Message From Our NRG Oncology Group Chairs

Thank you, Philip J. DiSaia, MD!

Formally announced at the summer NRG Oncology Seminannual Meeting in Philadelphia, Pennsylvania, Philip J. DiSaia, MD, will be retiring from his position as one of NRG Oncology Group Chairs. A world-renown researcher and gynecologic oncologist, DiSaia served as Chairman for the Gynecologic Oncology Group (GOG) prior to their integration into NRG Oncology. In addition to his work with NRG Oncology, Dr. DiSaia is a medical director of the MemorialCare Todd Cancer Institute at Long Beach Memorial, the Dorothy Marsh Chair and Professor of Reproductive Biology at the University of California, Irvine College of Medicine in Orange, California, and a recipient of numerous honors such as the Frederick Naftolin Award for Mentorship by the Society for Gynecologic Investigation (SGI).

DiSaia has devoted 38 years to the care and research of women with ovarian cancer and gynecological cancers as well as the identification of better methods of prevention, diagnosis, and treatment for affected patients. He has published over 400 peer-reviewed articles, abstracts, and book chapters, including “Danforth’s Obstetrics & Gynecology” and “Clinical Gynecology Oncology”. Dr. DiSaia helped develop the world’s first experimental model of ovarian epithelial cancer, and this model is being studied in an effort to develop affective immunotherapy for women with ovarian cancer. His research also includes studies on estrogen replacement therapy in breast cancer survivors, the use of tumor necrosis factors for advanced endometrial and ovarian cancer, the use of interferon with combination chemotherapy for advanced ovarian carcinoma, the relationship between BCRA1 and BRCA2 mutations and outcome in ovarian cancer, and in-vivo florescence detection using photosensitizers as novel interventions in ovarian cancers as well as studies on the correlation of a novel biomarker (MN) in cervical carcinoma.

NRG Oncology is incredibly grateful for the dedicated leadership Dr. DiSaia has provided in his 46 years of service to GOG and NRG Oncology and for the contributions he has made to the gynecologic cancer community. We wish him well in his future endeavors.
NRG Oncology at ASTRO 2017

The American Society for Radiation Oncology (ASTRO) will hold its 59th Annual Meeting September 24-27, 2017 at the San Diego Convention Center. Below are some of the NRG Oncology research highlights you can expect to see.

ASTRO Updates Insurance Coverage Recommendations for Proton Beam Therapy

ASTRO has issued an updated Proton Beam Therapy Model Policy regarding medical insurance coverage recommendations for the use of proton beam therapy to treat cancer. The new policy outlines two categories of appropriate clinical indications for proton beam therapy. Read the ASTRO press release for more information.

Clinical Trials Session

NRG Oncology/RTOG 0526
A Prospective Phase II Trial of Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Adenocarcinoma Following External Beam Radiotherapy (NRG Oncology/RTOG 0526): Initial Report of Late Toxicity Outcome

September 24, 2017
3:15 pm - 4:45 pm


NRG Oncology/GOG 0249
A Phase III Trial of Pelvic Radiation Therapy versus Vaginal Cuff Brachytherapy followed by paclitaxel/carboplatin Chemotherapy in Patients with High-Risk, Early Stage Endometrial Cancer: A Gynecology Oncology Group Study

September 25, 2017
2:15 pm - 3:45 pm


More information on the ASTRO 2017 Plenary Session can be found here.

Best of ASTRO

NRG Oncology/RTOG 0915
Long-term Follow-up on NRG Oncology/RTOG 0915 (NCCTG N0927): A Randomized Phase II Study Comparing 2 Stereotactic Body Radiation Therapy Schedules for Medically Inoperable Patients with Stage I Peripheral Non-Small Cell Lung Cancer

Lung 1 - SBRT Session
September 24, 2017
4:45 pm - 6:15 pm


NRG Oncology/RTOG 0129 and 0522
Development of Laryngeal Cancer Nomograms from Pooled Data of Two Trials of Concurrent Chemoradiation: NRG Oncology RTOG 0129 and 0522

H and N 1 - Chemoradiation for Head and Neck Cancer Session
September 25, 2017
10:45 am - 12:15 pm


More information about NRG Oncology presentations at ASTRO and other major scientific meetings.
NRG-GI003

A Phase III Randomized Trial of Protons Versus Photons for Hepatocellular Carcinoma

ENROLLING NOW
Further protocol information and documents for this study located on CTSU.org

**Primary Objective:** To determine if overall survival is different for hepatocellular carcinoma patients treated with protons compared to photons.

**Key Eligibility Criteria:**
- Pathologically or radiographically proven unresectable or locally recurrent hepatocellular cancer
- Child-Turcotte-Pugh (CTP) A or B7
- Prior chemotherapy, targeted biological therapy, surgery, transarterial chemoembolization (TACE), and ablation for present disease allowed

**Unique Protocol-Specific Requirements:**

1. **Complete & Submit the Letter of Intent (LOI)**
   - Participating sites must be able to deliver both treatment modalities *OR* partner with a proton facility.
   - Partnering sites are encouraged to discuss protocol logistics and to define roles of each center (e.g., who completes forms, who submits digital data, etc.) prior to registering patients.

2. **RT Credentialing Requirements**
   - Submit a CSI form to IROC Houston (www.irochouston.mdanderson.org *OR* complete on the protocol-specific page on the CTSU website). Indicate the RTF# of the proton site with which you wish to align. (i.e. RTF #XXXX)
   - Submit Facility Questionnaire – distinct for proton and photon.
   - Submit protocol-specific phantom irradiation (liver; see protocol for more details).

**Study Design:** Following confirmation of payment for both possible treatments to minimize crossover bias, patients will be stratified with respect to planned number of RT fractions (5 vs. 15) and tumor vascular thrombus (yes vs. no) and then randomized to one of two treatment arms. Treatment arm one will receive proton RT and treatment arm two will receive photon RT. One-hundred and sixty-seven randomized patients are required.

“Radiotherapy has emerged as an effective treatment for unresectable HCC. Most of the existing data uses photon-based techniques. A growing body of literature suggests that protons may be advantageous because of the unique dosimetric characteristics of protons. However, resource availability precludes the routine use of proton therapy for HCC. This study seeks to directly compare proton radiotherapy vs. photon radiotherapy in unresectable HCC in a phase III randomized trial. The primary endpoint is overall survival.”

Theodore S. Hong, MD - NRG-GI003 Principal Investigator

NRG-GU003

A Randomized Phase III Trial of Hypofractionated Post-Prostatectomy Radiation Therapy (HYPORT) Versus Conventional Post-Prostatectomy Radiation Therapy (COPORT)

ENROLLING NOW
Further protocol information and documents for this study located on CTSU.org

**Primary Objective:** To demonstrate that HYPORT does not increase patient reported gastrointestinal and genitourinary symptoms over COPORT at the 2-year time point.

“Moderate hypofractionation has been shown to be safe for the definitive treatment of prostate cancer. Whether the same is also true post-prostatectomy is a logical question and the primary objective of GU003.”

Mark Buuyounouski, MD - NRG-GU003 Principal Investigator
Recently Activated NRG Oncology Clinical Trials (continued)

NRG-GY011
A Randomized Surgical Window Pilot Investigation of the Relationship of Short Term Medroxyprogesterone Acetate (NSC #26386) Compared to Medroxyprogesterone Acetate Plus Entinostate (NSC #706995) on the Morphologic, Biochemical, and Molecular Changes in Primary Endometrioid Adenocarcinoma of the Uterine Corpus

**Primary Objective:** To determine whether the addition of histone deacetylase inhibitor, entinostat, in combination with medroxyprogesterone acetate in the pre-operative setting results in up-regulation of activated-progesterone receptors compared to medroxyprogesterone acetate alone.

**Study Design:** This study is designed as a two-arm, open label, randomized, surgical window trial with a short term medroxyprogesterone acetate reference arm and an experimental arm of short term medroxyprogesterone acetate followed by entinostat (given over three doses). Treatment will be given prior to standard of care surgery, hysterectomy, to test the validity of the proposed mechanism of action of entinostat in the short term.

ENROLLING NOW
Further protocol information and documents for this study located on CTSU.org

Linda Duska, MD - NRG-GY011 Principal Investigator

NRG-BN005
A Phase II Randomized Trial of Proton vs. Photon Therapy (IMRT) for Cognitive Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas

**Primary Objective:** To determine whether proton therapy, compared to photon radiotherapy, preserves cognitive outcomes over time as measured by the Clinical Trial Battery Composite (CTB COMP) score (calculated from the Hopkins Verbal Learning Test Revised [HVLT-R] Total Recall, HVLT-R Delayed Recall, HVLT-R Delayed Recognition, Controlled Oral Word Association [COWA] test, and Trail Making Test [TMT] Part A and Part B).

**Study Design:** Patients will register to step 1, complete neurocognitive assessments, and then move to step 2 for random assignment. Step 2 will stratify patients according to baseline cognitive function (impaired vs. not impaired), resection status (gross vs. subtotal), and 1p19q status (co-deleted vs. intact), and then randomly assign them to proton radiotherapy or photon radiotherapy. Adjuvant temozolomide starts 28 days after completion of radiotherapy on both arms.

ENROLLING NOW
Further protocol information and documents for this study located on CTSU.org

“Patients with IDH mutant low to intermediate gliomas may have long life expectancies and therefore are at risk for adverse effects of radiotherapy including cognitive dysfunction. This study is notable in that it seeks to determine if proton therapy, which spares normal brain tissues from excess radiotherapy, is associated with better cognitive and quality of life outcomes as opposed to photon (IMRT) therapy.”

David Grosshans, MD - NRG-BN005 Principal Investigator

NRG Oncology/RTOG 0631 Closure Notice

Due to successful accrual, NRG Oncology/RTOG 0631 “Phase II/III Study of Image-Guided Radiosurgery/SBRT for Localized Spine Metastasis” closed to accrual on August 4, 2017. Please be reminded that data collection and site IRB renewal for closed studies must continue until the study is terminated. Congratulations to the study team and all participating sites on the NRG Oncology/RTOG 0631 trial!
Featured NRG Oncology Publications

Results of NRG-RTOG 0436 Highlight the Need for Biomarkers in Treatment of Esophageal Cancer

The NRG Oncology/RTOG 0436 study has determined that adding an epidermal growth factor receptor (EGFR) inhibitor to a chemo-radiation regimen does not improve overall survival for patients with locally advanced esophageal cancer treated in a non-operative manner. These results are reported in “Effect of the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation Therapy for Patients with Esophageal Cancer – The NRG Oncology/RTOG 0436 Phase 3 Randomized Clinical Trial,” which was recently published in the Journal of the American Medical Association (JAMA) Oncology.

Read the full press release

The ABC Trials: Anthracyclines in Early Breast Cancer

Early breast cancer research demonstrated that a docetaxel and cyclophosphamide (TC) regimen was superior to the doxorubicin and cyclophosphamide (AC) regimen with improvement in overall survival at a median follow-up of 7 years. These findings led to collaborative efforts between US Oncology Research and the NSABP (subsequently NRG Oncology) to determine if TC6 was noninferior to TaxAC regimens in patients with high-risk human epidermal growth factor receptor 2-negative breast cancer. The results, “Anthracyclines in Early Breast Cancer: The ABC Trials – USOR 06-090, NSABP B-46-I/USOR 07132, and NSABP B-49 (NRG Oncology),” were recently published in the Journal of Clinical Oncology.

The ABC trials were a prospectively planned, jointly analyzed series of three adjuvant trials, which enrolled a total of 4,242 women: 2,125 women were randomly assigned to TC6 treatment and 2,117 were assigned to the standard TaxAC regimen. The three trials included US Oncology Research (USOR) 06-090, which compared TC6 to docetaxel, doxorubicin, and cyclophosphamide (TAC6), National Surgical Adjuvant Breast and Bowel Project (NSABP) B-46-I/USOR 07132 which compared TC6, TAC6, and TC6 with bevacizumab, and NSABP B-49, which compared TC6 with several standard AC and taxane combination regimens. The primary endpoint of the study was IDFS and a hazard ratio that exceeded 1.18 for the TC6 versus TaxAC treatment defined inferiority for TC6. After the trials observed 334 IDFS events, researchers determined that the hazard ratio exceeded the predetermined 1.18 inferiority threshold, which triggered an early reporting for futility. The observed HR for IDFS based on the ITT analysis demonstrated a 4-year IDFS of 1.23 for TC6 versus TaxAC, which corresponded to 4-year IDFS rates of 88.2% for TC6 and 90.7% for TaxAC.

Read the abstract

Nomograms Provide Accurate Prediction of Overall Survival and Progression-Free Survival for Patients with Oropharyngeal Cancer

NRG Oncology researchers recently developed and validated a nomogram that can predict 2-year and 5-year overall survival (OS) and progression-free survival (PFS) for patients with local-regionally advanced oropharyngeal squamous cell carcinoma (OPSCC) treated primarily with radiation-based therapy. This nomogram was developed with data from clinical trials NRG Oncology/RTOG 0129 and 0522. Results were published online in the Journal of Clinical Oncology on August 4, 2017.

Read the full press release
NRG Oncology NCORP Updates

Protocol Credentialing: Let IROC Help You

Credentialing requirements for the NCI-sponsored National Clinical Trials Network (NCTN) trials that use advanced technologies, new imaging techniques, or require new treatment processes for radiatiotherapy (RT) can sometimes appear to be mysterious and/or daunting. But it doesn’t have to be! Imaging and Radiation Oncology Core (IROC) Houston’s website (http://irochouston.mdanderson.org) lists the specific credentialing requirements for NCTN protocols. The requirements for credentialing might include any combination of questionnaires, knowledge assessment forms, benchmarks, phantom irradiations, etc. This website shows active protocols categorized by NCTN group. The first thing that an institution is asked to do is to complete a credentialing status inquiry (CSI) form. (http://mdanderson.org/RPC/Forms2/Tech_protocols/Clinic_user.aspx). This form includes institution information that allows IROC Houston staff to identify your institution and to determine if it is already credentialed for the requested protocol or, if not, what still has to be completed to be credentialed. An IROC Houston physicist assistant will contact the institution to explain any remaining requirements of the specified protocol. Once all of the credentialing requirements are completed, IROC Houston will issue the credentials for the institution to the appropriate NCTN groups, IROC QA Centers, and to the institution. In many cases, an institution can simply be grandfathered and approved for a protocol based on previously completed credentialing. The figure shows the general credentialing process.

Fig.

Congratulations to the NRG Oncology NCORP Pilot Grant Awardees

CCDR Pilot Grant Awardees

Alexi Wright, MD
PROTECT: Patient Reported Outcomes to Enhance Care on Treatment

Erin Hahn, PhD, MPH
Breast Cancer Screening Decisions in Younger Women: A Hybrid Effectiveness-Implementation Study

CPC Pilot Grant Awardees

Canhau Xiao, PhD, MSN
SNP’s Association with Fatigue and Physical Activity in HNC Patients: Pilot Study for Inflammatory Mechanisms as Associated with HPV

Kathleen Sturgeon, PhD
Exercise as Medicine: Improved Cancer Control and Management of Cardiotoxicity

ATTENTION NCORP SITES

The American Society of Clinical Oncology (ASCO) Research Community Forum will be held September 24-25, 2017, at the ASCO Headquarters in the Washington D.C. metro area. This forum provides the opportunity for physician investigators and research staff to network and collaborate on best practices and solutions to common challenges. The program includes training workshops on insurance coverage and molecular and precision medicine, presentations and panel discussions on advancing cancer care, policies, partnerships and more, as well as networking sessions.

More information about the event located on ASCO’s website

www.nrgoncology.org
NRG Oncology NCORP Updates (continued)

NRG Oncology/GOG 0278 Study News

**Evaluation of Physical Function and Quality of Life (QOL) Before and After Non-Radical Surgery Therapy (Extra Fascial Hysterectomy or Cone Biopsy with Pelvic Lymphadenectomy) for Stage IA1 (LVSI+) and IA2-IB1 (≤2CM) Cervical Cancer**

We are almost 2/3 of the way to complete accrual!

To date, we have accrued 141 patients and the sample size is 220 patients. This study is open group-wide, and all NRG Oncology members are eligible to enter patients on this study. This is an easy study for patients and investigators to participate. No randomization required.

Thank you to all of the sites that have accrued patients to NRG Oncology/GOG 0278.

**For those sites with active patients,** please don’t forget to administer QOL Study Surveys at baseline (pre-op), 4-6 weeks Post-Op, and then every 6 months (6, 12, 18, 24, 30, 36) for the study duration.

**QOL Study Surveys Include:** Bladder and Bowel Function Items, Female Functioning Index and 2 PROMIS items, GCLQ-Gyn Cancer Lymphedema Questionnaire, Functional Assessment Cancer Therapy FACT-Cx, and Impact of Events Scale (IES). Patients in the Fertility Preservation Group will also complete the Reproductive Items (ICF & RCS) in addition to the items above. See protocol section 7.4 for additional information regarding the QOL Study Surveys.

Amendments have made the protocol even easier!

1) All visits AFTER the 4-6 week postop visit can be performed by a local gynecologist or GYN Oncologist.

2) The Quality of Life Assessment should be completed at the scheduled time points and should be administered at the clinic visit, whenever possible. In the event that the QOL questionnaires are not administered at the clinic visit, the QOL assessments after the 4-6 week postop visit can be collected by telephone, mail, or fax as back-up methods, with telephone data collection being the preferred back-up method.

Common Questions and Misperceptions:

1. This is a study of **non-radical** surgery (simple hyst and nodes or cone biopsy and nodes). Hence, patients who are planned to undergo radical hysterectomy are **NOT** eligible.

2. All patients must have undergone a LEEP or cone biopsy pre-study to determine depth of invasion.

3. **Margins** -

   - **Radial margin**- If positive on LEEP/cone biopsy (depth <10mm) and patient wishes fertility preservation, then repeat cone biopsy with pelvic lymphadenectomy and ECC is acceptable on study (**Eligible**).

   However, if the patient does not wish fertility preservation (simple hysterectomy), repeat cone biopsy is **required pre-surgery** to confirm eligibility.

   - **ECC/Endocervical margin**- If ECC is dysplastic only and endocervical margin negative for cancer on LEEP/cone biopsy, patient is **eligible** for study.

   If ECC is cancer or endocervical margin is malignant on LEEP/cone biopsy and patient wishes fertility preservation, then repeat cone biopsy with pelvic lymphadenectomy and ECC is acceptable on study (**Eligible**).

   However, if the patient does not wish fertility preservation (simple hysterectomy), repeat cone biopsy is **required pre-surgery** to confirm eligibility.

   - **Exocervical margin**- As long as maximum width of visible or palpable tumor is/was <2.0cm, patient is **eligible** for either cone biopsy or simple hysterectomy. Colposcopy is advisable to determine eligibility.
NRG Oncology Semiannual Meeting

Top Accruing Sites
January 1, 2017 to June 30, 2017

Top Accruing National Community Research Program (NCORP) Sites
1. Kaiser Permanente NCI Community Oncology Research Program
2. Catholic Health Initiatives NCORP
3. Southeast Clinical Oncology Research Consortium, Inc., NCORP
4. Heartland Cancer Research NCORP
5. Metro-Minnesota NCORP

Top Accruing Lead Academic Participating Sites (LAPS)
1. University of Oklahoma Health Sciences Center LAPS
2. CWRU – Case Comprehensive Cancer Center LAPS
3. Washington University – Siteman Cancer Center LAPS
4. University of Pittsburgh Cancer Center LAPS
5. Wayne State University – Karmanos Cancer Center LAPS

Top Accruing Main Member Sites
1. Seoul National University Hospital
2. Cadence Cancer Center in Warrenville
3. Abington Memorial Hospital
4. Sutter Cancer Research Consortium
5. US Oncology Research LLC – The Woodlands

Top 10 Non-US Sites
1. Asan Medical Center
2. Seoul National University Hospital
3. CHUM – Hospital Notre-Dame
4. Saskatoon Cancer Center
5. University Health Network – Princess Margaret Hospital

NRG Oncology Activity
January 1, 2017 to June 30, 2017

NRG Oncology Trials Activated

By Disease Site:
- Brain/Spine Tumors: 4
- Breast Cancer: 7
- Gynecologic Cancer: 16
- Gastrointestinal: 5
- Genitourinary: 3
- Head & Neck Cancer: 5
- Lung Cancer: 5
- TOTAL: 35

Activated Studies
- BR006: Pembrolizumab for TNBC (Ph III) SWOG-led/NRG Collaboration
- LU002: Oligometastatic NSCLC (Systematic Therapy +/- RT to Gross Disease) (Ph II/III)
- GI001: RT for Unresectable Cholangiocarcinoma (Phase III)
- BR005: Imaging/biopsies Breast After Neoadjuvant Chemo (Ph II)
- GY009: Resistant Ovarian (Doxil/Bev. +/- Atezolizumab) (Ph II/III)
- CC004: Buproprion for Sex Desire (Ph II) NCORP Study
- BN003: Atypical Meningioma (Early vs. Deferred RT) (Ph III)
- GI003: Liver (IMRT/SBRT vs. Proton RT) (Ph III)
- GU003: Post-op prostate CA Standard v. HypoFx XRT (Ph III)
- BN005: Grade II/III Glioma (IMRT vs. Proton RT) (Ph II)

Upcoming Activations in 2017
- BR004: Met. Her2+ Breast (Std. Drugs +/- Pembrolizumab)
- GI004: Met. Colorectal (Std. Drugs +/- Atezolizumab)
- GU003: Post-op Prostate CA Standard vs. HypoFx XRT
- GU005: Localized Prostate CA (IGRT/SBRT vs. IGRT/IMRT)
- GU006: High-risk Prostate CA (RT +/- Anti-Androgen)
- GYO11: Endometrium: Preop Window Megace/Entinostat
- HN004: H&N CA (Pt-ineligible) RT/Cetux vs. RT/Durva
- DT001: Sarcoma (RT + AMG-232)

NRG Oncology Publications Volume
January 1, 2017 to June 30, 2017

Total: 182 Publications

Abstracts
- Accepted/In Press: 33 (43%)
- Presented: 25 (33%)
- Submitted: 17 (22%)
- Rejected: 1 (2%)
- TOTAL: 78

Articles
- Published/E-Pub: 56 (53%)
- Accepted/In Press: 5 (5%)
- Submitted: 16 (15%)
- Under NRG Review: 14 (13%)
- Rejected: 15 (14%)
- TOTAL: 106

NRG Oncology Biospecimen Bank by the Numbers

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January 1, 2017 to June 30, 2017
Patient-Reported Outcomes Data Completion Rates Unacceptably Low in NRG Oncology Trials

An increasing number of NRG Oncology trials have high rates of missing patient-reported outcome (PRO) data. For many trials, there is < 80% completion of PRO surveys, even at time points within the first year of patient registration; for some trials, PRO completion falls below 50%. These high rates of missing data threaten the validity of the PRO end points, and can make these data unpublishable. This, in turn, is problematic for the clinical trial participants who volunteer extra time to complete the PRO surveys in order to contribute new knowledge that may help future patients. It should be noted that PROs, like other end points in clinical trials, are not optional. Even for patients who have developed cancer progression and/or after treatment stops, PRO data should continue to be collected at trial-specified time points.

To address this issue, NRG Oncology has created a PRO Compliance Working Group, which meets regularly to review the PRO completion rates of all open NRG Oncology trials. The Working Group will identify trials and participating sites with high rates of missing data – and work with specific trial investigators, and site PIs and CRAs, to identify challenges in PRO data collection and potential ways for significant improvement. Further, PRO data completion will become a point of emphasis at site audits. The Working Group will continue to design and implement a multi-pronged approach to increase awareness of the importance of PRO end points and increase their completion across trials. To that end, please join us in improving our outcomes by emailing Ronald Chen, Chair of the Working Group (ronald_chen@med.unc.edu), to identify problems and solutions with PRO data collection.

NRG Oncology Protocol Support Committee (PSC) Column

Clinical Trials Nurse (CTN)/Clinical Research Associate (CRA) Educational Session July 2017

By Sally Brown, Melinda Weiblen, Co-facilitators Education and Training Working Group

The CTN/CRA educational session provided new content, new formats, and successfully met the goal of educating and keeping members up-to-date on important practices and NRG Oncology processes and initiatives. The sessions included:

1. Improving Diversity in Clinical Trial Enrollment, Challenges and Opportunities
2. Self-Care and Nursing: Experiencing Ways to Take Care of Us!
3. CTSU Updates
4. SDMC—Impact of Consent Withdrawal
5. Registration and Credential Repository and Delegation of Tasks Log

The aforementioned presentations were recorded and are available on the NRG Oncology website (CME is not available). Log onto the NRG Oncology website using your CTSU IAM log in, navigate to the “Nurses and CRAs” tab, then select the Education and Training link in the left column.

Notably, the afternoon session format changed to “Ask the Expert” round tables. There were 24 content-specific tables staffed by NRG Oncology headquarters content experts. Over seven rotations each lasting 20 minutes, participants circulated from table-to-table based upon unique needs and specific questions. It was an opportunity to ask outstanding questions and to learn from colleagues’ questions.

The Education and Training Working Group is currently developing the program for the next two meetings, a 4-hour educational session in January 2018 (Phoenix, AZ), and an all-day educational session in July 2018 (Philadelphia, PA). If you have any ideas for topics and/or speakers, please send a quick note to: NRG-PSC@nrgoncology.org.

All-day orientation will also be offered in January 2018 for individuals new to NRG Oncology who have one year or less of experience.

Low-Level Laser Therapy for the Prevention and Treatment of Oral Mucositis (OM)

By Karen Holeva

For patients with Head and Neck Cancer, treatment can cause a multitude of toxicities including but not limited to: changes in mastication and speech, xerostomia, dysphagia, and dysgeusia. Additionally, it can lead to oral mucositis (OM) with associated anorexia and pain. Supportive interventions can help ameliorate these symptoms.

continued on next page
NRG Oncology PSC Column (continued)

Low Level Laser Therapy for the Prevention and Treatment of Oral Mucositis (continued)

Multiple, randomized controlled trials indicate that low level laser therapy (LLLT) is a promising tool in both the prevention and the treatment of chemoradiotherapy-induced OM. LLLT or “light therapy,” uses lasers to improve tissue repair, reduce pain, inflammation, and the severity and duration of OM. LLLT is administered daily prior to a patient’s radiotherapy starting on the first day of treatment and continuously for the entire course of treatment.¹

LLLT treatment guidelines are available from the manufacturer and can be adapted to develop an institutional practice standard based upon the research and recommendations. Importantly, LLLT is initiated prophylactically. The probe is applied extra-orally and penetrates the right and left buccal mucosa, and then applied intra-orally to the tongue and soft palate. A complete oral assessment is performed during each LLLT treatment to identify areas of mucositis. If the patient develops intraoral lesions they are targeted directly with the intraoral probe for 1 minute to each noted lesion. The settings are: frequency 2.5 Hz, wavelength 660 nm, and power 75 mW, for 4.5 J of energy.

Some patients have noted stinging or burning when the intraoral probe is used, otherwise there are minimal side effects noted and no patients have discontinued LLLT during radiation therapy. Early results suggest a reduction in oral mucositis rates compared to historical controls.

Overall, head and neck cancer patients treated with chemoradiotherapy are at an increased risk for developing toxicities. Novel techniques such as LLLT aim to minimize oral mucositis rates and to reduce pain. Furthermore, recent randomized data shows that utilizing LLLT improves treatment compliance, reduces treatment breaks, and, in turn, leads to improved outcomes.

Reference:

NCI Registration and Credential Repository (RCR)

By now you should have heard about the new RCR requirements. The RCR launched on July 31, 2017. All individuals involved in the conduct of NCI-supported trials as an Investigator (IVR), Non-Physician Investigator (NPIVR), or Associate Plus (AP) (i.e., those needing access to OPEN and/or RAVE, conducting audits, or acting as primary points of contact for their organization) will utilize the RCR application to re-register at the time of their next annual registration. Note:

• At the time of your annual registration all IVRs, NPIVRs, and APs will need to provide confirmation of Human Subjects’ Protection (HSP) as well as Good Clinical Practice (GCP) training by providing copies of their certificates. A copy of their biosketch is also required.

• Currently, HSP training is only required once unless your certificate expires. GCP training is required every 3 years or sooner if the course you take expires before 3 years.

• Ensure investigators and coordinators at your site have CTEP IAM accounts. If your IVR is not sure if they have an IAM account, have them access the IAM application at https://eapps-ctep.nci.nih.gov/iam/, select “Request New Account,” and follow the steps to begin an account request (they will need their CTEP investigator ID). IAM will indicate if an account is already set up for the IVR.

• You can set up a Registration Coordinator (RC) for your investigators by e-mailing CTEPRegHelp@ctep.nci.nih.gov with a subject line of “Make Me a Registration Coordinator” and include the RC’s full name, CTEP person ID, CTEP site code, and a list of investigators (CTEP investigator ID and full name) for whom they will be the RC.

For more information about the RCR requirements go to the NRG Oncology Website and review the updated slides (dated July 28, 2017) from the presentation at the NRG Oncology PSC education session and the RCR link posted to “2017 Announcements” on the “News” page on the NRG Oncology website.
Back to Basics: The Informed Consent Process

By Donna White and Joan Cahill

Presentation of the informed consent document initiates an individual’s formal involvement with a clinical trial. The informed consent process provides the foundation for the clinical trial experience and can be a very positive process. However, for someone first experiencing the world of cancer treatment, it can also be frightening and lengthy. It is important for the caregiver to initiate the process in a relaxed and patient manner with plenty of time for discussion and questions. The individual needs to know up front that the decision to participate is entirely voluntary and he/she should be encouraged to deliberate with friends and family before making a decision. The consent process is an open dialogue that permits time for questions and answers, to express thoughts and concerns, and for explanations between the research staff and the potential participant.

The following are helpful reminders to make the consent process useful to the participant and compliant with regulatory authorities:

- Prior to meeting with the participant confirm that the most current consent version is used and IRB approval has not expired.
- Cover all the basics of the trial: purpose; risks, and benefits; alternatives to study participation; extra procedures involved and how they differ from standard care; what is expected of the participant; what is expected of the research staff; study contact information; and any of the costs the participant should expect to incur.
- Reiterate that participation is voluntary and there will not be a penalty or loss of benefits for not participating or for discontinuing participation.
- Allow and encourage questions and provide complete answers.
- To assess comprehension, ask the participant to describe in his/her own words what the trial is about, what he/she is expected to do, and what he/she believes will happen as a result of participation.
- Give ample time, without pressure, for a truly informed decision to be reached.
- Once the participant agrees to participate, verify again that the current IRB approved consent is being used because changes may have occurred; obtain required signatures with dates; double check to see that all parts of the document are completed, specimen boxes checked, initials present if applicable, and that dates are correct; provide a signed and dated copy of the informed consent to the participant.
- Document the entire process in the patient record (more than one entry as applicable).
- Encourage ongoing conversation and questions after participation begins; keep open lines of communication.

The informed consent process is an important first step in clinical trial participation. It is critical that each step is carefully completed to ensure participant comprehension and to remain compliant with federal regulations.

NCI Registration and Credential Repository (RCR) (continued)

Also, you are encouraged to read the RCR and the Delegation of Tasks Log (DTL) section (pages 4-6) of the recent CTSU Newsletter (Spring 2017 Edition), which is now posted to “2017 Announcements” on the “News” page on the NRG Oncology website. Continue to monitor the CTSU Bi-Monthly Broadcast for information as it becomes available.

Please be aware that not being registered properly or not being current with training and document submission could impact the ability to enroll participants to trials. Be prepared to provide the required information when you are due for annual registration. Please note that you do not need to re-register in RCR immediately after production release on July 31st. Your current access and registration level will be applied until the time of your next routine re-registration.

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