RTOG Semiannual Meeting Minutes

Committee Name:	**Advanced Technology Integration Steering/General Committee Meeting**
Meeting Date:	June 18, 2010
Meeting Time:	12:30 PM – 2:30 PM
Meeting Location:	Regency A – Loews Philadelphia Hotel, Phila., PA
Chair/Moderator:	Jeff Michalski, M.D.

1. Dr. Robert Timmerman discussed the rationale for the upcoming phase III trial of wedge resection vs SBRT for localized lung cancer. This will be an intergroup trial along with the ACOSOG.
2. Dr. Barthold reported progress on the target and normal tissue atlas development.
3. International Harmonization: Dr. Michalski updated the group on the brain tumor and pancreatic trials that are being done with EORTC collaboration. There are also registry projects with European investigators in EMBRACE and a potential international trial for intact cervical cancer.
4. **Modality Committee updates:**
    a. Proton Therapy—Dr. Gillin described the challenge of identifying institutions as "Proton Approved" due to the heterogeneous policies and procedures each of the unique proton centers have for dosimetric measurements and quality assurance. Furthermore, beam characteristics in some clinical scenarios raise concerns about dosimetric uncertainties. He proposed a phased approach to institutional approval for the use of protons. There would be three levels of approval based upon 1. technique (scattered vs scanned), 2. field size, 3. motion considerations, 4. agreement between calculated and measured doses, 5. field abutments and 4. image guidance. Category 1 would be "simple" and accommodate cases such as prostate only irradiation. Category 2 would be "intermediate" and accommodate most static scenarios including CSI. Category 3 would be the most "complex" with moving structures, precise localization and IMPT.
    b. IGRT: Dr. Kestin's reviewed his concept for IGRT in prostate cancer.

c. Stereotactic Radiotherapy Subcommittee Report: Dr. Timmerman reported that SRS protocol (0930) for acromegaly will now be reviewed by NINMS and not NCI. The spine radiosurgery is open. The spine phantom is preferentially sent to institutions that are already IGRT credentialed. Two trials are open for lung cancer, medically inoperable central lung cancer (0813) and a randomized phase II trial for peripheral inoperable lung cancer (0915). RTOG 0618 finished accrual. Other studies are in development for liver tumors, prostate cancer and breast cancer (oligometastatic disease)

d. Brachytherapy: Dr. Joe Hsu reported that either LDR or HDR brachytherapy is allowed on RTOG 0815. HDR can now be planned with US. The ITC has developed a mechanism for data submission using DICOM like images from ultrasound.

5. **Site Committee Liaisons:** Several of the ATIC Liaisons to clinical sites described protocol activity in their respective committees.

a. Lung Committee Liaison: Dr. Videtic reported three trials are open with ATIC support: 0617, the randomized trial comparing high-dose versus standard dose radiation therapy; 0813, the dose escalation trial for central lung tumors; and 0915, the lung SBRT trial for medically inoperable patients, a phase II trial of 34 Gray in one fraction versus 12 Gray in 4 fractions. Two studies are in development including 0839 for high dose, trimodality therapy with an investigational drug and the randomized phase III trial of surgery vs SBRT for NSCLC. 116 sites are credentialed for SBRT. A workshop was held and will be repeated for SBRT planning and credentialing. Proton therapy is being explored for lung cancer trials.

b. GU Committee Liaison: Dr. Krauss reported 6 prostate (local to metastatic) and 3 bladder cancer trials are open with support from ATIC. A randomized phase IIR trial of SBRT vs hypofractionated IMRT for low risk prostate cancer is in development and has been reviewed first by CTEP and now by DCP as the primary endpoint is QOL. 0924 is being developed for “High-Intermediate” risk prostate cancer randomizing them to receive hormones +/- pelvic XRT. A high risk protocol with XRT and hormones +/- abiraterone is being developed as is a HDR monotherapy protocol for low risk disease.

c. GI committee liaison: Dr. Hong reported the GI update. The 0848 protocol is accruing. Plans for IGRT in a pancreatic trial being developed by Dr. Ben-Josef will need to be adapted to use techniques such as, but not limited to, Active Breathing Control. Dr. Kachnic is developing a successor anal cancer trial with IMRT, chemotherapy +/- cetuximab.

d. Breast committee liaison: Dr. Chmura reported 0413 (PBI) has 3636 of 4300 registrations. 1014 (re-irradiation) is open and actively accruing. RTOG 1019 for oligometastatic disease is in development and a teleconference will be arranged to develop RT guidelines.

e. Gyn committee liaison: Dr. Portelance reported that 0724 (postop cervix) and 0921 (IMRT + CDDP + Bev) for endometrial cancer is accruing. A pending trial of IMRT and chemotherapy for locally advanced cervix has been proposed but the GYN steering committee has not approved it and consideration is being given to an international trial. The RTOG and GOG are collaborating on a high risk endometrial cancer trial of pelvic RT vs Vault Brachytherapy followed by carbo-taxol as well as a recurrent endometrial cancer trial of RT +/- chemotherapy.

f. Sarcoma committee liaison: Dr. Wang updated accrual for 0630, they are approximately 15 patients shy of their goal for cohort B. Atlases for extremity sarcoma anatomic compartments have been developed by Dr. Finkelstein with assistance of the ITC.

g. Brain Committee Liaison: Dr. Tsien reported that three ATIC trials are open for GBM (0825), Meningioma (0539)and spine metastases (0631). Protons will be allowed on the 0539 trial. The SRS for acromegaly (0930) has been deferred due to CTEP not supporting treatment of a non-malignant disease. The hippocampal sparing WBRT (0933) should open in the next meeting cycle. RTOG 0837 is being developed for newly diagnosed glioblastoma along with imaging correlates (ACRIN 6689)

h. H&N Committee Liaison: Dr. Kim reported that 0920 was activated on November 5, 2009. It employs IMRT and the use of IGRT is optional. Use of IGRT allows a PTV margin of 2.5mm-5.0mm. Lack of IGRT uses a margin of 10mm. RTOG 0619 has been closed due to sponsor stopping its support for vandetanib. 0912, a Phase IIR trial for anaplastic thyroid cancer is being developed with Dr. Nance Lee and Eric Sherman.

1008 is in development for high risk salivary gland tumors. 1016 will be a phase III trial of IMRT and cetuximab vs cisplatinum for HPV+ oropharynx cancer. 1024 will address HPV negative cancers.

6. **ATC Report:** Dr. Bosch gave the ATC report. More than 10,550 cases have been registered with digital data submission. Brainlab iPLAN and Elekta CMS XiO 4.6 have been demonstrated to be ATC compliant and Nucletron has demonstrated vendor compliance with US based HDR prostate plans. The ATC members work closely with DICOM working group and IHERO to define and develop data exchange standards. The Image guided Therapy QA Center (ITC) supports RPC phantom dosimetry efforts. The ATC has also supported atlas development for a variety of disease sites and normal anatomy.
7. **Medical Physics Report:** Dr. Gillin discussed proton therapy earlier in the session.
8. **Radiologic Physics Center Report:** Dr. Ibbott described the role of the RPC including 1. Assurance of constancy of basic machine calibration 2. Assurance of validity of treatment planning data, 3. Assurance of consistency of treatment records and 4. Credentialing of advanced technology procedures. The RPC monitors 1,768 institutions. They have developed phantoms for credentialing IMRT, IGRT, SRS and SBRT. Only 4 spine phantoms are available and more have been ordered to meet the demand for the SBRT spine protocol. The dosimetry pass rates for the various phantoms range from 68% to 82% at first attempt. The RPC expects to approve 2 proton sites in the next few months and another 3 sites are planned in the within the next year. The RPC performs beam measurements and QA, reviews treatment planning and CT procedures for proton centers. In the next cycle, the RPC plans to focus on approving proton centers, develop new phantoms, and support international participation (EORTC ERDA study).

RTOG Semiannual Meeting Minutes

Committee Name: **BIOSPECIMEN RESOURCE**
Meeting Date: June 19, 2010
Meeting Time: 7 AM
Meeting Location: Philadelphia, PA
Chair/Moderator: Fred Waldman

Attendees: Fred Waldman, Sharon Hartson-Stine, Tony Magliocco, Kathryn Winter, Richard Jordan, Sandy Devries, Fran Bradley, Roseann Bonnani, Jonathan Harris, Adam Dicker, Jeff Simko

1. CTEP review required:
   - New process – question will be when do they write the research plan? Prefer application and CTEP-acceptable research plan to be one in the same – may have to massage it at HQ.
   - Regulation that's not been enforced.
   - Fred:
     A. LOI that goes to Statistics and BR first;
     B. PI expands it for submission to CTEP according to our template.
   - Kathryn:
     A. July 1 notification to dz site TRP liaisons of new procedure including a rolling submission but quarterly reviews (July, October, January, April);
     B. Internal review with conference calls;
     C. Batched applications to be reviewed by Steering Committee;
     D. HQ revisions of applications for CTEP review.
   - Need to distinguish grant vs. tissue …… correlative science request for tissue only request vs. seed money request or grants like R01.

2. ST Form discussion – per emails.

3. Specimen arrives thawed to BR – ask institutional PI about re-draws.

4. Discussion of sFTP v. electronic forms – tabled.

5. Monitoring institutions for specimen submission:
   - Looking at this across dz sites;
   - Patient advocates really pushing since patients overwhelmingly want tissue used.
   - The issue is actually the protocol – cannot be mandatory unless it's tied to primary endpoint.
   - We must reword protocols that tissue is mandatory if patient consents.

6. International shipping:
   - Issues - $40,000 on internal fedex, $900 Hong Kong shipment & $1000 Israel;

- International accrual is low;
- Again look at protocols – no history on international shipments so we can make decisions – check out how SWOG deals w/ shipping.
- Need industry support when negotiating contracts – need to look at cost for international participation. Also requirements & storage should be monitored.

7. Process for reimbursements for sending tissue:
   - Overabundance of urine specimens;
   - Costing lots to store;
   - Solution: put in smaller tubes & RA should aliquot;
   - Costing out protocols – paying per protocol; bundling.

8. Material Log:
   - Want to start using 7/1;
   - OK to organize as per Sandy D./Sharon emails;
   - Monthly posting.

RTOG Semiannual Meeting Minutes

Committee Name: **Functional Imaging (Working Group)**
Meeting Date: June 19, 2010
Meeting Time: 7:30 – 8:30 AM
Meeting Location: Regency C – Loews Philadelphia Hotel, Philadelphia, PA
Chair/Moderator: Mitchell Machtay, M.D.

Report on Publications and Protocols Closed to Accrual

1. RTOG 0235/ACRIN 6668 (PET-SUV as a prognostic marker for NSCLC). Dr. Machtay reported on this study. It completed accrual (251 patients) in May 2009. It is hoped that by mid 2011, the primary data analysis (long term survival) can be performed, and thus perhaps submitted as a late-breaking abstract to 2011 ASTRO and/or RSNA. In the meantime, many secondary analyses are in progress, utilizing the ACRIN core facility. One such analysis (Dr. Nhitin Ohri from Jefferson) received external funding. There is also a plan for a manuscript correlating local versus central review results for SUV, to be written once all of the central reviews are completed.
2. RTOG 0515 (PET-based RT treatment planning). Dr. Machtay reported briefly, on behalf of Dr. Bradley. The results of this study were presented by Dr. Bradley at ASTRO 2009, and a manuscript is being written.
3. RTOG 0522 (PET for head and neck CA). Dr. David Schwartz reported. This study has also been closed for > 1 year. Although accrual was not as high as originally hoped for, at time of registration 127 sites committed to submitting PET scans; of the 127 cases, 19 were ineligible, withdrew, or registration errors were found leaving a total of 108 patients participated having their PET data submitted, making this one of the largest prospective studies of PET in head and neck cancer ever performed. Data are maturing.

Report on Currently Accruing Protocols

1. RTOG 0825/ACRIN6686 (RT/Temodar/Bevacizumab for Glioblastoma, with advanced MRI imaging components). Dr. Christina Tsien reported on this initiative of the RTOG brain committee in conjunction with ACRIN. RTOG 0825 has been open since April 2009, but accrual to the limited-institution advanced imaging portion of the study has been suboptimal (15 cases registered). This was extensively discussed among the attendees, with particular attention to reviewing some of the financial challenges to the local institutions. RTOG and ACRIN headquarters will further review the relevant issues, and work toward a plan to improve accrual.
2. RTOG 0837/ACRIN 6689 (RT/Temodar/cedirinib for Glioblastoma, with advanced MRI and PET imaging components).: As opposed to 0825/6686, this study just recently activated and it is premature to make any detailed assessment of its progress. However, the same issues noted above are relevant to this study, and will be reviewed at HQ.

Report on Protocols and Concepts in Development

1. Replacement study for RTOG 0235/ACRIN 6668: Dr. Spring Kong presented her institutional data (University of Michigan) from a prospective trial of PET scan during chemoradiotherapy (at a dose of 40-50 Gy). Based on these data, as well as great interest in the Lung Committee to study 'adaptive' radiotherapy treatment, Drs. Kong and Machtay proposed an RTOG study in which patients with stage III NSCLC would undergo

mid-treatment PET. They would then be randomized (phase IIR) to continue conventional chemoradiotherapy versus an adaptive RT field in which the final RT dose would be > 74 Gy. This study was discussed extensively and overall was very well received by the Working Group. It was decided to formally present this protocol concept to the Lung Committee (Dr. Bradley) and to ACRIN's Thoracic committee ASAP.

2. Developing study 1022 (Chemo-RT for pancreas CA, with PET scan components): This study was rejected as a single arm phase II design, but will likely be re-designed as a phase IIR study. RTOG will work with ACRIN to include a PET component. There was insufficient time to discuss this study in any detail.

Other Presentations

Dr. Christine Tsien gave an excellent scientific presentation on her work with advanced imaging MRI for glioblastoma. Her work is part of the basis for the imaging studies within RTOG 0825 and 0837. The Working Group agreed that this is an important line of research for RTOG.

Dr. Machtay and others led a brief discussion related to PET agents other than FDG. Currently, RTOG 0837/ACRIN 6689 has a small FLT-PET component. The members of the working group are enthusiastic about pursuing studies with FLT in other disease sites, as well as other novel PET tracers, especially hypoxia markers such as F-MISO.

Other Business

This Working Group will continue to meet at the RTOG semi-annual meeting, with majority favoring an early Saturday morning (7:30 a.m.).

RTOG Semiannual Meeting Minutes

Committee Name: **Health Services Research and Outcomes (HSRO)/CCOP/SYMPTOM MANAGEMENT**
Meeting Date: June 18, 2010
Meeting Time: 12:30-2:30 pm
Meeting Location: Philadelphia, PA
Chair/Moderator: Deborah Watkins Bruner, PhD, RN

Protocol Updates

Protocol Number (if assigned)	PI	Population	Phase	Modality	Discussion/Action
Concepts					
	Hamstra	**PSA or metastatic relapse post prostate RT**	**IIR**	**Intermittent LHRH agonist therapy vs. intermittent bicalutamide and finasteride**	Dr. Hamstra presented a concept for prostate cancer patients. Primary endpoint: Change in HRQOL (fatigue) at end of induction (6 months). The Committee approved this concept for further development (Note: The concept will need to go through the RTOG internal review process for further detail before being presented to RTOG Research Strategy committee for approval to develop).
	Wang	**Primary soft tissue sarcoma of extremity and body wall**	**IIR**	**Conventional RT vs. hypofrax RT**	Dr. Wang presented a concept for sarcoma patients. Primary endpoint: Major wound complication rate (15% reduction) in patients receiving preoperational conventional RT vs. hypofractionated RT; study to have QOL and TRP components. Dr. Berk asked what would be the next step (phase III) following this trial. A possible phase III design was not articulated to the group. Dr. Bruner stated that the Study Chairs must present a phase III follow up to this study to the Committee and provide solid metrics for the measurement of wound healing before the Committee would vote regarding further development of the concept.

Developing Protocols					
0938	**Bahary**	**Favorable risk prostate**	**IIR**	**Hypofrax RT**	Concept reviewed by DCP. Revisions are in progress for resubmission. DCP reviewers recommended changing primary endpoint: reviewers want to see change scores from baseline rather than from historical controls.
0933	**Mehta**	**Brain mets**	**II**	**WBRT hippocampal avoidance**	Final draft of protocol almost ready for DCP submission. New Neuropsych chair (CogState) added.
1012	**Berk**	**Lung**	**IIR**	**Manuka honey for esophagitis**	Dr. Berk reported that a 3rd arm will be added to the trial (routine care vs. liquid honey vs. honey lozenge) for a required sample size of 150. This will test if honey is effective due to its composition vs. viscosity. Also, a PRO-CTCAE component will be added.
Active Protocols					
0841	**Wagner**	**Patients about to begin or within 2 weeks of beginning RT for first tumor diagnosis**		**Depression screening**	Study will reopen to accrual July 1. The protocol has undergone substantial revision and has a new Principal Investigator, Dr. Lynne Wagner. Dr. Wagner discussed the revisions to the protocol (e.g., development of detailed safety plans; minor modifications to the study design and analyses; modification of the study interviews). The study will open to CCOP sites only for the first 6 months of accrual.
0831	**Bruner**	**Prostate**	**III**	**Tadalafil vs. placebo for erectile dysfunction**	Study still closed to accrual but the distribution problem with the study agent has been resolved and the trial will reopen by the end of the summer. Dr. Bruner discussed RT credentialing and participation in the protocol: Institutions that already have been credentialed for RT will not have to be re-credentialed for this protocol. The protocol will be amended following the meeting.

0631	**Ryu**	**Localized spine mets**	**II/III**	**Radiosurgery/SBRT for spine mets**	Dr. Ryu spoke about the difficulties that sites have been having obtaining the phantoms (for credentialing) for this study. He mentioned two developments that should help alleviate the problem for sites: 1) Sites should submit the information for the IGRT credentialing component first; they will be added to the priority list for receipt of a phantom; 2) Additional phantoms are being created so that 7 phantoms will be available for sites to use. Dr. Berk commented that this trial is important because if we do not do this trial we may never get SBRT accepted as a standard treatment.

Other Business:

- Dr. Bruner reported that CTEP is recommending that developing RTOG treatment trials with a patient-reported (PRO) endpoint be submitted from the CCOP/Symptom Management Committee and to DCP. She stated that she and the CCOP committee are very supportive of these trials; however, they were not included in the recent competitive renewal, as this is a recent change in process and has funding implications. These trials are not currently funded by the CCOP grant and we will need to request a supplement from DCP. Dr. Bruner also said she will require the Chairs of these studies to provide a strong rationale for the trial, and these trials will have to be prioritized. In addition, the trials have to appeal to CCOP sites and be feasible for these sites.
- Dr. Bruner encouraged Study Chairs to apply for BIQSFP funding for development of QOL and biomarker companion studies to active CCOP protocols or integration of QOL and biomarker endpoints in treatment protocols. This is an ongoing funding opportunity for the Group.
- Dr. O'Mara/DCP stated that it was preferable to submit randomized ph II trials vs. ph II single arm studies. DCP will accept ph II single arm trials if Chairs provide a strong argument as to why there is no comparator.
- Dr. Albert DeNittis was introduced as the new Chair of CCOP Membership.

Reports from working groups:

- Neurocognitive: Chaired by Dr. Corn. New computerized, patient-reported cognitive evaluation coming and credentialing will be revised as appropriate to the new method.
- Epidermal: Chaired by Drs. Dicker and Rodick. Biomarkers for response to EGFR are replacing skin toxicity as an area of interest.
- Mucositis: Chaired by Dr. Berk. Honey trial protocol 1012 in development, looking for additional concepts.
- Late Effects/Survivorship: Chaired by Drs. Konski and Scarantino. Possible developing studies reviewed included a "care path" for survivor to decrease post-treatment distress; a psycho-social team for lung cancer patients to increase overall survival; and yoga to decrease stress in survivors
- QOL: Chaired by Dr. Movsas, who stated that developing studies should have the same endpoint and time points across trials (e.g., RTOG protocols 0815 and 0924) so that analyses can be done across trials, with less patients needed. Dr. Bruner recommended that the Committee publish primary papers and QOL papers simultaneously.

- Pain Palliation: Chaired by Dr. Kachnic. Possible developing studies reviewed included zoledronic acid for bone mets to decrease pain; and a trial involving a radionucleotide, R223.

Special Populations Subcommittee: Dr. Heron reported on the subcommittee's revised goals/strategies over the next 6, 12, and 24 months. The group will be involved in a proposal for Dr. Roach's ancestral lineage project. The proposal is to use RTOG tissue data to genotype populations. The subcommittee would like RTOG study chairs to include plans for addressing accrual of special populations.

QOL Instrument Library: A brief write-up for the CogState assessments will be added to the online library on the RTOG web site.

Committee Priorities: Increase (25–30%) CCOP accrual to CCOP trials; applying for BIQSFP and other funding opportunities

RTOG Semiannual Meeting Minutes

Committee Name: **Medical Physics**
Meeting Date: Friday, June 18, 2010
Meeting Time: 4:00 PM – 6:00 PM
Meeting Location: Loews Philadelphia Hotel – Washington C Meeting Room
Chair/Moderator: Michael Gillin, Ph.D. and Co-Chair: James M. Galvin, D.Sc.

Major Issues

1. Harmonization in the cooperative group process both in the US and world wide, including data management challenges were discussed by this committee.

2. RTOG standards to limit the possibility of major errors on RTOG protocols, especially involving new technology was presented by J. Galvin and the following items were discussed by this committee.

    a. Re-credentialing criteria as technology evolves, e.g. Varian's new unit with the FFF beam option
    b. Formal risk analysis
    c. Formal education sessions on the issues

3. IGRT Issues and Developments were discussed and the challenges that the Reviewers have experienced with the data that is submitted to the Core Lab.

4. Proton Developments

Proton Approval Proposal for a Phased Approach was presented by J. Galvin on behalf of M. Gillin.
RTOG Recommendations to the NCI:

- These recommendations have been reviewed and approved by the following RTOG committees:
    - ATIC Committee
    - Medical Physics Committee
    - Proton Committee
- 1. There is no consensus on minimum standards to be met by proton centers for participation in NCI protocols using protons. Protons are less forgiving than photons.
- 2. The several proton delivery systems, which are currently in use, are very different, especially when compared to photon delivery systems.
- 3. There is limited expertise available to develop and critique proton approval programs.
- 4. Uniform definitions: A glossary of proton terms should be defined.

Approval Criteria

- 1. Technique (Scattered 1, Scattered 2, Scanned 1, Scanned 2, etc.)
- 2. Field Size (3 cm x 3 cm criteria)
- 3. Motion Management Considerations
- 4. Agreement between calculated and measured dose to a volume
- 5. Field Abutments
- 6. System for image guidance for patient setup

A Phased Approval Proposal for Protons

- Category 1
  - Field sizes equal to or greater than 3 cm x 3 cm
  - Intra-fraction motion not commonly considered in treatment planning
  - Agreement between calculated and measured dose to a volume 3 mm or better
  - Single target volume
  - Image guidance using phantom within 2 mm
  - Scanning beam or IMPT not allowed
  - Examples: Prostate
- Category 2
  - Same as category 1 except multiple targets which require abutting fields
  - Examples: Cranial spinal

- Category 3A - Agreement in dose to volume between calculated and measured dose within 1.5 mm
- Category 3B Small Fields, < 3 cm x 3 cm
- Category 3C Motion Management Required
- Category 3D IGRT within 1 mm
- Category 3E IMPT SFO
- Category 3F IMPT MFO

Proton Approval Recommendations:
The RTOG recommends to the NCI to approve proton facilities for Category 1 and Category 2 after a successful RPC site visit and after a successful transfer of treatment plans to the ITC.
The RTOG will work with the NCI, the RPC, the ITC, the ATC, and other appropriate groups to develop criteria for Category 3, as defined by RTOG priorities.
The RTOG requests that the NCI consider funding the RPC proton consultant for CY 2011.

The Advanced Technology Consortium (ATC) has facilitated the development of general guidelines for protocols that incorporate proton radiation therapy (PRT) as an option (http://atc.wustl.edu/credentialing/FINAL_PROTON_GUIDELINES_june_2007.pdf). The guidelines were previously communicated to all clinical trial groups by the National Cancer Institute (NCI), and this document (dated May 13, 2010) represents the latest version. There are potential advantages to patients from PRT but substantial concerns persist as protons are more sensitive than photons to uncertainties in the planning, optimization, and execution of radiation therapy. This reflects the nature of the interactions of protons with matter, and hence the need for credentialing and quality assurance procedures that are specific for PRT. The guidelines are intended to ensure that when PRT is employed in the setting of a multi-institutional co-operative group clinical trial neither patient safety nor the study is compromised. The guidelines only specify the MINIMUM required of any facility that uses PRT to treat those patients participating in any NCI-supported clinical trial that requires or allows PRT. They are not to be construed as prescriptive of standards of care.

5. CyberKnife issues were discussed and this committee was reminded that changing from any IMRT technique to CyberKnife dose delivery (note that CyberKnife dose delivery is considered to be a related approach that requires IMRT credentialing for use in RTOG protocols).

Reports from QA offices

RTOG HQ, including the Core lab

Betty O'Meara reported on the study chair final reviews for RT Quality Assurance. From January, 2010 to June, 2010 there were 98 cases reviewed using the film and pager review process which will end soon, as these trials close and the reviewers have completed their reviews. The target volume, organ at risk, and dose volume analysis scores were also discussed. The bar graph representation for the trials under digital data review has added the % Unacceptable for this committee to take note of any studies that may need immediate attention. There were no protocols noted with any increase in Unacceptable Variation scores since the last report in January, 2010.
The RTOG Core Laboratory is designed to support clinical trials, establish standards, provide individual institution quality assurance, data management and analysis, and report on technical and clinical results. In addition to supporting and establishing standards, the RTOG Core Laboratory provides education and research in clinical trial support. The Core Laboratory is managed by physicists and RTQA technical staff.
The RTOG Core Laboratory provides sites with education and training on comprehensive image management and standards, quality assurance, and technical qualifications. Posted on the RTOG Website is a link to the Radiation Therapy Orientation presentation that was presented at the latest RTOG Semi-Annual meeting or at RTOG Headquarters.

ATC/ITC

Walter Bosch presented the ITC Quality Assurance report to this committee describing the protocol case digital data submissions for RTOG protocols. Walter updated the protocol case digital data submission per protocol and the number of problems encountered that required human intervention by the ITC personnel for the time period of December 16, 2009 to May 16, 2010. Over 30% of the cases presented were due to various problems with the submitted data (i.e. missing protocol required elements, misuse of treatment planning system, problems with connecting to the SFTP server, and problems with TPS software. ITC also encountered problems with the some of the protocols in reference to the testing of digital data submission. To eradicate this issue, testing can be accomplished with the RPC phantom digital data submissions. There now is an increase in the number of phantom submissions compared to what has been seen in previous periods, and the rate of intervention has been diminished. The total # of protocol cases/credentialed/Phantom Digital Submissions goes back to the institution for clarification. ITC would provide a list of structure names to institutions to help sites with required digital data submission.

RPC

Geoff Ibbott updated this committee on the RPC's audits; site visits, TLD/OSLD monitoring, phantoms, and credentialing, for both US and international RTOG institutions. Per the RPC June report, the RPC is currently monitoring 1, 768 institutions of which 850 are RTOG members/affiliates/CCOPs and 96 are EORTC members. To date 5 Non-North American RTOG Members Institutions have been credentialed for IMRT. The anthropomorphic phantom pass/fail data for IMRT and SBRT credentialing was presented and it was noted that 48% (408 sites) of RTOG members have irradiated the IMRT H&N phantom and 14% (119 sites) had irradiated the

IMRT pelvic phantom. Approximately 8% (68 sites) of RTOG members have irradiated the lung phantom. The institutions listed on the TLD delinquent list for not having returned the TLD within 2 months have had letters sent to them by Federal Express with receipt requested by the institution. These reminder letters state that they need to complete the TLD monitoring and that their status is reported to this committee. The monitoring of the Proton facilities was discussed and Geoff will update this committee as more sites complete their monitoring. There are now seven clinical facilities that have been monitored at least once.

Other Business

Meeting was adjourned at 6:10 PM.

RTOG Semiannual Meeting Minutes

Committee Name: **Pathology**
Meeting Date: June 19, 2010
Meeting Time: 3:00-4:00 pm
Meeting Location: Philadelphia, PA
Chair/Moderator: Anthony Magliocco, MD

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1. 0617 – Q. Le looking at pretreatment v. post
2. Update inventory when it's exhausted. Not reviewing cases unless there's an ongoing study.
3. 0234 – Q. Le wants identified pathology.
4. Central Review: Need H&H and a block of highest grade portion of tumor. 0920 – how is El Nagaar being paid?
5. Discussion of electronic forms (w/ pull-down menu)
6. Integral studies
   - Integral markers for trial to proceed must be done in US in CLIA lab
   - Need MTA for Q. Le's Hong Kong review?
7. FFPE – question is slide v. plug or block. Sandy amends protocols as required.
8. TRP review process: still questions as to integral TRP –approved? MTAs required?
9. Authorship discussion – Q. Le & C. Chung support as it helps acceptance of a paper when shown that pathology is integral to study.

RTOG Semiannual Meeting Minutes

Committee Name: **PROTON WORKING GROUP**
Meeting Date: June 19, 2010
Meeting Time: 7:00 – 8:00 AM
Meeting Location: Washington C – Loews Philadelphia Hotel; Phila., PA
Chair/Moderator: Tom DeLaney, M.D.

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1. **Proton Therapy in Cooperative Group Trials**
   Jeff Michalski, M.D. presented the update Advanced Technology Consortium Guidelines for the Use of Proton Radiation Therapy in NCI Sponsored Cooperative Group Clinical Trials. The Advanced Technology Consortium (ATC) has facilitated the development of general guidelines for protocols that incorporate proton radiation therapy (PRT) as an option. The first version was promulgated in 2007 and the document has been updated to allow scanned beams.

2. **Credentialing of Proton Centers for Cooperative Group studies.**
   Geoff Ibbott, Ph.D. provided an update on credentialing of 7 U.S. and 1 Japanese proton centers for Cooperative Group Studies. It is expected that credentialing of several institutions will be completed shortly. Dr. Michael Moyers has been engaged as a consultant to help develop optimal procedures for credentialing assessment.

   – Michael Gillin, Ph.D. presented a proposal for a multi-level approval process based upon the technical complexity of the proton techniques, with Category 1 to include the most simple sites with field sizes equal to or greater than 3 cm x 3 cm, intra-fraction motion not commonly considered in treatment planning, agreement between calculated and measured dose to a volume 3 mm or better, single target volume, IGRT using phantom within 2 mm, scanning beam or IMPT not allowed (i.e. prostate), Category 2 to be intermediate to include multiple targets which require abutting fields (i.e. craniospinal radiation), and Category III :
   – Category 3A Agreement in dose to volume between calculated and measured dose within 1.5 mm
   – Category 3B Small Fields, < 3 cm x 3 cm
   – Category 3C Motion Management Required
   – Category 3D IGRT within 1 mm
   – Category 3E IMPT(Intensity Modulated Proton Therapy) Single Field Optimization
   – Category 3F IMPT (Intensity Modulated Proton Therapy) Multiple Field Optimization

   Dr. Gillin asked for approval of this proposal from the Proton Trials Working Group and this was approved without dissent.

3. **These protocols/ concepts were discussed:**

A. Comparison of Patient Reported Outcome of Proton Beam and Intensity Modulated Radiation Therapy (IMRT) in the Treatment of Patients with Low and Intermediate Risk Prostate Cancer : Jason Efstathiou, M.D.
   i. Randomized study
   ii. Registry study

   Grant funding is being sought to help support these studies.

B. Concurrent Proton Therapy and Chemotherapy in locally advanced stage IIIA/B Non-Small Cell Lung Cancer (NSCLC) (Joe Chang)

   Stage III chemoradiation 74 Gy with protons or alternatively randomized to protons versus photons.

   Will await guidance from Medical Physics Committee on when the proton institutions would be ready to deliver these Category 3 proton treatments.

B1. Michael Gillin, Ph.D. discussed some of the technical challenges on using protons for treating lung patients (Gillin)

C. RTOG 0930 (Developing) Phase II Trial Of Stereotactic Radiosurgery (SRS) To Treat Persistent Acromegaly Following Surgery (Protons allowed)
   This study had been discussed at the January 2010 meeting; will need to follow-up on its status

D. RTOG 0539 Phase II Trial Of Observation For Low-Risk Meningiomas And Of Radiotherapy For Intermediate and High-Risk Meningiomas
   This protocol is to allow IMRT or protons for treatment of the intermediate and high-risk patients.

E. Other protocols/concepts

   1. Radiotherapy with concomitant weekly docetaxel and abbreviated adjuvant hormonal therapy for high risk prostate cancer and greater than a 15% risk of pelvic lymph node involvement [Protons; IMRT or 3DCRT]
      Dr. Nichols indicated that this concept would be reviewed with the GU group.

   2. Phase II Trial of Image Guided Proton Therapy for Intradural Extramedullary Neurofibromas or Malignant Peripheral Nerve Sheath Tumors in NF1 Patients

      Dr. Henderson presented this concept. It was also forwarded to the CNS group. The groups will discuss whether there is sufficient interest to proceed with development of this concept.

RTOG Semiannual Meeting Minutes

Committee Name: **Translational Research Committee**
Meeting Date: June19, 2010
Meeting Time: 10:00 am-12:00 pm
Meeting Location: Philadelphia, PA; Loews Philadelphia Hotel, Regency A
Chair/Moderator: Adam Dicker, MD, PhD

1. New developments at RTOG HQ for the TRP: Dr. Adam Dicker
   - New TRP Administrator
   - Coordination of TRP procedures
   - New review process to come

2. Update of Biorepository: Dr. Fred Waldman
   - Priorities/activities
   - Inventory & types of specimens
   - Informatics/caTissue
   - Development of new trials – markers, criteria for collection, central review.
   - Specimen request process & MTA

3. Invited speaker: Dr. Ulrich Rodeck, Thomas Jefferson University

"Novel approaches to mitigate skin toxicity by EGFR inhibitors"

   - Discussion of molecular mechanism in toxicity & antibody masking
   - Possibility of Dr. Rodeck and Dr. Christine Chung working in partnership as they have common areas of interest.

4. Invited speaker: Dr. Isidore Rigoutsos, Thomas Jefferson University

"Von Newmann meets Sanger: Toward novel diagnostics and therapeutics"

   - Outline of the von Newmann architecture
   - Creator of the CPU, father of genomics, computational biology & informatics

5. Invited speaker: Dr. Zhongxing Liao, MD Anderson Cancer Center

"SNPs as biomarker to guide personalized radiation therapy for lung cancer"

   - Targeted therapies & SNPs as biomarkers
   - Improving efficacy of chemoradiotherapy for lung and esophageal cancers using molecular targeting strategies

RTOG Semiannual Meeting Minutes

Committee Name:	**Brain Tumor Translational Research Committee**
Meeting Date:	June18, 2010
Meeting Time:	6:00pm-9:00pm
Meeting Location:	Loews Philadelphia Hotel, Congress A
Chair/Moderator:	Arnab Chakravarti

The RTOG Brain Tumor Committee discussed allocation of archival RTOG tissues for correlative research purposes. There was general consensus to recommend that the following investigators proceed with formal TRP application for acquisition of tissues for correlative research purposes:

Kamalakannan Palanichamy, PhD: Cancer Stem Cell Markers for GBM
Pierre Robe, MD, PhD: Connexin Pathway in GBM
Abhijit Guha, MD: EGFR pathway in GBM

Progress on the NIH RC2 Challenge Grant was discussed and it was decided to us the RC2 grant as a conduit for preliminary data for the SPORE grant. Our objective would be to submit the SPORE grant during the latter half of 2011. The SPORE grant would be based upon tissues from RTOG 0825, using both treatment arms.

RTOG Semiannual Meeting Minutes

Committee Name: **Breast Translational Research**
Meeting Date: June 18, 2010
Meeting Time: 1:30 – 3:00 pm
Meeting Location: Regency C2 – Loews Philadelphia Hotel; Phila., PA
Chair/Moderator: Wendy Woodward, M.D., Ph. D.

Welcome
Introductions – contact info collected.
TRP Funding Update –significant funding unlikely to be available. Contacting veridex, and planning grant submissions to fund 10-14.

Completed Protocols:

- RTOG 98-04, Pathology review of DCIS cases – Dr. Sneige reviewed 10% of cases, N = 43. Report was presented. Summary – many cases were incomplete (uncut blocks, wrong tissue, missing paperwork etc..).
    - Action: Re-grouping with biospecimen resource and will re-send 43 complete sets for review.

Active Protocols:

- NSABP B-39/RTOG 04-13
- RTOG 1014, a phase II study of repeat breast preserving surgery and 3DCRT PBI
    - Activated as of June 2010 – CTC collection reviewed.
    - Action – present to research associates: highlighting the RTOG kits will have new tube (cellsave) and fed ex for shipping this tube only to MDACC within 24 hours of the blood draw for immediate processing.

Developing Protocols:

- RTOG 08-44 Hypofractionated ablative radiation for oligometastatic breast cancer (A. Minn/ S. Chmura) **–** Changing to phase 1 trial with toxicity endpoint. TRP component DOD funded.

- RTOG 1005**:** A Phase III Trial to Evaluate the Technical Feasibility IMRT/ 3DCRT to Deliver WBI to Patients Versus a 4-Week Course of Hypofractionated IMRT for Accelerated WBI with a Concomitant Boost. (Vicini/ Freedman) – Considering revising eligibility to meet expected event rate. TRP plan: SNPs and CT data archiving. Intrinsic subtype analysis.
    - SNP plan written by Bentzen/Rosenstein/Deasy
    - Will need funding – plans will remain flexible as technology/climate changes over time

- RTOG 0917 A Two-Arm, Stratified, Phase II, Paradigm-Shifting, Prospective Trial Investigating the Avoidance of Postmastectomy Radiation and Regional Lymph Node Radiation for Breast Cancer Patients with Clinical Stage T1,2N1 Disease Who Have Negative Lymph Nodes After Neoadjuvant Chemotherapy **(Buchholz/ Hunt/ White/ Julian) –** Rejected by CTEP. Further development under consideration.

- RTOG 10-17 Randomized Phase II Study Evaluating the Feasibility of 3DCRT/IMRT for Preoperative and Postoperative Local and Regional Nodal Irradiation Following Neoadjuvant Chemotherapy for Clinical Stage III Breast Cancer: (**White/Woodward/Meric-Bernstam**), predictors of radiation response.

    - Significant discussion – plan to change to a phase II randomized comparison with pCR endpoint

Concepts:

- A Phase II trial assessing locoregional control and cosmesis in patients treated with neoadjuvant chemotherapy followed by breast radiotherapy after achieving a MRI complete radiographic response **(J. DeLosSantos)**
    - TRP development pending research strategy review. Conference call with J.DeLS in the fall to discuss TRP

New:

Planning a research strategy meeting at headquarters in the fall to include breast radiation thought leaders and develop 5-10 year plan. Key speakers form this session will be invited as a part of a mini symposium with GYN in the January 2011 meeting.

Concept to be explored – can the rtog develop a protocol to bank tissue submitted from sites treating patients with recurrence independent of clinical protocols for future research?

RTOG Semiannual Meeting Minutes

Committee Name: **GI Translational Research**
Meeting Date: June 19, 2010
Meeting Time: 8:00-10:00 am
Meeting Location: Philadelphia, PA

EMAILS OF ATTENDEES: mazzonimm@lilly.com; bruce.minsely@uchospitals.edu; Christopher.willett@duke.edu; dgrisell@health-first.org; mresnick@lifespan.org; hsafran@lifespan.org; terencesio@gmail.com; Geoffrey.liu@uhn.un.ca; jeff.simko@ucsf.edu; RTOGManager@ucsf.edu; kwinter@acr-arrs.org; lisa.kachnic@bmc.org; joe@jhmi.edu; tshong1@partners.org; Darlene.gabeau@einstein.yu.edu; maursar@aol.com; pkmcallister@wisc.edu; kate.murphy@fightcrc.org; wenyin.shi@gmail.com; welliver@xrt.upenn.edu; magliocc@ucalgary.ca

NOTE:

1. 0436 project – monthly conference all request; need to help w/ compliance
2. Chris Willet – Amgen and funding issues
3. Edgar presentation – Caviolin-1 and GSK-3ß. They are submitting to TRP. Some uniformity would be favorable. Platform is HistoRx. It is our image analysis platform. Submit for tissue which will trigger dialogue on doing this in appropriate format.
4. Dipen Maru, MD Anderson
5. Funding issues – 9704 data set interest & biomarkers/normal tissue – trying to get an overall plan for tissue use to predict appropriate biomarkers for progressive study process
6. Need to be better organized as a group as to what institutions can do what types of analysis – teleconferencing every other month
7. Retreat idea discussed

RTOG Semiannual Meeting Minutes

Committee Name: **Genitourinary Translational Research**
Meeting Date: June 19, 2010
Meeting Time: 4:00-6:00 pm
Meeting Location: Philadelphia, PA
Chair/Moderator: Alan Pollack, MD, PhD

The focus of the meeting was on the potential to put together a P01 based on a theme of “Androgen Receptor Modulation for Prostate Cancer Treated with Radiotherapy ± Androgen Deprivation Therapy" . Potential projects were discussed. There is a wealth of prior biomarker data using immunohistochemistry to quantify expression from tumor tissue of patients treated on RTOG protocols 86-10 and 92-02. This work provides a foundation for moving forward into new areas and exploring mechanisms related to these biomarkers and new ones that have been identified more recently.

Other items discussed:

1) Prostate: Carver, Scardino: PTEN and ERG
2) Prostate: Alex Pearlman: Genomic analysis for the identification of patients at risk of metastasis.
3) Prostate: Mansoor Ahmed: EGR1 and pRB.
4) Bladder: Jason Efstathiou: Protocol 0712 and collection of urine samples. Protocol will be expanded
5) Bladder: Bill Shipley: VEGF still incomplete – at RTOG for over a year.

Action items: a teleconference will be arranged to initiate the process for a P01 retreat.

RTOG Semiannual Meeting Minutes

Committee Name: **GYN Translational Research**
Meeting Date: June 18, 2010
Meeting Time: 3:00-4:00 pm
Meeting Location: Philadelphia, PA
Chair/Moderator: David Gaffney, MD, PhD

Twenty-three investigators signed in for the GYN TRP meeting. Dr. David Gaffney gave an overview of active studies. Dr. Weidhaas was not able to be in attendance due to personal reasons. Additionally, an overview of samples From the RTOG tumor repository was provided to members present. Dr. Weidhaas had forwarded slides, and these were presented by Dr. Gaffney. He described the work that Dr. Weidhaas had been doing in micro RNA species in gynecologic oncology, and in oncology in general.

Next, Dr. Larissa Lee from Brigham and Women's Hospital in Boston provided a short power point presentation on her work in micro RNA species in endometrial cancer from the RTOG tumor tissue repository. Dr. Larissa Lee was a recipient of an ACR RTOG resident fellowship. Her presentation was well-received, and she will be presenting her work at ASTRO in the fall of 2010.

Dr. Tony Magliocco gave a presentation on aqua technology and describing the benefits of fluorescent based processes compared to standard immunohistochemistry. He gave an update on the RTOG/CARO collaboration. There is ongoing work performed by Dr. Doll and Dr. Magliocco in cervix cancer. The meeting was concluded by addressing questions from the membership. Grants relating to GYN TRP work were specifically encouraged.

David K. Gaffney, M.D., Ph.D.
Professor

DG:slmt

D: 06/28/2010
T: 06/28/2010
J: 5672

RTOG Semiannual Meeting Minutes

Committee Name: **Head & Neck Translational Research Program**
Meeting Date: June 18, 2010
Meeting Time: 3:00-4:00 PM
Meeting Location: Philadelphia, PA
Chair/Moderator: Christine H. Chung, MD

1. TRP Update

Two publications were accepted since the last meeting.

Ang KK, Harris J, Wheeler R*, et al.* Human papillomavirus and survival of patients with oropharyngeal cancer. *New England Journal of Medicine*; Epub June 7, 2010.

Chung CH, Zhang Q, Hammond E*, et al.* Integrating EGFR assay with clinical parameters improves risk classification for relapse and survival in head and neck squamous cell carcinoma. *Int J Radiat Oncol Biol Phys* 2010; *in press*.

Two abstracts were presented at the ASCO 2010 annual meeting.

Gillison M, Zhang Q, Ang KK*, et al.* Analysis of the effect of p16 and tobacco pack-years (p-y) on overall (OS) and progression-free survival (PFS) for patients with oropharynx cancer (OPC) in radiation therapy oncology group (RTOG) protocol 9003. *Proc Am Soc Clin Oncol* 2010; 28 Abst# 5510.

Chung CH, Dignam J, Hammond ME*, et al.* High Gli1 expression is associated with poor survival in head and neck cancer patients treated with radiation therapy (RTOG 9003). *Proc Am Soc Clin Oncol* 2010; 28 Abst #5552.

2. Presentation #1: Nasopharyngeal Carcinoma (Quynh Le, MD: Stanford University)

Dr. Le presented data on the use of post-treatment circulating EBV as a consistent and reproducible prognostic marker for outcomes (progression free and overall survival) in newly diagnosed NPC patients. She presented the data of using different primers, which produced consistent results with the BAM-HI primer being the most sensitive. She also showed the kinetic of decline during therapy for these patients. She concluded that based on these highly reproducible data in multiple countries, the RTOG is contemplating a phase III randomized trial using post-chemoradiation circulating EBV DNA level to randomize patients to either adjuvant chemotherapy or not and the type of chemotherapy used.

3. Presentation #2: Human papillomavirus in oropharyngeal cancer (OPC) from RTOG 9003 (Maura Gillison, MD, PhD: Ohio State University)

Dr. Gillison presented the data from RTOG 9003. Tumor HPV status for OPC patients was determined by a surrogate, p16 IHC (>70% expression positive). The p16 data were evaluable for 29% (190/646) of OPC patients and only 39% were pos. p16-pos tumors were associated with better Zubrod PS, absent anemia, and T1 stage, but not assigned treatment. Overall median pack-years (p-y) of tobacco smoking was high (38 p-y), but was lower for the p16-pos group (29 vs. 45.9 p-y, p=0.016). At median f/u of 9.3 years, p16-pos OPC patients had better OS (5-year 49.0 vs. 19.6%, p<0.0001; HR 0.43, 95%CI 0.31-0.61) and PFS (5-year 43.6 vs.19.0%, p<0.0001; HR 0.45, 95% CI 0.32-0.63) than p16-neg patients. At 5-years, local-regional failure was lower for p16-pos OPC (30.5 vs. 54.9%, p<0.001) but distant metastases (11.1 vs. 13.0%, p=0.71) and second primary tumors (SPT, 13.8 vs. 11.4%, p=0.40) were not. The hazard of death (OS) or progression and death (PFS) significantly increased by 1% per p-y of tobacco smoking (for both, HR 1.01, 95% CI 1.00-1.01, p<0.002), after adjustment for Zubrod PS, T stage, N stage and p16. The relative hazard of death or progression for p16-pos vs. neg patients and for p-y of tobacco smoking appears independent of treatment by radiotherapy or chemoradiation.

RTOG Semiannual Meeting Minutes

Committee Name: **Lung Translational Research**
Meeting Date: June 18, 2010
Meeting Time: 4:30-6:30 pm
Meeting Location: Philadelphia, PA
Minutes Recorder: Quynh Thu Le

1. Dr. Le opened the session and updated the progress of this group during last 6 months. This included (but not limited by) the followings:
    a. Continue enrolling patients to current opened RTOG studies: 0617, 0618, and 0915
    b. Update on the status tissue collection in the tissue bank for both recently closed and opened study (please see attached table)
2. Dr. Wendy Woodward, chair of the Breast TRP, updated the group on the current effort in the Breast Committee to implement circulating tumor cell collection as part of a correlative study in RTOG-1014. This will be the first RTOG effort to test the feasibility of collecting circulating tumor cells and will be performed at MD Anderson using a commercial system. The isolated cells, however, are fixed and cannot be used for any further studies.
3. Dr. Jonathan Beitler from Emory University presented his data on "Extracorporeal Detection of Circulating Cancer cells in Head and Neck Cancer Patients Using Pegylated Surface-Enhanced Raman scattering (SERs) Gold Nanoparticles and Laser Excitation". Preliminary data from his group suggested that a reasonable number of circulating tumor cells can be isolated from 18-20 head and neck cancer patients and these cells can be used for additional studies of gene and protein expression. This approach,

though preliminary, appears to yield exciting results. However, it's unclear whether it can be easily adapted for a group-wide study.

4. Dr. Jessica Donington from NYU presented her data on circulating Osteopontin as tumor marker for early stage NSCLC. She plans to propose this assay as a correlative study for the upcoming ACOSOG/RTOG study, randomizing high risk patients with early stage NSCLC to wedge resection versus SBRT.
5. Dr. Xing Liao, from MD Anderson, presented her data on TGF-b SNP as a marker for pulmonary toxicity and metastasis. They hope to validate their findings prospectively using both their institutional samples as well as samples from RTOG trials, possibly 0617 and 0839.
6. Dr. Christine Chung, from Vanderbilt, presented their data on a proteomic signature for EGFR targeted therapy, including cetuximab. This would be a potential predictive marker for Cetuximab benefit that can be tested using samples from 0617 and 0839.

3/26/10				Reviewed Cases	Reviewed Cases	Reviewed cases	Reviewed cases	Reviewed cases	Reviewed cases					
Study	# cases accrued	# cases w/ specimens	#cases with blocks	with blocks- no Tumor	with blocks with Tumor	available for FISH	available for DNA	potential # for TMA	**# cases with block for TMA w/ blood product**	# cases with block and blood product	# cases with Buffy coat	**Cases w/ Plasma**	**Cases w/ Serum**	**Cases w/ Urine**
0235	248	116	40	3	35	35	16	20	**0**	0	0	0	0	0
0324	93	69	32	3	17	17	8	12	**0**	0	0	0	0	0
0412	19	13	6	0	5	5	5	5	**2**	4	10	11	9	0
0617	234	150	81	0	76	76	47	36	**29**	66	131	132	131	125
0618	29	9	4	0	4	4	2	0	**0**	0	4	4	4	7

RTOG Semiannual Meeting Minutes

Committee Name: **Normal Tissue Translational Research**
Meeting Date: June 18, 2010
Meeting Time: 12:30-1:30 pm
Meeting Location: Philadelphia, PA
Chair/Moderator: Barry Rosenstein & Deborah Citrin

Attendance:

Barry Rosenstein, co-chair
Deborah Citrin, co-chair

Rosemary Wong	NCI	wongr@mail.nih.gov
Kyounghwa Bae	RTOG	KBae@phila.acr.org
Zhongxiang Liao	MDACC	zhaio@mdanderson.org
Dewlvin Simmons		dsimmons@frogdocs.com
Matt Parliament	Cross Cancer	Matthew.Parliament@albertaservices.ca
Soren Bentzen		Bentzen@HUMONC.WISC.EDU
Sharon Spencer		SSpencer@aubmc.edu
Fran Bradley	RTOG	
Alan Hartford	Dartmouth	Alan.c.hartford@hitchcock.org
Ritsuko Komaki	MDACC	rkomaki@mdanderson.org
Mitch Machtay		Mitchell.machtay@uhhospitals.org
Harry Ostrer		harry.ostrer@nyumc.org
Joe Deasy		deasy@radonc.wustl.edu
Fred Waldman		fred.waldman@ucsf.edu
Alex Pearlman		pearla02@nyumc.org
Lauren Carpiniello		Lauren.carpiniello@nyumc.org
Sarah Kerns		sarah.kerns@nyumc.org
Kas Badrozamani		kas_ray@hotmail.com
Joseph T. Chang		cgmhnog@gmail.com
Norm Coleman		ccoleman@mail.nih.gov
Sandy DeVries		rtog.manager@ucsf.edu
May Wahab		mwahab@med.miami.edu
Samy El-Sayed	Ottawa University	sel-sayed@toh.on.ca
Javier F. Torres-Roca	Moffit Cancer Center	Javier.torresroca@moffitt.org

Minutes

1. Meeting opened, welcome and introduction of speakers

2. Sarah Kerns provided and overview of her work on genetic risk factors for the development of adverse outcomes resulting from prostate radiotherapy. She

described work using GWAS to determine genetic predictors of ED. She described future studies using GWAS to evaluate for genetic predictors of urinary morbidity and proctitis. She discussed her plans to submit a proposal to RTOG to study SWAS in prostate cancer patients.

3. Matt Parliament discussed his pilot study of an integrated approach to predict normal tissue radiation toxicity using genomic biomarkers and dosimetry from RTOG 9406 and RTOG 0126. He described how the project ill be evaluating specific SNPs and will also utilize bioinformatics to correlate dose, SNP, and toxicity.
4. Joe Deasy discussed a proposed strategy for identifying and testing a genomic radiosensitivity signature that involved developing a database of known or probable radiation response genes from which to focus. He presented this as w work in progress with additional changes pending review and input from others in the group.
5. Meeting adjourned.