RTOG
Radiation Therapy Oncology Group

RTOG Report to ATC

ATC • AdvancedTechnologyConsortium
Providing support in quality assurance and data management for radiation therapy clinical trials

RTOG
Radiation Therapy Oncology Group

Image-Guided Therapy Center
An Advanced Technology Clinical Trials QA and Support Center

RPC Radiological Physics Center
Excellence through Quality Assurance

Resource Center for Emerging Technologies
Radiation Oncology, University of Florida

QARC
QUALITY ASSURANCE REVIEW CENTER

ACR
AMERICAN COLLEGE OF RADIOLOGY

RTOG Headquarters Report

RTOG Protocols supported by the ATC (as of June 16, 2006)

- 3D-CRT Protocols
  - Closed Protocols
    - RTOG 0319: Phase I/II Study to Evaluate 3D-CRT Irradiation Confined to Region of the Lumpectomy Cavity for Stage I/IIA Breast Carcinoma
      - 31 institutions credentialed; 58 patients registered to study; Target Accrual – 46 (study closed, data analysis continues)
    - RTOG 93-11: Phase I/II Dose Escalation Study Using 3D Conformal Radiation Therapy in Patients with Inoperable NSCLC
      - 27 institutions credentialed; 180 patients registered to study (study closed, data analysis continues)
    - RTOG 94-06: Phase I/II Dose Escalation Study Using 3D Conformal Radiation Therapy for Adenocarcinoma of the Prostate
      - 54 institutions credentialed; 1084 patients registered to study (study closed, data analysis continues)

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- 3D-CRT Protocols (cont.)
  - RTOG 98-03: Phase I/II Radiation Dose Escalation Study Applying Conformal Radiation Therapy in Supratentorial Glioblastoma Multiforme
    - 46 institutions credentialed; 210 patients registered to study; (study closed, data analysis continues)
  - Active Protocols
    - RTOG 0117: Phase I/II Dose Intensification Study using 3D-CRT and Concurrent Chemotherapy for Patients with Inoperable, Non-Small Cell Lung Cancer
      - 47 institutions credentialed; 41 patients registered to study; Target Accrual – 73
    - RTOG 0126: Phase III Randomized Study of High Dose 3D-CRT/IMRT versus Standard Dose 3D-CRT/IMRT in Patients treated for Localized Prostate Cancer (9/18/03 IMRT allowed)
      - 135 institutions credentialed (81 IMRT); 933 patients registered to study; Target Accrual – 1520

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- 3D-CRT Protocols (cont.)
  - RTOG 0413/NSABP B39: Phase III Study of Whole Breast RT versus Partial Breast Irradiation
    - 322 institutions credentialed (264-3DCRT, 189 Mammosite, 32 Multi-Cath); 1446 patients registered to study (488 3DCRT, 158 Mammosite, 62 Multi-Cath)
  - RTOG 0415: Phase III study of Hypofractionated 3D-CRT/IMRT versus Conventionally Fractionated 3D-CRT/IMRT in Patients Treated for Favorable-Risk Prostate Cancer
    - 72 institutions IMRT credentialed; 0 patients registered to study; Target Accrual – 1067
  - RTOG 0515: A Comparative study of Gross Tumor Volume Definition with or without PET Fusion for Patients with Non-Small Cell Lung Carcinoma, 3D-CRT.
    - 0 institutions credentialed; 0 patients registered to study; Target Accrual – 48

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- 3D-CRT Protocols (cont.)
  - RTOG 0521: PhaseIII study of Androgen Suppression (AS) and Radiation Therapy (RT) vs AS and RT followed by Chemotherapy with Docetaxel and Prednisone for Localized, High-Risk Prostate Cancer
    - 74 institutions credentialed (69 IMRT Phantom, 4 IMRT Benchmark, 1 3D-CRT); 18 patients registered to study; Target Accrual – 600
  - RTOG 0522: Phase III study of Concurrent Accelerated Radiation and Cisplatin Versus Concurrent Accelerated Radiation, Cisplatin, and Cetuximab (C225) [Followed by Surgery for Selected Patients] for Stage III and IV Head and Neck Carcinomas
    - 49 institutions IMRT credentialed; 14 PET Participants; 21 patients registered to study; Target Accrual – 720

- 3D-CRT Developing Protocols
  - RTOG 0617: Phase II/III study of Cetuximab in Combination with Concurrent 3D-CRT and Chemotherapy in Patients with Stage IIA/B Non-Small Cell Lung Cancer (NSCLC)

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- IMRT Protocols
  - Closed Protocols
    - RTOG 0022: Phase I/II Study of Conformal and Intensity Modulated Irradiation for Oropharyngeal Cancer
      - 36 institutions credentialed; 69 patients registered to study (study closed, data analysis continues)
    - RTOG 0225: Phase I/II Study of Conformal and Intensity Modulated Irradiation for Nasopharyngeal Cancer
      - 36 institutions credentialed; 68 patients registered to study (study closed, data analysis continues)
  - Active Protocols
    - RTOG 0126: Phase III Randomized Study of High Dose 3D-CRT/IMRT versus Standard Dose 3D-CRT/IMRT in Patients treated for Localized Prostate Cancer (9/18/03 IMRT allowed)
      - 135 institutions credentialed (81 IMRT); 933 patients registered to study; Target Accrual – 1520

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- IMRT Protocols (cont.)
  - RTOG 0234: A Phase II Study of Surgery followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of the Head and Neck
    - 52 institutions credentialed; 170 patients registered to study; Target Accrual – 230
  - RTOG 0415: Phase III study of Hypofractionated 3D-CRT/IMRT versus Conventionally Fractionated 3D-CRT/IMRT in Patients Treated for Favorable-Risk Prostate Cancer
    - 72 institutions IMRT credentialed; 0 patients registered to study; Target Accrual – 1067
  - RTOG 0418: Phase II Study of Intensity Modulated Radiation Therapy (IMRT) to the Pelvis +/- Chemotherapy for Post-Operative Patients with Either Endometrial or Cervical Carcinoma
    - 55 institutions credentialed; 1 patient registered to study; Target Accrual – 92
  - RTOG 0421: Phase III Head & Neck: Re-irradiation (GCSF)/IMRT
    - 40 institutions credentialed; 13 patients registered to study, Target Accrual – 240

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- IMRT Protocols (cont.)
  - RTOG 0521: PhaseIII study of Androgen Suppression (AS) and Radiation Therapy (RT) vs AS and RT followed by Chemotherapy with Docetaxel and Prednisone for Localized, High-Risk Prostate Cancer
    - 74 institutions credentialed (69 IMRT Phantom, 4 IMRT Benchmark, 1 3D-CRT); 18 patients registered to study; Target Accrual – 600
  - RTOG 0522: Phase III study of Concurrent Accelerated Radiation and Cisplatin Versus Concurrent Accelerated Radiation, Cisplatin, and Cetuximab (C225) [Followed by Surgery for Selected Patients] for Stage III and IV Head and Neck Carcinomas
    - 49 institutions IMRT credentialed; 14 PET Participants; 21 patients registered to study; Target Accrual – 720

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- IMRT Developing Protocols (cont.)
  - RTOG 0435: Phase III Study Unresectable H&N; IMRT/3D-CRT
  - RTOG 0529: Phase II Study Trial Evaluating Capecitabline, Cisplatin and IMRT (plus Cetuximab) in Carcinoma of the Anal Canal
  - RTOG 0534: Phase III trial of PBRT alone vs NC-STAD+PBRT vs NC-STAD+WPRT for Patients with a Rising PSA after Radical Prostatectomy, IMRT
  - RTOG 0539: Phase II Feasibility study of IMRT for Intermediate- and High-Risk Meningiomas, and of Observation for Low-Risk Meningiomas
  - RTOG 0615: Phase II study of Radiotherapy (IMRT) and Concurrent Cisplatin (CDDP) followed by Adjuvant Cisplatin and 5FU + Bevacizumab (BV) for Patients with Locally Advanced Nasopharyngeal Carcinoma (NPC)

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- IMRT Protocols (cont.)
  - Symptom Management
    - Phase III Dose Escalation Trial for Non-Operable Spinal Cord Compression due to Metastasis Comparing 30 Gy versus 39 Gy Utilizing SBRT/IMRT Techniques
  - Concepts
    - Phase III Study Hypofractionated Intensity Modulated Radiation Therapy (IMRT) with Incorporated Boost for early Stage Breast Cancer
      - Gary M. Freedman (Radiation Oncology)
    - Phase III Study Trial of Moderate Dose IMRT + Chemotherapy versus Conventional Dose IMRT for Resected Intermediate Risk Head and Neck Cancer
      - Mitchell Machtay, M.D.
    - Phase I/II Study Trial of FDG-PET/CT Guided Intensity Modulated Radiaton of Oropharyngeal Cancer
      - Dian Wang, M.D., Ph.D.

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- Brachytherapy Protocols
  - Active Protocols
    - RTOG 0116: Phase I/II Study of Extended Field External Irradiation and Intracavitary Brachytherapy Combined with Chemotherapy (Weekly Cisplatin-Arm 1) and Amifostine (Weekly Cisplatin and Amifostine-Arm 2) in Carcinoma of the Cervix with Positive Para-Aortic or High Common Iliac Lymph Nodes
    - RTOG 0232: Phase III Study Comparing Combined External Beam Radiation & Transperineal Interstitial Permanent Brachytherapy with Brachytherapy alone (IMRT added 6/2005)
      - 69 institutions Brachytherapy credentialed (66 IMRT); 210 patients registered to study; Target Accrual – 1520

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- Brachytherapy Protocols (cont.)
  - RTOG 0321: Phase I/II Prostate: High Dose Brachytherapy and External Beam
    - 17 institutions credentialed; 129 patients registered to study; Target Accrual – 110
  - RTOG 0413/NSABP B39: Phase III Study of Whole Breast RT versus Partial Breast Irradiation
    - 322 institutions credentialed (264-3DCRT, 189 Mammosite, 32 Multi-Cath); 1446 patients registered to study (488 3DCRT, 158 Mammosite, 62 Multi-Cath)

- Developing Protocols
  - RTOG 0417: Phase II Study of Iressa in Combination with Definitive RT and Cisplatin Chemo in Locally Advanced Cervical Cancer, Optional Brachy/CT
  - RTOG 0526: Sequential Cohort Phase II trial of Two Dose Levels of Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Adenocarcinoma following External Beam Radiotherapy

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 16, 2006)

- SBRT Protocols
  - Active Protocols
    - RTOG 0236: Phase II Study of Extracranial Stereotactic Radioablation in Treatment of Patients with Medically Inoperable Stage in NSCLC
      - 9 institutions credentialed; 5 Pending; 46 patients registered to study; Target Accrual – 52
    - RTOG 0438: Phase I Trial of Highly Conformal Radiation Therapy for Patients with Unresectable Hepatobiliary Cancer and Liver Metastases
      - 1 institution credentialed; 1 Pending; 1 patient registered to study; Target Accrual – 18
  - Developing
    - RTOG 0618: Phase II Trial of Sterertactic Body Radiation Therapy (SBRT) for Patient with Operable Early Stage Non-Small Cell Lung Cancer

RTOG
Radiation Therapy Oncology Group

ATC Review Workstation at RTOG HQ's in Philadelphia, PA

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IMAGE-GUIDED THERAPY CENTER [ITC]

Protocol RTOG-P0126 Dose-Volume Analysis QA Review for: Cross Cancer Institute

Patient Initials: P. W. Case #: 9 0126c0009

Group: 2 Dose Level: _____ Rx Dose: 72.93 (See Appendix I)

A. TARGET VOLUME ANALYSIS

Target	Volume (cc)	Percent Volume Receiving ≥ Rx Dose(D1)		ICRU Ref Dose (Gy)	2% Max Dose (Gy)	Min Dose (Gy)	Mean Dose (Gy)	Coverage Score
PTV1	310	100	% ≥ 55.8 Gy	73.0	74.4	57	73	1
PTV2	242.4	100	% ≥ 70.2 Gy		74.4	68	73.4	1
PTV	---	---	% ≥ --- Gy	"	---	---	---	---
CTV	113	99.3	% ≥ 70.2 Gy	"	74.4	65.4	74	1
GTV	89	100	% ≥ 70.2 Gy		74.2	72	74	1

Target Volume Coverage Score: 1 : $V_{RxD} \geq 98\%$, , 2 : $95\% \leq V_{RxD} < 98\%$, 3 : $V_{RxD} < 95\%$ or $V_{RxDCTVorGTV} < 100\%$.

B. DOSE HETEROGENEITY(DH) And CONFORMITY

	Conformity Index*	Dose Heterogeneity	Dose Heterogeneity Score
PTV(2)	---	1.02 ✓	1

Dose Heterogeneity (2% Max Dose/Rx dose): 1 : DH ≤ 1.07, 2 : 1.07 < DH ≤ 1.10, 3 : DH > 1.10

C. NORMAL STRUCTURE ANALYSIS (See appendix II for standard structure names)

Normal Tissue	Volume (cc)	% Vol ≥ Ref Dose (D1)	Ref Dose (D1) (Gy)	Max Dose (Gy)	Mean Dose (Gy)
Bladder	112	50	65.0	74.4	61.1
Left Femur	192	0	52.0	41	34.4
Right Femur	187	0	52.0	42	33.0
Rectum	87	30	60.0	74.3	49
Penile Bulb	9.3	55.2	70.0	73	68
Unspecified Tissue	23710	0.9	58.9	74.4	8

Reviewed by:	lquarles	Date:	12-1-04

After completing this form please FAX to the ITC: (314)747-5423.

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Radiation Therapy Oncology Group

Plan Summary

Image-guided Therapy Center

Protocol: 0126 Case: 0009
Plan Description: composite plan (Plan ID: totalhetero) Plan Date: Mon Nov 18 11:06:31 200

Calculation Volume Size: Width(x) 42.3(cm) x Depth(y) 28.8(cm) x Height(z) 26.1(cm)[142 x 145 x 88]
Center: X = 0.8, Y = -2.1, Z = 3.1 SITE: Prostate MD: cross

	1 (_____)	2 (_____)	3 (_____)	4 (_____)
Beam # (Field):				
Description:	>Ant(B1)	>Post(B2)	>Right(B3)	>Left(B4)
Machine ID:	15MVXRAYS	15MVXRAYS	15MVXRAYS	15MVXRAYS
Setup Distance:	100.0 cm SAD	100.0 cm SAD	100.0 cm SAD	100.0 cm SAI
Isocenter Depth:	ODI(_____) 11.4 cm	ODI(_____) 12.5 cm	ODI(_____) 20.4 cm	ODI(_____) 20.1 cr
Isocenter Coord:	0.8, -3.9, 2.7 cm	0.8, -3.9, 2.7 cm	0.8, -3.9, 2.7 cm	0.8, -3.9, 2.7 cr
Entry Point:	0.8, -3.9, 14.1 cm	0.8, -3.9, -9.8 cm	-19.5, -3.9, 2.7 cm	20.9, -3.9, 2.7 cr
Coll. Width(cone):	X1: 5.0 cm	X1: 5.2 cm	X1: 4.8 cm	X1: 4.0 cr
	X2: 5.0 cm	X2: 5.1 cm	X2: 4.1 cm	X2: 5.0 cr
Coll. Length(cone):	Y1: 6.3 cm	12.5 cm	12.5 cm	Y1: 6.3 cr
	Y2: 6.1 cm			Y2: 6.2 cr
Collimator Angle:	180 degrees	180 degrees	180 degrees	180 degree
Couch Angle:	180 degrees	180 degrees	180 degrees	180 degree
Head/Foot Orient:	Head to Gantry	Head to Gantry	Head to Gantry	Head to Gantry
Gantry Angle:	180 degrees	360 degrees	270 degrees	90 degree
Rotation Arc:	x x x	x x x	x x x	x x x
Comp Filter Used:	NO COMPENSATOR			
Bolus Used:	NO BOLUS USED	NO BOLUS USED	NO BOLUS USED	NO BOLUS USEI
Wedge(Normal):				
Wedge Orientation:				
ICRU Ref Pt (cGy):	1739 TD	1739 TD	1159 TD	1162 TI
Films Link/Aligned:	_____	_____	_____	_____

[Max Point Dose = 7472]
Page# 1 of 2 Plan Info (Total ICRU Dose: 7296 [Sampled Dose Value: 7300])

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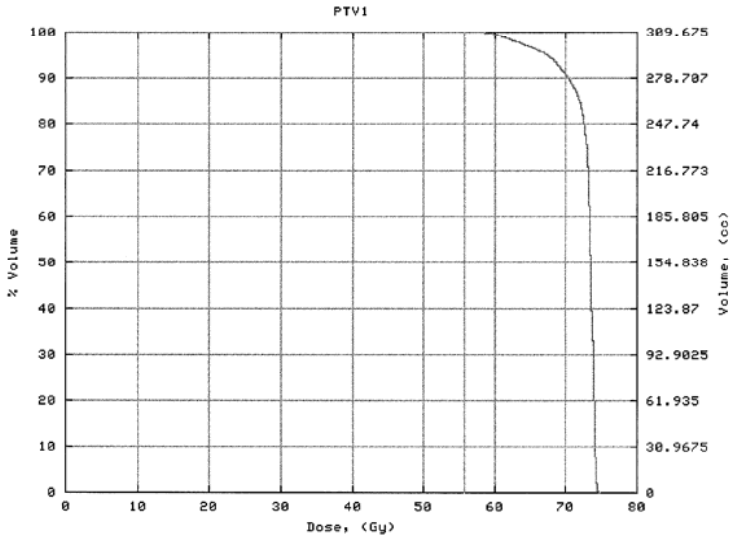
Image-guided Therapy Center **Remote Review Tool**

PROTOCOL: 0126
CASE: 0009
STRUCTURE: PTV1



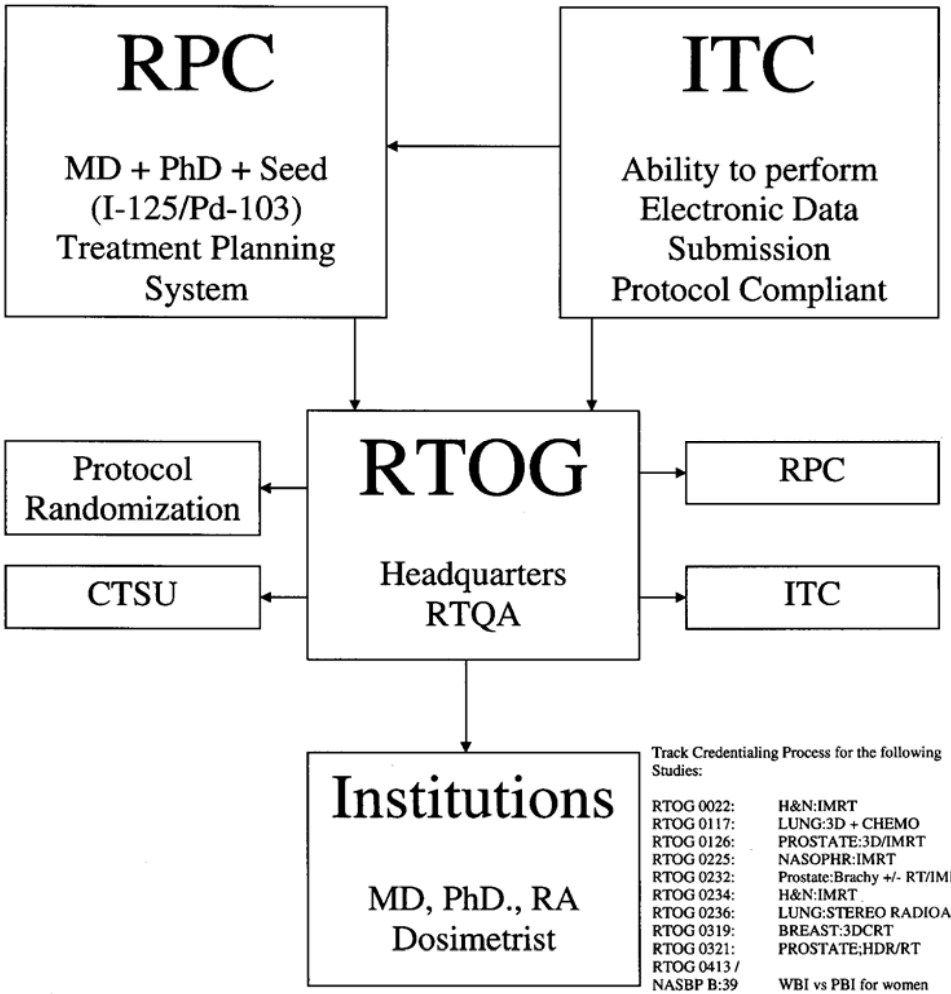
Plan ID	% Vol >= D1 (55.8 Gy)	% Vol >= Dref (55.8 Gy)	Max Dose (Gy)	Min Dose (Gy)	Mean Dose (Gy)
totalhetero	100.0	100.0	74.7	56.9	72.7

Calculated: Fri Apr 16 14:08:26 2004 (/web/RTOP/patient/0126c0009/olddump.dat)
Printed Fri Jan 14 09:48:51 CST 2005

Close window

RTOG
Radiation Therapy Oncology Group

RTOG 0232
Prostate – Brachytherapy
IMRT
Credentialing Process Notification



Track Credentialing Process for the following Studies:

RTOG 0022:	H&N:IMRT
RTOG 0117:	LUNG:3D + CHEMO
RTOG 0126:	PROSTATE:3D/IMRT
RTOG 0225:	NASOPHR:IMRT
RTOG 0232:	Prostate:Brachy +/- RT/IMRT
RTOG 0234:	H&N:IMRT
RTOG 0236:	LUNG:STEREO RADIOAB
RTOG 0319:	BREAST:3DCRT
RTOG 0321:	PROSTATE;HDR/RT
RTOG 0413 / NASBP B:39	WBI vs PBI for women
RTOG 0418:	CERVIX
RTOG 0421	H&N:RE-IRRADIATION
RTOG 0438:	GI:STEROTACTIC RADIOAB
RTOG 0515:	NSCLC: Vol. def. PET
RTOG 0521:	PROSTATE:3DCRT/IMRT
RTOG 0522:	H&N:3DCRT/IMRT (PET Opt.)

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Institution Approval Letter for RTOG – 0232

RTOG
Radiation Therapy
Oncology Group

Date

Principal Investigator, M.D.
Institution – RTOG # ; NCI # ; RTF #
Department of Radiation Oncology
Address
City, State, Zip

Dear Dr. :

The Credentialing process by the Radiological Physics Center (RPC) for prostate brachytherapy and Electronic Data Submission to the Image-Guided Therapy Center (ITC) for RTOG-0232 – A Phase III Study Comparing Combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy with Brachytherapy Alone for Selected Patients with Intermediate Risk Prostatic Carcinoma has been successfully met.

You are now approved to enter patients onto RTOG Prostate Implant Protocol 0232. A change in Radiation Oncologist, Physicist, treatment planning system, nuclide or seed model will require recredentialing by the RPC and/or ITC.

Sincerely,

Elizabeth A. Martin
Director, R.T. Quality Assurance

cc: Physicist
Research Associate
RTOG Randomization
ITC
RPC
CTSU

a leader in defining more effective cancer therapies

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1818 Market Street – Suite 1600, Philadelphia, PA 19103 www.rtog.org (215) 574-3189 or (800) 227-5463, ext. 4189

Supported by the Division of Cancer Treatment and Diagnosis, National Cancer Institute

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RTOG
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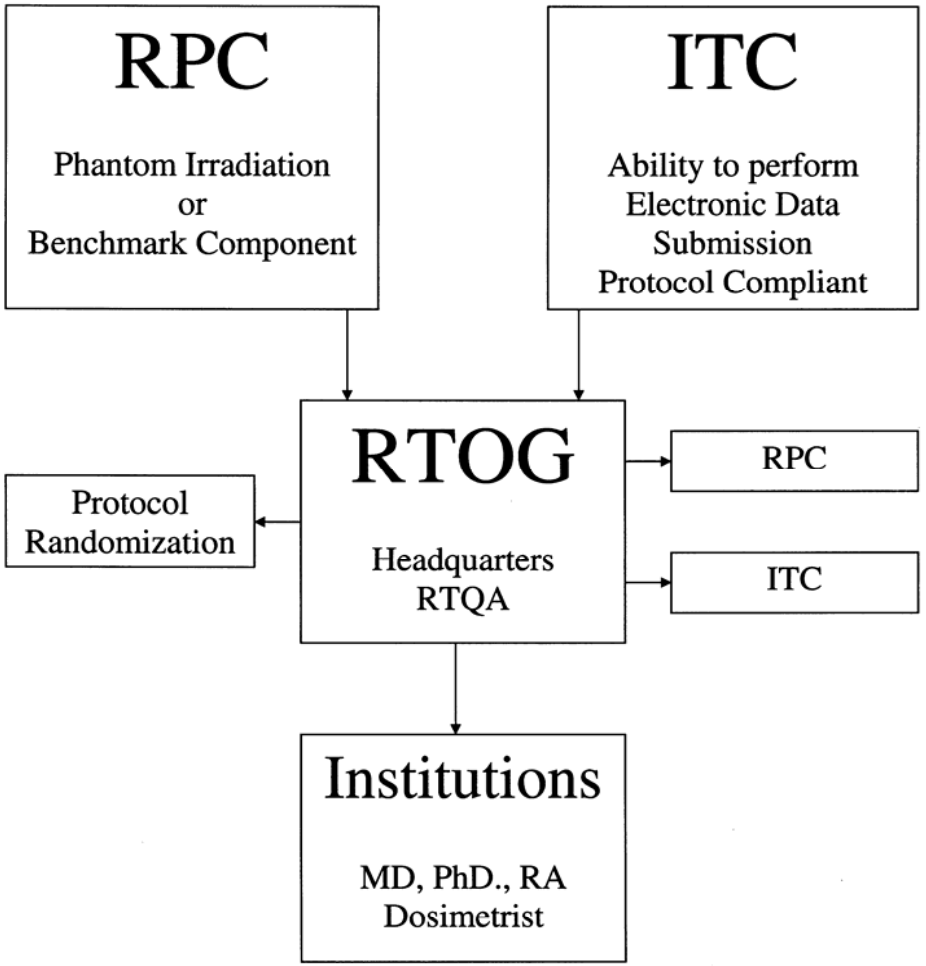
RTOG 0234
IMRT H&N – CHEMORT & C225
Credentialing Process Notification



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Institution Approval Letter for RTOG – 0234

RTOG
Radiation Therapy
Oncology Group

Date

Principle Investigator, M.D.
Institution – RTOG ; NCI # ; RTF #
Address
City, State, Zip

Dear Dr.:

The IMRT Head and Neck Benchmark component of the credentialing process reviewed by the Radiological Physics Center (RPC) and the ability to perform electronic data submission for RTOG 0234 – Phase II Randomized Trial of Surgery followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of the Head and Neck has been successfully met.

You are now approved to enter patients onto RTOG Protocol 0234.

If in the future you wish to enter patients onto other RTOG protocols using IMRT requiring the Benchmark Component of the credentialing process contact RTOG Headquarters for eligibility to participate.

Sincerely,

Elizabeth A. Martin
Director, R.T. Quality Assurance

cc: Physicist
Research Associate
RTOG Randomization
ITC
RPC

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Supported by the Division of Cancer Treatment and Diagnosis, National Cancer Institute

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RTOG 0236
Phase II Trial of Stereotactic Body Radiation Therapy (SBRT) in the Treatment of Patients with Medically Inoperable Stage I/II Non-Small Cell Lung Cancer

SCHEMA

REGISTER

Stereotactic Body Radiation Therapy (SBRT), 20 Gy per fraction for 3 fractions over 1½-2 weeks, for a total of 60 Gy

Institution Approval Letter for RTOG – 0236

RTOG
Radiation Therapy
Oncology Group

Date

, M.D.
Institution – RTOG # ; NCI # ; RTF #
Department of Radiation Oncology
Address
City, State, Zip

Dear Dr. :

Your institution has successfully completed the Lung Phantom Irradiation Dosimetry Test, Facility Questionnaire, Immobilization/Localization and Respiration Control Systems Test.

You can now enter patients on to RTOG Protocol 0236.

The Dry Run / Rapid Review will be reviewed on the actual case. The dosimetry will be reviewed and the study chair will determine if this and the drawn structures are protocol compliant and sufficient for the patient to go ahead with treatment. Since this test case (Dry Run / Rapid Review) is the first case entered from your institution, the scanning parameters, the structure outline, and the dosimetry will have to be according to protocol in order to pass the Dry Run / Rapid Review PRIOR TO DELIVERING ANY PROTOCOL TREATMENT. The plan will be reviewed centrally at the ITC, and suggestions regarding protocol compliance will be forwarded to your institution. The treatment plan for subsequent patients enrolled from your site will not be required to be centrally reviewed prior to treatment, but will be reviewed for protocol compliance at a later date.

However, the Immobilization/Localization and Respiration Control Systems Test must be repeated for the first 4 cases submitted from your institution and the results reviewed by James Galvin, D.Sc., Medical Physics Co-Chair. The data for the first patient entered must be reviewed and approved before you enter a second patient, and the results of the Immobilization/Localization and Respiration Control Systems Study for this patient must be approved prior to entering a third patient. At this point, any additional number of patients can be entered. You will have to send forward the results of the Immobilization/Localization and Respiration Control Systems Study for the third and fourth patients entered. Please refer to the attached information.

Sincerely,

Elizabeth A. Martin
Director, R.T. Quality Assurance

cc: Physicist
Research Associate
James Galvin, D.Sc.
RTOG Randomization
ITC
RPC

a leader in defining more effective cancer therapies

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Supported by the Division of Cancer Treatment and Diagnosis, National Cancer Institute

RTOG Protocol 0236

Immobilization/Localization and Respiration Control Systems Study

This study must be performed on a single patient, and approval received from RTOG Headquarters, before you attempt to enter your first patient on RTOG Protocol 0236. A similar study must be performed for the first patient entered on this protocol, and approval must be received from Headquarters prior to entering a second patient. This same procedure must be followed before entering a third patient. A fourth patient can be entered at the same time as the third, as well as, additional patients can also be entered at this time. However, the results of the Immobilization/Localization and Respiration Control Systems Study for the third and fourth patients entered on this protocol must be sent forward for review as quickly as possible. This information will be analyzed, but no further communication will be sent from RTOG Headquarters except in those situations where problems are detected. If problems are found, you could be asked to stop entering patients until the issue is resolved. In situations where no problems are found, the Immobilization/Localization and Respiration Control Systems Study will be discontinued after you have sent the data forward for the fourth patient you have entered on this protocol.

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Radiation Therapy Oncology Group

Status of RTOG 0236

Institution	RPC Acceptable	Letter Sent	Immobilization Acceptable	IRB
Cleveland Clinic Foundation	Yes	05/01/2006	Yes	07/01/2006
Duke University Medical Center	Yes	Pending		
Indiana University	Yes	12/30/2004	Yes	04/26/2007
Princess Margaret Hospital	Yes	12/30/2004	Yes	12/16/2006
Richard Roudebush VA Medical Center	Yes	Pending		05/25/2006
Thomas Jefferson University	Yes	03/03/2005	Yes	08/10/2006
University of Florida	Yes	Pending		11/16/2005
University of Rochester	Yes	11/07/2005	Took 1st case off protocol	08/25/2006
University of Texas MD Anderson Cancer Center	Yes	12/23/2005	Yes	11/16/2006
University of Wisconsin Hospital	Yes	09/07/205	Waiting for 1st case	10/09/2006
UT Southwestern Medical Center	Yes	05/20/2005	Yes	08/26/2006
Virginia Commonwealth University	Yes	Pending		
Wake Forest University Health Sciences	Yes	Pending		
Washington University	Yes	12/30/2004	Yes	03/22/2007

Total number of institutions = 9 (2 of them waiting for 1st case); 5 pending

ACR American College of Radiology

RTOG 0438
Phase I Trial of Highly Conformal Radiation Therapy for Patients with Liver Metastases

SCHEMA

All Patients will receive 10 fractions Monday-Friday for 2 weeks at the following levels; Dose escalation by 0.5 Gy to maximum of 50 Gy, as follows:

Dose level	Level I	†Level II	Level III	Level IV
Dose per fraction	3.5 Gy	4.0 Gy	4.5 Gy	5.0 Gy
Total dose	35 Gy	40 Gy	45 Gy	50 Gy

†Protocol Treatment Begins at Level II

Institution Approval Letter for RTOG – 0438

RTOG
Radiation Therapy
Oncology Group

Date

, M.D.
Institution – RTOG # ; NCI # ; RTF #
Department of Radiation Oncology
Address
City, State, Zip

Dear Dr. :

Your institution has successfully completed the Liver Phantom Irradiation Dosimetry Test, Facility Questionnaire, Immobilization/Localization and Respiration Control Systems Test.

You can now enter patients on to RTOG Protocol 0438.

The Dry Run / Rapid Review will be reviewed on the actual case. The dosimetry will be reviewed and the study chair will determine if this and the drawn structures are protocol compliant and sufficient for the patient to go ahead with treatment. Since this test case (Dry Run / Rapid Review) is the first case entered from your institution, the scanning parameters, the structure outline, and the dosimetry will have to be according to protocol in order to pass the Dry Run / Rapid Review PRIOR TO DELIVERING ANY PROTOCOL TREATMENT. The plan will be reviewed centrally at the ITC, and suggestions regarding protocol compliance will be forwarded to your institution. The treatment plan for subsequent patients enrolled from your site will not be required to be centrally reviewed prior to treatment, but will be reviewed for protocol compliance at a later date.

However, the Immobilization/Localization and Respiration Control Systems Test must be repeated for the first 2 cases submitted from your institution and the results reviewed by James Galvin, D.Sc., Medical Physics Co-Chair. The data for the first patient entered must be reviewed and approved before you enter a second patient, and the results of the Immobilization/Localization and Respiration Control Systems Study for this patient must be approved prior to entering a third patient. At this point, any additional number of patients can be entered. You will have to send forward the results of the Immobilization/Localization and Respiration Control Systems Study for the third and fourth patients entered. Please refer to the attached information.

Sincerely,

Elizabeth A. Martin
Director, R.T. Quality Assurance

cc: Physicist
Research Associate
James Galvin, D.Sc.
RTOG Randomization
ITC
RPC

a leader in defining more effective cancer therapies

1818 Market Street – Suite 1600, Philadelphia, PA 19103 www.rtog.org (215) 574-3189 or (800) 227-5463, ext. 4189

Supported by the Division of Cancer Treatment and Diagnosis, National Cancer Institute

RTOG Protocol 0438

Immobilization/Localization and Respiration Control Systems Study

This study must be performed on a single patient, and approval received from RTOG Headquarters, before you attempt to enter your first patient on RTOG Protocol 0438. A similar study must be performed for the first patient entered on this protocol, and approval must be received from Headquarters prior to entering a second patient. This same procedure must be followed before entering a third patient. However, once approval has been given to enter the third patient on the protocol, no additional Immobilization/Localization data needs to be gathered.

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Status of RTOG 0438

Institution	RPC Acceptable	ITC Acceptable	Letter Sent	Notes	IRB
University of Rochester	Yes				
Princess Margaret Hospital	Yes	Yes	01/30/2006	6/2/06 passed 1st case	10/21/2006

RTOG 0413
A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer

Randomization

GROUP 1*

Whole Breast Irradiation (WBI)

45-50 Gy in 25 (1.8-2.0 Gy) fractions to whole breast, followed by optional boost** to ≥ 60 Gy

GROUP 2*

Partial Breast Irradiation (PBI)***

34 Gy in 3.4 Gy fractions using multi-catheter interstitial brachytherapy

or

34 Gy in 3.4 Gy fractions using MammoSite® balloon catheter

or

38.5 Gy in 3.85 Gy fractions using 3D conformal external beam radiation

For all PBI techniques: RT given to index quadrant only, BID (with a fraction separation of 6 hours), in 5-10 days.

NSABP B-39 / RTOG 0413 Radiation Treatment Review

Main Menu

This review was completed 6/1/2005 10:52:31 AM.
Dose-Volume Analysis information cannot be updated.
This review has been assigned to Julia White

Case Number: 29 Change Case Number

Initials: SH
Modality / PBI Technique: 3D Conformal External Beam
Dose Level: 38.5 **Rx Dose:** 38.5 (Gy)

Date data submitted to ITC:

Contact Email | Contact Email | Contact Email | Contact Email

Click here for Target Volume Review Form

A. TARGET VOLUME ANALYSIS

Target	Volume (cc)	Percent Volume Receiving >= 0.90 Rx Dose(Gy)		ICRU Ref Dose (Gy)	Max Dose (Gy)	Min Dose (Gy)	Mean Dose (Gy)	Coverage Score
PTV_EVAL	246	100	34.6	38.50	40	30.2	39	1

B. DOSE HETEROGENEITY (DH) And CONFORMITY

	Dose Hetereogeneity	Dose Heterogeneity Score
PTV_EVAL	1.04	1

Dose Heterogeneity (Max Dose/Rx dose): 1: DH <= 1.20, 3: DH > 1.20

C. NORMAL STRUCTURE ANALYSIS (See appendix II for standard structure names)

Normal Tissue	Volume (cc)	% Vol >= Ref Dose		Ref Dose (Gy)		Max Dose (Gy)	Mean Dose (Gy)	Score	Criteria	
		1	2	1	2				1	2
Ipsilateral Lung	1696	2.4	---	11.6	13.5	36	1.1	1	< 15%	< 20%
Contralateral Lung	2153.3	0	---	1.9	3.85	0.4	0	1	< 15%	< 20%
Ipsilateral Breast	2022.1	34 / 10.1	---	19.25/38.5	21.17/40.42	40	15	1	< 60/35%	< 65/40%
Contralateral Breast	1882	0	---	1.2	3.08	1	0	1	Point	< 5%
Thyroid	8	0	---	1.2	3.08	0.2	0.1	1	Point	< 5%
Heart (Right Sided)	---	---	---	1.9	3.85	---	---	---	< 5%	< 10%
Heart (Left Sided)	660.3	0.4	---	1.9	3.85	4	0.2	1	< 40%	< 45%
Unspecified Tissue	25170.1	---	---	---	---	33	---	---	---	---

RTOG
Radiation Therapy Oncology Group

R. T. Quality Assurance Staff

Back Row L/R: Lorraine Quarles; Denise Manfredi; Tammy McGlade; Betty Martin; Joanne Hunter
Front Row L/R: Darlene Herd; Julie McIlvaine

ACR American College of Radiology

ATC Meeting Schedule

- Monthly teleconferences are held on the first Wednesday of each month to keep all ATC participants up to date on ongoing activities. Next call on July 5, 2006 at 2:00 CST.
- Bi-weekly teleconferences are held on Friday for RTOG/ITC/RPC Specific issues.
- ATC meeting at the RTOG Semi-Annual Meeting in Toronto, Canada, Fairmont Royal York, Thursday, June 22, 2006 at 8:00am – 5:00pm.
- ATC meeting at Fall COG Semi-Annual Meeting in Los Angeles, CA, Thursday-Friday, October 5-6, 2006.
- ASTRO Annual Meeting in Philadelphia, PA, November 5-9, 2006.
- ATC meeting at the RTOG Semi-Annual Meeting in Tampa, Florida, Tampa Marriott Waterside Hotel, Thursday, February 1, 2007 at 8:00am – 5:00pm.