Progress Report Scanning Cover Sheet

5U24CA081647-10

PI Name:	**PURDY, JAMES**
Org:	**WASHINGTON UNIVERSITY**
Start Date:	**07/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7502242**
Rec'd Date:	**05/01/2008** timely

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U24	CA81647-10

Total Project Period
From: 07/22/1999 Through: 06/30/2012

Requested Budget Period
From: 07/01/2008 Through: 06/30/2009

1. TITLE OF PROJECT
Advanced Technology QA Center

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
James A Purdy, Ph.D.
Washington University
660 S. Euclid Ave., Box 8224
St. Louis, MO 63110

2b. E-MAIL ADDRESS
purdy@radonc.wustl.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Radiation Oncology

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 314-362-9773 Fax: 314-362-9797

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Washington University
660 South Euclid Ave., Box 8018
St. Louis, MO 63110

3b. Tel: 314-747-4134 Fax: 314-362-0315

3c. DUNS: 068552207

4. ENTITY IDENTIFICATION NUMBER
1430653611A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		04/03/2008

6b. Federal Wide Assurance No. FWA00002284

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
John Michnowicz, Director, Grants & Contracts
660 South Euclid Ave., Box 8018
St. Louis, MO 63110

Tel: 314-747-4134 Fax: 314-362-0315

E-MAIL: G&C@msnotes.wustl.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A3381-01

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Washington University

DUNS: 068552207

Street 1: Image-GuidedTherapy QA Center

Street 2: 4511 Forest Park Blvd, 2nd floor

City: St. Louis	County: St. Louis
State: Missouri	Province:
Country: USA	Zip/Postal Code: 63108

Congressional Districts: 01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $1,400,118 8b. TOTAL $1,750,000

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported
☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
John Michnowicz, Director, Grants and Contracts

TEL: 314-747-4134 FAX: 314-362-0315 E-MAIL: G&C@msnotes.wustl.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Michelle L Kenney Acting for John Michnowicz DATE 4/29/08

MAY - 1 2008

2U24CA081647-10
Dr. James Purdy

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budget comparisons follow

no significant deviations in effort commitments

Program Director/Principal Investigator (Last, First, Middle): Purdy, James

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY	FROM 07/01/2008	THROUGH 06/30/2009	GRANT NUMBER 2U24CA081647-10

PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
James A. Purdy	PD/PI						
Walter R. Bosch	Associate Director	7.20	✓		59,616	14,410	74,026
John W. Matthews	Comp. Scientist	10.80	✓		103,109	24,985	128,094
William L. Straube	Med Physicist	10.32	✓		82,630	11,894	94,524
Roxanna Haynes	Med Dosimetrist	12	✓		64,148	18,764	82,912
Anna Eccher	QA Specialist	12	✓		61,838	15,540	77,378
Julie Birlew	Data Cntrl Coord	12	✓		34,165	9,094	43,259
Con't Page Subtotals	minor effort changes, OK				104,892	17,717	122,609
	SUBTOTALS →				510,398	112,404	622,802
CONSULTANT COSTS					477,255	108,816	586,071
NCIC							2,000 2,000
EQUIPMENT *(Itemize)*							
Computer hardware @$50,000 which includes commercial computer hardware systems for the development for the QuASA2R components.							50,000 50,000
SUPPLIES *(Itemize by category)*							
Film jackets, file folders, CD-R, printer cartridges $4,548							4,548 17,000
TRAVEL							
13 trips to NCI and Participating Institutions @ $1,000 each							13,000 13,255
PATIENT CARE COSTS	INPATIENT						
	OUTPATIENT						0
ALTERATIONS AND RENOVATIONS *(Itemize by category)*							
OTHER EXPENSES *(Itemize by category)*							
Annual computer maintence support $14,300 Software License for PC $4,000							
Postage, LD, Copier, Publications $4,200 License for TerMedica Evercore $8,000							30,500 18,500
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD							$ 722,850
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS						490,292 490,485
	FACILITIES AND ADMINISTRATIVE COSTS						186,976 190,887
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD *(Item 8a, Face Page)*							$ 1,400,118 1,436,059

5/12/2008

All deviations from previously established commitments and recommendations are minor and reasonable.
Award is subject to total cost cap of $1,750,000
Award will be made based on requests, pursuant to A-21 cost principles.

-

GRANT NUMBER 5 U24 CA081647-10 GMS Saved Date: Not
GRANTEE INSTITUTION WUSTL
P.I.: Purdy, James

Number of Projects: 1

Total Award Comparison Budget

MAIN BUDGET	Award 09	Rec 10	Req 10	Award 10	Req-Awd 09	Req-Rec	△%
Salaries	477,255	513,022	510,398	0	33,143	0	-1%
Fringe Benefits	108,816	116,971	112,404	0	3,588	0	-4%
PERSONNEL	586,071	629,993	622,802	0	36,731	0	-1%
CONSULTANTS	2,000	1,927	2,000	0	0	0	4%
EQUIPMENT	50,000	48,167	50,000	0	0	0	4%
SUPPLIES	18,768	16,377	4,548	0	(14,220)	0	###
TRAVEL	13,000	12,740	13,000	0	0	0	2%
INPATIENT	0	0	0	0	0	0	0%
OUTPATIENT	0	0	0	0	0	0	0%
ALTERATIONS	0	0	0	0	0	0	0%
OTHER	18,800	17,822	30,000	0	11,200	0	###
3RD PARTY DIRECT	477,975	476,409	490,292	0	12,317	0	3%
Total direct costs	1,166,614	1,203,435	1,212,642	0	46,028	0	1%
3RD PARTY F&A	199,294	193,559	186,976	0	(12,318)	0	-3%
total costs	1,365,908	1,396,994	1,399,618	0	33,710	0	0%

10 Year commited level(total)	0	0.00%	committed of recommended
10 Year commited level(less 3rd party F&A)	0	1,212,642	requested over committed
10 Year DC funding level (calculated)	0	0.00%	adjustment needed to req

100.00% FY08 funding level

Program Director/Principal Investigator (Last, First, Middle): Purdy, James A.

Detailed Budget for Next Budget Period – Direct Costs Only
Continuation

DETAILED BUDGET FOR NEXT BUDGET PERIOD DIRECT COSTS ONLY		FROM 07/01/2008		THROUGH 06/30/2009	GRANT NUMBER 2U24CA081647-10		
PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	CAL. Mnths	Acad. Mnths	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Jeff Michalski	Co-Inv	.60	.36		9,565	1,181	10,746
Joseph Deasy	Co-Inv	1.20			17,897	3,080	20,977
Divya Khullar	Bioinformaticist	3			17,800	4,228	22,028
Aditya Apte	Bioinformaticst	3			17,800	2,982	20,782
TBN	Physicist	5.64	2.4 cm		41,830	6,246	48,076
Daniel Low	Collaborator						
Robert Drzymala	Collaborator						
Sasa Mutic	Collaborator						
Jeff Bradley	Collaborator						
SUBTOTAL					$104,892	$17,717	$122,609

Consortium Direct Expenses Detail	Total
UCD – University of California, Davis	100,176
QARC – Univ of Mass	99,206
RPC – MD Anderson	79,365
ACR – American College of Radiology	211,545
TOTAL CONSORTIUM DIRECTS	$490,292
Consortium Indirect Detail	
UCD – University of California, Davis	52,092
QARC – Univ of Mass	25,794
RPC – MD Anderson	20,635
ACR – American College of Radiology	88,455
TOTAL CONSORTIUM INDIRECTS	$186,976
TOTAL CONSORTIUM DIRECTS AND INDIRECTS	**$677,268**

BUDGET JUSTIFICATION	GRANT NUMBER
	2U24CA081647-10

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

See attached

CURRENT BUDGET PERIOD	FROM	THROUGH
	07/01/2007	06/30/2008

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

None

Budget Justification:

James A. Purdy, Ph.D. ATC Principal Investigator – 0% FTE-WU plus (CM: 4.8) - UCDavis portion of grant)

Dr. Purdy, Adjunct Professor of Radiation Oncology at the Washington University School of Medicine and Professor and Vice-Chair, Department of Radiation Oncology at the University of California Davis serves as the Director of the Image-Guided Therapy Center (ITC) and is the Principal Investigator for the Advanced Technology QA Consortium (ATC) grant. In these roles, he is responsible for the overall vision, direction and coordination of the ITC/ATC efforts and for ensuring that the grant's goals are realized. Dr. Purdy works with the ITC-WU staff and the various ATC subcontractors, as well as the NIH Project Scientist (PS), Dr. Jim Deye and other NCI staff members, to coordinate all ATC grant efforts including the planning, organization, administration, allocation of responsibilities to ATC subcontractors, and the development of resources and relationships. This includes a weekly teleconference with all ITC-WU staff, plus periodic visits to ITC-WU, monthly teleconferences with ATC participants, cooperative groups, and/or the NCI PS as needed. He works closely with RTOG committees (Medical Physics, Advanced Technology Integration Committee (ATIC), and various site committees) and protocol study chairs in developing protocol specific QA guidelines and credentialing requirements for proposed ATC supported protocols and/or modification of ongoing protocols. He actively participates in the RTOG's semi-annual meetings and provides input to the RTOG's leadership regarding utilization of ATC resources and regularly provides a semi-annual report to both the Medical Physics Committee and the ATIC informing the participants of ATC's involvement with RTOG protocols. He also interacts with QARC, particularly those efforts directed at implementing digital data transfer and remote QA review with cooperative groups served by QARC. He also interacts with the RPC in the development of common QA guidelines and credentialing requirements for ATC supported protocols that RPC helps support (e.g., brachytherapy, IMRT, IGRT). Dr. Purdy will oversee ATC key personnel efforts to ensure that the development and implementation of the hardware/software needed to receive, archive, and remotely review clinical trial digital data is implemented in a timely fashion. He also will interact with vendors and other pertinent public organizations and work toward seamless integration of ATC software development efforts rather than use resources for competitive or redundant efforts. Dr. Purdy is responsible for the generation of all progress reports and other official reports from the ATC and the ITC pertinent to advanced technology clinical trials. He attends and chairs all ATC face-to-face meetings and is responsible for the ATC response to any questions or concerns put forth by the ATC Steering Committee, Evaluation Committee, or NCI. Salary requested on UC Davis ATC subcontract.

Walter R. Bosch, D.Sc., Co-Investigator, ITC Associate Director - Operations(CM: 7.2)

Dr. Bosch serves as Associate Director-Operations of the ITC, where he manages daily operations and information technology and works closely with Drs. Purdy and Michalski in coordinating ATC/ITC efforts. He provides the ITC technical expertise in three areas: (1) databases, (2) web-based QA tools, and (3) digital image communications. Database development and support activities involve directing development of databases and applications for tracking the review of credentialing and protocol case data for ATC-supported protocols. The development and support of web-based tools for remote review of imaging/treatment planning/verification (ITPV) data by reviewers outside ITC includes tools for the review of CT images, structure/target-volume contours, isodose contours, and dose-volume histograms. He helps maintain the ATC and ITC WWW sites and maintains on-line form submission for protocol participants. Dr. Bosch has represented the ATC in two DICOM working groups (WG7 and WG18), the IHE-RO Technical Committee, and the caBIG In Vivo Imaging Workspace. He continues to work with other members of the ATC to develop and test DICOM-based mechanisms for submission and QA review of treatment planning and image data.

Jeff M. Michalski, M.D., Co-Investigator, ITC Associate Director-Clinical - (CM: 0.60)

Dr. Michalski serves as Associate Director-Clinical of the ITC, where he provides clinical input and works closely with Drs. Purdy and Bosch in coordinating ATC/ITC efforts. Dr. Michalski is a well-established expert in the use of 3-D treatment planning and conformal therapy. He is currently chair of the RTOG's Advanced Technology Integration Committee (ATIC). His activities in the RTOG also include being the principal investigator for RTOG P0126. He is directly involved in protocol development for clinical trials that investigate

advanced technologies such as IMRT and image-guided brachytherapy. He provides clinical input to the ATC credentialing and protocol design efforts. The level of involvement cannot be specified since it will be variable.

Joseph Deasy, Ph.D., Co-Investigator, Director, Division of Bioinformatics and Outcomes Research – (CM: 1.2)

Dr. Deasy is chief of the Division of Bioinformatics and Outcomes Research in the Washington University Department of Radiation Oncology, where he has developed computational tools and methods for treatment plan optimization and modeling of treatment response. Dr. Deasy oversees the development and extension of the Computational Environment for Radiotherapy Research (CERR) software for reviewing and analyzing clinical imaging and treatment planning data and for sharing data and results with other investigators. Dr. Deasy will direct the development of CERR-based tools for use by ITC, RPC, RTOG, and QARC and the development of workflow and database management tools for the ITC.

William Straube, M.S. Medical Physicist –(CM: 10.32)

Mr. Straube provides the credentialing review for new institutions enrolling in advanced technology protocols supported by the ATC. In this function, he works closely with individual institutions seeking approval to register patients on these protocols. This entails educating participating institutions on the requirements of the particular protocols as well as on how to provide digital ITPV data to the ITC. Mr. Straube is proficient in handling problems with digital data submitted as well as the timeliness and quality of the data submitted by the individual institutions. In addition, Mr. Straube assists in the development of the ITC QA process tracking database. The ITC staff uses this database to track the submission and scoring of data submitted by participating institutions.

TBN Medical Physicist (CM: 5.64)

This individual will share duties with Mr. Straube (and provide valuable backup when needed) regarding the credentialing review for new institutions enrolling in advanced technology protocols supported by the ATC. In this function, the physicist works closely with individual institutions seeking approval to register patients on these protocols. This entails educating participating institutions on the requirements of the particular protocols as well as on how to provide digital ITPV data to the ITC.

John W. Matthews, D.Sc. Computer Scientist – (CM: 10.80)

Dr. Matthews provides the ITC technical expertise in the following areas: (1) the design and implementation of software tools for the exchange and analysis of ITPV digital data, and (2) the software design and implementation of Web based tools for remote access to the ITC's database of ITPV data. The first area involves maintaining both the RTOG Data Exchange and DICOM 3.0 based data exchange for the ATC QA review system. He works closely with TPS manufacturers in their implementation of the DICOM export to assure compliance with the ATC DICOM conformance statement. Dr. Matthews is involved in the design and implementation of Web-based tools for review of organs-at-risk and target volumes, including the ability to edit contours, measure distances, and interactively review DVHs. Dr. Matthews is also involved in maintaining the IT and networking infrastructure, including management of server and data storage systems as well as data backup and recovery.

Roxana Haynes Med Dosimetrist– (CM: 12)

Ms. Haynes provides the ITC support in the processing of digital and hard copy protocol data submitted by participating institutions in preparation for QA reviews by physician study chairs and other designated individuals. She helps maintain the QA database identifying review status of submitted data, communicates with submitting institutions to help resolve any problems with submitted data, and assists in preparing ITPV data for review and performing digital data integrity QA.

Anna Eccher, Quality Assurance Specialist –(CM: 12)

Ms. Eccher provides the ITC support in the processing of digital and hard copy protocol data submitted by participating institutions in preparation for QA reviews by physician study chairs and other designated individuals. She helps maintain the QA database identifying review status of submitted data, communicates

with submitting institutions to help resolve any problems with submitted data, and assists in preparing ITPV data for review and performing digital data integrity QA.

Julie Birlew Data Control Coordinator – (CM: 12)

Ms. Birlew provides the ITC support for processing the digital and hard copy protocol data submitted by participating institutions in preparation for digital data integrity QA (DDIQA) and protocol compliant QA (PCQA) reviews by physician study chairs and/or other designated individuals. She helps maintain the QA database identifying review status of submitted data, communicates with submitting institutions to help resolve any problems with submitted data.

Divya Khullar, Bioinformaticist – (CM:3.0)

Mr. Khullar develops and maintains CERR tools in the_Division of Bioinformatics and Outcomes Research in the Washington University Department of Radiation Oncology. He will provide support for DICOM import and export and conversion of RTOG data exchange files to DICOM.

Aditya Apte, Bioinformaticist – (CM: 3.0)

Mr. Apte develops and maintains CERR tools in the_Division of Bioinformatics and Outcomes Research in the Washington University Department of Radiation Oncology. He will provide support for the use of CERR-based tools by ITC, RPC, RTOG, and QARC.

Washington University Collaborators

Several other key members of the Washington University Department of Radiation Oncology faculty have agreed to contribute some time to this project. The level of involvement is such that although they will be consulted throughout the project, the percentage effort cannot be specified, since it will be variable/no salary.

- Daniel A. Low, Ph.D., Professor of Radiation Oncology.
- Robert E. Drzymala, Ph.D., Associate Professor of Radiation Oncology
- Sasa Mutic, M.S., Associate Professor of Radiation Oncology
- Jeff Bradley, M.D., Associate Professor of Radiation Oncology

Consultants

Funds ($2,000) are requested to support travel by other personnel in order to provide needed expertise (e.g., diagnostic imaging) regarding ATC efforts.

Equipment

Funds for computer hardware ($50,000/year) are requested for commercial computer hardware/software systems for the development of QuASA^{2}R components.

Supplies

Funds for office supplies and computer equipment/software (under $5,000 each category) ($4,548):

- Office Supplies, file folder and film jackets for submitted cases, CD-R and tape media for backups, printer cartridges, etc. ($4,548)

Travel

It is expected that there will be at least 4 face-to-face ATC meetings per year. There will be two to three representatives from the ITC attending the meetings. These meetings are expected to last one to two days. In addition, we also expect additional trips per year to respond to special needs of our collaborators or to attend DICOM WG 7 meetings, or national scientific meetings.

- 13 person trips/year @ $1000.00 per person = $13,000

Other Expenses $30,500

- Annual support for hardware and software in use at ITC. (14,300)

Vendor	System	Type	Latest Renewal Date	Latest Annual Cost
Hewlett-Packard	HP 9000 server (cancer)	HW/SW maint	18-May-07	$5700.00
Dell Computer	Prec 370 maintenance (itc370)	HW maint	20-Mar-08	$160.00
Dell Computer	PE 1850 maintenance (itcb)	HW maint	20-Mar-08	$1,150.00
Dell Computer	PE 1850 maintenance (itca)	HW maint	20-Mar-08	$900.00
Dell Computer	PV 745N maintenance (itcnas1)	HW maint	20-Mar-08	$300.00
TeraMedica	Recurring License Fee (Evercore)	SW license		$2,000.00
Cedara	MergeCOM-3 Toolkit	SW maint	21-Feb-06	$2,000.00
Hummingbird LTD	Exceed PC X-server (10)	SW maint	15-Feb-08	$270.00
WU/NTS	Thawte Secure Web Certificate	Service fee	27-Apr-07	$150.00
WU/NTS	MatLab license (3)	SW license	14-Jan-08	$210.00
Miscellaneous				$1460.00
			TOTAL	**$14,300.00**

- **Postage, Telephone, Copier, Miscellaneous ($4,200)**
  - Postage is required for the mailing of reports to the RPC, QARC, ACR and NCI, reports of the 3 credentialing procedures, interaction with the cooperative clinical study groups and the resolution of discrepancies with data submitted.
  - Much of the communication with all interested parties is by the telephone, fax and email. Support for these modes of communication is necessary.
  - Support for copying of reports and communications with the RPC, QARC, ACR and NCI, cooperative clinical study groups, and participating institutions is required.
  - Miscellaneous expenses include reprints of publications and artwork for presentations.

Licenses $12,000

- Licenses for PC software to be used for documentation preparation and presentations for ITC personal computers ($4,000).
- License for TeraMedica Evercore ($8,000)

Program Director/Principal Investigator (Last, First, Middle): Purdy, James

PROGRESS REPORT SUMMARY	GRANT NUMBER 2U24CA081647-09	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Purdy, James A.	FROM 09/28/2007	THROUGH 06/30/2008

APPLICANT ORGANIZATION
Washington University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Advanced Technology QA Center

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

See attached progress report.

PREAMBLE

The ATC is a "virtual entity" made up of the following Centers/Groups: (1) Image-Guided Therapy QA Center (ITC – Washington Univ. in St. Louis and UC Davis); (2) Radiation Therapy Oncology Group (RTOG) Headquarters Dosimetry Group, (3) Radiological Physics Center (RPC, M.D. Anderson Cancer Center), and (4) Quality Assurance Review Center (QARC). The ATC grant provides the primary funding for the ITC and provides supplementary funding to the other three groups to accomplish the ATC mission.

The original Washington University ATC grant (J.A. Purdy, PhD, PI; July 1, 1999 to June 30, 2002) was awarded in response to NCI RFA CA-98-006. However, the ATC concept dates back even further, as it grew out of the pioneering efforts of the Washington University 3DQA Center (now referred to as the ITC) and RTOG, which in 1994 partnered to provide QA for the 3D Oncology Group (3DOG) to conduct a prostate dose escalation study (94-06) using 3DCRT (Michalski et al. 2000, Purdy et al. 1996, Purdy et al. 1998). In 2002, the Washington University ATC grant was successful in its first renewal application (J.A. Purdy, PhD, PI; July 1, 2002 to June 30, 2007), and in 2007 was again successful in its competitive renewal application (J.A. Purdy, PhD, PI; July 1, 2007 to June 30, 2012). The new ATC now consists of the ITC, RTOG, RPC, and QARC and will complete its first year of the new 5-year award on June 30, 2008.

The overall mission of the ATC remains the same as in the previous grant - to facilitate and support NCI sponsored advanced technology clinical trials, particularly those requiring digital data submission. We strongly believe that advanced medical informatics can create an environment in which clinical investigators can receive, share, and analyze volumetric, multimodality imaging, treatment planning and verification (ITPV) digital data. Our ultimate goal is to improve the standards of care in the management of cancer by improving the quality of clinical trials medicine. The goals as specified in NCI RFA CA-07-503 for our ATC renewal application are to be accomplished through the following *developmental*, *coordination*, and *service* objectives:

1. Eliminate duplication of infrastructure developmental efforts and facilitate sharing of QA resources among cooperative groups.
2. Help to insure that appropriate and uniform QA procedures and criteria for advanced technology trials are developed across all cooperative groups.
3. Facilitate/help manage the uniform credentialing of institutions for advanced radiotherapy trial protocols.
4. Facilitate/manage digital data protocol submission.
5. Facilitate/manage the QA review of submitted data.
6. Further the development of methods for rapid analysis of volumetric treatment planning data.
7. Assist clinical trial cooperative groups in the development of clinical trials protocols including: (a) credentialing requirements; (b) target volume definitions; (c) quality assurance procedures; and (d) data submission instructions.
8. Develop, implement, and maintain innovative methods for electronic exchange of digital planning data between institutions participating in clinical trials and between QA Centers.
9. Develop, implement, and maintain innovative web-based software tools to facilitate protocol digital data reviews by Study Chairs, Dosimetry Groups, the Radiological Physics Center (RPC), and the Quality Assurance Review Center (QARC).

10. Develop, implement, and maintain archival treatment planning and QA databases that can be linked with the cooperative groups' clinical outcomes databases.
11. Demonstrate understanding of and ability to achieve compatibility with existing software and electronic health record standards, including the Cancer Bioinformatics Grid (caBIG) and DICOM RT.

To accomplish these goals, we have organized the ATC's efforts around the four specific aims listed below in Section A.

(A) SPECIFIC AIMS:
Specific aims for the ATC grant are as follows.

Specific Aim 1: Maintain and manage (and make incremental improvements as required to) the current electronic data submission of advanced technology protocol credentialing and case data, archival storage, and remote QA review process utilizing the ATC *QuASA²R (Quality Assurance Submission, Archive, Analysis, and Review)* system.

Specific Aim 2: Develop novel web-based remote-review tools that will enhance the efficient and effective review of 3DCRT, IMRT, SBRT, and brachytherapy protocols. The tools and interfaces will be designed by a multidisciplinary team of experts in the quality assurance of clinical trials. The design infrastructure of these tools will assist the development of future protocol processes such as image-guided radiation therapy (IGRT) and adaptive radiation therapy (ART) (Brabbins et al. 2005, Yan et al. 1998). *QuASA²R* is modular in architecture to promote the efficient design, testing, and implementation of tools and subsystems. Starting from a DICOM-based ITPV data archive with well-defined interfaces, our developmental approach will (a) allow the selective re-use and adaptation of existing *QuASA²R* system components, (b) enable the integration of a heterogeneous mix of commercial-off-the-shelf, open-source and custom software components; (c) facilitate testing and maintenance of system components, and (d) allow step-wise evolution/upgrading of the *QuASA²R* system to support technological advances in radiation therapy clinical trials. Emphasis will be on the development and improvement of web-based remote-review tools that achieve compatibility with existing software and electronic health record standards, including the Cancer Bioinformatics Grid (caBIG) and DICOM RT, and maintaining/developing archival multimodality ITPV, credentialing, and QA databases for the advanced treatment modalities that can be linked with the cooperative group's clinical outcomes database.

Specific Aim 3: Assist cooperative groups in the development and management of advanced technology clinical trials protocols including (a) tumor/target volume and organ at risk definitions; (b) credentialing requirements and evaluation criteria; (c) electronic data submission requirements/instructions; and (d) quality assurance review procedures.

Specific Aim 4: Serve as an educational resource to the nation's clinical trial cooperative groups and participating institutions for support of advanced technology radiation therapy clinical trials.

(B) STUDIES AND RESULTS (2007-08)
Several ATC face-to-face meetings were held and facilitated good communication among subcontractors. For the record, the following face-to-face meetings were held during this funding period:

- August 1, 2007, ATC meeting at QARC in Providence, RI

- October 27, 2007 ATC breakfast meeting at ASTRO in Los Angeles, CA
- January 17, 2008, ATC meeting held at RTOG Semi-annual meeting in San Diego, CA
- March 27-28, 2008, ATC meeting held at ITC in St. Louis, MO

In addition, RTOG Headquarters staff plays a key role in arranging for ATC bi-weekly teleconferences between RTOG, ITC, and RPC to review any issues pertaining specifically to RTOG advanced technology protocols supported by ATC. In addition, other ATC teleconference between ITC and QARC and between ITC and RPC are held focusing on those subcontractor specific issues. Most importantly, a weekly teleconference is held between Dr. Purdy and ITC-WU staff to review operation and on-going efforts.

Specific Aim 1: Maintain and manage (and make incremental improvements as required to) the current electronic data submission of advanced technology protocol credentialing and case data, archival storage, and remote QA review process utilizing the ATC *QuASA^{2}R (Quality Assurance Submission, Archive, Analysis, and Review)* system.

This aim reflects primarily the ATC service effort. The QuASA^{2}R clinical trials quality assurance (QA) system, developed by the ITC, provides multiple cooperative groups one of the most advanced medical informatics infrastructures currently in use for radiation therapy clinical trials QA. It currently supports QA review and outcomes analysis for both cooperative group and industrial/pharmaceutical clinical trials. Cooperative-group trials supported include those sponsored by the Radiation Therapy Oncology Group (RTOG), National Surgical Adjuvant Breast and Bowel Project (NSABP), New Approaches to Brain Tumor Therapy (NABTT), Japan Clinical Oncology Group (JCOG), and European Organization for Research and Treatment of Cancer (EORTC). QA and outcomes analysis for these trials have required the collection and review of nearly 7000 protocol case datasets from a broad spectrum of commercial imaging, treatment planning, and verification systems as shown in **Fig. 1**.

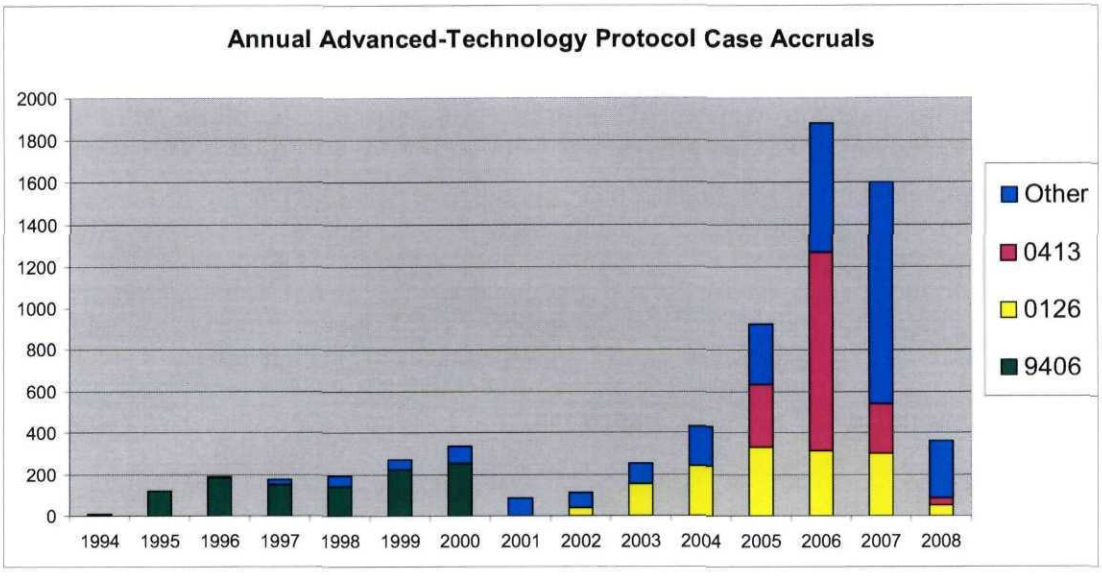

Figure 1.Number of protocol accruals on a per year basis submitted over 15+ Year Period using the ATC QuASA^{2}R method. 11 commercial TPS vendors (22 treatment planning systems/versions) have implemented ATC QuASA^{2}R compliant export capability and 536 institutions are now able to submit data to the ITC.

Protocol specific digital treatment planning data are sent to ITC via SFTP or media. The Protocol review process is now more clearly divided between the ITC and the cooperative group, The ITC is responsible for Digital Data Integrity QA (DDIQA) review which includes review for completeness of protocol required elements, format of data, spatial registration, dose scaling, and possible data corruption; and recalculation of all Dose Volume Histograms (DVHs). The cooperative group is responsible for Protocol Compliance QA (PCQA) review which includes review of target volume and organ at risk contours compliance and review of protocol dose prescription and dose heterogeneity compliance by cooperative group specific reviewer(s) such as the Protocol Study Chair (SC) using QuASA^{2}R's web-based *Remote Review Tool (RRT)*.

The ITC notifies the cooperative group when a case is ready for PCQA review and the cooperative group is then responsible for the rest of the review process. This clear division of QA review process has made it more efficient for the cooperative group to keep track of the status of their protocols for QA reports and data quality reports and allows the cooperative group to request (and monitor) delinquent data from the participating institution.

During this funding period, the ITC is maintaining rigorous DDIQA metrics for the protocols supported by the ITC and the data show that approximately 30% of submissions are problematic. Problems can be divided into three categories: (1) misunderstanding of protocol requirements, (2) misuse of treatment planning system (TPS) data export feature, and (3) updated TPS software whose data export feature is no longer compliant with QuASA^{2}R requirements. The time and effort required to perform DDIQA and prepare a case for PCQA varies, depending on protocol complexity. The statistics in Table 1 are reported per case registered and show very similar results to the data presented in 2006. The data are accumulated since March of 2006.

Table 1: March 10, 2006- Dec 13, 2007 - Protocol Case Digital data submissions per protocol and the number of problems encountered that required human intervention by the ITC personnel.

Disease Site	Number of cases Digitally Submitted	Problems Requiring Human Intervention	% Cases Requiring Human Intervention
Lung	45	14	31
Prostate 3D/IMRT	827	201	24
Prostate Seed	148	21	14
Partial Breast	997	260	26
Liver SBRT	6	2	33
Prostate 3D/IMRT with Nodal Volumes	209	104	50
H&N IMRT	417	107	26
Pelvic IMRT	147	35	24
TOTAL	**2796**	**744**	**27%**

In addition, several protocols require a rapid review process which is to be completed in 3 business days. The ITC is responsible for preparing the data for review and easily turns complete submissions around in less than 1 business day. The rest of the review process involves dosimetry and PI review for which 1 business day is allowed for each facet. In addition to protocol cases the ITC receives credentialing data in the form of digital data used by the RPC to evaluate IMRT and SBRT phantom irradiations. The DDIQA statistics for these submissions show a 31% problem rate.

Details regarding protocol accruals supported by the ATC are given in the following section per cooperative group.

1. Radiation Therapy Oncology Group (RTOG)

a. RTOG protocols completed that were supported by ATC QuASA^{2}R System (Note data analysis continues to be supported by ATC effort):

(1) RTOG 93-11: Phase I/II Dose Escalation Study Using 3DCRT in Patients with Inoperable NSCLC. (26 institutions credentialed; 180 patients registered to study; study closed 10/5/01; data analysis continues).

(2) RTOG 94-06: Phase I/II Dose Escalation Study Using 3DCRT for Adenocarcinoma of the Prostate. (54 institutions credentialed; 1084 patients registered to study; study closed 10/31/00; data analysis continues).

(3) RTOG 98-03: Phase I/II Radiation Dose Escalation Study Applying 3DCRT in Supratentorial Glioblastoma Multiforme. (46 institutions credentialed; 210 patients registered to study; study closed 9/3/03; data analysis continues).

(4) RTOG 0022: Phase I/II Study of 3DCRT and IMRT for Oropharyngeal Cancer. (32 institutions credentialed: 69 patients registered to study; study closed 1/14/04; data analysis continues).

(5) RTOG 0117: Phase I/II dose intensification study using 3DCRT and concurrent chemotherapy for patients with inoperable, non-small cell lung cancer (opened: 7/13/2001, accrual goals: 73; 51 institutions credentialed; 63 patients registered to study, study closed 11/27/07).

(6) 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 11/22/08; data analysis continues).

(7) RTOG 0234: A Phase II Randomized Trial of Surgery Followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of the Head and Neck (opened: 4/20/2004, accrual goals: 230 (ATC to collect data for IMRT cases only); 51 (IMRT) institutions credentialed. 238 patients registered to study (96 IMRT), study closed 12/1/06).

(8) RTOG 0236: Phase II Extracranial Stereotactic Radioablation in Treatment of Patients with Medically Inoperable Stage in NSCLC (opened: 5/26/04, accrual goals: 52; 8 institutions credentialed; 59 patients registered to study, study closed 10/13/06).

(9) RTOG 0319: Phase I/II to Evaluate 3DCRT Irradiation Confined to Region of the Lumpectomy Cavity for Stage I/IIA Breast Carcinoma. (opened: 8/15/2003, accrual goals: 46; 31 institutions credentialed; 58 patients registered to study; study closed 4/30/04).

(10) RTOG 0321: Phase I/II Prostate: High Dose Brachytherapy and External Beam. (opened: 7/30/04, accrual goals: 110; 18 institutions credentialed; 129 patients registered to study; study closed 5/26/06).

(11) RTOG 0421: Phase III Trial for Previously Irradiated Head and Neck Cancer: Reirradiation with or without Chemo (opened: 4/27/05, accrual goals: 240; 42 institutions credentialed; 15 patients registered to study), study closed 1/5/07 due to poor accrual.

(12) RTOG 0435: Phase III to evaluate the safety and efficacy of Palifermin (opened: 7/7/06, accrual goals: 298; 165 institutions credentialed; 21 patients registered to study, study closed 2/11/08).

(13) RTOG 0515: Phase II NSCLC Volume definition+/- PET (opened: 2/24/06, accrual goals: 48, 7 institutions credentialed; 52 patients registered to study, study closed 2/20/08)

(14) RTOG 0529: Phase II Mitomycin+ Cis +IMRT in Anal Ca (opened: 12/21/2006, accrual goals: 59; 152 institutions credentialed; 63 patients registered to study, study closed 3/21/08).

b. RTOG protocols that are active and being supported by ATC QuASA^{2}R system (as of March 31, 2008):

(1) RTOG 0126: Phase III randomize study of high dose 3DCRT/IMRT versus standard dose 3DCRT/IMRT in patients treated for localized prostate cancer. (opened: 3/21/2002, accrual goals: 1520; 264 institutions credentialed (205 IMRT); 1438 patients registered to study (437 IMRT).

(2) RTOG 0232: Phase III Study Comparing Combined External Beam Radiation & Transperineal Interstitial Permanent Brachytherapy with Brachytherapy alone (opened: 6/11/2003, accrual goals: 1520; 79 institutions credentialed. 349 patients registered to study).

(3) NSABP B39/RTOG 0413: Phase III Partial Breast Irradiation (opened: 3/28/05, accrual goals: 4200; 449 institutions credentialed (364 3DCRT, 270 Mammosite, 38 Multi-cath); 3048 patients registered to study (1148 3D, 283 Mammosite, 91 Multi-cath).

(4) RTOG 0415: Phase III Rand Conventional Fx 3DCRT/IMRT vs Hypo Fx 3DCRT/IMRT in Prostate Ca (opened: 4/18/06, accrual goals: 706; 230 institutions credentialed (87 IMRT); 419 patients registered to study)

(5) RTOG 0418: Phase II IMRT + / - chemo for post-op endometrial or cervical Ca (opened: 3/20/06, accrual goals: 92; 149 institutions credentialed; 95 patients registered to study).

(6) RTOG 0438: Phase I Unresect. Primary Bil Hepatobil. Ca & Liver Mets Extracranial Stereotactic RT (opened: 11/3/05, accrual goals: 18; 3 institutions credentialed; 14 patients registered to study).

(7) RTOG 0521: Phase III Trial for localized High Risk Prostate Cancer: Androgen Suppressioin with Radiation vs. Radiation with Chemotherapy and Prednisone. (opened: 12/8/05, accrual goals: 600; 266 institutions credentialed (220 IMRT); 309 patients registered to study).

(8) RTOG 0522: Phase III Trial Comparing Radiation and Cisplatin with/without Cetuximab for Advanced Head and Neck Cancer. (opened: 3/28/05, accrual goals: 720; 217 institutions credentialed; 504 patients registered to study).

(9) RTOG 0526: Phase II Salvage Brachy Hi Risk Prostate (accrual goals: approximately 150, 217 institutions credentialed. 3 patients registered to study).

(10) RTOG 0534: Phase III Post surgical Prostate (accrual goals: 1764; 44 institutions credentialed; 0 patients registered to study).

(11) RTOG 0615: Nasophayngeal Phase II IMRT & Cis & Bev (opened: 12/13/2006, accrual goals: 46, 150 institutions credentialed, 18 patients registered to study).

(12) RTOG 0617: Phase III High Dose 3DCRT/IMRT in NSCLC (opened: 11/27/2007, accrual goals: 512, 37 institutions credentialed, 7 patients registered to study).

(13) RTOG 0618: Phase II SBRT for Patients with Operable Early Stage NSCLC (Opened: 12/18/2007, accrual goals: 33, 10 institutions credentialed, 0 patients registered to study).

(14) RTOG 0622: Phase II Study Samarium 153 Prostate; (IMRT/3DCRT, opened 1/08/2008, 217 institutions credentialed, 0 patients registered to study).

(15) RTOG 0623: Phase II combined modality therapy for small cell lung cancer (opened 1/8/08, accrual goals: 44; 0 institutions credentialed, 0 patients registered to study).

(16) RTOG 0630: Phase II IGRT Large Size Soft Tissue Sarcoma (opened: 3/25/08, accrual goals: 102; 0 institutions credentialed, 0 patients registered to study).

c. RTOG pending protocols – ATC Resources Requested/Committed

(1) RTOG 0436: Phase III Esoph., Cetux/Cis/RT vs. Cis./Taxo/RT; 3DCRT

(2) RTOG 0539: Phase II Meningioma feasibility (accrual goals: not determined at this time)

(3) RTOG 0619: Phase IIR IMRT, Chemo, ZD6474 for High Risk Post-Op H&N

(4) RTOG 0621: Phase II Prostate RT/AS & Docetaxel; IMRT

(5) RTOG 0628: Phase II IMRT Locally Advanced Rectal

(6) RTOG 0631: Phase II Stereotactic Radiosurgery for Spine Mets

(7) RTOG 0713: Phase III IMRT Breast

(8) RTOG 0714: Phase III Resectable Pancreas IMRT 5-FU/Gem±erlot

(9) RTOG 0715: Phase II Study of Recurrent Breast 3DCRT

(10) RTOG 0811: Phase II Intermediate H&N Cancer IGRT + Erlotinib

(11) RTOG 0813: Phase II Stereotactic Radiosurgery for Centrally Located Lung Lesions

(12) RTOG 0814: Proton Beam Phase II in Locally Advanced Prostate Cancer

(13) RTOG 0816: Phase II HDR Brachy Prostate

(14) RTOG 0822: Phase II IMRT Cape & Oxal in Locally Advanced Rectal Cancer

(15) RTOG 0823: Phase I Lapatinib vs. Cape + IMRT for Pancreas Cancer

(16) RTOG 0836: 4D Imaging for Prostate IGRT

(17) RTOG 0838: Phase II IMRT + 5-FU, MMC, Cetux for Squamous Cell Anal Canal

It should be noted that RTOG Headquarters staff updates the Clinical Trials Support Unit (CTSU) RSS database with the RTOG advanced technology protocols credentialing requirements for participation and continue to identify and implement common identification numbers for patients on RTOG Protocols that utilize advance technology by using the RTOG member institution number, NCI number and the Radiation Therapy Facility number (RTF) which is assigned through the RPC.

It is also important to note the strong synergistic relationship between the ATC and the RTOG Advanced Technology Integration Committee (ATIC) as demonstrated by the continuing development of RTOG advanced technology protocols. The acknowledgement of the importance of this relationship is a key element in the upcoming RTOG grant proposal.

2. **National Surgical Adjuvant Breast And Bowel Project (NSABP)**
   The NSABP B39/RTOG 0413 protocol demonstrates the value of the ATC more than any other effort thus far. Individuals from two cooperative groups (NSABP and RTOG) and two other QA Centers (ITC and RPC) all worked together very closely to develop the protocol, credentialing criteria, QA review (including rapid review, timely review, and random review), training of institutions in submitting data using ATC's QuASA^{2}R system and training of reviewers in the use of the Remote Review Tool, and notification procedures to insure orderly and smooth conduct of this protocol. This effort continued during this funding period.

   (1) NSABP B39/RTOG 0413: Phase III Partial Breast Irradiation (opened: 3/28/05, accrual goals: 4200; 449 institutions credentialed (364 3DCRT, 270 Mammosite, 38 Multi-cath); 3048 patients registered to study (1148 3D, 283 Mammosite, 91 Multi-cath).

3. **New Approaches to Brain Tumor Therapy (NABTT)**
   The ATC is providing resources (including ITC personnel and use of the QuASA^{2}R clinical trials QA system) to facilitate the QA for the following NABTT studies. ITC performs DDIQA and facilitates PCQA is performed by NABTT physician reviewers (Dr. John Fivesh and/or Dr. Robert Lustig).

   (1) NABTT Protocol 0603: 3 institutions credentialed, 1 case submitted

4. **Gynocologic Oncology Group (GOG)**
   The ATC was contacted by the RPC and GOG and asked to provide resources (including ITC personnel and use of the QuASA^{2}R clinical trials QA system) to facilitate the QA for the following GOG studies. ITC will perform DDIQA and facilitate PCQA performed by the RPC.

   (1) GOG Protocol -0238: A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus: Thus far no institutions are credentialed and no cases have been submitted. An ATC webpage is in development.

5. **Children's Oncology Group (COG); Cancer and Leukemia Group B (CALGB); Eastern Cooperative Oncology Group (ECOG); Pediatric Brain Tumor Consortium (PBTC); Southwest Oncology Group (SWOG); and The American College of Surgeons Oncology Group (ACOSOG).**
   The ATC grant provides partial funding for QARC to support/manage the volumetric digital data submission for the above listed cooperative group's advanced technology clinical trials. Table 2 (presented at the March 28-29 ATC meeting at ITC) shows the number of case accruals submitted and processed by QARC as part of the ATC effort.

Table 2: As of March 20, 2008: Protocol and Number of Protocol Cases in which volumetric digital data submitted to QARC.

Protocol	*Number of Cases*
ACNS0121	45
ACNS0126	5
ACNS0331	43
ACOSOG Z4032	21
CALGB 80101	17
miscellaneous studies	248
Total of 379 cases from more than 100 institutions and more than 50 studies	

Dr. Tom Merchant (representing COG) attended the March 28-29 ATC meeting and met with Dr. T.J. FitzGerald and both agreed to work closely to encourage even more COG participants to submit complete volumetric digital data sets for COG case accruals.

Dr. FitzGerald pointed out that more and more institutions serviced by QARC are submitting digital data sets as shown in Fig. 2.

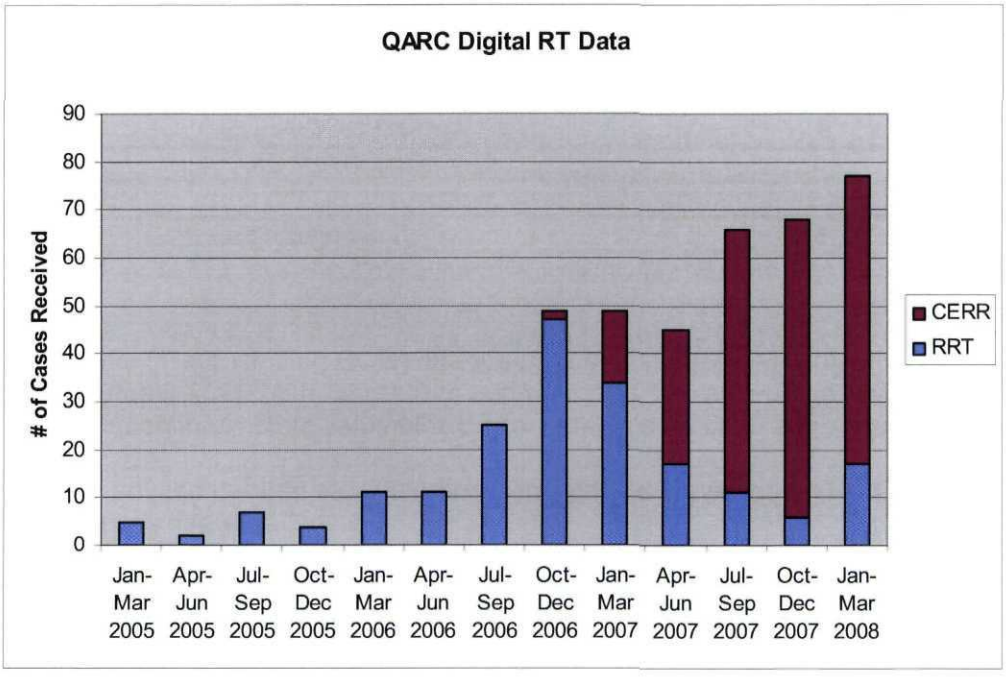

Figure 2.Digital RT data submitted to QARC and processed using either the open source software *Computational Environment for Radiotherapy Research* (CERR) or QuASA^{2}R's *Remote Review Tool* (RRT).

6. National Cancer Institute of Canada (NCIC)

During the past year QARC (Dr. FitzGerald) has assumed responsibility for facilitating ATC interactions with the National Cancer Institute of Canada (NCIC). Presentations of ATC infrastructure were given at the semi-annual meeting of NCIC in October of 2007. QARC was invited back to NCIC headquarters in Kingston, Ontario in December of 2007 and

demonstration of both imaging and radiation therapy treatment objects were reviewed via Webex to the committee including Dr. Parliament. Discussions were carried out concerning ATC(QARC) participation in both on-going Canadian clinical trials as well as industry collaboration. Dr. FitzGerald has been asked to return to the next meeting in Toronto (May 2008) to continue dialogue concerning opportunities for collaboration. Dr. FitzGerald expects the dialogue to include a discussion concerning further NCIC participation in NCI directed clinical trials.

7. Japan Clinical Oncology Group (JCOG)

The ATC is providing resources (including ITC personnel and use of the QuASA^{2}R clinical trials QA system) to facilitate the QA for the following JCOG studies. ITC performs DDIQA and facilitates PCQA performed by Dr. Satoshi Ishikura at the National Cancer Center Hospital East, Kashiwa, Japan. Digital data representing CT images, structure sets, treatment plans, 3D dose distributions, and DVHs are submitted by 14 institutions in Japan to Dr. Ishikura who then forwards these data to the ITC using the QuASA^{2}R system, where they are prepared for review. Dr. Ishikura or his designate then reviews the data using the RRT. (See ATC website for a list of participating institutions).

(1) JCOG 0403: Phase II Study of Stereotactic Body Radiation Therapy in Patients with T1N0M0 Non-Small Cell Lung Cancer (opened: 2005, accrual goals: 165; 14 institutions credentialed. 136 patients registered to study).

8. European Organization for Research and Treatment of Cancer (EORTC)

The ATC is providing resources (including ITC personnel and use of the QuASA^{2}R clinical trials QA system) to facilitate the QA for the following EORTC studies. ITC performs DDIQA and facilitates PCQA performed by Dr. Damien Weber (Hôpitaux Universitaires de Genève) using QuASA^{2}R's RRT.

(1) EORTC protocol 22042-26042: Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a Phase-II and observation study (accrual goals: 64; 3 institutions credentialed; 1 patient registered to study).

Most recently, the ATC(ITC) has been asked by Dr. Axelle Fortun-Van Renterghem, PhD, Budget and Contract Manager for EORTC, to submit a quotation(budget estimate) for services to support the Dummy Run and Individual Case Reviews of a randomized Phase III trial (100 institutions, 210 individual case reviews).

In addition, Dr. Purdy has been in discussion with Dr. Coen Hurkmans (Catharina Hospital, The Netherlands and member of the EORTC ROG) regarding collaborating with EORTC regarding further development of a common QA informatics platform for NCI and EORTC clinical trials. Dr. Hurkmans has indicated that he EORTC is now considering various scenario's of performing QA and that an expanded cooperation with ATC is one of the most promising options. He has indicated he will keep ATC informed about the developments in this area. If representatives from EORTC ROG attend this year's AAPM Annual Meeting in Houston, TX, ATC will meet with the ROG QA team members.

Finally, Dr. FitzGerald has initated a dialogue with EORTC similar to that described above regarding QARC support of NCIC trials. He will participate in a meeting planned at the NCI with EORTC officials in April 2008 and report back to ATC.

Hopefully all of these efforts can be harmonized and a robust synergistic ATC-QARC-EORTC relationship can be developed in the coming year.

9. Quality Research in Radiation Oncology (QRRO)

The ATC (Dr. Purdy) has contacted QRRO (Dr. Frank Wilson) and begun a dialog to see if there are any common efforts that could increase the synergy of both groups efforts. There has been positive interactions during this period. Drs. Bosch and Matthews were appointed to the QRRO *e-Data Committee,* chaired by Christopher Rose, M.D. and Phillip Devlin, M.D. (Vice-Chair). The ATC and QRRO are currently evaluating the use of the ATC *QuASA²R* system to support the QRRO Prostate Seed Implant Project. QRRO intends to gather 150 post-implant prostate seed plans from 15 centers and perform Dose-Volume Analysis (Target: V100, V150, D90; Rectum D_{avg}, D_{max}; Urethra D_{avg}, D_{max}). No dose recalculation or seed localization is anticipated. The suggested workflow is as follows: (a) Institutions submit brachy seed plan data (CTs, Structures, Doses, Plans) to ITC SFTP server (or on CD media); (b) ITC imports datasets into QuASA²R for DDIQA, including DVH re-calculation (modest effort for brachy seed plans); (c) Referee physician to evaluate / re-contour prostate using RRT; (d) Dose-volume statistics calculated using ITC DVH analysis scripts (like those used for RTOG studies). ITC is currently awaiting test datasets from Drs. Devlin's and Rose's institutions which will be processed by ITC and reviewed by Dr. Zelefsky to evaluate effectiveness of ITC tools for data review and analysis. If adequate, Drs. Wilson, Purdy, and Deye to finalize budget and payment schedule (depends on scope of work).

10. Cancer Bioinformatics Grid (caBIG)

The ATC is one of the funded participants in the caBIG *In Vivo* Imaging Workspace. ATC members are participating in weekly teleconference and providing use case examples for advanced technology radiation therapy clinical trials.

The ATC is also playing a key role in the RTOG 0522 National Cancer Imaging Archive (NCIA) project in which PET data are submitted by protocol participating institutions to the ACRIN Core Lab. ACRIN checks the PET images and uploads the image data to the CIP database. ITC receives the protocol case data (CT images, RT Structure sets, 3D Dose in either DICOM or RTOG formats). ITC performs DDIQA and RTOG performs PCQA and when approved, ITC converts the data to DICOM RT objects and uploads data to the NCIA. RTOG Headquarters staff is helping to coordinate this activity through monthly conference calls with RTOG ITC, ACRIN, CTEP and CIP individuals to ensure effective processes. Already a project using this data is emerging (led by Drs. Robert Jeraj, Mike Gillin, and Joe Deasy) that will assess the accessibility of the combined data and existing (or lack thereof) coordinated viewing capabilities. The ATC will make every effort to support this important project.

<u>Specific Aim 2</u>: Develop novel web-based remote-review tools that will enhance the efficient and effective review of 3DCRT, IMRT, SBRT, and brachytherapy protocols. The tools and interfaces will be designed by a multidisciplinary team of experts in the quality assurance of clinical trials. The design infrastructure of these tools will assist the development of future protocol processes such as image-guided radiation therapy (IGRT) and adaptive radiation therapy (ART) (Brabbins, et al. 2005, Yan, et al. 1998). *QuASA²R* is modular in architecture to promote the efficient design, testing, and implementation of tools and subsystems. Starting from a DICOM-based ITPV data archive with well-defined interfaces, our developmental approach will (a) allow the selective re-use and adaptation of existing *QuASA²R* system components, (b) enable the integration of a heterogeneous

mix of commercial-off-the-shelf, open-source and custom software components; (c) facilitate testing and maintenance of system components, and (d) allow step-wise evolution/upgrading of the *QuASA²R* system to support technological advances in radiation therapy clinical trials. Emphasis will be on the development and improvement of web-based remote-review tools that achieve compatibility with existing software and electronic health record standards, including the Cancer Bioinformatics Grid (caBIG) and DICOM RT, and maintaining/developing archival multimodality ITPV, credentialing, and QA databases for the advanced treatment modalities that can be linked with the cooperative group's clinical outcomes database.

This specific aim focuses on development/refining digital data exchange mechanisms and the development/refinement of the QuASA²R system. Development of the QuASA²R system has been guided by the considerable experience and success of ITC computer scientists and QA personnel in supporting advanced technology radiation therapy clinical trials, and the recognition of QA tool needs for future protocol processes, such as image-guided radiation therapy (IGRT) and adaptive radiation therapy (ART). The QuASA²R system supports Internet submission of data using the Secure FTP (SFTP/SSH2) protocol. Data may also be submitted using CD (DICOM or RTOG formats) or Tape cartridge (RTOG format only) media. The ITC SFTP server (ITCsubmit.wustl.edu) provides secure submission of data with individual accounts for institutions participating in advanced-technology protocols and treatment planning manufacturers testing data export capabilities. Users may submit data files, but may not access other users' data or system files. The flow of information through the QuASA²R system is diagrammed in **Fig. 3.**

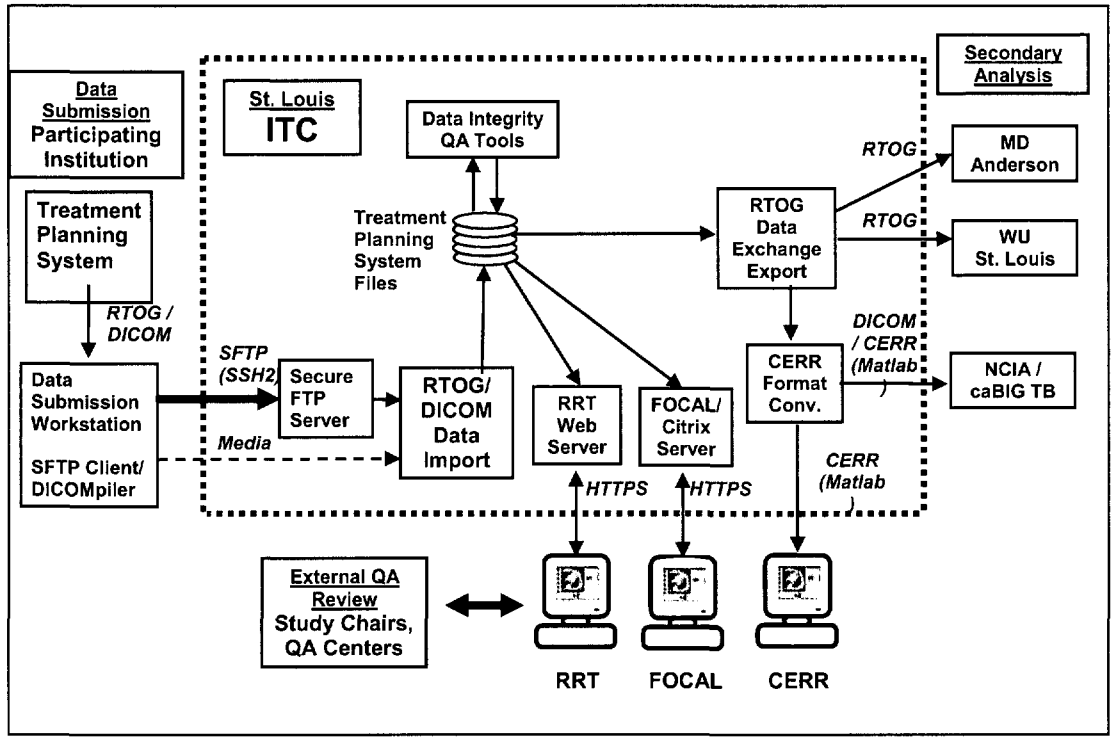

Figure 3. Diagram depicting QuASA²R *(Quality Assurance Submission, Archive, Analysis, and Review)* system components and data flow.

1. Digital Data Exchange

The QuASA^{2}R system supports the submission of images and digital treatment planning data as either DICOM RT objects or RTOG Data Exchange Format files. (The ATC web site, ***http://atc.wustl.edu/resources*** lists RTOG Format specifications and the ATC DICOM conformance statements). Diagnostic radiological images can be submitted as DICOM objects. Treatment verification images can be submitted as DICOM objects or JPEG files. Treatment planning system isodose images and DVH plots can be submitted as JPEG files. Files may be combined as "tar" or "zip" archives and may be compressed or encrypted (ZIP) prior to submission.

While the proportion of datasets submitted to the ITC using DICOM RT objects is currently less than one half of the total (see **Fig. 4**, below), the number of TP systems supporting export of *DICOM RT objects is growing, and is expected to exceed 50% of submissions in 2008. This is* due to the fact that two major TPSs are now shipping ATC-compliant DICOM-exporting versions and will eventually stop supporting their RTOG Data Exchange format exports.

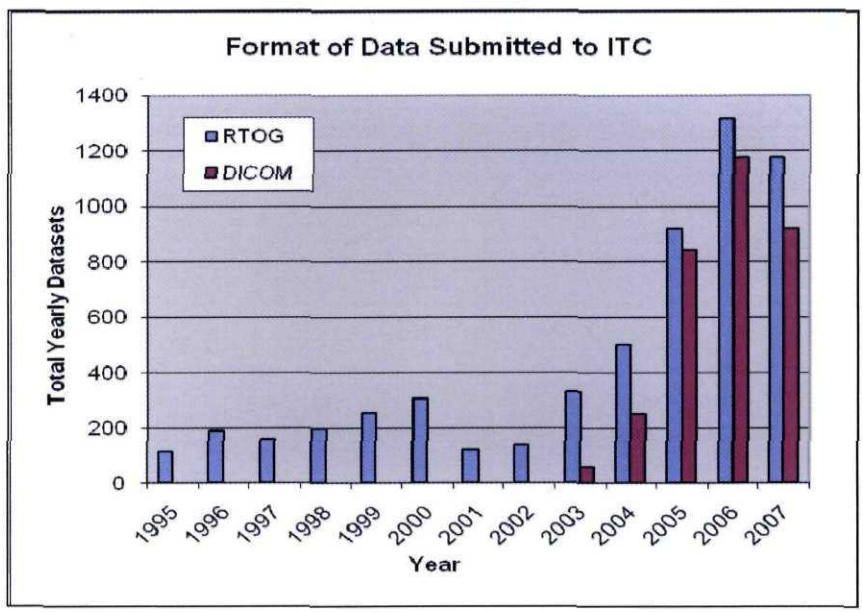

Figure 4. Number of protocol-case and credentialing (phantom) submissions received by the ITC per year showing the number submitted via RTOG Data Exchange and DICOM-RT formats.

The ITC continues to work directly with TP system vendors, as well as through the DICOM standards process and the IHE-RO initiative to assist in the implementation of ATC compliant DICOM export capabilities in commercial TP software. Note, the ATC was approved as an **Organizational Member of the International Integrating the Healthcare Enterprise** (IHE) as of March 6, 2008.

The ITC maintains a list of commercial ATC Compliant Treatment Planning Systems (TPS) on the ATC website which can produce data in a format suitable for submission on ATC-supported protocols (see **Figure 4**). In the past year, the ITC (mainly Dr. Matthews) has worked with over 7 TPS manufacturers (several with multiple software development groups). Currently, 11 TPS vendors (22 TP systems/versions) have achieved "ATC Compliant" status, meaning that a

clinical user of the TPS can submit a protocol compliant data set to the ITC. Note that two TPS's (CMS XiO and Philips Pinnacle[3]) have obtained ATC compliance in both data exchange formats. Since both of these TPS's are switching to DICOM export for their ATC compliant submissions, we anticipate that DICOM will shortly be our most commonly received format.

In addition to the 22 TP system/versions listed in Fig. 5, two institutions (the University of Michigan and Memorial Sloane-Kettering Cancer Center) use in-house developed TPSs that are ATC compliant. The University of Michigan has been submitting RTOG Data Exchange format datasets since the mid 1990s. The Memorial Sloane-Kettering Cancer Center has been submitting ATC compliant DICOM datasets since December of 2003.

In addition, Dr. Matthews has worked with an additional 7 vendors that have never been posted as ATC compliant. One of those vendors was close to compliant when it ceased operations in 2003.

Treatment Planning Systems			Exchange Format	Treatment Modality				
Vendor	System	Version[1]		3DCRT	IMRT	Seed Brachy	HDR Brachy	Protons
Accuray	MultiPlan	1.5.2	D		✓			
CMS	Focus/XiO	3.1	R	✓	✓	✓		✓
	XiO	4.3.1	D	✓	✓			
Elekta	RenderPlan 3D		R	✓				
	PrecisePlan	2.01	D	✓	✓			
Nomos	Corvus		R		✓[2]			
Nucletron	Helax TMS		R	✓	✓			
	TheraPlan Plus		R	✓				
	Oncentra MasterPlan	1.5	D	✓	✓			
	PLATO RTS	2.62	D	✓				
	PLATO BPS	14.2.6	D				✓	
	SPOT PRO		D			✓		
Philips	Pinnacle[3]		R	✓	✓			
	Pinnacle[3]	8.0h	D	✓	✓			
	AcqPlan	4.9	R	✓				
Prowess	Panther	4.41	D	✓	✓	✓		
Rosses Medical	Strata Suite CTPlan	4.0	R			✓		
RTek	PIPER	2.1.2	R			✓		
TomoTherapy	Hi-ART	3.0[3]	D		✓			
Varian	BrachyVision	6.5 (Build 7.1.67)	D				✓	
	Eclipse	7.1	D	✓	✓			✓
	VariSeed	7.1	D			✓		

Figure 5. ATC webpage (http://atc.wustl.edu/credentialing/atc_compliant_tps.html) maintained by the ITC lists ATC compliant treatment planning systems and their approved treatment modalities. (Under Exchange Format, R stands for RTOG Data Exchange and D for DICOM.)

2. ATC QuASA^{2}R Clinical Trials QA Review System

Supported data objects for the QuASA^{2}R system are listed in **Table 3.**

Table 3. List of data objects supported by QuASA^{2}R for digital data submission and review

Data Objects	Data Submission Format	Review Capabilities			
		RRT (web-based)	XiO (ITC) / FOCAL(VPN)	Secure HTTP download; DICOM viewer	ITC Image Viewer
CT Image (axial planes)	DICOM, RTOG	X	X	X	
MR Image (axial planes)	DICOM, RTOG	X	X	X	
Organ-at-risk/Target-volume contours	DICOM, RTOG	X	X		
3D Dose Distributions	DICOM, RTOG	X	X		
Dose-Volume Histograms	DICOM, RTOG	X	X		
Diagnostic Images (CT/MR/US/PET)	DICOM		X	X	
Treatment Plan specifications(beams, brachy sources)	DICOM, RTOG		X		
Treatment Verification Images (scanned films, EPID images)	DICOM, RTOG, JPEG				X
Screen-capture images (isodose images, DVH plots)	JPEG				X

The continuing emergence of new imaging and radiotherapy treatment modalities and their utilization in new advanced technology clinical trials requires continuing updates to the QuASA^{2}R system. Functional imaging for target definition and response assessment, 4-D imaging for motion assessment, 2-D and 3-D image-guided treatment delivery, and adaptive radiotherapy techniques represent new sources of data that must be reviewed and analyzed for these trials. To manage the collection and evaluation of these new data objects, the ITC is using a step-wise approach to implementation and upgrading of system components. This step-wise approach is important, since adding new capabilities must not disrupt continuous support of ongoing protocols. For this reason, the ITC has embraced a modular architecture philosophy with emphasis on well-defined interfaces, which promotes integration of commercial "off-the-shelf" and open-source software products, and focuses custom software component development on only those QA features required, but not otherwise available. By limiting the scope of module functions and using standards-based interfaces, maintenance/testing of new system components is also facilitated.

During this funding period, the ITC is replacing the current imaging/treatment planning/verification (ITPV) database (which utilizes a commercial treatment planning vendor's file format) with DICOM archive software supporting a tiered storage structure on a highly-redundant Network Attached Storage (NAS) hardware (Pillar Data Storage, San Jose, CA). The DICOM archive software, Evercore (TeraMedica, Milwaukee, WI) will provide storage for diagnostic imaging, DICOM RT, and meta-data related to the diagnosis, treatment, and outcomes assessment for protocol patients. As of Jan. 2008, NAS hardware (10 TB) has been installed at ITC and is being integrated with existing systems for SFTP data collection, protocol dataset backup, and web-based review. Acquisition of hardware and software for the Evercore archive is underway.

Also, updates to QA utilities that aid ITC staff in performing DDIQA continue to be implemented. Functions supported by these tools include DICOM consistency checking, data anonymization/ ID reconciliation, archive loading, query/retrieval, data format conversion (RTOG Data Exchange to DICOM RT), case data inventory/revision management, structure identification/contour editing, dose summation, DVH calculation, and web-based/thin-client review.

To facilitate the review and analysis of quantitative, functional imaging for target-volume delineation and treatment response in ATC-supported clinical trials, the ITC is evaluating the integration of commercial image viewing software (MIMvista, Cleveland, OH with the Evercore archive (**Fig. 6**). Important features of this tool include quantitative PET review, automatic/manual, multi-modality image registration, 3D/multi-planar contouring, image/contour deformation, and atlas-based segmentation.

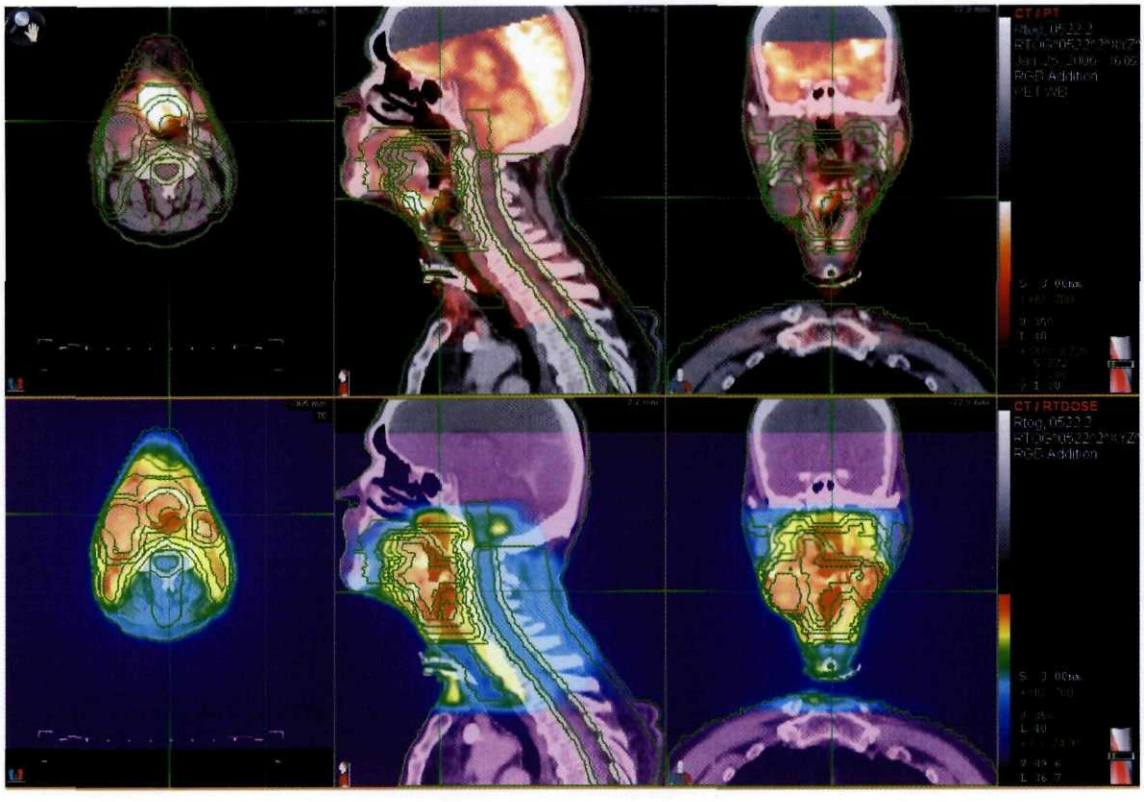

Figure 6. MIMvista display of RTOG 0522 data set (PET fused to planning CT with dose displayed)

Another major development has been the integration of the open source software *Computational Environment for Radiotherapy Research* (CERR) for converting non-DICOM data received by the ITC to DICOM RT objects, for QA review, and for secondary data analysis (Deasy et al. 2003). CERR is in regular use to prepare treatment planning data for inclusion in the National Cancer Imaging Archive as DICOM RT data objects and for studies that have specialized QA review needs (**Fig. 7**). The CERR/Matlab programming environment has also been used to develop a Film Dosimetry QA tool (Khullar et al. 2007). This tool is currently in production use at the RPC to facilitate quantitative comparison of film/TLD phantom dosimetry data with corresponding dose distributions computed by treatment planning (TP) systems. TP

datasets for RPC phantoms are submitted to the ITC for DDIQA, converted to CERR format, and forwarded to the RPC for analysis.

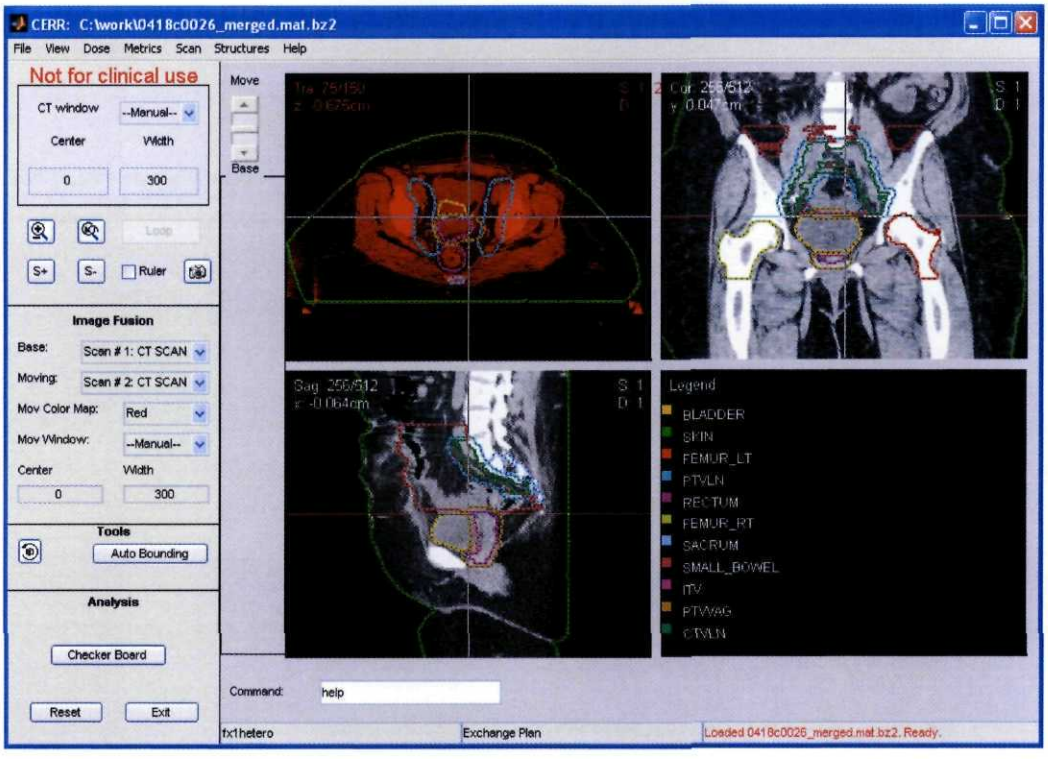

Figure 7. CERR display being used to support RTOG GYN trial having specialized needs: (a) requires review of contours from two different fused CT imaging studies one with bladder full and one with bladder empty; (b) and the need to review submissions simultaneously by two PIs at different locations.

QARC has become a key user of CERR and has fully integrated it into their daily workflow. During the past year Dr. Ken Ulin at QARC has made modifications to the code in many important areas including digital display of protocol objects. Two major improvements have been the integration of CERR into the MAX database at QARC and the ability to display CERR from remote access via server side display of objects through a web browser. These improvements will facilitate the potential integration of CERR into other ATC member sites via the intended migration of the QARC database into member sites. QARC now houses more than 300 radiation therapy protocol cases from more than 100 institutions submitted to QARC via digital data transfer. The majority of digital radiation therapy cases are submitted through the CERR mechanism. QARC has received more than 150 benchmark cases for both cooperative group and industry clinical trials in a digital format including many international clinical trial sites.

Cancer Bioinformatics Grid (caBIG)

Work is also underway to develop compatible interfaces between the QuASA^{2}R system and the NCI Cancer Bioinformatics Grid (caBIG) infrastructure. A demonstration of caGrid connectivity for distributed treatment plan review using CERR was presented at the RSNA 2007 meeting [Sharma 2007]. This work makes use of caBIG In Vivo Imaging middleware developed by Joel Saltz and colleagues at OSU to deploy CERR software as an integrated communication and review tool. A caGrid data service is used to store CERR objects and associated metadata. A

minor modification of the CERR client supports grid security and query/retrieval of CERR data for distributed review.

Summary - QuASA^{2}R System

The QuASA^{2}R system has demonstrated a continuing robustness (now having archived nearly 7000 volumetric data sets) while its modular design is allowing updates to meet the ever changing requirements of advanced technology clinical trials.

Specific Aim 3: Assist cooperative groups in the development and management of advanced technology clinical trials protocols including (a) tumor/target volume and organ at risk definitions; (b) credentialing requirements and evaluation criteria; (c) electronic data submission requirements/instructions; and (d) quality assurance review procedures.

This specific aim focuses on helping cooperative groups utilize standard nomenclature and definition and credentialing requirements in the clinical protocol. The RPC plays a key role in helping the ATC accomplish this effort, particularly in the development of anthropomorphic QA phantoms for advanced technology treatment techniques. QARC, RPC, ITC, and RTOG are all involved in some aspect of evaluation and credentialing of institutions to participate in such protocols. Feedback from participating medical physicists indicates that there is still work to be done in achieving uniformity in the credentialing process and providing clear instructions for the credentialing process.

To address such issues, Dr. Purdy appointed (at the March 27-28 ATC meeting), a standing committee (Marcia Urie (Chair), Dave Followill (Co-chair), Bill Straube, and Jim Galvin). This committee's mission is to help eliminate duplication of effort and help facilitate sharing of QA resources among cooperative groups and QA Centers; (2) help insure that appropriate and uniform QA procedures and criteria for advanced technology trials are developed across all cooperative groups; and assist clinical trial cooperative groups in the development of clinical trials protocols including: (a) credentialing requirements; (b) target volume definitions; (c) quality assurance procedures; and (d) data submission instructions.

Credentialing instructions and QA criteria for ATC supported protocols are posted (or linked to other QA Centers) on the ATC website. They address the following modalities:

- 3DCRT QA Criteria: Credentialing and QA criteria for institutions participating in clinical trials that utilize traditional 3DCRT and that require digital data submission have been established. See ATC's website at http://atc.wustl.edu and refer to RTOG protocol 0126,.
- IMRT QA Criteria: Credentialing and QA criteria for institutions participating in RTOG clinical trials that utilize IMRT and that require digital data submission have been established. See ATC's website at http://atc.wustl.edu and refer to RTOG protocol 0522. Note, the ATC developed the NCI guidelines (Palta et al. 2004), and helped in the revision and subsequent update that now allows use of IMRT for intra-thoracic treatments, and provides more detailed and specific guidelines for use of IMRT for intra-thoracic treatment protocols with the goal that they are clear enough to be consistently applied within all of the cooperative groups.
- Prostate Seed Implant QA Criteria: Credentialing and QA criteria for institutions participating in clinical trials that involve transrectal ultrasound guided permanent radioactive implantation and that require digital data submission have been established. See ATC's website at http://atc.wustl.edu and refer to RTOG protocol 0232.

- HDR Brachytherapy QA Criteria: Credentialing and QA criteria for institutions participating in clinical trials that involve high dose rate brachytherapy and that require digital data submission have been established. See ATC's website at http://atc.wustl.edu and refer to RTOG protocol 0321.
- SBRT QA Criteria: Credentialing and QA criteria for institutions participating in clinical trials that involve SBRT and that require digital data submission have been established. See ATC's website at http://atc.wustl.edu and refer to RTOG protocol 0617.

An important change in the activities of the RTOG over the past year was the introduction of protocols that use daily image guidance for studies that deliver standard dose fractionation. There were a few earlier protocols (RTOG 0236 and 0438) which used image guidance in the setting of hypofractionation. Both RTOG 0236 and 0438 were important for establishing guidelines for the use of IGRT as part of RTOG protocols. However, using IGRT as part of protocols with standard fractionation offers new considerations that the RTOG has addressed over the past year. The accomplishments over the past year relative to the use of IGRT in RTOG protocols are:

- Development of a set of guidelines for the use of IGRT as part of RTOG protocols
- Develop supplemental guidelines for limiting patient dose when IGRT is used in RTOG protocols
- Devising of a technique for verifying the targeting of treatment beams when image guidance techniques are used as part of RTOG protocols

A few of the major aspects of the guidelines are: 1) the requirement that the protocol discuss the method to be used for image registration, and 2) the frequency of imaging that is allowed. For daily imaging, the investigator is required to estimate the dose received by the patient as a result of the imaging process.

Through the ATC, the RTOG would like to see the entire radiation oncology community adopt the IGRT guidelines and techniques. This change is currently being considered by other protocols groups, and remains as a high-priority goal for the ATC members.

During the past year there has also been considerable progress in the development of credentialing mechanism for proton therapy. All members of ATC have contributed to this effort. NCI guidelines on the use of protons in cooperative group clinical trials with Drs. Urie and Gillin of ATC as authors have been developed with the support of Dr. Deye. At the request of the NCI/ATC, QARC and the RPC developed a strategy for credentialing institutions with both phantom and test case methods. The credentialing process includes a questionnaire developed and vetted by ATC. The overall process for credentialing is now close to being in place and will be an important asset for both pediatric and adult cooperative group clinical trials.

The credentialing processes developed have not only been shown to ensure institutions have the capability to submit digital data, but also has been instrumental in educating the participating institution in regard to the protocol requirements addressed in the next specific aim.

<u>Specific Aim 4</u>: Serve as an educational resource to the nation's clinical trial cooperative groups and participating institutions for support of advanced technology radiation therapy clinical trials.

This specific aim is being address through use of the ATC website (http://atc.wustl.edu) which has continued to be refined during this funding period. The ATC Website links to all the

consortium member websites, the NCI, and all cooperative group protocols the ATC is supporting. The ATC's website provides an overview, including history and mission, of the ATC's role in advanced technology clinical trials and is used to disseminate advisory QA and credentialing information and pertinent forms to current and potential participants in all ATC supported clinical trials, and to receive on-line submissions of certain protocol forms. The website provides simple access to valuable resources for institutions participating in these studies as well as for institutions preparing for certification. The data submission and QA review resources linked on the ATC website are for the use of study chairs, QA centers, and participants in ATC-supported clinical trials. A valid user account is required for their use.

The ATC distributed brochures at the 2007 AAPM and ASTRO Annual Meetings. This brochure provided information regarding the ATC's mission and the current ATC activities. Importantly, compliant data exchange capabilities of treatment planning vendors was listed.

The ITC is very involved in education of institutional personnel that are involved in registering, planning, and treating ATC supported protocol patients. The ITC routinely presents at the RTOG RA symposium that is held the Thursday before the RTOG meeting in January and June. The ITC is also available at the roundtable session on Friday morning of the RTOG meeting. An ITC physicist also spoke at the 2007 NSABP meeting both addressing the RAs and presenting at a workshop for the B39/0413 protocol which was attended by physicians as well as RAs.

The ATC presented at the AAMD meeting in Canada helping educate personnel on submission of data for ATC supported clinical trials.

In addition the ATC(ITC) was involved in presentations for a chairperson's workshops at the RTOG head quarters. These workshops are hosted to prepare physicians for their involvement in protocol development. The ITC presented the use of ATC tools for protocol review and credentialing.

The ATC continues to be active in assisting CDRP members to meet credentialing requirements for any ATC supported clinical trial.

The ATC has provided assistance to scientists regarding secondary analysis of multi-institutional clinical trials data supported by ATC: (1) NIH R01 Grant: Tucker/Thames (M.D. Anderson) using RTOG 9406 data; and (2) NIH R01 Grant: Bradley/Deasy (WU) using RTOG 9311 data. Guidelines to make requests for ATC supported protocol data more efficient have been developed and are posted on the ATC website.

EVALUATION METRICS AND MILESTONES

The following metrics/milestones have been documented for the period July 1, 2007- April 1, 2008:

Service Metrics:

- *Number of protocols being actively supported by ITC:* The ATC(ITC) received digital data for 17 protocols during this time period; 8 new protocols were activated during this time period and 4 protocols were closed.

- *Number of protocols cases in which a complete volumetric imaging data set was submitted and DDIQA performed:* 1,222 volumetric data sets.

- *Number of institutions credentialed for participation in advanced technology protocols:* A total of 571 institutions are credentialed and can submit volumetric digital data to the ATC(ITC); of these 87 were credentialed during this period.

- *Number (and name) of cooperative groups supported by ITC/QARC:* 7 Cooperative Groups are supported including NSABP, RTOG, NABTT, EORTC, JCOG, and GOG. 6 additional Cooperative Groups' advanced technology protocols are supported by QARC including COG, CALGB, ECOG, PBTC, SWOG, and ACOSOG. Discussions are underway with NCIC.

- *Number (and name) of new treatment planning systems/software versions that can submit digital data that are ATC compliant:*
  - The following systems were deemed ATC Compliant during the period July 1, 2007- April 11, 2008:
    - Accuray CyRIS MultiPlan ATC compliant for DICOM submission 8/22/2007
    - Nucletron SPOT-Pro ATC compliant for DICOM submission 4/7/2008
    - Philips Pinnacle3 ATC compliant for DICOM submission 3/5/2008
    - Prowess Panther ATC compliant for DICOM submission 11/20/2007
    - Tomotherapy Hi-ART ATC compliant for DICOM submission July 2007
  - The following systems were deemed ATC Vendor Complete during the period July 1, 2007- April 11, 2008:
    - SonoTECH HDRplus/FIxiplan Vendor Complete for DICOM submission 4/11/2008
  - Other Events:
    - CMS XiO DICOM submission has problem with HFP patient 3/24/2008
    - Siemens KonRad has clinical submission with coarse dose from St. Jude's, Memphis 3/11/2008

Coordination Metrics:

- Number and type of credentialing criteria for participation in advanced technology protocols that are uniform across RTOG, QARC, RPC, and ITC: *ATC is working to have uniform credentialing methods and criteria for the following modalities: 3DCRT, IMRT, Prostate Seed Implant, HDR Brachytherapy. Significant progress has been made on SBRT, IGRT, and proton radiation therapy.*

Research Metrics:

- Number of abstracts accepted at 2007 & 2008 AAPM and ASTRO Annual Meetings, RSNA InfoRad, SPIE conferences, and IEEE Medical Imaging Symposia, Computer Assisted Radiology and Surgery (CARS) Congress and Exhibits, and AAMI Events/Workshops: *16 abstracts/presentations given/submitted during this period*

- Number of peer-reviewed publications: *4 published or in press during this period*

- Number of chapter/proceedings publications: *0*

- Number and type of software tools that are developed and put into production use (with timeline showing start date and production use date): *As previously documented, the QuASA^{2}R system has demonstrated a continuing robustness (now having archived nearly 7000 volumetric data sets) while its modular design is allowing updates to meet the ever changing requirements of advanced technology clinical trials.*

Metrics - Cost-benefit Analysis of ATC initiative.

- Ratio of ATC total yearly funding to number of protocols in which a full set of volumetric ITPV was obtained and that can be linked to clinical outcome: *ATC yearly funding is $1.75M per year and there were 17 protocols; hence .$102,941/protocol. ATC(ITC0 received 1,222 volumetric data sets; hence $1,432/data set.*

- Ratio of ATC total yearly funding to number of abstracts published and/or presentations given at major clinical meetings reporting on primary clinical endpoint(s) of ATC supported protocols: *$109,375*

- Ratio of ATC total yearly funding to number of peer-reviewed publications reporting on primary clinical endpoint(s) of ATC supported protocols: *$437,500*

- Ratio of ATC total yearly funding to number of abstracts, presentations, and peer-reviewed publications reporting secondary analysis results using previous protocol ITPV and outcome data: *$87,500*

- Ratio of ATC total yearly funding to number of grant proposals submitted and those being supported using previously archived protocol ITPV and outcome data: *2 grants previously funded; one newly submitted; hence $533,333/grant*

Alternative Support Measures for ATC.

During this funding period the ATC has been proactive in seeking alternative funding sources as described below:

Direct Funding from Industry:

- ATC(ITC) is providing support to AstraZeneca to facilitate QA review of the radiation therapy portion of their protocol (ZD6474 Trial 62 HNSCC). This is a three institution study and thus far 15 case studies have been accrued.

- ATC(ITC) is in negotiation with Eli Lily and Company to provide support to facilitate QA review of the radiation therapy portion of one of their protocols that will utilize chemotherapy and radiation in locally advanced non-small cell lung cancer. This will be a phase III registration trial that will encompass multiple sites (on the order of 100) around the world (North America, South America, Europe, and Asia).and hopefully accrue approximately 600 patients over a 20-22 month time frame.

Investigator-Initiated Mechanisms (R01, PO1, etc.):

- Dr. Joe Deasy in collaboration with RTOG to Application Title: Subjective and Objective Characteristics of Fatigue in Prostate Cancer Treatment
  Proposed Project Period: 8/01/2008 - 7/31/2013
  Washington University requested dollars:

	First Year		All Years
Direct Costs (WUSTL)	$43,143	Direct Costs	$218,263

  ITC will receive consultant fees to de-archive treatment planning data.

  This would be the first detailed study of various factors causing radiotherapy-induced fatigue, including the 'dose-volume' effect. It will combine dose-volume factors with clinical data, patient biomarkers, and genomic biomarkers to produce a unique dataset.

- Future RTOG/ATC-related grants will include a CERR R01 (October submission).

Industry Provided Hardware/Software:

- ATC has solicited support from industry in terms of hardware/software to help in the development of the QuASA^{2}R-system. The following agreements are in place:
  - CMS: is providing ITC licenses (at no cost) for use of FocalSim and Xio software.
  - TeraMedica: has agreed to provide Evercore software to ITC and support training for an initial license fee of $6,000, and an annually recurring license fee of $2,000.
  - Varian Medical Systems: has agreed to provide (at no cost) an Eclipse Treatment Planning System to the ITC in St. Louis in support of ATC. Plans are now underway to obtain this system.
  - IMPAC: has agreed to install a MOSAIQ™ software system (at not costs) at the ITC facilities networked to the RTOG, QARC, RPC–all groups that conduct advanced technology RT clinical trials. However, any process-flow consultation, hardware, third-party software, implementation, training, and technical support costs is the ATC's responsibility.
  - Philips Medical Systems: has agreed to provide (at no cost) one Pinnacle work station with complete software and hardware (version 8.0) to the ITC in St. Louis in support of ATC.
  - TomoTherapy Inc.: has agreed to provide (at no costs) a data server for protocol case data storage and a workstation with appropriate software to access this data to the ITC in St. Louis in support of ATC.

  Dr. Purdy has appointed a standing ATC IT Committee (chaired by Dr. Walter Bosch, with IT representatives from each of the ATC subcontractors, along with Dr. Brenda Young representing ACRIN, and Dr. Joel Saltz (Ohio State University, representing caBIG) whose mission is to focus on the integration of these commercial products into the ATC informatics infrastructure (enterprise solutions) In addition, the ATC will continue to explore the idea of forming a Council of Industry Participants involved in radiation oncology advanced technologies and that support ATC. The group would meet once a year with the ATC members to discuss new tools needed, what is commercially available, caBIG updates, status of new, ongoing, and proposed advanced technology protocols.

(C) SIGNIFICANCE

Today, the credentialing, digital data submission, and QA for protocols using advanced technologies such as 3DCRT, IMRT, SBRT, and brachytherapy have become a priority for cooperative group trials. The ATC has continued to use the concepts pioneered with the 3DOG/RTOG 9406 protocol for credentialing, data submission, and QA. In this past year, significant progress continued in using the ATC QuASA^{2}R sytem. We strongly believe that the ATC has been successful in providing the most cost effective, efficient, and advanced QA review available for all Cooperative Groups conducting clinical trials utilizing advanced technologies. We feel strongly that our ATC QA consortium continues to represent the best single effort to date to merge the strengths of the national QA Centers and to develop a common database for outcome analysis.

(D) PLANS FOR THE NEXT PROJECT PERIOD (2008-09)

To accomplish the ATC goals listed at the beginning of this progress report, we will continue the ITC's successful collaborations with the RTOG, RPC, and QARC and address the 4 specific aims listed.

Service Efforts: ATC will continue to support the nation's cooperative group advanced technology clinical trials. We plan to target COG, SWOG, and CALGB and make them aware of the increased capability at QARC regarding receiving volumetric treatment planning and imaging digital data. RTOG will also make greater use of the ATC in support of their protocols.

Informatics Developmental Efforts:

Table 4: Timeline for QuASA^{2}R Upgrades/developments

	Project	Date
1	Pillar Data Storage System • Stable support for existing QuASA2R components • Flexible foundation for DICOM Archive	Installed at ITC Jan 2008 • Data backup, SFTP operational • NFS issues
2	DICOM-based RT Archive (TeraMedica Evercore) • Support for wide range of imaging and RT datasets	Work in progress • System specs Jan 2008 • Software license contract in progress for implementation at ITC
3	Data format conversion tools • DICOM conv. for legacy (RTOG) data • CERR conv. for phantom dosimetry • CERR conv. for distributed case review	Work in progress • Starting Jan 2007 • In use: Feb 2008 • Demo RSNA 2007
4	Diagnostic Image Review Tools • MIMvista • Hermes	Evaluation of systems in progress. Plan to purchase for implementation at ITC Spring/Summer 2008
5	Digital Data Integrity QA workflow tools (CERR) • DDIQA Server • Data anonymization / ID reconciliation • Archive loading • Case data management (inventory, revision) • DICOM consistency checks (DVTk) • Structure naming / Structure editing / Dose summation?	Begin Summer 2008
6	ITC DDIQA Server/Tape Backup Upgrade	Begin Summer 2008
8	Evaluate MAX Server for QA Workflow Management at ITC	Begin Summer 2008
9	Evaluate ACRIN TRIAD for Diagnostic Image Collection at ITC	Begin Summer 2008
7	QuASA2R / Commercial TPS Integration (CMS, Eclipse, Pinnacle,...)	Begin Fall 2008
10	Grid-enabled CERR for production case review at ITC • Secure download, seamless review • Anticipatory data push	Begin Fall 2008
11	Server-side review tools • Image Digest / QA Report Generator (CERR) • Multi-planar (T/S/C) tool for contour and dose review	Begin Spring 2009

Coordinate and promote uniformity in protocol credentialing and QA requirements: ATC, through its newly formed standing committee on this topic will address (1) protocol nomenclature (i.e., tumor/target volume and organ at risk definitions and prescription wording); and (2) credentialing requirements and evaluation criteria for uniformity across cooperative groups and clarity/reasonableness.

Serve as Educational Resource....: ATC will continue to modify/update the ATC website (http://atc.wustl.edu) in order to better support the nation's cooperative group advanced technology clinical trials and the participating institutions. The ATC member groups will continue to present at the major Annual Meeting and at cooperative group meetings, and to publish their findings when warranted.

References

Brabbins D, Martinez A, Yan D, Lockman D, Wallace M, Gustafson G, Chen P, Vicini F and Wong J. A dose-escalation trial with the adaptive radiotherapy process as a delivery system in localized prostate cancer: Analysis of chronic toxicity. Int. J. Radiat. Oncol. Biol. Phys. 61(2): 400; 2005.

Deasy JO, Blanco AI and Clark VH. CERR: A Computational Environment for Radiotherapy Research. Med Phys 30(5): 979-985; 2003.

Khullar D, Molineu A, Followill D, Bosch W, Willcut V, Simpson T, Ju T and Deasy JO. An Open-Source Software Tool to Support Film-Based IMRT Quality Assurance. (abstract). Med. Phys. 34: 2418; 2007.

Michalski JM, Purdy JA, Winter K, Roach III M, Vijayakumar S, Sandler HM, Markoe AM, Ritter MA, Russell KJ, Sailer S, Harms Sr. WB, Perez CA, Wilder RB, Hanks GE and Cox JD. Preliminary report of toxicity following: 3D radiation therapy for prostate cancer on 3DOG/RTOG 9406. Int. J. Radiat. Oncol. Biol. Phys. 46(2): 391-402; 2000.

Palta JR, Deye JA, Ibbott GS, Purdy JA and Urie MM. Credentialing of institutions for IMRT in clinical trials (Correspondence). Int. J. Radiat. Oncol. Biol. Phys. 59(43): 1257-1259; 2004.

Purdy JA, Harms WB, Michalski J and Cox JD. Multi-institutional clinical trials: 3-D conformal radiotherapy quality assurance. In 3-D Conformal Radiotherapy: A New Era in the Irradiation of Cancer: Meyer JL and Purdy JA, editors. Basel, Karger. 29: 255-263; 1996.

Purdy JA, Harms WB, Michalski JM and Bosch WR. Initial experience with quality assurance of multi-Institutional 3D radiotherapy clinical trials. Strahlentherapie und Onkologie 174(Supplement II): 40-42; 1998.

Yan D, Ziaga E and Jaffray D. The use of adaptive radiation therapy to reduce setup error: A prospective clinical study. Int. J. Radiat. Oncol. Biol. Phys. 41: 715-720; 1998.

Human Subjects: The ATC does not enroll patients on treatment protocols and has no direct contact with patients under this U24 grant. The ATC(ITC) does receive treatment records (digital and hard copy) containing identifiers from institutions participating in cooperative group clinical trials. These protocols include requirements to protect identifiers from improper use, and include requirements for informed consent and authorization. The participating institution at the time of patient enrollment obtains authorization. The role of the ITC is to evaluate and/or facilitate the evaluation of the submitted case data for compliance with the cooperative group protocols. The ITC would be unable to perform or facilitate this QA review without access to and use of the PHI. All treatment records are the property of the study group(s) at the conclusion of evaluation. The study group ensures that the protocol includes a plan to destroy identifiers at the appropriate time. Appropriate security features incorporating both physical and software restraints for maintaining confidentiality currently exist at the ITC. The other ATC members also have well-established procedures for handling patient data with proper regard for confidentially.

Vertebrate Animals: Not Applicable

(E) Publications

Abracts/presentations that involved ATC support are listed below:

1. D Khullar, A Molineu, D Followill, W Bosch, V Willcut, T Simpson, T Ju, and J Deasy. An Open-Source Software Tool to Support Film-Based IMRT Quality Assurance. (abstract) Amer Assoc Phys Med (AAPM), 2007; Minneapolis, MN.. Med. Phys. 34, 2418, 2007.
2. Bradley J; Graham M; Moughan J; Byhardt R; Govindan R; Fowler J; Purdy JA; Michalski J; Gore E; Choy H: Phase I/II Results of RTOG L-0117; a Phase I/II Dose Intensification Study Using 3DCRT and Concurrent Chemotherapy for Patients with Inoperable NSCLC, International Assoc Study of Lung Cancer (IASLC), Seoul, Korea. Lung Cancer, 2: abstract #PD5-2-4. 2007.
3. Tucker SL, Dong L, Bosch WR, Michalski J, Winter K, Lee AK, Cheung MR, Kuban DA, Cox JD, Mohan R: Fit of a Generalized Lyman Normal-Tissue Complication Probability (NTCP) Model to Grade ≥ 2 Late Rectal Toxicity Data From Patients Treated on Protocol RTOG 94-06 (abstract) Amer Soc Thera Rad Onc (ASTRO), 2007; Los Angeles, CA.. *Int. J. Radiat. Oncol. Biol. Phys.*, 69(3), S8-S9, 2007.
4. Cheung MR, Tucker SL, Dong L, Bosch WR, Michalski J, Winter K, Mohan R, Kuban D, Lee AK, Cox JD. Dose-Volume Analyses of Grade >/= 2 Late Rectal Toxicity Among Patients Treated on Protocol RTOG 94-06. (abstract) Amer Soc Thera Rad Onc (ASTRO), 2007; Los Angeles, CA. Int J Radiat Oncol Biol Phys, 69:S9.
5. Harari P; Harris J; Kies M; Myers JN; Foote RL; Machtay M; Rotman M; Khuntia Deepak; Straube W; Ang, K. Phase II Randomized Trial of Surgery Followed by Chemoradiation Plus Cetuximab for High-Risk Squamous Cell Carcinoma of the Head and Neck (RTOG 0234). (abstract) Amer Soc Thera Rad Onc (ASTRO), 2007; Los Angeles, CA. Int J Radiat Oncol Biol Phys, 69:S13.
6. Lee N; Harris J; Garden A; Straube W; Bosch W; Morrison W; Quivey J; Thorstadt Wade; Jones C; Ang, K. Phase II Multi-institutional Study of IMRT +/- Chemotherapy for Nasopharyngeal Carcinoma (RTOG 0225): Preliminary Results. (abstract) Amer Soc Thera Rad Onc (ASTRO), 2007, Los Angeles, CA. Int J Radiat Oncol Biol Phys, 69:S13-14.

7. Timmerman RD; Paulus R; Galvin J; Michalski J; Straube W; Bradley J; Fakiris AJ; Bezjak A; Videtic GM; Choy, H. Toxicity Analysis of RTOG 0236 Using Stereotactic Body Radiation Therapy to Treat Medically Inoperable Early Stage Lung Cancer Patients. (abstract) Amer Soc Thera Rad Onc (ASTRO) 2007, Los Angeles, CA, Int J Radiat Oncol Biol Phys, 69:S86.
8. Xiao Y; Straube W; Bosch W; Timmerman R; Galvin J: Dosimetric Evaluation of Heterogeneity Corrections for RTOG 0236: Hypofractionated Radiotherapy of Inoperable Stage I/II Non-Small Cell Lung Cancer. (abstract) Amer Soc Thera Rad Onc (ASTRO) 2007, Los Angeles, CA, Int J Radiat Oncol Biol Phys, 69:S46.
9. Bosch W, Straube W, Matthews J, et al. A Survey of the ITC Volumetric Treatment Planning Data Archive Supporting RTOG Advanced Technology Clinical Trials. (abstract) Amer Soc Thera Rad Onc (ASTRO), 2007,: Int J Radiat Oncol Biol Phys, 2007. 69:S195.
10. Michalski JM, Lawton C, El-Naqa I, Ritter MA, Pisansky T, Catton CN, Valicenti RK, Seider MJ, Sandler HM, Bosch W: Variation in the Definition of Clinical Target Volumes for Postoperative Conformal Radiation Therapy of Prostate Cancer (abstract) Amer Soc Thera Rad Onc (ASTRO), 2007; Los Angeles, CA. *Int. J. Radiat. Oncol. Biol. Phys.,* 69(3), S326.
11. Michalski J; Bae K; Roach III M; Markoe A; Sandler H; Ryu J; Parliament M; Straube W; Valicenti R; Cox J: Long-Term Toxicity Following 3d Conformal Radiation Therapy For Prostate Cancer On RTOG 9406, A Phase I/II Dose Escalation Study. (abstract) Amer Urology Assoc (AUA) 2007, Anaheim, CA.
12. Small Jr W, Mell LK, Anderson P, et al. Consensus Guidelines for Delineation of Clinical Target Volume for Intensity-Modulated Pelvic Radiotherapy in Postoperative Treatment of Endometrial and Cervical Cancer. Int J Radiat Oncol Biol Phys. 2007;2007 (Epub ahead of print)
13. Sharma A, Saltz *J, Pan T, Bosch W, Deasy J, Pu*rdy J: Application of caGrid® Middleware to Facilitate Quality Assurance for Advanced Technology Radiation Therap^{y} Clinical Trials (Abstract) In: Radiological Society of North America scientific assembly and annual meeting program. Oak Brook, Ill: Radiological Society of North America, 2007.
14. Bosch W, Matthews J, J Deasy, Michalski J, Straube W, Purdy, J: QuASA^{2}R –A Digital Data Quality Assurance Submission, Archive, Analysis, and Review System for Advanced Technology Clinical Trials in Radiation Therapy. Submitted AAPM 2008 Meeting, Houston, TX.
15. Straube W, Bosch W, Eccher A, Haynes R, Matthews J, Purdy, J: Update on Digital Data Integrity Quality Assurance for Multi-Institutional Advanced Technology Clinical Trials. Submitted AAPM 2008 Meeting, Houston, TX.
16. Straube W, Bosch W, Matthews J, Michalski J, O'Meara E, Purdy, J: Impact of Protocol Complexity and Clarity on Digital Data Integrity Quality Assurance (DDIQA) for Advanced Technology Clinical Trials Requiring Digit Data Submission to the Image-Guided Therapy QA Center (ITC). Submitted ASTRO 2008 Meeting, Boston, MA.

Publications that involved ATC support published or in press or are listed below:

1. Ibbott G, Hanson W, Martin E, et al. Dose Specification and Quality Assurance of RTOG Protocol 95-17, A Cooperative Group Study of 192-Ir Breast Implants as Sole Therapy. Int J Radiat Onco Biol Phys.69(5):1572-1578. 2007
2. Michalski J, Lawton C, El Naqa I, et al. RTOG Genitourinary Radiation Oncology Specialists Reach Consensus on Prostatic Fossa Clinical Target Volume for Radiation Therapy following Radical Prostatectomy. Presented at ASCO GU Cancers Symposium, San Francisco, CA, 2007. In Press.
3. Purdy JA. QA Issues In Conducting Multi-Institutional Advanced Technology Clinical Trials. Presented at ASTRO Quality Assurance Symposium, Dallas, TX, Int J Radiat Oncol Biol Phys. In Press.
4. Ibbott GS, Followill DS, Molineu HA, Lowenstein JR, Alvarez PE, Roll JE. Challenges in Credentialing Institutions and Participants in Advanced Technology Multi-institutional Clinical Trials. Int J of Radiat Oncol Biol Phys. In Press.

Program Director/Principal Investigator (Last, first, middle): Purdy, James A.

GRANT NUMBER
2U24CA081647-10

CHECKLIST

1. PROGRAM INCOME ***(See instructions.)***

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***

In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. FACILITIES AND ADMINSTRATIVE (F&A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will ***not*** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☒ DHHS Agreement dated: 6/7/2006; provisional as of 7/1/2010 ☐ No Facilities and Administrative Costs Requested.

☐ No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base $ 672,850 x Rate applied 52.00 % = F&A costs $ 349,882

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

☐ Salary and wages base ☒ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.):*

Program Director/Principal Investigator (Last, First, Middle): Purdy, James A.

SENIOR/KEY PERSONNEL REPORT

Place this form at the end of the signed original copy of the application. Do not duplicate.

GRANT NUMBER
2U24CA081647-09

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PD/PI, Res. Assoc.)	Months Devoted to Project		
				Cal	Acad	Summer
James A. Purdy	Ph.D.	8377	PI	4.8		
Walter Bosch	D.Sc.	5097	Associate Director	7.20		
John Matthews	D.Sc.	5461	Comp. Scientist	10.80		
William Straube	M.S.	7617	Med. Physicist	10.32		
Joseph Deasy	Ph.D.	4930	Co-Investigator	1.20		
Jeff Michalski	M.D.	6954	Co-Investigator	.60		
Andrew Vaughan	Ph.D.	9105	PI-Subcontract	.12		
Thomas Fitzgerald	M.D.	1808	PI - Subcontract	.6		
Marcia Urie	Ph.D.	2667	Chief Physicist	1.44		
Kenneth Ulin	Ph.D.	9408	Senior Physicist	.96		
Geoffrey Ibbott	Ph.D.	0859	PI-Subcontract	.60		
David Followill	Ph.D.	2988	Research Physicist	.60		
Walter Curran	M.D.	2896	Group Chair	0		

no major changes in levels of effort from previous year

KEY PERSONNEL OTHER SUPPORT

2.4 other
0.12 this
2.52 total
OK

Vaughan, Andrew

ACTIVE

P01 CA105049-3 (Diaz) 9/23/2007 – 6/30/2010 1.8 calender
Loyola University/NIH $200,000(direct cost only)
Molecular Genetics of MLL Associated Leukemia

The major goals: Dissection of the mechanism that controls and/or initiates DNA cleavage at 11q23 driving *MLL* translocations to partner genes linked to therapy-related leukemia

NAS2-03 144 (Vaughan) 8/01/2007 – 7/31/2008 .30 calender
UC Santa Cruz/NASA Ames $29,900(direct cost only)
Joint Radiation Biomarker Research

The major goals: Analysis of radiation responsive biomarkers in irradiated patient material including transcript response of buccal cavity and skin cells. The goal is to identify both radio-responsive genes and responses indicative of clinical disease outcome.

07-003089 (Vaughan) 12/19/2007 – 12/18/2008 .30 calender
Merck & Co., Inc. $41,000 (direct cost only)
Mechanism of Radiation Sensitization of SAH(Vorinostat)

The major goal : Analysis of biological response of Vorinostat (SAHA) in irradiated cells lines in terms of DNA damage and its repair.

OVERLAP

None

4.8 this
1.33 other
6.13 total
OK

Purdy, James

ACTIVE

U10 CA21661-32 (ACR) 1/1/2002 – 12/31/2007 .43 calendar
American College of Radiology (ACR) Pending renewal
Radiation Therapy Oncology Group (RTOG)
Subcontract to support co-chair of RTOG IGRT Committee activities within ACR/RTOG grant
Purdy - PI of ACR/RTOG subcontract

79666CBS10 (BAH) 10/1/2005-9/30/2008 .90 calendar
Booz Allen Hamilton Inc.(BAH) $24,000(direct cost -current yr)
caBIG Imaging Workspace Subject Matter Expert (SME)
Subcontract to support activities within the IMG Work Group "Adoption Advocate" Workgroup Participation
Purdy – PI of caBIG subcontract

OVERLAP

None

For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

Walter R. Bosch

7.2 this
no other
7.2 total
OK

Active

5 U24 CA 81647-09 (James A. Purdy) 07/01/07–6/30/12 Effort: (CM: 7.20)
NIH/NCI $1,166,614 (DC Current Year)
Advanced Technology QA Center

The goals of this grant are (1) to develop quality assurance programs in three-dimensional conformal therapy that will be uniform to all Cooperative Groups who choose to participate in this program; (2) develop equivalent programs in brachytherapy to multiple body part sites to ensure uniformity and quality assurance and establish standards in normal tissue tolerance; (3) establish uniform guidelines in database interpretation that allow for all dose-volume histogram analysis for tumor volume and normal tissue to be housed in one database; (4) to provide appropriate storage and interpretation of diagnostic x-rays required for protocol analysis; and (5) develop QA programs for further advanced technology treatment programs such as Intensity Modulated Radiation Therapy.

Overlap: None

For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

CURRAN, W.J.

4.2 other
no this
4.2 total
OK

ACTIVE

5 U10 CA021661-32S2 (Curran) 01/1/02 - 12/31/08 4.20 calendar
NIH/DC $9,419,324
Radiation Therapy Oncology Group (RTOG)
Main Goal: RTOG is an NCI-funded cooperative group seeking to improve upon the outcome of selected cancer patients through well-executed clinical trials. Dr. Curran serves as Group Chairman and full Member Principal Investigator to carry out multi-disciplinary cancer clinical trials in a cooperative group setting. The department also receives support for participation in clinical trials.

5 U10 CA037422-20 (Curran) 06/01/94 - 05/31/10 0.00 calendar
NCI/DCPC $1,546,497
RTOG Community Clinical Oncology Research Base
Main Goal: This program seeks to expand the RTOG mission to community-based cancer programs and to
cancer prevention and control strategies.

1 U24 CA114734-03 (Curran) 09/14/05 – 03/31/10 0.00 calendar
NCI $793,043
RTOG Tissue Bank
Main Goal: The RTOG recognizes the importance of a tissue resource of present and future correlative trial. The specific aims of this tissue bank are: (1) To acquire, store, and track blood, leukocytes and tissue samples from RTOG patients entered on Phase III clinical trials in compliance with policies and procedures of the Group Banking Committee of NCI. (2) To preserve the maximum amount of tissue in each sample by expert block, tissue array and sample preparation, by laser capture of appropriate tissue elements, and by appropriate tissue quality assurance. (3) To market, and distribute samples equitably to all qualified investigators by a standardized method developed or modified collaboratively with the Group Banking Committee of NCI

2 U24 CA 081647-08 (Purdy) 07/01/07 - 06/30/11 0.00 calendar
NCI/DCTD $300,000
Advanced Technology QA Center
Main Goal: To capitalize on the infrastructure and strengths of the existing national quality assurance programs to create an Advanced Technology Radiation Therapy Clinical Trials Support QA Consortium.

PENDING

NONE

OVERLAPS

NONE

For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

Deasy, Joseph A.

7.2 other
1.2 this
8.4 total
OK

pending awards cannot create overcommitment

ACTIVE:

Varian Medical Systems, Deasy (PI) 5/13/06-5/12/08 Effort: CM 1.20
Advanced Radiation Therapy Development Proj. $71,841 (for Deasy sub-project)

There are three novel projects included in this agreement, including: IMRT quality assurance, exploring tumor control vs. dose distribution characteristics, and exploring potential clinical tests of radiation repair pathway effectiveness. The project led by Deasy focuses on gathering animal data related to the effect of uniform vs. non-uniform dose distributions. The rationale is to better support and define potential advantages of boosting dose distributions which are typically made uniform in current clinical practice.

Tomotherapy, Low (PI) 1/1/06-12/31/08 Effort: CM 1.8
Tomotherapy Inc. $864,000 (2 Years)
Pre-Clinical Research Projects and Clinical Studies based on TomoTherapy. Work by Deasy's group focuses on outcomes driven treatment planning, in particular models and tools to estimate outcomes, and algorithms to drive treatment planning based on outcomes.

R01 CA085181, Deasy (PI) 7/1/99-11/30/09 Effort: CM 2.64
NIH $170,673 (Year 8)
Normal Tissue Complication Modeling for Radiotherapy

The broad goal is to improve mathematical models of radiotherapy outcomes based on dose distributions and image characteristics. Specific projects include: improving tools to gather and analyze data; working to gather better clinical and laboratory data for modeling; improving algorithms to build statistical models; and improve methods to more effectively use the models in radiotherapy treatment planning.

5 U24 CA 81647 (James A. Purdy) 07/01/07–6/30/12 Effort: CM: 1.20
NIH/NCI $1,166,614 (DC Current Year)
Advanced Technology QA Center

The goals of this grant are (1) to develop quality assurance programs in three-dimensional conformal therapy that will be uniform to all Cooperative Groups who choose to participate in this program; (2) develop equivalent programs in brachytherapy to multiple body part sites to ensure uniformity and quality assurance and establish standards in normal tissue tolerance; (3) establish uniform guidelines in database interpretation that allow for all dose-volume histogram analysis for tumor volume and normal tissue to be housed in one database; (4) to provide appropriate storage and interpretation of diagnostic x-rays required for protocol analysis; and (5) develop QA programs for further advanced technology treatment programs such as Intensity Modulated Radiation Therapy.

1RO1 CA118200-01A2 7/01/07-6/30/12 Effort: CM: 1.20
Subcontract with Massachusetts General Hospital $75,000 (DC)
Management of Breathing Effects in Radiotherapy Planning

The goal of this grant are to develop a shared cross-platform toolset, and techniques, and test data sets that will eventually be publicly archived for use by other researchers.

R01 HL074019-01, Zheng (PI) 4/1/05-3/31/09 Effort: CM: 0.36
NIH $250,000
Quantification of Regional Myocardial Oxygenation by MRI

The goal is to optimize and validate a series of clinical viable MRI techniques to measure myocardial OEF and MVO2 reliably and consistently.

Pending

NIH (PI: Low) 7/1/08-6/30/13 Effort: CM: 0.84
Development of a Micrort System $1,250,000 (TDC)

The overall aim of this project is to develop novel conformal small-animal irradiator, suitable for studying genetic markers of radiation response and radiobiological models at therapeutic dose levels.

K25 (PI: El Naqa) 4/1/08-3/31/12 Effort: CM: 0.60
NIH $479,793 (TDC)
Predicting Radiotherapy Outcomes by Combining Physical and Biological Factors

The goal is to test the combination of biological/biomarker data and dose data to improve the ability to predict radiotherapy complications. In particular, we will use blood-based biomarkers as well as treatment dose distribution characteristics to potentially improve the ability to predict (or avoid radiation pneumonitis).

NIH (subcontract) 1/1/08-12/31/08 Effort: CM: 0.36
MD Anderson $29,031 (DC)
Tools for Monte Carlo Based Dosimetry

NIH (subcontract) 8/1/08-7/31/13 Effort: CM:1.2
Subcontract –Fox Chase (ACR) $218,263

Subjective and Objective Characteristics of Fatigue in
Prostate Cancer Treatment

BJH Foundation (PI: El Naqa) 7/1/08-6/30/09 Effort: CM: 0.36
FLT-PET as a Biomarker of Radiotherapy $109,238 (no salary requested)
Response in Lung Cancer

The investigators propose a feasibility study to prospectively monitor the uptake of FLT in a cohort of 25 non-small cell lung cancer (NSCLC) patients who receive radiotherapy as part of their treatment. By analyzing FLT-PET/CT patient data at pre-treatment and mid-treatment, they hypothesize that they will be able to predict disease persistence and tumor local probability more accurately.

American Cancer Society (PI: Wang) 1/1/09-12/31/12 Effort: CM: 0.60 (Yr 2)
Research Scholar Grant $939,399
A Comprehensive Prognostic Model to Predict Cervical Cancer Outcome

The objectives of this study is (1) to identify candidate microRNAs as promising cervical cancer biomarkers for outcome prediction; (2) to identify candidate microRNA-targeted genes as cervical cancer biomarkers; and (3) to construct and validate a prognostic model for cervical cancer outcome prediction based on microRNAs, microRNA targets, and predictive clinical features.

Overlap:
There is no scientific overlap with the applications under consideration. If any grant is funded, Dr. Deasy will adjust his effort accordingly on his other grants.

OTHER SUPPORT

1.8 months other
0.6 months this
2.4 months total
OK

FITZGERALD, TJ

ACTIVE

CA29511-29 (FitzGerald) 1/1/07 – 12/31/12 1.2 Calendar Months
NIH/NCI $1,381,549
Quality Assurance Review Center

Provides data acquisition and management service support to the Radiation Oncology and Diagnostic Imaging Committees of six (6) National Cooperative Groups and assures the integrity of radiation therapy data through comprehensive case management, dosimetry and volume review. Provides protocol review, data management, case review, physics QA and site credentialing services to improve protocol compliance.
Role: PI

CA81647-09 (Purdy) 7/01/07 - 6/30/12 .6 Calendar Months
NIH/NCI/RRP $125,000
Advanced Technology QA Center

Capitalizes on the infrastructure and strengths existing among the National QA programs which include the Image-Guided Therapy Center (ITC), Radiological Physics Center (RPC), Radiation Therapy Group (RTOG) and Quality Assurance Review Center (QARC). QARC is implementing digital data transfer and remote QA review with the Children's Oncology Group (COG) and Pediatric Brain Tumor Consortium (PBTC).
Role: Co-Investigator

CA80098 (Schnall) 1/01/08 – 12/31/10 .6 Calendar Months
NIH/NCI $187,447
Virtual Imaging Evaluation Workspace in Cooperative Groups

Collaboration of ACRIN, CALGB and QARC providing image collection and processing services to NCI-sponsored Cooperative Groups and other NCI-sponsored multicenter clinical trials by facilitating development of standardized approaches to image acquisition and analysis, caBIG compliant interoperable IT infrastructure and harmonized quality assurance.
Role: Co-Investigator

OVERLAP: None

Other Support

0.6 months this
11.4 months other
12 months total
OK

FOLLOWILL, DAVID S.

ACTIVE

5 U10 CA 10953-40 (Ibbott) NIH/NCI Radiological Physics Center	1/1/05 - 12/31/10 $2,003,245	9.60 calendar

The major goal of this project is to assure that the radiation dose to protocol patients is clinically comparable for all patients entered onto all cooperative clinical trial protocols and is within the guidelines of the treatment protocol.

SBIR Phase II Application (Simon) NIH/NCI Benchmark Beam Data: Improved Accuracy in Radiotherapy	2/1/06 - 6/30/08 $107,034	1.80 calendar

The aim of this project is to provide measured benchmark megavoltage (MV) photon-beam data to the radiation oncology physics community for use in clinical quality assurance (QA). The specific aims for Phase II of this project include: 1) Implementation of the strategy for gathering full datasets that will be adequate for widespread distribution to therapy centers throughout the country; 2) implementation of data review, validation and collation so that the data can be made available for down-loading from the web or distribution on CD-ROM to all clinics; 3) production for distribution of the benchmark datasets. All of these deliverables are achieved via the four commercial products that will be developed under this contract: 1) the *Standard Phantom*, 2) the *Beam Commissioning QA Software*, 3) the *Independent Dose Calculation* Engine, and 4) Structured Data Set for Planning Research.

OVERLAP

Radiological Physics Center: The ATC does not overlap RPC activities, but contributes to them by providing an infrastructure for electronic submission and review of treatment plans. The ATC grant supports the RPC's participation on this project, primarily by funding travel to meetings and contributing to the evaluation of data collected through use of the RPC phantoms for credentialing and the evaluation of benchmark submissions.

Phase II Benchmark Beam Data: There is potential minimal overlap with the ATC grant. If by coincidence, the institutions selected for the benchmark measurements happen to be institutions that have risen on the RPC's priority list to a high value, the initial visit to the institution might be supported by the SBIR grant rather than by the RPC grant. In this case, the RPC will select another institution from its priority list to visit. Should the institution also participate in advanced technology clinical trials, the institution might use the tools and procedures developed by the RPC on the ATC grant.

For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. ***Include the principal investigator's name at the top and number consecutively with the rest of the application.*** The sample below is intended to provide guidance regarding the type and extent of information requested.
For instructions and information pertaining to the use of and policy for other support, see Other Support in the PHS 398 Part III, Policies, Assurances, Definitions, and Other Information.
Note effort devoted to projects must now be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.

0.6 months this
8.16 months other
8.76 months total
OK

IBBOTT, GEOFFREY S.

ACTIVE

5 U10 CA 10953-40 (Ibbott) 1/1/05 - 12/31/10 7.56 calendar
NIH/NCI $2,003,245
Radiological Physics Center

The major goal of this project is to assure that the radiation dose to protocol patients is clinically comparable for all patients entered onto all cooperative clinical trial protocols and is within the guidelines of the treatment protocol.

SBIR Phase II Application (Simon) 2/1/06 - 6/30/08 .60 calendar
NIH/NCI $107,034
Benchmark Beam Data: Improved Accuracy in Radiotherapy

The aim of this project is to provide measured benchmark megavoltage (MV) photon-beam data to the radiation oncology physics community for use in clinical quality assurance (QA). The specific aims for Phase II of this project include: 1) Implementation of the strategy for gathering full datasets that will be adequate for widespread distribution to therapy centers throughout the country; 2) implementation of data review, validation and collation so that the data can be made available for down-loading from the web or distribution on CD-ROM to all clinics; 3) production for distribution of the benchmark datasets. All of these deliverables are achieved via the four commercial products that will be developed under this contract: 1) the Standard Phantom, 2) the Beam Commissioning QA Software, 3) the Independent Dose Calculation Engine, and 4) Structured Data Set for Planning Research.

OVERLAP

Radiological Physics Center: The ATC does not overlap RPC activities, but contributes to them by providing an infrastructure for electronic submission and review of treatment plans. The ATC grant supports the RPC's participation on this project, primarily by funding travel to meetings and contributing to the evaluation of data collected through use of the RPC phantoms for credentialing and the evaluation of benchmark submissions.

Phase II Benchmark Beam Data: There is potential minimal overlap with the ATC grant. If by coincidence, the institutions selected for the benchmark measurements happen to be institutions that have risen on the RPC's priority list to a high value, the initial visit to the institution might be supported by the SBIR grant rather than by the RPC grant. In this case, the RPC will select another institution from its priority list to visit. Should the institution also participate in advanced technology clinical trials, the institution might use the tools and procedures developed by the RPC on the ATC grant.

For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

John Matthews

10.8 this
no other
10.8 total
OK

Active

5 U24 CA 81647-09 (James A. Purdy) 07/01/07–6/30/12 Effort: (CM: 10.80)
NIH/NCI $1,626,703 (DC Current Year)
Advanced Technology QA Center

The goals of this grant are (1) to develop quality assurance programs in three-dimensional conformal therapy that will be uniform to all Cooperative Groups who choose to participate in this program; (2) develop equivalent programs in brachytherapy to multiple body part sites to ensure uniformity and quality assurance and establish standards in normal tissue tolerance; (3) establish uniform guidelines in database interpretation that allow for all dose-volume histogram analysis for tumor volume and normal tissue to be housed in one database; (4) to provide appropriate storage and interpretation of diagnostic x-rays required for protocol analysis; and (5) develop QA programs for further advanced technology treatment programs such as Intensity Modulated Radiation Therapy.

Overlap: None

For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

0.36 months this
5.64 months other
6 months total
OK

MICHALSKI, JEFF, M.D.
ACTIVE:

5 U10 CA21661 (Michalski) 1/1/02 -12/31/08 Effort: CM:1.20
NIH/NCI (Subcontract within ACR grant) $20,036
Radiation Therapy Oncology Group Chairman's Grant
Walter J. Curran, M.D., Principal Investigator

Dr. Michalski is the chair of the Image Guided Radiation Therapy Committee. This committee fosters the development and managementof clinical trials using new and innovative technologies in the field of Radiation Oncology. He works closely with the site committee chairs to identify investigators and specific rsearch projects that employ 3D Conformal Radiation Therapy or Intensity Modulated Radiation Therapy. He also works with co-chairs in Brachytherapy, Stereotactic Radiotherapy, Medical Physics and the Image-Guided Therapy QA Center to establish quality guidelines regarding the implementation of these technologies within studies conducted by the RTOG.

Dr. Michalski is also the principal investigator on bothPhase I and Phase II clinical trials investigating radiation dose escalation in glioma and prostate cancer. He is also the principal investigator for the RTOG at Washington University.

Overlap:
There is no scientific overlap

5 P30 CA91842 (PI: Eberlein) 08/02/01-06/30/09 Effort: CM: 2.40
NCI $2,614,379
Cancer Center Support Grant
The Alvin J. Siteman Cancer Center (SCC) of Barnes-Jewish Hospital and Washington University School of Medicine is a comprehensive, fully integrated, multidisciplinary clinical and laboratory research center. The goals of the SCC Clinical Trials Office led by Dr. Michalski are to develop infrastructure such that all SCC patients will have the opportunity to participate in clinical trials; encourage active participation of community physicians in clinical trials.
Role: Director, Clinical Trials Core

Overlap:
There is no scientific overlap

1 R01 CA101734-03 9/1/03-8/31/08 Effort: CM: 1.20
NIH/NCI $200,250
Positron Emission Tomography in Prostate Cancer
Farrokh Dehdashti, M.D., Ph.D., Principal Investigator

To determine if imaging by PET with carbon-11 acetate will lead to better treatment of patients with a new diagnosis of patients with prostate cancer. The specific purpose of this research is to determine if acetate-11

PET scans tend to identify prostate cancer in patients before treatment by surgery or radiation therapy where standard diagnostic tests have shown no cancer outside of the prostate.

Overlap:
There is no scientific overlap.

8 RCA095662B 01/01/04-6/30/08 Effortt: CM: 0.84
NIH/NCI $28,306
Survivor QOL/Spouse Satisfaction after Prostate Therapy
(subcontract with Beth Israel Deaconess Medical Center)
Martin Sanda, M.D., Principal Investigator

Dr. Michalski is the institutional PI on this NIH multi-institutional grant to study the effects of cancer therapy on the Health Related Quality of Life of men with prostate cancer. He coordinates recruitment of patients and data collection for the Division of Urologic Surgery and the Department of Radiation Oncology.

Overlap:
There is no scientific overlap.

5 U24 CA 81647-09 (James A. Purdy) 07/01/07–6/30/12 Effort: (CM: .36)
NIH/NCI $1,626,703 (DC Current Year)
Advanced Technology QA Center

The goals of this grant are (1) to develop quality assurance programs in three-dimensional conformal therapy that will be uniform to all Cooperative Groups who choose to participate in this program; (2) develop equivalent programs in brachytherapy to multiple body part sites to ensure uniformity and quality assurance and establish standards in normal tissue tolerance; (3) establish uniform guidelines in database interpretation that allow for all dose-volume histogram analysis for tumor volume and normal tissue to be housed in one database; (4) to provide appropriate storage and interpretation of diagnostic x-rays required for protocol analysis; and (5) develop QA programs for further advanced technology treatment programs such as Intensity Modulated Radiation Therapy.

Overlap: None

Pending

8 RCA095662 (renewal) 12/01/08-11/30/13 Effort: CM: .24
NIH/NCI $200,000
Survivor QOL/Spouse Satisfaction after Prostate Therapy
(subcontract with Beth Israel Deaconess Medical Center)
Martin Sanda, M.D., Principal Investigator

Dr. Michalski is the institutional PI on this NIH multi-institutional grant to study the effects of cancer therapy on the Health Related Quality of Life of men with prostate cancer. He coordinates recruitment of patients and data collection for the Division of Urologic Surgery and the Department of Radiation Oncology.

For New and Competing Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED
For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

William Straube

10.32 this
1.2 other
11.52 total
OK

Active

5 U24 CA 81647 (James A. Purdy) 07/01/07–6/30/08 Effort: (CM: 10.32)
NIH/NCI $1,166,614 (DC Current Year)
Advanced Technology QA Center
Role: ITC Associate Director

The goals of this grant are (1) to develop quality assurance programs in three-dimensional conformal therapy that will be uniform to all Cooperative Groups who choose to participate in this program; (2) develop equivalent programs in brachytherapy to multiple body part sites to ensure uniformity and quality assurance and establish standards in normal tissue tolerance; (3) establish uniform guidelines in database interpretation that allow for all dose-volume histogram analysis for tumor volume and normal tissue to be housed in one database; (4) to provide appropriate storage and interpretation of diagnostic x-rays required for protocol analysis; and (5) develop QA programs for further advanced technology treatment programs such as Intensity Modulated Radiation Therapy.

Overlap: None

1 R01 CA107558-01A1 R. Martin Arthur (PI) 06/15/05-05/30/08 Effort: CM: 1.20
NIH/NCI $814,000
3D Noninvasive Temperature Estimation with Ultrasound
Role: Co-Investigator

Determine the temperature dependence of back scattered ultrasound to see if it can be used as a thermometer for thermal therapies.

Overlap: None

Pending

None

0.96 this
1.92 other
2.88 total
OK

OTHER SUPPORT

ULIN, K

ACTIVE

CA29511-29 (FitzGerald) 1/01/07 - 12/31/012 1.92 Calendar Months

NIH/NCI $1,381,549
Quality Assurance Review Center

Provides data acquisition and management service support to the Radiation Oncology and Diagnostic Imaging Committees of six (6) National Cooperative Groups and assures the integrity of radiation therapy data through comprehensive case management, dosimetry and volume review. Provides protocol review, data management, case review, physics QA and site credentialing services to improve protocol compliance.
Role: Senior Physicist

CA81647-09 (Purdy) 7/01/07 - 6/30/12 .96 Calendar Months
NIH/NCI/RRP $125,000
Advanced Technology QA Center

Capitalizes on the infrastructure and strengths existing among National QA programs which include the Image-Guided Therapy Center (ITC), Radiological Physics Center (RPC), Radiation Therapy Group (RTOG) and Quality Assurance Review Center (QARC). QARC is implementing digital data transfer and remote QA review with the Children's Oncology Group (COG) and Pediatric Brain Tumor Consortium (PBTC).
Role: Senior Physicist

OVERLAP: None

1.44 this
no other
1.44 total
OK

URIE, MM

ACTIVE

CA81647-09 (Purdy) 7/01/07 - 6/30/12 1.44 Calendar Months
NIH/NCI/RRP $125,000
Advanced Technology QA Center

Capitalizes on the infrastructure and strengths existing among National QA programs which include the Image-Guided Therapy Center (ITC), Radiological Physics Center (RPC), Radiation Therapy Group (RTOG) and Quality Assurance Review Center (QARC). QARC is implementing digital data transfer and remote QA review with the Children's Oncology Group (COG) and Pediatric Brain Tumor Consortium (PBTC).
Role: Physics Director

OVERLAP: None

CONSORTIUMS

ACR – AMERICAN COLLEGE OF RADIOLOGY

RPC – MD ANDERSON

UCD – UNIVERSITY OF CALIFORNIA, DAVIS

QARC – UNIVERSITY OF MASSACHUSETTS

ACR™
AMERICAN COLLEGE OF RADIOLOGY

www.acr.org

April 10, 2008

Kathy Feurer, Research Administrator
Washington University School of Medicine
Department of Radiation Oncology
4511 Forest Park
St. Louis, MO 63108

Re: Advanced Technology QA Center – CA81647-10

Dear Ms. Feurer:

The American College of Radiology is ready to participate in the Advanced Technology QA Center grant CA81647-10. The direct and indirect costs for our participation in this Year 10 will be $300,000.

The appropriate programmatic and administrative personnel involved in this grant at ACR are aware of the NIH Consortium Grant Policy and are prepared to establish the necessary inter-institutional agreement consistent with this policy.

Sincerely,

Harvey L. Neiman, MD

Harvey L. Neiman
Executive Director, ACR

HEADQUARTERS
1891 Preston White Dr
Reston, VA 20191
(703) 648-8900

GOVERNMENT RELATIONS
1701 Pennsylvania Ave NW, Suite 610
Washington, DC 20006
(202) 223-1670

CLINICAL RESEARCH
1818 Market St, Suite 1600
Philadelphia, PA 19103
(215) 574-3150

Consortium - ACR - American College of Radiology

total costs unchanged from CRL

Program Director/Principal Investigator (Last, First, Middle): Curran, Walter J

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY	FROM 07/01/2008	THROUGH 06/30/2009	GRANT NUMBER CA81647-10

PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Walter J Curran Jr	PD/PI						
Elizabeth O'Meara	Director ATQA	.60			5,675	1,703	7,378
Denise Manfredi	Dosim	12.0			73,405	22,022	95,427
Lorraine Quarles	Dosim	6.0			39,878	11,963	51,841
SUBTOTALS →					118,958	35,688	154,646

CONSULTANT COSTS		
EQUIPMENT *(Itemize)*		
SUPPLIES *(Itemize by category)* Office Supplies		1,200
TRAVEL		8,360
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*		
OTHER EXPENSES *(Itemize by category)* Telephone $5,400 Reprod $500		5,900
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD		$ 170,106
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	26,735
	FACILITIES AND ADMINISTRATIVE COSTS	14,704
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD *(Item 8a, Face Page)*		$ 211,545

PHS 2590 (Rev. 11/07) Page ____ **Form Page 2**

Program Director/Principal Investigator (Last, First, Middle): Curran, Walter J

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY	FROM 07/01/2008	THROUGH 06/30/2009	GRANT NUMBER CA81647-10

PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Walter J Curran Jr	PD/PI		✓				
James Galvin MD	RTOg Co-PI	.60	✓		9,565	2,870	12,435
Ying Xiao, PhD	Med Physicist	1.20	new post		11,000	3,300	14,300
		lost 1.5 FTE dosimetrist					
					110,660	33,198	143,858
	SUBTOTALS →				20,565	6,170	26,735

CONSULTANT COSTS		
EQUIPMENT *(Itemize)*		1,236
SUPPLIES *(Itemize by category)*		8,446
TRAVEL		
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*		
OTHER EXPENSES *(Itemize by category)*		5,897
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD		$ 26,735
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	26,422
	FACILITIES AND ADMINISTRATIVE COSTS	14,704
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD *(Item 8a, Face Page)*		$ 41,439

203,536

PHS 2590 (Rev. 11/07) Page ____ **Form Page 2**

BUDGET JUSTIFICATION	GRANT NUMBER
	CA81647-10

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

No significant changes.

CURRENT BUDGET PERIOD	FROM	THROUGH
	07/01/07	06/30/08

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

We will not have an unobligated balance that is greater than 25% of the current year total budget.

BUDGET JUSTIFICATIONS

AMERICAN COLLEGE OF RADIOLOGY
Subcontract Total Budget Year 10 $300,000

PERSONNEL ($154,646)

RTOG Group Chair, Walter J. Curran, Jr., M.D.

Dr. Curran is the Group Chair of the Radiation Therapy Oncology Group, and directs the research efforts of the Group. He has wide experience in the conduct and planning of radiation therapy trials, and will contribute his knowledge and expertise to the project as required. He will work with the Group Statistician and the Principal Investigator in developing strategies as the project progresses. No salary support is requested for Dr. Curran.

Director-Statistics, Research & Operations, Kathryn Winter, MS

Ms. Winter has overall responsibility for the statistical integrity of the project. Ms. Winter is the Acting Group Statistician for the Radiation Therapy Oncology Group, and has experience in the development, execution, analysis and reporting of clinical trials. No salary support is requested for Ms. Winter.

Senior Director, Clinical Trials Informatics, Brenda K. Young, B.A., CCRA

Ms. Young has wide experience in the conduct of radiation therapy trials. She leads the informatics initiatives for the American College of Radiology including formal representation on caBIG workspaces (CTMS and Imaging), Group Banking Committee, and the Uniform Protocols in Imaging Clinical Trials (UPICT) consortium. Ms. Young is instrumental in the development of the ACR Clinical Trials Data Warehouse and will facilitate new initiatives among the Advanced Technology Consortium participants. No salary support is requested for Ms. Young.

Director, RT Quality Assurance, Elizabeth O'Meara, B.S., CCRP, R.T.T. (.60 calendar months)

Ms. O'Meara will appropriately direct all inquiries received in the ACR office related to delivery of therapy, etc. She will be the liaison between the QA center in St. Louis and the ACR office in Philadelphia on treatment issues.

Dosimetrist, Denise Manfredi, R.T.T. (12 calendar months)

Salary support is requested for Ms. Manfredi, who is responsible for performing the QA reviews of RTOG advanced technology clinical trials (3DCRT/IMRT protocols) using the Image-Guided Therapy Center (ITC) web-based remote review tools (RRT), which utilizes a secure web server. The treatment planning data (images, contours, and calculations) are sent to the Image-Guided Therapy Center (ITC) at Washington University in St. Louis for digital collection and compiling and review of the digital images and treatment planning data received from RTOG institutions and made available to the RT Quality Assurance Department at RTOG headquarters via the ITC website for QA reviews. The dose-volume analysis of case data is ongoing in RTOG protocols. The web-based ITC Remote Review Tool (RRT) allow the visualization of images, structure sets, and dose distributions for the RTOG RT QA dosimetrist to provide QA reviews for RTOG Protocols. This includes:

a) Image segmentation reviews and correction (contours);
b) Rx image vs. Tx image evaluation for fields shape and isocenter placement;

c) Dosimetric evaluation of protocol compliance (dose and fractionation).
d) Participation in conference calls for specific issues on advanced technology protocols;
e) Resource for continued learning/education of the credentialing process for advanced technology protocols;
f) Review of all advanced technology protocols that are processed through the ATC to help ensure uniformity of guidelines.

After the dose volume analysis (DVAs) are completed, then they are transmitted directly to the investigator at the RTOG member institution.
This function was formerly provided by the ITC at Washington University. The DVAs are now performed by the RTOG RT Quality Assurance Dosimetrists.

Dosimetrist, Lorraine Quarles, R.T.T, (6 calendar months)

Salary support is requested for Ms. Quarles, who will provide QA reviews of advanced technology clinical trials (3DCRT/IMRT protocols) using the Advanced Technology Consortium (ATC) web-based remote review tools (RRT), which utilizes a secure web server. This includes:

a) Image segmentation reviews and correction (contours);
b) Rx image vs. Tx image evaluation for field shape and isocenter placement;
c) Dosimetric evaluation of protocol compliance (dose and fractionation);
d) Participate in conference calls for specific issues on advanced technology protocols;
e) Resource for continued learning/education of the credentialing processes for advanced technology protocols;
f) Review of all advanced technology protocols that are collaborated through the ATC to help ensure uniformity of guidelines.

SUPPLIES ($1,200)

Based on experience and projected workload, we expect these costs to cover the purchase of general stationery items needed for operations at RTOG Headquarters.

TRAVEL ($8,360)

Funding is requested for travel to St. Louis for the ACR staff as follows:

General meetings four per year in St. Louis (overnight) for one staff member:

$600 (air fare) + ($185 per diem X 2 days) = $970 x4 trips=$3,880

Funding is requested for travel for two ACR/RTOG staff members to attend the ATC session at the RTOG Semi-Annual meetings. The ATC session is held on Thursday from 8:00 a.m. to 5:00 p.m. prior to the start of the regular RTOG agenda.

$600 (air fare) + ($185 per diem X 2 days) x 2 tripsx 2 staff = $3,880

Funding is requested for travel to NCI for ATC Steering Committee Meetings

2 trips x 1 staff to NCI = 2 trips x $300=$600

OTHER EXPENSES ($5900)

Funding is requested for telephone services ($5,400) and postage (express mail: $500). These costs are based on historical charges to an earlier grant dedicated to the development of the (3D QA center) now Image-Guided Therapy QA Center (ITC), and reflect actual expenditures.

SUBCONTRACTS ($41,439)

Thomas Jefferson University ($41,439)

James Galvin, D.Sc. (.60 calendar months)

Dr. Galvin is responsible for establishing the credentialing procedures for protocols that employ adaptive strategies. It is anticipated that tools for completing this task will be provided by IMPAC, TeraMedica, Hermes, BrainLAB, and Computerized Medical Systems. The ITC developed Method 1 tool will also be available. The process will involve receiving image datasets from various institutions and checking their fusion procedure. The institutions handling of targets that move during treatment will also be assessed. Dr. Galvin will write procedures for processing the different datasets sent forward. He will also train other individuals so that these checks can be performed routinely.

Ying Xiao, PhD., Medical Physicist (1.20 calendar months)

Dr. Xiao will be assigned to all protocols that include an adaptive strategy. She will have the responsibility of credentialing new institutions (not previously entering patients on an "adaptive" protocol) for participation in their assigned protocol.

INDIRECT COSTS ($88,455)

ACR indirect costs are calculated at 52% of direct costs, in accordance with the negotiated rate agreement with DHHS.

Purdy, James A., Ph.D.
U24 CA81647

AMERICAN COLLEGE OF RADIOLOGY
RADIATION THERAPY ONCOLOGY GROUP
PROGRESS REPORT
7/1/07-6/30/08

During this funding period, the American College of Radiology (ACR), through the Radiation Therapy Oncology Group (RTOG), collaborates with the Advanced Technology Consortium (ATC) for Quality Assurance, which consists of the Image-guided Therapy Center (ITC), the Radiological Physics Center (RPC), the Quality Assurance Review Center (QARC), and the RTOG Headquarters-RT Quality Assurance (RT QA) Group. This arrangement utilizes each group's strengths and avoids duplication of the existing programs and thus develops uniformity in QA for advanced technology trials throughout all participating Cooperative Groups.

An important change in the activities of the RTOG over the past year is the introduction of protocols that use daily image guidance for studies that deliver standard dose fractionation.

There where a few earlier protocols (RTOG 0236 and 0438) which used image guidance in the setting of hypofractionation. Both RTOG 0236 and 0438 were important for establishing guidelines for the use of IGRT as part of RTOG protocols. However, using IGRT as part of protocols with standard fractionation offers new considerations that the RTOG has addressed over the past year. The accomplishments over the past year relative to the use of IGRT in RTOG protocols are:

- Development of a set of guidelines for the use of IGRT as part of RTOG protocols
- Develop supplemental guidelines for limiting patient dose when IGRT is used in RTOG protocols
- Devising of a technique for verifying the targeting of treatment beams when image guidance techniques are used as part of RTOG protocols

In developing any of the tools or techniques described above, it is important to make sure that each approach is as general as possible. It is through this mechanism that the RTOG has the ability to adapt to different techniques and systems. Thus, the RTOG can adapt to an ever-changing environment, and they can disseminate their guidelines and techniques to other institutions.

Through the ATC, the RTOG would like to see the entire radiation oncology community adopt its guidelines and techniques. This change is currently being considered by other protocols groups, and remains as a high-priority goal for the ATC members.

A few of the major aspects of the guidelines are: 1) the requirement that the protocol discuss the method to be used for image registration, and 2) the frequency of imaging that is allowed. For daily imaging, the investigator is required to estimate the dose received by the patient as a result of the imaging process.

Specifically, the ACR (RTOG Headquarters Group) provides:

1) medical dosimetrists' QA review of advanced technology clinical trials using the ATC web-based remote review tools (RRT) on the ATC Review Workstation at RTOG Headquarters in Philadelphia, PA, which utilizes a secure web server. The dose-volume analysis of case data is ongoing in RTOG protocols. The remote review tools have been user friendly and RTOG staff continually work with ITC to add features to the RRT, which will streamline the review process. This is accomplished through conference calls to clarify and update the case reviews;
2) Target Volume QA Review and Organs at Risk Review with the Study Chairs on Advanced Technology Protocols via web access;
3) the RTOG Headquarters staff arranges for the ongoing ATC conference calls with the other QA centers for case review and protocol specific issue calls biweekly Friday mornings;
4) host and coordinate the ATC Meetings held on the Thursday at all the RTOG Semi-Annual Meetings;
5) patient registration and clinical outcome data management and statistical support for the ongoing RTOG clinical trials evaluating advanced technologies;

6) their expertise in the areas of design, monitoring, and analysis for any new clinical trial utilizing advanced technologies;
7) a review of all advanced technology protocols that are processed through the ATC to help ensure uniformity of guidelines for data submission;
8) their expertise in maintaining and improving in the current electronic link between the RTOG's clinical trial database and the ITC's treatment planning and verification (TPV) database;
9) credentialing process monitoring through the ITC, RPC, and RTOG RT QA Department with flow diagram and electronic credentialing notification letter to all participants;
10) update the Clinical Trials Support Unit (CTSU) RSS database with the advanced technology protocols credentialing requirements for participation;
11) continue to identify and implement common identification numbers for patients on RTOG Protocols that utilize advance technology by using the RTOG member institution number, NCI number and the Radiation Therapy Facility number (RTF) which is assigned through the RPC;
12) continue to work diligently with National Surgical Adjuvant Breast and Bowel Project (NSABP) and RTOG Headquarters on the Phase III Study of Whole Breast versus Partial Breast Irradiation;
13) resource for continued learning/education of the credentialing processes and specific requirements for Advanced Technology protocols through presentations at the Research Associates Orientations and Study Chair Workshops;
14) coordinate monthly conference calls for protocols requiring diagnostic components between CTEP and CIP to ensure effective processes.

RTOG Protocols supported by the ATC (Updated to April 1, 2008)

- 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 93-11: Phase I/II Dose Escalation Study Using 3D Conformal Radiation Therapy in Patients with Inoperable NSCLC. 26 institutions credentialed, 180 patients registered to study (study closed, data analysis continues).
- 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).
- RTOG H-0022: Phase I/II Study of Conformal And Intensity Modulated Irradiation for Oropharyngeal Cancer. 32 institutions credentialed, 69 patients registered to study (study closed, data analysis continues).
- RTOG L-0117: Phase I/II dose intensification study using 3DCRT and concurrent chemotherapy for patients with inoperable, nonsmall cell lung cancer. 51 institutions credentialed, 63 patients registered to study (study closed).
- RTOG P-0126: Phase III randomize study of high dose 3DCRT/IMRT(9/18/03) versus standard dose 3DCRT/IMRT(9/18/03) in patients treated for localized prostate cancer. 264 institutions credentialed, 1444 patients registered to study.
- RTOG 0225: Phase II IMRT +/- Chemotherapy for Nasopharyngeal Cancer, 36 institutions credentialed, 68 patients registered to study (study closed, data analysis continues).
- RTOG 0232: Phase III Comparing Combined External Beam Radiation & Transperineal Interstitial Permanent Brachytherapy with Brachytherapy Alone For Selected Patients With Intermediate Risk Prostatic Carcinoma, 79 institutions credentialed, 349 patients registered to study.
- RTOG 0234: A Phase II Randomized Trial of Surgery Followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of the Head and Neck (ATC to collect data

for IMRT cases only), 89 IMRT institutions credentialed, 238 patients registered to study, 104 IMRT, (study closed).

- RTOG 0236: Phase II Extracranial Stereotactic Radioablation in Treatment of Patients with Medically Inoperable Stage in NSCLC, 9 institutions credentialed, 59 patients registered to study, (study closed).

- RTOG 0319: Phase I/II to Evaluate 3DCRT Irradiation Confined to Region of the Lumpectomy Cavity for Stage I/IIa Breast Carcinoma, 31 institutions credentialed, 58 patients registered to study, (study closed).

- RTOG 0321: Phase I/II Prostate: High Dose Brachytherapy and External Beam, 18 institutions credentialed, 129 patients registered to study, (study closed).

- RTOG 0413/NSABP B-39: Phase III Study of Whole Breast RT versus Partial Breast Irradiation, 522 institutions credentialed (424 3DCRT, 296 Mammosite, 47 Multi-cath), 3054 patients registered to study (1148 3DCRT, 283 Mammosite, 91 Multi-cath).

- RTOG 0415: Phase III Rand Conventional Fx 3DCRT/IMRT vs Hypo Fx 3DCRT/IMRT in Prostate Cancer, 230 institutions credentialed (82 IMRT), 419 patients registered to study.

- RTOG 0418: Phase II IMRT + / - chemo for post-op endometrial or cervical Cancer, 149 institutions credentialed; 95 patients registered to study.

- RTOG 0421: Phase III Trial for Previously Irradiated Head and Neck Cancer: Reirradiation with or without Chemo, 80 institutions credentialed, 15 patients registered to study (study closed due to poor accrual).

- RTOG 0435: Phase III to evaluate the safety and efficacy of Palifermin, 165 institutions credentialed, 21 patients registered to study (study closed).

- RTOG 0438: Phase I Unresect. Primary Bil Hepatobil. Cancer & Liver Mets Extracranial Stereotactic RT, 3 institutions credentialed, 14 patients registered to study.

- RTOG 0515: Phase II NSCLC Volume definition+/- PET, 5 institutions credentialed, 52 patients registered to study.

- RTOG 0521: Phase III Trial for localized High Risk Prostate Cancer: Androgen Suppressioin with Radiation vs. Radiation with Chemotherapy and Prednisone, 235 institutions credentialed (220 IMRT), 309 patients registered to study.

- RTOG 0522: Phase III Trial Comparing Radiation and Cisplatin with/without Cetuximab for Advanced Head and Neck Cancer, 217 institutions credentialed, 504 patients registered to study.

- RTOG 0526: Phase I/II Salvage Brachy Hi Risk Prostate, 217 institutions credentialed, 3 patients registered to study.

- RTOG 0529: Phase II Mitomycin+ Cis + IMRT in Anal Cancer, 152 institutions credentialed, 63 patients registered to study (study closed).

- RTOG 0534: Phase III Whole Pelvis vs. Prostate Bed in High Risk Patients, 44 institutions credentialed, 0 patients registered to study.

- RTOG 0615: Nasophayngeal Phase II IMRT & Cis & Bev, 150 institutions credentialed, 18 patients registered to study.

- RTOG 0617: Phase III High Dose 3DCT in NSCLC, 37 institutions credentialed, 7 patients registered to study.
- RTOG 0618: Phase II SBRT for Patients with Operable Early Stage NSCLC, 10 institutions credentialed, 0 patients registered to study.
- RTOG 0622: Phase II Study Samarium 153 Prostate; IMRT/3DCRT, 217 institutions credentialed, 0 patients registered to study.
- RTOG 0630: Phase II IGRT Large Size Soft Tissue Sarcoma, 0 institutions credentialed, 0 patients registered to study.

Developing RTOG Protocols (ATC resources committed)

- RTOG 0436: Phase III Esoph., Cetux/Cis/RT vs. Cis./Taxo/RT; 3DCRT
- RTOG 0539: Phase II Meningioma feasibility (accrual goals: not determined at this time)
- RTOG 0619: Phase IIR IMRT, Chemo, ZD6474 for High Risk Post-Op H&N
- RTOG 0621: Phase II Prostate RT/AS & Docetaxel; IMRT
- RTOG 0628: Phase II IMRT Locally Advanced Rectal
- RTOG 0631: Phase II Stereotactic Radiosurgery for Spine Mets
- RTOG 0713: Phase III IMRT Breast
- RTOG 0714: Phase III Resectable Pancreas IMRT 5-FU/Gem±erlot
- RTOG 0715: Phase II Study of Recurrent Breast 3DCRT
- RTOG 0811: Phase II Intermediate H&N Cancer IGRT + Erlotinib
- RTOG 0813: Phase II Stereotactic Radiosurgery for Centrally Located Lung Lesions
- RTOG 0814: Proton Beam Phase II in Locally Advanced Prostate Cancer
- RTOG 0816: Phase II HDR Brachy Prostate
- RTOG 0822: Phase II IMRT Cape & Oxal in Locally Advanced Rectal Cancer
- RTOG 0823: Phase I Lapatinib vs. Cape + IMRT for Pancreas Cancer
- RTOG 0836: 4D Imaging for Prostate IGRT
- RTOG 0838: Phase II IMRT + 5-FU, MMC, Cetux for Squamous Cell Anal Canal

Publications

Publications in press or published since last report:

Bradley J; Graham M; Moughan J; Byhardt R; Govindan R; Fowler J; Purdy JA; Michalski J; Gore E; Choy H: Phase I/II Results of RTOG L-0117; a Phase I/II Dose Intensification Study Using 3DCRT and Concurrent Chemotherapy for Patients with Inoperable NSCLC, International Assoc Study of Lung Cancer (IASLC), Seoul, Korea. Lung Cancer, 2: abstract #PD5-2-4.

Bosch W, Straube W, Matthews J, et al. A Survey of the ITC Volumetric Treatment Planning Data Archive Supporting RTOG Advanced Technology Clinical Trials. Paper presented at: Int J Radiat Oncol Biol Phys, 2007. 69:S195.

Cheung M, Tucker S, Dong L, et al. Dose-Volume Analyses of Grade >/= 2 Late Rectal Toxicity Among Patients Treated on Protocol RTOG 94-06. Paper presented at: Proc Amer Soc Thera Rad Onc (ASTRO), 2007; Los Angeles, CA. Int J Radiat Oncol Biol Phys, 69:S9.

Harari P; Harris J; Kies M; Myers JN; Foote RL; Machtay M; Rotman M; Khuntia Deepak; Straube W; Ang, K. Phase II Randomized Trial of Surgery Followed by Chemoradiation Plus Cetuximab for High-Risk Squamous Cell Carcinoma of the Head and Neck (RTOG 0234). Paper presented at: Proc Amer Soc Thera Rad Onc (ASTRO), 2007; Los Angeles, CA. Int J Radiat Oncol Biol Phys, 69:S13.

Ibbott G, Hanson W, Martin E, et al. Dose Specification and Quality Assurance of RTOG Protocol 95-17, A Cooperative Group Study of 192Ir Breast Implants as Sole Therapy. Int J Radiat Onco Biol Phys. 2007;69(5):1572-1578.

Lee N; Harris J; Garden A; Straube W; Bosch W; Morrison W; Quivey J; Thorstadt Wade; Jones C; Ang, K. Phase II Multi-institutional Study of IMRT +/- Chemotherapy for Nasopharyngeal Carcinoma (RTOG 0225): Preliminary Results. Proc Amer Soc Thera Rad Onc (ASTRO), Los Angeles, CA. Int J Radiat Oncol Biol Phys, 69:S13.

Michalski J; Bae K; Roach III M; Markoe A; Sandler H; Ryu J; Parliament M; Straube W; Valicenti R; Cox J: Long-Term Toxicity Following 3d Conformal Radiation Therapy For Prostate Cancer On RTOG 9406, A Phase I/II Dose Escalation Study. Amer Urology Assoc (AUA), Anaheim, CA, 2007.

Michalski J, Lawton C, El Naqa I, et al. RTOG Genitourinary Radiation Oncology Specialists Reach Consensus on Prostatic Fossa Clinical Target Volume for Radiation Therapy following Radical Prostatectomy. Paper presented at: ASCO GU Cancers Symposium, IN PRESS; San Francisco, CA.

Small Jr W, Mell LK, Anderson P, et al. Consensus Guidelines for Delineation of Clinical Target Volume for Intensity-Modulated Pelvic Radiotherapy in Postoperative Treatment of Endometrial and Cervical Cancer. Int J Radiat Oncol Biol Phys. 2007;2007.

Straube W, Bosch W, Matthews J, Michalski J, O'Meara E, Purdy, J: Impact of Protocol Complexity and Clarity on Digital Data Integrity Quality Assurance (DDIQA) for Advanced Technology Clinical Trials Requiring Digit Data Submission to the Image-Guided Therapy QA Center (ITC). Submitted ASTRO 2008 Meeting, Boston, MA.

Timmerman RD; Paulus R; Galvin J; Michalski J; Straube W; Bradley J; Fakiris AJ; Bezjak A; Videtic GM; Choy, H. Toxicity Analysis of RTOG 0236 Using Stereotactic Body Radiation Therapy to Treat Medically Inoperable Early Stage Lung Cancer Patients. Proc Amer Soc Thera Rad Onc (ASTRO), Los Angeles, CA, Int J Radiat Oncol Biol Phys, 69:S86.

Xiao Y; Straube W; Bosch W; Timmerman R; Galvin J: Dosimetric Evaluation of Heterogeneity Corrections for RTOG 0236: Hypofractionated Radiotherapy of Inoperable Stage I/II Non-Small Cell Lung Cancer. Proc Amer Soc Thera Rad Onc (ASTRO), Los Angeles, CA, Int J Radiat Oncol Biol Phys, 69S46.

Program Director/Principal Investigator (Last, first, middle): Curran, Walter J

GRANT NUMBER
CA81647-10

CHECKLIST

1. PROGRAM INCOME ***(See instructions.)***
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. FACILITIES AND ADMINSTRATIVE (F&A) COSTS
Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will ***not*** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☒ DHHS Agreement dated: February 27, 2006 ☐ No Facilities and Administrative Costs Requested.

☐ No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base $ 170,106 x Rate applied 52.00 % = F&A costs $ 88,455

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

☐ Salary and wages base ☒ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.)*:
No indirect costs calculated for ACR from the subcontract with Thomas Jefferson University.

Program Director/Principal Investigator (Last, First, Middle): Purdy, James

SENIOR/KEY PERSONNEL REPORT

Place this form at the end of the signed original copy of the application. Do not duplicate.

GRANT NUMBER
CA 81647-10

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PD/PI, Res. Assoc.)	Months Devoted to Project		
				Cal	Acad	Summer
Walter J. Curran, Jr.	M.D.	2896	Group Chair	0	0	0
Elizabeth O'Meara	RT.T.	4007	Director ATQA	.60		
Denise Manfredi	RT.T	8256	Dosimetrist	12.0		
Lorraine Quarles	RT.T.	5945	Dosimetrist	6.0		

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
NCIH	2	U24	CA081647 09

Total Project Period
From: 7/22/1999 Through: 06/30/2012

Requested Budget Period
From: 07/01/2008 Through: 06/30/2009

1. TITLE OF PROJECT
Advanced Technology Radiation Therapy Quality Assurance Review Consortium

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Geoffrey S. Ibbott, Ph.D.
Department of Radiation Physics
UT M. D. Anderson Cancer Center
1515 Holcombe Blvd., Unit 547
Houston, TX 77030

2b. E-MAIL ADDRESS
gibbott@mdanderson.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Radiation Physics

2d. MAJOR SUBDIVISION
Hospital

2e. Tel: 713-745-8989 Fax: 713-794-1364

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The University of Texas
M. D. Anderson Cancer Center
1515 Holcombe Blvd.
Houston, TX 77030

3b. Tel: 713-745-9400 Fax: 713-745-8171

3c. DUNS: 800772139

4. ENTITY IDENTIFICATION NUMBER
1746001118A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		4/18/07

6b. Federal Wide Assurance No. FWA363

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Shana Foster, MBA
Manager, Grants and Contracts
UT M. D. Anderson Cancer Center
1515 Holcombe Blvd., Unit 202
Houston, TX 77030
Tel: 713-745-9400 Fax: 713-745-8171
E-MAIL: awardnotice@mdanderson.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A-3343-1

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Applicant
DUNS:
Street 1:
Street 2:

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $79,365 8b. TOTAL $100,000

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City:	County:
State:	Province:
Country:	Zip/Postal Code:

Congressional Districts: #7

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Melinda Cotten, C.R.A., Executive Director, Office of Sponsored Programs

TEL: 713-792-3220 FAX: 713-794-4535 E-MAIL: osp@mdanderson.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Melinda Cotten DATE 4/18/08

PHS 2590 (Rev. 11/07) Face Page Form Page 1

total costs for this consortium are unchanged at $100,000

Consortium -RPC MD Anderson

Program Director/Principal Investigator (Last, First, Middle): Ibbott, Geoffrey S.

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY	FROM 07/01/2008	THROUGH 06/30/2009	GRANT NUMBER CA 081647-10

PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Geoffrey S. Ibbott	PD/PI	.60	✓		9,565	2,678	12,243
David Followill	Research Physicist	.60	✓		9,183	2,571	11,754
Andrea Molineu	Research Physicist	1.20	✓		13,764	3,854	17,618
Scott Davidson	Grad. Res. Asst.	6.0	✓		13,000	3,640	16,640
Paul Holguin	Database Admin.	1.20	✓		8,663	2,426	11,089
SUBTOTALS →					54,175	15,169	69,344

CONSULTANT COSTS		
EQUIPMENT *(Itemize)*		
SUPPLIES *(Itemize by category)*		
TLD dosimeters	1,000	
Radiochromic film	3,555	
Phantom supplies	2,266	
		6,821
TRAVEL		3,200
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*		
OTHER EXPENSES *(Itemize by category)*		
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD		$ 79,365
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD *(Item 8a, Face Page)*		$ 79,365

BUDGET JUSTIFICATION	GRANT NUMBER CA 081647-10

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

Personnel

Dr. Geoffrey S. Ibbott is the Principal Investigator on the Radiological Physics Center (RPC) grant and has been Director of the RPC since 2001. He is both nationally and internationally known for his knowledge of quality assurance of radiation therapy as it applies to the individual clinic and in a cooperative clinical trial setting. He serves as a member on the Radiation Therapy Committee of many of the clinical trial groups and represents the RPC at many of their group meetings. Dr. Ibbott will supervise the implementation and use of ATC tools at the RPC.

David Followill, Associate Director on the RPC grant, and Andrea Molineu are physicists employed with the RPC and will have the responsibility to attend meetings of the clinical trials groups and those of this grant activity, to supervise phantom design and Eclipse commissioning.

Paul Holguin, Database Administrator, is responsible for developing the mechanisms and web forms necessary for electronic data exchange, data archiving, and to develop any specialized software or databases needed to analyze any submitted data.

Scott Davidson, Graduate Research Assistant, will complete development and implementation of 3D dosimeters, as well as collaborate with CERR to develop the capabilities for comparison of measured data with treatment plans. This will include the implementation of a Monte Carlo calculation capability at the RPC.

CURRENT BUDGET PERIOD	FROM 07/01/2007	THROUGH 06/30/2008

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

Budget Justification (cont'd)

Radiochromic film, TLD, and phantom supplies are required to generate credentialing materials, reports of dosimetry results, design of phantoms, interaction with study groups, and the resolution of any dosimetry discrepancies encountered.

Radiochromic Film (79 sheets@ $45 each)	$3,555
TLD (1,000 @ 1.00 ea)	$1,000
Phantom Supplies	$2,266
	$6,821

Travel

There will be two meetings per year to meet with the NCI to discuss the progress and direction of the work on the RFA. There will be 2 representatives from the RPC at these meetings. Although much of the organization of this Consortium is expected to be conducted by conference calls and electronic communication, it is expected that there will be 1 meeting of the steering committee in St. Louis. There will be 2 representatives from the RPC at this meeting. We anticipate one more trip to respond to special needs. The travel to each meeting is expected to last 2 days.

Transportation	2 airline trips @$1000/trip	$2,000
	Per Diem – 4 days @ $150/day	$600
	4 ground transport @ $150/trip	$600
		$3,200

Other Expenses

Copier: The copier rental is supported by the RPC grant (CA 10953). Other components in the Section of Outreach Physics reimburse the RPC grant for copier use. There will be the need for copying of reports and communications with the steering committee, study groups, participating institutions and other collaborators of this project.

PROGRESS REPORT SUMMARY	GRANT NUMBER CA 081647-09	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Geoffrey S. Ibbott	FROM July 1, 2007	THROUGH June 30, 2008

APPLICANT ORGANIZATION
University of Texas M. D. Anderson Cancer Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Advanced Technology Radiation Therapy Quality Assurance Review Consortium

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Has there been a change in the other support of senior/key personnel since the last reporting period? No.

Will there be, in the next budget period, a significant change in the level of effort for the PD/PI(s) or other senior/key personnel designated on the Notice of Award from what was approved for this project? No.

Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total approved budget? No.

A. Specific Aims

The specific aims of the Radiological Physics Center (RPC), specific to the ATC, focus on the strengths of the RPC which include; 1) Development of anthropomorphic QA phantoms for advanced technology treatment techniques; 2) Credentialing of institutions to participate in advanced technology protocols; and 3) Maintaining communications with all cooperative study groups. Under the umbrella of the ATC, the RPC has worked to establish and maintain communication and collaboration with the other QA offices, minimize duplication of effort, and ensure that credentialing procedures are managed uniformly and consistently.

B. Studies and Results

The primary activities accomplished during the past year include:

Anthropomorphic Phantoms:
The RPC has developed a number of anthropomorphic phantoms to verify radiation dose delivery, dose homogeneity across a target organ or organ at risk, and field placement. These phantoms are used to evaluate institutions wishing to participate in clinical trials involving advanced technologies such as IMRT and stereotactic radiosurgery. In some cases, these protocols involve dynamic treatment techniques. The QA phantoms all consist of a water-filled outer plastic shell with inserts containing tissue equivalent imageable targets and critical structures. Each phantom also includes TLD and film dosimeters. [1, 2, 3] Since 2001, the RPC head and neck IMRT phantom has been sent to more than 355 institutions and has been irradiated more than 475 times. The RPC pelvis IMRT phantom has been irradiated more than 97 times. The RPC thorax SRS phantom, which includes lung equivalent material, has been irradiated 43 times by more than 35 institutions.

Credentialing processes:
Over the past year, the RPC has been involved in the credentialing processes for a number of advanced technology protocols. These include 20 trials conducted by the RTOG, 1 NSABP trial, 1 CALGB trial, 1 GOG trial, and 5 NCCTG trials. Most of these trials involved the delivery of IMRT or stereotactic radiosurgery, and many required that one of the

RPC anthropomorphic phantoms be irradiated. Several protocols permit the use of a calculation benchmark in lieu of RPC phantom; however, the RPC phantom always satisfies a requirement for a calculation benchmark. Through the communications facilitated by the ATC, the RPC ensures that the phantoms are available to any study group that wishes this level of credentialing for advanced technology clinical trials.

The RPC's stereotactic brain phantom is recommended by several study groups to its members to evaluate their SRS capability. The phantom is not required for credentialing for any specific protocol, but is recommended as a QA device. Study groups that have recommended its use include several for which QARC performs chart reviews.

Several CT-based treatment planning benchmarks have been developed by the RPC and QARC that are now made available on both the RPC and QARC web sites. Institutions can submit their calculations to either RPC or QARC for review. The RPC has instituted procedures for notifying QARC whenever an institution completes a benchmark.

The RTOG has indicated interest in developing a clinical trial to assess the use of proton beams to treat prostate cancer. At least one other study group, the Children's Oncology Group (COG) has permitted the use of protons on clinical trials. It is now proposed that participating institutions undergo regular audits from the RPC, including periodic measurements of radiation beam output calibration and on-site dosimetry evaluations. They will also be expected to perform a phantom irradiation procedure to evaluate their delivery of proton beam therapy. In response, the RPC has evaluated its TLD monitoring program to determine the characteristics of the TLD system when irradiated with protons. The program was found to perform acceptably, and TLD were subsequently mailed to the five existing proton facilities. Most of these have now been returned and all the results have all fallen within the RPC's 5% acceptability criteria. A total of 47 proton beams have been evaluated with TLD. The RPC will use ATC funds to assemble some additional equipment needed to perform on-site dosimetry reviews. Procedures will be developed and visits to proton treatment centers will be scheduled.

Remote review tools:
The RPC uses the remote review tools developed by the ITC to evaluate treatment plan information submitted by institutions. The remote review tools are also used by physicians participating with the RPC in its credentialing processes to evaluate clinical treatment plans submitted by institutions for compliance with the protocol.

Study group interactions:
The RPC regularly attends all cooperative study group meetings. At many of these meetings, RPC physicists give presentations describing the ATC and the role of RPC in the consortium. The RPC is also represented at the AAPM Working Group on Clinical Trials. This is a forum that allows the Quality Assurance Offices (QAO) to review and collaborate on methods of improving the quality of radiotherapy data in clinical trials.

Software development:
The RPC has, since the inception of the program of credentialing with anthropomorphic phantoms, evaluated the phantom irradiations with software developed in house. However, the RPC has needed a more sophisticated evaluation capability, to more completely compare institutions' phantom irradiations with their treatment plans. To address this need, the RPC has issued a subcontract to Washington University for the development of software tools based on the CERR package produced by Dr. Joe Deasy. The tools, which have largely been developed, permit the RPC to perform a 2D comparison, and to calculate a gamma index distribution. [4] Over the next several months, the RPC will re-evaluate phantom irradiations performed during the past year to establish appropriate acceptability criteria using the gamma index method. Treatment planning data submitted to the ITC during 2007 will be transferred to the RPC for this purpose.
For the evaluation of treatment planning benchmarks and patient treatment plans, the RPC has for many years relied on software developed in house. The RPC has neither the resources nor expertise to update the software as treatment plans increase in complexity and as advanced technologies such as SBRT and IMRT are introduced into more clinical trials. Instead, the RPC has issued a subcontract to Washington University for the development of a Monte-Carlo based dose calculation capability. Preliminary evaluations of the software have been performed and it is expected that this testing will continue throughout the next year.

C. Significance
Credentialing of institutions and individuals for various protocols verifies that institutions are prepared with equipment, staff, and procedures before entering an advanced technology protocol. The use of anthropomorphic phantoms, treatment planning benchmarks, and evaluation tools allows the RPC to assure the cooperative groups that the institutions can deliver the prescribed dose to the target of interest within specific criteria. The ATC grant helps to support some of this

work. Cooperative groups planning advanced technology protocols are aware of the resources available to them from this grant.

D. Plans

Anthropomorphic phantoms:
The RPC anthropomorphic phantoms continue to undergo evaluation and modification. Modifications envisioned for the future will permit use of several of the phantoms with proton beams. The ATC grant will help support some of this work.

Remote review tools:
The RPC will continue to investigate the use of remote review tools developed by the ITC. Further developments are expected that will enhance the use of the CERR software by the RPC to evaluate phantom irradiations.

As more institutions replace conventional localization films with electronic images, it is becoming necessary for the RPC to evaluate brachytherapy dosimetry using electronic images. The RPC acquired a Varian Eclipse treatment planning system to facilitate this development. The ITC, under the ATC grant, transfers institutions' treatment plans to the RPC for evaluation with this system.

Benchmarks:
The RPC has upgraded its routine benchmark treatment plans to CT-based benchmarks. However, the RPC will develop more sophisticated treatment planning benchmarks to be able to thoroughly evaluate the capability of institutions to develop 3D plans.

HIPAA:
The RPC has been educated in the requirements of HIPAA regulations and has submitted modified protocol procedures to the parent institution. We will continue to follow developments in this area and make sure that our procedures are compliant.

Interaction with study groups:
The RPC will continue to attend meetings of all study groups and offer its assistance in regards to radiotherapy QA issues. The RPC will also participate in the steering committee of this grant in an effort to better focus our efforts to meet the needs of each cooperative study group.

Research involving human subjects:
No patients receive treatment under the activities of this grant. Our association with patients is by review of radiotherapy treatment records. The review of this grant by the human surveillance committee concerns primarily our procedures for handling patient data with the proper regard for confidentiality.

E. Publications

1. Molineu A, Followill DS, Balter PA, Hanson WF, Gillin MT, Huq MS, Eisbruch A, Ibbott GS. Design and implementation of an anthropomorphic quality assurance phantom for intensity-modulated radiation therapy for the Radiation Therapy Oncology Group. Int J Radiat Oncol Biol Phys 63:577-83, 10/2005.

2. Followill D, Radford DA, Cherry C, Molineu A, Fisher G, Hanson WF, Ibbott GS. Design, development, and implementation of the Radiological Physics Center's pelvis and thorax anthropomorphic quality assurance phantoms. Med Phys 34:2070-6, 5/2007.

3. Ibbott GS, Followill DS, Molineu HA, Lowenstein JR, Alvarez PE, Roll JE. Challenges in Credentialing Institutions and Participants in Advanced Technology Multi-institutional Clinical Trials. Int J of Radiat Oncol Biol Phys. In Press.

4. An Open-Source Software Tool to Support Film-Based IMRT Quality Assurance. D Khullar, A Molineu, D Followill, W Bosch, V Willcut, T Simpson, T Ju, and J Deasy. Med. Phys. 34, 2418 (2007) (Abstract).

F. Project-Generated Resources
The ATC Grant helps to support the RPC's credentialing programs, and tools for remote review of computer planning data are used by the RPC to conduct rapid, timely, and retrospective reviews of patients' treatment plans. The design of our credentialing tools and statistics on the passing rates and number of participating institutions are shared with the ATC members, study groups and the radiation oncology community through presentations, publications, and our web site.

Consortium -RPC MD Anderson

Program Director/Principal Investigator (Last, first, middle): Ibbott, Geoffrey S.

GRANT NUMBER
CA 081647- 10

CHECKLIST

1. PROGRAM INCOME ***(See instructions.)***
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)
N/A	N/A	N/A

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. FACILITIES AND ADMINSTRATIVE (F&A) COSTS
Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will ***not*** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☒ DHHS Agreement dated: 11/1/04 ☐ No Facilities and Administrative Costs Requested.

☐ No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base $ 79,365 x Rate applied 26 % = F&A costs $ 20,635

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

☐ Salary and wages base ☒ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.):*

Program Director/Principal Investigator (Last, First, Middle): Ibbott, Geoffrey S.

SENIOR/KEY PERSONNEL REPORT

Place this form at the end of the signed original copy of the application. Do not duplicate.

GRANT NUMBER
CA 081647-09

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Months Devoted to Project		
				Cal	Acad	Summer
Geoffrey S. Ibbott	Ph.D.	0859	PI	.60		
David S. Followill	Ph.D.	2988	Research Physicist	.60		
Andrea Molineu	M.S.	5263	Research Physicist	1.20		

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	2	U24	CA081647-09

Total Project Period
From: 7/22/1999 Through: 6/30/2012

Requested Budget Period
From: 7/1/2008 Through: 6/30/2009

1. TITLE OF PROJECT
Advanced Technology QA Center

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Andrew Vaughan, Ph.D.
4501 X Street, Rm 0140
Sacramento, CA 95817

2b. E-MAIL ADDRESS
andrew.vaughan@ucdmc.ucdavis.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Radiation Oncology

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 916-734-8726 Fax: 916-703-5069

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The Regents of the University of California
Office of Research, Sponsored Programs
1850 Research Park Drive, #300
Davis, CA 95616

3b. Tel: 530-747-3828 Fax: 530-747-3929

3c. DUNS: 04-712-0084

4. ENTITY IDENTIFICATION NUMBER
1946036494A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		1/13/08

6b. Federal Wide Assurance No. FWA00004557

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Barry M. Klein
Vice Chancellor for Research
Office of Research, Sponsored Programs
1850 Research Park Drive, #300
Davis, CA 95616

Tel: 530-747-3828 Fax: 530-747-3929

E-MAIL: vcresearch@ucdavis.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: The Regents of University of California

DUNS: 04-712-0084

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $ 100,176 8b. TOTAL $ 152,268

Street 1: 4501 X Street, R0140

Street 2:

9. INVENTIONS AND PATENTS ☐ No ☐ Yes

If "Yes, ☐ Previously Reported ☐ Not Previously Reported

City: Sacramento County: Sacramento

State: CA Province:

Country: USA Zip/Postal Code: 95817

Congressional Districts: IV

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Andrew Jones – Contracts and Grants Analyst

TEL: 530-747-3926 FAX: 530-747-3929 E-MAIL: anjones@ucdavis.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)*

DATE 4/2/08

total costs unchanged from CRL

Consortium - Univ of California, Davis

Program Director/Principal Investigator (Last, First, Middle): Vaughan, Andrew

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY	FROM 7/1/08	THROUGH 6/30/09	GRANT NUMBER 2 U24 CA081647-10

PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Andrew Vaughan	PD/PI	.12	0.24		0	0	0
James Purdy	Medical Physicist	4.8	✓		76,520	10,713	87,233
SUBTOTALS →							87,233

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)* Laptop Replacement, Printer, Software Licenses	4,500
TRAVEL 8 Trips @ $1,000/Trip	8,000
PATIENT CARE COSTS – INPATIENT	
PATIENT CARE COSTS – OUTPATIENT	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)* Postage, publication, posters	443
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD	$ 100,176
CONSORTIUM/CONTRACTUAL COSTS – DIRECT COSTS	
CONSORTIUM/CONTRACTUAL COSTS – FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD *(Item 8a, Face Page)*	$ 100,176

BUDGET JUSTIFICATION

Personnel:

Andrew Vaughan, Ph.D.: Principal Investigator: (CM .12)

Dr. Vaughan, Professor, Department of Radiation Oncology at the University of California Davis is a well-established expert in cancer biology. He will serve as the Principal Investigator for this subcontract since Dr. Purdy is the overall Principal Investigator for the ATC grant, and will provide biological input to the ATC protocol design efforts. The level of involvement cannot be specified since it will be variable. No salary is requested.

James A. Purdy, PhD: Medical Physicist (CM 4.80):

Dr. Purdy is the Principal Investigator for the Advanced Technology Consortium (ATC) grant at Washington University and Medical Physicist on the ATC subcontract at UC Davis. Dr. Purdy will continue to serve as the Director of the Image-Guided Therapy Center (ITC), with the main component of the ITC at Washington University in St. Louis (ITC-WU) and an adjunct component located at the University of California, Davis (ITC-UCD). In these roles, Dr. Purdy is responsible for the overall vision, direction, and coordination of the ATC grant as well as the ITC and for ensuring that the grant aims are realized. Dr. Purdy provides key input into the design and development of any new ATC software needed to accomplish the ATC mission. Dr. Purdy is responsible for the generation of all this grant's progress reports and official reports from the ATC and the ITC pertinent to advanced technology clinical trials. He attends and chairs all ATC required meetings and primary teleconferences and is available to answer any questions raised by the ATC Steering Committee, Evaluation Committee, or NCI. Less salary than effort due to NIH cap. Difference in salary to be paid by department.

Equipment

None

Supplies

We are requesting funds for computer equipment/software ($4,500) as listed:

- Computer replacement ($3000)
- Printer for ATC use ($750)
- Licenses for PC software for ITC-Davis personal computers for data analysis, documentation preparation, and presentations (e.g., MATLAB, Office, Photoshop) ($750).

Travel

It is expected that there will be at 4 face-to-face ATC meetings at the various QA Centers per year. These meetings are expected to last one to two days. It is also expected that there will be at least 2 ATC meetings per year at the RTOG semi-annual meeting. In addition, Dr. Purdy will need to travel to ITC-WU periodically. In addition, we also expect 1 additional trip per year for Dr. Purdy or his designate to respond to special needs of ATC collaborators or to attend other cooperative group meetings to promote ATC efforts. In addition, there is expected to be at least 1 Steering Committed meeting and 1 Evaluation Committee meeting in which Dr. Purdy must attend. 8 personal trips/year @ $1000.00 per person = $8,000

Other Expenses

- Postage, Poster, Miscellaneous ($443)
  - Postage is required for the mailing of reports to the ATC subcontractors, NCI, and interaction with the cooperative clinical study groups.

Specific Aims

The specific aims of the UC Davis contribution to this consortium are to support the administrative branch of the Image-guided Therapy QA Center (ITC) located at the University of California Davis Medical Center (UCD). The reason for this branch is because Washington University in St. Louis (WU) remains the NIH grantee institution and Dr. Purdy remains the Principal Investigator on this grant (Adjunct Professor at WU with no salary). The UCD ATC subcontract supports Dr. Purdy's ATC grant efforts. In this arrangement, the main component of the ITC resides at WU (henceforth referred to as ITC-WU), and is augmented by an administrative branch at UCD (henceforth referred to as ITC-UCD). Dr. Purdy serves as ITC Director for both branches. The goals as specified in the RFA for our ATC renewal application are to be accomplished through the following *developmental*, *coordination*, and *service* objectives:

1. Eliminate duplication of infrastructure developmental efforts and facilitate sharing of QA resources among cooperative groups.
2. Help to insure that appropriate and uniform QA procedures and criteria for advanced technology trials are developed across all cooperative groups.
3. Facilitate/help manage the uniform credentialing of institutions for advanced radiotherapy trial protocols.
4. Facilitate/manage digital data protocol submission.
5. Facilitate/manage the QA review of submitted data.
6. Further the development of methods for rapid analysis of volumetric treatment planning data.
7. Assist clinical trial cooperative groups in the development of clinical trials protocols including: (a) credentialing requirements; (b) target volume definitions; (c) quality assurance procedures; and (d) data submission instructions.
8. Develop, implement, and maintain innovative methods for electronic exchange of digital planning data between institutions participating in clinical trials and between QA Centers.
9. Develop, implement, and maintain innovative web-based software tools to facilitate protocol digital data reviews by Study Chairs, Dosimetry Groups, the Radiological Physics Center (RPC), and the Quality Assurance Review Center (QARC).
10. Develop, implement, and maintain archival treatment planning and QA databases that can be linked with the cooperative groups' clinical outcomes databases.
11. Demonstrate understanding of and ability to achieve compatibility with existing software and electronic health record standards, including the Cancer Bioinformatics Grid (caBIG) and DICOM RT.

To accomplish these goals, we have organized the ATC's efforts around the four specific aims listed in Section A.

Specific Aim 1: Maintain and manage (and make incremental improvements as required to) the current electronic data submission of advanced technology protocol credentialing and case data, archival storage, and remote QA review process utilizing the ATC *QuASA^{2}R (Quality Assurance Submission, Archive, Analysis, and Review)* system.

Specific Aim 2: Develop novel web-based remote-review tools that will enhance the efficient and effective review of 3DCRT, IMRT, SBRT, and brachytherapy protocols. The tools and interfaces will be designed by a multidisciplinary team of experts in the quality assurance of clinical trials. The design infrastructure of these tools will assist the development of future protocol processes such as image-guided radiation therapy (IGRT) and adaptive radiation therapy (ART) [Yan 1998; Brabbins 2005]. *QuASA^{2}R* is modular in architecture to promote the efficient design, testing, and implementation of tools and subsystems. Starting from a DICOM-based ITPV data archive with well-defined interfaces, our developmental approach will (a) allow the selective re-use and adaptation of existing *QuASA^{2}R* system components, (b) enable the integration of a heterogeneous mix of commercial-off-the-shelf, open-source and custom software components; (c) facilitate testing and maintenance of system components, and (d) allow step-wise evolution/upgrading of the *QuASA^{2}R* system to support technological advances in radiation therapy clinical trials. Emphasis will be on the development and improvement of web-based remote-review tools

that achieve compatibility with existing software and electronic health record standards, including the Cancer Bioinformatics Grid (caBIG) and DICOM RT, and maintaining/developing archival multimodality ITPV, credentialing, and QA databases for the advanced treatment modalities that can be linked with the cooperative group's clinical outcomes database.

Specific Aim 3: Assist cooperative groups in the development and management of advanced technology clinical trials protocols including (a) tumor/target volume and organ at risk definitions; (b) credentialing requirements and evaluation criteria; (c) electronic data submission requirements/instructions; and (d) quality assurance review procedures.

Specific Aim 4: Serve as an educational resource to the nation's clinical trial cooperative groups and participating institutions for support of advanced technology radiation therapy clinical trials.

(B) Studies and Results (Year 09)

The primary activities accomplished this past year with regard to each specific aim are summarized below:

- UCD has provided adequate space and computer network connectivity for Dr. Purdy's ATC/ITC activities.
- Dr. Purdy has coordinated and directed ITC activities by conducting weekly ITC teleconferences between the two ITC branches and visited ITC-WU several times during this funding period.
- Dr. Purdy participates in the multiple monthly teleconferences between ATC subcontractors held during this funding period.
- Dr. Purdy organized and chaired the four ATC meetings held during this funding period.
- Dr. Purdy assisted Dr. Deye in planning the ATC steering committee held Nov. 6, 2007, and was responsible for answering questions raised by the Steering Committee.
- Dr. Purdy interacted with ATC subcontractors in as listed below:
  - worked closely with RTOG committees (Medical Physics, Advanced Technology Integration Committee (ATIC), and the various disease site committees) and protocol study chairs in developing QA guidelines and credentialing requirements for advanced technology radiation therapy protocols and/or modification of ongoing protocols. He provided input to the RTOG leadership regarding utilization of ATC resources and provided an ATC report to both the Medical Physics committee and the IGRT committee documenting ATC's involvement with RTOG studies at each of the semi-annual RTOG meetings.
  - worked with the Quality Assurance Review Center (QARC) in their efforts in the ATC grant, particularly those directed at implementing digital data transfer and remote QA review.
  - worked with the Radiological Physics Center (RPC) in the development of common QA guidelines and credentialing requirements for advanced technology protocols that RPC helps support.
- Dr. Purdy provided key input to ITC-WU regarding the development/refinement of ATC Web-based remote review tools in order to accomplish the ATC mission.
- Dr. Purdy was responsible for the generation of this grant's overall progress report and other official reports from the ATC and the ITC pertinent to advanced technology clinical trials.

Specific aim 1 reflects primarily the ATC service effort. The QuASA^{2}R clinical trials quality assurance (QA) system, developed by the ITC, provides multiple cooperative groups one of the most advanced medical informatics infrastructures currently in use for radiation therapy clinical trials QA. It currently supports QA review and outcomes analysis for both cooperative group and industrial/pharmaceutical clinical trials. *Cooperative-group trials supported include those sponsored by the Radiation Therapy Oncology Group* (RTOG), National Surgical Adjuvant Breast and Bowel Project (NSABP), New Approaches to Brain Tumor Therapy (NABTT), Japan Clinical Oncology Group (JCOG), and European Organization for Research and Treatment of Cancer (EORTC). QA and outcomes analysis for these trials have required the collection and review of nearly 7000 protocol case datasets from a broad spectrum of commercial imaging, treatment planning, and verification systems as shown in **Fig. 1**.

Protocol specific digital treatment planning data are sent to ITC-St. Louis via SFTP or media. The Protocol review process is now more clearly divided between the ITC and the cooperative group, The ITC is responsible for Digital Data Integrity QA (DDIQA) review which includes review for completeness of protocol required elements, format of data, spatial registration, dose scaling, and possible data corruption; and recalculation of all Dose Volume Histograms (DVHs). The cooperative group is responsible for Protocol Compliance QA

(PCQA) review which includes review of target volume and organ at risk contours compliance and review of protocol dose prescription and dose heterogeneity compliance by cooperative group specific reviewer(s) such as the Protocol Study Chair (SC) using QuASA^{2}R's web-based *Remote Review Tool (RRT)*.

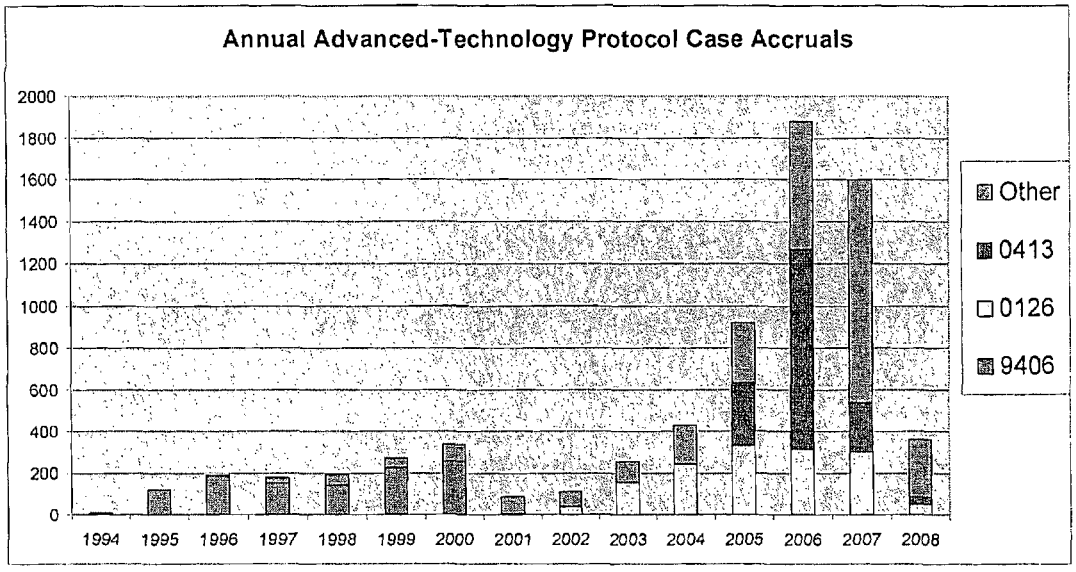

Figure 1.Number of protocol accruals on a per year basis submitted over 15+ Year Period using the ATC QuASA^{2}R method. 11 commercial TPS vendors (20 TPSs) have implemented ATC QuASA^{2}R compliant export capability and 536 institutions are now able to submit data to the ITC.

Specific aim #2 focuses on development/refining digital data exchange mechanisms and the development and refinement of the QuASA^{2}R system (Fig. 2) in order to support advanced technology radiation therapy clinical trials, and the recognition of QA tool needs for future protocol processes, such as image-guided radiation therapy (IGRT) and adaptive radiation therapy (ART).

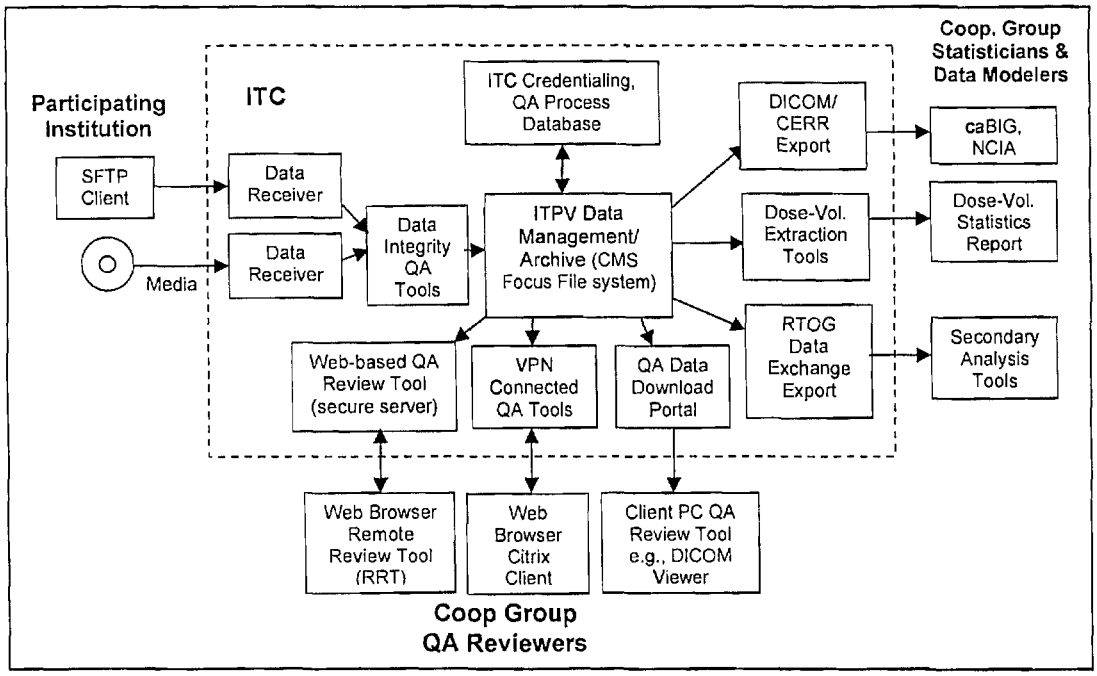

Figure 2. Diagram depicting QuASA^{2}R (*Quality Assurance Submission, Archive, Analysis, and Review*) system components and data flow.

The QuASA^{2}R system supports Internet submission of data using the Secure FTP (SFTP/SSH2) protocol. Data may also be submitted using CD (DICOM or RTOG formats) or Tape cartridge (RTOG format only) media. The ITC SFTP server (ITCsubmit.wustl.edu) provides secure submission of data with individual accounts for institutions participating in advanced-technology protocols and treatment planning manufacturers testing data export capabilities. Users may submit data files, but may not access other users' data or system files. The flow of information through the QuASA^{2}R system is also diagrammed in Fig. 2. Once imported into the ITC treatment plan review file system, submitted data may be reviewed from any Internet-connected web browser using the ITC Remote Review Tool (RRT) as shown in Figures 3A and 3B. The RRT provides a display of axial patient images with overlaid OAR/TV contours and user-defined iso-dose curves and DVHs. RRT users can also edit contours on axial images, re-calculate DVHs for these user-defined structures, and display point doses on axial images.

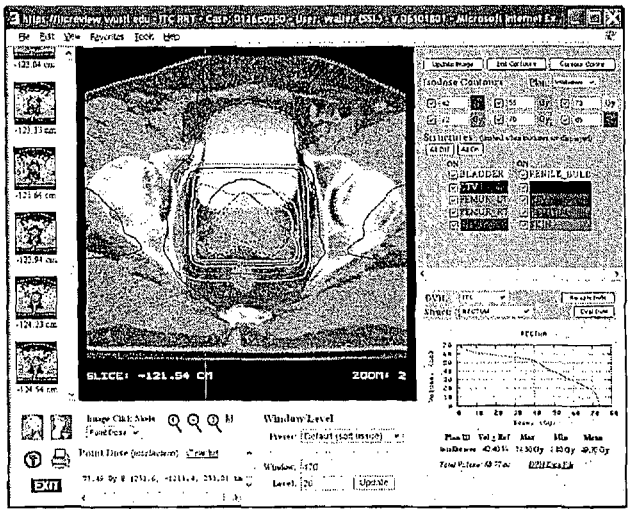

Figure 3A. WWW-based Remote Review Tool (RRT) that allows reviewer to review target volume and organs-at-risk contours, and selected isodoses overlaid on axial CT images, and dose-volume histograms, including dose-volume statistics.

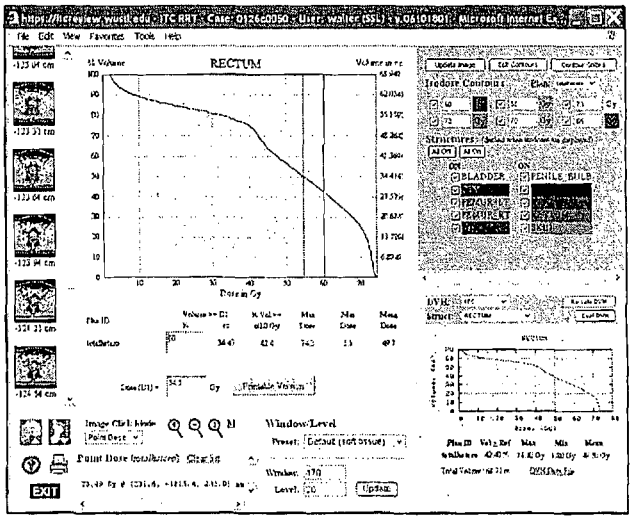

Figure 3B. Interactive dose-volume histogram evaluation applet.

Specific aim #3 focuses on helping cooperative groups utilize standard nomenclature, definitions, and credentialing requirements in the clinical protocol. At the March ATC meeting, Dr. Purdy appointed a standing ATC committee (Marcia Urie (Chair), Dave Followill (Co-chair), Bill Straube, and Jim Galvin) whose mission is to help eliminate duplication of effort and help facilitate sharing of QA resources among cooperative groups and QA Centers; (2) help insure that appropriate and uniform QA procedures and criteria for advanced technology trials are developed across all cooperative groups; and assist clinical trial cooperative groups in the development of clinical trials protocols including: (a) credentialing requirements; (b) target volume definitions; (c) quality assurance procedures; and (d) data submission instructions. Credentialing and QA criteria for ATC supported protocols are posted on the ATC website. They address the following modalities: (1) 3DCRT QA Criteria (See ATC's website at http://atc.wustl.edu and refer to RTOG protocol 0126); (2) IMRT QA Criteria (refer to RTOG protocol 0522); Note, the ATC developed the revised NCI guidelines allowing use of IMRT for intra-thoracic treatments, and updated them giving more detailed and specific guidelines for use of IMRT for intra-thoracic treatment protocols with the goal that they are clear enough to be consistently applied within all of the cooperative groups; (3) Prostate Seed Implant QA Criteria (refer to RTOG protocol 0232); (4) HDR Brachytherapy QA Criteria (refer to RTOG protocol 0321; (5) SBRT QA Criteria (refer to RTOG protocol 0617).

During the past year there has also been considerable progress in the development of a credentialing mechanism for proton therapy. All members of ATC have contributed to this effort. The credentialing process

includes a questionnaire developed and vetted by ATC and a phantom dosimetry test. The overall process for credentialing is now close to being in place and will be an important asset for both pediatric and adult cooperative group clinical trials.

Specific aim #4 focuses on ATC efforts designed to help educate institutional personnel that are involved in registering, planning, and treating ATC supported protocol patients. The ATC routinely presents at the RTOG RA symposium that is held the Thursday before the RTOG meeting in January and June, and is also available at the roundtable session on Friday morning of the RTOG meeting. An ATC representative also spoke at the 2007 NSABP meeting both addressing the RAs and presenting at a workshop for the B39/0413 protocol which was attended by physicians as well as RAs.

This specific aim is also being address through the ATC website (http://atc.wustl.edu) which has continued to be refined during this funding period. The ATC Website links to all the consortium member websites, the NCI, and all cooperative group protocols the ATC is supporting. The ATC's website provides an overview of the ATC's role in advanced technology clinical trials and is used to disseminate advisory QA and credentialing information and pertinent forms to current and potential participants in all ATC supported clinical trials, and to receive on-line submissions of certain protocol forms. The website provides simple access to valuable resources for institutions participating in these studies as well as for institutions preparing for certification. The data submission and QA review resources linked on the ATC website are for the use of study chairs, QA centers, and participants in ATC-supported clinical trials. A valid user account is required for their use.

The ATC also distributed brochures at the 2007 AAPM and ASTRO Annual Meetings. This brochure provided information regarding the ATC's mission and the current ATC activities. Importantly, compliant data exchange capabilities of treatment planning vendors was listed.

(C) Significance

Today, the credentialing, digital data submission, and QA for protocols using advanced technologies such as 3DCRT, IMRT, SBRT, and brachytherapy have become a priority for cooperative group trials. The ATC has continued to use the concepts pioneered with the 3DOG/RTOG 9406 protocol for credentialing, data submission, and QA. In this past year, significant progress was made in using ATC QuASA^{2}R. To date, over 500 institutions (and nearly 7000 digital data sets successfully submitted) have satisfactorily completed this process.

In this past year, under Dr. Purdy's leadership, significant progress was made in integrating the efforts of all subcontractors in meeting the goals of the ATC. The ATC will continue to provide an already well-established advanced technology QA review process (ATC QuASA^{2}R system) while seeking opportunities to develop an even more effective QA digital data receipt and review systems. We strongly believe that the ATC has been successful in providing the most cost effective, efficient, and advanced QA review available for all Cooperative Groups conducting clinical trials utilizing advanced technologies. We feel strongly that our ATC QA consortium continues to represent the best single effort to date to merge the strengths of the national QA Centers and to develop a common database for outcome analysis.

(D) Plans for the Next Project Period (Year 10: 2008-09)

- Dr. Purdy will continue to serve as the Principal Investigator for the Advanced Technology QA Consortium (ATC) U24 grant and Director of the Image-Guided Therapy Center (ITC). In this roles, he is responsible for the overall vision, direction and coordination of the ATC/ITC efforts and for ensuring that the grant's goals are realized.
- Dr. Purdy will coordinate and direct ITC activities by conducting weekly ITC teleconferences between the two ITC branches and visiting ITC-WU periodically during this funding period.
- Dr. Purdy will continue to organize and chairother ATC teleconferences held during this funding period.
- Dr. Purdy will continue to organize and chair the multiple face-to-face ATC meetings to be held at each of the QA Centers comprising the ATC.

- Dr. Purdy will assist Dr. Deye in planning the next ATC Steering Committee, and will be responsible for answering any questions raised by the Steering Committee.
- Dr. Purdy will assist Dr. Deye in planning the first ATC Evaluation Committee, and will be responsible for answering any questions raised by the Evaluation Committee.
- Dr. Purdy will oversee Consortium key personnel from each of the sub-contractors to ensure that the planning, organization and administration of activities and personnel within the individual subcontracted entity is well aligned with the overall goals and priorities of the ATC. Specifically, Dr. Purdy will
  - work closely with RTOG committees (Medical Physics, Advanced Technology Integration, and the various disease site committees) and protocol study chairs in developing QA guidelines and credentialing requirements for advanced technology radiation therapy protocols and/or modification of ongoing protocols. He will provide input to the RTOG leadership regarding utilization of ATC resources and provide an ATC report to both the Medical Physics committee and the IGRT committee documenting ATC's involvement with RTOG studies at each of the semi-annual RTOG meetings.
  - work closely with the QARC in their efforts to implement digital data transfer and remote QA review for selected protocols.
  - work closely with the RPC in the development of common QA guidelines and credentialing requirements for advanced technology protocols that RPC helps support.
- Dr. Purdy, working with the Consortium key personnel, will be responsible for anticipating the QA data-analysis needs of radiotherapy clinical trials as they employ advanced technologies and providing for these needs in an efficient and timely manner. This responsibility will include the development and implementation of the ATC QuASA^{2}R system hardware, software and personnel that are needed to archive and remotely review the clinical trial data.
- Dr. Purdy will, where appropriate, establish collaborations with existing private or public organizations and will work toward seamless integration of efforts rather than competition or redundancy of efforts
- Dr. Purdy will continue to be responsible for the generation of this grant's progress report and other official reports/correspondence from the ATC and the ITC pertinent to advanced technology clinical trials.

Human Subjects: The efforts supported by this grant do not involve enrolling patients on treatment protocols and has no direct contact with patients. The ITC-WU does receive treatment records (digital and hard copy) containing identifiers from institutions participating in RTOG or other cooperative group clinical trials. These protocols include requirements to protect identifiers from improper use, and include requirements for informed consent and authorization. The participating institution at the time of patient enrollment obtains authorization. The role of the ITC is to evaluate and/or facilitate the evaluation of treatment records for compliance with the cooperative group protocols. The ITC would be unable to perform or facilitate this QA review without access to and use of the PHI. All treatment records are the property of the study group(s) at the conclusion of evaluation. The study group ensures that the protocol includes a plan to destroy identifiers at the appropriate time. Appropriate security features incorporating both physical and software restraints for maintaining confidentiality currently exist at the ITC. All ATC members have well-established procedures for handling patient data with proper regard for confidentially.

Vertebrate Animals:
Not Applicable

(E) Publications
Publications that involved ATC support in press or published are listed below:

1. Bosch W, Matthews J, Straube W, Purdy J: QuASAR: Quality Assurance Submission, Analysis, and Review System for Advanced Technology Clinical Trials in Radiation Therapy, in the Proceedings of the XVth International Conference on the Use of Computers in Radiation Therapy, June 4-7, 2007, Toronto, Canada, edited by Jean-Pierre Bissonnette, Published by Novel Digital Publishing, Oakville, Ontario, Canada, p. 98-102, 2007.
2. Matthews JW, Bosch WR: Explicit-VR Transfer Syntax Limits the Value Multiplicity of DICOM Data Elements with Decimal String (DS) Value Representation. *Phys. Med. Biol.,* 51:L11-L12, 2006.

3. Vicini F, Winter K, Straube W, Wong J, Pass H, Rabinovitch R, Chafe S, Arthur D, Petersen I, McCormick B: A phase I/II trial to evaluate three-dimensional conformal radiation therapy confined to the region of the lumpectomy cavity for Stage I/II breast carcinoma: initial report of feasibility and reproducibility of Radiation Therapy Oncology Group (RTOG) Study 0319. *Int. J. Radiat. Oncol. Biol. Phys.*, 63(5):1531-1537, 2005.

4. Molineu M, Followill DS, Balter PA, Hanson WF, Gillin MT, Huq MS, Eisbruch A, and Ibbott GS. Design and Implementation of an Anthropomorphic Quality Assurance Phantom for Intensity-Modulated Radiation Therapy for the Radiation Therapy Oncology Group. Int J Radiat Oncol Biol Phys, Vol. 63(2): 577–583, 2005.

5. Michalski, J.M., Winter, K., Purdy, J.A., Parliament, M.B., Wong, H., Perez, C.A., Roach III, M., Bosch, W., and Cox, J.D.: Toxicity After Three-Dimensional Radiotherapy for Prostate Cancer on RTOG 9406 Dose Level V.? *Int. J. Radiat. Oncol. Biol. Phys*, 62(3):706-713, 2005.

6. Bradley J, Graham M, Winter K, Purdy J, Komaki R, Roa W, Ryu J, Bosch W, and Emami B: Toxicity and Outcome Results of RTOG 9311; a Phase I/II Dose Escalation Study using Three-Dimensional Conformal Radiotherapy in Patients with Inoperable Non-Small Cell Lung Carcinoma. *Int J Radiat Onco Biol Phys*, 61 (2):318-328, 2005.

7. Roach III M, Winter K, Michalski J, Cox J, Purdy J, Bosch W, Lin X, and Shipley W: Penile Bulb Dose and Impotence After Three-Dimensional Conformal Radiotherapy for Prostate Cancer on RTOG 9406: Findings From A Prospective, Multi-Institutional, Phase I/II Dose-Escalation Study. *Int J Radiat Onco Biol Phys*, 60 (5):1351-1356, 2004.

8. Palta, JR, Deye, JA, Ibbott, GS, Purdy, JA, and Urie, MM: Credentialing of institutions for IMRT in clinical trials (Correspondence). *Int. J. Radiat. Oncol. Biol. Phys*, 59(43):1257-1259, 2004.

9. Michalski J, Winter K, Purdy JA, Perez C, Ryu J, Parliament M, Valicenti R, Roach III M, Sandler H, Markoe A, Cox J. "Toxicity After Three-Dimensional Radiotherapy for Prostate Cancer with RTOG 9406 Dose Level IV". *Int J Radiat Onco Biol Phys*, 58(3): 735-742, 2004.

10. Valicenti R., Winter K, Cox J, Sandler H, Bosch W, Vijayakumar S, Michalski J, Purdy JA. "RTOG 94-06: Is the Addition of Neoadjuvant Hormonal Therapy to Dose-Escalated 3D Conformal Radiation Therapy for Prostate Cancer Associated with Treatment Toxicity." *Int J Radiat Onco Biol Phys* 57(3): 614-620, 2003.

11. Michalski J, Winter K, Purdy JA, Wilder R, Perez C, Roach III M, Parliament M, Pollack A, Markoe A, Harms Sr WB, Sandler H, Cox J. "Preliminary Evaluation of Low Grade Toxicity with Conformal Radiation Therapy for Prostate Cancer on RTOG 94-06 Dose Levels I & II." *Int J Radiat Onco Biol Phys* 56(1): 192-198, 2003.

12. Michalski J, Winter K, Purdy J, Wilder R, Perez C., Roach III M, Parliament M, Pollack A, Markoe A, Harms Sr WB, Sandler H, and Cox J: Trade-Off to Low Grade Toxicity with Conformal Radiation Therapy for Prostate Cancer on RTOG 94-06. Sem in Rad Oncol 12 (1 (Suppl 1)):75-80, 2002.

13. Ryu J, Winter K, Michalski J, Purdy J, Markoe A, Earle J, Perez C, Roach III M, Sandler H, Pollack A, and Cox J: Interim Report of toxicity from 3DCRT for prostate cancer on 3DOG/RTOG 9406, Level III (79.2 Gy). Int J Radiat Onco Biol Phys 54:1036-1046, 2002.

14. Michalski JM, Winter K, Purdy JA, Wilder R, Perez CA, Roach M, Parliament MB, Pollack A, Markoe A, Harms WB, Sandler HM, and Cox JD: Grade 2 toxicity on RTOG 9406: Robbing Peter to pay Paul?, in Biological and Physical Basis of IMRT and Tomotherapy. Edited by B.R. Paliwal, D.E. Herbert, J.F. Fowler, M.P. Mehta, Medical Physics Publishing, Madison, WI, pp. 48-54, 2002.

15. Purdy JA, Harms WB, Michalski JM, Bosch WR: Quality Assurance for 3-D CRT/IMRT Multi-Institutional Clinical Trials, in 3-D Conformal and Intensity Modulated Radiation Therapy. Edited by J.A. Purdy, W.H. Grant III, J.R. Palta, E.B. Butler, and C.A. Perez, Advanced Medical Physics Publishing, Madison, WI, pp. 553-560, 2001.

16. Michalski JM, Purdy JA, Harms WB, Bosch WR. 3-D CRT for Prostate Cancer: An Update of RTOG 94-06, in 3DCRT and IMRT. Edited by J.A. Purdy, W.H. Grant III, J.R. Palta, E.B. Butler, and C.A. Perez, Advanced Medical Physics Publishing, Madison, WI, pp. 477-482, 2001.

17. Matthews JW, Harms WB, Bosch WR, Purdy JA, Digital data exchange for multi-institutional clinical trials in 3D conformal radiotherapy and prostate brachytherapy, in The Use of Computers in Radiation Therapy (Proceedings of the XIIIth International Conference, Heidelberg, Germany), edited by W. Schlegel and T. Bortfeld, Springer Publishing, Berlin, p. 116-118, 2000.

18. Bosch WR, Harms WB, Matthews JW, Purdy JA, Database infrastructure for multi-institutional clinical trials in 3D conformal radiotherapy and prostate brachytherapy, in The Use of Computers in Radiation Therapy (Proceedings of the XIIIth International Conference, Heidelberg, Germany), edited by W. Schlegel and T. Bortfeld, Springer Publishing, Berlin, p. 483-485, 2000.

19. J. M. Michalski, J. A. Purdy, K. Winter, M. Roach, S. Vijayakumar, H. M. Sandler, A. M. Markoe, M. A. Ritter, K. J. Russell, S. Sailer, W. B. Harms, C. A. Perez, R. B. Wilder, G. E. Hanks and J. D. Cox: Preliminary Report of Toxicity Following 3D Radiation Therapy For Prostate Cancer on 3DOG/RTOG 9406. Int J Radiat Oncol Biol Phys 46 (2):391-402, 2000.

20. Harms, W.B. and Purdy, J.A.: Technical Requirements for Participating in 3-D CRT Multi-Institutional Clinical Trials, in A Practical Guide to 3-D Planning and Conformal Radiation Therapy, edited by J.A. Purdy and G. Starkschall. Advanced Medical Publishing, Inc., Madison, Wisconsin, p. 323-340, 1999.

21. Purdy, J.A., Harms, W.B., Michalski, J.M., and Bosch, W.R.: Initial Experience with Quality Assurance of Multi-Institutional 3D Radiotherapy Clinical Trials. Strahlentherapie und Onkologie 174(II):40-42, 1998.

22. Bosch, W.R., Lakanen, T.L., Kahn, M.G., Harms, W.B. and Purdy, J.A.: An Image/Clinical Database for Multi-Institutional Clinical Trials in 3D Conformal Radiation Therapy, in Proceedings of XII International Conference on the use of Computers in Radiation therapy, edited by D.D. Leavitt and G. Starkschall, Medical Physics Publishing, Madison, WI, p. 455-457, 1997.

23. Harms, W.B., Bosch, W.R. and Purdy, J.A.: An Interim Digital Data Exchange Standard for Multi-Institutional 3D Conformal Radiation Therapy Trials, in Proceedings of XII International Conference on the use of Computers in Radiation therapy, edited by D.D. Leavitt and G. Starkschall, Medical Physics Publishing, Madison, WI, p. 465-468, 1997

24. Purdy, J.A., Harms, W.B., Michalski, J. and Cox, J.D.: Multi-Institutional Clinical Trials: 3-D Conformal Radiotherapy Quality Assurance, in 3-D Conformal Radiotherapy, A New Era in the Irradiation of Cancer, edited by J.L. Meyer and J.A. Purdy, Volume 29 of Frontiers of Radiation Therapy and Oncology, S. Karger AG, Basel, p. 255-263, 1996

Abstracts

1. Eisbruch A, Harris J, Chao C, Garden A, Straube W, Schultz C, Sanguineti G, Jones C, Bosch W, and Ang KK: Phase II Multi-Institutional Study of IMRT for Oropharyngeal Cancer (RTOG 00-22): Early Results (abstract). *Int. J. Radiat. Oncol. Biol. Phys.*, 66(3), Supplement, Page S46.

2. Khullar D, Molineu A, Followill D, Bosch W, Willcut V, Simpson T, Ju T, Deasy J: An Open-Source Software Tool to Support Film-Based IMRT Quality Assurance. (Abstract) Med. Phys., 34(6), 2418, 2007.

3. Sharma A, Saltz J, *Pan T, Bosch W, Deasy J, Purdy* J: Application of caGrid® Middleware to Facilitate Quality Assurance for Advanced Technology Radiation Therapy Clinical Trials (Abstract) In: Radiological Society of North America scientific assembly and annual meeting program. Oak Brook, Ill: Radiological Society of North America, 2007.

4. Molineu A, Alvarez P, Hernandez N, Followill DS, Ibbott GS: Report of Quality Assurance Measurements that were Performed Prior to Irradiations of a Head and Neck IMRT Anthropomorphic Phantom (abstract). *Int. J. Radiat. Oncol. Biol. Phys.*, 66(3), Supplement, Page S128.

5. Purdy JA, Bosch WR, Straube WL, Matthews JW, Haynes RJ, Michalski JM, Martin EA, Winter K, Curran Jr. WJ, and Cox JD: A Review of the Activities of the ITC in Support of RTOG Advanced Technology

Clinical Trials (abstract). *Int. J. Radiat. Oncol. Biol. Phys.*, 66(3), Supplement, Page S134.

6. Alvarez P, Molineu A, Hernandez N, Followill DS, and Ibbott GS: Analysis of Multiple Irradiations of an Anthropomorphic Thorax Phantom containing Lung Heterogeneities (abstract). *Int. J. Radiat. Oncol. Biol. Phys.*, 66(3), Supplement, Page S685.
7. Bosch W, Matthews J, Ulin K, Urie M, Yorty J, Straube W, FitzGerald TJ, Purdy J: Implementation of ATC Method 1 for Clinical Trials Data Review at the Quality Assurance Review Center (Abstract). Med. Phys. 33(6): 2109, 2006.
8. Matthews J, Bosch W, Straube W, Purdy J: ITC Assists Developers of ATC Compliant DICOM Export for Clinical Trials (Abstract). Med. Phys. 33(6): 2117, 2006.
9. Bosch W, O'Leary S, Matthews J, Frouhar V, Palta J, Field C, Pho L, Purdy J: Testing of ATC Method 2 for Supporting QA of Cooperative Group Advanced Technology Clinical Trials Requiring Digital Data Submission (Abstract). Med. Phys. 33(6): 2139, 2006.
10. Purdy J, Lehmann J, Wessol D, Cogliati J, Milvich M, Frederickson C, Nigg D, Wemple C: Implementation of MINERVA/PEREGRINE as an ATC review tool (Abstract). Med. Phys. 33(6): 2272, 2006.
11. Perks J, Price RA, Goetsch S, Chen A, Purdy J: Feasibility Study into Glass Rod Detectors as a "Postal Dosimeter" (Abstract). Med. Phys. 33(6): 2104, 2006.
12. Straube W, Bosch W, Matthews J, Haynes R, Purdy J: Digital Data Integrity QA for Multi-Institutional Clinical Trials (Abstract). Med. Phys. 33(6): 2087, 2006.
13. Fox W, Berkey B, Michalski J, Purdy J, Simpson J, Kresl J, Curran J, Diaz A, Mehta M, and Movsas B: Health-Related Quality of Life and Cognitive Status in Patients with Glioblastoma Multiforme Receiving Escalating Doses of Conformal Three-Dimensional Radiation on RTOG 9803 (Abstract). *Int. J. Radiat. Oncol. Biol. Phys.*, 63, Supplement 1, Page S78, 2005.
14. Straube W, Matthews J, Bosch W, and Purdy JA:DVH Analysis: Consequences for Quality Assurance of Multi-Institutional Clinical Trials (Abstract). Med. Phys.32(6): 2021, 2005.
15. Hope AJ, El Naqa I, Bradley J, Vicic M, Lindsay PE, Bosch WR, Purdy JA, Deasy J: Radiation Pneumonitis/Fibrosis Risk Based on Dosimetric, Clinical, and Location-Related Parameters (Abstract). *Int. J. Radiat. Oncol. Biol. Phys.*, 60(1): S204, 2004.
16. Michalski JM, Winter K, Roach M, Markoe AM, Sandler HM, Ryu J, Parliament M, Purdy JA, Valicenti RK, and Cox JD: Clinical Outcome of Patients Treated with 3D Conformal Radiation Therapy for Prostate Cancer on RTOG 9406 (Abstract). *Int. J. Radiat. Oncol. Biol. Phys.*, 60(1): S169, 2004.
17. Werner-Wasik M, Seiferheld W, Michalski JM, Gilbert M, Purdy JA, Simpson J, Kresl J, Curran WJ, Diaz A, Mehta M: Phase I/II Conformal Three-Dimensional Radiation Therapy Dose Escalation Study in Patients with Supratentorial Glioblastoma Multiforme: Report of the RTOG 98-03 Protocol (Abstract).. *Int. J. Radiat. Oncol. Biol. Phys.*, 60(1): S163, 2004.

CHECKLIST

1. PROGRAM INCOME ***(See instructions.)***

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***

In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. FACILITIES AND ADMINSTRATIVE (F&A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will ***not*** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☒ DHHS Agreement dated: 06/30/04 ☐ No Facilities and Administrative Costs Requested.

☐ No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base $ 100,176 x Rate applied 52.00 % = F&A costs $ 52,092

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

☐ Salary and wages base ☒ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.):*

2008-2009 budget year

Program Director/Principal Investigator (Last, First, Middle): Vaughan, Andrew

SENIOR/KEY PERSONNEL REPORT

Place this form at the end of the signed original copy of the application. Do not duplicate.

GRANT NUMBER
CA081647

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PD/PI, Res. Assoc.)	Months Devoted to Project		
				Cal	Acad	Summer
Vaughan, Andrew	Ph.D.	9105	PI	.12		
Purdy, James	Ph.D.	8377	Med. Physicist	4.8		

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	2	U24	CA81647-10

Total Project Period
From: 7/22/1999 Through: 6/30/2012

Requested Budget Period
From: 7/1/2008 Through: 6/30/2009

1. TITLE OF PROJECT
Advanced Technology Radiation Therapy Clinical Trials Support (ATC)

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)

Thomas J FitzGerald, MD
University of Massachusetts Medical School
272 W. Exchange Street, Suite 101
Providence, Rhode Island 02903

2b. E-MAIL ADDRESS
TJFitzGerald@QARC.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Radiation Oncology

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 401-454-4301 Fax: 401-454-4683

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)

University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655

3b. Tel: 508-856-2119 Fax: 508-856-5004

3c. DUNS: 603847393

4. ENTITY IDENTIFICATION NUMBER
1D4600228444

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		02/20/2008

6b. Federal Wide Assurance No. 00004009

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Patricia M McNulty, Research Funding Director
UMMS, 55 Lake Avenue North, Worcester, MA 01655

Tel: 508-856-2119 Fax: 508-856-5004

E-MAIL:
Patricia.McNulty@umassmed.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: UMass Medical School - QARC (off-site)
DUNS: 603847393
Street 1: 272 West Exchange Street, Suite 101
Street 2:
City: Providence County: Providence
State: Rhode Island Province:
Country: United States Zip/Postal Code: 02903
Congressional Districts: 02

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 99,206 8b. TOTAL $ 125,000

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Patricia M. McNulty Director, Research Funding

TEL: 508-856-2119 FAX: 508-856-5004 E-MAIL: research.funding@umassmed.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* DATE 4/15/2008

total costs unchanged from CRL

Consortium - QARC - Univ of Mass
Program Director/Principal Investigator (Last, First, Middle): Purdy, James Aaron

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY	FROM 7/1/2008	THROUGH 6/30/2009	GRANT NUMBER CA81647-10

PERSONNEL (Applicant organization only)		Months Devoted to Project			DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Thomas J FitzGerald	PD/PI	.60	✓		0	0	
Marcia M Urie, PhD	Chief Physicist	1.46	✓		18,921	7,672	26,593
Richard Hanusik	IS Director	4.40			39,098	15,854	54,952
	reduced from 12.43 cm other effort to 4.4 cm						
SUBTOTALS →					58,019	23,526	81,545

CONSULTANT COSTS		
EQUIPMENT *(Itemize)*		
SUPPLIES *(Itemize by category)*		
TRAVEL		
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*		
OTHER EXPENSES *(Itemize by category)*		
Kenneth Ulin, PhD		17,661
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD		$ 99,206
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
	FACILITIES AND ADMINISTRATIVE COSTS	25,794
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD *(Item 8a, Face Page)*		$ 125,000

Program Director/Principal Investigator (Last, First, Middle): Purdy, James Aaron

BUDGET JUSTIFICATION	GRANT NUMBER
	CA81647-10

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

The budget for QARC is structured to provide physics and IS salary support for continued participation in ATC. Dr. Marcia Urie has made significant contributions to the ATC regarding the use of protons in Cooperative Group Clinical Trials. She will continue this effort in year 10. In addition she has been charged with the co-leadership of the credentialing committee to assure common tools and evaluation criteria among all the Groups for advanced technologies. She will work to develop a strategy and tools to evaluate IGRT, ART, and multimodality imaging protocols. 12% FTE of Dr. Urie's time is requested.

Over the past year, Dr. Kenneth Ulin has made major contributions to the ATC in the customization of CERR. He will continue this effort. In addition, he will contribute to the credentialing strategies for IGRT and other advanced technologies. He is integral to the ATC solutions for a common database and remote review tools. 10% of Dr. Ulin's time is requested. Over the next year development of a common informatics infrastructure is a high priority for the ATC. The use of the QARC database MAX developed by, Mr. Richard Hanusik, is identified as an important component of this development. Mr.Hanusik will work with the ATC toward this goal. 37% FTE Mr. Hanusik is requested.

CURRENT BUDGET PERIOD	FROM	THROUGH
	7/1/2007	6/30/2008

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

None

Program Director/Principal Investigator (Last, First, Middle): Purdy, James Aaron

PROGRESS REPORT SUMMARY	GRANT NUMBER CA81647-09	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR	FROM	THROUGH
Thomas J FitzGerald, MD	07/01/2007	06/30/2008

APPLICANT ORGANIZATION

University of Massachusetts Medical School

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)

Advanced Technology Radiation Therapy Clinical Trials Support (ATC)

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. *Vertebrate Animals (Complete Item 7 on the Face Page)*		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Quality Assurance Review Center (QARC) is privileged to be involved with the Advanced Technology Consortium (ATC). During the past year we have been able to expand our interactions with the ATC and have been directly involved with process improvements including software development important to the mission of ATC. This has permitted expansion the effort in integrating ATC processes into digital data acquisition and clinical data management for the cooperative group trial mechanism.

QARC has become the key user of the computational environment for radiation research (CERR) software platform and has fully integrated CERR into the daily workflow at QARC. During the past year Dr. Ulin at QARC has made modifications to the code in many important areas including digital display of protocol objects. Two major improvements have been the integration of CERR into the MAX database at QARC and the ability to display CERR from remote access via server side display of objects through a web browser. These improvements will facilitate the potential integration of CERR into ATC member sites via the intended migration of the QARC database into member sites. QARC now houses more than 300 radiation therapy protocol cases from more than 100 institutions submitted to QARC via digital data transfer. The majority of digital radiation therapy cases are submitted through the CERR mechanism. QARC has received more than 150 benchmark cases for both cooperative group and industry clinical trials in a digital format including many international clinical trial sites. This has been made possible due to the environment of information sharing and software integration espoused by the mission of the consortium with the full support of Dr. Purdy.

During the past year QARC has assumed responsibility for facilitating ATC interactions with the National Cancer Institute of Canada (NCI-C). Presentations of ATC infrastructure were given at the semi-annual meeting of NCI-C in October of 2007. We were invited back to NCI-C headquarters in Kingston, Ontario in December of 2007 and demonstration of both imaging and radiation therapy treatment objects were reviewed via Webex to the committee including Dr. Parliament. Discussions were carried out concerning ATC participation in both on-going Canadian clinical trials as well as industry collaboration. We have been asked to return to the next meeting in Toronto (May 2008) to continue dialogue concerning opportunities for collaboration. We expect the dialogue to include a discussion concerning further NCI-C participation

in NCI directed clinical trials. A similar dialogue has been initiated with the EORTC with a possible meeting planned at the NCI with EORTC officials in April 2008.

During the past year there has been considerable progress in the development of credentialing mechanism for proton therapy. All members of ATC have contributed to this effort. A position paper on the use of protons in cooperative group clinical trials with Drs. Urie and Gillin of ATC as authors has been published with the support of Dr. Deye. At the request of the ATC, QARC and the RPC developed a strategy for credentialing institutions with both phantom and test case methods. The credentialing process includes a questionnaire developed and vetted by ATC. The process for credentialing is now in place and will be an important asset for both pediatric and adult cooperative group clinical trials.

QARC continues to work with ATC members and caBIG to further promote open source strategies for data and software integration for digital image and radiation therapy object review. It is anticipated that the integrated project which will grid enable the MAX database will move forward in the near future with funding from caBIG. Once complete, this product will be distributed to ATC members as a vehicle to support distributed review of both imaging and radiation therapy treatment objects. This will serve as a mechanism to familiarize members to the MAX database; and, in turn, facilitate MAX integration into the daily workflow for ATC members when migration of the database to member sites is complete. ATC member sites with validation processes directed by Dr. Bosch will formally vet the strategy for migration of the MAX database this year. If successful a strategy will be developed by consortia members for enterprise function.

QARC continues to integrate institution-credentialing functions with ATC members. IMRT credentialing with the RPC continues to be an integrated process. QARC and RPC collaborate on the new three-dimensional credentialing mechanism with more than 70% of submission submitted in a digital format for review.

QARC is involved with ACRIN in the virtual imaging expanded workspace (VIEW). QARC will bring process improvements in digital imaging acquisition developed through VIEW and integrate them into ATC function. The objective will be to make these processes as well as processes developed for 21 CFR Part 11 compliance available to consortia members.

QARC is very appreciative of the outstanding leadership of Dr. Purdy and the continued outstanding effort of Dr. Deye. QARC is privileged to be involved with such exceptional investigators and we look forward to continued effort to make digital data acquisition strategies transparent to the cooperative group clinical trials mechanism.

Program Director/Principal Investigator (Last, first, middle): Purdy, James Aaron

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CHECKLIST

1. PROGRAM INCOME ***(See instructions.)***
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instuctions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. FACILITIES AND ADMINSTRATIVE (F&A) COSTS
Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will ***not*** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☒ DHHS Agreement dated: February 25, 2004 ☐ No Facilities and Administrative Costs Requested.

☐ No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base $ 99,206 x Rate applied 26.00% % = F&A costs $ 25,794

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

☐ Salary and wages base ☐ Modified total direct cost base ☐ Other base *(Explain)*

☒ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.)*:

Off-site campus rate

Program Director/Principal Investigator (Last, First, Middle): Purdy, James Aaron

SENIOR/KEY PERSONNEL REPORT

Place this form at the end of the signed original copy of the application. Do not duplicate.

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All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PD/PI, Res. Assoc.)	Months Devoted to Project		
				Cal	Acad	Summer
Thomas J FitzGerald	MD	1808	PI	.6		
Marcia M Urie	PhD	2667	Chief Physicist	1.44		
Kenneth Ulin	PhD	9408	Senior Physicist	.96		