

Post-Meeting Edition

Report from the Chair *by Roseann Bonanni*



Several updates were given at the June RTOG Research Associates Meeting. The first order of business was a thank you note from Dr. Curran on behalf of the RTOG Foundation for the \$150 contribution from the RAs that was collected during the January RTOG meeting. Thank you to everyone who contributed.

Kristine Symes resigned as secretary of the RA Committee as of the June, 2004 meeting. I want to thank Kris for all her help during her term as secretary. Sharon Bryne from Albert Einstein Medical Center responded to my call for a volunteer to fill the position. Thank you Sharon and welcome to the committee.

Once again our thanks to the Education Committee for the developing the outstanding program for the meeting.

I'm sure by now you realized Headquarters has relocated to 1818 Market St., seven blocks from their original location. I have toured the new facility and the offices are very nice – you can walk around without tripping over files!

At the RA Committee meeting Elaine Motyka-Welch gave the Headquarters update:

- All studies activated from now on will have mandatory Web registration. Web registration for pre-existing studies will be mandatory by January, 2005.
- Adeers has a new version which allows adverse event reporting for commercial drugs, radiation therapy and surgery on newly activated studies. RTOG will adopt this as its only AE reporting system.
- The RTOG Quality Control Committee reported that auditors are finding deficiencies with the inventory records of institutional pharmacies. The committee is looking to develop a pharmacy committee

Our next meeting is in Phoenix, Arizona in January 2005 and we are planning another great set of RA session. If any of you have any questions or suggestions regarding the RA Committee, please e-mail me at roseann.bonanni@mail.tju.edu or if you do not have e-mail, FAX me your comments at 215-955-5331.



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Research Strategy Committee *by Lisa Chen, MPH, JD*

A number of protocols were reviewed at the RA Research Strategy Committee meeting

- Liz Elliot gave a brief update on RTOG 9913 (Biafine for Head & Neck RT).
- Dr. Babu Zachariah gave a short presentation on RTOG 0315 (Sandostatin versus Placebo for Chemoradiation Induced Diarrhea for Patients with Anal or Rectal Cancer) and encouraged the RAs to enroll patients onto the study.
- Dr. Lawrence Berk, Chair of the Integrative Oncology Committee and Chair of CCOP Membership Committee gave a presentation on how RAs can be involved with developing protocols for RTOG through these two committees.
- Susan Provins gave a brief update on her protocol concept for the use of ginger to treat RT induced nausea and vomiting.



Linda Chen
212-305-7001
ljc8@columbia.edu

Disease Discipline Committee *by Joanne Ciconte, BS, CTR, CCRP*

The priority for this meeting was the ongoing development of the Acuity Scoring Tool. An enthusiastic and diverse group of RAs reviewed and tested a draft of the scoring tool. The comments and suggestions collected at the meeting will be reviewed and incorporated into the tool for presentation at the next meeting.

Larry Korman, RA Disease Discipline Committee Co-Chair, gave a brief overview of the role of CRAs in providing coverage for the disease site committees. Larry encouraged everyone to report all newsworthy, instructional, and interesting highlights from the semi-annual meeting to him for publication in the RA Reporter.

If you would like to learn more about the functions of this committee please contact Larry Korman or me.



Joanne Ciconte
215-955-8619
joanne.ciconte@
mail.tju.edu

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Editors

Larry Korman, RN, BSN, OCN
Jane Gardner, RN, BPE, MSc, CCRP

Article Submission

Larry Korman, Rn, BSN, OCN
Sidney Kimmel Comprehensive Cancer Center at
Johns Hopkins
Weinberg Building
Radiation Oncology, Suite 1447
401 N. Broadway Street
Baltimore, M.D 21231
410.614.3158 FAX: 410.502.1419
kormala@jhmi.edu



Extra! Extra! Extra!

We are looking for individuals to write articles for the RA Reporter. If you want to share the knowledge, apply within. Please notify either Jane Gardner, 403-944-8391, janegard@cancerboard.ab.ca or Larry Korman, 410.614.3158, kormala@jhmi.edu.

Education Committee *by Susan Provins, CCRA & Sharon Prokop, RN, BSN, OCN*

At the RTOG summer meeting, approximately one hundred RAs and nurses attended the RA educational sessions. The panel presentation, "Adverse Events: Evaluation and Reporting" was thoroughly covered by two outstanding speakers: Ann Setser, RN, BSN, M.Ed, Patient Safety/Adverse Event Monitor/Manager for the Cancer Therapy Evaluation Program, NCI; and Markus Renschler, MD, V.P. Oncology Clinical Development, Pharmacyclics, Inc. Ms. Setser detailed CTCAE v3.0 changes as well as AdeERS notification for adverse event reports for cooperative group studies. Dr. Renschler presented key information from the perspective of pharmaceutical trials. Each showed examples from practice on what is to be included in initial and follow up reports. Those who attended, rated the session overall as 3.64 on a scale of 1 (lowest) to 4 (highest).

The afternoon scientific session, "Current Modality Update of Breast Cancer" was equally informative and engaging in its scope and importance to RTOG research objectives. The past, present, and future trends for breast cancer treatment research and outcomes were presented. Lynn Dworzanin, MS, RN, CS, from LD Oncology Consulting, PC, in Ann Arbor, Michigan, spoke about incidence, screening, detection, diagnosis, and staging, as well as treatment options, for the different stages of breast cancer including chemotherapy and biotherapy. Julia White, MD, Associate Professor Department of Radiation Oncology at the Medical College of Wisconsin, addressed treatment options, specifically surgical and radiation-based options, with emphasis on partial breast irradiation and the upcoming NSABP/RTOG Intergroup trial comparing various types of partial breast radiation delivery methods. This session's composite rating was 3.92 overall, making it one of the all-time highest rated sessions.

The Education Committee is working hard to provide two more stimulating sessions for the upcoming meeting in Phoenix. The panel presentation will focus on Physics 101 for the research associate and neuro-oncology will be the subject for the afternoon RA scientific session.

Application will be made to the Oncology Nursing Society (ONS) for contact hours. The Society of Clinical Research Associates (SoCRA) already designates the RA Educational Committee's activities as meeting the criteria for continuing education units. Please send questions, suggestions or recommendations for educational topics or speakers to Sharon Prokop or Susan Provins.



Susan Provins
514-934-8040
sprovins@hotmail.com



Sharon Prokop
prokops@karmanos.org

Poster Contest *by Deborah Olsen*

The RTOG research associate poster contest is an annual event that takes place at the summer meetings. The intent of the contest is to add interest and diversity to the meetings. The most recent meeting, in Washington, D.C., did not have any posters on display but we are hoping that there will be entries for the June meeting, in 2005, in Philadelphia, PA. In the past, we have been fortunate to have several corporate sponsors that have made it possible for us to award the first place poster winner with educational grant money that can be used for travel to a conference of the winner's choosing. Posters can be educational or research based. Please contact Deborah Olsen for more information.



Deborah Olsen
305-243-4243,
dolsen@med.miami.edu

Outcomes Committee *by Darlene Johnson, MBA, CCRP, FAAMA*



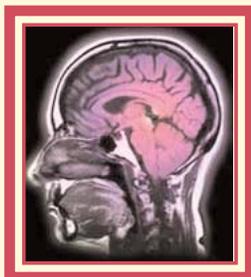
The RTOG Outcomes Committee, chaired by Deborah Bruner, Ph.D., consists of the Special Populations, Economic Impact, and Quality of Life Subcommittees. Since the last meeting RTOG 0247 was activated. This study, Randomized Phase II Neoadjuvant Combined Modality Therapy for Locally Advanced Rectal Cancer, includes quality of life measures. The EORTC QLQ – C30 & CR38 are included along with the SAQ. The committee would like comments from the CRA's as to the ease of use of the tools.

Several proposed and developing concepts were discussed followed by reports from the QOL, Economic Impact and Special Population chairs. Dr. Bruner is working with others to explore the idea of bringing in nursing studies to the RTOG focusing on symptom management clusters. More information will follow.

A discussion was held about how to disseminate the information obtained by the Outcomes Committee to the public and a suggestion was made that it be available in the Research Advocacy Newsletter. It was suggested that the Research Advocacy website be placed on RTOG consent forms so that patients could access the studies to learn results. This will be discussed further and information will be forthcoming.

The Outcomes Committee has been busy submitting publications. If you are interested in learning more about RTOG Outcomes - the model developed by the Outcomes Committee can be found in the publication Quality of Life Research, Vol. 13, pages 1025-1041, 2004.

Brain Tumor Committee *by Gayle Mallon, CCRP*

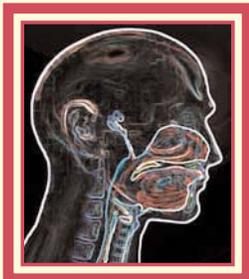


Members of the RTOG Brain Committee reviewed the committee's active and developing protocols. RTOG 9813 is a study that compares Temozolomide given with radiation versus BCNU given with radiation for anaplastic astrocytoma, to improve survival in this patient population. Accrual has been approximately 6 patients per month. The study has additional per case support from Schering-Plough that is awarded after confirmation of patient eligibility. Please note that this study requires central pathology review prior to randomization.

RTOG 0227 is a trial of multi-agent chemotherapy followed by radiation and maintenance chemotherapy for patients with primary CNS lymphoma. Six of the required 64 patients had been accrued as of the June meeting. This study is temporarily closed for review of toxicities.

Unfortunately, these were the only brain trials open at the time of the meeting. In the last six months four brain studies have been closed to accrual. Within the next couple of months two GBM and a brain metastases study will open.

Head & Neck Cancer Committee *by Joanne Mancini, RN*



The Head & Neck Committee, chaired by Kian Ang, M.D., reviewed the status of the committee's active and developing protocols.

At the time of the meeting RTOG H0022 had accrued 48/72 patients. In reviewing the patient specific forms for this study, it is noted that the palpable nodes must be adequately drawn to assure adequate RT dose is being delivered.

NCI has approved an amendment to RTOG 0129 to increase the sample size from 480 to 720 patients. With this additional accrual, the study is estimated to close approximately one year from now. A replacement trial is being discussed using C225 and Bevacizumab.

RTOG H0225 has accrued 18/64 patients. Eighteen centers have been credentialed. Enrollment is encouraged and study completion is estimated for May 2007.

RTOG 0244 is open and 9 institutions have IRB approval. Six patients have been accrued. An amendment to allow post-op chemotherapy has been approved.

RTOG H0234 has had no enrollment thus far. The complexity of this protocol is high. The C225 is being supplied for participating patients and additional funding is being sought to help support the trial.

There was much discussion regarding new and developing studies. Discussion of developing studies included using re-irradiation plus chemo for recurrent cancer, prevention of second primary occurrence using Celebrex, a mucositis trial using Palifermin IV vs. placebo, and an intra-arterial chemo plus RT study for unresectable head & neck cancer requiring interventional radiology support.

The salivary gland transfer protocol will be activated sometime in July. Institutions are encouraged to submit this study to their IRB's when activated.

A chemoprevention trial using Celebrex to prevent second primary tumors will be submitted to the NCI for approval within a few days. Also, a cancer control study for the prevention of xerostomia, with a treatment plan similar to RTOG 9709, was presented using RT plus Amifostine and Pilocarpine.

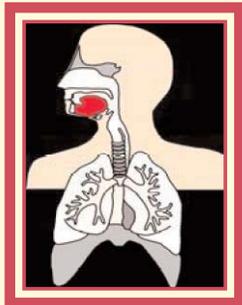
Genitourinary Cancer Committee *by Joanne Ciconte, BS, CTR, CCRP*



The symposium for the RTOG Winter 2005 meeting will be organized by the GU Committee and entitled, Biochemical Endpoints after Radiotherapy for Prostate Cancer.

The active protocols were reviewed by the committee and included:

- RTOG 9902 - watch for amendments on eligibility to increase PSA level to 150 as means of increasing accrual.
- RTOG 0126 - The amendment to allow IMRT has been completed.
- RTOG 0232 - Remember that there is separate credentialing for Palladium-103 versus Iodine-125 seeds. All data must be digitally submitted.



Progress reports on current studies for resectable and unresectable NSCLC and SCLC were given. Some studies may have their accrual goals downsized (e.g., Neovastat); others have been revised in an effort to increase accrual. One such revised study is 0213, which now gives clinicians an additional dose/fraction option. When submitting this revision to your IRB, stating that the additional option represents a biologically equivalent dose to the original prescription may allay IRB fears that the new option adds to the degree of risk to potential participants.

The “Ping-Pong” trial (RTOG 0017) is inching towards completion with 30 of the planned 42 patients enrolled. One DLT was seen at the 450 mg dose of gemcitabine. The current dose is 600 mg of gemcitabine.

The 3D study (RTOG 0117) will soon be reopened after assessment for toxicity. Accrual after reopening will be to Level 2 (74 GY).

Attendees were told about the efficacy of C225 in head & neck cancer (Study proven doubling of median survival and statistically significant improvement in overall survival at 2 & 3 years.) These stats were touted as an incentive to enroll patients in a fairly new trial, 0324, which utilizes RT and C225.

An interesting report was given on RTOG 0236, stereotactic RT for medically inoperable early stage lung tumors. It was reported that the results after stereotactic RT are as good as those for surgery for Stage I tumors. This may pique the oncologists’ interest in pursuing this option for inoperable patients. The Phase I trial found the MTD to be 24 Gy in 3 fractions, therefore, the dose in this Phase II study is 20 Gy in 3 fractions.

An update on the two prophylactic cranial irradiation (PCI) trials (RTOG 0212 & 0214) was given. The importance of talking to the patient about PCI when (s)he is first seen for lung treatment was stressed. In RTOG 0214 where the randomization is PCI vs. observation, the advantage of observation according to study requirements can be presented as attractive from the viewpoint of close, vigilant monitoring with quick treatment when/if needed. Regarding RTOG 0212, we were reminded that patients may be entered on study if no overt evidence of lung disease is seen on a CXR. Dr. Choy, Lung Committee Chair, stated that these two trials are the only PCI trials ongoing in North America and it is important to complete them.

As has been the custom, a portion of the Lung Committee Meeting was directed to an educational session; this meeting the topic was “4D” conformal radiation therapy. Representatives from GE, Varian and Phillips spoke on technological improvements in RT. We have 3D treatment—but 3D does not deal with the problem of tumor motion during normal respiration. Tumor motion may vary from 5 mm to > 1 cm and from treatment to treatment.

The representatives presented their company’s strategy for handling the problem of tumor motion. Some of the techniques discussed were: fused 4D PET/CT plans; respiratory “gating” techniques using image processing tools and breathing techniques; use of a marker block on the patient’s chest with the treatment machine going off and on automatically; “tracking” technique using fluoroscopy instead of a marker block; and, patient education using biofeedback after placement of a beacon transponder to help localize the tumor.

continued on next page

The advanced technology described in this session is exciting, yet bewildering in its complexity (at least to this writer). The hope is that new technology can help to defeat the local failure problem in lung cancer. Dr. Choy stated that the survival for Stage III lung cancer has doubled since the 1980's to 17.7 months. In part, this is due to improvements that have been made in the delivery of RT.

RA Panel Presentations *Adverse Events: Evaluation & Reporting*

Radiation Intervention Pathway Added to AdEERS

by Ann Setser, BSN, Med

The June 1, 2004 release of the Cancer Therapy Evaluation Program (CTEP), NCI's Adverse Event Expedited Reporting System (AdEERS) includes modifications to accept expedited reports for modalities other than agents. The significant changes include a pathway for radiation, surgery, devices, commercial agents, non-CTEP INDs and any combination of these modalities.

Primary objectives of the Radiation Intervention Pathway are to minimize variations in the methods and completeness of reporting serious adverse events occurring on radiation oncology clinical trials, to expand radiation terminology standards, and to improve the quality of safety data.

RTOG was involved in the customization of radiation-specific terms, definitions, and nomenclature that appear in the lists of values (LOV) for 'Types of Radiation', 'Administration Route', 'Schedule', 'Unit of Measure', and 'Adjustment'. Other significant changes in the Radiation Pathway include the deletion of data fields appropriate for agents, and the addition of attribution assignment (for each adverse event) to radiation intervention.

The original AdEERS was released in 1998 and has evolved because of feedback CTEP received from Clinical Research Associates and nurses who actually use the system. Radiation Associates are encouraged to submit to CTEP comments and recommendations for changes to the Radiation Intervention Pathway so that the needs of the radiation oncology community relative to serious adverse event reporting are met. All comments/queries submitted via e-mail are maintained in a Change Management System and are addressed by the CTEP AdEERS team monthly. ADEERSMD@tech-res.com .

Ann Setser, BSN, Med
Nurse Consultant
Office of the Associate Director
Cancer Therapy Evaluation
Program
National Cancer Institute
6130 Executive Blvd. Suite 6116
Bethesda, MD 20892
301.435.9197
setsera@ctep.nci.nih.gov

Serious Adverse Event Reporting in Industry Trials

by Markus Renschler, M.D., *Pharmacyclis, Inc.*

To protect the safety of the public and to assure that the prescription drugs that get approved for marketing are safe and effective, the conduct of clinical trials with investigational agents is tightly regulated by a number of laws. The Food and Drug Administration (FDA) in the US and Health Canada have adopted the International Conference on Harmonization (ICH) Guidelines "Good Clinical Practice" and "Safety Data Management" into law. By signing the FDA Form 1572, each investigator enters an agreement with the government to comply with these regulations and to strictly adhere to the study protocol. The investigator also agrees to report adverse experiences that occur in the course of the investigation in accordance with federal regulations.

Adverse events (AEs) are defined as an "untoward medical occurrence". This could be an unfavorable sign, abnormal laboratory findings, a symptom or another disease. Importantly, the definition of adverse event does not imply a causal relationship. Thus unrelated medical events are adverse events. In cancer trials, often seen complications, such as infections, cancer progression, or pulmonary emboli would be considered adverse events. A fracture from a car accident would be considered an AE.

Serious adverse events (SAE) are defined as an adverse drug experience that results in one of the following outcomes:

- Death
- Life-threatening adverse drug experience
- Inpatient hospitalization
- Prolongation of hospitalization
- Persistent or significant disability/incapacity
- Congenital abnormality/birth defect
- Important medical events that don't meet above criteria, but when, based upon appropriate medical judgment, they may
 - o Jeopardize patient
 - o Require medical or surgical interventions to prevent one of the outcomes listed above.

The definition is a regulatory definition, based on the outcome, and not on the severity of the event. An inpatient hospitalization for social reasons is still a serious adverse event.

When you become aware of an SAE, you need to contact the pharmaceutical company that sponsors the trial (the "Sponsor") within 24 hours. Minimum criteria for reporting are met when you have the following information:

- An identifiable patient
- A suspected medicinal product
- Identifiable reporting source
- Event or outcome that is serious

Many protocols will require you to report SAEs for control arm patients as well, even if they are not exposed to an investigational drug. Check with the sponsor on their requirements for reporting the event (typically as SAE-form, plus supporting documents, like a admission history and physical examination). You may also have to report the SAE to your local ethics committee.

The sponsor then has the responsibility to report the SAE to regulatory agencies worldwide within 7 calendar days if the event was a death or life-threatening, otherwise within 15 days.

You can find more information at:

<http://www.fda.gov/oc/gcp/default.htm>
<http://www.fda.gov/cder/guidance/iche2a.pdf>
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4>

Upcoming Meetings of Interest

*ONS 5th Annual Institutes of Learning
November 5-7, 2004 Nashville, TN*

*RTOG Meeting
January 20 - 23, 2005
Sheraton Wild Horse Resort Phoenix, AZ*



OCTOBER 2003 STITCHES

Atlantic Health Sciences Corporation

Oncology Clinical Trials Group Saint John Regional Hospital New Brunswick, Canada



Saint John is the oldest incorporated city in Canada, founded by the United Empire Loyalists in 1783. It is situated in the picturesque Bay of Fundy in Southern New Brunswick, bordering on Maine, USA and located at the mouth of the Saint John River.

The Bay of Fundy has the highest tides in the world. A local phenomenon is the Reversing Falls where strong tidal fluctuations of 30 feet, reverse the river's flow for several miles upstream twice daily.

During the summer months Saint John is a port destination for many cruise ships and throughout the year we are home to many international shipping companies as our harbor is ice free.

The Atlantic Health Sciences Corporation (AHSC) is New Brunswick's largest multi-facility, accredited Regional Health Authority. Comprised of 12 hospitals and health centres extending across 200km, AHSC serves a catchment population of 200,000 in the southwestern part of the province. Our centre is located at the Saint John Regional Hospital facility, a 650 bed provincial, tertiary care teaching centre that includes oncology, cardiology and neurosurgery. We are affiliated with Dalhousie University Medical School and participate in the Oncology Residency and the Family Medical Residency Programs.

Our centre employs five radiation oncologists, two medical oncologists, and one hematologist; they all work closely with the clinical trials department staff. The clinical trials team is comprised of one full-time RN clinical research coordinator, three part time RN clinical research coordinators and an administrative assistant.

Our centre currently participates in approximately 64 studies in affiliation with RTOG, NCIC CTG, NSABP and CTSU to name a few. During the year 2003, there were approximately 190,970 inpatient and outpatient radiation treatments and 9,067 inpatient and outpatient chemotherapy treatments at our centre. Our oncology department sees approximately 1,100 new patients each year.

Within our department we have a 21 bed inpatient oncology unit, a ten bed outpatient chemotherapy treatment area, an outpatient radiation treatment facility and an outpatient day clinic.

We have had the pleasure of working with RTOG since 1992 and look forward to a continued collaboration for years to come.

Foundation for Cancer Research & Education

Welcome to Phoenix - The Valley of the Sun!

- Home of The Foundation for Cancer Research and Education
- Site of the Next RTOG Meeting.

The Foundation is the non-profit research entity for Arizona Oncology Services (AOS). Unique to RTOG, we are one of only two private practice Full Member institutions. The Foundation consists of 13 centers (four hospital based, a central office and eight ACR certified free-standing clinics), 20 radiation oncologists, five NP/PA staff, four study coordinators and two other study staff members. The two farthest centers are 61 miles apart. The Foundation's motto is "have office will travel" as staff travels among the centers to visit with the patients for their convenience. Coordinating with other specialty offices, in addition to our practice, becomes an art form much like juggling!

The Foundation became an RTOG Affiliate Member on December 30, 1998, enrolled its first patient in January 1999 and was granted Full Membership by the end of that year having entered 88 patients. Since then we have consistently been in the top 10 institutions for accrual, averaging over 60 patients per year.



Foundation staff from left: Norissa Honea, Gigi Swenson, Terry Thomas, Rayme Beaudry and Kate Quintero. Not Pictured Margie Snyder.

Recently, we added our first affiliate institution where we provide data support.

Proud of our site and what we have to offer our patients, we fill a vital niche for radiation clinical trials for this region. The Foundation and AOS treat over 4000 patients per year and was the first facility in Arizona to offer IMRT and prostate and breast brachytherapy treatments. We are the first and only group to offer patients state-of-the-art radiosurgery with Novalis, Cyberknife and Gamma knife. We reach out to the community through our sponsorship of educational events, celebrations, and support groups.

In January you will be traveling to our fine state. We promise it will not be 112 degrees out as it is today. People flock to our state in droves for the winter months due to our beautiful weather, scenery and desert sunsets. You can play golf in the valley and then travel a few hours and hit the ski slopes. The meeting will be taking place at the Wild Horse Pass Sheraton. The Hotel has entertainment, gambling (yes gambling) and several restaurants (PF Changs) and shopping facilities (Nordstrom) nearby. We look forward to seeing you there!



Foundation physicians from front row left: Drs. Burton Speiser, Irene Taw, Luci Chen, David Beyer, John Kresl, Coral Quiet, Emily Grade, Gregory Maggass, Diane Recine, Timothy Galang, Farley Yang, David Brachman (PI), Jeffrey Richmond, David Steinway, Thomas Canty, Robert Kuske, Mark McLaughlin, Christopher Biggs, Thomas Taylor and Nicholas Flores.

Baptist Hospital of Miami



Andre Abitbol, MD; Lourdes Moreno, LPN; Alan Lewin, MD.

The dynamic blend of leading-edge medical care and old-fashioned commitment to the community is the strength and spirit of Baptist Hospital of Miami. Opened in 1960, it is the flagship hospital of the five-hospital Baptist Health South Florida, South Florida's largest not-for-profit healthcare organization. Baptist Hospital, located in south Miami-Dade County, has 567 beds and approximately 1500 physicians on its medical staff. It includes the Baptist Cardiac and Vascular Institute and Baptist Children's Hospital.

Baptist Hospital has been one of the most respected medical centers in South Florida. Its full range of medical and technological services is a natural choice for an ever-growing number of people throughout the region, including the

Caribbean, Central and South America. Baptist's Italian renaissance architecture and beautiful grounds offer an atmosphere of warmth and welcome. A beautiful pineapple fountain greets all who enter and is the symbol of hospitality as well as their commitment to service excellence. Inside the hospital, a highly qualified staff and the finest diagnostic and treatment facilities provide a model for service equaled by few other community hospitals. In 1998, Baptist Hospital was recognized as a Magnet Hospital for Nursing Excellence by the American Nursing Credentialing Center and was the first hospital in the state to receive this distinguished designation.

Baptist and South Miami Hospitals comprise the Baptist South Miami Regional Cancer Program which is accredited by the prestigious Commission on Cancer of the American College of Surgeons. They have provided specialized cancer care for over 20 years and treat more than 3,500 patients annually.

Radiation oncology services at Baptist Hospital include a complete range of treatment options. These services include intensity modulated radiation therapy (IMRT), multi-leaf collimator, 3-dimensional treatment planning, stereotactic radiosurgery, brachytherapy and radioimmunotherapy. Support services in the department include a specially trained oncology social worker and a registered dietitian Other services available are a variety of collaborative medicine therapies, interdenominational pastoral care staff, Genetic Risk Education Service, Cancer Resource Service, educational programs and support groups.

Clinical trials at Baptist Hospital Radiation Oncology Department have been done in association with RTOG since 1987 under the leadership of Drs. Andre Abitbol and Alan Lewin.

Advances in cancer treatment continue at an exciting pace, and the Baptist Hospital Radiation Oncology Department remains committed to leading the way. It remains among the region's busiest community cancer treatment centers, thanks to the dedicated staff of physicians and healthcare professionals, as well as the patients and their families. Together, they're a great team making remarkable strides in cancer care.



Who to Call at RTOG

Subject	Department	Number to Call
Study Accrual <i>A listing of case accrual is available on the RTOG website and is updated weekly.</i>	Protocol Development & Regulatory Compliance	215-573-3191
Additional Labels <i>Requests should be faxed into RTOG. The form is available on the RTOG website under Forms/Miscellaneous. Please note the first set of labels is sent out by Randomization. Please call the Randomization Desk (215-574-3191 or 3192) if you have not received these.</i>	Data Management	215-574-3214
Admin. Issues RE: Protocol Start-up	Protocol Development & Regulatory Compliance	215-574-3195
Blood Samples <i>Many RTOG protocols have their blood samples submitted to LDS Hospital. Please check the protocol for the appropriate place for submission of blood samples.</i>	LDS Hospital	801-408-5626
Case Calendars <i>The form to request a case calendar or calendar extension is available on the RTOG website under Forms/Miscellaneous. Please note the first case calendar is sent out by Randomization when the patient is registered.</i>	Data Management	215-574-3214
Consent Issues	Protocol Development & Regulatory Compliance	215-574-3195
Data Quality Scores	RTOG Administration	215-574-3173
Dose Reduction <i>for chemo, hormone, e nonXRT(section 7 of protocol)</i>	Protocol Research Associate, Data Management	215-574-3214
Dosimetry Form Submission <i>All "T" Forms except T1&TF, films & scans</i>	RT Quality Assurance	215-574-3219
Drug Request/Drug Delivery	Protocol Development & Regulatory Compliance	215-574-3185
Financial/Reimbursement Questions	RTOG Administration	215-574-3205
Forms <i>Forms for all RTOG open studies and several closed studies are available on the RTOG website. If you need to request forms, please call Randomization at 215-574-3191 or fax your request to 215-574-0300.</i>		
Form Completion Questions/Assessments <i>(sections 11&12 of protocol)</i>	Protocol Research Associate, Data Management	215-574-3214
Forms Due Report Questions	Data Management	215-574-3214
Membership/Contract Issues	RTOG Administration	215-574-3205
Pathology Slides & Blocks	Pathology Clerk	215-574-3192
Patient Eligibility <i>(Sections 3&4 of protocol)</i>	Protocol Research Associate, Data Management	215-574-3214
Patient Registration Procedure	Protocol Development & Regulatory Compliance	215-574-3191
Protocol Results for Yearly IRB Reports	Statistics	215-574-3175 or 214-574-3203
Publication Questions	RTOG Publications	215-574-3163
Radiation Therapy Administration	RT Quality Assurance	215-574-3219
Regulatory Questions <i>(U.S.A. only)</i>	Protocol Development & Regulatory Compliance	215-574-3185
Regulatory Questions <i>(Canadian Institutions)</i>	Protocol Development & Regulatory Compliance	215-574-3162
Website Problems	RTOG Web Master	215-574-3241
Web Data Collection Issues/ Web Site Not Working	RTOG MIS	215-574-3196 or 215-717-2768

Research Associates Committee

Chair

Roseann Bonanni
Thomas Jefferson University Hospital
111 S. 11th St.
Philadelphia, PA 19107
215-955-8619 roseann.bonanni@mail.tju.edu

Co-Chair

Darlene Johnson
University of South Florida
12901 Bruce B. Downs
Tampa, FL 33612
813-979-3861 johnson@moffitt.usf.edu

Secretary

Sharon Byrne, MSN, RN
Albert Einstein Medical Center
5501 Old York Road
Philadelphia, PA 19141
217-456-6316 bymes@einstein.edu

Education Co-Chair

Sharon Prokop
Barbara Ann Karmanos Institute
3990 John Road
Detroit, MI 48201 prokops@karmanos.org

Education Co-Chair/ Quality Control

Susan Provins
Montreal General Hospital
1650 Cedar
Montreal, Quebec, Canada H3G 1A4
514-934-8040
sprovins@medphys.mgh.mcgill.ca

RA Research Strategy

Jackie Fisher
Oakwood Hospital
18101 Oakwood Blvd.
Dearborn, MI 48123 fisherj3@oakwood.org

RA Research Strategy Co-Chair

Lisa Chin
Columbia-Presbyterian Medical Ctr.
Dept. Of Radiation Oncology
212-305-7001
fax 212-305-7001 ljcs8@columbia.edu

Poster Contest

Deb Olsen
University of Miami
D-31, PO Box 016960
Miami, FL 33101
305-243-4243 dolson@med.miami.edu

Disease Discipline

Joanne Ciconte
Thomas Jefferson University Hospital
111 S. 11th St.
Philadelphia, PA 19107
215-955-8619 joanne.ciconte@mail.tju.edu

Communications

Jane Gardner
Tom Baker Cancer Center
1331-29 Street N.W.
Calgary, Alberta, Canada T2N4N2
403-944-8391 janegard@cancerboard.ab.ca

Disease Discipline/ Communication Co-Chair

Larry Korman
Sidney Kimmel Comprehensive
Cancer Center at Johns Hopkins
401 N. Broadway St.
Baltimore, MD 21231
410-614-3158 kormala@jhmi.edu

Quality Control

Clare Brooks
RAD Association of Sacramento
5271 F Street
Sacramento, CA 95819
916-454-6699 rabrooks@radiologic.com
and Sharon Prokop (see above)

Membership Chair

Bonnie Sauder
Moffitt Cancer Center
129001 Magnolia Drive
Tampa, FL 33612
813-979-8400 ext.1946
sauderb@moffitt.usf.edu

Immediate Past Chair/ Corporate Relations/ New Investigators

Joyce Neading
Summa Health System/Akron City
525 E. Market St.
Akron, Ohio
330-375-4221 neadinja@summa-health.org

RTOG Headquarters

Elaine Motyka-Welch
RTOG
1818 Market Street, Suite 1600
Philadelphia, PA 19103
215-574-3216 emotyka@phila.acr.org

Research Associates Support List

The RA's listed below have volunteered to assist other RA's working with the protocols listed below. Phone numbers, faxes and emails are listed at the end. The RA support list is intended to provide a networking system among RTOG Research Associates. You may want to speak with someone prior to opening a protocol to see if they encountered any problems and how they solved them or how they handle a specific area, such as documentation of medication, patient visit, etc. If you would like to add your name or make a correction to the list contact Jane Gardner at (403) 944-8391 or email at janegard@cancer-board.ab.ca.

91-15 Judith Stumpf	96-01 Clare Brooks Karen Christie	98-05 Sharon Prokop	99-10 Clare Brooks Karen Christie Sharon Prokop Theresa Thomas
94-02 Theresa Thomas	97-02 Judith Stumpf	98-09 Judith Stumpf Susan Proe	99-14 Clare Brooks
94-03 Judith Stumpf	97-04 Clare Brooks Susan Proe Judith Stumpf	99-10 Judith Stumpf	Breast Beth Davis
94-08 Christine Armetta Clare Brooks Karen Christie Norissa Honea Sharon Prokop Judith Stumpf Theresa Thomas	97-12 Sharon Prokop Judith Stumpf	98-11 Christine Armetta Clare Brooks Karen Leifeste Susan Proe	H&N Beth Davis Norissa Honea
94-10	97-14 Susan Proe	98-13 Theresa Thomas	JPR-7 CTSU Judith Stumpf
94-13	98-02 Theresa Thomas	99-02 Clare Brooks Sharon Prokop	Other Barbara Svendson Carole Coyne
95-01	98-04 Christine Armetta	99-04 Norissa Honea	Pancreas Larry Korman
95-13 Judith Stumpf			

Clare Brooks, BS, CCRP, 916-454-6699, FAX 916-452-7151, rabrooks@radiological.com

Karen Christie, MA,CTR,CCRP, 252-816-2900, FAX 252-816-2900, christiek@mail.ecu.edu

Susan Connor-Proe, M.S.Ed, CRCC, 716-275-5971, 716-275-1531, susanproe@urmc.rochester.edu

Carole L. Coyne, BS, BA, CCRP, CRC, 407-648-3800, FAX 407-425-5203, CAROLE@orhs.org

Beth Davis, CCRP, 510-204-3428, FAX 510-649-9857, Bdavis@salick.com

Christine Armetta, BS,MBA,CCRP, 215-750-5328, FAX 215-891-6058, CArmetta@che-east.org

Norissa Honea, RN, MSN, OCN, 602-274-4484, FAX 602-287-9406, norissa@azoncology.com

Larry Korman, RN, BSN, OCN, 410-614-3158, FAX 410-502-1419, kormala@jhmi.edu

Kathy Leifeste, RN,MSN, AOCN, 908-994-8995, FAX 908-629-8289, KLeifeste@trinitas.org

Sharon Prokop, RN,BSN,OCN, 313-745-2472, FAX 313-745-2314, prokops@karmanos.org

Judith A. Stumpf, LPN, CCRP, 319-589-2468, FAX 319-589-2368, judith.stumpf@finleyhospital.org

Theresa Thomas, MS, CCRC, 602-274-4484, FAX 602-287-9406, theresa@azoncology.com

Research Associates Committee

RTOG Research Associates Membership Form

Instructions: Please type or print your information very clearly.

Are you new to RTOG? **or** Would you like to update your information?

Ms. Mr.

Last Name _____

First Name _____

Job Title _____

Degree(s) _____

Institution Name _____

Institution Number _____

Is your institution a Full Member Affiliate Member CCOP

If Affiliate, who is your Full Member Institution? _____

Mailing Address _____

Telephone _____

Fax _____

E-mail Address _____

Can you receive attachments? yes no

Does your institution have a Web site? yes no

What is the Web site address? _____

Does your program or department have a Web site? yes no

What is the Web site link? _____

Principal Investigator's Name _____

Return this form to:

Bonnie Sauder

Radiation Oncology Program (MCC-RADTHER)
H. Lee Moffitt Cancer Center & Research Institute
1290 Magnolia Drive
Tampa, FL 33612

or

FAX: (813) 979-7231