Coming soon:
RTOG 0929, *A Randomized, Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblastoma*

RTOG 1014, *A Phase II Study of Repeat Breast Preserving Surgery and 3D-Conformal Partial Breast Irradiation (PBRI) for Local Recurrence of Breast Carcinoma*

GOG 248, *A Randomized Phase II Trial of Temsirolimus or the Combination of Hormonal Therapy Plus Temsirolimus in Women with Advanced, Persistent, or Recurrent Endometrial Carcinoma*

E5508, *Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC*

NSABP C-11, *A Phase III Study Evaluating the Role of Preoperative Chemotherapy and Bevacizumab in Patients with Potentially Resectable Hepatic Colorectal Metastases*

If your site is interested in participating in any of these studies please contact Rolma Gano at 215-955-7954 or Rolma.gano@jeffersonhospital.org.

**Regulatory Update:** The following studies have had recent consent form changes and updated letter posted on the repository website:
If these studies pertain to your site please visit the repository at: [http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/](http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/). Please contact Rolma Gano with any repository or other regulatory related questions.

**Quality Assurance Update:**
At the Network CRA meeting last month, Kelly presented some information from the SoCRA annual conference. One of the presentations at SoCRA was given by Lynn Blair-Anton from Vanderbilt University, who offered the "O SNAP" acronym for exceptional research coordination:
- **Offer your Opinion** - Provide your input prior to accepting any study at your site.
- **Screening Plan** - Where will patients be seen for care, who can you involve in the process?
- **KNOW your study** - Know your studies better than your PI! Radiate competence and confidence.
- **Attitude** - You never get a second chance to make a first impression. What you do, how you look, what you say, how you say it matters!
- **Proximity** - Close proximity and immediate access to patients translates to higher enrollment.

All Powerpoint presentations from SoCRA can be found on their website at [http://www.socra.org/html/SoCRA_Annual_Conference_Presentations.htm](http://www.socra.org/html/SoCRA_Annual_Conference_Presentations.htm).
CTSU Update:

**ACTION LETTER FOR CARBOPLATIN**: NCI/CTEP has issued an Action Letter to alert investigators of a modification of area under the curve (AUC)-based dosing of carboplatin (NSC 241240) in studies sponsored by NCI/CTEP. The purpose of this Action Letter is to alert investigators of a modification of area under the curve (AUC)-based dosing of Carboplatin and to request affected trials be amended to reflect this information. However, physicians should use the new method for carboplatin dose determination at the patient’s next treatment even if that is before protocol or IRB approval. Protocols affected are: **N063D, R0617, SWOG 0819, E1305, E1308, E2508, E3508, E4508, E5508, and E2603**

**Changes to the Reporting of Secondary Malignancies**: CTEP, NCI has recently changed the procedure for reporting AML/MDS and other Secondary Malignancies. Effective immediately:

1. All cases of treatment-related secondary malignancies (including AML and MDS) must be reported via the AdEERS Application on CTEP's website, [https://webapps.ctep.nci.nih.gov/ctep/plsql/gadeers_main_review$.startu](https://webapps.ctep.nci.nih.gov/ctep/plsql/gadeers_main_review$.startu). Non-treatment related secondary malignancies should not be reported via AdEERS.


3. Please continue to submit a copy of the pathology report confirming
the diagnosis of AML/MDS or a secondary malignancy, to supplement the AdEERS report, to both ECOG and CTEP. If reporting AML/MDS, please also submit a copy of the Cytogenetics Report (if available).

Please contact Joshua Schoppe with any CTSU related issues at 215-955-0448 or Joshua.Schoppe@jeffersonhospital.org

ECOG Update:

**E5508**, *Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC* is in the process of opening at TJUH. If your site is interested in participating please contact Joshua Schoppe.

**E1505**, *Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (> 4 cm) - IIIA Non-Small Cell Lung Cancer (NSCLC)*, addendum #9 has been TJUH IRB approved. This approval has updated the risks of bevacizumab and all patients on active treatment or within 30 days of receiving bevacizumab should be re-consented. Pages affected by these changes include 12 through 16 inclusively.

**E5202**, *A Randomized Phase III Study Comparing 5-FU Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers*, has temporarily closed as of October 7, 2010 based on a recent data review by ECOG. This review of E5202 was undertaken due to the recent press release regarding the outcomes of the AVANT study, a Genentech/Roche-sponsored international Phase III trial of FOLFOX or XELOX plus or minus bevacizumab for the adjuvant therapy of colon cancer. AVANT did not meet its primary endpoint.
for disease-free progression, and the efficacy data from AVANT favored the FOLFOX alone arm. The observed adverse events in AVANT were consistent with those previously reported in pivotal trials of bevacizumab across tumor types for approved indications. Based on their review, the ECOG Data Monitoring Committee has recommended the following actions be taken for E5202: The randomization of high-risk patients should be stopped and high-risk patients currently being treated with bevacizumab should stop the drug. Accrual to the study has been suspended to allow consideration of how to best complete the study’s biomarker objectives. All patients currently enrolled in the high-risk arm of the trial are to continue adjuvant therapy with mFOLFOX6 as described in the protocol document. Those assigned to the observation arm should also continue to be followed according to the protocol.

**ECOG FALL MEETING NOV 5th-7th:** Fall Group Meeting Registration is closing fast! Meeting registration will be done completely online again for this meeting. To register for the Group Meeting, please use the following link below. Please note that the schedule is updated on an ongoing basis. ECOG strongly recommends that all meeting attendees check the most current schedule online before making travel arrangements, as ECOG will not be responsible for ticket change fees due to scheduling changes.

[https://www.regonline.com/ECOG_Fall2010](https://www.regonline.com/ECOG_Fall2010)

If you have an ECOG related question please contact Joshua Schoppe.

**NSABP Update:**

**B-43:** Amendments #2 and #3 were posted in the website September 30, 2010. For details please refer to the correspondence at [https://members.nsabp.pitt.edu/B43_Amendment_2_3_Memo.pdf](https://members.nsabp.pitt.edu/B43_Amendment_2_3_Memo.pdf).

Patients who are in treatment or consented before approval of the amendments and revised consent "must receive updated information....this must adequately documented in the patient's record".
B-46-I: Amendments #1, #2, and #3 were posted September 22, 2010. Please refer to the correspondence in the Division of Industry Trials area on the NSABP website for details. These amendments do not require significant changes to the consent form.

NSABP has posted a document with detailed instructions for scheduling of protocol therapy for the holidays. It can be located in the Members Area under the Treatment Trials News link and is entitled: "Scheduling NSABP Protocol Therapy During the Holidays".

NSABP has announced their next group meeting. It is scheduled for March 24-27, 2011 in Boca Raton, FL. Meeting and travel information will be sent mid-January.

If you have an NSABP related question please contact Vicki Squire at vicki.squire@jeffersonhospital.org or at 215-503-5641.

RTOG Update: 
The RTOG 0436 August & September Newsletter is posted on the RTOG website at http://www.rtog.org/members/protocols/0436/0436broadcast.html. Kudos to Aria Health, Albert Einstein, and Jefferson for enrolling patients to this trial so far!

RTOG 0617, A Randomized Phase III Comparison of Standard-Dose (60 Gy) Versus High-Dose (74 Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel +/- Cetuximab in Patients With Stage IIIA/IIIB Non-Small Cell Lung Cancer, based on a recent amendment the TJUH IRB has mandated a re-consent. Risk on pages 10-11 have changed, due to a newly issued CAEPR for cetuximab. All patients on active treatment or within thirty days of receiving active treatment should be re-consented.
Registration for the **RTOG Semiannual Meeting** is now available at [https://registrations.acr.org/rtog](https://registrations.acr.org/rtog). The meeting will be held in San Diego, January 13-16, 2011. The meeting agenda and brochure can be found on the RTOG website at [http://www.rtog.org/meeting/main.html](http://www.rtog.org/meeting/main.html).

For those of you participating in **RTOG 0825**: RTOG urges you to strongly consider participation in the blood sample collection portion of this trial. RTOG recently received approval to undertake a large scale study to determine the clinical and genomic predictors of toxicity with temozolomide and bevacizumab with these samples, and the participation of your site is critical and essential to the success of this analysis. Please note the following:

- Blood samples can be obtained any time during the course of participation in this trial, even if the patient is in the post-randomized salvage component.
- The blood sample does **NOT** need to be spun down at the participating site. Specific instructions for blood collection are included in the protocol in Section 10 and Appendix VII.
- There is payment to sites for specimen submission. Reimbursement information is included in Section 10.6 of the protocol.

Please contact Joshua Schoppe or Vicki Squire with any RTOG related issues.

**Jefferson Oncology Group (JOG) Update:**
If your site has any JOG inquiries please contact either Josh Schoppe or Vicki Squire.

**Jefferson Kimmel Cancer Center Network Homepage:**
Upcoming Events:
Geriatric Oncology Conference, Philadelphia, PA: November 3
ECOG Fall Meeting, Ft. Lauderdale, FL.: November 5-7
JKCNN CRA Meeting, Philadelphia, PA: December 8
RTOG Semiannual Meeting, San Diego, CA: January 13-16
NSABP Semiannual Meeting, Boca Raton, FL: March 24-27

The Clinical Research E-News Archive is now located on the Kimmel Cancer Center webpage under the JKCCN Member Area:
http://www.kimmelcancercenter.org/jkccn/e-newsletters.html

Please provide feedback and any suggestions to Joshua Schoppe at 215-955-0448 or email Joshua.schoppe@jeffersonhospital.org