The Clinical Research E-News

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Studies that are coming soon to TJU:

**SWOG0421, Phase III Study of Docetaxel and Atrasentan versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer.**

**SWOG0518, Phase III Prospective Randomized Comparison of Depot Octreotide Plus Interferon Alpha Versus Depot Octreotide Plus Bevacizumab (NSC #704865) in Advanced, Poor Prognosis Carcinoid Patients.**

**E1508, A Randomized Phase II Study of Cisplatin and Etoposide in Combination with either Hedgehog Inhibitor GDC-0449 or IGF-1R MOAB IMC-A12 for Patients with Extensive Stage Small Cell Lung Cancer,** was activated nationally on July 16, 2009. TJUH will be participating in this trial.

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

**Regulatory Update:** The following studies have had recent *consent* form changes posted on the repository website:

- R0521
- R0415
- R0537
- R0126
- C80405
- R0524: suspended to patient entry (letter on repository).
If any of these studies pertain to your site please visit the repository at: http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/. Please contact Rolma Mancinow at with any repository or other regulatory related questions.

**Quality Assurance Update: New IRB re-consenting policy:** A deserved thank you goes out to Jennserville Regional Hospital, Pocono Medical Center, Ephrata Cancer Center and Sparta Cancer Center for your hard work and diligence in preparing for recent cooperative group audits.

Please contact Kelly Shipman with any QA related issues at Kelly.shipman@jeffersonhospital.org or 215-955-2135.

**CTSU Update:**

**N0147, Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer,** request letter for KRAS test results should be given to patients enrolled in study N0147 prior to the activation of Addendum 9 (activated by the NCCTG August 18, 2008) who would like to obtain their KRAS result. The patient must sign the request letter, which should be sent in by the treating institution. The treating physician is responsible for receiving and relaying the KRAS results to the patient and answering any future questions about those results. Please note that if the patient decides to receive KRAS test results that it must be documented in the patient’s research record. The letter is available on the CTSU website under the “Documents” menu for N0147.

If you have a CTSU related question please contact Joshua Schoppe at Joshua.schoppe@jeffersonhospital.org or 215-955-0448.
ECOG Update:
**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*, will re-open to accrual effective August 10, 2009. The activation of Addendum #10 includes an update to the consent form regarding the outcome of NSABP C-08. This is in compliance with CTEP’s revised procedures regarding enrollment of new subjects in situations in which new or modified risk information is considered to represent an alteration in the overall risk-benefit relationship for subjects. Accrual of new patients must remain suspended until the IRB of record has reviewed and approved this addendum. We expect this will be reviewed and approved by the TJU IRB during the week of August 24, 2009.

**FALL 2009 ECOG GROUP MEETING:** Registration is now OPEN:
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. The schedule provided is for current reference only and is subject to change at any time. 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_Fall2009

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

**NSABP Update:** No new updates. Check back in 2 weeks.

If you have an NSABP related question please contact Vicki Squire at vicki.squire@kimmelcancercenter.org or at 215-503-5641.
RTOG Update: RTOG 0614, RANDOMIZED, PHASE III, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF MEMANTINE FOR PREVENTION OF COGNITIVE DYSFUNCTION IN PATIENTS RECEIVING WHOLE-BRAIN RADIOTHERAPY, was recently opened to accrual. Please note the stipulations issued by the TJU IRB in order to open this study at your institution:

1) The risks for Whole-Brain Radiotherapy (WBRT) were removed from the main consent for RTOG 0614 at the request of the IRB, because this treatment is considered to be standard of care. Because of this change to the sponsor's template consent, the IRB requested to review each participating institution's standard radiotherapy consent form to ensure it contains all the risks for WBRT. If you are interested in participating in RTOG 0614, please include a copy of your institution's RT consent form with your amendment materials.

2) One of the eligibility criteria for this protocol is a score of 18 or higher on the Mini-Mental Status Examination (MMSE) at baseline. The TJU IRB mandated that any patient with a score of less than 24 on the MMSE should be provided with the surrogate consent form for this study, which has been posted on the repository.

RTOG 0521 will close to accrual on Friday, August 21, 2009 at 5pm, because it has met its accrual objective. RTOG 0320 and 0424 closed to accrual on Tuesday, August 11, 2009.

The main consents for RTOG 0521 and RTOG 0415 were recently updated with the addition of CIRB contact information, per the sponsor's template consents. The following information was also added to the "Voluntary Consent and Subject Withdrawal" section of the RTOG 0415 consent: "It is important to tell the study doctor if you are thinking about stopping so any risks from the radiation can be evaluated by him/her."
If you have an RTOG related question please contact Kelly Shipman.

Jefferson Oncology Group (JOG) Update:

Celgene: RV-MDS-PI-244, A Phase I/II Optimal Dose Study of Lenalidomide in the Non-5q- LOW and INT-1 Risk MDS patients. This trial is IRB approved and activated. Additional network sites are needed. If your site is interested, please contact Joshua Schoppe by August 21, 2009.

Upcoming Events:

The American Society of Hematology is now accepting abstract submissions for the 2009 Annual Meeting. The deadline for abstract submission is Tuesday, August 18, 2009, 11:59 p.m. PDT. More information can be found in the ASH Call for Abstracts:

Quarterly CRA Meeting: September 16, 2009
SWOG Group Meeting, Chicago, IL: Oct. 21-24, 2009
ECOG Group Meeting, Baltimore, MD: November 6-8, 2009
NSABP Group Meeting, Atlanta, GA: November 20-21, 2009
Quarterly CRA Meeting: December 9, 2009

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

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