

- Interview with Kaye Schöffner
  - Register today for the 9th Annual Meeting September 24-26, 2009
- Inside Mile Stones:**

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**CCCWFU CCOP Research Base**

**Mile Stones**

Wake Forest University Baptist

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Comprehensive Cancer Center



## CCCWFU CCOP Research Base Open Protocols

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

**97106** A Randomized Study to Determine whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors  
**Kathryn Greven, MD, PI**

**97405** Phase III Study of Soy, Venlafaxine (EffexorXR™), and Soy + Venlafaxine on Hot Flash Symptoms in Men with Prostate Cancer  
**Mara Vitolins, RD, PhD, PI**

**More protocols will open soon!**

**Register Today!**

**9th Annual Meeting**  
**September 24-26, 2009**  
**Asheville, North Carolina**

# Mile Stones

CCCWFU CCOP RESEARCH BASE

A Semi-annual Newsletter  
Summer 2009 Volume 6 Issue 2

## Research Base Ninth Annual Meeting



The Research Base 9<sup>th</sup> Annual Meeting will be held on September 24-26, 2009 at the Renaissance Hotel in Asheville, NC. Once again the fall foliage of the Blue Ridge Parkway and downtown Asheville will provide the

backdrop of our meeting. Thursday afternoon offers the attendee an opportunity for a hands-on workshop with the new Research Website as well as training on an appointment basis for certification for the Donepezil trial. The meeting will open with a presentation from Betty Ferrell, PhD (insert title), followed by round tables, an open forum discussion on proposed research base concepts, presentations on recruitment and re-

tention issues, and communication with cancer patients. The reception will be held on the "Top of the Plaza" which is located on the top floor of the Renaissance Hotel and affords spectacular views all around. Saturday morning will open with a presentation from Dr. Jeff White, Director of the Office of Complimentary and Alternative Medicine at the National Cancer Institute. The meeting will close with reviews of open protocols as well as protocols in development. Registration is now open and can be faxed, emailed, or submitted online by September 11. The room block at the Renaissance is available until August 24. All information regarding the annual meeting can be found by visiting our website at [www.wfubmc.edu/cancer/researchbase/Annual+Meeting](http://www.wfubmc.edu/cancer/researchbase/Annual+Meeting). See you in Asheville! Contact Lisa Hawkins at (336) 716-0891 or [lhawkins@wfubmc.edu](mailto:lhawkins@wfubmc.edu) with questions.

## Featured Study: Donepezil 91105

**Steve Rapp, PhD, PI**

*"Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients"*

This open study is testing if the acetylcholinesterase inhibitor, donepezil (Aricept), can improve the overall cognitive functioning (primary outcome) and specific cognitive functioning, mood, quality of life and fatigue (secondary outcomes) among adult patients who are at least 6 months post partial or whole brain irradiation.

To facilitate and simplify enrollment we made several important changes to the protocol including:

- Adding a \$40 gift for participating (2, \$20 Wal-Mart cards offered after the first and last assessment)
- Simplifying and reducing medication exclusions. Patients on stable or decreasing doses of steroids, anticholinergics, anti-epileptics, antidepressants, sedatives or benzodiazepines, analgesics, methylphenidate or dexamphetamine, are eligible
- Permitting hormonal therapy for patients with breast or prostate cancer
- Allowing enrollment of patients who have received single fraction stereotactic radiosurgery (SRS) in addition to whole or partial brain irradiation
- Allowing patients who have received prophylactic cranial irradiation and patients who have received Gliadel Wafers in addition to fractionated external beam irradiation (but not GliaSite or other brain brachytherapy)

*(Continued on page 2)*

## The Learning Curve

by Robin Rosdhal RN, OCN

**Protocol 98308** (CLL / Ginseng) Information continues to be entered into the data base for analysis. Due to the volume of data it will be some months before trial results are available. Many of your patients have expressed interest in which protocol arm they received, active drug (Ginseng) vs. placebo. To obtain this information send an e-mail request with the patient's name/initials and protocol identification number. It is the sites responsibility to notify their patients. Again, thank you for the fantastic accrual of almost 300 patients in 2 months to the CLL / Ginseng protocol. This was a major accomplishment.

**Protocol 91105** (Donepezil / Brain Irradiated Patients) Amendment # 7 which contains expanded eligibility criteria was recently approved. The required time frame for some MRI's are now based on WHO Grade allowing an expanded eligibility period. WHO Grade 1, MRI within 12 months, WHO Grade 2 within 6 months, WHO Grade 3/4 within 3 months. PCI and brain metastasis are also within 3 months. Patients must complete chemotherapy prior to registration but there is no waiting period from end of treatment to enrollment. View all amendment

### Donepezil *(Continued from page 1)*

When considering patients for **91105** please remember that they can be years post brain irradiation. Thus, many patients you follow, including former pediatric brain tumor patients, are eligible. Enrollees must only be at least 6 months post irradiation without an upper limit.

We have also developed efficient training methods for your research nurse to become skilled in the administration of our simple neurocognitive assessment battery. We use a web-based training video, self-study and face-to-face experiential methods that can be arranged conveniently at your site.

This study is among several studies with neurocognitive endpoints we plan to offer through the CCCWFU CCOP Research Base in the coming years, so now is an excellent time to prepare your clinic to become involved. If you or your staff have any questions regarding the study please feel free to contact me (srapp@wfubmc.edu) or Robin Rosdhal, RN ([rosdhal@wfubmc.edu](mailto:rosdhal@wfubmc.edu)) directly for more information.

changes on our website.

An upcoming amendment will require site personnel to review the PHQ prior to the patient leaving the testing area. The PHQ is the last questionnaire in each booklet. If question number 9 has a score of 1, 2, or 3 (anything besides "0") or the total of all columns added together equals 19 or greater the patient will need evaluating for major depression which might include suicidal thoughts. Suggested interventions include notification of site physician, psychiatry consultation, counseling and/or medications. Patients who are have suicidal ideations and have a plan/ methods for carrying out suicide should be sent to an Emergency Room. Guidelines are listed in the protocol and appendices.

**Protocol 97106** (Arginmax / Sexual function in Female Cancer Survivors) A few minority slots are still available.

**Protocol 97405** (Soy Protein / Effexor / Hot flashes in Prostate Cancer) NCI has approved a request for this protocol to be opened by CTSU. This will allow for a broader range of eligible patients. We look forward to working with all the CTSU sites.

## Interview with Kaye Shoffner, RN, BSN, OCN

Q: How long have you worked in research/health care?

A: Almost 2 years in Research/ 4 years in Oncology/ 28 years in nursing.

Q: Describe your role with the Research Base?

A: I am a Clinical Research Nurse at Alamance Regional Medical Center - Cancer Center, in Burlington, NC. I work with the Research Base to identify, screen and enroll new patients to our research protocols. I then work one-on-one with the patients and physicians from the consent process through the follow-up period scheduling appointments for MDs, labs and scans, ordering medications and supplies, etc.; then collecting and submitting the required data for each phase of the individual protocols. I sometimes think of our department as being on the "front lines" of research.

Q: What effective methods have you found to accrue and retain patients on studies?

A: Our research team screens all new patients on a daily basis for possible research candidates. We also meet with our physicians on a regular basis to update them about what protocols we have open and ask if they have any appropriate patients. We have even obtained lists of patients who meet the general criteria of a particular protocol and approached our physicians with names of possible candidates to consider. Our physicians are all very receptive to having their patients participate in research studies whenever appropriate, and this certainly helps make patient accrual easier. Our research team meets weekly to update each other on where we are at with our individual protocols, and my teammates have made several referrals to me as well. I have even made posters and, with

local IRB approval, placed them at strategic locations in effort to "solicit" patient interest in 2 of the CCCWFU protocols: 97106 with success, and 97405 with no luck yet. I am always open to new ideas for recruiting patients!

As for retaining patients on studies, I think it helps to keep in contact with participants. Call them and ask how they are doing rather than wait for them to call with a problem. Many times we can reassure them if they are experiencing an annoying side effect or even get them started on supportive therapy before they become discouraged about the study. Discuss their expectations ahead of time and make sure they understand ALL aspects of the study before they actually consent. Don't ever let them think they are "on their own". I try to be a source of support and encouragement to my patients.

Q: What are your hobbies outside of work?

A: My hobbies include reading, shopping, swimming and most recently, motorcycle riding with my husband (I am just a passenger at present).

Q: What is an interesting fact about yourself that you would like to share with Milestone's readers?

A: I have just been accepted to graduate school at Pfeiffer University and will pursue my Masters Degree in Healthcare Administration beginning in the fall.

Kaye is a tremendous asset to the Research Base and we wish to thank her for all her hard work and dedication.