Summary for Radiation Therapists
TROG 08.03 RAVES Trial

A phase III multi-centre randomised trial comparing adjuvant radiotherapy (RT) with early salvage RT at biochemical recurrence in patients with positive margin and/or stage pT3 disease following radical prostatectomy

All protocols, guidelines and forms relevant to the technical aspects of this trial are available at our website:

www.trog-raves.org

Refer to Section 8 of the trial protocol for full details of protocol radiation therapy.

Planning Simulation

- Patient SUPINE. Immobilisation as per your departmental policy.
- Full bladder and empty rectum as per department policy for simulation and treatment.
  - If possible, rectal diameter should not exceed 5cm
- CT from the bottom of the SI joints to 2cm below the ischial tuberosities
- Recommended slice thickness: 2.5-3mm, but no more than 5mm.

IV contrast with delayed scanning (at least 10 minutes) and MRI may be employed to aid delineation of the anastomosis/penile bulb. **NB: if the bladder has been filled with contrast then a "bulk" correction, using typical values for normal tissue, should be applied.**

Contouring / Structure Definition

Structures to be contoured: please label structures as defined in **bold.**
Illustrated guidelines can be found at:

http://www.trograves.org/HTMLPages/quality_assurance.htm

- **CTV -** Surgical bed, ensure all tumour bed clips are included
- **PTV -** A uniform margin of 10mm from CTV. Ensure the PTV expansion does not encompass the full circumference of the rectal wall.
- **Rectum -** Contour external surface of the rectum as a solid organ

  - Superiorly from the recto-sigmoid junction (where the rectum turns horizontally into the sigmoid colon usually at the inferior border of the sacro-iliac joint), to at least 15mm superior to CTV.
  - Inferiorly to 15mm inferior to the inferior border of the CTV.
- **LF -** Left femur from the acetabulum to the inferior edge of the treatment field.
- **Bladder -** Whole external surface to the slice above the anastomosis.
- **Anastamosis -** A contour at the level of the anastamosis. The anastomosis can be identified on axial, coronal and sagittal reconstructions as the slice inferior to the last slice where urine is visible. If planning system does not support a structure defined on only one CT slice, ensure the anastomosis slice number is noted on the relevant form
- **AC –** Anal Canal. If delineated (not a protocol requirement)

Interpolation may be used if it is not normal clinical practice to contour on all slices.

Dosimetry

- Isocentric technique to be used
- Beam energy ≥6MV photons.
- Field arrangements use a minimum of 3 fields.
- MLC or blocks with at least 5 half-value-layers used to conform beam apertures to PTV in three-dimensions.
- Real or virtual wedges may be employed.
- Dose matrix maximum grid spacing is 2.5mm x 2.5mm or smaller for both conformal and IMRT techniques.
- All treatment fields for the appropriate technique to be delivered at each fraction

Centres wishing to use inverse planned IMRT techniques should contact the Technical Review Committee **prior to entering patients** and refer to the document '*Quality assurance and credentialing requirements for sites using inverse planned IMRT techniques'* which can be found on our website

www.trog-raves.org

Dose Specifications

- 64Gy in 32 fractions (5 fractions per week or 9 fractions per fortnight).
- **Prescribed to ICRU 50 reference point.**
  - Centre of the PTV, or intersection of the beam axes if close to the PTV centre.
  - The dose at the point should be clinically relevant and representative of the dose throughout the Planning Target Volume (PTV).
  - The point should be easy to define in a clear and unambiguous way.
  - The point should be selected where the dose can be accurately determined.
  - The point should be selected in a region where there is no steep dose gradient.

PTV:

- **The Maximum dose** (D2, dose to 2% of the PTV) shall be no more than 107% of the total dose.
- **Minimum isodose** covering the PTV (D98, dose covering 98% of the
- PTV) shall be at least 95% of the total dose.
- **Rectum:**
  - V 60Gy <40%
  - V 40Gy <60%
- **Lt Femur:**
  - V 35Gy <100%
  - V 45Gy <60%
  - V 60Gy <30%

IMRT specific:

1. For IMRT plans, the dose should be prescribed as follows:
   - The D98 (dose covering 98% of the PTV) shall be at least 95% of the total dose.
   - The mean dose to the PTV will be within -1% and +2% of the prescribed dose.
   - The maximum dose should be contained within the CTV, and must be contained within the volume bounded by the PTV.
   - The dose outside the PTV will be minimised.
   - It is recognised that treatment plans created with an IMRT technique demand extra precision in treatment delivery due to the presence of high dose gradients. Therefore planning techniques shall be robust in the presence of inter (and intra-) fraction organ motion.

Treatment Techniques / Options

If the DVH constraints cannot be met (particularly those for the rectum) the following options are available. Consult with treating RO as to the preferred priority of options for individual cases.

***NOTE that for IMRT techniques a 10mm posterior expansion is mandatory.**

- **Option 1 :**
  - **Single Phase**: Treat the PTV to 64Gy with a 3D expansion around the CTV of 1cm with the posterior PTV margin expansion reduced to 5mm for the entire treatment.

- **Option 2 :**
  - **IMRT**: Treat the PTV to 64Gy with a uniform 3D expansion around the CTV of 1cm. Utilise forward planning optimisation parameters to limit dose to the rectum. Please note sites wishing to use IMRT must have been credentialed prior to using this technique as an option.

Any deviations from the recommended typical single phase approach require the RO and RT to include comments and / or documentation on the form "TROG 08.03 QA2 Checklist RT Planning**"**

Treatment Verification

- All beam parameters (field size and shielding) are to be visually checked and verified with the planning data on at least one occasion during the first week of treatment.
- Patient position must be radiographically verified at least once in the **first week of treatment and weekly thereafter**.
- Centres using IMRT techniques are expected to demonstrate that an imaging policy is in place, which is appropriate for the margins specified in this protocol. Sites will be required to describe their imaging protocol in detail on the Facility Questionnaire.

QA Program

Site Information & Dry Run

Prior to entering patients into the trial, centres must complete a **dry run planning exercise and complete** forms **'TROG 08.03 Facility Questionnaire'** and **'TROG 08.03 Dry Run Data Submission'.** Forms and instructions are available at:
http://www.trograves.org/HTMLPages/quality_assurance.htm

- **Please Note**: Sites must undergo independent IMRT credentialing if they wish to treat with an IMRT technique. Please refer to the **Quality Assurance and credentialing requirements for sites using IMRT.**
http://www.trog-raves.org/Documents/QA%20and%20credentialing%20IMRT%20RAVES_Version%202_280110.pdf

Radiation Therapy Technical Review

All patients will undergo rapid review. Submit treatment plan **at least 1 week prior to treatment**. Feedback will be provided in a timely manner. If any major protocol deviations are identified, timely modification of the treatment plan will be discussed.

Data submission

- Prior to exporting the plan, ensure dosimetry meets the specifications above.
- Ensure that **only** the relevant volumes and structures that have been used for the plan are included in the data upload as below:

CTV	Rectum	Bladder
PTV	LF	Anastamosis
AC (*if contoured*)		

(Please do not send other contours as they make it difficult for the reviewing team)

- Data file/s exported from the treatment planning system in **DICOM RT** or **RTOG** format, including planned dose, treatment fields, DVH data, reference images and regions of interest.
- Screen dumps showing all 3 orthogonal viewing planes at the intersection of the PTV – ICRU reference point and demonstrating dose to the PTV at the ICRU reference point, as well as a screen dump of the DVH showing CTV, PTV, (seminal vesicles if delineated as a separate structure), rectum, left femur and bladder.

- Isodose lines on screen dumps displayed as: max, 100%, 95%, 90%, 70%, 50%, 20%.
- Please ensure that **all relevant forms** are completed and included with the export of data files.
- It is imperative that the submitting RO provide pathology details to ensure a full and timely review of your case.
- Additional data is required for IMRT submissions. Therefore it is important that you refer to the Quality assurance and credentialing requirements for sites using inverse planned IMRT techniques

All data submission for the Dry Run exercise and the Trial is to be electronic through the TROG central office CQMS Database. Specific instructions for saving the completed exercise in electronic format and uploading data via CQMS may be found on the TROG web site: www.trog.com.au in the members section under 'Quality Assurance Programme' or requested by emailing qa@trog.com.au

It is important that once data submission is complete that you notify the TROG office – email:

Melissa.Crain@mater.health.nsw.gov.au **or**
Claudia.Koller@mater.health.nsw.gov.au

- Specific instructions for exporting treatment planning data from each of the commercial treatment planning systems are available through a link on our website**:**

  http://www.trog.com.au/Default.aspx?tabid=297

For any queries about the electronic submission of the treatment plan for review please email:

RAVES.Therapist@petermac.org

All protocols, guidelines and forms relevant to the technical aspects of this trial are available at our website:

www.trog-raves.org

RT Contacts:

Please direct any queries regarding to one of the QA Review team members below at

- **Andrea Paneghel** – Radiation Therapist
Andrea.Paneghel@petermac.org

- **Luke Williams -** Radiation Therapist
Luke.Williams@petermac.org

- **David Willis -** Radiation Therapist
David.Willis@petermac.org

- **Cate Sproston -** Radiation Therapist
Cathryn.Sproston@petermac.org

or

(RAVES.Therapist@petermac.org)