

Mile Stones

CCCWFU CCOP Research Base

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Out and About with June

CCCWFU CCOP Research Base Protocol 91105: A Phase III Double Blind Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients is now open to accrual. In order to put patients on this trial, Neurocognitive Battery Administration Certification is required.

There are two different ways to receive your certification. The first is to submit an audio tape (on micro cassette) of you administering the Neurocognitive Battery. The tape will be reviewed and feedback/certification will be sent to you. Or, if you prefer, I can visit your site, observe your administration and you will receive feedback/certification instantaneously which would allow you to immediately begin accruing patients at your site.

If you would like to schedule an appointment for a visit from me, contact me at jsteede@wfubmc.edu or 336-716-6733.

June Hetcher - Steele

Mile Stones

CCCWFU CCOP RESEARCH BASE

A Semi-annual Newsletter
Winter 2008 Volume 5 Issue 1

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Save the Date:
8th Annual
Meeting
September
25-27, 2008
WinstonSalem, NC

CCCWFU CCOP Research Base Received 5 Years Funding from the NCI

The Comprehensive Cancer Center of Wake Forest University (CCCWFU) Community Clinical Oncology Program Research Base, one of six NCI-funded cancer center research bases in the United States, was awarded 5 years of funding from 2007 through 2012 (years 9 through 14 of our grant). The grant was 13 inches tall and weighed 9 pounds! Dr. Ed Shaw, Principal Investigator, was a proud papa when Lisa Hawkins, Administrative Secretary for the Research Base, delivered the grant to the NCI, and even happier when it scored well in a very competitive environment for cooperative group/ cancer center research bases as well as CCOPs. Virtually every member of Wake Forest's CCOP Research Base contributed to the grant in some way. Along with Dr. Shaw, the leadership team includes Dr. Glenn Lesser (co-PI), Drs. Michelle Naughton and Mara Vitolins (co-leaders, Cancer Prevention/Control), Dr. Doug Case (Lead Biostatistician), Gina Enevold (Administrator), Dr. Steve Rapp (Leader, Cognitive Function Research), and our newest member, Vivian Schiedler, RN, Oncology Nurse and Director of Clinical Oncology Research from Moses Cone Cancer Center in Greensboro. We are excited to be providing our participating CCOPs and Prevention Members high quality cancer prevention/control clinical trials for 5 more years. Thank you for your support.

Ed Shaw, MD

Outstanding Site Accrual

The CCCWFU CCOP Research Base Accrual Year runs from March 1 to the last day of February each year. Our accruals for 2007-2008 year have been outstanding! Our accrual goal for this year was 210 and we have surpassed that number by nearly 40%. There has been a tremendous response to the Argin-Max study for women (thank you Forsyth Regional Cancer Center, Dr. Judy Hopkins, and Elizabeth White!). And, accruals for the CoQ10 study have been great as well, in fact, the study just closed (though it will reopen for an additional 36 patients in the next month or so). So far, 9 sites have opened the newly activated donepezil phase 3 study and 7 of those sites already have certified staff. With this enthusiasm from site members, we are looking forward to another great accrual year for 2008-2009. Thanks to all sites that have worked so hard this year!

Gina Enevold, MSN, RN, GNP

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The Learning Curve

The Research Base would like to thank you for the great job recruiting patients this year. Our year runs from March 1st until the end of February the following year. With this being a Leap Year you have an extra day to get in those last minute registrations. As of Valentine's Day, we had 290 patients accrued this year. Help us hit the 300 mark by putting lots of patients on study in the remainder of February!

When registering a new patient, if the last four digits of their social security number begins with "0", you must enter the last five digits instead.

The computer system does not recognize a "0" as a beginning number. 233490268 Incorrect = 0268 Correct = 90268

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

Drug has arrived! Patients are ready to be enrolled. If you are in need of neurocognitive training, log on to the Research Base web-site, go to Protocol 91105. Click on the link for viewing the instructional video. When ready for certification contact June Fletcher-Steede.

Unless you have passed the certification procedure you will not be able to register a patient to this protocol.

Ping Tan (computer programmer) is setting up a program to assist with the data collected from the neurocognitive booklets. This will limit the areas that will need to be scored by the sites. The Rey Ostrich Figure (ROCF) needs to be submitted with the testing booklet to data management. These will be scored at WFU.

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

Currently patients receive Wal-Mart gift cards as compensation for the Baseline and 12 week biopsies. In the past Exxon and Shell gift cards were used. If you have any of these old cards at your site please contact me.

97405 Randomized Study of Sov Protein and Effexor on Vasomotor Symptoms of Men with Prostate Cancer

If your site needs samples of the Soy Protein / Casein powder please let me know. These samples may be given to potential patients for them to try prior to registration. Staff may take a sample home to evaluate the mixing Robin Rosdhal RN, OCN possibilities. (336) 713-6519

Soy/ Venlafaxine (EffexorXR™) Update

The Soy Effexor study has randomized 25 participants and only one participant has not completed the 3 month intervention. We are accruing about 3 participants per month. The study needs 151 more men to adequately test whether the treatments are better than placebo for reducing hot flashes in these men. If you tasted the smoothies at the annual meeting you know that the men who agree to participant will likely enjoy consuming the study powder! Keep up the good work and if you have any questions about the study feel free to contact Mara Vitolins at (336) 716-2886 or mvitolin@wfubmc.edu.

Mara Vitolins, RD, PhD

Open Protocols

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, PI

91105 Phase III Study of Donepezil vs. Placebo in Irradiated Brain Tumor Patients

Steven Rapp, PhD, Pl

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 Flush Symptoms in Men with Prostate Cancer Mara Vitolins, RD, PhD, Pl

98301 Phase II Study of St. John's Wort for the Treatment of Hot Flushes in Women with a History of Breast Cancer Michelle Naughton, PhD, Pl

Missy Dyar (Continued from page 3)

family. I have a spoiled rotten 12 year old and an even worse spoiled rotten husband. We are certified foster parents although, we do not have any children presently. We have a small farm and currently have 5 horses, 1 goat, 2 cats, and 3 dogs. In our spare time, we enjoy horse back riding. We have some beautiful Tennessee Walking Horses and we are always ready to go ride. So anytime you are in the area, come over and ride. I also enjoy gardening. Every year I always have a huge vegetable garden. I also have a large collection of daylilies that I really enjoy.

Missy Dyar

The CCCWFU CCOP Research Base would like to thank Missy and her colleagues for all of their hard work and dedication to patients on WFU clinical trials. The Spartanburg CCOP is a valuable asset to the CCCWFU CCOP Research Base.

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Research Base Annual Meeting

The 7th Research Base Annual Meeting was held September 27-29, 2007 in Asheville, NC at the beautiful Renaissance Hotel. Nestled in the heart of downtown, the Renaissance Hotel offered meeting attendees the convenience of downtown shopping, art galleries and a vast array of dining and nightlife options.

This year's annual meeting is going to be held at Graylyn International Conference Center in Winston-Salem, NC. Meeting attendees will experience a unique blend of old



world charm, innovative technology and a personal touch that would make the Gray family proud. Graylyn is listed in the National Register of Historic Places and is one of the finest examples of Norman Revival architecture in the country. A perfect combination of a modern, sophisticated conference facility and an enchanting, historic residence, Graylyn is sure to captivate from the moment you arrive at the estate gates.



In room amenities include such things as full-size desks, internet connectivity, irons and ironing boards, hair dryers, and Gilchrist and Soames® toiletries. Coffee service stations will be provided throughout the guest room wing each morning. During free time, feel free to explore the Estate. Stay indoors, curled up by one of the many fireplaces or in the Mediterranean-style sunroom. Enjoy the exercise room or billiards room. Retreat outside for tennis, or walking and running trails. Meeting attendees will enjoy extensive buffets during breakfast and lunch, while

evening dining is leisurely with table service and specially designed menus. And ... they provide free Dove bars to all guests as a bedtime snack!

Complimentary shuttle service will be provided from the Greensboro Airport to the Estate in Winston-Salem. Transportation will be provided by the Estate to Reynolda House, Reynolda Village, and the Wake Forest University Campus. The meeting dates are September 25-27, 2008. Mark your calendars now and plan to attend.

Contact Lisa Hawkins at lhawkins@wfubmc.edu or 336-716-0891 with any questions.

Spotlight on: Missy Dyar

I work in the Oncology Research Department at Anmed Health in Anderson

South Carolina. We are an affiliate of Upstate Carolina CCOP in Spartanburg, South Carolina. We are a small office of 3 full-time staff members: Rhonda Ballew and Stephanie Fielding (Research Nurses) and Minerva Daniels (Secretary/CRA). I also have a wonderful part time helper by the name of Katie Manson who helps me tremendously. She helps keep all of my paperwork in order and does a terrific job. I contribute great teamwork to what makes our program work. All of the staff in our office work to remind the MD's of cancer control and prevention protocols. Our motto here at Anmed is "We're in this together" and our teamwork in this department reflects that attitude.

I have worked in a variety of areas in our hospital which has helped me tremendously in the research department. I worked in surgery and was crosstrained for recovery, outpatient, and endoscopy. I also worked on our oncology unit at Anmed as well as a couple of different surgeons in our area. My experience has taught me one thing.... I learn something new everyday. I am truly amazed at the advances in oncology today; thanks to research. I have been in the research department for a little over 4 years total. I originally was doing treatment trials and continue to pick up on the overflow as needed. Just recently, I have started concentrating on cancer control and prevention trials. I enjoy doing these trials and I think that shows in my enthusiasm to enroll patients.

As far as accruing patients, I try to look at all the new patients that come through the medical oncologist office, radiation oncologist office, and our chemoinfusion center. I continuously remind all of our doctors of protocols available that might be of interest to them. For example, I visit the urologist offices and

remind them of the prostate hot flash study. I do the same with the radiation oncologist and the medical oncologist. My enthusiasm for a good protocol is contagious.

I also do presentations in different venues. I try to attend support group meetings and encourage patients to participate in clinical trials. I do presentations for Anmed for seminars on different types of cancer such as



breast cancer and colon cancer. I will be working with our internal support system starting in February called Cancer Care 101 which educates patients on services offered at our facility. I do presentations at community functions to educate our community about clinical trials.

I love a challenge and I guess it reflects in my desire to always look for new and innovative ways to recruit participants.

I have found the best why to retain patients is to build a good rapport with them. I always try to make each patient feel special and give each patient individualized care. I like to touch base with every patient weekly or biweekly and try to answer any questions a patient may have regarding their cancer care.

When I am not working, I like to spend time with my

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