



**Technical Research Workshop  
Wednesday April 11<sup>th</sup> 2007  
Heritage Hotel, Rotorua, New Zealand**

**SPONSOR**



**TECHNICAL RESEARCH WORKSHOP COMMITTEE**

Scott Babington, Deidre Cornes, Martin Ebert, Peter Greer (Secretary), Joan Hatton, Annette Haworth (Physics Convenor: Scientific Program), Bronwyn Hilder, Melissa Jacobson (Chair), Rachel Kearvell, Tomas Kron, Trevor Leong, Kathryn Neilson (RT Convenor: Scientific Program), Lisa Roberts

**Professor Jatinder Palta**  
**Professor and Chief Physicist, University of Florida**

Jatinder Palta established the Resource Centre for Emerging Technologies (RCET) in the USA in 1998. Jatinder is a Professor and Chief of Radiation Physics at the Department of Radiation Oncology, University of Florida and he specialises in clinical radiation physics and Intensity-Modulated Radiation Therapy (IMRT). Prof Palta has published more than 90 papers in peer reviewed journals and is a fellow of the American Association of Physicists in Medicine. Prof Palta has served as a member of AAPM Task Group committees and currently chairs the IMRT AAPM sub-committee. RCET provides resources to facilitate the conduct of NCI sponsored advanced technology radiation therapy. The RCET system provides a Web-based secure data submission, retrieval and archiving facility with Web-based 2D / 3D visualization tools, rapid review tools and storage of clinical data objects in a content-based relational database for retrieval and data mining.



**Jenny Cox**  
**Associate Professor of Radiotherapy, University of Sydney**

Jenny Cox has many years experience in radiation therapy practice and education and graduated in 2004 with the first PhD in radiation therapy awarded in Australia. Jenny received the Australian Varian award for significant contribution in radiation therapy in 2005 and holds the position of Cancer Institute NSW Associate Professor of Radiation Therapy. This is an appointment at the University of Sydney, with clinical positions in four hospitals, with the aim of increasing higher education, research and evidence-based practice among radiation therapists. Jenny is currently co-supervising the research degrees of eleven students, seven of whom are radiation therapists, and all of whom work in the broader medical radiations field. Her first radiation therapist doctoral student will graduate this year.



**Professor Michael Findlay**  
**Director, Cancer Trials New Zealand**

Michael Findlay is a Medical Oncologist and Professor of Oncology at the Faculty of Medical and Health Sciences, The University of Auckland, New Zealand. He is also the Director of Cancer Trials New Zealand (CTNZ) and Deputy Chair of the Australasian GI Trials Group. He graduated from the University of Otago with an MBChB in 1983 and completed his Doctor of Medicine in 1995 in the field of Gastrointestinal Cancer Research.

# Technical Research Workshop



8.30– 8.35am	<b>Welcome &amp; Opening of Workshop</b>	<b>Melissa Jacobson</b>
<b>8.35 – 10.00</b>	<b>Session 1: Educational Session</b>	<b>Chair: Kathryn Neilson</b>
8.35 – 9.00	<b>Ethics</b>  <i>An introduction to ethical issues for RTs and physicists. There will be a focus on radiation exposure for patients in the context of clinical trials.</i>	<b>Michael Findlay</b>
9.00 – 10.00	<b>Protocol Development</b>  <i>Discussion will focus on strategies to develop a clinical trial concept through the stages of trial development including writing a protocol, budgeting and implementation. CTNZ protocol development templates will be used to demonstrate practical methods to be implemented when developing a technical based trial. A hypothetical 'Verification of the isocentre using Cone Beam CT' trial proposal has been developed to provide an example of the steps to be carried out when developing a technical trial proposal.</i>	<b>Michael Findlay</b>
10.00 – 10.15	<b>Morning Tea</b>	
<b>10.15 – 1.30</b>	<b>Session 2: Presentation Session</b>	<b>Chair: Annette Haworth</b>
10.15 – 10.55	<b>The World Wide Web and a new paradigm in reporting &amp; reviewing radiotherapy data</b>  <i>This presentation will provide an overview of RCET and its role in clinical trial QA, infrastructure requirements of a remote review system, applications (including routine patient plan review, data mining etc), examples of use in clinical trials, future developments and collaborative opportunities.</i>	<b>Jatinder Palta</b>
10.55 – 11.35	<b>Advice for starting research: how to motivate people and get them to participate</b>  <i>Jenny will present on the benefits of being involved in research for Radiation Therapists, how to get started and create a research culture and how to successfully carry out a project. Jenny will share experience in collaboration between a clinical site and the University, and the associated benefits, and discuss what Masters by research entails.</i>	<b>Jenny Cox</b>

11.35 – 11.45	<b>TROG CQMS</b>	<b>Brett Shrum</b>
	<p><i>A major component of the NH&amp;MRC Enabling Grant awarded to TROG is the development of CQMS, Central Quality Management System, which will house all the data required for QA of TROG trials. The system will be accessed via a web interface so that all data requiring review, including radiotherapy treatment planning images, can be reviewed online at any time. This represents a huge step forward in efficiency compared to the current system allowing TROG to coordinate trials more efficiently, with an effective means to track, analyse and therefore manage quality issues.</i></p>	
11.45 – 12.10	<b>Technical Initiatives Showcase</b>	
	<ul style="list-style-type: none"> <li>• <b>Australian Centre for Clinical Dosimetry</b></li> </ul>	<b>Tomas Kron</b>
	<p><i>A workshop was conducted last year to gauge interest and assess feasibility of an Australian Centre for Clinical Dosimetry (ACCD). There was general agreement that there is a need within Australia for an ACCD. The ACCD will address QA issues, provide essential support for clinical trials (including fulfilling overseas requirements for dosimetry confirmation to participate in multi-national trials) and constitutes a 'risk reduction' strategy.</i></p>	
	<ul style="list-style-type: none"> <li>• <b>CREDiT<sup>©2006</sup> Software</b></li> </ul>	<b>Kathryn Neilson</b>
	<p><i>Christchurch Radiotherapy Development Tool (CREDiT<sup>©2006</sup>) is an Access database designed to store patient demographics, planning parameters (including DVH import) and acute treatment related radiation toxicities. The database also contains well developed tools that allow analysis and manipulation of the data entered for large cohorts of patients. The application of CREDiT to in-house research and the potential for clinical trial use will be briefly discussed.</i></p>	
	<ul style="list-style-type: none"> <li>• <b>The need for assessment of new technology in clinical trials: examples of VARIAN equipment in the treatment room</b></li> </ul>	<b>Tomas Kron</b>
	<p><i>This presentation will highlight examples of new technology (On-Board Imager, Cone Beam CT and Gating) which while attractive still have to prove their clinical role. Opportunities for incorporating relevant questions in clinical trials as secondary endpoints will be explored.</i></p>	
12.10 – 1.00	<b>Split RT/Physicist Session</b>	<b>RT Facilitator: Rhonda Coleman</b>
	<p><i>These forums will feature interactive discussion on research positions within Australasia to allow ideas and input on increasing the role of RTs and physicists in radiation research. Delegates are invited to bring personal experience to the discussion, in particular to highlight novel ideas they have been exposed to which have increased the role of these professions in participating in clinical research.</i></p>	<b>Physics Facilitator: Tomas Kron</b>
1.00 – 1.30	<b>Summary &amp; Feedback from RT &amp; Physicist Sessions</b>	
1.30 – 2.00	<b>Lunch</b>	

**1.00 – 2.00 Discussing a Clinical Trial with a Patient****Facilitator:  
Fran Boyle**

*The focus of the workshop is on providing a safe learning environment where participants explore effective ways to handle difficult situations that occur regularly in their work with patients. There is an emphasis on providing practical experience and on finding ways to transfer the skills learned during the workshop back into the workplace. The TROG 07.01 trial 'A phase III study of radiation dose escalation and fractionation in women with non-low risk ductal carcinoma in situ (DCIS) of the breast' will be used as an example to provide participants with a practical example in which to take findings from the workshop back to their workplace. Participants explore issues such as:*

- *Explaining a clinical trial (randomisation, equipoise etc);*
- *Discussing standard and alternative treatments;*
- *Balancing patient autonomy with clinical experience; and*
- *Identifying patient's questions and concerns.*

**3.30 – 3.45 Afternoon Tea****3.45 – 4.55 Communications Workshop continued****4.55 – 5.00 Summary & Close of Workshop****Melissa Jacobson****COMMUNICATIONS WORKSHOP SPONSOR**

# Facilitated Communications Workshop

## Trial Executive Summary



### TROG 07.01 A randomised phase III study of radiation doses and fractionation schedules in non-low risk ductal carcinoma in situ (DCIS) of the breast.

Protocol Version: DRAFT 9 September 2006  
 Date First Patient Entered: TBA  
 Accrual Target: 610

**Objective:** **Overall aim:** To individualise treatment selection for women with non-low risk DCIS of the breast following breast conserving surgery to achieve long term disease control with minimal toxicity.  
**Specific aims:**  
 1. To evaluate time to local recurrence, overall survival, treatment toxicity and cosmetic outcome in women with DCIS treated with breast conserving surgery followed by:  
 ♦ whole breast RT alone *versus* whole breast RT plus tumour bed boost;  
 ♦ RT using the standard fractionation schedule *versus* the shorter schedule.  
 2. To compare quality of life, psychological distress, perceived risk of invasive breast cancer and perceived cosmetic outcomes among women in the treatment arms.  
 3. To identify biomarkers or molecular signatures of DCIS that are predictive of invasive recurrence of DCIS and normal tissue side-effects to facilitate therapy individualisation.

**Design:** Women will be randomised to receive one of the following four treatments:  
 ♦ Whole breast RT alone using standard fractionation schedule  
 ♦ Whole breast RT alone using shorter fractionation schedule  
 ♦ Whole breast RT plus tumour bed boost using standard fractionation schedule  
 ♦ Whole breast RT plus tumour bed boost using shorter fractionation schedule

**Inclusion Criteria:**

1. Women aged  $\geq 18$  years with histologically proven pure DCIS of the breast
2. Bilateral mammograms performed within 12 months prior to randomisation
3. Treated with BCS (primary excision or re-excision) with complete microscopic excision and no direct tumour extension to any resection margin
4. Women who are at high risk of local recurrence due to age  $< 50$  years; OR age  $\geq 50$  years plus at least one of the following: symptomatic presentation; palpable tumour; multifocal disease; microscopic tumour size  $\geq 1.5$  cm; intermediate/high nuclear grade; central necrosis; comedo histology; and radial surgical margin  $< 10$  mm
5. Assessed to be suitable for BCT including WBRT
6. Maximum breast width  $< 25$  cm
7. ECOG performance status 0, 1 or 2 and patient's life expectancy  $> 5$  years
8. No previous DCIS or invasive cancer of the contralateral breast
9. No serious non-malignant disease that precludes definitive surgical or radiation treatment
10. Written informed consent

**Exclusion Criteria:**

1. Multicentric disease or extensive microcalcifications that could not be completely excised by breast conserving surgery with radial margin involvement\*. \*Patients with involvement of the superficial and/or deep margin are eligible if surgery has removed all of the intervening breast tissue from the subcutaneous tissue to the pectoralis fascia.
2. Maximum width of breast tissue  $> 25$  cm.
3. Pathologically node-positive on examination using H & E staining.
4. Locally recurrent breast cancer.
5. Previous DCIS or invasive cancer of the contralateral breast.
6. Other concurrent or previous malignancies *except*:  
 ♦ Non-melanomatous skin cancer;  
 ♦ Carcinoma in situ of the cervix or endometrium; *and*  
 ♦ Invasive carcinoma of the cervix, endometrium, colon, thyroid and melanoma treated five years prior to study admission without disease recurrence.
7. Serious non-malignant disease that precludes definitive surgical or radiation treatment (e.g. scleroderma, systemic lupus erythematosus, cardiovascular/pulmonary/renal disease).
8. ECOG performance status  $\geq 3$ .

9. Women who are pregnant or lactating.

**Early Closure Criteria:**

Consideration will be given to stopping the trial early if either of the following occurs:

- a) Accrual is inadequate (less than 70 patients per year once most centres are open for accrual)
- b) Unacceptable radiotherapy acute toxicity
- c) A clearly more effective treatment becomes available

**Pre-treatment Evaluation and Investigations:**

	<b>Evaluation</b>	<b>Prior to randomisation</b>
Clinical assessment	History of <ul style="list-style-type: none"> <li>• Connective tissue disorder</li> <li>• Rheumatoid arthritis</li> <li>• Cardiovascular disease</li> <li>• Diabetes</li> <li>• Tobacco use</li> <li>• Other malignancies</li> </ul> ECOG performance status Bra size Physical examination	< 3 months prior
Radiology	Bilateral mammograms	< 12 months prior
Pathology	Formal reporting of definitive surgical specimen at treating centre Optional blood collection	Prior to randomisation
Toxicity	Baseline assessment <ul style="list-style-type: none"> <li>• CTCAE v3.0</li> </ul>	< 2 weeks prior
Cosmetic outcome	Baseline assessment <ul style="list-style-type: none"> <li>• EORTC Cosmetic Rating System</li> <li>• Quantitative assessment of breast cosmesis</li> </ul>	< 2 weeks prior
Quality of life	Baseline assessment <ul style="list-style-type: none"> <li>• HADS</li> <li>• Distress thermometer</li> <li>• EORTC QLQ-C30</li> <li>• Body Image Scale</li> <li>• BCTOS</li> <li>• Cancer Worry Scale</li> </ul>	< 2 weeks prior

**Trial Contact Details: ~**

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**Co-ordinating Centre**

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Trial Centre  
Peter MacCallum Cancer Centre  
St Andrews Place, East Melbourne VIC 3002

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**Trial Chairperson**

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Division of Radiation Oncology  
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**Trial Management Committee**

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A/Prof Geoff Delaney, Liverpool Hospital  
A/Prof Peter Graham, St George Hospital  
Dr Jennifer Harvey, Princess Alexandra Hospital  
A/Prof David Christie, East Coast Cancer Centre  
Dr Scott Carruthers, Royal Adelaide Hospital  
Dr David Bryam, Launceston General Hospital  
Dr David Blakey, Peter MacCallum Cancer Centre  
Prof David Joseph, Sir Charles Gairdner Hospital  
Dr Margaret Latham, Royal Perth Hospital  
Dr Rosemary Balleine  
A/Prof Ian Campbell  
A/Prof Michael McKay  
A/Prof Christine Clark  
Dr Penelope Schofield  
A/Prof Michael Bilous  
Dr Elizabeth Salisbury  
Dr Nirmala Pathmanathan  
Mr David Willis, Peter MacCallum Cancer Centre

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**Data Manager (For patient registration or randomisation, protocol and forms)**

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**Statistician**

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## Resources for Further Information

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**International Conference on Harmonisation - Good Clinical Practice (ICH GCP)**

<http://www.ich.org/LOB/media/MEDIA482.pdf>

**Therapeutic Goods Administration (TGA)**

[www.tga.gov.au](http://www.tga.gov.au)

**Australian Clinical Trials Handbook**

<http://www.tga.gov.au/ct/cthandbook.htm>

**National Statement on Ethics**

[www.nhmrc.gov.au/publications/\\_files/e35.pdf](http://www.nhmrc.gov.au/publications/_files/e35.pdf)

**Australian Clinical Trials Registry (ACTR)**

[www.actr.org.au/](http://www.actr.org.au/)

**Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)**

[www.arpansa.gov.au/](http://www.arpansa.gov.au/)

**Royal Australian and New Zealand College of Radiologists (RANZCR)**

[www.ranzcr.edu.au/](http://www.ranzcr.edu.au/)

**NZ Medsafe**

[www.medsafe.govt.nz](http://www.medsafe.govt.nz)

**Health Research Council of New Zealand**

[www.hrc.govt.nz](http://www.hrc.govt.nz)

**Cancer Trials New Zealand (CTNZ)**

[www.ctnz.auckland.ac.nz/](http://www.ctnz.auckland.ac.nz/)

**Cancer Therapy Evaluation Program (CTEP)**

[www.ctep.cancer.gov/](http://www.ctep.cancer.gov/)

**Common Terminology Criteria for Adverse Events (CTCAE v3)**

[www.ctep.cancer.gov/forms/CTCAEv3.pdf](http://www.ctep.cancer.gov/forms/CTCAEv3.pdf)

**EORTC Quality of Life QLQ-C30**

[www.eortc.be/home/qol/ExplQLQ-C30.htm](http://www.eortc.be/home/qol/ExplQLQ-C30.htm)

**Resource Centre for Emerging Technologies (RCET)**

[www.rcetsystem.org/](http://www.rcetsystem.org/)

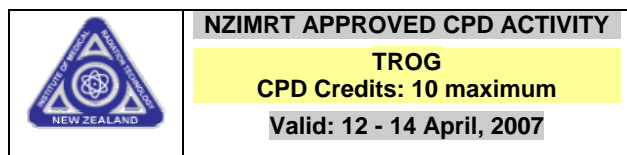
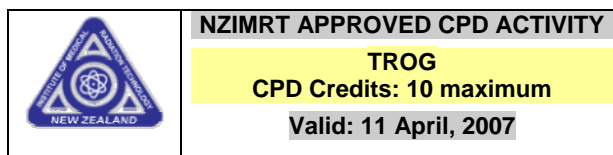
**Pam McLean Cancer Communications Centre**

<http://www.mcleancentre.org/>

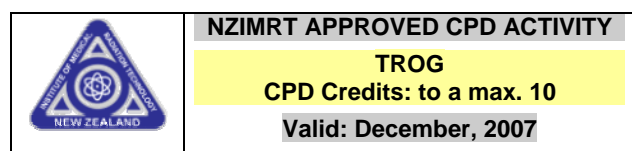
### Radiotherapy CPD Appellations

Approval has been granted by the Australian Institute of Radiography (AIR) and the New Zealand Institute of Medical Radiation Technology (NZIMRT) for CPD appellation for TROG activities relating to clinical research that provide professional development opportunities. Renewal will be sought as applicable for ongoing activities.

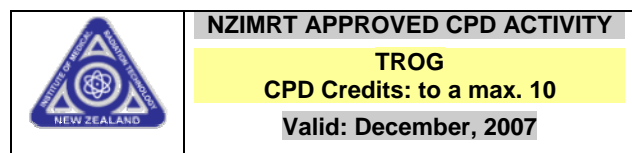
**TROG Technical Research Workshop & Annual Meeting: participation in sessions**  
(*NZIMRT: Verification of attendance by organiser required on CPD Evaluation Form*)



Site activities relating to the Level I/III dosimetric inter-centre comparison pelvic phantom project ('Elvis'): eg. preparation, planning and/or treatment



Other TROG activities: eg. collation of site radiotherapy documentation RT QA reviews.



For further information contact:  
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**NZIMRT  
CONTINUING PROFESSIONAL DEVELOPMENT PROGRAMME**

<b>Name:</b>		<b>C P D  E V A L U A T I O N  F O R M</b>
<b>Event:</b>	<b>Date:</b>	
<b>CPD Credits:</b>	<b>Group 1:</b>	
<b>Summary of Event:</b>		
<b>Professional Value: (What I learnt from this activity)</b>		
		<b>Study Day Workshop Seminar Lecture Conference Invited Speaker</b>