



Investigational New Drug Fellowship in Medical Oncology

INTRODUCTION

The Department of Oncology located at the Juravinski Cancer Centre is offering a 1-2 year Investigational New Drug (IND) Fellowship. The Juravinski Cancer Centre (JCC) in Hamilton, Ontario, Canada is one of the five largest cancer centres in North America, and has evolved to become one of the leading Canadian centres in the study of Investigational New Drugs (IND). In addition to being the top accruer to IND studies to the National Institute of Canada Clinical Trials Group (NCIC-CTG) over the past five years, the centre has also been actively involved with industry-sponsored IND studies. The areas of focus for early phase drug development at the JCC include:

- i) targeting cell signalling resulting in the malignant phenotype,
- ii) interrupting processes involved in invasion and metastasis,
- iii) immunomodulation and immunotherapeutic approaches.

Duration: 1 - 2 year Fellowships

Start Date: July 1, 2019

Funding: Available at the PGY6 level

Deadline Date for Applications: September 1, 2018

Invitations for interviews will be given to selected applicants. Incomplete applications will not be accepted.

These studies have involved the full-spectrum of initial phase I studies to determine maximum tolerated dose, as well as subsequent phase II and III efficacy studies. In a number of these studies, JCC investigators have played a leading role in protocol development as well as serving as national principal investigators. The JCC Clinical Trials Department has established expertise in carrying out such studies and the Systemic Therapy Program has expert staff and the facilities for supporting such studies.

The JCC is an active participant in the NCIC-CTG through the Investigational New Drug Committee. In addition, the centre is a member of the Princess Margaret Hospital Phase I and Phase II Consortia, which are supported by the NCI-US. Through these consortia, exciting new agents licensed through the NCI-US are available for study, as well as providing consortium members the opportunity to develop protocols in-house and propose translational research studies to be done in concert with the clinical studies. In addition, the JCC works with a broad network of pharmaceutical and biotech companies to carry out early phase studies with a variety of new agents.

McMaster University is world renowned for its program in Clinical Epidemiology and Biostatistics and provides a 1 or 2 year program with basic training in health research. **The two-year Clinical Research Fellowship** provides fellows an opportunity to obtain a *Master's of Science Degree in Health Research Methodology (HRM)* for more information on the HRM Program and registration deadline please visit the following website <http://fhs.mcmaster.ca/hrm/about.html>

Translational research is becoming an increasingly important component of IND studies. The opportunities to participate in such research projects exist through the ongoing basic research studies at the JCC and McMaster University.

OBJECTIVES

To allow the fellow to:

- gain expertise in the design and development of investigational new drug protocols
- develop experience in taking protocols through the PRC and REB approval process
- gain experience in the clinical implementation and monitoring of patients entered onto IND protocols through working with clinical trials personnel and clinical investigators.

RESOURCES

Mentorship

A staff medical oncologist with significant involvement and interest in IND studies will be designated as the supervisor of the fellow. A supervisory committee will consist of the supervisor, the head of the JCC residency program and the head of Medical Oncology.

Trial Design

Courses will be selected from those offered by CE&B to learn basics of trials methodology and design. Where appropriate, the fellow will interact with personnel from the Ontario Clinical Oncology Group (OCOG) to gain experience in clinical trials methodology, especially trial monitoring and data analysis.

McMaster Clinical Investigator Program

The fellow may take part in the Royal College of Physicians and Surgeons accredited Clinical Investigator Program (CIP) at McMaster University. For further information about the CIP please click on link <http://fhs.mcmaster.ca/cip/>

Protocol Development and the Approval Process

New protocols will be developed with supervision of the supervisor. Critical review and assessment of protocols that have been written elsewhere will be undertaken by the fellow, in conjunction with the supervisor. The fellow will be expected to evaluate protocols that are submitted to the Protocol Review Committee and will attend and participate in the discussions at committee meetings. For selected protocols, the fellow will be expected to be responsible for the local implementation of the protocol (as co-PI) and take responsibility for submission to the Protocol Review Committee (PRC) and Research Ethics Board (REB) (preparation of REB form, modification of consent, communication with clinical trials and Hamilton Health Sciences (HHS laboratory and imaging programs re: resources) and presentation to PRC and REB when required.

Investigational New Drug Group (IND) Rounds

The fellow will be expected to attend and present research proposals or preliminary results at monthly IND group meetings.

IND Seminars

The fellows will be expected to:

Attend the weekly seminars

- Topics to be covered will include: molecular and clinical tumour biology, principles of pharmacokinetics, Phase I and II trial design, tumour response criteria including laboratory and imaging correlates of tumour response as well as a monthly IND journal club.
- Fellows will have the opportunity to critically review protocols being developed, as well as review protocols developed elsewhere during these seminars

JCC Regional Oncology Rounds

The fellow will be expected to present at these rounds at least once during the fellowship.

Clinical Experience

The fellow will follow patients on phase I/II and selected phase III studies. S/he will attend the IND clinics where these patients will be followed. S/he will participate in recruitment of patients onto studies and develop expertise in evaluation of toxicity, and measurement of response of patients on study.

TIME COMMITMENTS

- 20-40% of time will be devoted to clinical experience and direct patient interaction
- The fellow will spend up to four half-days in the clinic taking part in the evaluation and follow-up of patients in Investigational New Drug studies. S/he will interact with the clinical trials nurses and data managers from the Department of Clinical Trials assigned to the phase I/II studies s/he is involved with.
- S/he will be expected to carry out a research project related to the clinical trials that s/he is involved in and s/he will be expected to complete, write-up and present the findings of the project, and to submit a manuscript on the findings to a peer-reviewed journal.
- 40% of time will be spent on theory of trials design and evaluation and course work
- 20-40% of time will be allowed for development of specific research projects and research time
- it is expected that a minimum one year (and optimally a two year) commitment will be made by the fellow to allow completion of the fellowship objectives
- the fellow will be expected to take part in after hours and weekend coverage which will be negotiated at the start of the fellowship

SALARY

The salary for the fellowship will be at the PGY6 level.

AUTHORSHIP OF MANUSCRIPTS AND TRAVEL

The fellow will be expected to write an abstract/manuscript for any publications arising from protocols in which a major role was played. The fellow will be funded for travel to one national and one international meeting annually to present the results on the trials in which there was major involvement.

Application Requirements:

1. Must have completed specialty in Medical Oncology
2. CPSO licensing to practice in the Province of Ontario
3. Curriculum vitae - include information on teaching and research positions, list of publications, certificates, awards, scholarships, memberships, etc.
4. Three appropriate professional letters of reference, one from the Residency Program Director
5. Covering letter outlining personal learning goals and preliminary thoughts for development of a research/clinical project
6. Medical School transcripts

Forward completed application **no later than September 1, 2018** to:

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Website: www.fhs.mcmaster.ca/oncology

For more information on our Fellowship Program and to download application please visit:

https://fhs.mcmaster.ca/oncology/fellowship_program.html

Note: All qualified candidates are encouraged to apply. However, Canadian citizens and permanent residents will be considered first for these positions. McMaster University is strongly committed to employment equity within its community, and to recruiting a diverse faculty and staff. The University encourages applications from all qualified candidates, including women, members of visible minorities, Aboriginal peoples, members of sexual minorities and persons with disabilities.