The Clinical Research E-News

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Now Open:
ECOG 1697, Phase III Randomized Study of Four Weeks High Dose IFN-A2B in Stage T2B NO, T3A-B NO, T4A-B NO, and T1-4, N1A, 2A, 3 (microscopic) Melanoma

NSABP P-5, Statin Polyp Prevention Trial in Patients with Resected Colon Cancer

RTOG 0915, Randomized Phase II Study Comparing 2 Stereotactic Body Radiation Therapy (SBRT) Schedules for Medically Inoperable Patients with Stage I Peripheral Non-Small Cell Lung Cancer

Coming soon:
NSABP FC-6, A Phase II Study to Determine the Surgical Conversion Rate in Patients Receiving Neoadjuvant mFOLFOX7 Plus Cetuximab for Unresectable Wild-Type K-RAS Colorectal Cancer with Metastases Confined to the Liver

RTOG0920, A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer.

RTOG 0937, Randomized Phase II Study Comparing Prophylactic Cranial Irradiation Alone to Prophylactic Cranial Irradiation and Consolidative Extra-Cranial Irradiation for Extensive Disease Small Cell Lung Cancer (ED-SCLC)
CALGB10403, An Intergroup Phase II Clinical Trial for Adolescents and Young Adults with Untreated Acute Lymphoblastic Leukemia (ALL)

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:

- E4508
- N0577
- BETH
- R0825
- R0524
- E4402
- B-35
- E1508
- ALTTO
- GOG 258
- GOG 249
- R0436
- R0815
- S0819
- FB-6
- C40101
- C80101
- E4805
- E3204 letter about study closure
- GOG 136 letter about study closure
- E4697
- R0937
- BEST
- JOG 57
- GOG 258
- R0526
- S0221
- E4A03
- GOG 218
- R0915
- NSABP P-5
- E1697
- R0614

If these studies pertain to your site please visit the repository at: http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/. Please contact Rolma Gano with any repository or other regulatory related questions.
Quality Assurance Update:
Audit Tip: Please visit the JKCCN Policies & Procedures Manual on our website for the latest source documents, including study-specific eligibility forms, oral medication records, concomitant medication logs, and our consent review source document.

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

CTSU Update:
CALGB80405, A Phase III Trial of Irinotecan / 5-FU / Leucovorin or Oxaliplatin / 5-FU / Leucovorin with Bevacizumab, or Cetuximab (C225), or with the Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum, released Update #7 on June 15, 2010 to update the risk factors for both Arms A and B. This update will be submitted to the TJU IRB and that office will determine if a mandatory re-consent is necessary.

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

ECOG Update:
E2804, The BeST Trial: A Randomized Phase II Study of VEGF, RAF kinase, and mTOR Combination Targeted Therapy (CTT) with Bevacizumab, Sorafenib and Temsirolimus in Advanced Renal Cell Carcinoma, released Addendum #9 on July 7, 2010. This addendum contains changes to the Sorafenib CAEPR and consent form. This addendum will be submitted to the TJU IRB and that office will determine if a mandatory re-consent is necessary.
**E2805**, ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma, will release Addendum #10 on July 21, 2010. This addendum contains changes to the Sorafenib CAEPR and consent form. This addendum will be submitted to the TJU IRB and that office will determine if a mandatory re-consent is necessary.

**E4508**, Three-Arm Randomized Phase II Study of Carboplatin and Paclitaxel in Combination with Cetuximab, IMC-A12 or Both for Advanced Non-small Cell Lung Cancer Patients Who Will Not Receive Bevacizumab-based Therapy, released Addendum #3 on June 16, 2010. This addendum updates the addresses the clarification to the risk profile of Cetuximab. Current patients on study may continue on treatment provided they are made aware of the updated risks. New patients do not need to wait for this addendum to be approved by the TJU IRB per CTEP.

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

**NSABP Update:**
**NSABP P-5**, Statin Polyp Prevention Trial in Patients with Resected Colon Cancer, is OPEN to accrual at TJUH and available to our Cancer Network affiliates. Although P-5 is a prevention trial, accrual will be counted in the interventional or treatment category. The accrual goal is 1,740. Scott Goldstein, MD, is serving as Principal Investigator. The primary aim of the trial is to determine if the administration of 5 years of postoperative rosvuvastatin affects the 5-year occurrence of adenomatous polyps of the colon or rectum, metachronous colorectal carcinoma and colon cancer recurrence in patients with resected colon cancer.

**NSABP R-04**, A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or
without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum, is projected to reach its accrual goal by late July 2010 or early August 2010 according to NSABP. As of July 7, 2010, R-04 has accrued 1581 patients, or 98% of the total of 1606 patients required to complete accrual. 25 patients are still needed to complete accrual.

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

RTOG Update:
Please see this week's E-Newsletter supplement that includes updates from the recent RTOG Semiannual Meeting in Philadelphia.

A new version of the RTOG 0920 newsletter has been posted on the RTOG website at http://rtog.org/members/protocols/0920/0920broadcast.html.

RTOG recently instituted a new policy regarding passwords. This policy has been expanded to include both internal and external applications including all Web Data Entry applications. This change includes requirements that the password be at least 8 characters long, that it contains characters and numbers, and that it be changed every 90 days. All accounts have been reset and users must now change their passwords.

Walter J. Curran, MD, was elected to a fourth four-year term as Group Chair at the recent RTOG semiannual meeting by the Group's Full Member Principal Investigators. Said Curran: "As Group Chair I will continue to work with our member investigators to develop effective strategies for testing novel radiation techniques that, either alone or in combination with pharmacologic agents, improve the survival and quality of life of men and women diagnosed with cancer."
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:
http://www.kimmelcancercenter.org/jkccn/. This page contains links to the Remote Access Portal as well as the clinical trial document repository.

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