In order to better align ourselves with the National Cancer Institute (NCI) guidelines the Sidney Kimmel Cancer Center (SKCC) clinical research body has undergone an important reorganization and is now named the Clinical Research Organization (CRO). The CRO encompasses all clinical cancer research done in the SKCC into three arms: Early Drug Development Office (EDDO), Clinical Trials Office (CTO) and the Regional Network Office (RNO). These arms are served by the Quality Assurance and Process Improvement Unit (QPIU) and the Protocol Support Unit (PSU).

Title: A Randomized, Multi-center Phase III Study of Nivolumab versus Sorafenib as First-Line Treatment in Patients with Advanced Hepatocellular Carcinoma

Sponsor: BMS

PI: Ashwin Sama, MD

Purpose: The purpose of this study is to compare the overall survival (OS) and time to progression (TTP) of Nivolumab to Sorafenib in subjects with advanced HCC who have not received prior systemic therapy. TTP will be determined from assessments by a blinded independent central review (BICR) based on RECIST 1.1.

Inclusion Criteria:
1. Patient must have advanced hepatocellular carcinoma and not eligible for curative surgical and/or locoregional therapies, or progressive disease after surgical and/or locoregional therapies
2. Patients must have at least one measurable untreated lesion defined by RECIST 1.1
3. Patients must have a ECOG PS of 0 or 1
4. Patients must have Child-Pugh Class A

Exclusion Criteria:
1. Patients must not have known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC
2. Patients must not prior liver transplant.

Treatment:
Arm A: 240 mg Nivolumab (30 min IV) every 2 weeks
Arm B: 400 mg Sorafenib PO BID

Coordinator:
Courtney Brant
Pager: (877) 656-5581
Ext: 3-5743
Email: Courtney.Brant@jefferson.edu
Title: TELEPORT STUDY: A Pilot Feasibility Trial - Examining the Use of Telehealth in Post Radiation Therapy Visits (IRB#15D.580)

PI: Nicole Simone, M.D.

Purpose: To investigate the feasibility of conducting a future phase 2 randomized study comparing telehealth and in person visits for patients returning for a post-radiation treatment visit.

Treatment: Telehealth visit for the first post treatment follow up. Follow up visit 3-8 weeks after completion of radiation treatment.

Inclusion Criteria:
1. Patients currently undergoing or planned to start radiation treatment with curative, adjuvant or palliative intent
2. Age ≥18
3. KPS score > 60
4. Patients must be capable to read and speak English and provide study specific informed consent prior to study entry
5. Patients must have access to a computer or smartphone and internet connection at home on which they would be willing to do a telehealth study
6. Pennsylvania residents

Exclusion Criteria:
1. Patients under the age of 18
2. KPS score ≤ 60
3. No access to computer, smartphone or internet
4. Unable to read and/or speak English
5. Decisionally impaired patients
6. Patients not residing in Pennsylvania

Coordinator:
Kimberly Weller
Phone 215-955-8619
Email: Kimberly.Weller@jefferson.edu

OPEN TO NETWORK PARTICIPATION:

NRG-CC003: Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer

PENDING FOR NETWORK PARTICIPATION:

EA6134: Randomized Phase III Trial of Dabrafenib + Trametinib Followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab Followed by Dabrafenib + Trametinib at Progression in Patients with Advanced BRAFV600 Mutant Melanoma
Regulatory Update:

3/14/16  SELECT-1-Amendment
         revisions to consent form only
3/14/16  NSABP FC-7-Amendment Activation Ltr #3
         revisions to protocol & consent
3/17/16  ECOG 1412
         IRB received IND Safety report spreadsheet
3/18/16  A041202-Amendment review Ltr Update #3
         revisions to protocol & consent
3/23/16  NRG CC003-Approval Ltr
3/24/16  ECOG 2408-Amendment Ltr
         revisions to consent form only
4/8/16   NRG CC003-Amendment Ltr
         patient information & recruitment amendment
4/15/16  NSABP B50-I -Activation Ltr Update #6
         revisions to protocol & consent

National Coverage Analysis Pilot - The CTSU pilot for National Coverage Analysis (NCA) development is now underway. NCAs will be developed for new NCTN Phase III treatment trials and select Phase II trials as well as cross network NCORP cancer control and prevention trials activated after May 1, 2016.

The NCAs are provided by the CTSU as a guidance tool for institutions to assist with billing compliance. Institutions that chose to utilize these tools are responsible for the verification and modification of the coverage analysis in compliance with their institutional guidelines and are ultimately responsible for modifications specific for their local coverage determinations.

Notification of new and updated NCAs will be included in the CTSU Bimonthly Broadcast under the NCTN or NCORP Trial Updates section. NCA postings for the following trials:
- ALLIANCE - A071102
- ALLIANCE - A081105
- ALLIANCE - A151216
- NRG - NRG-CC001
- NRG - NRG-CC003
- NRG - NRG-HN001
- NRG - NSABP-B-55
- SWOG - S1500

CTSU cont.

CTSU Regulatory Submission Portal, on the CTSU website is anticipated to release in May 2016. The Portal will provide sites with an easier and more efficient way of submitting regulatory documents and information to the CTSU.

It is intended to streamline and centralize the process of regulatory submission and provide a mechanism for sites to verify the status of regulatory submissions as they are reviewed and processed by the CTSU in the Regulatory Support System (RSS). In the future, the Portal will be enhanced to allow users to respond directly to inquiries from the CTSU.

The Regulatory Submission Portal will be available on the CTSU members’ website (log-in is required). To access the Site Registration Portal, you must have an Active CTEP-IAM account and affiliation with an institution on a Network roster.

Note: The Regulatory Submission Portal was previously called Site Registration Portal; it has been updated with a new name to properly reflect the purpose of this new system.

Updated Form FDA 1572
The CTSU was recently notified that the U.S. Food and Drug Administration (FDA) posted an update version of the Statement of Investigator, Form FDA 1572. The new OMB expiration date for this form is February 28, 2019. For trials requiring study-specific 1572 forms, the CTSU will no longer accept submissions containing the previous version as of July 1, 2016.

The updated form is located on the FDA’s website:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsFor ms/Forms/UCM074728.pdf

Please feel free to contact the CTSU Regulatory Office Help Desk at 1-866-651-CTSU if you have any questions.
CTSU cont.

Protocol Credentialing in Radiotherapy:
The Imaging and Radiation Oncology Core (IROC) Houston Quality Assurance (QA) Center administers the NCTN RT credentialing program. The primary purpose of the credentialing process is to verify an appropriate level of competency at institutions in an attempt to minimize patient trial deviations. There are different credentialing requirements, depending on the specific protocol, treatment site, complexity of the treatment, and treatment modality.

The requirements for credentialing might include any combination of questionnaires, knowledge assessment forms, benchmarks, phantom irradiations, etc. To assist the institutions as to the specific requirements for a trial, the credentialing requirements for specific protocols can be found on IROC Houston’s website http://irochouston.mdanderson.org. This website shows active and inactive protocols categorized by network study group.

In preparing to locally open a trial, the first thing that an institution is asked to do is to complete a credentialing status inquiry (CSI) form, http://rpc.mdanderson.org/RPC/Forms2/Tech_protocols/Clinic_user.aspx. This form includes basic institution information that allows IROC Houston staff to identify your institution and 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, organizations, IROC QA Centers and to the institution.

NRG cont.

If an investigator already received a user account, the investigator would be automatically assigned to the BRCA Analysis Testing training module. This training module will be available in the "My Training" tab of the portal (click on "Navigation" and the drop down menu appears).

Translational Science Biospecimens

Shipped to the NRG Oncology Biospecimen Bank:
Two research plasma kits will be provided per patient:
- The Research Plasma kit is ordered first and used to ship the first two plasma specimens (PB09 and PB10).
- The Final Plasma kit is used to submit the final plasma specimen (PB11) and should not be ordered until the time of disease progression or end of treatment.

The Arm II PK or Arm III PK kit should be ordered after randomization, as contents are dependent on the arm to which the patient is randomized. Proof of patient randomization may be requested prior to kit shipment. Please have the NRG patient ID available when ordering PK kits.

- For NRG GY004, the Arm II and Arm III PK kits should be used to ship the future use whole blood (WB04), in addition to the PK plasma specimens.

ACTIVATION OF PROTOCOL EA3132

Phase II Randomized Trial of Adjuvant Radiotherapy with or Without Cisplatin for p53 Mutated, Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN), took place on March 29, 2016. http://www.ecog.org/ecoginst/prot/pdf/HEADNECK/EA3132AD0.PDF. If your site is interested in opening this trial please contact Joshua Schoppe.

CHANGE OF KIT ORDERING INSTRUCTIONS EFFECTIVE

April 12, 2016: As of April 12, 2016 Specimen Collection/Shipping Kits are provided by CENETRON CENTRAL LABORATORIES and may be ordered ONLINE at www.cenetron.com for the following protocols: E2108, E2810, E5103-PACCT01 EL112LAB and EA6141. For accruing trials, baseline kits may be ordered immediately following registration. Kits for trial with separate kits for follow-up for collections, kits may be ordered within one month prior to visit. Please complete the online form.
ECOG cont. completely, including the valid ECOG-ACRIN protocol number, ECOG-ACRIN patient case number, and complete shipping address. If information is missing the kit processing will be delayed. Ordering process: Proceed to www.cenetron.com. Click the “Order Kits” button at the top right. Questions regarding kits can be directed to projectmanagement@cenetron.com or call the Cenetron clinical trials group at 512-439-2000.

Protocol Notice: EA6134, A Randomized Phase III trial of Dabrafenib + Trametinib followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab followed by Dabrafenib + Trametinib at Progression in Patients With Advanced BRAFV600 Mutant Melanoma, is reopened effective April 11, 2016.

ECOG-ACRIN has received notification from the NCI that studies that were temporarily closed to accrual on February 2, 2016 due to an acute shortage in the supply of Dabrafenib mesylate (NSC 763760) capsules and Trametinib DMSO (NSC 763093) tablets for research studies can re-open to new accrual. Because the supply of both dabrafenib and trametinib for research studies remains limited, CTEP will be closely monitoring drug inventory to ensure continued supply of the agents for on-going and new patients.

Spring 2016 ECOG-ACRIN Meeting will take place at Boston Marriott Copley Place from Thursday May 12th through Saturday May 14th. There are no registration fees to attend the meeting for ECOG-ACRIN, NCI, and non-industry members so I encourage all to attend.

Upcoming Events:

- **ECOG-ACRIN Spring 2016 Meeting**: May 12-14, 2016 - Boston, MA
- **Genomics Symposium**: May 19, 2016 - Philadelphia, PA
- **Palliative Care Symposium**: June 3, 2016 - Philadelphia, PA
- **CRA Research Update**: June 15, 2016 - Philadelphia, PA
- **NRG Oncology Semi-Annual Meeting**: July 14-16, 2016 - Dallas, TX
- **CRA Research Update**: September 14, 2016 – Philadelphia PA

The Clinical Research E-News Archive is now located on the Sidney Kimmel Cancer Center webpage under the SKCN Member Area: http://isley.kcc.tju.edu/skcn/e-newsletters.html

Sidney Kimmel Cancer Network Homepage: http://isley.kcc.tju.edu/skcn/ - This page contains links to the Remote Access Portal as well as the clinical trial document repository.
### Contact Information:

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Office: 215-955-9923</th>
<th>Email</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cynthia Perez, CCRP</td>
<td>Sr. Outreach Coordinator</td>
<td></td>
<td><a href="mailto:cynthia.perez@jefferson.edu">cynthia.perez@jefferson.edu</a></td>
<td>NRG Update inquiries, CTSU or Clinical Research E-Newsletters</td>
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<td></td>
<td>Editor, E-Newsletter</td>
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<td></td>
</tr>
<tr>
<td>Joshua Schoppe, MPH,</td>
<td>CCRP Senior Director, RNO</td>
<td></td>
<td><a href="mailto:joshua.schoppe@jefferson.edu">joshua.schoppe@jefferson.edu</a></td>
<td>ECOG-ACRIN Update inquiries or CIRB</td>
</tr>
<tr>
<td>Rashada Dawson, MBA</td>
<td>Outreach Coordinator</td>
<td></td>
<td><a href="mailto:rashada.dawson@jefferson.edu">rashada.dawson@jefferson.edu</a></td>
<td>Pending Studies or Regulatory Update inquiries</td>
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