SECTION A – INTRODUCTION

CSRT PROJECT OVERVIEW

Beginning in May 2006, in the face of increasing cancer burden and human resource pressures, the Ministry of Health and Long-Term Care (MOHLTC) funded a series of projects to investigate a new health care provider role – the "clinical specialist radiation therapist" (CSRT). The results of the CSRT Demonstration Project showed a number of positive impacts in local radiation treatment programs. In March 2011, the CSRT Sustainability Project was approved for a three-year period. During that time, an additional 10 positions were piloted according to project guidelines and work began on strategies to ensure the long term implementation of the CSRT role across Ontario beyond the life of the projects. Efforts are ongoing to understand and articulate the positive benefits the CSRTs have on their local programs. Data consistently show impact on both quantity and quality, including the improvement of both the patient and provider impact. A collective and concise description of the CSRT impact is an ongoing focus as is the establishment of standards and consistent approaches to CSRT implementation and integration. To this end, work with the College of Medical Radiation Technologists of Ontario is ongoing in order that the new role can be characterized and documented in alignment with the regulatory requirements.

In November 2013, the MOHLTC approved a new phase of the project – the CSRT Integration Phase – with a proposed end date of March 2016. The focus of this phase was to roll out palliative radiation therapy CSRTs across sites that were not currently engaged with the project and has resulted in the implementation of palliative positions in 3 new sites and the addition of 4 "other" positions in centres that have existing CSRT positions in place. As a result, there are 25 approved CSRT positions in Ontario, with 23 of them filled fulltime beginning Fall 2014. Two additional CSRT pilot positions will be filled between December 2014 and May 2015.

While the project continues to collect and report on the efforts of individual CSRTs in their respective positions, permanent integration efforts are also being advanced through the establishment of "permanent" CSRT positions in the provincial cancer centres. The CSRT positions at the Odette Cancer Centre have been approved and are now permanent while positive progress continues to be made at the remaining 2 original sites – Juravinski Cancer Centre (Hamilton) and Princess Margaret Hospital (Toronto) – as well as at our other partner sites around the province.

One of the most important initiatives related to the sustainability of the CSRT role is knowledge dissemination and promotion of the positive benefits of the role. CSRTs continue to undertake innovative and practice changing activities as well as writing and presenting about their work. The Project continues to seek out and promote opportunities to share experiences including publication of Project work and presentations and workshops at relevant professional gatherings. These communication strategies in combination with the current momentum in the Project combine to favorably impact on the long term sustainability of the CSRT role in the

Ontario cancer care system and have garnered several professional awards for specific CSRTs and their teams.

This document will serve as a guide to developing and advancing all CSRT positions including standard metrics that every CSRT will be required to utilize and guidance on how to measure the positive impact(s) of individual positions in line with project expectations.

PROJECT BACKGROUND, TIMELINES AND DELIVERABLES

Project Genesis

Ontario began exploring the introduction of advanced practice for radiation therapists in 2003 in response to unprecedented and well-documented challenges in the radiation treatment environment. Unique local service pressures related to specific demographic or professional challenges, treatment delays, service expansion, health human resource issues in cancer- related disciplines, care gaps, and a desire for quality improvement and for more rapid adoption of innovation led the radiation therapy community to begin examining ways in which the provision of radiation treatment could be improved. A preliminary examination by the Ontario Radiation Therapy Advanced Practice Steering Committee concluded that there was interest and value in piloting advanced practice roles in radiation therapy. These efforts ultimately led to the development and implementation of the CSRT role in the context of the CSRT Demonstration Project, and finally, to the CSRT Sustainability Project.

Project Overview

The Advanced Practice Radiation Therapy ("APRT") Development Project, under the auspices of CCO, was officially launched in August 2004 following a successful application to the Ministry for funding of a two year-pilot project to August 2006. This phase of the Project was designed to examine the feasibility of developing an advanced practice role in radiation therapy as a possible strategy for addressing systematic challenges in the delivery of timely, high-quality radiotherapy services to the people of Ontario.

The APRT Development Project involved seven investigators in four Ontario Regional Cancer Centres. During the Developmental Phase investigators:

- established the scopes of practice of the proposed positions against local service needs;
- identified and quantified (where possible) the potential benefits of these new roles to patients and the cancer care system; and
- assessed the readiness of the inter-professional health care team to accept this new role.

In response to the positive findings of the APRT Development Project, the Ministry provided funding for the CSRT Demonstration Project as part of the HealthForceOntario strategy. Phase I of the CSRT Demonstration Project, which began in March of 2007, was a pilot study in which five CSRT positions were implemented at two Ontario Regional Cancer Centres in the Greater Toronto Area. Phase I evaluated the potential benefits of CSRTs to patients and the cancer care system. The Project Team developed a set of standard measurement tools for the CSRTs' use. The tools facilitated collection of consistent and reliable data that could be used to draw conclusions about the effects of CSRTs on programs and services.

In March 2008, the CSRT Project Team provided an evaluation report to the Ministry on key outcomes of Phase I of the CSRT Demonstration Project. Data and information obtained during Phase I suggested that a number of important benefits could be realized through implementation of the CSRT role, and that stakeholders – including patients and the interprofessional team – supported the role. Phase I also established that CSRTs could safely and effectively provide some services that are traditionally performed by Radiation Oncologists, allowing the Oncologists to focus on other discipline-specific activities that cannot be delegated. CSRTs were also able to achieve notable reductions in wait times and improve access to services during the period of study. The evaluation report for Phase I emphasized the flexibility offered by the CSRT within the interprofessional team by allowing programs to shift or modify the focus of the CSRT across the patient care pathway in response to changing pressures over time.

Based on the findings from Phase I, the evaluation report recommended continued investigation of the existing positions to further evaluate the impacts of the CSRT role, add robustness to the growing database, and establish the education and training required to adequately prepare CSRTs for practice. The report also endorsed an expanded phase for the creation of new CSRT positions to test the transferability of the advanced practice concept to other cancer centre environments and patient populations.

In light of the early positive results from Phase I, and in support of the recommendations from the Project Oversight Committee, the Ministry provided additional funding to extend the Project for one year. This phase of the Project, which ran from April 2008 to March 2009, became known as Phase I Extension. The Extension Phase allowed the existing CSRTs to continue their clinical work, collect the data required to create a robust and rigorous CSRT- specific dataset, and fill any data gaps identified in Phase I.

With the continued success of Phase I, the province also provided concurrent funding for Phase II of the CSRT Demonstration Project, from August 2008 to March 2010. Phase II involved the introduction of five additional CSRT positions in cancer centres outside the Greater Toronto Area, consistent with the recommendation contained in the evaluation report for Phase I of the Project.

Phase II focused on the examination of how the CSRT role could be modified to create positions that meet different system and population needs. Consistent with Ontario's broader health human resources strategy, the province hoped to establish that CSRTs could help smaller centres improve access to service, including traditionally "harder to reach" populations such as Francophone or Aboriginal communities. The Project continued to build upon existing data, address gaps, and determine whether the draft competency profile was transferable across and customizable for varying cultures and patient populations. The CSRTs added in Phase II also collected data using the standard measurement tools to expand and enhance the larger CSRT dataset. Phase II also tested the usability of the tools and methods developed in earlier phases

of the Project. These materials included the CSRT Tool Kit, the site selection processes, the Prior Learning and Assessment Process and the competency profile.

The Ministry provided additional funding for a final extension of Phase I, referred to as *Phase I Extension 2 (or IE^2)*, from April 2009 to March 2010. During this final phase, in combination with ongoing data collection, the Project turned its focus to understanding the issues related to sustainability of the role in alignment with provincial and CCO priorities. Recommendations were formulated to incorporate the CSRT role into models of care to assist in health human resource planning for the optimization of patient care. This final "Demonstration" phase was also used to begin disseminating project findings through scholarly avenues and to collaborate with national and provincial professional bodies with a view to developing mechanisms for establishing and monitoring practice standards for CSRTs. The Summative Report was submitted to the Ministry in May, 2010 including a recommendation for a "sustainability" phase of the project.

In March 2011, the Ministry awarded funding for the CSRT Sustainability Project – a three-year project that outlines and supports the remaining activities necessary to ensure consistent and standard development and deployment of CSRT positions as needed throughout the system (April 1st, 2010 – March 31st, 2013). These include controlled transition of existing CSRTs into permanent team members, the development of up to 9 additional CSRT positions across the province and the formalization of the CSRT role through standard setting and valid certification processes.

Based on the positive results of the CSRT Sustainability Project, the next CSRT Project phase – the CSRT Integration Project – was initiated in November 2013 and is proposed to continue until June 2016. The CSRT Integration Project includes:

- A focused rollout of the Palliative Radiation Therapy CSRT to centres that are not currently engaged in the CSRT Project. It was felt that this kind of position could address a need that is common across all Ontario jurisdictions;
- Collaboration with CCO's Models of Care initiative and the development of policy and processes which support the formalization of the CSRT role within Ontario; and
- Continued support of project activities to maintain momentum in order to realize sustainability and permanence of the CSRT role including:
    - ongoing data collection
    - work towards the establishment of a national certification process
    - knowledge translation activities

CSRT ROLE EXPECTATIONS AND GOALS

The CSRT Integration Project is the final phase of a series of projects that were funded to explore if the introduction of a new health care provider role – the Clinical Specialist Radiation Therapist – could alleviate some of the well documented pressures in the radiation medicine system and/or improve the efficiency of the system. It was hoped that this could be accomplished by CSRTs assuming responsibility for activities traditionally performed by other members of the team (primarily radiation oncologists) increasing the continuity of care and decreasing identified gaps in the overall process.

The benefits of implementing a CSRT have been well documented in the current CSRT sites by both longstanding and newer CSRTs. The current "sustainability" phase is designed to assess if the role is useful in a variety of settings and practice cultures establishing the generalizability of the findings to date.

Because the Project involves a partnership between the clinical site and the overall Project, there are expectations at both the host site and the Project that need to be addressed. Within your host site, you will begin orientation to your pilot position and the existing team, eventually followed by a development phase where the education and training required to develop the necessary skills will begin. You are expected to be the driver of your own progress through the identification of learning needs/gaps and the progression of your integration into the existing team. Your direct supervisor and departmental supervisor should assist you with a workplan that makes sense and continues to evolve based on your development.

As part of a larger Project, there are a variety of documentation and reporting requirements. The instructions, timelines and templates you require to meet these expectations are included here in this book (and in e-form to be provided) and will be reviewed as part of the new CSRT orientation. As each CSRT position is slightly different than the next, there is no ONE WAY to do anything, and customizations to suit your home environment will possibly need to be made to various tools to make them work for you. This is perfectly acceptable, but any deviations from the planned approach should be discussed with the Project Manager, Nicole Harnett. Everything you need to complete these tasks have been agreed to by your department and any issues you are having should be brought to you departmental supervisor as soon as they are identified. If you have having difficulty resolving an issue of support or access to information, this should be brought to the attention of Nicole immediately for assistance in finding a solution.

In addition, as part of the broader agreement between CCO and your cancer centre, there will be a "funding letter" that outlines the expectations of you and your department regarding the Project deliverables. These are built upon the reporting timelines and tools that are included here. As the pilot CSRT**, it is your responsibility to ensure you are on track for reporting expectations and to submit your reports on time.** If you anticipate that you will not make a

deadline (as per the Timeline) you should notify your department supervisor and Nicole as soon as you are aware.

Finally, those who are responsible for the creation of the vision for this position had specific and concrete objectives in mind. Along with those came expectations about where and how you would work within the team. From time to time, the original vision requires some revision to adjust to the realities of the team or the clinic or the patient population. This is not unexpected but needs to be discussed with Nicole to ensure the position is not changing so much that it will fall outside the parameters of this Project. The "Process for Deviation from Approved Implementation Plan" (in the following section) outlines the steps involved in navigating a situation when the actual CSRT position starts to evolve from the originally approved plan.

PROCESS FOR REPORTING DEVIATION FROM APPROVED IMPLEMENTATION PLAN

The Project recognizes that challenges may arise during the implementation and integration of the CSRT positions and will provide support regarding the navigation of such challenges. To ensure that all the management of any barriers or challenges that may arise with respect to meeting the Project deliverables is consistent and equitable, a three-step process has been developed. Hospitals are encouraged to work with the CSRT Sustainability Project Integration Support Team to navigate the process detailed below, mitigate challenges and develop solutions, where appropriate.

- The continuation of the CSRT position is expected to follow the original implementation plan and timelines submitted and agreed upon during prior phases of the Project ("approved plan").
- At any time when the continuation and integration of the CSRT position into the program/service begins to face challenges, the following process for managing the issues should be followed.

Level 1 – at any time across the year of implementation:

- Within one week of the identification of a barrier (e.g. a major issue that could prevent the position from being successfully implemented as planned) to implementation according to the approved plan is encountered, the responsible manager or his/her delegate will contact the CCO Project Manager by phone or email to report the nature of the issue and to seek assistance for resolution or alteration of approved plan. This initial reporting should be followed by a written report from the site to the CCO Project Manager within 2 weeks of identification of the issue/barrier.
- The CCO Project Manager will work with the local supervisor and implementation team to find suitable strategies for resolution, including the possible connection of this manager with another at another site.
- All actions, including a revised plan where appropriate, will be documented and circulated by the CCO Project Manager to the Project Oversight Committee (POC) for information purposes.

If resolution is not found, the situation will escalate to Level 2.

Level 2 – at any time when the situation warrants urgent and high level input, or after Level 1 actions have been unsuccessful:

- If the onsite responsible manager feels that the project is not going according to the approved plan or if Level 1 strategies have not been effective, the supervisor will contact the CCO Project Manager in writing.

- The CCO Project Manager will communicate with the POC to apprise members of the situation and for development of in-depth strategies for resolution, redirect or intervention. Strategies may include onsite visits, interviews, teleconference calls, etc.
- All actions, including a revised plan where appropriate, will be documented and circulated by the CCO Project Manager to the POC.

Level 3 – when satisfactory resolution cannot be reached within the mandate of the Project:

- Any time that a resolution includes changing the approved plan, the change must be deemed to be appropriate within the scope of the Project. If resolution is NOT possible and the position is discontinued, the Hospital shall notify the CCO Project Manager in writing as soon as practicable. In such event, CCO shall have the right, in its sole discretion, to either withhold any unused portion of the CSRT funding provided in respect of such CSRT's services or require the Hospital to reimburse CCO for such unused portion of the CSRT funding provided in respect of the unfilled CSRT position.

REPORTING TEMPLATES

Reporting templates will be included in the e-copy of the document that will be distributed in December 2014.

OVERVIEW OF THE STANDARDIZED MEASURES PACKAGE AND PROTOCOLS

The Clinical Specialist Radiation Therapist (CSRT) Demonstration Project has developed a package of "standardized measurement tools" for use in this stage of the Project. The package will be used by each of the CSRTs to assist in the collection of evidence regarding the potential impact this new role could have on the radiation therapy process in the Ontario cancer care system. It is hoped that standardized tools will help to improve the power of the results and increase the generalizability of the conclusions.

With the key foci of the MOHLTC in mind – decreased wait times, increased access and improved health of Ontarians - the Project team categorized the various elements to be measured into 3 key themes:

QUANTITY

- Does the new model save the system money or allow for increased patient capacity with the same money?
- Does the new model allow patients to enter/move through the system more quickly?
- Does the new model reduce the cost of human resources required to meet existing patient demands and/or optimize the use of human resources?
  (while maintaining patient and provider experiences as well as patient outcomes)

QUALITY

- Does the new model improve patient experience, outcomes and/or provider experiences? (e.g. new services, process streamlining, standard setting, etc.)

INNOVATION AND KNOWLEDGE TRANSLATION

- Does the new model bring the promise of improved patient treatment, care and/or outcomes? (e.g. new technique, adoption of new technology, etc.)

The tools included in the package represent a combination of existing validated tools from other previously published studies, tools and questions piloted during earlier phases of the Project and new questions developed by the investigators.

There is also a "Development" section that provides the tools and templates to guide the new CSRT in the implementation of the pilot position, to facilitate the appropriate education and training and to help build the evidence base required to maximize the positive impact of this new role in the radiation medicine domain.

SECTION B – CSRT DEVELOPMENT

CSRT PROCESS FLOW MAP

To ensure that each CSRT has a good understanding of the clinical processes within the area he/she will be working, each CSRT is required to complete a process flow map. The map should identify all the steps in the patient journey (including the steps that do not include direct patient contact) and should highlight those time periods along the care path that the CSRT is planning to be/will be involved in. As the map is being created, the CSRT should identify process gaps that can be improved upon or rectified (only those that you are able to affect) and mark these on the flow map with a short bullet point description on what change will be achieved. This information will then feed into planning for "how" the change will be achieved – including the learning that is required, the team members that are impacted, the measures that will be required to assess impact and success, etc.

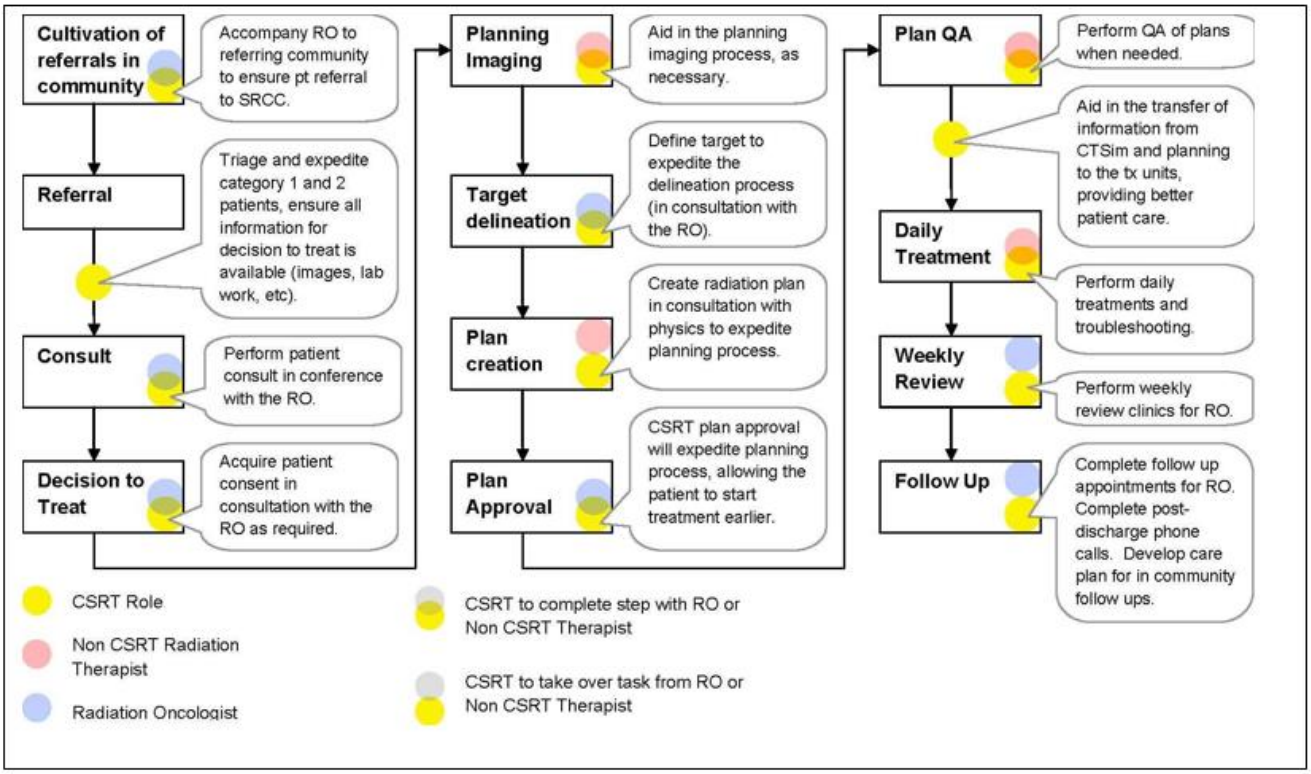
For example, your centre may be experiencing long wait times between referral to consult. In your process map, you may have identified that part of the reason for this long wait time is due to the volume of inappropriate referrals that radiation oncologists are seeing. The CSRT may, therefore, propose a review of the referral triaging process and implementation of a new process that can be undertaken by the CSRT, subsequently measuring wait time changes/number of appropriate referrals across time.

This link will take you to the Cancer Care Ontario website where the PEPPA Framework Tool Kit is posted. From pages 51 – 56 of this document you will find information and strategies for building your process map. There is no need for you to conduct formal stakeholder sessions, but you should review your map with key members of the team you will be working within to ensure you have captured everything correctly.

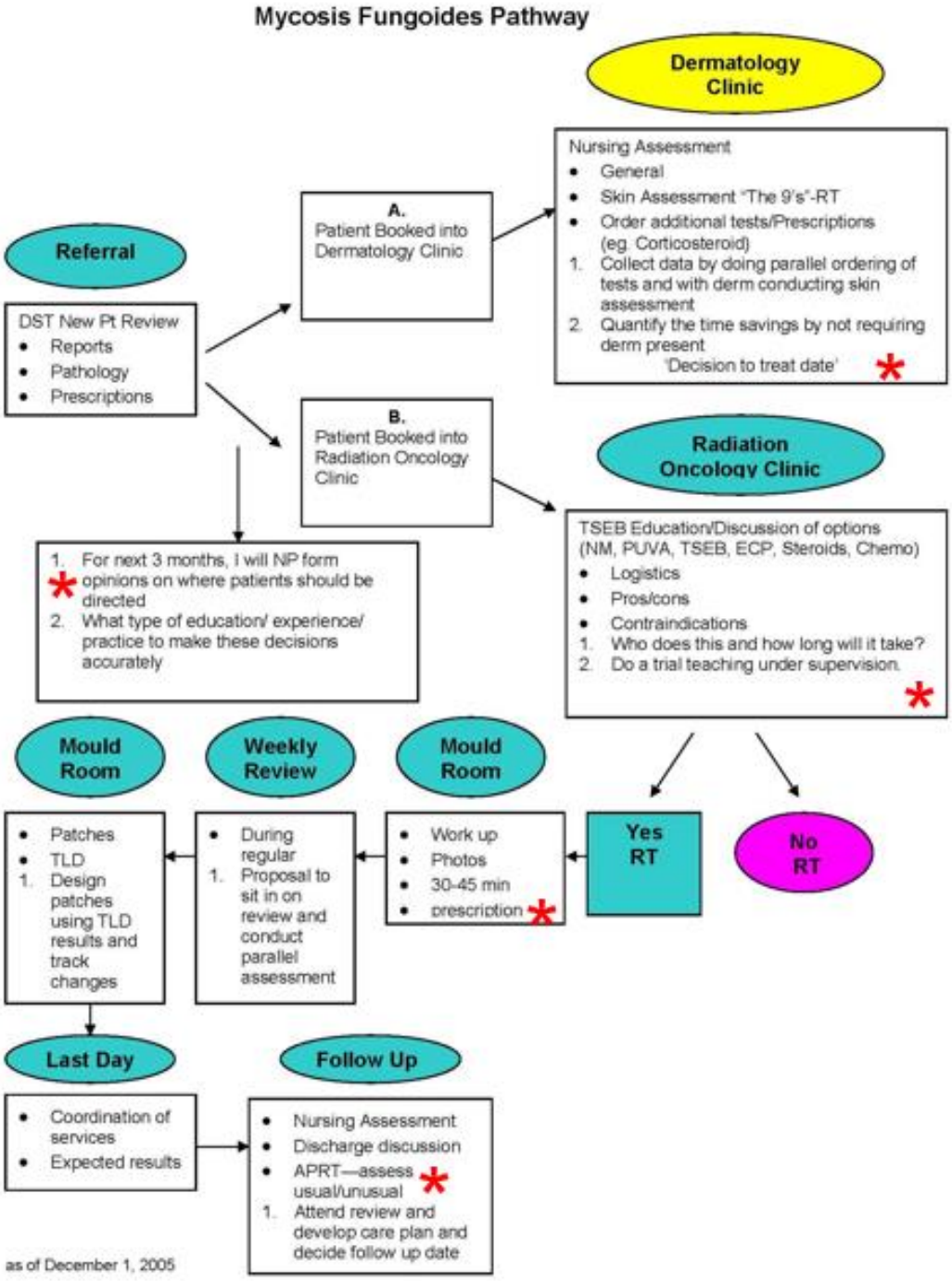
Team To Do List

- ❑ Review pages 51 – 56 in the PEPPA Framework Tool Kit.
- ❑ Assess the flow chart provided as part of the position. Review with your team members and update accordingly. Identify the activities that accompany each of the steps and assign the professional primarily responsible for the activity.
- ❑ Complete your revised process map by **December 8, 2014** and send to Nicole for review.

Example 1 – Southlake Regional Cancer Centre



Example 2 – Juravinski Cancer Centre



COMPETENCY DEVELOPMENT PLAN

One of the expectations of you as you develop this new pilot CSRT position is that you will either hone existing advanced knowledge and skills or develop new ones that will serve to advance the objectives of the position. You will work with your local team to understand what knowledge, skills and competencies are required, but it will be up to you to establish what your learning needs or gaps are related to the development of each skill. The Competency Development Plan is created for you to clearly map out what you want to achieve, how you will achieve it and how you will know when you have achieved it. Built on an adult learning model of the "Learning Contract" you will use this plan to guide your education and skills development while in your pilot position. It is a fluid document that may need revising as you learn more about what is possible in your position and with the team and as expectations evolve.

Team To Do List

- ❑ Meet with your Direct Supervisor/team to identify the overall goals for the pilot position.
- ❑ Use the development table to map out your learning strategies relating the position expectations to your pre-existing knowledge and skills and identify any gaps that must be addressed.
- ❑ Document and review your learning map with your Direct Supervisor and your departmental supervisor and finalize.
- ❑ Submit your development plan to Nicole by **December 8, 2014**.

COMPETENCY DEVELOPMENT PLAN

Objectives (List your objectives for learning, developing skills, etc.):

1.
2.
3.
…..

Objectives	Will be able to perform	How will I get there	Evidence of successful completion	Resources needed
1.				
2.				
3.				
….				

Timeline:

Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov

EXAMPLE

COMPETENCY DEVELOPMENT PLAN

Objectives (List your objectives for learning, developing skills, etc.):

1. *Proficiency in Contouring:* ***Female Pelvis***
2. *Advanced knowledge of* ***xxx***

Objectives	**Will be able to perform**	**How will I get there**	**Evidence of successful completion**	**Resources needed**
1. Contour Female Pelvis ***1.1****: Learn female pelvis anatomy* *i. Self-study* *ii. Tutorial with clinical supervisor/delegates* ***1.2****: Contour tumor & OAR on CT/MR* *i. Self-study GEC-ESTRO guidelines* *ii. Practice contouring*	*Contour target* *- GTV/CTV* *- Pelvic lymph nodes* *Contour OARs* *- Rectum* *- Sigmoid* *- Bladder*	*Train by MR-guided cervix group* *- Jason Xie* *Attend Weekly Gynae Rounds*	*10 patients contoured (reviewed by Jason Xie)*	*Anatomy Books (Perez)* *GEC-ESTRO guidelines* *PMH protocols*

Timeline:

May	**June**	**July**	**Aug**
1.1 *– Learn & practice contouring Female Pelvis*		***1.2*** *– Contour 10 patients*	

CONCORDANCE PROJECT PLANNING

Each position needs to develop tailored project(s) to examine the CSRT's ability to complete specified activities against a "gold standard". In most cases, the gold standard is a radiation oncologist or group of radiation oncologists. The goal of this activity is to build evidence that the CSRT is competent to complete the assigned activities. As this data will be unique for all sites, examples of different types of consensus information will be discussed, in general terms, for your reference.

i. **Patient Treatment Consensus**: Data examining the CSRT's recommendations for treatment type, patient management and medication use. Examples include:
   - Triage of patient referrals for suitability
   - Type of treatment recommended by the CSRT (ie. 4-field or 2-field breast technique)
   - Changes in treatment based on patient assessment (yes/no response; i.e., Did the CSRT's recommendation correspond to that of the Radiation Oncologist?)
   - Detection and scoring of treatment side effects and planned course of management
   - Medication(s) required for management of patient condition

ii. **Treatment Planning Consensus**: Data examining the CSRTs' decisions for radiation treatment technique and dose and related decisions (i.e. bolus, etc.). Examples include:
   - Placement of field borders
   - Scan positioning and borders
   - Placement of bolus or other ancillary equipment
   - Immobilization technique
   - Contouring of GTV, CTV and other regions of interest
   - Decisions regarding starting, stopping, pausing, adapting radiation treatment
   - Type and magnitude of field changes made by the Radiation Oncologist
   - Type and magnitude of dose changes made by the Radiation Oncologist

Once the CSRT has established learning objectives and identified areas along the treatment trajectory where focus will be placed, the skills required will be decided. Once established, it will be up to the CSRT and the supervisor/team to find or develop the appropriate tool to measure concordance between the CSRT and relevant profession representing the gold standard.

It is expected that the CSRT will develop methods with input from Project members – existing CSRTs and their managers, Project Manager and Coordinator, and Research Analyst. Many of these metrics have been developed by existing CSRTs and have been drawn from the literature. It is in the best interest of the Project if we use consistent metrics wherever possible.

Team To Do List

- ❑ Once you have decided what knowledge and skills you will be developing and providing evidence for, you will have an understanding about what concordance activity(s) will be appropriate.

- ❑ Work with your Direct Supervisor, published literature and Project members to choose a metric to assess concordance for each activity. These should be proposed and discussed with Nicole/Laura by **December 19th**.

- ❑ Write up method(s) for your initial projects and submit to Nicole for review and comment in your draft report due **February 9, 2015**. This should be written up as you would for an abstract.

NEW SKILL/ACTIVITY	
Description	**Details**
Purpose: *Given Radiation Oncologists (RO) time constraints, we explore the delegation of target delineation of the prostate for permanent seed treatment planning to an advanced practice clinical specialist (CSRT) in brachytherapy. This pilot work was conducted to determine the feasibility of CSRT lead prostate contouring on TRUS volume studies for patients undergoing LDR prostate brachytherapy.*	***Study design****: CSRT and RO contours were exported to MIMVISTA (1) for analysis. Total prostate volume, union and intersection of prostate contours were calculated. DICE index (2) was calculated to compare the similarities between the contourers. A DICE value of 1.0 means complete concordance while a DICE value of 0.0 means complete discordance.*

- ❑ Begin collecting concordance when you and your supervisor agree that you have developed the necessary knowledge and skills to perform the activity (this should be happening in late Spring/early Summer 2015).

- ❑ Enter your data in the relevant spreadsheet (attached).

- ❑ Include spreadsheet in your final report on **May 4, 2015.**

SECTION C – MEASURES

1. QUANTITY

WAIT TIMES

Introduction

The proposed wait time data is currently collected by all hospitals in Ontario as per CCO standards. Thus, the ability of each hospital to obtain access to this information should not be of issue. You will need to liaison with your Data consultants at your local hospital to determine how this information may be captured for your project.

Definitions

CCO has developed wait time data based on the definitions below. These concepts will be used to achieve the wait time objective in this project.

Specialist Referral Date: The date on which a request for consultation with a specialist (e.g., Radiation Oncologist or Medical Oncologist) is received in the specialist office from the referring physician. Even if the specialist does not accept the referral at this time, this date does not change.

- Example: date on fax or date of the phone call

Ready-to-Treat (RTT): The date on which any planned delay (other cancer treatment first, patient choice, physician choice) is over, and the patient is ready to begin treatment from both a social/personal and medical perspective.

Urgency Category: This new data element will be captured at the time of Decision-to-Treat (DTT). The treating physician will assign a priority category (numbered 1-3 based on Clinical Conditions), which will be used to assess whether the system is treating patients, as the physician believes it should.

Urgency Category	Radiation Treatment
1	Patients who have an immediately life-threatening condition (e.g., neurological compromise with cord compression, superior vena cava syndrome), which is expected to be treated on an emergent basis.
2	Patients who are not considered emergent, but, in the opinion of the treating physician,[1] the treatment should start within one week. This category would include, for example, very aggressive tumours and some palliative cases.
3	All patients who, in the opinion of the treating physician, do not meet the criteria of category 1 or 2.
4	N/A

Team To Do List

- ❑ Review the CCO Wait Times presentation (**Appendix A**).

- ❑ **In December**, use your developing process map and discussions with your team/supervisors to identify the areas along the pathway where it is expected this position will impact positively on wait times. Meet with the staff who control the wait time data for your Centre. Orient the Data consultant regarding your current project and your future data needs. While you may not know the exact indicators you will use at this point, it's good to get an idea of how requests for data will work – i.e. turnaround time, request processes, etc. They may even be able to provide ideas for what data they have that can be used to track impact.

- ❑ **In December**, once your process map is complete and you are becoming familiar with the routines and process of the program/service you are working within, the areas of impact you may have should be clear. Ideas for y**our wait times data projects should be discussed with Nicole/Laura by December 19th.**

- ❑ **In February** - Initiate another meeting with your Data consultant to describe the necessary data (refer to the excel file titled, "Wait Times & Access to Care Data Collect" on the worksheet "CCO Wait Time Data"). Baseline data collection should be for a 3-month retrospective time period of "normal" operations (i.e. not over Christmas or when the lead oncologist is away, etc.) **This should begin by March 2nd and be completed by March 31st.**

  - Collect the following variables:
  - Subject Number (note this should NOT be hospital IDs)
  - Referral Date
  - Consult Date
  - RTT
  - Treatment Start Date
  - Urgency Category

  Please specify with the Data consultants to record the dates in the following manner: 14-Mar-07, (dd-mmm-yy). Also, instruct this person to place the data onto a generic excel file. The CSRT will be required to transfer the data onto the study excel file.

  The study excel file will automatically calculate the time between certain data variables for you. Please do not enter them yourself. Also, if a data link

has been broken (i.e., you are unable to see the automatic calculation), highlight the box in yellow, notify Nicole and she will fix this problem during the data analysis.

Follow up with colleagues about data entry – Are there any issues? Complete another quality control check. Report any problems of this check to Nicole.

- **By April 13, 2015:** After obtaining the retrospective Wait Time data the CSRT or Project Assistant will transfer this information to the blue variables titled "Baseline Data" and send the file to Nicole/Laura. This baseline data will form part of the final report due to the MOHLTC on May 15, 2015.

At a point in time when the CSRT has made a full integration into the team and is making good progress with knowledge and skills development, including concordance activities, it is time to think about collecting the "post-CSRT" prospective data. This should normally be happening in Fall 2015. **Final data will be required in March 2016.**

- **One month before prospective data collection:** Send a reminder email to Data consultants that you will be requiring the prospective Wait Time data to be pulled early next month. Complete random quality control checks.

- **Month one**: At the beginning of the month, obtain the prospective Wait Time data for the month and transfer this information to green variables titled, "After CSRT Implementation" and send the file to Nicole/Laura by month end.

Repeat this cycle for three consecutive months and submit final spreadsheet with final report March 25, 2016.

THROUGHPUT AND TIME SAVINGS

Please examine each section carefully to determine if it is appropriate for your site to collect.

This section discusses site-specific data requirements to validate the concept of 'Quality'. In the excel file "Wait Time & Access to Care Data Collect" under the worksheet, "Access to Care" you will find the potential variables your site may collect.

The Project does not expect that each site will be able to obtain all the information nor would it be of value to do so. In addition, the variables under each section described below do not represent the totality of data that each site could consider collecting in order to obtain the required information. You are expected to determine and acquire all the site-specific information that may be used to enhance the overall project. If further details are required to expand our understanding of your clinic or department, Nicole will follow-up with you for this information.

In order to reduce the potential "data collection crunch" at the end of this phase of the Project, it is expected that each site will collaborate with their Data consultant, Project Assistant, and other helpers to acquire the information throughout the study, rather than at its end.

Data for this section will usually be collected during two time periods. The first time point occurs before the CSRT position has begun (for a 3-month period). For example, if the CSRT position starts July 1st (of any given year), you will be collecting the relevant data starting the April 1st BEFORE the CSRT position was implemented to July 1st (equaling 3 months). The second time point occurs after the CSRT position has been active for a period of time. In this case, you will be collecting prospective information for a 2-month period (see Timelines). If you are unclear about these timelines, please contact Nicole right away for clarification.

We recognize that it may not be possible to retrieve certain information for the time period prior to the CSRT position starting. As an alternative, baseline information may be collected in the first several months of the CSRT position; however, this is not an ideal solution and should be discussed with Nicole prior to changing your team's protocol. If you wish to collect data outside of the suggestions below, speak with Nicole about its validity to the project's goal.

It is important to note that many of the activities under this heading, 'Throughput and Times Savings', will also result in improved quality of care – whether they lead to increased patient satisfaction or patient outcomes, or improved provider experience, the impact on these elements should be documented in the Quality section of your report.

A) Clinical Trials Use

If your clinic/department/disease site is active, to any degree, in accruing patients for Clinical Trials, you should obtain the following:

i. Number of patient referrals to Clinical Trials from your clinic.
ii. Number of patients placed onto the Clinical Trial from your clinic.
iii. Number of active clinical trials appropriate for your disease site area in your clinic.

B) Patient Follow-up Calls

If your program expects the CSRT to perform follow-up calls to its patients, please assess the feasibility of recording data on this process. We would like to determine the CSRT's ability to complete this task and provide additional resources for patients outside of clinic appointments. Note that while this activity might build capacity in the program/clinic, there may also be some "quality" gains that should be documented in the Quality section of your report.

i. Total number of follow-up calls made in three months prior to the CSRT position being implemented.
ii. Number of calls completed by the "usual person" (i.e., does the nurse normally complete this task?) in the three months prior to the CSRT position.
iii. Number of calls completed by the CSRT for a 2 month period once CSRT is deemed competent to do so.
iv. Categories of actions proposed by CSRT in response to patient assessment.
v. Create 1-2 descriptive paragraphs on the type of calls and the role of the CSRT.
vi. Improved patient satisfaction with follow up care.

C) New Patient Referrals

In order to examine the CSRT's ability to facilitate patient's access to new consultation appointments, referral information is necessary.

i. Number of appropriate new patient referrals to your clinic.
ii. Number of inappropriate new patient referrals to your clinic.
iii. Total number of new patient referrals to your clinic.
iv. Total number of appropriate referrals actually booked.
v. Number of new patient referrals to the Hospital.

D) Follow-Up Patient Appointments

In order to examine the CSRT's ability to facilitate patient's access to follow-up appointments, attendance information is necessary.

i. Total number of follow-up appointments scheduled in your clinic.
ii. Number of follow-up appointments patients attended.
iii. Number of follow-up appointments patients cancelled (any reason).
iv. Number of follow-up appointments doctor/healthcare employees cancelled (any reason).
v. Total number of follow-up appointments to the Hospital.

E) Pager System

If your clinic supports a paging system that allow patients to page a nurse to inquire about health concerns, please asses the feasibility of recording data on this process. We would like to determine the CSRT's ability to complete this task and provide additional resources for patients outside of clinic appointments.

i. Volume of pages that are assumed by the CSRT related to the personal originally responsible for taking pages.
ii. Log of nature of pages handled by the CSRT and time it takes.
iii. Number of pages directed to the CSRT instead of the Resident/Attending Physician/Radiation Oncologist etc. (for shared positions when phone calls are made by more than one individual)
iv. Create 1-2 descriptive paragraphs on the type of pages taken and the role of the CSRT.

F) Treatment/Imaging Equipment Use

This section is a generic variable that can include any treatment or imaging equipment within the CSRT's practice. As the CSRT will be involved with streamlining various protocols in their department, we would like to examine the CSRT's ability to decrease equipment wait times and increase equipment access and utilization. Data can include machines such as the use of CT, MRI, fMRI, and machines used for treatment, simulations and ORs (not inclusive).

For each site appropriate machine, please record the following information:

i. Total number of appointments that can be booked.
ii. Number of filled (used) appointment time slots.
iii. Number of empty (never used) appointment time slots.
iv. Average wait time for appointment per month (in days, one decimal).

v. Average wait time for appointment per time period (3 months before CSRT implementation and between January 1st and February 28th; in days, one decimal).

Team To Do List

- ❑ Determine the types of data/activities that pertain to the CSRT position and the nature of the data that will be required. Discuss with Data Consultant(s) and supervisor/team. **Finalize your decisions with Nicole/Laura by December 19th.**

- ❑ Baseline data collection should be for a 3-month retrospective time period of "normal" operations (i.e. not over Christmas or when the lead oncologist is away, etc.

- ❑ If needed, send email reminders to Data consultants to obtain information by assigned deadline.

- ❑ Insert all data in the excel file, "Wait Times & Access to care Data Collect" under the worksheet, "Access to Care".

At a point in time when the CSRT has made a full integration into the team and is making good progress with knowledge and skills development, including concordance activities, it is time to think about collecting the "post-CSRT" prospective data. This should normally be happening in Fall 2015. **Final data will be required in March 2016.**

- ❑ **One month before prospective data collection:** Send a reminder email to Data consultants that you will be requiring the prospective Wait Time data to be pulled early next month. Complete random quality control checks.

- ❑ **Month one**: At the beginning of the month, obtain the prospective Wait Time data for the month and transfer this information to green variables titled, "After CSRT Implementation" and send the file to Nicole/Laura by month end.

Repeat this cycle for three consecutive months and submit final spreadsheet with final report March 25, 2016.

SECTION C – MEASURES

2. QUALITY

COMPETENCY ASSESSMENT

A various points along the development pathway of the CSRT, competency assessment shall be completed. The competency assessment form includes all the competencies as outlined in the CSRT Competency Profile developed by the CSRT Demonstration Project. The evaluation form included here is designed using the standard template used for the radiation oncology residents in the University of Toronto, Department of Radiation Oncology Residency Program and is therefore a familiar format for the majority of supervisors.

At prescribed times (as per the Activities and Reporting Timeline) the direct supervisor(s) (and other stakeholders as identified within the program) will be asked to complete the assessment form. Each assessor will fill in the assessment and review the responses with the CSRT to identify areas of improvement and direct future education and position adjustments. It is not expected, during the life of this project, that the CSRT will achieve competence in all areas. Emphasis should be placed on the competencies that align with the concordance activities and the skills required as dictated by the Competency Development Plan.

The completed and reviewed assessments will also be sent to Nicole Harnett for review and central analysis.

Team To Do List – *dates will be finalized in next issue of "**Timeline**".*

- ❑ Review the Competency Assessment Form with your Direct Supervisor(s) in advance of the assessment cycle.
- ❑ Answer any questions or forward questions/concerns to Nicole at your earliest convenience.
- ❑ Distribute the Form to your supervisor(s) by ***TBD*** and request responses by ***TBD***. Send a reminder after 2 weeks if you not received the completed form.
- ❑ Include in your package for your final report on **March 25, 2016.**

CLINICAL SPECIALIST RADIATION THERAPIST (CSRT)
COMPETENCY EVALUATION FORM

CSRT:	**Date:**
Supervisors:	**Clinical Site:**

Objectives for Competency of Clinical Specialist Radiation Therapists

In addition to those expected of a licensed Radiation Therapist, the Clinical Specialist Radiation Therapist is expected to hold additional competencies that qualify them as advanced practitioners. These competencies fall under the following three main categories:

1. **Clinical:** Works as a member of the interdisciplinary care team to provide optimal patient care for radiotherapy patients
   - in *the defined patient population*
   - at any point in the patient journey
   - in a variety of settings (e.g. outpatient, new patient, follow up, treatment review, at outreach clinic, etc.) and
   - in person or at a distance (remote consultation, email, telephone, telehealth etc.)

2. **Technical:** Utilizes advanced oncologic, radiobiological and dosimetric knowledge to optimize the use of available technology for the provision of tailored radiation therapy treatment to patients

3. **Professional:** Functions as a leader, role model, educator, researcher and mentor in radiation therapy and especially in their area of specialization

Evaluation of CSRT Competence

Please rate the CSRT's performance in the objectives listed below using the following scale:

Rating	Description	Rating	Description
1 = Unacceptable	Many major deficiencies	4 = Very good	No deficiencies of consequence
2 = Needs to improve	Several important deficiencies	5 = Outstanding	No deficiencies
3 = Good	Satisfactory performance	NA = Not assessed	

1. CORE CLINICAL COMPETENCIES

	1	2	3	4	5	NA	Initials
1. Ensure that all relevant patient information is available for clinical decision making							
2. Assess the patient's physical condition							
3. Assess the patient's emotional condition							
4. Obtain informed consent for required diagnostic procedures, therapeutic interventions or radiation therapy treatments							
5. Formulate and prescribe an effective plan for patient care and/or treatment							
6. Implement an effective plan for patient care and/or treatment							
7. Communicate the results of specific tests/procedures							
8. Prescribe/dispense correct pharmaceutical from defined and approved formulary							

2. CORE TECHNICAL COMPETENCIES

	1	2	3	4	5	NA	Initials
1. Provide autonomous technical consultation for all relevant clinical, diagnostic and technical information at all phases of the radiation therapy planning and treatment process and technical advice to team members or other health care professionals							
2. Implement clinical decisions by interpreting and integrating available imaging and clinical information.							

3. CORE PROFESSIONAL COMPETENCIES

	1	2	3	4	5	NA	Initials
RESEARCH AND EVIDENCE-BASED PRACTICE (EBP)							
1. Conduct original research to contribute to the professional knowledge							

base							
2. Lead and participate in continuous quality improvement of program/service/department as a member of the interprofessional health care team							
3. Lead the ongoing development of best professional practices using evidence-based approaches							
LEADERSHIP (L)							
1. Optimize the function of the health care team through continual assessment, audit, evaluation and strategic visioning as a key member of the interprofessional health care team							
2. Create and maintain a team to ensure safe and effective practice							
3. Coach and mentor staff, students, other health care providers							
EDUCATION (E)							
1. Develop an educational activity to address an identified need/gap							

Strengths and Areas Needing Improvement: Strengths:

Areas Needing Improvement:

Overall Evaluation:

Satisfactory **Marginal** **Unsatisfactory** Please discuss results with CSRT.	**Date:** **Supervisor's Signature:** **Supervisor's Name:** ***(please print)***

CSRT's Comments

Evaluation discussed with Supervisor: *Yes* *No*

CSRT's Signature: **Date:**

STAKEHOLDER SATISFACTION

Introduction

During previous phases of the Clinical Specialist Radiation Therapist (CSRT) Project, Stakeholders responded with enthusiastic support for advance practice roles in radiation therapy. The results of all team evaluations indicated a strong interest and readiness in radiation medicine programs to implement and sustain the CSRT role. Stakeholders' opinions were obtained using a variety of methods, including questionnaires, interviews, and clinical observations. Respondents focused on the positive ability of potential CSRT positions to facilitate clinics and provide consistency for patients. In the previous project phase, the most common opinions expressed by stakeholders regarding the value of the CSRT role were:

- Increased efficiency and communication among all members of the healthcare team;
- Opportunities for delegation of acts/procedures;
- More effective and timely follow-up of patients for assessment of symptom management and response;
- Improved quality of life for patients;
- Increased job satisfaction for health care professionals;
- A "one-stop" communication and resource centre for physicians, nurses, radiation oncologists, and other health care professionals; and
- Positive effect on organization, scheduling and general decision-making within multi-disciplinary clinics.

In terms of challenges, the evaluation did identify role definition, role confusion, and professional scope of practice issues as the key barriers to successful implementation. It is important to note that these issues are entirely consistent with those seen in a wide body of research literature on advanced practice roles in general.

Now that we understand what Stakeholders believe the CSRT role can do for them, it is important to show whether this is the case, while limiting the potential challenges. During this project phase, we will be using a variety of standardized research methods across all sites to enhance the generalizability and validity of our results. This will ensure that we obtain the greatest scientific rigor within our project and decrease the amount of investigator influence or bias.

Overall Design

The Stakeholder analysis consists of four components:

1) Stakeholder Questionnaire (**Appendix B**)
2) Radiation Therapist Questionnaire (**Appendix C**)
    a. Questions 1-4 are from The NIOSH Generic Job Stress Questionnaire
    b. Question 5 was developed by the investigators of this study
    c. Question 6 was identified in the Job Content Instrument Questionnaire
3) Manager Questionnaire (**Appendix D**)
4) Direct Supervisor Interview (**Appendix E**)

Each component will be explained in detail below. A simple overview of the questionnaires will be provided in this section; however, a more detailed explanation with a copy of the questionnaire is available in associated appendices (Appendices B – E) for your reference.

Stakeholders: These are individuals who are highly affected by CSRT endeavors and are most closely involved in the processes of the CSRT's work. In the hospital setting, examples include physicians and nurses working in unison with the CSRT.

1) Stakeholder Questionnaire

Project Design

This is a qualitative questionnaire design that is disseminated at only one time point, near the end of the CSRT role during this project phase. This questionnaire is given to all front-line stakeholders EXCEPT for the Direct Supervisor(s) as we would like to identify how Stakeholder's perceive the CSRT position after it has been active for an extended period time (i.e., benefits and problems). As this is a program evaluation task, research ethics approval is not needed; however, a letter from the Ethics Board will be needed as previously completed.

Instruments

The questionnaire was designed for the sole purpose of this study, as there is no validated questionnaire examining the implementation of a CSRT role (**Appendix B**). However, the questions are basic in nature and structure and thus, it is not believed that this lack of testing will greatly impact our study.

Methods

- Once appropriate Stakeholders have been identified and confirmed by Nicole, the study is able to begin.
- It will be the CSRTs responsibility to print off and collate the Stakeholder Questionnaire as needed. Please include an envelope with each questionnaire (study title, contact information, and drop off location).
- A third party (i.e. Project Assistant) will disseminate the questionnaires and get verbal confirmation that the stakeholders understand the Information Form.
- A three-week interval should be allowed for the questionnaires to be collected. Collection options should be clear and simple. Remember to send email reminders about the study.
- Once collection has been completed, the Project Assistant and Site Investigator will monitor data collection and input.
- The Project Assistant should insert data in the provided database (see excel file "Stakeholder Data Collect" under the worksheet titled, "FL Stakeholder Questionnaire"). All personal identifiers made by the stakeholders on the questionnaires should be removed from the electronic data.
- The raw electronic data should be completed ***by February 9, 2015***.

Team To Do List (will be updated when 2015/16 "Timelines" are established).

- ❑ Have your local Research Ethics Board provide you with written confirmation that ethics approval is not needed for this quality assurance project. Send Nicole a copy of this letter via email.

- ❑ Provide a list of Stakeholders to Nicole via email, listing only their position and level of involvement. Do not provide the Stakeholder's names. Nicole will confirm with you that these are the appropriate type of individuals to include in this project.

- ❑ Determine who the third party/Project Assistant is and where the questionnaires can be dropped off. It is best to use the same person for this position throughout the entire CSRT study.

- ❑ Send out the Front-Line Stakeholder Questionnaire ***January 5, 2015***. Collect by ***January 19, 2015*.**

- ❑ Keep track of the number of stakeholders you send questionnaires to.
  A TOTAL OF_____QUESTIONNAIRES WERE DISSEMINATED.

- ❑ Send out an email reminder about the deadline - should be 2 weeks after delivery of the questionnaires at the latest.

- ❑ Collection finishes THREE weeks after dissemination.
  A TOTAL OF_____QUESTIONNAIRES WERE COLLECTED.

- ❑ Insert the data in the excel file "Stakeholder Data Collect" for the worksheet titled, "FL Questionnaire" ***by January 30, 2015***.

- ❑ Submit preliminary pre-CSRT data in draft report by ***February 9, 2015.***

2) Radiation Therapist Questionnaire

Project Design

This is a quantitative and qualitative questionnaire design that is disseminated at only one time point, near the end of the CSRT role during this project phase. Our previous investigation showed that the CSRT role is likely to improve recruitment and retention by increasing career opportunities and job satisfaction for Radiation Therapists. The current project will measure the baseline level of job satisfaction in this population and quantitatively determine if this satisfaction level will increase with the CSRT role.

The questionnaire is only given to the Radiation Therapists, regardless of their interaction with the CSRT. The CSRT does not fill out this questionnaire. As this is a program evaluation task, research ethics approval is not needed; however, a letter from the Ethics Board will be needed as previously completed.

Instruments

In order to determine the level of job satisfaction held by radiation therapists, a short questionnaire was compiled. A total of six questions will be used to achieve this (**Appendix C**). Questions 1-4 on the Radiation Therapist Satisfaction Questionnaire were pulled from the NIOSH Generic Job Stress Questionnaire generated by the National Institute for Occupational Safety and Health (1988). Question 5 was developed by the investigators of this study to specifically examine the CSRT role. Question 6 was identified in the Job Content Instrument Questionnaire designed by Karasek (1988). These questions will be used for the purpose of this project, with one alteration. An open-ended qualitative section has been created to allow greater insight into the current attitudes, motivations, beliefs Radiation Therapists hold regarding their profession.

Methods

- It will be the CSRTs responsibility to print off and collate the Radiation Therapist Questionnaire as needed. Please include an envelope with each questionnaire (study title, contact information, and drop off location).
- A third party (i.e. Project Assistant) will disseminate the questionnaires. It is recommended that these questionnaires be placed in each Radiation Therapist's mailbox to make for greater ease during this portion of the study; however, it is will be the choice of the site hospital to decide the best plan of action.
- The Radiation Therapist Questionnaire will be administered by January 5th. A two-week interval will be allowed for the questionnaires to be collected. Collection options should be the same as the previous collection process. Again, reminder emails should be sent out about the study.
- The Project Assistant and Site Investigator will monitor data collection and input.

- The Project Assistant should insert this data in the provided database (see excel file "Stakeholder Data Collect" for the worksheet titled, "RT Questionnaire"). All personal identifiers made by the Radiation Therapists on the questionnaires should be removed from the electronic data.
- The raw electronic data should be completed ***by April 13, 2014***.

Team to Do List

- ❑ Contact your local Research Ethics Board to provide you with written confirmation that ethics approval is not needed for this quality assurance project. Send Nicole a copy of this letter via email.

- ❑ Determine who the Project Assistant is and where the questionnaires can be dropped off by ***February 16, 2014***. It is best to use the same person throughout this study.

- ❑ Hand out the Radiation Therapist Questionnaire ***by March 2, 2015***.

- ❑ Keep track of the number of Radiation Therapists you send questionnaires to. A TOTAL OF_____QUESTIONNAIRES WERE DISSEMINATED.

- ❑ Send out an email reminder about the survey deadline one week following survey distribution at the latest.

- ❑ Collection finishes TWO weeks after dissemination.
  A TOTAL OF_____QUESTIONNAIRES WERE COLLECTED.

- ❑ Insert the data in the excel worksheet titled, "RT Questionnaire" and submit as part of the draft report ***by March 30, 2015.***

3) Manager Questionnaire

Project Design

Managers for each role will be asked to complete the Manager Questionnaire near the end of the CSRT position. The purpose of the questionnaire is to gain insight into the current status of the CSRT position, its greatest successes and challenges to date, and any improvements that the CSRT Sustainability Project Integration Support Team can make to facilitate the implementation of CSRT role. The questionnaire will be disseminated without the involvement of the CSRT, by a third party, and is only included in this package for each role to be aware of the type of questions that will be addressed. As this is a quality assurance task, research ethics approval is not needed.

Note that those individuals who will be invited to participate in the Manager Questionnaire should not receive the Stakeholder Questionnaire.

Instruments

In order to obtain feedback from managers, a short questionnaire was compiled. A total of five questions will be used to obtain insight into the current status of the CSRT position, its greatest successes and challenges to date, and any improvements that the CSRT Sustainability Project Integration Support Team can make to facilitate the implementation of CSRT roles (see **Appendix D**).

Methods

- A third party will disseminate the Manager Questionnaires, without the involvement of the CSRT.
- The Manager Questionnaire will be distributed by ***TBD***. A three-week interval will be allowed for the questionnaires to be completed. Reminder emails will be sent out about the questionnaire by a third party, without the involvement of the CSRT.
- Questionnaires should be completed and returned as requested by ***TBD.***

Team to Do List

- ❑ Confirm who the Manager Questionnaire should be sent to and who will distribute and collect them with Nicole via email by ***TBD***.

- ❑ The Project Assistant should insert this data in the provided database (see excel file "Stakeholder Data Collect" for the worksheet titled, "Manager Questionnaire"). All personal identifiers made by the managers on the questionnaires should be removed from the electronic data.

- ❑ Submit final data as part of the final report ***due TBD***.

4) Direct Supervisor Interview

Project Design

Direct Supervisors for each position will be asked to participate in an interview near the end of the CSRT pilot. The purpose of the interview is to gain insight into the integration of the CSRT position, the benefits and challenges of the position, scope of duties and impact of the position. The interview will be conducted without the involvement of the CSRT, by a third party, and is only included in this package for each role to be aware of the type of questions that will be addressed. As this is a quality assurance task, research ethics approval is not needed.

Note that those individuals who will be invited to participate in the Direct Supervisor Interview should not receive the Stakeholder Questionnaire.

Instruments

In order to obtain feedback from Direct Supervisors, a short list of interview questions was compiled. A total of ten questions will be used to obtain insight into the integration of the CSRT position, the benefits and challenges of the position as well as the scope of duties and impact of the position (**Appendix E**).

Methods

- A third party will conduct the Direct Supervisor Interviews without the involvement of the CSRT.
- The Direct Supervisor Interviews will be conducted ***by TBD.*** A three-week interval will be allowed for the interviews to be completed. Reminder emails about the interviews will be sent out by a third party, without the involvement of the CSRT.
- All interviews should be completed ***by TBD***.

Team to Do List

- ❑ In January, notify your supervisor(s) that they will be contacted by the Project to set up an interview time.

- ❑ Confirm who should participate in the Direct Supervisor Interviews (and provide relevant contact information) with Nicole via email before ***TBD***.

IMPROVED PROCESSES

Introduction

There is some overlap between the concepts of quantity and quality. However, as has been stated, quality includes:

- improving the patient experience – reduction in inappropriate referrals, addition of new patient services, activities focused on streamlining workflow, etc.
- improving patient outcomes – introduction/enhancement of quality assurance processes, development/introduction of treatment/care standards, etc.
- improving the provider experience – activities focused on streamlining workflow, introduction of practice standards or policies, etc.

There are many areas where a CSRT can improve the patient experience and outcomes across the care path as well as improve provider experience. To better refine these concepts to tangible tasks, examples include:

- reduction in inappropriate referrals
- addition of new patient services
- activities focused on streamlining workflow
- introduction/enhancement of quality assurance processes
- introduction of practice standards or policies

Although you may have collected data on some of the above activities to report in your Quantity section, there are other less quantifiable outcomes of the work that you do. It is these acts of improving and/or changing the process or service provided and the descriptions of their impact that are important for the Quality section.

Let's review some examples to differentiate the two concepts:

1. **Improving Patient & Provider Experience:** 95% (n=47) of all clinical radiotherapy review clinics finished on time. This is an improvement of ~15% from the period prior to the implementation of the Breast CSRT position, resulting in approximately 315 minutes of time saved per year.
    - While the time savings for the radiation oncologists from the CSRT conducting the reviews are reported under "Quantity", the "Quality" aspects (e.g. improving patient and provider experience) are reported here.

2. **Improving Patient Outcomes:** Lead for CCO's H&N COP Standardized Consensus Nomenclature and Clinical Volumes Working Group which has been devised to strategize around the feasibility of developing a provincial contouring standards and consensus guidelines.

- This is an example of an activity that has no direct impact on wait times, volumes of patients or how quickly they traverse the system, but will lead to improved patient treatment, ultimately improving patient outcomes.

3. **Improving Patient Outcomes & Improving Patient/Provider Experience:** At assessment and planning during the CT simulation, 3 patients required urgent care plan changes as the CSRT noticed abnormalities on the planning scan that required further diagnostic assessment. One patient was subsequently sent for an urgent MRI which discovered an impending cord compression. Two patients had fractures and were sent for emergency orthopaedic consultation. The incorporation of the CSRT role across a patient's care pathway allows for the unique ability to review and understand the care plan as a whole rather than compartmentalized, ultimately improving care quality.
   - Several aspects of this position may be reported under Quantity, but the continuity of care provided makes the progression through the system easier for the patient and clearer for the providers of care.

For any process improvement that you are able to complete, please compile a table such as the one below to add to your final reports. Note that the amount of information you provide per improvement should be at the level of an abstract submission.

Description of Process Improvement Activity	Category of Improvement: Patient experience Patient outcomes Provider experience	Data to Support Improvement **sample size, time period, numerator, denominators, etc.*	Impact Conclusion

Team To Do List

- ❑ Using your process map, work with your Direct Supervisor/team to identify the areas where you expect to have impact on current processes. Finalize these ideas with Nicole/Laura by **January 23, 2015**. These ideas should be outlined in your preliminary report due **February 9, 2015**.

- ❑ Collect baseline data for the current process for a 3-month period of "normal" functioning during a time before the CSRT was in place.

- ❑ When ready, collect the new data and make an entry in the "Improved Processes" Table provided.

- ❑ Submit baseline results with your final report on **May 4, 2015**.

- ❑ At a time when the CSRT feels they fully integrated into the team and has completed most of the goals for developing the position, a prospective data collection cycle should be implemented. Notify the Data Consultant(s) when data collection should begin and enter this data into the "Improved Processes" Table provided.

- ❑ Submit this data as part of the 2015/16 final report ***due TBD***.

PATIENT SATISFACTION

Introduction

The patient is the centre of everything we do in the radiation therapy department. While not all activities take place with direct patient contact, the ultimate goal of any activity or change is to improve patient experience and/or patient outcome. In earlier phases of the CSRT Projects, it was concluded that while a change in patient outcome would be difficult to measure in the timeframes given, it would be possible to assess patient satisfaction with the care they received. It was further concluded that good or improved patient satisfaction with a new model of care could possibly lead to improved patient outcome through better quality of life, increased understanding of the processes, increased compliance with care plans and an overall comfort with seeking out information in a timely manner.

In order to capture the level of patient satisfaction of the radiation therapy patients, a survey was designed using the "Patient Satisfaction Questionnaire" which was originally designed and validated by the Rheumatism Research Unit at the University of Leeds (Hill, 1997). The modified version was altered to make the questionnaire more generic for use in all clinics, rather than clinic specific (Mortimer Market Centre: Service User Satisfaction Survey; Miles et al., 2003). Generally, the cancer population is highly constrained when completing research due to the acuteness of their symptoms, anxiety and the complexity of their clinic visits. To ensure that the participants do not feel burdened by our research, the survey was limited to a minimal number of questions - 6 questions for patients who were not seen by the CSRT and 10 for patients who were seen by a CSRT (**Appendix F and G**). The questionnaire takes approximately 3-5 minutes to complete.

The results from the Demonstration and Sustainability phases of the project showed that patients were equally as satisfied with care they received from the CSRTs as they were with the care they received from other health care providers. If the patients are satisfied and the level of care is maintained or improved, this could result in a number of positive impacts on the system and bode well for the long term adoption of the CSRT as a member of the existing health care team for Ontario's broader cancer system.

Now in the Integration phase, the Project has set out to evaluate the new pilot positions in various centres across the province to further understand the impact of the CSRT and to add robustness to the existing data set related to patient satisfaction.

To this end, you will need to decide what methodology you will use to gather your 2 sets of data for this project. It will require an application to the Research Ethics Board in your institution and all the relevant elements of proper research project. We have provided a set of draft templates that you will use to implement your individual patient satisfaction study in your clinical environment, including a Patient Information Letter (**Appendix H**) and Application for Review by Research Ethics Board (**Appendix I**). There are many elements of these documents

that will need to be customized to your department, patient population, etc. and we have tried to highlight where those are likely to be. Do not hesitate to suggest a change to a section not highlighted if it makes sense in your specific situation. Also, you are encouraged to confer with the more experienced CSRTs around keys to success with this aspect of the data collection.

Team To Do List

- ❑ Identify who will serve as your research assistant for this activity as soon as possible.
- ❑ Contact your local REB to acquire the necessary documentation, policies, processes and timelines. Speak to them about the possibility of an "Expedited Review" given that this protocol has been employed a number of times around the province (and may have already been run in your department).
- ❑ Identify the method you will use to capture the "non-CSRT" patient data and "post-CSRT" data by **December 12, 2014**. Meet with your assistant to review process.
- ❑ Complete and submit the REB application by **January 9 2015**.
- ❑ Prepare packages and mail lists while you await approval.
- ❑ Once Ethics approval is received, begin distribution of surveys to your "non-CSRT" or "pre-CSRT" patient population. Enter data as it is received.
- ❑ Submit any preliminary "pre-CSRT" data with your preliminary report due on **February 9, 2015.** Final "pre-CSRT" data should be submitted with the final report due on **May 4, 2015.**
- ❑ At a time when the CSRT feels they fully integrated into the team and has completed most of the goals for developing the position, a prospective data collection cycle should be implemented. Notify the Data Consultant(s) when data collection should begin and enter this data into the "Before CSRT Patient Satisfaction" table provided.
- ❑ Submit data as part of the 2015/16 final report ***due TBD***.

Patient Satisfaction of a
Clinical Specialist Radiation Therapist Role Protocol

Investigators: [List, with credentials]

Contact: [Project Assistant or relevant person]

NOTE: This protocol has been generically created to provide your site a template to work from when designing the study procedures. Please add descriptive text as you see fit and remember to include any site-specific Research Ethic Board requirements that may not be included.

The CSRT Position is supported and funded by the
Ministry of Health and Long-Term Care (MOHLTC)

Purpose

This study is designed to examine the impact of Clinical Specialist Radiation Therapist (CSRT) positions on patient satisfaction in Ontario. The current project will analyse the effects of this role in the [CLINIC NAME] at [HOSPITAL NAME].

Background

Ontario began exploring the introduction of advanced practice roles for radiation therapists in 2003 in response to well-documented challenges in the radiation treatment environment. Treatment delays, service expansion, health human resource issues in cancer-related disciplines, care gaps, and a desire for quality improvement and innovation led the radiation therapy community to begin examining ways in which the provision of radiation treatment could be improved.

A preliminary examination by the Ontario Radiation Therapy Advanced Practice (ORTAP) Steering Committee concluded that there was interest and value in piloting advanced practice roles in radiation therapy. The CSRT Project, under the auspices of Cancer Care Ontario, was officially launched in August 2004 following a successful application to the Ministry of Health and Long-Term Care for funding of a two-year pilot project. This phase of the CSRT Project was a "Developmental Phase", designed to pilot test five proposed advanced roles for radiation therapists in a variety of settings, where advanced roles are defined as distinct and separate from entry-level and expanded roles in their knowledge, skills, judgment, responsibility, authority and educational preparation. The pilot project was designed to explore the value and feasibility of creating newly defined advanced roles for radiation therapists within the existing health care team. To that end, investigators, deployed at each of the local cancer centres, established the scopes of practice of the proposed roles against local service needs, identified and quantified (where possible) the potential benefits of these new roles to the patient and system, and assessed the readiness of the interprofessional health care team to accept these new professionals.

The evaluation demonstrated the value of the CSRT role and indicated that the implementation of CSRTs in Ontario's cancer system has the potential to offer a number of benefits for patients, for radiation therapists and other cancer-related health professionals, and for Ontario's cancer system more broadly.

This was validated in a 3-year Demonstration Project, also funded by the Ministry of Health and Long Term Care that ran from 2007 – 2010. As a result of the results from both the Development and Demonstration phases of the Project, the Ministry of Health and Long Term Care announced a new health care professional role: the Clinical Specialist Radiation Therapist. This new title will be used to define radiation therapists practicing at an advanced level with advanced knowledge and skills. MOHLTC also granted funding for the continuation of the work establishing the CSRT roles in Ontario. In March 2011, the CSRT Sustainability Project was approved for a three-year period. During that time, an additional 10 positions were piloted

according to project guidelines and work began on strategies to ensure the long term implementation of the CSRT role across Ontario beyond the life of the projects. Data consistently show impact on both quantity and quality, including the improvement of both the patient and provider impact. A collective and concise description of the CSRT impact is an ongoing focus as is the establishment of standards and consistent approaches to CSRT implementation and integration. To this end, work with the College of Medical Radiation Technologists of Ontario is ongoing in order that the new role can be characterized and documented in alignment with the regulatory requirements.
In 2013, the Ministry of Health and Long-Term Care (MOHLTC) approved the Integration phase. The focus of this phase was to roll out palliative radiation therapy CSRTs across sites that were not currently engaged with the project and has resulted in the implementation of palliative positions in 3 new sites and the addition of 4 "other" positions in centres that have existing CSRT positions in place.. The current study is a subset of this broader, province-wide investigation, examining patient satisfaction of the CSRT role within designated clinical environments.

Site Description

- *general description of the clinic and its population*
- *what is the CSRT's role in the clinic and why this clinic/disease site was chosen*
- *how the CSRT will impact this population of patients*

Study Rationale

As the CSRT role is new to Ontario and Canada, it is necessary to investigate potential patient benefits from its activation in order to support the role's permanency in the Ontario Healthcare System. Although preliminary studies by the MOHLTC have shown a potential positive impact with the existing CSRT positions, additional research needs to be conducted to examine the impact of new pilot CSRT positions on patient satisfaction.

Methodology

The following section pertains to the tasks associated with [*CLINIC NAME, HOSPITAL NAME*], in which the CSRT is employed. The remaining provincial CSRTs have created their own site- specific protocols and will obtain ethics approval from their local Research Ethics Board.

Study Design

a) A pre and post mail-out survey design will be used to examine the study objectives. This will capture patient satisfaction from two sub-populations within the same [*clinic/department etc*.]: 1) those who received care from the CSRT and 2) those who received care from other healthcare professionals (for a time period prior to the activation of the CSRT position).
OR

b) A one-point dissemination survey design will be used to examine the study objectives. This will capture patient satisfaction from two sub-populations within the same [*clinic/department etc*.]: 1) those who received care from the CSRT and 2) those who received care from other healthcare professionals.]

Participants

A total of [*NUMBER*] patients will be sent an Information Sheet and patient satisfaction questionnaire at this site. Of these, [*NUMBER*] patients will be asked to respond to a questionnaire that does not include the CSRT related questions, as this sub-population received care from a doctor, nurse, or another healthcare professional. More specifically, patients who were seen in the clinic four months before the CSRT position was implemented will be asked to participate. The remaining [NUMBER] surveyed patients will be recruited for participation after they have received care in the [BLANK clinic] by the CSRT. [*When not using a pre/post design, insert the following: All patients will be recruited from the clinic in which the CSRT participates, throughout the CSRTs role – limit this to an achievable number of months. This will include patients who have and have not encountered the CSRT during their clinic visit.]*

Inclusion Criteria

- *Patients who received care in the [CLINIC NAME] at [Hospital NAME].*
- *[Add any specific disease sites or population characteristics].*
- *Patients who were seen in the clinic during the four months prior to the CSRT working in the clinic or*
- *Patients who were seen in the clinic by the CSRTs between [dates to be determined by CSRT and team].*

*[****For "other" design: Change the Inclusion Criteria's last two bullets to suit the time line and procedure determined for your study.]*

Exclusion Criteria

- *Any patient who is known to be deceased, regardless if this has not been updated in the hospital records (ensures patient family members are not unnecessarily burdened). [***Exclude if handing the surveys out during clinic hours only]*
- *An inability to read the English language or find an interpreter as the questionnaire has been validated in one language only.*
- *Patients who were seen in the clinic prior to the CSRT working in the clinic cannot have been scheduled an appointment with the CSRT. [***Exclude if handing the surveys out during clinic hours only]*

Instrument

The current study examines satisfaction level through a modified "Patient Satisfaction Questionnaire" which was originally designed and validated by the Rheumatism Research Unit

at the University of Leeds (Hill, 1997). The modified version was altered to make the questionnaire more generic for use in all clinics, rather than clinic specific (Mortimer Market Centre: Service User Satisfaction Survey; Miles et al., 2003). A few alterations to the demographic portion of the questionnaire have been made (i.e., removed unnecessary questions such as employment status). Generally, the cancer population is highly constrained when completing research due to the acuteness of their symptoms, anxiety and the complexity of their clinic visits. To ensure that the participants do not feel burdened by our research, the survey was limited to a minimal number of questions (6 questions for patients who were not seen by the CSRT and 10 for patients who were seen by a CSRT; **Appendix F and G**). The questionnaire takes approximately 3-5 minutes to complete (each question has a five point scale of "strongly agree" to "strongly disagree").

A few alterations to the demographic portion of the questionnaire have been made (i.e., removed unnecessary questions such as employment status; **Appendix A**). Also, the survey given to patients who were seen by the CSRT will contain additional questions about their experience with this role (**Appendix B**).

Procedure [*expand/alter as needed*]

The CSRT position is tentatively scheduled to begin in *[INSERT*]; the exact date is not guaranteed. Thus, all the following time lines refer to the start of this project and do not designate a specific month.

Patients who meet the participation criteria will be identified by the [Data Consultant]. All patient names and addresses will be given to the Project Assistant. This individual will maintain the patient's confidentiality and conduct the tasks necessary to complete this study in accordance with the Research Ethics Board standard policies. Patient names will be retrieved at the start of the CSRT's position and on a weekly basis between Month 4 and Month 7 Week 4 of their position. *[****Change timeline as needed*] CSRT and Project Assistant will collate the Information Form and Questionnaire placing it into an envelope that contains a stamped and addressed return envelope for the patient. All questionnaires will be mailed to the patient's home to ensure that they are in a comfortable environment when filling out the survey. [*Insert appropriate methodology for your clinic and patient population. Please note that it is possible to use a variety of dissemination plans but it is best to limit it down to one or two. For patients who do not wish to complete the survey at the time of their appointment, the Research Assistant can offer to call the participant. However, this needs to be noted in the methodology section.]*

Patients will be provided with a local contact number if they wish to discuss the study or participation. As the CSRT will have direct contact with the patients who receive a questionnaire, the CSRT (at all sites) will not have access to the raw data, even though there are minimal identifiers such as age and gender. This individual will only receive access to the aggregate results upon the completion of the MOHLTC study CSRT position (after 9 months in the role). The CSRT's role within this project will include organizing, collating, mailing the

surveys, report writing, and dissemination of results; The Project Assistant will collect the surveys and input the data. A designated Statistician will complete the data analysis.

Significance

Proposed benefits to the scientific community and society include examining the positive benefits of a Clinical Specialist Radiation Therapist position on patient satisfaction. As this study focuses on the aggregation of patient results from five unique advanced practice positions, our results will show the general value of this role across a range of disciplines. In addition, this comprehensive study is the first of its kind worldwide to examine this role's impact on patient satisfaction.

Patient participants may not experience any direct benefits from this study, other than a sense of having their opinions being recognized by Hospital Administration.

CSRT SAFETY OCCURRENCE PROTOCOL

Understanding the Safety Occurrence

Introduction

As the CSRT position evolves to include more complex duties, it is important to demonstrate that each position can maintain a gold standard in safety. The purpose of this project is to directly examine the safety of the CSRT role and the tasks involved. This does not include monitoring the clinic or non-CSRT associated healthcare provider incidences.

The proposed safety occurrence data is currently collected by all hospitals in Ontario. The method and definitions used in each hospital, however, is unique. Thus, we have derived definitions for the purpose of this study that each CSRT should use when completing this project.

Definitions

Each incident is to be categorized using two distinct considerations: Actual and Potential:

- **Actual:** Classify the incident in the context of what actually transpired, which includes the impact of any intervention undertaken.
- **Potential:** Classify the incident in terms of the clinical impact should it not have been discovered.

Radiation Incident: An occurrence in which there is a problem with the process of planning and/or delivery of radiation treatment. If the incident leads to any harm, then the related injuries or complications may or may not be serious. Serious incidents that involve the significant risk of loss of life, limb, or function signal the need for immediate investigation and response, not only because of the potential or actual outcome for the patient, but also because of the perceived problems with the process and underlying structure of treatment planning and delivery.

Classifications of a Radiation Incident:

- **Severe Type I:** Hardware or software errors that have a high probability of causing an unacceptable outcome for the patient or that pose an unacceptable risk to staff or members of the public. (Note: These errors do not include those for which a bulletin has been issued by the manufacturer).
- **Severe Type II:** Errors in total dose (>25%) or targeting errors that have a high probability of producing an unacceptable outcome for the patient, e.g., Treatment of the Wrong Site, Treatment of the Wrong Patient, Exceeding Tolerance Dose.
- **Major:** Any incident that will result in a clinically significant compromise in treatment outcome but does not fall within the Severe category, e.g., (depending on the details associated with the incident) Misplacement of Field, Incorrect Shielding, Incorrect Beam Parameters, Breach of Protocol.
- **Minor:** Any identified incident that does not fall within the Severe or Major categories.

Non-Radiation Incident: All those potential and actual incidences that do not fall under the Radiation Incident Definition.

Classifications of a Non-Radiation Incident:

- **Major:** Any incident that will result in a significant compromise in outcome such as a fall with physical injury.
- **Minor:** Any identified incident that does not result in a significant compromise outcome such as a fall with no physical or minimal injury.

Procedure

The CSRT Safety Occurrence data will be completed throughout the CSRT's position and should be considered an ongoing task. The CSRT will be responsible for monitoring Actual and Potential Safety Occurrences as defined above that is directly related their own actions or position. For example, an occurrence that is directly related to a CSRT's action would be: a) he/she prescribes the wrong radiation or medication dose or b) the CSRT may forget to secure valuable equipment that could be stolen. In regards to occurrences that are related to the CSRT position, this could include the CSRT identifying that a physician (for your patient) prescribed the wrong radiation or medication for which you have to change. Another example of this is identifying equipment, which the CSRT uses, is not maintained properly by another colleague. If you require further clarification as to what is or is not an occurrence please contact Nicole Harnett.

All necessary actions to deter or mend the occurrence should be taken in accordance with your hospital's standard procedures.

When an occurrence of any kind has happened or potentially could happen, you should discuss this with your manager as soon as possible in detail. A hospital Safety Occurrence Report should

be completed within 24 hours of the occurrence and signed and dated as directed. Nicole Harnett should be contacted in regards to any "Actual Occurrence" directly related to the CSRT's actions within 24 hours as well.

Record your information in the "Wait Time and Access to Care Data Collect" database under "Safety Occurrence Data".

Team To Do List

- ❑ Remember this is an ongoing project and the Safety Occurrences should be tracked throughout your position.
- ❑ Nicole Harnett should be contacted in regards to any "Actual Occurrences" caused by or directly related to the CSRT within 24 hours.
- ❑ Record the information directly into the "Wait Time and Access to Care Data Collect" database under "Safety Occurrence Data".

SECTION C – MEASURES

3. INNOVATION – CREATION OF NEW KNOWLEDGE AND KNOWLEDGE TRANSLATION

Introduction

With advanced knowledge, skills and judgment in their area of specialization, the CSRTs are perfectly poised to lead and direct initiatives that create new ways of thinking about radiation therapy as well as to adopt new techniques and approaches that are being discovered and reported by others. In this regard, the CSRTs become engaged in projects in their respective departments ranging from the investigation of new techniques (new knowledge/techniques) to the local implementation of innovative and effective procedures/approaches reported elsewhere. These initiatives bring with them a promise of improved patient care, experience and/or outcomes and as such are critical to departments dedicated to delivering the highest quality care to their patients.

These activities can be categorized under a number of headings including:

- A new services
- A new process or model of care
- Program evaluation
- New knowledge creation
- Knowledge translation/adoption

Examples

The tables below are for recording your innovations and knowledge translation activities. Examples have been inserted in some cases to illustrate the nature of activities that are suitable for the categories.

INNOVATIONS	
Category	**Descriptions**
New Service	***Media-facilitated Follow Ups:*** *As Lead, a grant proposal has been written and submitted for the initiation and evaluation of impact of a new CSRT led telemedicine follow-up care program via phone, email and/or video conference. Follow up appointments are not currently standard practice in the PROP Program.*
New Process / Model of Care	***Outcome Monitoring and Analysis:*** *The CSRT manages a database to collect information on palliative and radical H&N cases: disease free survival, severity and dissipation of treatment related sequelae, time to recurrence, second primaries, long term complications, persistent disease, etc. Future analyses will be conducted to look for recurrence trends that will inform treatment decisions for the H&N population.*

Program Evaluation	***Attendance patterns related to current funding model****: Data was collected for 21 skin clinics (Sep 11 – Mar 12) resulting in 282 patients booked for appointments. Of these, 19 (7%) failed to show for their appointment. Of the patients who clinic and were potentially new radiation cases, 30% (78/263) were previously seen for other lesions (BCC or SCC) and 70% (185/263) were valid new cases to the program. Analysis of this data is currently underway and potential actions to improve patient attendance and understand/report on the patient population relative to the funding model are currently in the initial stages attended clinic and were potentially new radiation cases, 30% (78/263) were previously seen for other lesions (BCC or SCC) and 70% (185/263) were valid new cases to the program. Analysis of this data is currently underway and potential actions to improve patient attendance and understand/report on the patient population relative to the funding model are currently in the initial stages*

NEW KNOWLEDGE/TECHNIQUES	
Project Description (attach abstract if available)	**Details**
***Technique Change**: In Princess Margaret Hospital, left sided breast cancer patients undergoing whole breast irradiation are screened through a protocol for the moderate deep inspiration breath-hold (mDIBH) technique to decrease cardiac toxicity. The breast CSRT is collaborating with a Radiation Oncologist to use ultrasound to identify patients who would benefit from the heart sparing mDIBH technique.*	Collaborators/Supervisors: CSRT Role:

KNOWLEDGE TRANSLATION/ADOPTION	
Details	**Descriptions**
Knowledge Translation/Adoption	***Implementation of new process**: After attending a workshop on patient teaching for active breathing control and its positive impact on the ability of the patient to maintain a consistent breathing pattern during treatment, the CSRT returned to home clinic and worked with local leadership to develop a program for augmented patient teaching and coaching. Data collection underway.*

These categories form the basis of ongoing monitoring of the CSRT of the impact they are having. While initial activities will be identified and monitored during the ramp up and stabilization of the position implementation, it is fully expected that some activities will be suspended and new ones added as the position evolves and the team adjusts to the new team member. It is ideal of the CSRT continues to monitor all the activities that they undertake in this area to provide ongoing evidence of positive impact.

Team To Do List

- ❑ Using your process map, work with your Direct Supervisor/team to identify the areas where you expect be participating in knowledge creation or adoption. Finalize these ideas with Nicole/Laura by **January 23, 2015**. These ideas should be outlined in your preliminary report due **February 9, 2015**.

- ❑ When ready, collect the new data and make an entry in an "Innovation" Table formatted in a similar manner to the tables demonstrated above.

- ❑ Submit any initial information with your final report on **May 4, 2015**.

Stakeholder Questionnaire

Instructions: Please take a moment to describe your feelings about the following questions. If you require more room to respond, please continue your answer on the back of the paper.

Please circle your answer	Not at all	A little but	Undecided	Moderately	A lot
Do you feel the Clinical Specialist Radiation Therapist (CSRT) is an important role within the health care system?	1	2	3	4	5

1) Describe what you believe the CSRT role ***is to date and what it should be in the future***.

2) Describe the extent you believe the CSRT role has changed the care of patients and the healthcare system:

a. Please describe the ***beneficial*** changes:
(e.g., patient interactions, access to care, wait times, quality of work life)
Please describe any changes that are ***problematic*** to the care of patients and the healthcare system: (e.g., patient interactions, access to care, wait times, quality of work life)
Do you have any other comments about the CSRT role?

Radiation Therapist Questionnaire

Based on the type of work you do in your job, please check your response to the following questions:

Knowing what you know now, if you had to decide all over again whether to take the type of job you now have, what would you decide?

I would... ❑ Decide without hesitation to take the same job ❑ Have some second thoughts ❑ Decide definitely NOT to take this type of job

Briefly comment why you made this choice:

If you were free right now to go into any type of job you wanted, what would your choice be?

I would... ❑ Take the same job ❑ Take a different job ❑ Not want to work

Briefly comment why you made this choice:

If a friend of yours told you he/she was interested in working in a job like yours, what would you tell him/her?

I would... ❑ Strongly recommend it ❑ Have doubts about recommending it ❑ Advise against it

Briefly comment why you made this choice:

All in all, how satisfied would you say you are with your job?

I am... ❑ Very satisfied ❑ Somewhat satisfied ❑ Not too satisfied ❑ Not at all satisfied

1. **How familiar are you with the CSRT role and the position(s) at your centre?**

I am... ❑ Very familiar ❑ Somewhat familiar ❑ Not too familiar ❑ Not at all familiar

1. **Whether you would like to become a Clinical Specialist Radiation Therapist or not, do you think this position will help positively address the three main issues impacting Radiation Therapist job satisfaction:**

   i. **Lack of career opportunities**

It would… ❑ Strongly address the issue ❑ Somewhat address the issue ❑ Only address the issue a little bit ❑ Not address the issue at all

   ii. **Low wages**

It would… ❑ Strongly address the issue ❑ Somewhat address the issue ❑ Only address the issue a little bit ❑ Not address the issue at all

   iii. **Opportunities to specialize**

It would… ❑ Strongly address the issue ❑ Somewhat address the issue ❑ Only address the issue a little bit ❑ Not address the issue at all

2. **Do you have any patient safety concerns associated with the Clinical Specialist Radiation Therapist role?**

   ❑ Yes ❑ No

   If yes, what are your concerns?

   How likely is it that you will find a new job in the next year?

It is… ❑ Very likely ❑ Somewhat ❑ Not at all

Thank you for participating in this project.

Please return this questionnaire to [INSERT NAME AND INFO].

Manager Questionnaire

Please answer the following questions based on your local experience with the CSRT Demonstration Project to date. Given that you may have had different experiences with different positions, I would like to ask that you complete one form for each CSRT position you currently support (where appropriate) with the understanding that you may be copying common content from one form to the next where comments/experiences have been similar.

Completed forms should be returned to Nicole Harnett **by February 9, 2014**. (nicole.harnett@rmp.uhn.on.ca).

Please circle your answer	Not at all	A little but	Undecided	Moderately	A lot
Do you feel the Clinical Specialist Radiation Therapist (CSRT) is an important role within the health care system?	1	2	3	4	5

1) What is the current status of your CSRT position(s)?

2) What have been the greatest successes to date with your CSRT position(s)?

3) What have been the biggest challenges faced in developing and implementing your local CSRT position(s)? And have they changed/subsided/increased over time?

4) In your opinion, what could the CSRT Sustainability Project Team do to facilitate increased support for the CSRT role and ease the challenges faced in implementation of CSRT positions?

If you have any questions or comments, please do not hesitate to contact Nicole. We thank you for taking the time to provide this important feedback as Cancer Care Ontario moves forward with the full integration of the CSRT role in Ontario.

Direct Supervisor Interview

1) Describe your involvement with the CSRT in your program.

2) Describe what was easy or difficult in the integration of the CSRT position (not the individual) into your local program?

3) Did the job description and associated duties of the CSRT position stay as originally planned or did they evolve into something else? If so, or if not, how and why?

4) Comment on the individual in the CSRT position to competently complete advanced activities.
    a. Probe: Education and training
    b. Probe: Concordance studies
    c. Do you believe the CSRT in the current position is practicing at an advanced level? If so, or if not, how and why?

5) What do you believe have been the benefits of the CSRT position in your program? Challenges of the CSRT position?
    a. Probe: Describe the extent you believe the CSRT's position and advanced duties have impacted or could impact:
        - For each component below, has the CSRT position impacted: Yes No Unsure. If so, or if not, how and why?
            - Team member job satisfaction.
            - Overall RT job satisfaction.
            - Patient satisfaction.
            - Access to care for patients where underserviced populations receive improved access and where existing patients receive access to all services available to them.
            - Patient wait times.

6) Comment on any safety concerns you have regarding the CSRT role (i.e., patient or staff).

7) What would you keep the same about the CSRT role? What would you expand or change?

Please circle your answer	Not at all	A little but	Undecided	Moderately	A lot
Do you feel the Clinical Specialist Radiation Therapist (CSRT) can play an important role within the radiation therapy system?	1	2	3	4	5

8) Would you recommend expanding this role to other clinical areas or disease sites?
    - ❑ Yes
    - ❑ No
    - ❑ Unsure

9) Have you had any comments or feedback from colleagues on the CSRT position?

10) Any other comments?

[Hospital Name]'s
Patient Satisfaction Survey

This questionnaire has been designed to tell us about your overall opinion of the care that you received from the health care provider who you saw in [CLINIC TYPE at INSERT HOSPITAL]. It is *not* a test and there are no right or wrong answers. We are interested in *your* opinions and impressions.

Please follow the instructions carefully and if you have any questions please ask to speak to [INSERT NAME], the study co-ordinator.

The first section asks for basic information about you. Remember that this questionnaire is anonymous so we cannot identify you.

Please tick or fill in the blank, as appropriate, in each item.

Q1 What is the date today? _____/_____/_____
(dd/ mm / yy)

Q2 Have you ever had an appointment in the [TYPE] clinic before?

No ☐1
Yes ☐2

Q3 Who was your appointment with?

Nurse ☐1
Doctor ☐2
Clinical Specialist ☐3
Radiation Therapist

Q4 What is your age? _____(years)

Q5 What is your gender?

Male ☐1
Female ☐2

The following questions are intended to see how you personally feel about the care you have received in [CLINIC NAME]. The person that you saw refers to the health care professional who asked the questions about your medical history and symptoms (Doctor, Nurse, or Clinical Specialist Radiation Therapist). Read each item carefully, and then decide whether you agree or disagree with the statement. ***Please circle the number which most closely represents your feelings and answer all questions unless instructed otherwise****.*

		Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree
1	I was told everything that I want to know about my condition	1	2	3	4	5
2	I felt that the problem that I came with was sorted out properly	1	2	3	4	5
3	I felt that I was in good hands	1	2	3	4	5
4	No matter how long I had to wait it is worth it	1	2	3	4	5
5	I was satisfied with the care that I received in the clinic today	1	2	3	4	5
6	I felt that I was treated as a person rather than a disease	1	2	3	4	5

PLEASE GIVE YOUR COMPLETED QUESTIONNAIRE TO RECEPTION OR MAIL IT TO THE FOLLOWING ADDRESS:
[INSERT STUDY COORDINATOR NAME AND ADDRESS]

CSRT Patient Satisfaction Questions

The [HOSPITAL] is investigating the value of adding a Clinical Specialist Radiation Therapist position to the [CLINIC] team. This is a comprehensive and advanced role for the radiation therapist. To help us in determining the value of this position, we ask that you complete the following questions.

7. Was the Clinical Specialist Radiation Therapist part of your care team? No

Yes

Not sure

If "**No"** or "**Not Sure"** – You are finished.

If "**Yes",** please complete the remaining questions.

		Poor	**Fair**	**Unsure**	**Good**	**Excellent**
8	Overall, my experience with the Clinical Specialist Radiation Therapist was:	1	2	3	4	5

		Strongly Agree	**Agree**	**Unsure**	**Disagree**	**Strongly Disagre e**
9	How much do you agree or disagree that having a Clinical Specialist Radiation Therapist on your care team was important **to your understanding of treatment**?	1	2	3	4	5
10	How much do you agree or disagree that having a Clinical Specialist Radiation Therapist on your care team was important **to your care at the Cancer Centre**?	1	2	3	4	5

11. Are there any other comments that you would like to make about the Clinical Specialist Radiation Therapist?

PLEASE GIVE YOUR COMPLETED QUESTIONNAIRE TO RECEPTION OR MAIL IT TO THE FOLLOWING ADDRESS:

[INSERT STUDY COORDINATOR NAME AND ADDRESS]

[INSERT HOSPITAL LOGO]
PATIENT PARTICIPANT INFORMATION LETTER

Title of Study: Patient satisfaction a Clinical Specialist Radiation Therapist role
Principal Investigator: "EXAMPLE: Joe Crock, M.B., B.S., F.R.C.P.(c), Radiation Oncology, Juravinski Cancer Centre, Hamilton Health Sciences"
Sponsor: Ministry of Health and Long-Term Care

You are being invited to participate in a research study conducted by [PI NAME] because you had an appointment in the [CLINIC NAME, HOSPITAL NAME] and were seen by a healthcare professional (e.g., Physician, Nurse, and/or Clinical Specialist Radiation Therapist). This position is supported and funded by the Ministry of Health and Long-Term Care. In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study. Once you understand what is in the Information Sheet, you will need to decide if you want to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician.

WHY IS THIS RESEARCH BEING DONE?

A new Radiation Therapist role is being examined in Ontario that involves advanced practice skills. The person in this role is called a Clinical Specialist Radiation Therapist (CSRT). We want to know your level of satisfaction with your most recent appointment in the [CLINIC NAME, HOSPITAL NAME] and with the healthcare professional you saw (e.g., Physician, Nurse, and/or CSRT). If we can determine your level of satisfaction, this may give us some evidence that the Clinical Specialist Radiation Therapist position is beneficial to patients and the healthcare system.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to determine your level of satisfaction with your appointments held in the [CLINIC NAME, HOSPITAL NAME] and see if it is the same or different to patients who were seen by another healthcare professional in the same clinic.

WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?

If you volunteer to participate in this study, we will ask you to do the following:

- Complete the survey that is stapled to this Information Sheet
- Mail the survey to the Project Assistant [***or Hand in the survey to INSERT]

No money or prizes will be given to you for partaking in the study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There is little risk in participating in this study. You may experience some emotional discomfort when filling out the questionnaire if you did not have a positive interaction with the healthcare staff. If you feel any discomfort, you may decline to complete the question(s) and remove yourself from the study by not mailing in the survey. Also, you may speak with your doctor about any feelings you experience during the study and they can support you or refer you to the right person for help. If you decide later that you want to remove your information from this study, you can do so by calling us.

If you choose to take part in this study, you will be told about any new information that might affect your willingness to continue.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

[INSERT NUMBER] patients will be asked to participate from [NAME] hospital. This study is also being conducted at other hospitals in Ontario. Approximately 300 patients will be asked to participate across Ontario.

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?

You may not experince any benefits from this study, other than a sense of having your opinions heard. Benefits for society may include some insight into the possible beenfits of the CSRT position. This study will be the first of its kind worldwide to examine this role's impact on patient satisfaction and its potnetial benefits to organizational efficiency.

IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

It is important for you to know that you can choose not to take part in the study. Your treatment and care at the hospital will not be affected by your choice to participate or not. If you do not want to fill out the questionnaire but still want to voice your opinions, you can mail a letter to the hospital about this.

WHAT INFORMATION WILL BE KEPT PRIVATE?

Your data will not be shared with anyone unless we have your consent or the law requires it. All your personal information will be removed and changed to a number. All data will be securely kept in a locked office. Any published results will not contain identity information.

To make sure there is proper monitoring of the study, a member of the [INSERT REB NAME] may look at your research data and medical records. No records with personal identifiers will be allowed to leave the hospital. By mailing in the survey, only you or your legally acceptable representative allow for this type of access.

CAN PARTICIPATION IN THE STUDY END EARLY?

You are able to withdraw from the study at any time. This will not affect the quality of care you receive. You are able to remove your data from the study. You may refuse to answer any questions you don't want to answer and still remain in the study. The investigator may pull out of this research if something happens that justifies it.

WILL THERE BE ANY COSTS?

There is no cost to participate in this study.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?

If you have any questions about the research, contact [NAME NUMBER]. If you have any questions about participations rights, contact: [Patient Relations Specialist NUMBER].

APPLICATION FOR REVIEW BY RESEARCH ETHICS BOARD

For use by investigators performing research to be reviewed by the Research Ethics Boards (REBs) of: St. Joseph's Healthcare Hamilton; Hamilton Health Sciences/McMaster University, Faculty of Health Sciences; and other affiliated institutions.

This form can be downloaded at this link

Complete the application in NO smaller than 10 point font; handwritten submissions are NOT acceptable

(HHS/FHS REB Version - REVISED OCTOBER 2006)

Please refer to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans prior to completion of this form

Project #

SECTION A – GENERAL INFORMATION

1. FULL STUDY TITLE:

Patient satisfaction with the care they receive from a Clinical Specialist Radiation Therapist (CSRT)

KEYWORDS – List up to 5 keywords that describe this project: **i)** advanced practice **ii)** radiation therapist **iii)** patient satisfaction **iv)** survey design **v) models of care**

2. RESEARCH PERSONNEL

Is this a student project? If YES, specify: Post-doc PhD Master's Undergrad Resident/Fellow

A. LOCAL PRINCIPAL INVESTIGATOR (LPI): LRI must have an appointment at the institution where the REB application is being submitted for review. LPI may not be a student, fellow, or resident.

Title:	First Name: SITE LEAD INVESTIGATOR	Surname:	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State: ON	Postal/Zip:	Country: Canada
Phone/ext:	Pager:	Email:	Fax:

B. PRINCIPAL INVESTIGATOR (PI), IF DIFFERENT FROM LPI ABOVE:

If PI is a student/trainee, specify: Post-doc PhD Master's Undergrad Resident/Fellow

Title:	First Name:	Surname:	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State:	Postal/Zip:	Country:
Phone/ext:	Pager:	Email:	Fax:

C. CO-INVESTIGATOR(S) (CO-I):

CO-I #1:

If CO-I is a student/trainee, specify: Post-doc PhD Master's Undergrad Resident/Fellow

Title:	First Name: CSRT INVESTIGATOR	Surname:	
Institution:		Department/Division:	

Street Address: Line 1			
Line 2			
City:	Province/State: ON	Postal/Zip:	Country: Canada
Phone/ext:	Pager:	Email:	Fax:

CO-I #2:

If CO-I is a student/trainee, specify: Post-doc PhD Master's Undergrad Resident/Fellow

Title:	First Name: Nicole	Surname: Harnett	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State:	Postal/Zip:	Country:
Phone/ext: 416-946-4501, ext. 5756	Pager:	Email: Nicole.Harnett@rmp.uhn.on.c	Fax: 416-946-6521

CO-I #3:

If CO-I is a student/trainee, specify: Post-doc PhD Master's Undergrad Resident/Fellow

Title:	First Name: INCLUDE AS NEEDED	Surname:	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State:	Postal/Zip:	Country:
Phone/ext:	Pager:	Email:	Fax:

FOR ADDITIONAL CO-INVESTIGATORS, COMPLETE AN ADDITIONAL SHEET (see Appendix 2) AND ATTACH

D. Study Coordinator or other Research Administrative Contact for this Application (if not the applicant):

Not Applicable

Title:	First Name: PROJECT ASSISTANT	Surname:	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State:	Postal/Zip:	Country:
Phone/ext:	Pager:	Email:	Fax:

In addition to the LPI, please indicate to whom correspondence also should be sent (max 1 person):

Administrative Contact Research Coordinator PI CO-I (Specify): Nicole Harnett

3. STUDY PERIOD:

Expected Start Date: 01/Sept/12 (dd/mmm/yy) Anticipated End Date: 31/Aug/13 (dd/mmm/yy)

4. STUDY LOCATIONS:

Hamilton Health Sciences	**CHEDOKE**	
	GENERAL	
	JURAVINSKI CANCER CENTRE	
	JURAVINSKI HOSPITAL (fmrly HENDERSON)	
	MUMC	
	OTHER (specify):	
St. Joseph's Healthcare Hamilton	**SJH**	
	CMHS	
	CAHS	
	OTHER (specify):	
McMaster University	**MAIN CAMPUS (i.e. not MUMC)**	
	OTHER (specify):	
St. Peter's Hospital	**SPH**	
	OTHER (specify):	
Community	**Specify:**	
Other	**Specify:**	

5. IS THIS AN INVESTIGATOR-INITIATED STUDY? YES NO

6. MULTI-CENTERED STUDIES

(a) Is this a multi-centered study? YES NO

(b) Will the application be reviewed by other Research Ethics Boards (REBs)? YES NO
If YES, specify: HHS/FHS REB SJH REB McMaster REB OTHER
and attach any REB approvals from other jurisdictions. ATTACHED TO FOLLOW

(c) Has the study been denied approval by any other REB? YES NO
If YES, please attach REB letter.

7. SOURCES OF STUDY FUNDING OR IN-KIND SUPPORT

(a) In the table below, identify all sources of financial or in-kind support for this study (i.e.. include both internal and external, public or private sources, e.g. funding sponsors, agencies, departmental, hospital or university sources). If funding or support is <u>not</u> required, check: NA and go to Q8

FUNDING SOURCES AND IN KIND SUPPORT: (please check all that apply)

Name	Funding Status	If Funding Pending, Expected Date of Decision
Ministry of Health and Long-Term care	**Applied Received In-Kind (specify:) Primary source of funds**	
	Applied Received In-Kind (specify:) Primary source of funds	
	Applied Received In-Kind (specify:) Primary source of funds	
	Applied Received In-Kind (specify:) Primary source of funds	

(b) Budget (Attach a Budget Summary – Please use the template found in Appendix 1)

Total Budget	**$ 1,800,000**
Local Budget	**$** 50,000
Indicate where funds will be administered (check one only):	
Hamilton Health Sciences	
St. Joseph's Healthcare Hamilton	
McMaster University – Faculty of Health Sciences	
McMaster University – Office of Research Services	
Other (specify): Juravinski Cancer Centre	

8. CONFLICT OF INTEREST:

Will any investigators, members of the research team, and/or their partners or immediate family members:

(a) Function as an advisor, employee, officer, director or consultant for a study-related sponsor(s) or funding source (i.e. identified in Q7)? YES NO NA

(b) Have direct or indirect financial interest in the drug, device or technology employed including patents or stocks) in this research study? YES NO NA

(c) Receive any personal benefit, e.g., a financial benefit such as remunerations, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, honorarium, or other benefits from the sponsor (apart from fees for service) etc. as a result of, or connected to this study? YES NO NA

If YES, please describe the benefits and explain how they will be managed to ensure that participant rights and welfare are not affected. The Ministry of Health and Long-Term Care (MOHLTC) has approved funding for the implementation of additional Clinical Specialist Radiation Therapist (CSRT) positions in Ontario. Previous research has shown that this new role is a potential benefit to the Ontario Healthcare System, both for healthcare professionals and patients. In order to quantitatively demonstrate this potential benefit, the current study is an examination of patient's satisfaction level - to identify if those who encountered the CSRT during their clinic visit have a similar or different level of satisfaction from those patients who encountered a non-CSRT health professional in the same clinic. These results will be compared for significant positive differences. The current study funds the Co-Investigator [INSERT NAME] as the CSRT for our hospital. Ms./Mr/ [INSERT NAME] positions mandates the CSRT to conduct research, of which this project is one aspect of that. To ensure the safety and confidentiality of patients, the CSRT (at each site) will not have access to the raw data (even though there are minimal identifiers) and will only receive access to the aggregate results. The CSRT's role within this project will include organizing, collating, and mailing the surveys. A Project Assistant will collect the surveys and input the data. A designated Statistician will complete the data analysis. The Project Supervisor for all sites is Nicole Harnett, who is an investigator in this study. She will have no direct interaction with the patients to ensure that she does not inadvertently alter their opinions or participation rate. Nicole Harnett will be directly responsible for maintaining the data integrity across all sites and will have direct access to the raw data.

8. FUNDING AGREEMENT (Note: Agreements must be reviewed and signed by authorized institutional officials):

Will there be a signed contract/agreement with a study-related funding source? YES NO NA

If YES, will it in any way limit your access to the research data, or limit your right to publish the study results? YES NO

If YES, please explain. The MOHLTC will possess ownership of the data obtained from this study. All dissemination of the results by the investigators must be approved by the MOHLTC prior to initiation. All investigators are welcomed to submit requests for publications, presentations etc. in writing.

9. CLINICAL TRIALS:

(a) Is this a clinical trial involving a <u>new</u> investigational drug, device, natural health product, <u>or</u> a drug, device or natural health product used for an indication <u>outside</u> the parameters of the approved Health Canada Notice of Compliance (NOC) or Drug Identification Number (DIN) application or Medical Device Licence, as applicable? YES NO NA

(b) If YES, has the Sponsor or the Institution/Investigator initiating the study filed a Clinical Trial Application or Medical Device Licence Application with Health Canada? YES NO

(c) If YES, indicate who submitted the Clinical Trial Application to Health Canada as the Sponsor of the study (i.e. will take responsibility for the initiation and management of the study as per Health Canada regulations and GCP guidelines)?

Local Principal Investigator
Principal Investigator

Funding Source (i.e. industry/pharma/biotech) – Specify Name:

(d) Attach a copy of the Health Canada "No Objection" Letter (NOL). (**Note: NOL must be received prior to final approval. Study may NOT commence without Health Canada approval.**) ATTACHED TO FOLLOW

Specify: NOL Control #: Date:

10. INTERNAL APPROVALS:

(a) Does this study involve a Medical Directive(s)?
Formal Medical Directives affecting clinical care require approval by a sub-committee of the Medical Advisory Committee (MAC) of the hospital (e.g. RNs giving routine post-op analgesia on behalf of the physician). If this research proposal contains similar delegated responsibilities for members of the research team, it is the responsibility of the Local Principal Investigator to ensure that appropriate approval has been obtained from the MAC. (Refer to College of Physicians & Surgeons of Ontario)

YES NO

If YES, briefly describe the order/procedure(s):

(b) Does this study involve an infectious agent? YES NO

(c) Does this study involve a biosafety hazard? YES NO

(d) Does this study include genetic testing or storage of tissues/samples? YES NO

If YES, attach a separate consent form addressing the special concerns related to genetic testing or storage of tissues/samples. (Note: See Informed Consent Checklist attached).

SECTION B – DESCRIPTION OF PROPOSED RESEARCH

PART I:

Provide a summary (10 lines maximum) of the research proposal in language suitable for a press release or for inclusion as minutes in a document aimed at lay personnel (e.g. the Board of the Hospital or the University). DO NOT use jargon or medical short forms. UNDER THE FOLLOWING HEADINGS PLEASE INDICATE:

(a) Main Research Question(s): Does the implementation of the Clinical Specialist Radiation Therapist position positively affect patient satisfaction?

(b) What is being studied? The level of satisfaction derived at an appointment in the [CLINIC NAME] will be compared between patients who were seen by the Clinical Specialist Radiation Therapist and those who were seen by another healthcare professional.

(c) Why is this research important? This research is important because it may provide further support for the inclusion of an Clinical Specialist Radiation Therapist role in the Ontario Healthcare System. As the enhancement of patient care is one of the ultimate goals of this System, it is necessary to observe alterations in satisfaction levels based on the role being implemented.

PART II: (THIS SECTION MUST BE COMPLETED EVEN IF PROTOCOL IS ATTACHED)

1. PROTOCOL #: and DATE:

2. DESCRIBE THE RATIONALE AND PURPOSE OF THE STUDY (250 word limit): This study has been designed to examine the implementation impact of Clinical Specialist Radiation Therapist (CSRT) positions on patient satisfaction in Ontario. The current project will analyze the effect of this role in the [CLINIC NAME] at [HOSPITAL NAME]. As this role has not been formalized in Canada, it is necessary to investigate potential patient benefits from its activation in order to provide evidence to support the role's permanency in the Ontario Healthcare System. To date, preliminary reseach has been conducted with current investigational CSRT roles that examines this role's impact on patient satisfaction. This has resulted in positive preliminary information which demonstrates that the CSRT is able to conduct quality clinical and radiological care that maintains patient satisfaction. These studies are continuing and the current proposal will add to the rigor of the dataset.

3. SAMPLE SIZE:

(a) Indicate how the sample size was determined): Approximately [INSERT] patients are needed to complete this study. This is based on an estimate that 50% of patients seen during the study period, from each site, will respond to the survey.

(b) The anticipated number of participants locally: INSERT

(c) The total number of participants anticipated study-wide (for multi-centered studies): 300

4. DESIGN / METHODOLOGY

(a) Indicate the study design (check all that apply):

Clinical Trial - indicate phase (select **all that apply**):

Pilot	Phase I	Phase II	Phase III	Phase IV
Other	Randomized	Double Blind	Single Blind	Open Label

Active Comparator:

- If an active comparator is used, is this the standard of care? YES NO
- Provide justification that the active comparator is the standard of care and that a state of clinical equipoise* exists regarding the merits of the regimens to be tested:

* Clinical equipoise means a genuine uncertainty on the part of the expert medical community about the comparative therapeutic merits of each arm of a clinical trial. The tenet of clinical equipoise provides a clear moral foundation to the requirement that the health care of subjects not be disadvantaged by research participation. http://www.ncehr.medical.org/english/code_2/sec07.html - Note2

Placebo Controlled. If a placebo is used, how is this justified (e.g. no alternative standard treatment available)? Include any provisions in place to reduce the risks to subjects assigned to placebo (e.g. increased monitoring, rescue medication):

Retrospective Data Analysis (select **all that apply**):
Health Records/Chart Review
Electronic Database (specify):
Outside Institution (specify):
Other (specify):

Tissue:
Retrospective Prospective

Genetic Study

Qualitative: (attach the interview guide, questionnaire, survey, etc.)
Questionnaire Survey Focus Groups
Interviews Other (specify):

Other (describe): Quantitative questionnaire

(b) **Clinical Trial Registration**

The REB strongly supports the recommendations of the International Committee of Medical Journal Editors (ICMJE) regarding the requirement for registration of all clinical trials on a publicly accessible and recognized registry. (For info access this link)

Is this Clinical Trial fully registered with a registry that meets the ICMJE (International Committee of Medical Journal Editors) standard? YES – has been registered
NO – not currently registered

If YES, specify the registry name and registration identifier number:

If NO, indicate: YES – will be registered
N/A – not a clinical trial
NO – will not be registered

If NO, indicate why inclusion in a registry is not possible or desirable:

AND include the following statement in the Informed Consent Document:
"This clinical trial will not be registered with a recognized, publicly-accessible clinical trial registry and therefore it is unlikely the study results will be published by established medical journals."

(c) **Dissemination of Clinical Trial Results**

The REB feels that every effort should be made to make clinical trial results public, but also recognizes that not all submissions get accepted for publication or presentation.

Is there an intention to make the results of this clinical trial publicly available through one of some of the following methods? (select all that apply)
N/A – not a clinical trial
YES – peer reviewed journal publication and/or presentation at conference or scientific meeting
YES – clinical trial registry
OTHER (describe)

(d) **Setting (check all that apply):**

Outpatient Inpatient ICU Community Emergency Dept.

Other (specify):

(e) **Participants:**

Provide a brief description of participants:

Participant descriptors (please check all of the following descriptors that apply):

Healthy Volunteers	Children	Aboriginal	Elderly
Incompetent to Consent	Cancer patients	Mental Health patients	Incarcerated
Nursing Home Residents	Incurable disease	Emergency situations	
Unemployed/impoverished	Third party /surrogate consent (please justify)		

Inclusiveness: Are there any age, ethnicity, language, gender or race-related inclusion or exclusion criteria?

YES NO

If YES, please justify:

(f) **Study interventions (check all that apply):**

Diagnostic:

Imaging Lab Other:

Intervention/Treatment:

Chemotherapy	Radiotherapy	Surgery	Medical Device
Gene therapeutic	Physiological	Interview/survey/focus group/questionnaire	
Cognitive/Behavioural	Drugs	Other (specify):	

List all the drugs to be used in this study. Please include brand name and generic name and/or investigational designation. (This includes the study drugs PLUS any other medications specified in the protocol that the participant will receive while on this study).

Investigational Drug	Generic Name	Brand Name

(g) **What are the primary and secondary outcome measures?** (i.e." What" will the study measure?)
Primary: A positive 10% change in patient satisfaction levels as indicated on the subscale "Overall Satisfaction".
Secondary: A positive 5% change in patient satisfaction levels as indicated on the two subscales: a) Quality and competence of technical care and b) Provision of information.

(h) **Measurements (i.e. "How" will the study measure it?)** The current study examines patient satisfaction level using a modified version of the "Patient Satisfaction Questionnaire" originally designed and validated by the Rheumatism Research Unit at the University of Leeds (Hill, 1997). The modified version was altered to make the questionnaire more generic for use in all clinics, rather than clinic specific (Mortimer Market Centre: Service User Satisfaction Survey; Miles et al., 2003). A few alterations to the demographic portion of the questionnaire have been made (i.e., removed unnecessary questions such as employment status). The survey has been shortened to accommodate the needs of the cancer populaton. Also, additional questions relating to the patient's interactions with the CSRT role will be administered to those who were seen by the CSRT.

(i) **Plan for data analysis. Briefly explain how data will be analyzed.** The survey will be analysed in accordance with the standardized procedures as noted in Miles et al. (2003). Descriptive statistics will provide estimates of

central tendency and variation for each demographic variable. A statistician will conduct the statistical analysis examining for differences between the questions of this study using t-tests and ANOVAs.

(j) **MONITORING**

Is there a steering committee?	YES	NO	NA
Is there a plan for monitoring of the study? (e.g., sponsor-site visits)	YES	NO	NA
If YES, describe: Nicole Harnett will over see the different site's study to ensure that the data is being collected and entered appropriately, and the study is completed in accordance to the ethical standards of each local Research Ethics Board.			
Is an interim analysis planned?	YES	NO	
Is there a data safety monitoring board (DSMB)?	YES	NO	NA
If YES, is it independent of the sponsor?	YES	NO	

SECTION C – DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH

1. **What are the proposed benefits to the participants, the scientific community or society that would justify asking individuals to participate?** Patient participants may not experience any direct benefits from this study, other than a sense of having their opinions recognized by hospital administration. Proposed benefits to the scientific community and society include validating the potential positive benefits of an Clinical Specialist Radiation Therapist position on patient satisfaction. As this study focuses on the aggregation of patient results from each unique advanced practice position currently implemented, our results will show the general value of this role across a range of disciplines. In addition, this comprehensive study is the first of its kind worldwide to examine this role's impact on patient satisfaction.

2. **Specify the risks to participants involved in this study** (e.g. physical risks such as pain, discomfort, injury, side effects; psychological risks such as participants feeling demeaned, worried, upset, or embarrassed); social or economic risk such as invasion of privacy or breach of confidentiality)**.** Although it is not anticipated that the participants will incur any psychological risks, they may experience some emotional discomfort in regards to filling out the questionnaire if their experience at the hospital was not positive. However, as they will be recording their satisfaction level, it is possible that the participant may experience some release of this discomfort and may feel that their opinions will be heard. There are no physiological risks associated with this study.

3. **How will you manage and minimize the risks?** Patients will be able to discontinue their participation in the study or opt not to answer any questions (at any point in time) that may relieve emotional discomfort. [****Depending on the population and CSRT role, this portion will change. Please insert the best method for dissemination here. Options include, mailing the survey, telephone calls, hand delivery by Research Assistant, etc.]. All questionnaires will be mailed to the patient's home to ensure that they are in a comfortable environment when filling out the survey. As well, patients will be provided with a local contact number if they wish to discuss any personal implications of the study.

4. **Payments to participants:**
   (a) Will participants be reimbursed for expenses? YES NO
   If YES, please provide amount(s) and item(s) covered:
   (b) What other inducement or compensation is offered to participants? Patients will not receive compensation for their participation.

SECTION D – PLAN FOR OBTAINING INFORMED CONSENT

Complete the attached "Informed Consent Checklist" prior to completing this section. Participants may not be approached directly by research staff: they must first be approached by someone within their 'circle of care' for permission for the research staff to speak to them about the research and prior to review of their medical record.

1. (a) Indicate how potential participants will be identified, through one or more of the following (check all that apply):

a.	From the investigator's own patients	
b.	From patients proposed by another healthcare provider (with the patient's consent)	
c.	From lists of patients identified by Health Records Dept (initial contact must be made by the patient's attending physician or another member of the patient's healthcare team)*	
d.	From databases of patients who have previously given consent to be approached for research studies (consent forms must be archived and accessible)*	
e.	From internal REB approved advertising within this institution	
f.	From external REB approved advertising. Specify:	
g.	By REB approved direct approach of the public (e.g. random digit dialing, direct approach in public places, snowballing, etc.). Specify:	
h.	Other. Specify:	

* N.B. The custodian of the database must obtain the patient's permission to provide his/her name to the researcher unless prior consent has been given at the time the patient's data was entered into the database.

(b) How will potential participants be approached? Patients seen in clinic during the four months prior to the Clinical Specialist Radiation Therapist position being implemented and during Month 4 and Month 7 Week 4 of the role being implemented will be mailed a questionnaire and information letter. [****This will changed based on the dissemination process. If you are handing the surveys out in clinic by a Research Assistant, please state this or any other appropriate information For the palliative population, please try to have the surveys handed out prior, during, or immediately after clinic.].

2. Describe the relationship between the investigator(s) and the participant(s). If the investigator is also the participant's treating physician, how will you avoid undue influence? Who will obtain consent? The patients will have the right to accept participation (through mailing the questionnaire to the Project Assistant [****handing back the survey to the Research Assistant. Insert other information as needed]) or non-participation (through discarding the questionnaire). The CSRT, who is the Co-Investigator, may have direct contact with the patient who will receive a questionnaire regarding their level of satisfaction. To ensure the safety and confidentiality of patients, the CSRT (at all sites) will not have access to the raw data (even though there are minimal identifiers) and will only receive access to the aggregate results upon the completion of the MOHLTC study CSRT position (after 9 months in the role). The CSRT's role within this project will include organizing, collating, and mailing the surveys. A Project Assistant will collect the surveys and input the data. A designated Statistician will complete the data analysis.

3. Are participant's competent to consent? YES NO

If NO, describe the alternate source of consent. If a minor, describe the procedure to be used and describe how you will obtain assent / consent.

4. How will you assure ongoing consent from research participants? Patients will be made aware that they are able to leave any question unanswered if they prefer, and that this or refusal to participate will not result in alternative treatment or care at the hospital. Any degree of refusal can occur at any point during the study. They will also be made aware that the study may not personally benefit them and that they will not receive remuneration for their participation.

5. What procedures will be followed for participants who wish to withdraw, either during or after the study? All patients who wish to withdraw from the study will be able to have their written and electronic information obtained/created destroyed through shredding (put into confidential disposal bin) or permanently deleted from the computer's hard drive. Patient names will be stored in a separate password protected file for purposes of mailing the

survey only. All eletronic data will present a random numeric code. If the results of the study are published, no patient names will not be used and no information from their participation will be included in the data analysis.

6. **Will you be contacting participants either by telephone or letter during the project?** YES NO
If YES, append a copy of the letter/telephone script or list of questions with the research protocol. APPENDED.

SECTION E – STEPS TO BE TAKEN TO ENSURE CONFIDENTIALITY OF DATA

1. **(a) If you require person level data, are you collecting any of the following personal identifiers?**

DIRECT IDENTIFIERS	✓	INDIRECT IDENTIFIERS	✓
Full Name (recommend initials)		Initials	
Address		Full Date of Birth (day/month/year)	
Telephone number		Age at time of data collection or year of birth	
OHIP #		Full Postal Code (recommend first 3 digits only)	
Social Insurance Number		First 3 Digits of Postal Code	
Email Address		Healthcare Provider (recommend type of provision, e.g. Family Physician, VON)	
Medical Record Number		Discharge Date	
Full Face Photograph		Other date (e.g. date of service)	
OTHER-		Fax Number	
		Medical Device Identifier	
		Certificate/License Number	
		Vehicle Identification*	
		OTHER -	

* Vehicle Identification numbers (VIN) and serial numbers including license plates.
NOTE: Investigators should plan to collect person level data at the lowest level of identifiability necessary to achieve the study objectives. We recommend using only initials and first 3 digits of postal codes. Even a dataset without direct identifiers may present risk of indirectly identifying data subjects if the dataset contains sufficient information about the individuals concerned. For advice, consult the CIHR Best Practices for Protecting Privacy in Health Research

If you are collecting person level data, you are required to:
1. segregate/strip all direct identifiers from other clinical data
2. assign a unique study identifier (i.e. a randomly generated or meaningless ID number)
3. store the Master list linking study ID with identifiable material in a separate computer file and/or physical location
4. ensure that Master list is locked and password protected

(b) Attach data collection form or list of fields to be collected. ATTACHED

(c) If you are collecting any of the above personal identifiers, justify why each item is required: The patient's full name and address will be required to mail the questionnaire to their home. [****If you are not mailing surveys, delete the answers in Section E #1a,1c]

2. **Do you plan to link the locally collected data with any other dataset(s)** (e.g. OHIP data, census tract data)? YES NO
If YES, identify the dataset, identify how the linkage will occur, and provide a list of data items contained in it. Data from each CSRT patient satisfaction study associated with the MOHLTC funding will be aggregated. Nicole Harnett will oversee this aggregate data.

3. **Indicate the steps to be taken to ensure security of data with personal identifiers.** Please check all that apply.

PROCEDURAL MEASURES	
Data access to the segregated/identified data will be limited to a "need to know" basis*	
There will be an audit trail of access to electronic records	
PHYSICAL	
Completed data abstraction forms will be stored in locked filing cabinets in secure location – Specify: [Project Assistant]	
Computers will be housed in locked secure location – Specify: [Project Assistant]	

Data file backup will be stored in a separate, locked secure location – Specify: [Nicole Harnett's Office]	
Other – Specify:	
TECHNICAL	
Data will be stored on a computer which is password protected	
Data will be stored in a computer file which is password protected	
Frequent backups of data will occur	
Data will be stored on computer systems with virus protection	
Data will be stored on computer systems with uninterrupted power source	

* Reminder: All changes to previously approved research plans require approval, including any change in persons given access to the data.

4. **(a) Will data be sent outside of the institution where it was collected and/or will you be receiving data from other sites** (for example, in the case of a multi-site study where you are the coordinating site receiving data)**?**

YES If YES, explain why it is necessary to send/receive data outside of the institution where it was collected.

As this is a multi-centred study, it is necessary to have one person oversee the aggregation of the data, this person being Nicole Harnett.

NO

(b) How will the data be sent or received?

Transmission of data via:	**Sent?**	**Rec'd?**
	■	■
Email (Attach encryption protocol)		
Private Courier (Must be able to trace delivery)		
Canada Post Xpresspost or Priority Courier (Regular mail may not be used)		
Other – Specify:		

(c) Where will data be sent? The data will be eletronically sent to Nicole Harnett.

(d) Specify the names and affiliations of persons outside of your research team (e.g. technical service providers, other researchers) who will have access to the data.

* Data sent or received by the institution will require that the parties enter into an information transfer agreement before the data transfer takes place.

Nicole Harnett is [insert affiliation here]: overseeing and coordinating the entire MOHLTC CSRT project.

5. **Will the data be entered into an ongoing electronic database for future use in another research study?**

(Note: Any secondary analysis must be approved by the REB prior to implementation.) YES NO

If YES, specify where it will be stored, who will be the custodian (i.e. the person responsible for data storage and integrity), who will have access to it, and security measures.

6. **(a) How long do you plan to keep the data?** Specify: The data will be kept for a period of five years following any publication.

(Note: You are required to destroy identifiers or links at the earliest possible time.)

(b) Will data be: destroyed, anonymized (e.g., the key identifying the link between data and the individual's identity is deleted)?

SECTION F – RESOURCES UTILIZATION AGE FOR
HAMILTON HEALTH SCIENCES/McMASTER FACULTY OF HEALTH SCIENCES

Requirements:

- It is the responsibility of the applicant to ensure that all areas from which resources will be required have been consulted and have indicated agreement by signing this form.
- Approval of the project is conditional upon satisfactory completion of this section.
- A separate resources form must be filled in for St. Joseph's-based and for Hamilton Health Sciences-based research.

Institutional Services, Staff or Equipment:

- If your participant will be admitted to hospital and/or will require any hospital services as a requirement of this study, which are over and above standard treatment, you **must** obtain appropriate signatures in areas listed below.
- If the study involves more than one unit or service in the hospital, signatures **must** be obtained from all areas involved.
- In all cases, budgets should cover institutional costs (e.g. nursing time for data collection, incremental costs associated with drugs being used in study) for Hospital/Centre participation in research, unless agreed upon by the appropriate Director/Administrator.
- All applications for studies involving drug administration, even if dispensed directly to participants by the Investigator, require the appropriate Pharmacy signature.

Human Resources:

- When budgeting for research personnel, the applicant is advised to contact the Human Resources Office to ensure that all necessary calculations for personnel costs are included. McMaster: employ@mcmaster.ca HHS: recruitment@hhsc.ca SJH: jnikpal@stjosham.on.ca

Space:

- Investigators are expected to accommodate all features of research in their present space allocation (staff, records, materials storage, etc). Approval from the REB does **not** constitute approval for additional space. The following individuals may be contacted to facilitate negotiation of additional space at the following locations:
    - **Faculty of Health Sciences:** Marie Townsend, 905-525-9140, x22515, townsend@mcmaster.ca
    - **Hamilton Health Sciences:** Deidre Henne, 905-521.2100, x74862, henne@hhsc.ca
    - **St. Joseph's:** John Woods, 905-522-1155, x5129, jwoods@stjosham.on.ca

Health Records/Decision Support Services:

1.	Will you require **Health Records** to pull charts for you?	YES	NO
2.	Will you require **Decision Support** to identify your research population?	YES	NO
3.	Do you require patient specific data from **Decision Support** to support your project?	YES	NO
4.	Do you require summary cost data to support your project?	YES	NO
5.	If YES to any of 1 to 4 above, have you allowed for these services in the budget?	YES	NO

CHECK AREAS BELOW WHERE RESOURCES ARE REQUIRED (✓)

#	✓	AREA	Type Name of Authorized Official OR Designate	Signature
1		**Decision Support**	[INSERT]	
2		**Health Records**		
3		**Laboratory Services**		
4		**Medication/Drugs (Pharmacy)**		
5		**Radiology/Diagnostic Imaging Resources**		
6		**Nuclear Medicine Resources**		

7		**Radiation Safety**		
8		**EMROC (Emergency Medicine Research Committee)**		
9		**Other – specify:**		

APPROVALS ARE REQUIRED FROM INDIVIDUALS RESPONSIBLE FOR NURSING AND CLINICAL CARE OF EACH PATIENT AREAS TO BE UTILIZED

10		**Inpatient Area(s) – Specify area(s) and provide signature(s) as applicable**		
		Area 1	**Name**	**Signature**
		Area 2	**Name**	**Signature**
		Area 3	**Name**	**Signature**
11		**Outpatient Area(s) – Specify area(s) and provide signature(s) as applicable**		
		Area 1 [INSERT]	**Name [INSERT]**	**Signature**
		Area 2	**Name**	**Signature**
		Area 3	**Name**	**Signature**

SECTION G –SIGNATURE PAGE FOR REB APPLICATION
HAMILTON HEALTH SCIENCES/McMASTER FACULTY OF HEALTH SCIENCES

SIGNATURE OF LOCAL PRINCIPAL INVESTIGATOR:

I assume full responsibility for the scientific and ethical conduct of the study as described in this REB application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and any other relevant regulations and guidelines. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and experienced or will undergo appropriate training to fulfill their role in this project.

I have obtained all necessary resource utilization signatures as noted above and all costs associated with the use of these resources have been declared.

Signature of the LPI Date

Signature of the PI (if different from above) Date
(If PI is not local, a faxed signature is permitted – please attach)

SIGNATURE FOR STUDENT PROJECTS (if applicable):
(Student Supervisor must sign above where indicated for LPI)

Student Signature Date
(For student projects – e.g. Post-doc, PhD, Master's, Undergrad, Resident/Fellow)

HAMILTON HEALTH SCIENCES/McMASTER HEALTH SCIENCES

REB Application Signature Page
For Medical Director, Chief of Department and Administrative Director/Manager/Supervisor

COMPLETE THIS PAGE FOR EACH CLINICAL DEPARTMENT/PROGRAM INVOLVED

Director, Clinical Services / Clinical Leader's Review*[†]:

I have reviewed the attached protocol and confirm that the

Department of

(or) Program of

have the resources (space, personnel, patient population) necessary to support this research. I have taken into consideration any research which is planned or already in progress in the Department/Program in making my assessment.

Printed Name:
Director, Clinical Services (or Clinical Leader[†])

Signature Date

Printed Name:
Vice-President (for non-medical only[†])
Signature Date

Chief of Department Review (Must be the last signatures obtained):

CHECK [✓]:
I have reviewed this protocol.

I confirm that is a member in good standing of the medical staff of Hamilton Health Sciences/McMaster University.

I confirm that s/he has the credentials/expertise to conduct the research being proposed in this application.

I agree that the Department of has the resources (space, personnel and patient population) to support this research.

CHIEF OF DEPARTMENT

Printed Name:
Chief of Department

Signature Date

* Hamilton Regional Laboratory Medicine Program exempted.
† For non-medical protocols, signatures of the Clinical Leader & appropriate Vice-President must be obtained

Research Ethics Board

CHECKLIST

THIS FORM MUST BE COMPLETED & AFFIXED TO THE FRONT OF YOUR PACKAGE

Check [✓] all that apply:

Affiliation

If the Principal Investigator is not a staff member of Hamilton Health Sciences or McMaster University, there must be named as Locally Responsible Investigator a staff member who will be responsible for the conduct of the research at HHS/McMaster sites.

Required Signatures

The Principal Investigator must sign and date the application form in the space provided.
The Clinical Chief & Administrative Director/Manager/Supervisor of the relevant department/program must sign and date the application form in the space provided.

If the study uses the following services, corresponding signatures must be on the application:

Decision Support --- Director/Designate.
Health Records – Director/Designate.
Laboratory Services --- Director/Designate.
Medications/Drugs --- Director/Designate.
Radiology/Diagnostic Imaging Services --- Director/Designate.
Nuclear Medicine Resources --- Director/Designate.
Radiation Safety --- Director/Designate.
EMROC (Emergency Medicine Research Committee) – Director/Designate.
In Patient / Outpatient Services - the relevant Director/Designate.

Lay Statement

Readability should be at a Grade 8 level.

Forms/Attachments/# of Copies Required

Provide **three** copies of the application (including **one** with original signatures) consisting of the:

- ***Typed*** Application for Review by Research Ethics Board with all applicable sections complete;
- Consent form/Information documents and recruitment advertisements/posters;
- Research Protocol (include see Guidelines for content);
- Letters of approval from hospital/university REBs in other jurisdictions, if applicable;
- Approval Letters from Health Canada, if applicable (see Sec A.10);
- A product monograph or investigator's brochure if the study includes an investigational agent not yet approved by Health Canada;
- Approval Letters from Infection Control or Biosafety Committee, if applicable (see Sec A.11);
- Budget Summary (Appendix 1); and
- Informed Consent Checklist (Appendix 3).

In addition to the above materials, please forward via email attachment (email to: mazzedeb@hhsc.ca) or on computer diskette, an electronic copy of the Application for Review and the Information/Consent form(s).

Administrative Fee for REB Review of Industry-Sponsored Studies

$2,000 (Cdn) administration fee payable to "McMaster University" included for all industry-sponsored research projects. Questions regarding payment details may be directed to the CSD office (905-525-9140, ext. 22258).

Projects must be submitted by 1600hrs on the last Tuesday of the month to the HHS/FHS Research Ethics Board, attention of Deborah Mazzetti, 1057 Main St W, Suite 1, Hamilton, ON L8S 1B7 (905-527-4322, ext. 42013) for consideration at the Research Ethics Board meeting held on the 3rd Tuesday of the following month.

Projects not conforming to the ABOVE requirements will be returned to the Investigator.

RESEARCH ETHICS BOARD
BUDGET TEMPLATE

Estimated Itemized Cost Per Participant

		# Visits	X	Cost	=	Total
History & Physical (or other remuneration to investigators)			**X**		**=**	
Imaging:	X-rays		**X**		**=**	
	Ultrasound		**X**		**=**	
	Bone Scans		**X**		**=**	
	CT Scans		**X**		**=**	
	MRI		**X**		**=**	
	Other – specify		**X**		**=**	
Lab Work:	Haematology		**X**		**=**	
	Chemistry		**X**		**=**	
	Urinalysis		**X**		**=**	
	Other – specify		**X**		**=**	
ECG			**X**		**=**	
Endoscopy/OR			**X**		**=**	
Pharmacy:	Medication Costs – Mandatory: list all drugs being used_____(if free, enter "0")		**X**		**=**	
	Admin Costs					
Reimbursements and other payments to participants			**X**		**=**	
				Total cost per participant	**=**	0.00 **(a)**
Total Participant costs:		participants	**X**	**(a)**	**=**	0.00 **(b)**
PERSONNEL COSTS						
1. Nurse/Coordinator @ $	/hr x	hrs/patient x	patients		**=**	50,000
2. Nurse/Coordinator @ $	/hr x	hrs/patient x	patients		**=**	
3. Nurse/Coordinator @ $	/hr x	hrs/patient x	patients		**=**	
				Total Personnel:	**=**	**50,000(c)**
EQUIPMENT COSTS						
Specify Equipment -					**=**	0.00
				Total Equipment:	**=**	0.00 **(d)**
ADMINISTRATIVE COSTS						
Administrative (meetings, telephone, stationery, etc.)					**=**	0
				Total Administrative Costs:	**=**	0.00 **(e)**
INDUSTRY-SPONSORED STUDIES						
Overhead for Industry-sponsored studies NOT INDUSTRY SPONSERED					**=**	0.00
REB Admin Fee for Industry-sponsored studies ($2,000)					**=**	0.00
				Total Indirect Costs:	**=**	0.00 **(f)**
				Total Cost for Complete Study:	**=**	50,000 **(b+c+d+e+f)**

N.B. If your budget is reported as cost/patient enrolled, be sure to provide a detailed justification of what is included in the cost/patient (i.e. how many hours of nursing time, etc.). Remember to contact Human Resources when budgeting for personnel costs.

APPENDIX 2

ADDITIONAL CO-INVESTIGATORS (CO-I)

CO-I #4:

If CO-I is a student/trainee, specify: Post-doc PhD Master's Undergrad Resident/Fellow

Title:	First Name:	Surname:	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State:	Postal/Zip:	Country:
Phone/ext:	Pager:	Email:	Fax:

CO-I #5:

If CO-I is a student/trainee, specify: ☐ Post-doc ☐ PhD ☐ Master's ☐ Undergrad ☐ Resident/Fellow

Title:	First Name:	Surname:	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State:	Postal/Zip:	Country:
Phone/ext:	Pager:	Email:	Fax:

CO-I #6:

If CO-I is a student/trainee, specify: Post-doc PhD Master's Undergrad Resident/Fellow

Title:	First Name:	Surname:	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State:	Postal/Zip:	Country:
Phone/ext:	Pager:	Email:	Fax:

CO-I #7:

If CO-I is a student/trainee, specify: Post-doc PhD Master's Undergrad Resident/Fellow

Title:	First Name:	Surname:	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State:	Postal/Zip:	Country:
Phone/ext:	Pager:	Email:	Fax:

CO-I #8:

If CO-I is a student/trainee, specify: Post-doc PhD Master's Undergrad Resident/Fellow

Title:	First Name:	Surname:	
Institution:		Department/Division:	
Street Address: Line 1			
Line 2			
City:	Province/State:	Postal/Zip:	Country:

Phone/ext:	Pager:	Email:	Fax:

This form is available in MS WORD & WP formats and can be downloaded at this link

INFORMED CONSENT CHECKLIST

GENERAL REQUIREMENTS: **Check[✓] all applicable**

- Print the Information sheet and Consent form on appropriate letterhead (e.g. St. Joseph's Healthcare, Hamilton; McMaster University; Hamilton Health Sciences; or Hamilton Regional Cancer Centre), with the title of the study, names of the Principal/Local Principal Investigator and funding Sponsor (also identify internally funded sources/sponsors) at the top, pages numbered appropriately and version date included. Ensure use of the proper names of institutions, sites, sponsors, etc. avoiding use of acronyms or abbreviations.
- The Information sheet should begin with the phrase "You are being invited to participate in a research…."
- Ensure the Information sheet is written consistently in the second person ("You"/"your")
- The Consent portion should be written in the first person singular ("I", "me", "my") and should indicate that the participant understands and agrees to participate in the research.
- Ensure a thorough check for spelling, punctuation and grammar (including consistency in the use of "you/I"). Also ensure that all consent materials are printed in a suitable type-size for easy reading by participants.
- Avoid use of acronyms on information/consent materials that form actual words while abbreviating the study title. To avoid any possibility of unduly influencing participants, do not use acronyms that may give participants the expectation of a favourable outcome (e.g. the "W.O.N.D.E.R. D.R.U.G." study).
- Research participants must be informed if their physician will receive a fee for enrolling them in a study.
- A sentence identifying the person that participants should contact with any questions concerning the rights of trial participants:
  - **FOR ST. JOSEPH'S HEALTHCARE STUDIES**: "If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Research Ethics Board, St. Joseph's Healthcare Hamilton, 905-522-1155, Ext. 3537."
  - **FOR HAMILTON HEALTH SCIENCES/FHS McMASTER UNIVERSITY STUDIES**: "If you have any questions regarding your rights as a research participant you may contact the Office of the Chair of the Hamilton Health Sciences / Faculty of Health Sciences Research Ethics Board at 905-521-2100, Ext. 42013."
- Ensure sufficient space is provided for both the printed name and signature of each person completing the Consent portion (participant, person obtaining consent, witness and investigator), together with the date of each signature and that initials are on each page of the consent form.
- If the participant is a minor,(7 – 15) the participant should sign to give assent to the research in addition to the guardian's consent.
- Include a sentence in the Consent Form stating that "I will receive a signed copy of this form".

READABILITY:

- nsure the Information sheet and Consent form are at a Grade 8 reading level.
  - To check readability of consent materials using Microsoft Word, go to "Tools"→"Spelling & Grammar"→ "Options"→"Show Readability Statistics". When Word finishes checking spelling and grammar, it displays information about the reading grade level.

CONFIDENTIALITY:

- Describe procedures to ensure confidentiality of data and anonymity of participants. Provide information on length of retention and security of data. If information will be released to any other party for any reason, state the person/ agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure.
- If activities are to be audio- or videotaped, describe the participant's right to review the tapes, who will have access, if they will be used for educational purposes, and when they will be erased.

MEDICAL ACTS:

- If investigators propose to include their own patients in a study, the invitation to participate should be made and the informed consent should be obtained by persons on whom the participant has no dependency.
- That a physician is a co-investigator and sign the Consent form if medical intervention is part of the study.

GENETICS:

- For studies involving genetic research or banking of tissue, inform the participant how long the sample will be stored; explain that the sample will be used for genetic research; explain who has control and ownership of the sample (e.g. "The analysis of your DNA sample may contribute to the creation of commercial products from which you will receive no financial benefit"); inform participant whether they will have access to genetic information; and indicate

whether there may be a future secondary use of sample.

- For protocols containing sub-studies involving genetic research or banking of tissue, a separate consent is required, either as a separate section following the main study consent form, or as a stand-alone consent form.

Excerpts from Section 4.8 "Informed Consent of Trial Subjects"
ICH Good Clinical Practice: Consolidated Guidelines adopted by Health Canada

.8.4 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

4.8.6 The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

(a) That the trial involves research.

(b) The purpose of the trial.

(c) The trial treatment(s) and the probability for random assignment to each treatment.

(d) The trial procedures to be followed, including all invasive procedures.

(e) The subject's responsibilities.

(f) Those aspects of the trial that are experimental.

(g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.

(h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

(i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

(j) The compensation and/or treatment available to the subject in the event of trial-related injury.

(k) The anticipated prorated payment, if any, to the subject for participating in the trial.

(l) The anticipated expenses, if any, to the subject for participating in the trial.

(m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

(n) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

(o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

(p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

(q) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

(r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

(s) The expected duration of the subject's participation in the trial.

(t) The approximate number of subjects involved in the trial.