TRANS-TASMAN RADIATION ONCOLOGY GROUP INC
(ACN: 132 672 292)

RAVES—Radiotherapy **A**djuvant **V**ersus **E**arly **S**alvage

TROG 08.03: A Phase III Multi-Centre Randomised Trial Comparing Adjuvant Radiotherapy (RT) with Surveillance and Early Salvage RT in Patients with Positive Margins or Extraprostatic Disease Following Radical Prostatectomy

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Case Report Forms

Version 4.1: 25 February 2016

Coordinating Trial Centre

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Instructions

Completion of Case Report Forms

INSTRUCTIONS FOR COMPLETING CASE REPORT FORMS (CRF)

Write clearly using a black pen.

1. **Errors**: **Do not** use correction fluid or other masking agents. Instead draw a single line through the error and write your initials and the date next to the correction.

2. **Missing Data:** Please complete **all** items on case report forms. Use the following codes for missing data:

ND = not done

NA = not applicable

3. **Tick Boxes:** Please indicate choice of tick box as follows: ☐ → ☑

4. **Patient Initials:** Whenever possible, please record three-character patient initials at randomisation. If the patient does not have a middle initial, utilise the format X-X, putting a dash in place of the middle initial.

5. **Patient ID numbers:** The RAVES randomisation system generates patient ID numbers that vary from 4 to 7 digits. The last three digits correspond to the the squesnce of the patient at your site. The first 1-4 digits correspond to your site code, and will be the same for all your patients. If your patient ID number is less than 7 digits, please put a dash through the extra boxes.

Examples:

1	2	3	4	0	0	1

First patient recruited at site with 4 digit code (1234)

-	-	-	2	0	0	1

First patient recruited at site with 1 digit code (2)

INSTRUCTIONS FOR SUBMITTING COMPLETED CASE REPORT FORMS

The originals of all completed case report forms and quality of life (QOL) questionnaires must be sent to the Coordinating Trial Centre at the address below:

RAVES Clinical Trial Centre Manager
Adult Oncology Research Centre
Auckland Hospital
PO Box 92024
Auckland 1142
New Zealand

The original signed Consent Form and a photocopy of all completed case report forms and patient questionnaires should be retained by the treating institution.

Index of Forms

To Randomise a Patient

1. Before completing any pre-randomisation forms, check that the patient consent form is signed and dated by the patient and investigator.
2. Check that the eligibility criteria have been satisfied.
3. Complete the Pre-Randomisation Patient Assessment **[A1]**, Pre-Randomisation Patient Questionnaires **[A2]**, and the Randomisation form **[A3]**.
4. Log onto randomisation website **https://www.ctru.auckland.ac.nz/raves** and follow instructions.
5. Eligible patients will be randomised to either Arm 1 (adjuvant radiotherapy) or Arm 2 (salvage radiotherapy).
6. Print out or save the screen that displays the randomisation result for your files as the system will not generate a separate confirmation page.
7. Complete the randomisation details on page 2 of form **[A3**].
8. Enter the randomisation number at the top of each page of forms **[A1 - A3]**.
9. Make copies of these forms for your site, and mail the original pages **[A1 - A3]** to the Coordinating Trial Centre.

TROG 08.03
Radiotherapy
Adjuvant **V**ersus
Early **S**alvage
(RAVES study)

Schedule of Assessments: Arm 1 (ART)

Arm 1 (Adjuvant Radiotherapy- ART)

TIME POINT			ASSESSMENT	Pre-Random-isation	Day 1 RT	End RT*	6 weeks post-RT	6 month-ly to end of trial relative to random-isation	Annually to end of trial relative to random-isation
RANDOM-ISATION			Randomisation data and stratification factors	[A3]					
			Medical history physical exam	[A1]					
			ECOG performance status	[A3]					
			Co-morbidity index	[A1]					
RANDOMISATION	**RADIOTHERAPY**	**ANNUAL FOLLOW UP**	PSA	[A3]			[C3]	[B2]	[B2]
			Clinic visit	[A1]	[C1]	[C2]	[C3]	[B2]	[C4]
			Adverse events	[A1]	[C1]	[C2]	[C3]		[C4]
			EORTC Quality of Life	[A2]	[C1Q]	[C2Q]	[C3Q]*		[C4Q]*
			HADS anxiety/ depression	[A2]	[C1Q]	[C2Q]	[C3Q]*		[C4Q]*
			SHIM: Sexual Health Inventory for Men	[A2]					[C4Q]*
			Health Resource Use Questionnaire						[C4Q]
ONCE ONLY FORMS			Radiotherapy Treatment Summary	To be completed after treatment. [T]					
			Central pathology review	Post-Randomisation [P]					
			Optional: RAVES Genetic Study (sputum collection & questionnaire)	Biological Sub-studies [D]: To document patient decision regarding biological sub-studies (recommended at 6 months post-randomisation)					
			Optional: RAVES Tissue Banking Study (donation of tumour block)	Biological Sub-studies [D]: To document patient decision regarding biological sub-studies (recommended at 6 months post-randomisation)					

* To be done prior to PSA result being revealed to patient.

Schedule of Assessments: Arm 2 (SRT)

Arm 2 (Salvage Radiotherapy- SRT)

TIME POINT	ASSESSMENT	Pre-Random-isation	3 monthly to end of trial relative to random-isation	Annually to end of trial relative to random-isation	IF SRT REQUIRED**		
					Day 1 RT	End RT	6 weeks post-RT
RANDOM-ISATION	Randomisation data and stratification factors	[A3]					
	Medical history physical exam	[A1]					
	ECOG performance status	[A3]					
	Co-morbidity index	[A1]					
RANDOMISATION / RADIOTHERAPY / ANNUAL FOLLOW UP	PSA	[A3]	[B1]	[B1]	[B1]		[C3]
	Clinic visit	[A1]	[B1]	[C4]	[C1]	[C2]	[C3]
	Adverse events	[A1]		[C4]	[C1]	[C2]	[C3]
	EORTC Quality of Life	[A2]		[C4Q]*	[C1Q]	[C2Q]	[C3Q]*
	HADS anxiety/ depression	[A2]		[C4Q]*	[C1Q]	[C2Q]	[C3Q]*
	SHIM: Sexual Health Inventory for Men	[A2]		[C4Q]*			
	Health Resource Use Questionnaire			[C4Q]			
ONCE ONLY	Radiotherapy Treatment Summary	To be completed after treatment. [T]					
	Central pathology review	Post-Randomisation [P]					
	Optional: RAVES Genetic Study (sputum collection & questionnaire)	Biological Sub-studies [D]: To document patient decision regarding biological sub-studies (recommended at 6 months post-randomisation)					
	Optional: RAVES Tissue Banking Study (donation of tumour block)	Biological Sub-studies [D]: To document patient decision regarding biological sub-studies (recommended at 6 months post-randomisation)					

* To be done prior to PSA result being revealed to patient.

** If SRT is required, the patient crosses over to the Arm 1 schedule and forms.

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Pre-Randomisation Patient Assessment [A1] (p. 1 of 4)**

☐ Yes ☐ No Has the patient consented to the trial?

The following assessments are required **prior to randomisation** and **after consent is given**:

- Patient information (**[A1]** page 1)
- Co-morbidities index (**[A1]** page 2)
- Adverse Events (**[A1]** pages 3 and 4)
- Patient questionnaires: EORTC QoL, HADS, SHIM (form **[A2]** pages 1-7)

Patient information

☐☐☐☐☐☐ Clinic visit date (ddmmyy)

☐☐☐.☐ Patient's weight (kg)

☐☐☐.☐ Patient's height (cm)

Ethnicity

☐ Please ask the patient to select the ethnicity which best describes them from the list below. Enter the corresponding number in the box.

1.	Caucasian		
2.	Asian (specify): _____	7.	Australian Aborigine
		8.	Torres Strait Islander
3.	Maori	9.	Other (specify): _____
4.	Samoan		
5.	Tongan	10.	Multiple (specify): _____
6.	Other Pacific Island (specify):		

Trial Schedule Reminder

If your patient is randomised to:		The next clinic visit is due:	**AND**	The next PSA is due:
• Adjuvant RT (Arm 1)	→	Day 1 of RT		6 weeks post-RT
• Salvage RT (Arm 2)	→	6 months from randomisation		3 months from randomisation

For all patients: Central pathology review is required. Refer to the Protocol and CRF Form P for details.

Co-morbidity Index

Does the patient currently have, or have a history of, any of the following conditions:

	Tick if YES	Tick if NO
Myocardial infarction		
Heart failure		
Angina, intermittent claudication, or abdominal aortic aneurysm		
Other malignancies (except basal skin carcinoma)		
Peptic ulcer disease (medically or surgically treated, but not reflux)		
Cerebrovascular accident (stroke) or Transient Ischaemic Attacks		
Diabetes mellitus (medically treated)		
Chronic obstructive pulmonary diseases		
Dementia		
Connective tissue/autoimmune diseases (for example: Sarcoid, systemic lupus erythematosus, Wegener's granulomatosis, rheumatoid)		
Liver disease (any LFT > 1.5 times normal)		
Kidney diseases (renal function > 1.5 times normal)		
Bowel diseases: Crohn's disease, ulcerative colitis		
Hypertension (or on anti-hypertensive therapy)		
Hypercholesterolaemia (or using cholesterol lowering agents)		

Number of other current and past medical diagnoses requiring regular monitoring or medication: ☐

Number of recommended or prescribed medications taken regularly *(excluding complementary medicines)* : ☐

Please enter the grade of current symptoms in the box. Enter **ND** if *not done*.
All AEs are scored using CTCAE v.3.0.

Adverse Events : Genitourinary

Cystitis

0 = None
1 = Asymptomatic
2 = Frequency with dysuria; macroscopic haematuria
3 = Transfusion; IV pain medications; bladder irrigation indicated
4 = Catastrophic bleeding; major non-elective Intervention indicated

☐ Tick if *not assessable*
Reason: _____

Urethral Stricture/ Stenosis

0 = None
1 = Asymptomatic, radiographic or endoscopic findings only
2 = Symptomatic but no hydronephrosis, sepsis, or renal dysfunction; dilation or endoscopic repair or stent placement indicated
3 = Symptomatic and altered organ function (e.g., sepsis, hydronephrosis, or renal dysfunction); operative intervention indicated
4 = Life-threatening consequences; organ failure or operative intervention requiring organ resection indicated

☐ Tick if *not assessable*
Reason: _____

Urinary Incontinence

0 = None
1 = Occasional (e.g., with coughing, sneezing, etc., pads not indicated)
2 = Spontaneous, pads indicated
3 = Interfering with ADL; intervention indicated (e.g., clamp, collagen injections)
4 = Operative intervention indicated (e.g., cystectomy or permanent urinary diversion)

☐ Tick if *not assessable*
Reason: _____

Urinary Retention

0 = None
1 = Hesitancy or dribbling, no significant residual urine; retention Occurring during the immediate postoperative period
2 = Hesitancy requiring medication; or operative bladder atony requiring indwelling catheter beyond immediate postoperative period but for less than 6 weeks
3 = More than daily catheterization indicated; urological intervention indicated (e.g., TURP, suprapubic tube, urethrotomy)
4 = Life-threatening consequences; organ failure (e.g., bladder rupture); operative intervention requiring organ resection indicated

☐ Tick if *not assessable*
Reason: _____

Urinary Frequency/ Urgency

0 = None
1 = Increase in frequency or nocturia up to 2 x normal, enuresis
2 = Increase > 2 x normal, but less than hourly
3 = ≥ once per hour; urgency or catheter Indicated

☐ Tick if *not assessable*
Reason: _____

Haemorrhage, GU

0 = None
1 = Minimal or microscopic bleeding, intervention not indicated
2 = Gross bleeding, medical intervention or urinary tract irrigation indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (ie haemostasis of bleeding site)
4 = Life threatening consequences; major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

Continued on next page

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Pre-Randomisation Patient Assessment [A1] (p. 4 of 4)**

Please enter the grade of current syptoms in the box. Enter **ND** if *not done* and tick **NA** if *not assessable.*
All AEs are scored using CTCAE v.3.0.

Adverse Events : Gastrointestinal

☐ **Diarrhoea**

0 = None
1 = Increase of < 4 stools per day over baseline; mild increase in ostomy output compared to baseline
2 = Increase of 4-6 stools per day over baseline; IV fluids indicated < 24 hrs; moderate increase in ostomy output compared to baseline; not interfering with ADL
3 = Increase of ≥ 7 stools per day over baseline; incontinence; IV fluids ≥ 24 hrs; hospitalization; severe increase in ostomy output compared to baseline; interfering with ADL
4 = Life-threatening consequences (e.g., hemodynamic collapse)

☐ Tick if *not assessable*
Reason: _____

☐ **Proctitis**

0 = None
1 = Rectal discomfort, intervention not indicated
2 = Symptoms not interfering with ADL; medical intervention indicated
3 = Stool incontinence or other symptoms interfering with ADL; operative intervention indicated
4 = Life-threatening consequences (e.g. perforation)

☐ Tick if *not assessable*
Reason: _____

Adverse Events : Sexual Function

☐ **Erectile Dysfunction**

0 = None
1 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not indicated
2 = Decrease in erectile function (frequency/ rigidity of erections), erectile aids indicated
3 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not helpful; penile prosthesis indicated

☐ Tick if *not assessable*
Reason: _____

☐ **Haemorrhage, GI (rectal)**

0 = None
1 = Mild, intervention (other than iron supplements) not indicated
2 = Symptomatic and medical intervention or minor cauterization indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)
4 = Life-threatening consesequences, major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

☐ **Incontinence (anal)**

0 = None
1 = Occasional use of pads
2 = Daily use of pads
3 = Interfering with ADL; operative intervention indicated
4 = Permanent bowel diversion indicated

☐ Tick if *not assessable*
Reason: _____

Adverse Events : Others

☐ Tick if *the patient did not experience any other AEs*

☐ **Specify*:**_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

☐ **Specify*:**_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

* Refer to CTCAE v 3.0 and use exact term or specify other (http://ctep.cancer.gov/reporting/ctc.html). **If more than two Other Adverse Events are present:**

☐ Tick and record additional events on form [**AE]**.

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐
D D M M Y Y

EORTC Quality of Life Questionnaire - C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Today's date (dd/mm/yy):

Your birthdate

Approved for use by the EORTC 2008.

		Not at all	A little	Quite a bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself, or using the toilet?	1	2	3	4

During the past week:		**Not at all**	**A little**	**Quite a bit**	**Very Much**
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4
16.	Have you been constipated?	1	2	3	4

EORTC Quality of Life Questionnaire - C30 (version 3, continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
17. Have you had diarrhoea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment Caused you financial difficulties?	1	2	3	4

For the following questions, please circle the number between 1 and 7 that best applies to you.

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

EORTC Quality of Life Questionnaire - PR25

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you. The information that you provide will remain strictly confidential.

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
31. Have you had to urinate frequently **during the day**?	1	2	3	4
32. Have you had to urinate frequently **at night**?	1	2	3	4
33. When you felt the urge to pass urine, did you have to hurry to get to the toilet?	1	2	3	4
34. Was it difficult for you to get enough sleep, because you needed to get up frequently at night to urinate?	1	2	3	4
35. Have you had difficulty going out of the house because you needed to be close to a toilet?	1	2	3	4
36. Have you had any unintentional release (leakage) of urine?	1	2	3	4
37. Did you have pain when you urinated?	1	2	3	4
38. Answer this question only if you wear incontinence aid. Has wearing an incontinence aid been a problem for you?	1	2	3	4
39. Have your daily activities been limited by your urinary problems?	1	2	3	4
40. Have your daily activities been limited by your bowel problems?	1	2	3	4
41. Have you had any unintentional release (leakage) of stools?	1	2	3	4
42. Have you had blood in your stools?	1	2	3	4
43. Did you have a bloated feeling in your abdomen?	1	2	3	4
44. Did you have hot flushes?	1	2	3	4
45. Have you had sore or enlarged nipples or breasts?	1	2	3	4
46. Have you had swelling in your legs or ankles?	1	2	3	4

EORTC Quality of Life Questionnaire - PR25 (continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
47. Has weight **loss** been a problem for you?	1	2	3	4
48. Has weight **gain** been a problem for you?	1	2	3	4
49. Have you felt less masculine as a result of your illness or treatment?	1	2	3	4
50. To what extent were you interested in sex?	1	2	3	4
51. To what extent were you sexually active (with or without intercourse)?	1	2	3	4

PLEASE ANSWER THE NEXT FOUR QUESTIONS ONLY IF YOU HAVE BEEN SEXUALLY ACTIVE OVER THE LAST 4 WEEKS.

52. To what extent was sex enjoyable for you?	1	2	3	4
53. Did you have difficulty getting or maintaining an erection?	1	2	3	4
54. Did you have ejaculation problems (eg dry ejaculation)?	1	2	3	4
55. Have you felt uncomfortable about being sexually intimate?	1	2	3	4

SEXUAL HEALTH INVENTORY FOR MEN (SHIM)

Today's date: (dd/mm/yy)

PATIENT INSTRUCTIONS

Sexual health is an important part of an individual's overall physical and emotional well-being. Erectile dysfunction is one type of very common sexual complaint. There are many different treatment options for erectile dysfunction. This questionnaire is designed to help you and your physician identify if you may be experiencing erectile dysfunction and to potentially discuss treatment options.

Each question has several responses from which you are asked to choose the one that best describes your own situation. Please be sure that you select at least one but only one response by circling the number that best fits your answer.

Over the past six months:

1. How do you rate your confidence that you could get and keep an erection?		VERY LOW	LOW	MODERATE	HIGH	VERY HIGH
		1	2	3	4	5
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	NO SEXUAL ACTIVITY	ALMOST NEVER/ NEVER	A FEW TIMES/ MUCH LESS THAN HALF THE TIME	SOMETIMES (ABOUT HALF THE TIME)	MOST TIMES (MUCH MORE THAN HALF THE TIME)	ALMOST ALWAYS/ ALWAYS
	0	1	2	3	4	5
3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	DID NOT ATTEMPT INTER-COURSE	ALMOST NEVER/ NEVER	A FEW TIMES (MUCH LESS THAN HALF THE TIME)	SOMETIMES (ABOUT HALF THE TIME)	MOST TIMES (MUCH MORE THAN HALF THE TIME)	ALMOST ALWAYS/ ALWAYS
	0	1	2	3	4	5
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	DID NOT ATTEMPT INTER-COURSE	EXTREMELY DIFFICULT	VERY DIFFICULT	DIFFICULT	SLIGHTLY DIFFICULT	NOT DIFFICULT
	0	1	2	3	4	5
5. When you attempted sexual intercourse, how often was it satisfactory for you?	DID NOT ATTEMPT INTER-COURSE	ALMOST NEVER/ NEVER	A FEW TIMES (MUCH LESS THAN HALF THE TIME)	SOMETIMES (ABOUT HALF THE TIME)	MOST TIMES (MUCH MORE THAN HALF THE TIME)	ALMOST ALWAYS/ ALWAYS
	0	1	2	3	4	5

Hospital Anxiety and Depression Scale (HADS)

Today's **date (ddmmyy)**

Clinicians are aware that emotions play an important part in most illnesses. This questionnaire is designed to help the research team know how you and other patients feel. Read each statement below and:

- **Tick the box next to the response** which comes closest to how you have been feeling **in the past week.**
- Please note that your doctor will not routinely be provided with your completed questionnaire. If you have any concerns you would like to address, please tell your doctor.

Don't take too long over your replies. Your immediate reaction to each item will probably be more accurate

During the past week:

1. I feel tense or "wound up"

- ☐ Most of the time
- ☐ A lot of the time
- ☐ From time to time, occasionally
- ☐ Not at all

2. I still enjoy the things I used to enjoy

- ☐ Definitely as much
- ☐ Not quite so much
- ☐ Only a little
- ☐ Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen

- ☐ Very definitely and quite badly
- ☐ Yes, but not too badly
- ☐ A little, but it doesn't worry me
- ☐ Not at all

4. I can laugh and see the funny side of things

- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much now
- ☐ Not at all

5. I feel as if I am slowed down

- ☐ Nearly all the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

6. I get a sort of frightened feeling like "butterflies" in the stomach

- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often
- ☐ Very often

7. I have lost interest in my appearance

- ☐ Definitely
- ☐ I don't take as much care as I should
- ☐ I may not take quite as much care
- ☐ I take just as much care as ever

8. I feel restless as if I have to be on the move

- ☐ Very much indeed
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all

Continued on the next page

Hospital Anxiety and Depression Scale (HADS)

Continued from previous page

During the past week:

9. Worrying thoughts go through my mind

- ☐ A great deal of the time
- ☐ A lot of the time
- ☐ Not too often
- ☐ Very little

10. I feel cheerful

- ☐ Never
- ☐ Not often
- ☐ Sometimes
- ☐ Most of the time

11. I can sit at ease and feel relaxed

- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

12. I look forward with enjoyment to things

- ☐ As much as I ever did
- ☐ Rather less than I used to
- ☐ Definitely less than I used to
- ☐ Hardly at all

13. I get sudden feelings of panic

- ☐ Very often indeed
- ☐ Quite often
- ☐ Not very often
- ☐ Not at all

14. I can enjoy a good book or radio or television programme

- ☐ Often
- ☐ Sometimes
- ☐ Not often
- ☐ Very seldom

Now check that you have answered all 14 questions

Thank you

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Randomisation Form [A3] (p. 1 of 2)**

INCLUSION CRITERIA (all answers must be **YES** for the patient to be eligible)

		YES	NO
1.	Prior Radical Prostatectomy (RP) for adenocarcinoma of the prostate.	☐	☐
2.	Capable of starting RT within 6 months of RP: ☐☐☐☐☐☐ **Date of RP** (dd/mm/yy)	☐	☐
3.	Histological confirmation of adenocarcinoma of the prostate with the Gleason score reported.	☐	☐
4.	Patients **must have at least one** of the following risk factors: (tick all that apply) ☐ Positive margins ☐ Extraprostatic extension without seminal vesicle involvement (pT3a) ☐ Extraprostatic extension with seminal vesicle involvement (pT3b)	☐	☐
5.	ECOG performance status of either 0 or 1: (please tick box below) ☐ 0 = fully active, able to carry on all pre-disease performance without restriction ☐ 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, eg, light house work, office work	☐	☐
6.	Most recent PSA ≤ 0.10 ng/ml following RP and prior to randomisation ☐.☐☐ **Post-operative** PSA (ng/mL)***** ***** The "<" symbol cannot be entered on the electronic randomisation system. If relevant, please enter it on this form.	☐	☐
7.	Patient able to adhere to the specified follow-up schedule and complete the Quality of Life and anxiety/depression self-assessments.	☐	☐
8.	Written informed consent obtained prior to pre-randomisation evaluations: ☐☐☐☐☐☐ **Date of consent** (dd/mm/yy)	☐	☐
9.	Completion of all pre-randomisation evaluations: (tick if completed) ☐ Pre-randomisation patient assessment (**[A1]** page 1) ☐ Pre-randomisation co-morbidities (**[A1]** page 2) ☐ Pre-randomisation adverse events (**[A1]** pages 3 & 4) ☐ Pre-randomisation patient questionnaires (**[A2]** pages 1-7)	☐	☐

Continue on the next page

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Randomisation Form [A3] (p. 2 of 2)**

EXCLUSION CRITERIA (all answers must be **NO** for the patient to be eligible)

		YES	NO
1.	Previous pelvic RT	☐	☐
2.	Androgen deprivation prior to or following RP	☐	☐
3.	Evidence of nodal or distant metastases	☐	☐
4.	Co-morbidities that would interfere with the completion of treatment and/or 5 years of follow-up	☐	☐
5.	Concurrent cytotoxic medication	☐	☐
6.	Hip prosthesis	☐	☐

STRATIFICATION FACTORS:

		YES	NO
1.	RT Institution: _____		
2.	Surgical margins positive	☐	☐
3.	Seminal vesicle involvement (pT3b)	☐	☐
4.	☐☐ Gleason score		
5.	☐☐☐.☐ ng/mL **Pre-operative** PSA (most recent)		

Investigator* (print)_____

(signed)_____ Date (dd/mm/yy) ☐☐☐☐☐☐

* The Investigator should be the clinician responsible for patient's treatment. If not, please record the name of the treating Investigator: _____

To randomise this patient, please log on to the randomisation website at:
https://www.ctru.auckland.ac.nz/raves
Complete the on-line form and record the results below.

RANDOMISATION ALLOCATION

☐☐☐☐☐☐ **Randomisation date (ddmmyy)**

☐☐☐☐ – ☐☐☐ **Registration number assigned**
(enter on top of forms **[A1]**, **[A2]** & **[A3])**

☐ **Arm 1 = Adjuvant RT commenced within 4 months of RP (standard)**

☐ **Arm 2 = Active surveillance with early salvage RT following a rising PSA (experimental)**

Name of person randomising: _____

Signed: _____ Date (ddmmyy) ☐☐☐☐☐☐

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**PSA Pre-Salvage RT Arm 2 [B1] (p. 1 of 1)**

1. Time from Randomisation

- Complete form B1 for each **3 monthly** PSA result during years 0-5, and each **6 monthly** PSA result from year 6 onwards. Clinic visits and PSA tests are due +/- 28 days from the target date.

☐☐ Years ☐☐ Months (consult the Schedule of Assessments for this patient)

2. Clinic Visit

- Clinic visits are required **6 monthly from randomisation** for the first 5 years, and **annually thereafter.**

☐ Please tick box if this is a time point when a clinic visit is not required and go to section 3.

- **Annually** from randomisation:

☐☐☐☐☐☐ **Clinic visit date** (dd/mm/yy)

☐ Please tick box if the required 6 monthly clinic visit was not done.

Reason visit not done or done out of time frame: _____

3. PSA

☐☐☐☐☐☐ **PSA date** (dd/mm/yy) ☐ Please tick box if the PSA test was not done

☐☐☐.☐☐ **PSA level** (ng/mL)

Reason PSA was not done or done out of time frame: _____

4. Salvage Radiotherapy Criteria (Rising PSA)

☐ Yes ☐ No Is the PSA $\geq$ 0.20 ng/ml?

☐ Yes ☐ No ☐ N/A **If yes**, is it rising when compared with the previous measurement?

If you answered **yes** to both questions, then **SRT is required**.
If SRT is required, please:

- Fax or email Form B3 to Coordinating Trial Centre (see instructions on [B3])
- Attach the de-identified PSA results that trigger SRT to form B3.
- RT must start ***no later than 4 months after the first PSA result $\geq$ 0.20 ng/mL***
- Please refer to RT QA guidelines for specific planning and treatment data requirements
- The patient crosses over to the Arm 1 schedule and forms as per table on CRF page 4.

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐ (D D M M Y Y)

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**PSA Post-RT Arms 1 & 2 [B2] (p. 1 of 1)**

1. Time from Randomisation

- Complete form B2 for each **6 monthly PSA test, due relative to randomisation.** Clinic visits and PSA tests are due +/- 28 days from the target date.

☐☐ **Years** ☐☐ **Months** (consult the Schedule of Assessments for this patient)

2. Clinic Visit

- Clinic visits are required **6 monthly from randomisation** for the first 5 years, and **annually thereafter.**

- Please complete form **[C4]** for **annual** clinic visits.

☐ Please tick box if the required 6 monthly clinic visit was not done.

☐☐☐☐☐☐ **Clinic visit date** (dd/mm/yy)

Reason visit not done or done out of time frame: _____

3. PSA

☐☐☐☐☐☐ **PSA date** (dd/mm/yy) ☐ Please tick box if the PSA test was not done

☐☐☐.☐☐ **PSA level** (ng/mL)

Reason PSA was not done or done out of time frame: _____

4. Biochemical Failure Criteria

☐ Yes ☐ No Is the PSA ≥ 0.40 ng/ml?

☐ Yes ☐ No ☐ N/A **If Yes**, is it rising when compared with the previous PSA value? (See protocol Section 13 for details.)

If you answered **yes** to both questions, this constitutes biochemical failure.
If biochemical failure has occurred for the first time, please:

- Attached the de-identified PSA results to this form
- Report at next annual assessment (form C4 or C5).

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐ (D D M M Y Y)

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**PSA: Salvage RT Notification [B3] (p. 1 of 1)**

To: RAVES Coordinating Trial Centre

Email: ***Preferred***
carolfb@adhb.govt.nz
bcaudwell@adhb.govt.nz

From: _____

Fax: +64 9 375 7053

PSA Results: If Salvage Radiotherapy Required

- Only PSA results that trigger SRT (≥.20 ng/mL) must be reported on [B3]. Please attach de-identified PSA results to this form.
- Any PSA result triggering SRT must be reported, regardless of whether the PSA test was done according to the trial schedule.

☐☐☐☐☐☐ **PSA date** (dd/mm/yy)

☐☐☐.☐☐ **PSA level** (ng/mL)

Salvage Radiotherapy

RT must start no later than 4 months after the first PSA result ≥0.20 ng/mL. To facilitate Timely QA Reviews, please alert the Trial Centre with the planned SRT start date. If the start date subsequently changes, please let the Trial Centre know.

☐☐☐☐☐☐ **Planned start date of salvage RT (dd/mm/yy)**

☐ Tick if salvage RT start date is still to be confirmed. ***Please notify the Trial Centre once the start date is available.***

REMINDERS: Planning data is due within at least one week prior to the patient's RT start date for Timely Review. Data must be submitted electronically via TROG's Central Quality Management System (CQMS).

☐ Tick box if patient will not receive salvage radiotherapy, and indicate reason below:

Reason: _____

_____

_____

- *Please submit the original **form [B3]** and the **de-identified PSA result** to the Trial Centre.*
- *Please refer to **RT QA guidelines** for specific planning and treatment data requirements.*
- *Patient assessment is required at RT start, RT end, and 6 weeks post-RT **(Forms [C1], [C2] and [C3]).***

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Radiotherapy Treatment Day 1 [C1] (p. 1 of 3)**

Clinic visit date (dd/mm/yy):

☐☐☐☐☐☐

The clinic visit date can be during the first week following the radiotherapy start date.

☐ Tick box if clinic visit not done

Reason: _____

Note: The next clinic visit is required at the end of radiotherapy, and can be done during the last week of RT.

Patient Questionnaires (Form C1Q)

Are the Quality of Life and HADS forms completed?

☐ Yes ☐ No EORTC C30 **[C1Q]** (pages 1 & 2)

If no, please explain why: _____

☐ Yes ☐ No EORTC PR25 **[C1Q]** (pages 3 & 4)

If no, please explain why: _____

☐ Yes ☐ No HADS **[C1Q]** (pages 5 & 6)

If no, please explain why: _____

PSA Arm 2 (Salvage RT) ONLY

PSA day 1 of RT

Date of PSA (ddmmyy):

☐☐☐☐☐☐

☐☐.☐☐ PSA level (ng/mL)

☐ Please tick box if the PSA assessment was not done on day 1 of RT .

Reason:_____

Continued on next page

All AEs must be scored using Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0. Please enter the grade of current symptoms.

Adverse Events : Genitourinary

Cystitis

0 = None
1 = Asymptomatic
2 = Frequency with dysuria; macroscopic haematuria
3 = Transfusion; IV pain medications; bladder irrigation indicated
4 = Catastrophic bleeding; major non-elective Intervention indicated

☐ Tick if *not assessable*
Reason: _____

Urethral Stricture/Stenosis

0 = None
1 = Asymptomatic, radiographic or endoscopic findings only
2 = Symptomatic but no hydronephrosis, sepsis, or renal dysfunction; dilation or endoscopic repair or stent placement indicated
3 = Symptomatic and altered organ function (e.g., sepsis, hydronephrosis, or renal dysfunction); operative intervention indicated
4 = Life-threatening consequences; organ failure or operative intervention requiring organ resection indicated

☐ Tick if *not assessable*
Reason: _____

Urinary Incontinence

0 = None
1 = Occasional (e.g., with coughing, sneezing, etc., pads not indicated)
2 = Spontaneous, pads indicated
3 = Interfering with ADL; intervention indicated (e.g., clamp, collagen injections)
4 = Operative intervention indicated (e.g., cystectomy or permanent urinary diversion)

☐ Tick if *not assessable*
Reason: _____

Urinary Retention

0 = None
1 = Hesitancy or dribbling, no significant residual urine; retention
Occurring during the immediate postoperative period
2 = Hesitancy requiring medication; or operative bladder atony requiring indwelling catheter beyond immediate postoperative period but for less than 6 weeks
3 = More than daily catheterization indicated; urological intervention indicated (e.g., TURP, suprapubic tube, urethrotomy)
4 = Life-threatening consequences; organ failure (e.g., bladder rupture); operative intervention requiring organ resection

☐ Tick if *not assessable*
Reason: _____

Urinary Frequency/Urgency

0 = None
1 = Increase in frequency or nocturia up to 2 x normal, enuresis
2 = Increase > 2 x normal, but less than hourly
3 = ≥ once per hour; urgency or catheter Indicated

☐ Tick if *not assessable*
Reason: _____

Haemorrhage, GU

0 = None
1 = Minimal or microscopic bleeding, intervention not indicated
2 = Gross bleeding, medical intervention or urinary tract irrigation indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)
4 = Life threatening consequences; major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

Continued on next page

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Radiotherapy Treatment Day 1 Adverse Events [C1] (p. 3 of 3)**

All AEs must be scored using Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0. Please enter the grade of current symptoms.

Adverse Events: Gastrointestinal

☐

Diarrhoea

0 = None
1 = Increase of < 4 stools per day over baseline; mild increase in ostomy output compared to baseline
2 = Increase of 4-6 stools per day over baseline; IV fluids indicated < 24 hrs; moderate increase in ostomy output compared to baseline; not interfering with ADL
3 = Increase of ≥ 7 stools per day over baseline; incontinence; IV fluids ≥ 24 hrs; hospitalization; severe increase in ostomy output compared to baseline; interfering with ADL
4 = Life-threatening consequences (e.g., hemodynamic collapse)

☐ Tick if *not assessable*
Reason: _____

☐

Proctitis

0 = None
1 = Rectal discomfort, intervention not indicated
2 = Symptoms not interfering with ADL; medical intervention indicated
3 = Stool incontinence or other symptoms interfering with ADL; operative intervention indicated
4 = Life-threatening consequences (e.g., perforation)

☐ Tick if *not assessable*
Reason: _____

Adverse Events: Sexual Function

☐

Erectile Dysfunction

0 = None
1 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not indicated
2 = Decrease in erectile function (frequency/ rigidity of erections), erectile aids indicated
3 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not helpful; penile prosthesis indicated

☐ Tick if *not assessable*
Reason: _____

☐

Haemorrhage, GI (rectal)

0 = None
1 = Mild, intervention (other than iron supplements) not indicated
2 = Symptomatic and medical intervention or minor cauterization indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)
4 = Life-threatening consequences, major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

☐

Incontinence (anal)

0 = None
1 = Occasional use of pads
2 = Daily use of pads
3 = Interfering with ADL; operative intervention indicated
4 = Permanent bowel diversion indicated

☐ Tick if *not assessable*
Reason: _____

Adverse Events : Others

☐ Tick if *the patient did not experience any other AEs*

☐

Specify*:_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

☐

Specify*:_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

* Refer to CTCAE v 3.0 for diagnosis terminology (http://ctep.cancer.gov/reporting/ctc.html).
If more than two Other AEs are present:

☐ Tick and record additional events on form **[AE]**.

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐ (D D M M Y Y)

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Radiotherapy Treatment Day 1 Patient Questionnaires [C1Q] (p. 1 of 6)**

EORTC Quality of Life Questionnaire - C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Your birthdate: ☐☐☐☐☐☐ (D D M M Y Y) **Today's date:** ☐☐☐☐☐☐ (D D M M Y Y)

Approved for use by the EORTC 2008.

	Not at all	A little	Quite a bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself, or using the toilet?	1	2	3	4

During the past week:

	Not at all	A little	Quite a bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

EORTC Quality of Life Questionnaire - C30 (version 3, continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
17. Have you had diarrhoea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment Caused you financial difficulties?	1	2	3	4

For the following questions, please circle the number between 1 and 7 that best applies to you.

29. How would you rate your overall <u>health</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall <u>quality of life</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

EORTC Quality of Life Questionnaire - PR25

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you. The information that you provide will remain strictly confidential.

Approved for use by the EORTC 2008.

During the past week:

		Not at all	A little	Quite a bit	Very Much
31.	Have you had to urinate frequently **during the day**?	1	2	3	4
32.	Have you had to urinate frequently **at night**?	1	2	3	4
33.	When you felt the urge to pass urine, did you have to hurry to get to the toilet?	1	2	3	4
34.	Was it difficult for you to get enough sleep, because you needed to get up frequently at night to urinate?	1	2	3	4
35.	Have you had difficulty going out of the house because you needed to be close to a toilet?	1	2	3	4
36.	Have you had any unintentional release (leakage) of urine?	1	2	3	4
37.	Did you have pain when you urinated?	1	2	3	4
38.	Answer this question only if you wear incontinence aid. Has wearing an incontinence aid been a problem for you?	1	2	3	4
39.	Have your daily activities been limited by your urinary problems?	1	2	3	4
40.	Have your daily activities been limited by your bowel problems?	1	2	3	4
41.	Have you had any unintentional release (leakage) of stools?	1	2	3	4
42.	Have you had blood in your stools?	1	2	3	4
43.	Did you have a bloated feeling in your abdomen?	1	2	3	4
44.	Did you have hot flushes?	1	2	3	4
45.	Have you had sore or enlarged nipples or breasts?	1	2	3	4
46.	Have you had swelling in your legs or ankles?	1	2	3	4

EORTC Quality of Life Questionnaire - PR25 (continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
47. Has weight **loss** been a problem for you?	1	2	3	4
48. Has weight **gain** been a problem for you?	1	2	3	4
49. Have you felt less masculine as a result of your illness or treatment?	1	2	3	4
50. To what extent were you interested in sex?	1	2	3	4
51. To what extent were you sexually active (with or without intercourse)?	1	2	3	4

PLEASE ANSWER THE NEXT FOUR QUESTIONS ONLY IF YOU HAVE BEEN SEXUALLY ACTIVE OVER THE LAST 4 WEEKS.

52. To what extent was sex enjoyable for you?	1	2	3	4
53. Did you have difficulty getting or maintaining an erection?	1	2	3	4
54. Did you have ejaculation problems (e.g. dry ejaculation)?	1	2	3	4
55. Have you felt uncomfortable about being sexually intimate?	1	2	3	4

Hospital Anxiety and Depression Scale (HADS)

						Today's date (dd/mm/yy)

Clinicians are aware that emotions play an important part in most illnesses. This questionnaire is designed to help the research team know how you and other patients feel. Read each statement below and:

- **Tick the box next to the response** which comes closest to how you have been feeling **in the past week.**
- Please note that your doctor will not routinely be provided with your completed questionnaire. If you have any concerns you would like to address, please tell your doctor.

Don't take too long over your replies. Your immediate reaction to each item will probably be more accurate

During the past week:

1. I feel tense or "wound up"

- ☐ Most of the time
- ☐ A lot of the time
- ☐ From time to time, occasionally
- ☐ Not at all

2. I still enjoy the things I used to enjoy

- ☐ Definitely as much
- ☐ Not quite so much
- ☐ Only a little
- ☐ Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen

- ☐ Very definitely and quite badly
- ☐ Yes, but not too badly
- ☐ A little, but it doesn't worry me
- ☐ Not at all

4. I can laugh and see the funny side of things

- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much now
- ☐ Not at all

5. I feel as if I am slowed down

- ☐ Nearly all the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

6. I get a sort of frightened feeling like "butterflies" in the stomach

- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often
- ☐ Very often

7. I have lost interest in my appearance

- ☐ Definitely
- ☐ I don't take as much care as I should
- ☐ I may not take quite as much care
- ☐ I take just as much care as ever

8. I feel restless as if I have to be on the move

- ☐ Very much indeed
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all

Continue on next page, please

Hospital Anxiety and Depression Scale (HADS)

Continued from previous page

During the past week:

9. Worrying thoughts go through my mind

- ☐ A great deal of the time
- ☐ A lot of the time
- ☐ Not too often
- ☐ Very little

10. I feel cheerful

- ☐ Never
- ☐ Not often
- ☐ Sometimes
- ☐ Most of the time

11. I can sit at ease and feel relaxed

- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

12. I look forward with enjoyment to things

- ☐ As much as I ever did
- ☐ Rather less than I used to
- ☐ Definitely less than I used to
- ☐ Hardly at all

13. I get sudden feelings of panic

- ☐ Very often indeed
- ☐ Quite often
- ☐ Not very often
- ☐ Not at all

14. I can enjoy a good book or radio or television programme

- ☐ Often
- ☐ Sometimes
- ☐ Not often
- ☐ Very seldom

Now check that you have answered all 14 questions

Thank you

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Radiotherapy Treatment End of RT [C2] (p. 1 of 3)**

Clinic visit date (dd/mm/yy):

☐☐☐☐☐☐

The clinic visit can occur during the last week of radiotherapy.

☐ Tick box if clinic visit not done. Reason: _____

Patient Questionnaires (Form C2Q)

Have the patient questionnaires been completed?

☐ Yes ☐ No EORTC C30 **[C2Q]** (pages 1 & 2)

If no, please explain why: _____

☐ Yes ☐ No EORTC PR25 **[C2Q]** (pages 3 & 4)

If no, please explain why: _____

☐ Yes ☐ No HADS **[C2Q]** (pages 5 & 6)

If no, please explain why: _____

Radiotherapy QA

Radiotherapy Post-Treatment Quality Assurance is due within 4 weeks of treatment end date.

Reminder

Patient must have a PSA test and clinic visit 6 weeks following the end of radiotherapy.

Continued on next page

All AEs must be scored using Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0. Please enter the grade of current symptoms.

Adverse Events : Genitourinary

Cystitis

0 = None
1 = Asymptomatic
2 = Frequency with dysuria; macroscopic haematuria
3 = Transfusion; IV pain medications; bladder irrigation indicated
4 = Catastrophic bleeding; major non-elective Intervention indicated

☐ Tick if *not assessable*
Reason: _____

Urethral Stricture/Stenosis

0 = None
1 = Asymptomatic, radiographic or endoscopic findings only
2 = Symptomatic but no hydronephrosis, sepsis, or renal dysfunction; dilation or endoscopic repair or stent placement indicated
3 = Symptomatic and altered organ function (e.g., sepsis, hydronephrosis, or renal dysfunction); operative intervention indicated
4 = Life-threatening consequences; organ failure or operative intervention requiring organ resection indicated

☐ Tick if *not assessable*
Reason: _____

Urinary Incontinence

0 = None
1 = Occasional (e.g., with coughing, sneezing, etc., pads not indicated)
2 = Spontaneous, pads indicated
3 = Interfering with ADL; intervention indicated (e.g., clamp, collagen injections)
4 = Operative intervention indicated (e.g., cystectomy or permanent urinary diversion)

☐ Tick if *not assessable*
Reason: _____

Urinary Retention

0 = None
1 = Hesitancy or dribbling, no significant residual urine; retention
Occurring during the immediate postoperative period
2 = Hesitancy requiring medication; or operative bladder atony requiring indwelling catheter beyond immediate postoperative period but for less than 6 weeks
3 = More than daily catheterization indicated; urological intervention indicated (e.g., TURP, suprapubic tube, urethrotomy)
4 = Life-threatening consequences; organ failure (e.g., bladder rupture); operative intervention requiring organ resection

☐ Tick if *not assessable*
Reason: _____

Urinary Frequency/Urgency

0 = None
1 = Increase in frequency or nocturia up to 2 x normal, enuresis
2 = Increase > 2 x normal, but less than hourly
3 = ≥ once per hour; urgency or catheter Indicated

☐ Tick if *not assessable*
Reason: _____

Haemorrhage, GU

0 = None
1 = Minimal or microscopic bleeding, intervention not indicated
2 = Gross bleeding, medical intervention or urinary tract irrigation indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)
4 = Life threatening consequences; major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

Continued on next page

Radiotherapy Treatment End of RT Adverse Events [C2] (p. 3 of 3)

All AEs must be scored using Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0. Please enter the grade of current symptoms.

Adverse Events: Gastrointestinal

Diarrhoea

0 = None
1 = Increase of < 4 stools per day over baseline; mild increase in ostomy output compared to baseline
2 = Increase of 4-6 stools per day over baseline; IV fluids indicated < 24 hrs; moderate increase in ostomy output compared to baseline; not interfering with ADL
3 = Increase of ≥ 7 stools per day over baseline; incontinence; IV fluids ≥ 24 hrs; hospitalization; severe increase in ostomy output compared to baseline; interfering with ADL
4 = Life-threatening consequences (e.g., hemodynamic collapse)

☐ Tick if *not assessable*
Reason: _____

Proctitis

0 = None
1 = Rectal discomfort, intervention not indicated
2 = Symptoms not interfering with ADL; medical intervention indicated
3 = Stool incontinence or other symptoms interfering with ADL; operative intervention indicated
4 = Life-threatening consequences (e.g., perforation)

☐ Tick if *not assessable*
Reason: _____

Adverse Events: Sexual Function

Erectile Dysfunction

0 = None
1 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not indicated
2 = Decrease in erectile function (frequency/ rigidity of erections), erectile aids indicated
3 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not helpful; penile prosthesis indicated

☐ Tick if *not assessable*
Reason: _____

Haemorrhage, GI (rectal)

0 = None
1 = Mild, intervention (other than iron supplements) not indicated
2 = Symptomatic and medical intervention or minor cauterization indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)
4 = Life-threatening consequences, major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

Incontinence (anal)

0 = None
1 = Occasional use of pads
2 = Daily use of pads
3 = Interfering with ADL; operative intervention indicated
4 = Permanent bowel diversion indicated

☐ Tick if *not assessable*
Reason: _____

Adverse Events : Others

☐ Tick if *the patient did not experience any other AEs*

Specify*:_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

Specify*:_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

* Refer to CTCAE v 3.0 for diagnosis terminology (http://ctep.cancer.gov/reporting/ctc.html).
If more than two Other AEs are present:

☐ Tick and record additional events on form **[AE]**.

Form completed by (print)_____

(signed)_____ Date: | | | | | | | (D D M M Y Y)

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Radiotherapy Treatment End of RT Patient Questionaires [C2Q] (p. 1 of 6)**

EORTC Quality of Life Questionnaire - C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Your birthdate: ☐☐☐☐☐☐ (D D M M Y Y) **Today's date:** ☐☐☐☐☐☐ (D D M M Y Y)

Approved for use by the EORTC 2008.

		Not at all	A little	Quite a bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself, or using the toilet?	1	2	3	4

During the past week:

		Not at all	A little	Quite a bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4
16.	Have you been constipated?	1	2	3	4

EORTC Quality of Life Questionnaire - C30 (version 3, continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
17. Have you had diarrhoea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment Caused you financial difficulties?	1	2	3	4

For the following questions, please circle the number between 1 and 7 that best applies to you.

29. How would you rate your overall <u>health</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall <u>quality of life</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

EORTC Quality of Life Questionnaire - PR25

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you. The information that you provide will remain strictly confidential.

Approved for use by the EORTC 2008.

During the past week:

		Not at all	A little	Quite a bit	Very Much
31.	Have you had to urinate frequently **during the day**?	1	2	3	4
32.	Have you had to urinate frequently **at night**?	1	2	3	4
33.	When you felt the urge to pass urine, did you have to hurry to get to the toilet?	1	2	3	4
34.	Was it difficult for you to get enough sleep, because you needed to get up frequently at night to urinate?	1	2	3	4
35.	Have you had difficulty going out of the house because you needed to be close to a toilet?	1	2	3	4
36.	Have you had any unintentional release (leakage) of urine?	1	2	3	4
37.	Did you have pain when you urinated?	1	2	3	4
38.	Answer this question only if you wear incontinence aid. Has wearing an incontinence aid been a problem for you?	1	2	3	4
39.	Have your daily activities been limited by your urinary problems?	1	2	3	4
40.	Have your daily activities been limited by your bowel problems?	1	2	3	4
41.	Have you had any unintentional release (leakage) of stools?	1	2	3	4
42.	Have you had blood in your stools?	1	2	3	4
43.	Did you have a bloated feeling in your abdomen?	1	2	3	4
44.	Did you have hot flushes?	1	2	3	4
45.	Have you had sore or enlarged nipples or breasts?	1	2	3	4
46.	Have you had swelling in your legs or ankles?	1	2	3	4

EORTC Quality of Life Questionnaire - PR25 (continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
47. Has weight **loss** been a problem for you?	1	2	3	4
48. Has weight **gain** been a problem for you?	1	2	3	4
49. Have you felt less masculine as a result of your illness or treatment?	1	2	3	4
50. To what extent were you interested in sex?	1	2	3	4
51. To what extent were you sexually active (with or without intercourse)?	1	2	3	4

PLEASE ANSWER THE NEXT FOUR QUESTIONS ONLY IF YOU HAVE BEEN SEXUALLY ACTIVE OVER THE LAST 4 WEEKS.

52. To what extent was sex enjoyable for you?	1	2	3	4
53. Did you have difficulty getting or maintaining an erection?	1	2	3	4
54. Did you have ejaculation problems (e.g. dry ejaculation)?	1	2	3	4
55. Have you felt uncomfortable about being sexually intimate?	1	2	3	4

Hospital Anxiety and Depression Scale (HADS)

Today's date (dd/mm/yy)

Clinicians are aware that emotions play an important part in most illnesses. This questionnaire is designed to help the research team know how you and other patients feel. Read each statement below and:

- **Tick the box next to the response** which comes closest to how you have been feeling **in the past week.**
- Please note that your doctor will not routinely be provided with your completed questionnaire. If you have any concerns you would like to address, please tell your doctor.

Don't take too long over your replies. Your immediate reaction to each item will probably be more accurate

During the past week:

1. I feel tense or "wound up"

- ☐ Most of the time
- ☐ A lot of the time
- ☐ From time to time, occasionally
- ☐ Not at all

2. I still enjoy the things I used to enjoy

- ☐ Definitely as much
- ☐ Not quite so much
- ☐ Only a little
- ☐ Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen

- ☐ Very definitely and quite badly
- ☐ Yes, but not too badly
- ☐ A little, but it doesn't worry me
- ☐ Not at all

4. I can laugh and see the funny side of things

- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much now
- ☐ Not at all

5. I feel as if I am slowed down

- ☐ Nearly all the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

6. I get a sort of frightened feeling like "butterflies" in the stomach

- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often
- ☐ Very often

7. I have lost interest in my appearance

- ☐ Definitely
- ☐ I don't take as much care as I should
- ☐ I may not take quite as much care
- ☐ I take just as much care as ever

8. I feel restless as if I have to be on the move

- ☐ Very much indeed
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all

Continue on next page, please

Hospital Anxiety and Depression Scale (HADS)

Continued from previous page

During the past week:

9. Worrying thoughts go through my mind

- ☐ A great deal of the time
- ☐ A lot of the time
- ☐ Not too often
- ☐ Very little

10. I feel cheerful

- ☐ Never
- ☐ Not often
- ☐ Sometimes
- ☐ Most of the time

11. I can sit at ease and feel relaxed

- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

12. I look forward with enjoyment to things

- ☐ As much as I ever did
- ☐ Rather less than I used to
- ☐ Definitely less than I used to
- ☐ Hardly at all

13. I get sudden feelings of panic

- ☐ Very often indeed
- ☐ Quite often
- ☐ Not very often
- ☐ Not at all

14. I can enjoy a good book or radio or television programme

- ☐ Often
- ☐ Sometimes
- ☐ Not often
- ☐ Very seldom

Now check that you have answered all 14 questions

Thank you

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Radiotherapy Treatment Summary [T] (p. 1 of 2)**

Radiotherapy Summary

☐☐.☐ **Total dose in Gy to ICRU point**

Phase 1: ☐☐.☐ **Prescribed dose (Gy)** ☐☐ **Number of fractions**

☐ Tick if single phase plan was used.
Note: A two phase technique is permitted only with prior approval of the RAVES QA Committee.

Phase 2: ☐☐.☐ **Prescribed dose (Gy)** ☐☐ **Number of fractions**

☐☐☐☐☐☐ Date treatment started (dd/mm/yy)

☐☐☐☐☐☐ Date treatment finished (dd/mm/yy)

☐☐ Duration in days of unplanned breaks in treatment (i.e. not weekends/holidays or planned maintenance)

Indicate reason(s) for unplanned breaks in treatment below (tick all that apply):

☐ Radiotherapy Adverse Event
☐ Non-treatment related Adverse Event
☐ Progressive Disease
☐ Patient refusal to continue treatment
☐ Public holiday
☐ Other (specify): _____

Imaging:

What type of imaging device was used to confirm accuracy of treatment delivery? *Tick all that apply.*

☐ MV ☐ kV ☐ MVCBCT ☐ kVCBCT ☐ Other:_____

Record the frequency, reference source and correction method below. *If more than one type of imaging was used, record details for each additional device on page 2.*

Device type	**Frequency: wk 1** *Tick all that apply*	**Frequency: wk 2 onwards**	**Reference Source**	**Correction Method**
☐	☐ Day 1 ☐ Day 2 ☐ Day 3 ☐ Day 4 ☐ Day 5	☐ Daily ☐ Weekly ☐ Other: _____	☐ Bony anatomy ☐ Fiducial markers ☐ Surgical clips ☐ Soft tissue	☐ Online ☐ Offline

If more than one imaging device is used, please complete page 2.

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐ (D D M M Y Y)

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Radiotherapy Treatment Summary [T] (p. 2 of 2)**

Radiotherapy Summary

Imaging: *Continued*

Device type	Frequency: wk 1 *Tick all that apply*	Frequency: wk 2 onwards	Reference Source	Correction Method
☐	☐ Day 1	☐ Daily	☐ Bony anatomy	☐ Online
	☐ Day 2	☐ Weekly	☐ Fiducial markers	☐ Offline
	☐ Day 3	☐ Other: ____________	☐ Surgical clips	
	☐ Day 4		☐ Soft tissue	
	☐ Day 5			

Device type	Frequency: wk 1 *Tick all that apply*	Frequency: wk 2 onwards	Reference Source	Correction Method
☐	☐ Day 1	☐ Daily	☐ Bony anatomy	☐ Online
	☐ Day 2	☐ Weekly	☐ Fiducial markers	☐ Offline
	☐ Day 3	☐ Other: ____________	☐ Surgical clips	
	☐ Day 4		☐ Soft tissue	
	☐ Day 5			

Device type	Frequency: wk 1 *Tick all that apply*	Frequency: wk 2 onwards	Reference Source	Correction Method
☐	☐ Day 1	☐ Daily	☐ Bony anatomy	☐ Online
	☐ Day 2	☐ Weekly	☐ Fiducial markers	☐ Offline
	☐ Day 3	☐ Other: ____________	☐ Surgical clips	
	☐ Day 4		☐ Soft tissue	
	☐ Day 5			

Device type	Frequency: wk 1 *Tick all that apply*	Frequency: wk 2 onwards	Reference Source	Correction Method
☐	☐ Day 1	☐ Daily	☐ Bony anatomy	☐ Online
	☐ Day 2	☐ Weekly	☐ Fiducial markers	☐ Offline
	☐ Day 3	☐ Other: ____________	☐ Surgical clips	
	☐ Day 4		☐ Soft tissue	
	☐ Day 5			

Form completed by (print)________________________________

(signed)________________________________ Date: ☐☐ ☐☐ ☐☐
D D M M Y Y

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Radiotherapy Treatment 6 Weeks Post - RT (Arms 1 and 2) [C3] (p. 1 of 3)**

Clinic visit date (dd/mm/yy):

☐☐☐☐☐☐

- If the 6 week post-RT visit date is +/- 28 days from a 6 monthly or annual clinic visit target date, only the 6 week post-RT assessments need to be completed.

☐ Tick box if clinic visit not done.

Reason: _____

Patient Questionnaires (Form C3Q)

Are the Quality of Life and HADS forms completed?

☐ Yes ☐ No EORTC C30 **[C3Q]** (pages 1 & 2)

If no, please explain why: _____

☐ Yes ☐ No EORTC PR25 **[C3Q]** (pages 3 & 4)

If no, please explain why: _____

☐ Yes ☐ No HADS **[C3Q]** (pages 5 & 6)

If no, please explain why: _____

PSA

Date of PSA (dd/mm/yy):

☐☐☐☐☐☐

☐☐.☐☐ PSA level (ng/mL)

☐ Please tick box if the 6 week post-RT PSA assessment was not done.

Reason: _____

Reminder

The next trial follow-ups are due: 6 monthly from randomisation (years 1-5) **AND** PSA is due 6 monthly from randomisation (years 1-10)
12 monthly from randomisation (years 6-10)

Continued on next page

All AEs must be scored using Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0. Please enter the grade of current symptoms.

Adverse Events : Genitourinary

Cystitis

0 = None
1 = Asymptomatic
2 = Frequency with dysuria; macroscopic haematuria
3 = Transfusion; IV pain medications; bladder irrigation indicated
4 = Catastrophic bleeding; major non-elective Intervention indicated

☐ Tick if *not assessable*
Reason: _____

Urethral Stricture/Stenosis

0 = None
1 = Asymptomatic, radiographic or endoscopic findings only
2 = Symptomatic but no hydronephrosis, sepsis, or renal dysfunction; dilation or endoscopic repair or stent placement indicated
3 = Symptomatic and altered organ function (e.g., sepsis, hydronephrosis, or renal dysfunction); operative intervention indicated
4 = Life-threatening consequences; organ failure or operative intervention requiring organ resection indicated

☐ Tick if *not assessable*
Reason: _____

Urinary Incontinence

0 = None
1 = Occasional (e.g., with coughing, sneezing, etc., pads not indicated)
2 = Spontaneous, pads indicated
3 = Interfering with ADL; intervention indicated (e.g., clamp, collagen injections)
4 = Operative intervention indicated (e.g., cystectomy or permanent urinary diversion)

☐ Tick if *not assessable*
Reason: _____

Urinary Retention

0 = None
1 = Hesitancy or dribbling, no significant residual urine; retention
Occurring during the immediate postoperative period
2 = Hesitancy requiring medication; or operative bladder atony requiring indwelling catheter beyond immediate postoperative period but for less than 6 weeks
3 = More than daily catheterization indicated; urological intervention indicated (e.g., TURP, suprapubic tube, urethrotomy)
4 = Life-threatening consequences; organ failure (e.g., bladder rupture); operative intervention requiring organ resection

☐ Tick if *not assessable*
Reason: _____

Urinary Frequency/Urgency

0 = None
1 = Increase in frequency or nocturia up to 2 x normal, enuresis
2 = Increase > 2 x normal, but less than hourly
3 = ≥ once per hour; urgency or catheter Indicated

☐ Tick if *not assessable*
Reason: _____

Haemorrhage, GU

0 = None
1 = Minimal or microscopic bleeding, intervention not indicated
2 = Gross bleeding, medical intervention or urinary tract irrigation indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)
4 = Life threatening consequences; major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

Continued on next page

All AEs must be scored using Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0. Please enter the grade of current symptoms.

Adverse Events: Gastrointestinal

Diarrhoea

0 = None
1 = Increase of < 4 stools per day over baseline; mild increase in ostomy output compared to baseline
2 = Increase of 4-6 stools per day over baseline; IV fluids indicated < 24 hrs; moderate increase in ostomy output compared to baseline; not interfering with ADL
3 = Increase of ≥ 7 stools per day over baseline; incontinence; IV fluids ≥ 24 hrs; hospitalization; severe increase in ostomy output compared to baseline; interfering with ADL
4 = Life-threatening consequences (e.g., hemodynamic collapse)

☐ Tick if *not assessable*
Reason: _____

Proctitis

0 = None
1 = Rectal discomfort, intervention not indicated
2 = Symptoms not interfering with ADL; medical intervention indicated
3 = Stool incontinence or other symptoms interfering with ADL; operative intervention indicated
4 = Life-threatening consequences (e.g., perforation)

☐ Tick if *not assessable*
Reason: _____

Adverse Events: Sexual Function

Erectile Dysfunction

0 = None
1 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not indicated
2 = Decrease in erectile function (frequency/ rigidity of erections), erectile aids indicated
3 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not helpful; penile prosthesis indicated

☐ Tick if *not assessable*
Reason: _____

Haemorrhage, GI (rectal)

0 = None
1 = Mild, intervention (other than iron supplements) not indicated
2 = Symptomatic and medical intervention or minor cauterization indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)
4 = Life-threatening consequences, major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

Incontinence (anal)

0 = None
1 = Occasional use of pads
2 = Daily use of pads
3 = Interfering with ADL; operative intervention indicated
4 = Permanent bowel diversion indicated

☐ Tick if *not assessable*
Reason: _____

Adverse Events : Others

☐ Tick if *the patient did not experience any other AEs*

Specify*:_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

Specify*:_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

* Refer to CTCAE v 3.0 for diagnosis terminology (http://ctep.cancer.gov/reporting/ctc.html).
If more than two Other AEs are present:

☐ Tick and record additional events on form **[AE]**.

Form completed by (print)_____

(signed)_____ Date: | | | | | | | (D D M M Y Y)

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Radiotherapy Treatment 6 Weeks Post- RT Patient Questionnaires [C3Q] (p. 1 of 6)**

EORTC Quality of Life Questionnaire - C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Your birthdate: ☐☐☐☐☐☐ (D D M M Y Y) **Today's date:** ☐☐☐☐☐☐ (D D M M Y Y)

Approved for use by the EORTC 2008.

		Not at all	A little	Quite a bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself, or using the toilet?	1	2	3	4

During the past week:

		Not at all	A little	Quite a bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4
16.	Have you been constipated?	1	2	3	4

EORTC Quality of Life Questionnaire - C30 (version 3, continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
17. Have you had diarrhoea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment Caused you financial difficulties?	1	2	3	4

For the following questions, please circle the number between 1 and 7 that best applies to you.

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

EORTC Quality of Life Questionnaire - PR25

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you. The information that you provide will remain strictly confidential.

Approved for use by the EORTC 2008.

During the past week:

		Not at all	A little	Quite a bit	Very Much
31.	Have you had to urinate frequently **during the day**?	1	2	3	4
32.	Have you had to urinate frequently **at night**?	1	2	3	4
33.	When you felt the urge to pass urine, did you have to hurry to get to the toilet?	1	2	3	4
34.	Was it difficult for you to get enough sleep, because you needed to get up frequently at night to urinate?	1	2	3	4
35.	Have you had difficulty going out of the house because you needed to be close to a toilet?	1	2	3	4
36.	Have you had any unintentional release (leakage) of urine?	1	2	3	4
37.	Did you have pain when you urinated?	1	2	3	4
38.	Answer this question only if you wear incontinence aid. Has wearing an incontinence aid been a problem for you?	1	2	3	4
39.	Have your daily activities been limited by your urinary problems?	1	2	3	4
40.	Have your daily activities been limited by your bowel problems?	1	2	3	4
41.	Have you had any unintentional release (leakage) of stools?	1	2	3	4
42.	Have you had blood in your stools?	1	2	3	4
43.	Did you have a bloated feeling in your abdomen?	1	2	3	4
44.	Did you have hot flushes?	1	2	3	4
45.	Have you had sore or enlarged nipples or breasts?	1	2	3	4
46.	Have you had swelling in your legs or ankles?	1	2	3	4

EORTC Quality of Life Questionnaire - PR25 (continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
47. Has weight **loss** been a problem for you?	1	2	3	4
48. Has weight **gain** been a problem for you?	1	2	3	4
49. Have you felt less masculine as a result of your illness or treatment?	1	2	3	4
50. To what extent were you interested in sex?	1	2	3	4
51. To what extent were you sexually active (with or without intercourse)?	1	2	3	4

PLEASE ANSWER THE NEXT FOUR QUESTIONS ONLY IF YOU HAVE BEEN SEXUALLY ACTIVE OVER THE LAST 4 WEEKS.

52. To what extent was sex enjoyable for you?	1	2	3	4
53. Did you have difficulty getting or maintaining an erection?	1	2	3	4
54. Did you have ejaculation problems (e.g. dry ejaculation)?	1	2	3	4
55. Have you felt uncomfortable about being sexually intimate?	1	2	3	4

Hospital Anxiety and Depression Scale (HADS)

						Today's date (dd/mm/yy)

Clinicians are aware that emotions play an important part in most illnesses. This questionnaire is designed to help the research team know how you and other patients feel. Read each statement below and:

- **Tick the box next to the response** which comes closest to how you have been feeling **in the past week.**
- Please note that your doctor will not routinely be provided with your completed questionnaire. If you have any concerns you would like to address, please tell your doctor.

Don't take too long over your replies. Your immediate reaction to each item will probably be more accurate

During the past week:

1. I feel tense or "wound up"

- ☐ Most of the time
- ☐ A lot of the time
- ☐ From time to time, occasionally
- ☐ Not at all

2. I still enjoy the things I used to enjoy

- ☐ Definitely as much
- ☐ Not quite so much
- ☐ Only a little
- ☐ Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen

- ☐ Very definitely and quite badly
- ☐ Yes, but not too badly
- ☐ A little, but it doesn't worry me
- ☐ Not at all

4. I can laugh and see the funny side of things

- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much now
- ☐ Not at all

5. I feel as if I am slowed down

- ☐ Nearly all the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

6. I get a sort of frightened feeling like "butterflies" in the stomach

- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often
- ☐ Very often

7. I have lost interest in my appearance

- ☐ Definitely
- ☐ I don't take as much care as I should
- ☐ I may not take quite as much care
- ☐ I take just as much care as ever

8. I feel restless as if I have to be on the move

- ☐ Very much indeed
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all

Continue on next page, please

Hospital Anxiety and Depression Scale (HADS)

Continued from previous page

During the past week:

9. Worrying thoughts go through my mind

- ☐ A great deal of the time
- ☐ A lot of the time
- ☐ Not too often
- ☐ Very little

10. I feel cheerful

- ☐ Never
- ☐ Not often
- ☐ Sometimes
- ☐ Most of the time

11. I can sit at ease and feel relaxed

- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

12. I look forward with enjoyment to things

- ☐ As much as I ever did
- ☐ Rather less than I used to
- ☐ Definitely less than I used to
- ☐ Hardly at all

13. I get sudden feelings of panic

- ☐ Very often indeed
- ☐ Quite often
- ☐ Not very often
- ☐ Not at all

14. I can enjoy a good book or radio or television programme

- ☐ Often
- ☐ Sometimes
- ☐ Not often
- ☐ Very seldom

Do you know the result from your most recent PSA test? ☐ **Yes** ☐ **No**

Now check that you have answered all 14 questions

Thank you

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Annual Follow-Up [C4] (p. 1 of 5)**

Complete form **[C4]** annually from randomisation.

Clinic visit date (dd/mm/yy): ☐☐☐☐☐☐

☐ Tick box if clinic visit not done. Reason: _____

Please select year from randomisation:

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

PSA (forms [B1], [B2] or [B3])

- If the patient ***has not*** received RT, please report PSA on form **[B1]**.
- If the patient ***has*** received RT, please report PSA on form **[B2]**.
- If the patient had a PSA test that triggered SRT (Arm 2), please complete form **[B3].**

☐ Yes ☐ No Have the PSA form(s) been completed?

Reminder:

PSA assessment schedule:	**Pre-RT**	**Post-RT**
	3 monthly from randomisation	6 monthly from randomisation

Patient Questionnaires

Have the Patient Questionnaires been completed?

☐ Yes ☐ No EORTC C30 (form **[C4Q]** pages 1 & 2)

If no, please explain why: _____

☐ Yes ☐ No EORTC PR25 (form **[C4Q]** pages 3 & 4)

If no, please explain why: _____

☐ Yes ☐ No HADS (form **[C4Q]** pages 5 & 6)

If no, please explain why: _____

☐ Yes ☐ No SHIM (form **[Q]** page 7)

If no, please explain why: _____

☐ Yes ☐ No Health Resource Use (form **[Q]** page 8)

If no, please explain why: _____

Continued on next page

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Annual Follow -Up Adverse Events [C4] (p. 2 of 5)**

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

Adverse Events : Genitourinary

All AEs must be scored using CTCAE v.3.0. Please enter the grade of current symptoms.

☐ **Cystitis**

0 = None
1 = Asymptomatic
2 = Frequency with dysuria; macroscopic haematuria
3 = Transfusion; IV pain medications; bladder irrigation indicated
4 = Catastrophic bleeding; major non-elective Intervention indicated

☐ Tick if *not assessable*
Reason: _____

☐ **Urethral Stricture/Stenosis**

0 = None
1 = Asymptomatic, radiographic or endoscopic findings only
2 = Symptomatic but no hydronephrosis, sepsis, or renal dysfunction; dilation or endoscopic repair or stent placement indicated
3 = Symptomatic and altered organ function (e.g., sepsis, hydronephrosis, or renal dysfunction); operative intervention indicated
4 = Life-threatening consequences; organ failure or operative intervention requiring organ resection indicated

☐ Tick if *not assessable*
Reason: _____

☐ **Urinary Incontinence**

0 = None
1 = Occasional (e.g., with coughing, sneezing, etc., pads not indicated)
2 = Spontaneous, pads indicated
3 = Interfering with ADL; intervention indicated (e.g., clamp, collagen injections)
4 = Operative intervention indicated (e.g., cystectomy or permanent urinary diversion)

☐ Tick if *not assessable*
Reason: _____

☐ **Urinary Retention**

0 = None
1 = Hesitancy or dribbling, no significant residual urine; retention
Occurring during the immediate postoperative period
2 = Hesitancy requiring medication; or operative bladder atony requiring indwelling catheter beyond immediate postoperative period but for less than 6 weeks
3 = More than daily catheterization indicated; urological intervention indicated (e.g., TURP, suprapubic tube, urethrotomy)
4 = Life-threatening consequences; organ failure (e.g., bladder rupture); operative intervention requiring organ resection

☐ Tick if *not assessable*
Reason: _____

☐ **Urinary Frequency/Urgency**

0 = None
1 = Increase in frequency or nocturia up to 2 x normal, enuresis
2 = Increase > 2 x normal, but less than hourly
3 = ≥ once per hour; urgency or catheter Indicated

☐ Tick if *not assessable*
Reason: _____

☐ **Haemorrhage, GU**

0 = None
1 = Minimal or microscopic bleeding, intervention not indicated
2 = Gross bleeding, medical intervention or urinary tract irrigation indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)
4 = Life threatening consequences; major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

Continued on next page

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

Adverse Events: Gastrointestinal

☐

Diarrhoea

0 = None
1 = Increase of < 4 stools per day over baseline; mild increase in ostomy output compared to baseline
2 = Increase of 4-6 stools per day over baseline; IV fluids indicated < 24 hrs; moderate increase in ostomy output compared to baseline; not interfering with ADL
3 = Increase of ≥ 7 stools per day over baseline; incontinence; IV fluids ≥ 24 hrs; hospitalization; severe increase in ostomy output compared to baseline; interfering with ADL
4 = Life-threatening consequences (e.g., hemodynamic collapse)

☐ Tick if *not assessable*
Reason: _____

☐

Proctitis

0 = None
1 = Rectal discomfort, intervention not indicated
2 = Symptoms not interfering with ADL; medical intervention indicated
3 = Stool incontinence or other symptoms interfering with ADL; operative intervention indicated
4 = Life-threatening consequences (e.g., perforation)

☐ Tick if *not assessable*
Reason: _____

Adverse Events: Sexual Function

☐

Erectile Dysfunction

0 = None
1 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not indicated
2 = Decrease in erectile function (frequency/ rigidity of erections), erectile aids indicated
3 = Decrease in erectile function (frequency/ rigidity of erections) but erectile aids not helpful; penile prosthesis indicated

☐ Tick if *not assessable*
Reason: _____

☐

Haemorrhage, GI (rectal)

0 = None
1 = Mild, intervention (other than iron supplements) not indicated
2 = Symptomatic and medical intervention or minor cauterization indicated
3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)
4 = Life-threatening consequences, major urgent intervention indicated

☐ Tick if *not assessable*
Reason: _____

☐

Incontinence (anal)

0 = None
1 = Occasional use of pads
2 = Daily use of pads
3 = Interfering with ADL; operative intervention indicated
4 = Permanent bowel diversion indicated

☐ Tick if *not assessable*
Reason: _____

Adverse Events : Others

☐ Tick if *the patient did not experience any other AEs*

☐

Specify*:_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

☐

Specify*:_____

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

* Refer to CTCAE v 3.0 for diagnosis terminology (http://ctep.cancer.gov/reporting/ctc.html).
If more than two Other AEs are present:

☐ Tick and record additional events on form **[AE]**.

Continued on next page

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Annual Follow-Up [C4] (p. 4 of 5)**

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

Rectal Examination

A rectal exam is recommended if:

- PSA is rising compared to the previous measurement **AND**
- Local failure is not documented

Was a rectal exam performed? ☐ Yes ☐ No ☐ Not Required

☐☐☐☐☐☐ **If yes**, give date (dd/mm/yy)

Androgen Deprivation Therapy

Has androgen deprivation therapy been started? ☐ Yes ☐ No

☐☐☐☐☐☐ **If yes** and started since last assessment, give start date (dd/mm/yy)

☐☐☐☐☐☐ Stop date (ddmmyy) Or tick if: ☐ Ongoing ☐ Intermittent

Relapse

Has the patient relapsed? ☐ Yes ☐ No

If the patient has not relapsed, please sign and date at bottom.
If no relapse has occurred, do not complete the remainder of this form.

Biochemical Failure

☐ Has biochemical failure occurred? Please fill in the box to the left with one of the following numbers:
1 = yes **2 = no** **3 = previously reported** **4 = not assessed**

If yes (1), please complete below:

Please record the first date the PSA* was ≥ 0.40 ng/mL:

☐☐☐☐☐☐ (dd/mm/yy) ☐☐☐.☐☐ PSA level (ng/mL)*

☐ Tick box if biochemical failure peviously reported on form **[B1]** or **B2]**.

Continued on next page

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Annual Follow-Up [C4] (p. 5 of 5)**

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

Biochemical Failure

If a **confirmatory PSA** was done, please record the results below.

☐☐☐☐☐☐ PSA date (dd/mm/yy) ☐ Tick box if confirmatory PSA was not done

☐☐☐.☐☐ PSA level (ng/mL)*

* Send the de-identified PSA results to the Trial Centre with the patient initials and registration number written on the top of the page.

Treatment Failure

Apply one of the following numbers to answer each question: **1 = yes 2 = no 3 = previously reported 4 = not assessed 5 = inevaluable**

Local Failure

☐ Has a local palpable mass been identified? **If yes (1)**, date (dd/mm/yy) ☐☐☐☐☐☐

☐ Has a biopsy-proven local failure been identified?* **If yes (1)**, date (dd/mm/yy) ☐☐☐☐☐☐
Procedure:_____

☐ Has any other local failure been identified?* **If yes (1)**, date (dd/mm/yy) ☐☐☐☐☐☐
Procedure:_____
Specify: _____

Regional

☐ Has nodal failure been identified? **If yes (1)**, date (dd/mm/yy) ☐☐☐☐☐☐
(Requires CT or MRI of abdomen and pelvis)*
Procedure:_____

☐ Has any other regional failure been identified?* **If yes (1)**, date (dd/mm/yy) ☐☐☐☐☐☐
Procedure:_____
Specify: _____

Distant Failure

☐ Has bone metastasis been identified? **If yes (1)**, date (dd/mm/yy) ☐☐☐☐☐☐
(Requires plain X-ray, bone scan, CT, or MRI)*
Procedure:_____

☐ Has any other distant failure been identified?* **If yes (1)**, date (dd/mm/yy) ☐☐☐☐☐☐
Procedure:_____
Specify: _____

*** Send de-identified report(s) or results for any investigation documenting relapse to the Trial Centre**

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐ (D D M M Y Y)

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Annual Follow– Up Patient Questionnaires [C4Q] (p. 1 of 8)**

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

EORTC Quality of Life Questionnaire - C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Your birthdate: ☐☐☐☐☐☐ (D D M M Y Y) **Today's date:** ☐☐☐☐☐☐ (D D M M Y Y)

Approved for use by the EORTC 2008.

	Not at all	**A little**	**Quite a bit**	**Very Much**
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself, or using the toilet?	1	2	3	4

During the past week:

	Not at all	**A little**	**Quite a bit**	**Very Much**
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Annual Follow– Up Patient Questionnaires [C4Q] (p. 2 of 8)**

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

EORTC Quality of Life Questionnaire - C30 (version 3, continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
17. Have you had diarrhoea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment Caused you financial difficulties?	1	2	3	4

For the following questions, please circle the number between 1 and 7 that best applies to you.

29. How would you rate your overall <u>health</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall <u>quality of life</u> during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Annual Follow– Up Patient Questionnaires [C4Q] (p. 3 of 8)**

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

EORTC Quality of Life Questionnaire - PR25

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you. The information that you provide will remain strictly confidential.

Approved for use by the EORTC 2008.

During the past week:

		Not at all	A little	Quite a bit	Very Much
31.	Have you had to urinate frequently **during the day**?	1	2	3	4
32.	Have you had to urinate frequently **at night**?	1	2	3	4
33.	When you felt the urge to pass urine, did you have to hurry to get to the toilet?	1	2	3	4
34.	Was it difficult for you to get enough sleep, because you needed to get up frequently at night to urinate?	1	2	3	4
35.	Have you had difficulty going out of the house because you needed to be close to a toilet?	1	2	3	4
36.	Have you had any unintentional release (leakage) of urine?	1	2	3	4
37.	Did you have pain when you urinated?	1	2	3	4
38.	Answer this question only if you wear incontinence aid. Has wearing an incontinence aid been a problem for you?	1	2	3	4
39.	Have your daily activities been limited by your urinary problems?	1	2	3	4
40.	Have your daily activities been limited by your bowel problems?	1	2	3	4
41.	Have you had any unintentional release (leakage) of stools?	1	2	3	4
42.	Have you had blood in your stools?	1	2	3	4
43.	Did you have a bloated feeling in your abdomen?	1	2	3	4
44.	Did you have hot flushes?	1	2	3	4
45.	Have you had sore or enlarged nipples or breasts?	1	2	3	4
46.	Have you had swelling in your legs or ankles?	1	2	3	4

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

EORTC Quality of Life Questionnaire - PR25 (continued)

Approved for use by the EORTC 2008.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very Much**
47. Has weight **loss** been a problem for you?	1	2	3	4
48. Has weight **gain** been a problem for you?	1	2	3	4
49. Have you felt less masculine as a result of your illness or treatment?	1	2	3	4
50. To what extent were you interested in sex?	1	2	3	4
51. To what extent were you sexually active (with or without intercourse)?	1	2	3	4

PLEASE ANSWER THE NEXT FOUR QUESTIONS ONLY IF YOU HAVE BEEN SEXUALLY ACTIVE OVER THE LAST 4 WEEKS.

52. To what extent was sex enjoyable for you?	1	2	3	4
53. Did you have difficulty getting or maintaining an erection?	1	2	3	4
54. Did you have ejaculation problems (e.g. dry ejaculation)?	1	2	3	4
55. Have you felt uncomfortable about being sexually intimate?	1	2	3	4

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Annual Follow-up Patient Questionnaires [C4Q] (p. 5 of 8)**

☐☐☐☐☐☐ **Today's date** (dd/mm/yy)

SHIM: Sexual Health Inventory for Men

PATIENT INSTRUCTIONS

Sexual health is an important part of an individual's overall physical and emotional well-being. Erectile dysfunction is one type of very common sexual complaint. There are many different treatment options for erectile dysfunction. This questionnaire is designed to help you and your physician identify if you may be experiencing erectile dysfunction and to potentially discuss treatment options.

Each question has several responses from which you are asked to choose the one that best describes your own situation. Please be sure that you select at least one but only one response by circling the number that best fits your answer.

Over the past six months:

1. How do you rate your confidence that you could get and keep an erection?		VERY LOW	LOW	MODERATE	HIGH	VERY HIGH
		1	2	3	4	5
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	NO SEXUAL ACTIVITY	ALMOST NEVER/ NEVER	A FEW TIMES/ MUCH LESS THAN HALF THE TIME	SOMETIMES (ABOUT HALF THE TIME)	MOST TIMES (MUCH MORE THAN HALF THE TIME)	ALMOST ALWAYS/ ALWAYS
	0	1	2	3	4	5
3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	DID NOT ATTEMPT INTER-COURSE	ALMOST NEVER/ NEVER	A FEW TIMES (MUCH LESS THAN HALF THE TIME)	SOMETIMES (ABOUT HALF THE TIME)	MOST TIMES (MUCH MORE THAN HALF THE TIME)	ALMOST ALWAYS/ ALWAYS
	0	1	2	3	4	5
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	DID NOT ATTEMPT INTER-COURSE	EXTREMELY DIFFICULT	VERY DIFFICULT	DIFFICULT	SLIGHTLY DIFFICULT	NOT DIFFICULT
	0	1	2	3	4	5
5. When you attempted sexual intercourse, how often was it satisfactory for you?	DID NOT ATTEMPT INTER-COURSE	ALMOST NEVER/ NEVER	A FEW TIMES (MUCH LESS THAN HALF THE TIME)	SOMETIMES (ABOUT HALF THE TIME)	MOST TIMES (MUCH MORE THAN HALF THE TIME)	ALMOST ALWAYS/ ALWAYS
	0	1	2	3	4	5

Hospital Anxiety and Depression Scale (HADS)

Today's date (dd/mm/yy)

Clinicians are aware that emotions play an important part in most illnesses. This questionnaire is designed to help the research team know how you and other patients feel. Read each statement below and:

- **Tick the box next to the response** which comes closest to how you have been feeling **in the past week.**
- Please note that your doctor will not routinely be provided with your completed questionnaire. If you have any concerns you would like to address, please tell your doctor.

Don't take too long over your replies. Your immediate reaction to each item will probably be more accurate

During the past week:

1. I feel tense or "wound up"

- ☐ Most of the time
- ☐ A lot of the time
- ☐ From time to time, occasionally
- ☐ Not at all

2. I still enjoy the things I used to enjoy

- ☐ Definitely as much
- ☐ Not quite so much
- ☐ Only a little
- ☐ Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen

- ☐ Very definitely and quite badly
- ☐ Yes, but not too badly
- ☐ A little, but it doesn't worry me
- ☐ Not at all

4. I can laugh and see the funny side of things

- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much now
- ☐ Not at all

5. I feel as if I am slowed down

- ☐ Nearly all the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

6. I get a sort of frightened feeling like "butterflies" in the stomach

- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often
- ☐ Very often

7. I have lost interest in my appearance

- ☐ Definitely
- ☐ I don't take as much care as I should
- ☐ I may not take quite as much care
- ☐ I take just as much care as ever

8. I feel restless as if I have to be on the move

- ☐ Very much indeed
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all

Continue on next page, please

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

Hospital Anxiety and Depression Scale (HADS)

Continued from previous page

During the past week:

9. Worrying thoughts go through my mind

- ☐ A great deal of the time
- ☐ A lot of the time
- ☐ Not too often
- ☐ Very little

10. I feel cheerful

- ☐ Never
- ☐ Not often
- ☐ Sometimes
- ☐ Most of the time

11. I can sit at ease and feel relaxed

- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

12. I look forward with enjoyment to things

- ☐ As much as I ever did
- ☐ Rather less than I used to
- ☐ Definitely less than I used to
- ☐ Hardly at all

13. I get sudden feelings of panic

- ☐ Very often indeed
- ☐ Quite often
- ☐ Not very often
- ☐ Not at all

14. I can enjoy a good book or radio or television programme

- ☐ Often
- ☐ Sometimes
- ☐ Not often
- ☐ Very seldom

Do you know the result from your most recent PSA test? ☐ **Yes** ☐ **No**

Now check that you have answered all 14 questions

Thank you

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Annual Follow– Up Patient Questionnaires [C4Q] (p. 8 of 8)**

☐ **Year 1** ☐ **Year 2** ☐ **Year 3** ☐ **Year 4** ☐ **Year 5** ☐ **Year 6**

☐ **Year 7** ☐ **Year 8** ☐ **Year 9** ☐ **Year 10** ☐ **Other:**_____

Health Resource Use Questionnaire

Please answer the questions below, which relate to admissions to hospital during the past year.

1. Have you been admitted to hospital during the last 12 months?

☐ Yes ☐

Do not complete the remainder of this form.

2. If yes, how many times were you admitted to hospital? ☐

3. Please describe the reason you were admitted to hospital, and the number of nights you spent in hospital. Complete a separate line for each admission if you were admitted more than once.

1. Reason for admission:_____

Number of nights in hospital for admission **1**: ☐

2. Reason for admission:_____

Number of nights in hospital for admission **2**: ☐

3. Reason for admission:_____

Number of nights in hospital for admission **3**: ☐

4. Reason for admission:_____

Number of nights in hospital for admission **4**: ☐

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Central Pathology Review [P] (p. 1 of 1)**

Central Pathology Review Submission

To be completed post-randomisation

Date slides sent: (dd/mm/yy) ☐☐☐☐☐☐

REMINDER:
When de-identifying slides:
1. Do not place any label s on the underside of the slide.
2. Do not cover up the reference numbers on each slide that correspond to the report.

Checklist:

☐ **Slides from the patient's radical prostatectomy specimen:**

Number of slides submitted: _____

If all prostate specimen slides used for the original diagnosis are not submitted, specify reason:

_____

_____

_____

☐ **Pathology report**

Return address for slides:

Name: _____

Position: _____

Address: _____

Address:_____

Email: _____ Tel: _____

Please send the original completed form to the Coordinating Trial Centre, and enclose a copy with the slide shipment.

Address for all sites except those located in Western Australia:

Professor Warick Delprado
Director - Histopathology
Douglass Hanly Moir Pathology
14 Giffnock Avenue
Macquarie Park NSW 2113

Address for all sites based in Western Australia:

Dr Ronnie Cohen
PO Box 1337
West Leederville
Western Australia 6901

Please contact the Trial Centre for the RAVES Central Pathology Review Slide Labelling, Packaging and Shipping Guidelines

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐ (D D M M Y Y)

Biological Sub-studies

Please document the patient's consent to the biological sub-studies and send to the Trial Centre following consent. Re-send the fully completed form after the shipment(s) are done.

1. Has the patient been offered participation in the two optional Biological Sub-studies? ☐ Yes ☐

If no, please document the reason and *do not complete the remainder of this form*.

Reason: _____

2. If yes, has the patient consented to either or both of the sub- ☐ Yes ☐

If no, *do not complete the remainder of this form.*

If the patient has consented to either or both sub-studies, please indicate the scope of consent below:

3. RAVES Genetic Study (saliva collection plus questionnaire) ☐ Yes ☐

If no, go to question 4.

Date of consent (dd/mm/yy): ☐☐☐☐☐☐

Has the saliva sample been collected? ☐ Yes ☐

Saliva sample shipment date (dd/mm/yy): ☐☐☐☐☐☐

Has the patient completed the RAVES Genetic Study questionnaire? ☐ Yes ☐

If yes, please attach completed questionnaire.

If no, please document reason:_____

4. RAVES Tissue Banking Study (tumour block) ☐ Yes ☐

Date of consent (dd/mm/yy): ☐☐☐☐☐☐

Tumour block shipment date (dd/mm/yy): ☐☐☐☐☐☐

Please contact the Trial Centre for additional details regarding sample collection, processing, storage, and submission.

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐ (D D M M Y Y)

TROG 08.03 Radiotherapy Adjuvant Versus Early Salvage (RAVES study)	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	Adverse Events (Supplemental Form) [AE] (p. 1 of 1)

Other Adverse Events

- Complete this form only if there are more than two Other Adverse Events to be documented on forms **[A1]**, **[C1]**, **[C2]**, **[C3]**, or **[C4]**.
- Please enter the grade of each event in the box.
- Refer to CTCAE v 3.0 for Adverse Event diagnosis terminology (http://ctep.cancer.gov/reporting/

Clinic visit date: (dd/mm/yy) ☐☐☐☐☐☐

☐ **Specify:**____________________

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

☐ **Specify:**____________________

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

☐ **Specify:**____________________

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

☐ **Specify:**____________________

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

☐ **Specify:**____________________

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

☐ **Specify:**____________________

0 = None
1 = Mild Adverse Event
2 = Moderate Adverse Event
3 = Severe and undesirable Adverse Event
4 = Life-threatening or disabling Adverse Event

Page _____of _____

Form completed by (print)________________________________

(signed)________________________________ Date: ☐☐☐☐☐☐ D D M M Y Y

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Patient Withdrawal Form [Y1] (p. 1 of 1)**

Date of patient withdrawal (dd/mm/yy):

☐☐☐☐☐☐

Please tick the appropriate box:

☐ Withdrawal of consent by patient

☐ Partial withdrawal (Please notify Trial Centre in writing)

☐ Investigator's decision

☐ Other (specify): _____

Please refer to protocol section 6.3 for additional guidelines regarding patient withdrawals.

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐ (D D M M Y Y)

TROG 08.03 **R**adiotherapy **A**djuvant **V**ersus **E**arly **S**alvage **(RAVES study)**	Patient Initials ☐☐☐ Reg Number ☐☐☐☐☐☐☐	**Death Form [Y2] (p. 1 of 1)**

Date of death (dd/mm/yy):

☐☐☐☐☐☐

Primary cause of death (choose only one):

☐ Prostate cancer (documented regional, nodal, or distant failure)

☐ Treatment related

☐ Other malignancy: _____

☐ Other (specify): _____

Form completed by (print)_____

(signed)_____ Date: ☐☐☐☐☐☐ (D D M M Y Y)