Comprehensive Research Experience for Medical Students (CREMS) 2022 Supervisor and Project Information Form

Please complete and return via email ONLY to crems.programs@utoronto.ca by **February 18, 2022**.

Supervisor Information

NOTE: CREMS will not support pre-determined pairings of students and supervisors. Supervisors must agree to open their projects to all students and interview all that are interested.

Name:
Dr. Kelvin Chan

Email:
Kelvin.chan@sunnybrook.ca

Department:
Department of Medicine

Hospital/Research Institution:
Sunnybrook Research Institute

SGS Department(s) (if applicable):
Yes, IHPME

ORCID ID (see https://orcid.org/ – If you do not have an ORCID ID we encourage you to sign up for one)**:**
https://orcid.org/0000-0002-2501-3057

Location of Work:
Sunnybrook Health Sciences Centre

Field of Research (up to 4 keywords):
Health services research, Medical Oncology

Student contact time (number of hours per week YOU are available to the student for any concerns or to review progress)**:**
1 hour per week

Project Information

NOTE: If this project is selected, this information will be posted on CREMS website for interested student applicants to view research opportunities.

PROJECT TITLE:

Real-world outcomes of nivolumab for patients with recurrent head and neck cancer(HNC)

PROJECT DESCRIPTION:

Including background, aim(s), methodS and significance of the project. **Maximum 300 words.**

Background: Patients with recurrent HNC have high morbidity due to the absence of effective treatments. The pivotal Checkmate-141 trial, nivolumab, an immunotherapy with a monthly cost of $CAD8604.44, demonstrated significant improvement in median survival of 2.4 months, and was added to Ontario's public formulary in 2018. However, Post-market surveillance and observational studies found conflicting clinical benefit and safety results. Most of these studies were institutional-based without a comparator and had limited sample size. For this CREMS project, we proposal a real-world population-based study to evaluate the comparative outcomes of nivolumab in patients with recurrent HNC.

Aims: To examine the effectiveness, safety, and cost-effectiveness of nivolumab compared to standard chemotherapy(docetaxel, capecitabine, paclitaxcel +/- carboplatin) in patients with recurrent HNC.

Methods: The CREMS student will work with methodologists and clinicians to develop a study protocol for a retrospective observational study of recurrent HCN patients who received nivolumab (cases) or chemotherapy (controls). The study cohort will be linked to population-based administrative datasets to ascertain baseline and clinical characteristics for propensity-score adjustments. Primary outcomes include: 1) overall survival (index date of first treatment to death or end of study period), 2) safety (unplanned hospitalization and emergency department visits), and 3) cost-effectiveness (incremental cost-effectiveness ratio).

Significance: In 2017, CanREValue Collaboration established an initiative to evaluate the real-world outcomes of funded cancer drugs at ICES and in partnership with cancer agencies and research network in all provinces (e.g. Ontario Health-Cancer Care Ontario). Our group works closely with public payers from provincial cancer agencies and the CREMS student will have the opportunity to collaborate with decision-makers who lead initial funding of nivolumab in Ontario. The results of the project will also help to inform the development of a process for reassessing funded cancer drugs. Past projects from this initiative have resulted in peer-reviewed publications (e.g. JAMA Oncology).

Is this project remote-capable (in case of new restrictions) or have an alternative remote option?

☒ Yes, remote capable   ☐ No

☐ Yes, alternate remote option. Please specify (100 words max): Click or tap here to enter text.

If human subjects are involved, have the appropriate Research Ethics Board approvals been obtained?

☐ Yes   ☐ No   ☒ Not Applicable

If yes, please list the application submission date:

Do you expect this work will be published?

☒ Yes ☐ No ☐ Uncertain / Other

Research Environment and Student Roles and Responsibilities

Please be specific as possible. Please describe the research environment, including availability of required facilities/equipment/expertise, supervisor's experience and mentorship plans. Please clearly outline the student role(s) and responsibilities related to the project, potential educational value, and indicate who will serve as the student's direct report for daily oversight (PI, PHD student, technician, etc.). **Maximum 300 words.**

The CREMS summer student will have the opportunity to formulate a research protocol and will have access to a population-based datasets to investigate the research question. He/she will learn and perform advanced health services and health economic data analysis under the guidance of Dr. Kelvin Chan (MD, PhD in biostatistics). Responsibilities will include designing study protocol/study cohort, analyzing data and interpreting the results. The students will also lead the summarization of the findings in at least one abstract(s) and/or manuscript(s) for peer-reviewed publication. The project is planned to start and finish during the allotted time for CREMS as REB approval has already been obtained. He/she will also have the opportunity to become involved in one other study of their choice based on clinical interest (to be determined at the start of placement). The student will report directly to Dr. Chan (medical oncologist) who will provide substantial mentorship and guidance in 1-hr weekly meetings. Expert researchers and collaborators including medical oncologist, methodologist, and health economists, are also available for one-on-one support to help the student advance the project.

Acknowledging the ongoing COVID-19 pandemic, this project can be fully completed remotely with remote access to datasets. Despite the remote conditions, the student will be fully integrated within the research team. The student will be given access to Microsoft Teams and will participate in weekly team meeting. He/she will also be an active member of the Canadian Centre for Applied Research in Cancer Control, which includes clinicians and applied health researchers across Canada, as well as CanREValue Collaboration which includes stakeholders and decision-makers from Health Canada, Canadian Agency for Drugs and Technologies in Health, and provincial Ministries/Department of Health representatives. He/she will have the opportunity to attend meetings to learn and gain perspectives on the process of cancer drug funding decisions in Canada