

Mile Stones

CCCWF CCOP RESEARCH BASE

A Semi-annual Newsletter
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Breast Biomarkers Study Opening Soon

by Jim Urbanic, MD

The largest study to be conducted by the Wake Forest CCOP Research Base was recently approved by the NCI. CCCWF 97609, "Impact of Genomics and Exposures on Disparities in Breast Cancer Radiosensitivity" (a.k.a. Breast Biomarkers Study) is being finalized for distribution to our CCOP members in September of 2011. The Co-Principal investigators of this research study are James Urbanic, MD of the Department of Radiation Oncology at Wake Forest School of Medicine and Jennifer Hu, PhD of the Department of Epidemiology and Public Health at the University of Miami School of Medicine. Both investigators have led other successful Research Base studies.

The study population will be stage 0-IIIa breast cancer patients who have completed either breast conserving surgery (i.e., lumpectomy or quadrantectomy) or mastectomy and will be receiving adjuvant radiotherapy to the whole breast or chest wall. Sequential (but not concurrent) chemotherapy will be allowed as will either sequential or concurrent hormonal /targeted therapies including Herceptin. All radiotherapy schedules of at least 40 Gy will be appropriate for inclusion on this study including so-called "short-course" regimens.

We plan to accrue 1000 patients to this study. One of the strengths of the Wake Forest Research Base is our ability to accrue patients from across a wide spectrum of races/ethnicities. This will be key to the success of this study as we will be attempting to develop and validate predictive biomarkers for RT-induced acute and chronic skin reactions and qual-

ity of life differences for Whites, Black/African Americans, Hispanic/Latinos, Asians/Native Hawaiians/Pacific Islanders, and American Indian/Alaskan Natives. Additionally, we have several other aims. These include a plan to: 1) develop polygenic models of RT-induced skin reactions with a comprehensive evaluation of genome-wide non-synonymous single nucleotide polymorphisms; 2) evaluate the levels of DNA damage and radiosensitivity in lymphocytes before and after RT and test the hypothesis that individuals with more severe acute and chronic RT-induced skin reactions will have higher RT-induced DNA damage and radiosensitivity; 3) test the effect of gene-gene and gene-smoking interactions on RT-induced skin reactions; and 4) assess race-ethnic differences in RT-induced skin reactions, DNA damage, and radiosensitivity and to determine if the gene effects are consistent across race-ethnicities (gene-race/ethnic interactions).

The outcome from this research will provide insight into the roles of genetic susceptibility in acute and chronic RT-induced skin reactions at the individual level. As we learn more about the contributions of and interactions among genetic susceptibility to more severe skin reactions, we can develop targeted preventive strategies for those predicted to be at higher risk.

Patients will be assessed at multiple time points with a battery of clinical assessment tools in addi-

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tion to the blood and urine samples that will be obtained at baseline and the completion of radiotherapy. The clinical assessments will include a detailed dermatologic scoring tool (Skindex 16), the Breast Cancer Risk Study Questionnaire, quality of life and function metric, the Oncology Nursing Society acute skin toxicity scale, the FACT B, RTOG late skin toxicity scale, and standardized clinical photographs. All of these data will generate a powerful database which we can use to assess the impact of therapy on the lives of our patients across multiple different populations.

In summary, we are excited to offer this clinical study to our CCOP, MB-CCOP, and Prevention Members. We look forward to your continued support and participation.

Jim Urbanic, MD, PI

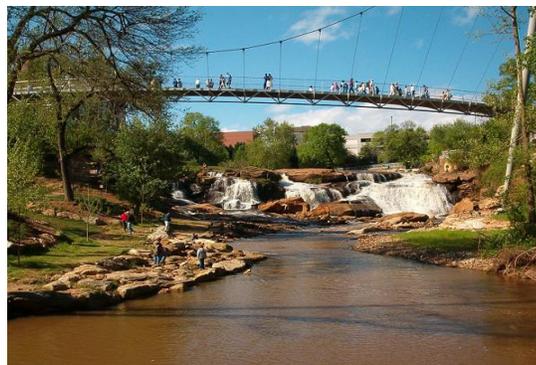
Mark your calendars! 11th Annual Meeting



The CCCWF CCOP Research Base
11th Annual Meeting
Greenville, SC
Hyatt Regency Hotel

October 20-22, 2011

The agenda for this year's Annual Meeting is packed with educational opportunities. Dr. Sebastian Kaplan of Wake Forest Baptist Health will be leading a motivational training course related to a soon-to-open smoking cessation cancer control trial (Feasibility of Delivering a Quitline Based Smoking Cessation Intervention in Lung Cancer Patients Receiving Outpatient Treatment: A Pilot Study). Dr. Wortia McCaskill-Stevens, Acting Chief, Community Oncology and Prevention Trials Research Group with NCI and Dr. Bettina Beech, co-Director of Wake Forest's Maya Angelou Center for Health Equity will be leading a session focusing on minority recruitment and retention to cancer prevention/control clinical trials. Dr. Ed Shaw will speak on preventing oncology healthcare provider burnout. In addition, closed study results will be discussed, and over 20 protocols, both open and in development, will be reviewed. This meeting promises to be one of the most informative yet. [Registration](#) for the meeting is open and a room block is being held at the [Hyatt Regency](#) in downtown Greenville SC until September 21, 2011 at the rate of \$115 per night. If you have any questions, suggestions or need additional information regarding the meeting, contact Lisa Autry at 336-716-0891 or launtry@wakehealth.edu.



Liberty Bridge at Falls Park in downtown Greenville

The Learning Curve

by Robin Rosdhal RN, OCN

Here's some more information on the Breast Biomarkers Study featured in the opening article of this issue. It is in the last phases prior to being opened and posted on the website. There are some specifics with this protocol that you need to be aware of. First, there are two different radiotherapy regimens allowed on this protocol. One regimen is a hypo-fractionated course consisting of 16 fractions of radiation, 267 cGy per fraction. Patients are allowed an additional boost at the treating physicians' discretion. The other regimen utilizes standard fractionation, 180 or 200 cGy per fraction for 25-30 fractions. The total dose must be at least 40 Gy.

Second, blood and urine specimens for biomarkers will be obtained twice, once prior to the patient starting radiation and again the last day of radiation. Sites will be provided with lab kits containing supplies that include special tubes for the blood. Read specific handling and shipping instructions in the protocol. Since the main objective of the study is to correlate clinically assessed skin toxicity with blood/urine biomarkers, timely and correct submission of the biospecimens is key.

Photographs are to be taken prior to the first radiation treatment and at specified times during the protocol. An additional paragraph has been added to the end of the routine consent for patients to provide written permission to have photographs taken. We do allow patients to opt out of having their photographs taken but still participate in the study. This information will be required at registration.

We have three other protocols which will open in the next few months. One is a chemobrain study that will require your neuro-cognitive testing skills. Eligibility criteria include females with a history of invasive breast cancer who have completed chemotherapy in the last 1 to 5 years and have symptoms of cognitive dysfunction.

The other soon to open protocols are related to smoking cessation. One for patients with stage I-IIIa/B non-small cell lung cancer or limited stage small cell lung cancer. These patients will be evaluated for enrollment in a study involving the use of a Quitline intervention. The second protocol randomizes patients to memantine vs. placebo (memantine can reduce the craving smokers have for nicotine). It is for survivors of non-metastatic breast, prostate, colorectal cancers or Stage I/II non-small cell lung cancer.

Join us at the annual meeting to learn more about these exciting protocols. It will be your turn to say WOW!!!!!!!!!!!!!!!!!!!!!!



New Study Conference Call Training

The Research Base plans to offer informational conference calls for open protocols and concepts/protocols in development. The quarterly calls will be available to physicians, administrators, research nurses, data managers, regulatory staff, and others interested in Wake Forest's menu of cancer prevention/control clinical trials. There will be plenty of time for questions and answers. Information on the specific day, time and dial-in number will be distributed in the weekly broadcast email during the several weeks prior to each call.



Out and About with June

The CCCWF CCOP Research Base would like to welcome our newest member: Gundersen Lutheran Health Systems in La Crosse, WI.

99211: Feasibility of delivering a Quitline-based smoking cessation intervention in lung cancer patients receiving outpatient treatment will be opening soon. A training session for the motivational interviewing/counseling component of this study will be held at the Annual Meeting. For those who can't attend the annual meeting, an additional training session offered at a later date. If your site is interested in participating in this study, please make plans to attend the Research Base Annual Meeting this October in Greenville, SC.

If you have any questions regarding these audits, please contact me at jsteede@wakehealth.edu or 336- 716-6733.

Open Protocols

91105 Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients
Steven Rapp, PhD, PI

97509 A Feasibility Study of Armodafinil for Brain Radiation-Induced Fatigue
Ed Shaw, MD, PI

97609 Impact of Genomics and Exposures on Disparities in Breast Cancer Radiosensitivity
Jim Urbanic, MD, PI

98110 A Randomized Phase II Dose Finding Study of ArginMax with or without Phosphodiesterase-5 Inhibitors for Its Effect on Erectile Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with Radiotherapy
Jim Urbanic, MD, PI

Welcome New Staff

Please join us in welcoming Holly Sluder to the Data Management Center. Holly will be working with sites to collect and input data. She can be reached at (336) 713-6566 or hsluder@wakehealth.edu.