the norms for the research area, applicant experience and total research funding of the applicant.
  - Evidence that the personnel, facilities and infrastructure required to conduct the research are available
- b) Quality of project (5 points)
  - Importance of the research question
  - Strength of the rationale for the research approach and methodology
  - Potential of the project to create new knowledge
  - Originality of the proposed research, in terms of the hypotheses/research questions addressed, novel technology/methodology, and/or novel applications of current technology/methodology
- c) Relevance of the project to the Society's Research Theme(s) and alignment with the Medical Cannabis research priority (Low or High)

• Applicants are advised to make convincing arguments as to the relevance of the intended proposal to the Society's strategic research theme.

Applications that receive a low score on Relevance or a score of 3.4 or lower on either of the other two criteria will not be invited to submit a full application.

All applicants will be notified of the result of the LOI review by September 2<sup>nd</sup>, 2016; successful applicants will then be invited to submit a full application.

#### FULL APPLICATION

Full applications to the SOG competition must be submitted using the online form and include the following:

- Application Cover Page (signed by the institution, NPI and all CPIs).
- Non-confidential Lay Summary of the project (max. 1,145 words)
- Description and role of all team members (NPI, CPIs, Collaborators/Partners, Consumers and Trainees)
- CIHR (Common Format) CVs of the NPI and all CPIs (5 years max.)
- Project proposal
  - 1) Scientific Summary (max. 5,000 words)
  - 2) List of References (max. 10,000 words)
  - 3) Knowledge Transfer plan (max. 400 words)
  - 4) Timelines and Milestones (max. 400 words)
  - 5) Relevance (max. 700 words)
  - 6) 1-page PDF attachment of timeline and milestones; maximum 10-page PDF attachment of Appendix materials
- Team member/collaborator letters (one letter from each co-Principal Investigator and collaborator)
- Budget (use template provided) and budget justification (max. 700 words)
- Non-Confidential Lay Summary (Lay Title, Lay Summary, Project Description, Description of Project's Results/Impacts,) (max. 950 words)

#### **Full Application Review Process**

All Submissions will be reviewed for eligibility and completeness. Applications that are deemed ineligible or incomplete will be triaged from the competition.

# It is the responsibility of the applicant to ensure that applications are complete at the time of submission. Incomplete or late applications will not be considered.

The applications will then be assessed by a panel of peers including members of the Scientific Advisory Committee (SAC) and arthritis consumers:

- Quality of NPI and the research team
- Quality of research project
- Relevance of the proposal to the strategic theme(s) and the medical cannabis research priority

Each proposal will be scored out of 20 points plus Low or High for Relevance:

- a) Quality of NPI and the research team (10 points)
  - Qualifications of the applicant(s), including training, experience and independence (i.e. relative to career stage)
  - Experience of the applicant(s) in the proposed area of research and with the proposed methodology
  - Expertise of the applicant(s), as demonstrated by scientific productivity over the past five years (e.g. publications, books, grants held, etc.). Productivity should be considered in the context of the norms for the research area, applicant experience and total research funding of the applicant.
  - Evidence that the personnel, facilities and infrastructure required to conduct the research are available
- b) Quality of project (10 points)
  - Importance of the research question, proposed project and objectives
  - Strength of the rationale for the research approach and methodology
  - Potential of the project to create new knowledge
  - Originality of the proposed research, in terms of the hypotheses/research questions addressed, novel technology/methodology, and/or novel applications of current technology/methodology
- c) Relevance of the proposal to arthritis and to The Society's Research Theme(s) and alignment with the medical cannabis research priority (Low, High)
   It is the applicant's responsibility to make convincing arguments on Relevance of their proposals to The Society's research Themes and the medical cannabis research priority.

Applications that receive a 6.9 or lower score on either of the first two criteria or receive a "Low" Relevance score will be triaged.

# It is the responsibility of the applicant to ensure that applications are complete at the time of submission. Incomplete or late applications will not be considered.

Applicants will be notified of the results by November 30<sup>th</sup>, 2016.

#### **RESEARCH PROGRAM GUIDELINES**

Applicants are expected to read and comply with <u>The Society's Research and Training Program</u> <u>Guidelines and Policies</u>.

#### **CONTACT INFORMATION**

The Arthritis Society 1700-393 University Ave Toronto, ON M5G 1E6 Tel 416-979-7228 Ext 3320 E-mail: <u>research@arthritis.ca</u>