Form I: BTI Internship Program Mentor Application

A.1: Mentor information		
Name Sameer Parpia Assistant Professor & Biostatistician	Institution McMaster University	Department Oncology

A.2: Co-mentor information (if applicable)		
Name	Institution	Department

A.3: Research proposal (maximum two pages)

Title
Radiotherapy for the Treatment of Breast and Lung Cancers

Ontario Clinical Oncology Group

The Ontario Clinical Oncology Group (OCOG) is an academic-based clinical trials development and coordination organization within the Department of Oncology at McMaster University which focuses on clinical cancer research. It works with networks of clinician investigators locally, provincially, nationally and abroad to conduct trials which address clinically relevant questions. OCOG's Coordinating & Methods Centre is located in the Juravinski Hospital & Cancer Centre of Hamilton Health Sciences, and includes methodologists, statisticians, clinician researchers, information technologists, and research staff. OCOG currently has over 20 ongoing clinical research studies in lung, prostate, breast and bladder cancers. This provides the statistical intern to be exposed to multiple cancer related studies that require methodological and biostatistical expertise.

The intern will primarily be involved in three projects involving radiation therapy for treatment of breast and lung cancers:

LUMINA - Breast irradiation (BI) is given following breast conserving surgery (BCS) to reduce the risk of local recurrence (LR) and prevent mastectomy. BI is an inconvenient and costly therapy requiring daily treatments for up to 3 to 6 weeks and is associated with significant short and long term toxicity. Recent studies suggest a cost-effective immunohistochemistry (IHC) approach to distinguish luminal A breast cancer independently predicts for low risk of LR following BCS. We hypothesize that clinico-pathological characteristics combined with IHC assessment for luminal A breast cancer can identify women at sufficiently low risk for LR so as to avoid BI. The objective is to determine if women > 55 years of age with clear margins of excision (> 1mm) after BCS for node negative breast cancer with tumours < 2cm and luminal A characteristics (ER and PR positive, Her2 negative and Ki67 < 13.25%) who are treated with adjuvant endocrine therapy for at least 5 years have an acceptable low risk of LR at 5 years. This is an ongoing multi-centre prospective cohort study. Consenting eligible patients, whose tumours were assessed centrally with Ki67 <13.25% were enrolled. Patients are followed every 6 months for the first 2 years and then yearly with a clinical exam and mammography. The primary outcome is LR. Important secondary outcomes include regional and distant recurrence, second primary cancer including contralateral breast cancer, and death.

LUSTRE – This is a Canadian phase III randomized controlled trial of stereotactic body radiotherapy (SBRT) versus conventionally hypofractionated radiotherapy (CRT) for the treatment of stage I medically inoperable non-small cell lung cancer. Eligible patients are randomized in a 2:1 fashion to either SBRT (48 Gy in 4 fractions for peripherally located lesions; 60 Gy in 8 fractions for centrally located lesions) or CRT (60 Gy in 15 fractions). The primary outcome of the study is 3-year local control (LC). The projected sample

size is 324 patients. Important secondary outcomes include overall survival, disease-free survival, toxicity, radiation-related treatment death, quality of life, and cost-effectiveness.

OPAR - This is a multi-centre randomized phase II trial in women with invasive carcinoma of the breast with negative axillary nodes or Ductal Carcinoma In-situ (DCIS) treated by Breast Conserving Surgery (BCS). Eligible, consenting patients will be randomly allocated to receive radiotherapy of 3 Dimensional Conformal Radiation Therapy (3DCRT) Accelerated Partial Breast Irradiation (APBI) 30 Gray (Gy) in 5 daily fractions of 6Gy or 27.5Gy in 5 daily fractions of 5.5Gy over one week. Patients will be followed at 12, 24, 36 and 60 months post randomization. Cosmetic outcome will be measured using photographs and evaluated by a panel of trained radiation oncologists. Radiation toxicity will be assessed using National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE).

As a result of being based within the trials group, the intern will be a key member of the research team and have the opportunity to be involved in each of the above projects. The intern will collaborate with investigators of these studies to conduct appropriate statistical analysis and that will be used for abstracts, manuscripts and potential planning of new studies. Furthermore, the intern will have the opportunity to be involved in the 1) design and development of new studies followed by grant proposal preparation, 2) consultation with Department of Oncology residents/fellows on their research projects, and 3) methodological research arising from design or analysis issues in the trials. Lastly, they will gain valuable experience interacting with clinicians, trial coordinators, data staff and IT personal involved in the day to day running on studies

This proposal is line with OICR plan to continue to support design, planning, conduct and analysis of clinical trials in Ontario. In addition, the intern will acquire valuable skills and experience that will enable them to contribute to cancer research in the future.