

# Mile Stones

## CCCWFU CCOP RESEARCH BASE

Winter 2006 Volume 3 Issue 1

### Inside this issue:

Research Base Core Lab	1	In May of 2004 the Comprehensive Cancer Center of Wake Forest University (CCCWFU) CCOP Research Base opened a new resource for its participants, the Research Base Core (RB Core) Lab. Of the six NCI sponsored Research Bases, Wake Forest is the only one with a Core Lab. It was created to provide our participating CCOPs with materials needed to collect blood and tissue samples, instructions on processing and packaging samples, and appropriate shipping methods to meet federal requirements of biohazardous materials. In short, the RB Core Lab is one stop shopping. Sites can feel assured that everything associated with specimen procurement will be provided by the Core Lab, whose services are provided to sites free of charge, including shipping and handling.
Fifth Annual Meeting	2	The Core Lab enables us to study endpoints other than survival, response, and quality of life. Examples of blood/tissue endpoints include blood antioxidant levels and tissue gene expression on the Juice Plus head and neck cancer chemoprevention study and blood Co-Enzyme Q10 levels on the Co Q10 fatigue study.
Making a Difference: <i>The Journal of Clinical Oncology</i>	2	The Research Base Core Lab is maintained by Andrea Rice, who has 10 years of experience working in a pharmacology lab at Wake Forest University. The knowledge Andrea has for shipping and handling requirements of infectious substances is exceptional. A reoccurring training class for International Air Transportation Association (IATA) regulations is required every 2 years at WFU for all personnel involved in shipping hazardous materials.
The Learning Curve	3	Andrea's main functions are to ship specimen kits, receive, store, and catalogue blood and biopsy samples that are received by the Core Lab. She is also involved in study development. If a researcher is interested in a correlative study endpoint measured by a particular blood test or tissue assay in the lab, Andrea researches the proper methods for specimen collection, handling, and shipping, then assists the Principal Investigator and staff from the Research Base Protocol Office to write these guidelines into the protocol document. It is very important that clinical research staff familiarize themselves with the portion of the protocol that deals with specimen collection, handling and shipping. We all want our efforts to produce quality data!
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### Mark your calendars:

**CCCWFU CCOP  
Annual Meeting  
October 27 & 28  
Charleston, SC**

Please be diligent about processing specimens that require protection from light and heat by keeping them in foil and cold (e.g., on CCCWFU 97202, the CoQ10 study and CCCWFU 60A02, the Juice Plus study, both of which have plasma and serum portions). Foil is now included in the kits to remind research staff of its importance and may be the difference between proper and improper specimen handling and shipping.

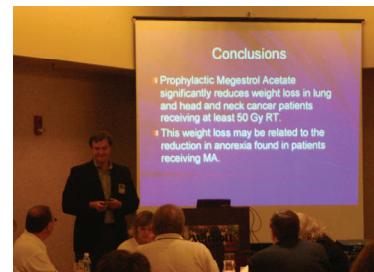
The best way to obtain shippers is to email Andrea Rice at [arice@wfubmc.edu](mailto:arice@wfubmc.edu) and request the protocol-specific specimen kit(s) needed. Also, specify the number of kits needed and as well as your current shipping address (no Post Office Box numbers) please.

Specimens should be shipped to the Core Lab by overnight FedEx for morning delivery, and should be sent no later than Thursday. Specimens should not be sent to arrive on a Saturday, Sunday or a holiday. Please call or e-mail Andrea prior to specimen shipment. She will be anticipating the arrival of your shipment.

## Fifth Annual Meeting



The Research Base Fifth Annual Meeting was held at the Marriott Grande Dunes Resort in Myrtle Beach, SC on September 29th, 2005. The 63 registered participants enjoyed morning roundtable discussions, a business meeting luncheon with awards and an afternoon presentation of open and developing studies. Guests mingled during an evening reception in the courtyard.



## Great News: We can make a difference!

A manuscript describing results of the Research Base's Phase II Study of Donepezil (Aricept) for Irradiated Brain Tumor Patients has been accepted for March 2006 publication by *The Journal of Clinical Oncology*. The study was presented at the November 2004 meeting of the Society for Neuro-Oncology by its PIs, Drs. Steve Rapp and Ed Shaw. Dr. Rapp received the American Brain Tumor Association Quality of Life Award for his presentation. This study demonstrated an improvement in energy level, mood, and cognitive function in long-term survivors of partial or whole brain radiation who took a 6 month course of Aricept. Dr. Rapp has written a Phase III prospective randomized placebo controlled double blind study for donepezil in this patient population as a joint study between the Wake Forest and MD Anderson CCOP Research Bases. He submitted a R01 grant to the NCI to fund the study and should hear whether he was awarded the funding sometime this month.

### Three Research Base study abstracts presented at the American Society for Therapeutic Radiology and Oncology Meeting in October 2005:

Dr. Michael Farmer (Wake Forest radiation oncology resident) presented an abstract on two Phase III trials, the Effect of Megestrol Acetate on Weight and Health Related Quality of Life in Lung Cancer Patients (CCCWFU 98199) and Head and Neck Cancer Patients (CCCWFU 97300) Receiving Curative Radiation Therapy. The following CCOP physicians were coauthors on the study: M. Farmer MD<sup>1</sup>, D. Case PhD<sup>1</sup>, G. Lesser MD<sup>1</sup>, D. Monitto MD<sup>2</sup>, S. Smathers MD<sup>3</sup>, B. May MD<sup>4</sup>, R. Allison MD<sup>5</sup>, M. Naughton, PhD<sup>1</sup>, R. McQuellon PhD<sup>1</sup>, W. Blackstock MD<sup>1</sup>, K. Greven MD<sup>1</sup>, E. Shaw, MD<sup>1</sup>.

1. Wake Forest University School of Medicine, Winston-Salem, NC
2. Upstate Carolina CCOP, Spartanburg, SC
3. Southeast Cancer Control Consortium, Ashville, NC
4. Southeast Cancer Control Consortium, Kingsport, TN
5. East Carolina University Brody School of Medicine, Greenville, NC

ASTRO continued on page 4

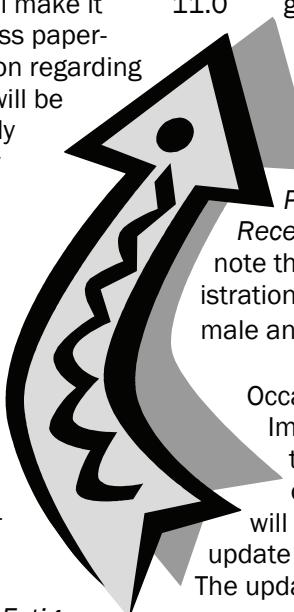
## The Learning Curve

Protocol amendments will be posted less frequently than before. Beginning in January 2006, amendments will only be posted two or three times per year. This will make it much easier for everyone since there will be less paperwork. An exception is if there is new information regarding patient safety, in which case the amendment will be addressed promptly. Look for continued weekly updates on the Research Base website for any news that may impact your site.  
[www1.wfubmc.edu/cancer/  
CCWFU+CCOP+Research+Base](http://www1.wfubmc.edu/cancer/CCWFU+CCOP+Research+Base)

Several of our upcoming protocols will feature a new Registration Checklist / Eligibility Form. These are designed to meet protocol specific eligibility requirements and to match the on-line registration screen. If you have your checklist / eligibility form completed, you will be able to quickly register a patient using the on-line registration system.

*Protocol 97202 CoQ10 for Treatment Related Fatigue in Breast Cancer Patients:* This protocol will be amended to

allow baseline lab specimens to be drawn within 2 weeks of registration. The hemoglobin level is still required to be  $\geq 11.0$  gm/dl at baseline, but even if the patient's hemoglobin level drops below this range after patient registration, they may remain on protocol. All supportive care measures to maintain hemoglobin levels should be used.



*Protocol 97102 Oxandrin/ Megace in Patients Receiving Chemotherapy for Solid Tumors:* Please note that on the stratification section of the on-line registration the "F" and "M" are being changed to read Female and Male. I hope this clarification is helpful.

Occasionally a site may have original Bioelectrical Impedance Analysis (BIA) RJL System information that prints out slightly different when entered into our computer database. If this occurs, the site will receive an updated analysis. Please place this update in your patient chart (source documentation). The updated information is meant to be an addition to your original BIA analysis and not a replacement.

***Robin Rosdhal RN, OCN***



## Spotlight on Claudette Phinney

Claudette Phinney is a research nurse at the Cancer Center of the Carolinas in Greenville, South Carolina. She was a triage nurse for 19 years and has worked in research for the past seven. Claudette has led the way in accruals for the CoQ10 study with 38 patient accruals as of 1/3/06. She shared her secrets of success with us at the 2005 Research Base Annual Meeting. Here are some examples:

- Recruit patients by checking daily clinic schedules, talk with physicians and work with enthusiastic doctors that refer patients.
- Send out emails to clinics reminding them about open studies.
- Give prospective patients consent packets with pink breast cancer pins or other small gifts when they complete the study.

In her free time, Claudette enjoys working in her yard and traveling to the beach. She is a foster mom to a 9 year old soccer player. During the annual meeting, Claudette won the award for best data submissions. Claudette, thank you for all you do!



## Open Protocols

### Cancer Control and Prevention

**97102** A Phase III Randomized Study Comparing the Effects of Oxandrolone (Oxandrin®) and Megestrol Acetate (Megace®) On Lean Body Mass, Weight, Body Fat, and Quality Of Life in Patients with Solid Tumors and Weight Loss Receiving Chemotherapy **Glenn Lesser, MD, PI**

**97202** A Phase III Randomized Double-Blind Placebo-Controlled Study of Oral Coenzyme Q10 to Relieve Self-Reported Cancer Treatment Related Fatigue in Breast Cancer Patients **Glenn Lesser, MD, PI**

**60A02** A Phase II Randomized Placebo Controlled, Double Blinded Trial to Evaluate the Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients **Steve Akman, MD, PhD, PI**

### Cancer Treatment

**91202** A Phase II Trial of Thalidomide and Procarbazine in Adult Patients with Recurrent or Progressive Malignant Gliomas **Glenn Lesser, MD, PI**

**71103** Phase II Study of Single Agent Depsipeptide (FK228) in Metastatic or Unresectable Soft Tissue Sarcomas **Paul Savage, MD, PI**

## Protocols In Development

### Cancer Control and Prevention

**97405** Phase II studies of Soy, Venlafaxine (Effexor), and Soy + Venlafaxine on Vasomotor Symptoms of Men with Prostate Cancer **Mara Vitolins, RD, PhD, PI**

**98301** Phase II study of St. John's Wort for the Treatment of Hot Flashes in Women with a History of Breast Cancer **Michelle Naughton, PhD, PI**

**91105** Phase III Study of Donepezil in Irradiated Brain **Steven Rapp, MD, PI**

**97106** Phase III Double Blinded Randomized Study to Determine Whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors **Kathryn Greven, MD and Brigit Miller, MD, coPIs**

## ASTRO *continued from page 2*

Dr. Jerome Butler (also a Wake Forest radiation oncology resident) presented an abstract on a Phase III Double-Blind Prospective Randomized Study of the Effect of d-threo-methylphenidate HCl (d-mpH) on Quality of Life in Brain Tumor Patients Receiving Radiation Therapy (CCWFU 97600). The following CCOP physicians were coauthors on the study: J. Butler MD<sup>1</sup>, D. Case PhD<sup>1</sup>, J. Atkins MD<sup>3</sup>, B. Frizzell MD<sup>2</sup>, G. Sanders MD<sup>3</sup>, P. Griffin MD<sup>4</sup>, G. Lesser MD<sup>1</sup>, K. McMullen MD<sup>1</sup>, R. McQuellon PhD<sup>1</sup>, M. Naughton MD<sup>1</sup>, S. Rapp PhD<sup>1</sup>, V. Stieber MD<sup>1</sup>, E. Shaw MD<sup>1</sup>.

1. Wake Forest University School of Medicine, Winston-Salem, NC
2. Southeast Cancer Control Consortium, High Point, NC
3. Southeast Cancer Control Consortium, Goldsboro, NC
4. Upstate Carolina CCOP, Spartanburg, SC

### Sudoku Answer

4	7	2	8	6	5	3	1	9
3	9	1	7	4	2	8	5	6
6	5	8	3	9	1	7	2	4
7	2	6	1	5	8	4	9	3
9	1	4	6	7	3	5	8	2
5	8	3	4	2	9	1	6	7
1	3	7	9	8	6	2	4	5
2	4	9	5	1	7	6	3	8
8	6	5	2	3	4	9	7	1

## Data Management



### Refuse Further Treatment vs. Withdraw Consent

In Resbie's (**Research Base**) world of Data Management, there is a difference between "Refused Further Treatment" and "Withdraw Consent". If a patient refuses active protocol treatment after therapy has begun, the data collection may continue according to protocol **unless** the patient also *withdraws consent* which would discontinue any protocol follow-up. The patient does not have to use the words "withdraw consent", but simply may communicate his or her desire to no longer be involved with the study. When a patient refuses further treatment, the research staff and physician should inquire as to the reasons why and ascertain if the patient also wishes to withdraw consent. There are patients who no longer want to take treatment but are willing to be followed ("Refused Further Treatment"). Then, there are those who no longer want treatment **and** no longer want to be bothered with any kind of follow-up ("Withdraw Consent"). The desire to "Withdraw Consent" can occur after the active treatment phase has been completed which essentially means the patient doesn't want to be bothered with more follow-up.

## Sudoku

Rules: Each of the numbers 1 through 9 must appear only once in each row, each column and each 3x3 block. (Answer on page 4.)

4						3	
	9				2		6
6	5				1		2
7		6			8		
9		4				5	2
			4			1	7
	3		9			4	5
2			5			3	
		5					1

## Joking Around

**Customer:** These get-well cards are all blank!

**Sales person:** They're placebos.

## Contact Information

\*NEW PAGER NUMBERS: (336) 716-2440 + EXTENSION

<i>Protocol Information Office</i>		FAX: (336) 716-6275		
Gina Enevold, MSN, RN, GNP Administrator (336) 716-4035 genevold@wfubmc.edu Pager extension: 6943*	June Fletcher-Steede, BS, RT (R)(T), CCRP Site Coordinator (336) 716-6733 jsteede@wfubmc.edu Pager: (336) 806-6944	Del Jones Assistant Project Manager Protocol Development (336)716-3020 deljones@wfubmc.edu Pager extension: 4280*	Megan Whelen, BS Assistant Project Manager Regulatory (336)716-5992 mwhelen@wfubmc.edu Pager extension: 4350*	Lisa Hawkins Administrative Assistant (336) 716-0891 lhawkins@wfubmc.edu Pager extension: 1689*

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CCWFU+CCOP+RESEARCH+BASE

## Inside Mile Stones

- Publication of Donepezil (Aricept) study
- Audits in 2006
- Research Base Core Lab
- Spotlight on Claudette Phinney

## Out and About with June



10-9-8-7-6-5-4-3-2-1...2006

\*\*\* A New Audit Cycle Year\*\*\*

January 1 rings in more than just a new year. It also brings with it the new audit cycle. All sites are scheduled for an audit in 2006. The plan is to have all audits complete by June 1, 2006, since the CCCWFU CCOP Research Base competing renewal grant is being submitted in July, and Dr. Shaw wants audits complete before the submission.



If you attended the Research Base annual meeting, you will find some information about audits in your meeting book in the handout section. If you did not attend the annual meeting or have any questions about what is involved in an audit or about the audit process in general, please don't hesitate to contact June at (336) 716-6733 or [jsteede@wfubmc.edu](mailto:jsteede@wfubmc.edu).

More information regarding your audit will be coming soon.

*June Fletcher-Steede*

### Welcome New CCOP Site!

Christiana Care Health Services Newark, Delaware

