

Register Today for the 10th Annual Meeting



The Hilton Riverside in the Historic district of Wilmington, NC will be the host site of the 10th Annual CCCWFU CCOP Research Base Meeting. Located on the Riverwalk just across the Cape Fear River from the Battleship North Carolina the Hilton Riverside is just a short walk from shopping, restaurants and historic attractions. Rooms overlook views of the Battleship and historic downtown. You can explore the scenic Riverwalk and historic homes by foot, horse-drawn carriage or riverboat.

The Research Base meeting will open with a lunch presentation by Drs. Suzanne Danhauer and Kathryn Weaver on "Research Issues in Developing and Implementing Behavioral Intervention Studies through the CCCWFU CCOP Research Base." It will be followed by a special workshop by Jnani Chapman, RN, BSN, CYT, CMT and Dr. Stephanie Sohl entitled "Yoga Research in Cancer Treatment & Beyond" including a cancer focused yoga class led by Jnani. Friday morning's session will open with a talk from Dr. Charles Loprinzi from the Mayo Clinic. During lunch, Dr. Ed Shaw will continue with his series on grief and loss with a lecture on "Saying Good-bye" followed by a special session on the presentations from the June 2010 ASCO meeting. On Saturday, open and developing protocols will begin the day, followed by a lunchtime panel discussion on the "Secrets to Successful Accrual" presented by our top accruing CCOPs. A proposed concept forum session will close the meeting.

There are no registration fees associated with this meeting. To register just access the Research Base website at www.wfubmc.edu/cancer/researchbase and follow the annual meeting links under the general information tab.

15 Physicians Credit Hours
16 Nursing Credit Hours

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Armodafinil Study Opens

by Edward Shaw, MD

On Thursday, 8/5/10, we opened "A Phase II Double-Blind Feasibility Study of Armodafinil for Brain Radiation-Induced Fatigue". This study is for any adult undergoing curative brain RT for a primary brain tumor. Patients receiving concomitant chemotherapy are eligible (e.g., glioblastoma patients receiving Temodar®). We allow patients to enter as late as 5 fractions into their RT. Patients with brain metastases are not eligible. The most common side effect of brain RT is fatigue. Armodafinil (trade name Nuvigil®) is a new drug developed and manufactured by Cephalon, Inc., the corporate sponsor for our study. It is chemically related to modafinil (Provigil®) but more potent and less toxic. We hope it will prevent brain RT-induced fatigue. Eligible patients will be randomized to armodafinil 150mg daily or placebo daily. They will have to limit their caffeine intake to 600mg daily or less, the equivalent of 6 cups coffee, 12 cups tea, or 12 cans of caffeinated soda. The main toxicity to watch for is headaches. Assuming toxicity is minimal and there is a suggestion of efficacy, we will likely follow this Phase II study with a larger Phase III trial. Please alert your radiation oncologists to this study. Patients with benign brain tumor receiving RT alone, e.g., meningiomas and pituitary adenomas, are eligible but typically won't be on the medical oncologist's radar. We will be accruing 54 patients to the study and anticipate the study will be open for one to one and a half years. Please open it at your sites!

The Learning Curve

Protocol 91105 (Donepezil/Placebo in Irradiated Brain Tumor Patients) – Thanks to all of you, accrual is increasing at a nice steady pace. At the annual meeting we will have information available regarding the neurocognitive test battery and how it relates to the anatomy of the human brain. If any site needs Wal-Mart gift cards for participants, please contact Robin Rosdhal at (336) 713-6519.

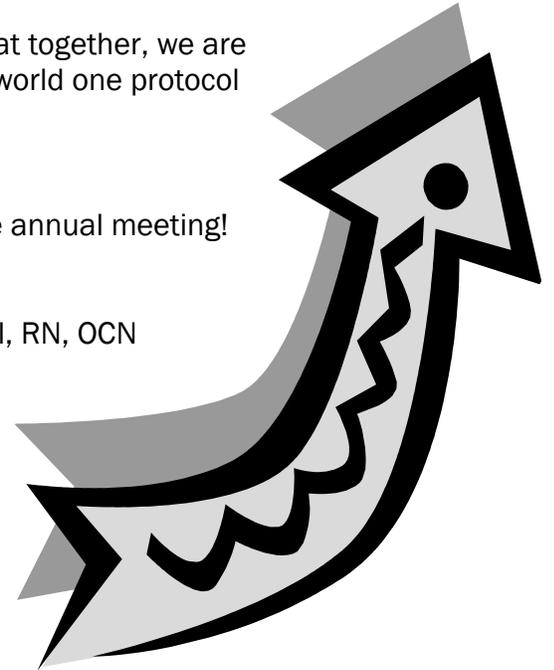
Protocol 97309 (Yoga or Wellness Education during Breast Cancer Treatment) - It has been a learning curve for us (Research Base) to collect data for an integrative treatment study. Even though there are many recognizable aspects of the Yoga/Wellness classes, how to capture that data for analysis has been an interesting process. There have been amendment changes mainly to the forms to better obtain information needed to meet the primary and secondary objectives. The sites that have this protocol open are paving the way for similar protocols in the future that will be available across the U.S.

Protocol 97509 (Armodafinil for Brain Radiation-Induced Fatigue) – see article earlier in the newsletter about this study.

Remember that together, we are changing the world one protocol at a time!

See you at the annual meeting!

Robin Rosdhal, RN, OCN



Out and About with June

Now that CCCWFU CCOP Research Base Protocol 97509: A Feasibility Study of Armodafinil for Brain Radiation-Induced Fatigue is open to accrual, there are two Research Base protocols that require the Neurocognitive Battery Administration Certification. Anyone already trained and certified for CCCWFU 91105 (Donepezil Study) will automatically be considered certified for 97509 (Armodafinil Study) (7.6 Certification Requirements and Procedures for Neurocognitive Testing.)

Once again during the Research Base Annual Meeting in October, appointments will be available if you would like to become certified (or would like to have a refresher) in the Administration of the Neurocognitive Battery. If you would like to make an appointment (times are limited) or if you have any questions, please contact me at jsteede@wfubmc.edu or 336-716-6733.

June Fletcher-Steede

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Credit Statements

The Wake Forest University School of Medicine designates this educational activity for a maximum of 15 AMA PRA *Category 1* Credit(s)[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity.

"This continuing nursing education activity was approved by the North Carolina Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation."

This activity has been approved for a maximum of 16 contact hours. Each participant should claim only those credits that he/she actually spent in this activity.

If you have any questions about this meeting, please contact Lisa Autry Hawkins at (336) 716-0891 or lhawkins@wfubmc.edu



USS North Carolina Battleship docked in Wilmington, NC



Fountain at Airlie Gardens in Wilmington, NC

Thursday (10/07/10)

<u>Time</u>	<u>Event</u>
12:00	Lunch: "Research Issues in Developing and implementing Behavioral intervention Studies through the CCCWFU CCOP Research Base"
1:00	"Yoga Research in Cancer Treatment & Beyond" Workshop

Friday (10/08/10)

<u>Time</u>	<u>Event</u>
7:30	Breakfast Service
8:00	Welcome & Meeting Overview
8:15	"The NCCTG Chemotherapy-Induced Peripheral Neuropathy Experience"
9:30	Break
9:45	Round Tables
11:15	ASCO Presentations & Study Results
12:45	Lunch: "Saying Goodbye"
1:45	Business Meeting
6:00	Reception with Entertainment

Saturday (10/09/10)

<u>Time</u>	<u>Event</u>
7:30	Breakfast Service
8:00	Developing Protocol Review
10:00	Break
10:15	Open Protocol Review
12:00	Lunch with Panel Discussion – Secrets for Successful Accrual
1:00	Proposed Concept Forum/Developing Study Review