Wake Forest University Baptist
MEDICAL CENTER
Comprehensive Cancer Center

Mile Stones
CCCWFU CCOP Research Base
Medical Center Boulevard
Winston Salem, NC 27157
336.716.0891
www.wfubmc.edu/cancer/researchbase

Inside Mile Stones:

- Annual Meeting Registration
- High Point Regional Spotlight
- History of Research Base
- New Updates to Protocols

Data Management: Reminders

When registering a new patient, please remember to fax the consent, HIPAA, and eligibility forms right away. This is the foundation of our chart and is key to establishing the patient record.

Please complete the entire header on each data form. We have to be certain that all patient data is matched to the correct patient. All forms must include the patient ID number, date, and the visit (baseline, one month, follow-up, etc). This helps enormously with the continuity of data and keeps the patient on track with the study requirements.

And lastly, the patient medication diary is crucial in determining when the patient actually took the study drug. Assign one month per page (just like a regular calendar) and have the patient sign and date it. Remind them to bring the calendars in for each office visit so that you can correct any discrepancies or answer any questions they may have.

Welcome New CCOP Site!

Cancer Research for the Ozarks

Springfield, MO

Mile Stones

CCCWFU CCOP Research Base

A Semi-annual Newsletter
September 2006 Volume 3 Issue 2

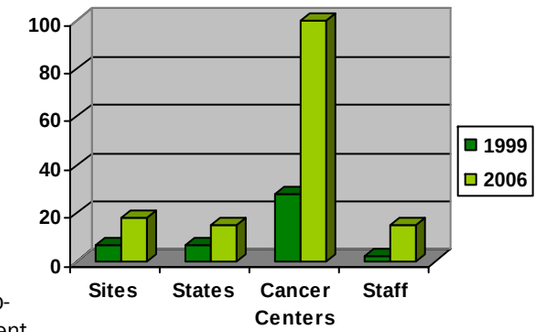
Inside this Issue:

CCCWFU CCOP Annual Meeting
October 27 & 28
Charleston, SC
Register online at
www.wfubmc.edu/cancer/research base

The Comprehensive Cancer Center of Wake Forest University (CCCWFU) Community Clinical Oncology Program (CCOP) is one of six Cancer Center Research Bases funded by the National Cancer Institute's (NCI) Division of Cancer Prevention (DCP). The goals of the CCCWFU CCOP Research Base are to:

1. Reduce cancer incidence and improve quality of life by providing high-quality cancer prevention and control clinical trials for the physicians, research nurses, clinical research professionals, and patients from participating CCOPs, Minority-Based CCOPs, and Prevention Members.
2. Prevent or reduce the symptoms of cancer and treatment related symptoms by utilizing conventional pharmacologic agents, botanical and natural products, complementary and alternative therapies, and behavioral and/or education interventions in open-label Phase II and randomized (+/- placebo-controlled) (+/- double-blind) Phase III trials.
3. Increase recruitment and retention on Research Base clinical trials, with a particular emphasis on under-represented populations including racial and ethnic minorities, women, adolescents, and the elderly.

The CCCWFU CCOP RB was initially funded in 1999. At that time, membership included 3 CCOP and 4 Non-CCOP participants for a total of 28 community cancer centers in 7 states. At present, there are 12 CCOP and 6 non-CCOP participants. This represents about 100 community cancer centers in 15 states. An additional 8 CCOPs and one non-CCOP are considering joining. Our full time staff has grown as well to approximately 15 people at present.



The Research Base emphasizes cancer control (i.e., symptom management) studies, with a focus on botanical and natural products. Cancer prevention studies are also part of the Research Base menu. Our goal is to conduct practice changing cancer prevention/control research that will improve patient outcomes. Research Base studies are designed to be "user friendly." Almost without exception, study drugs are provided at no cost to the patient. Patient follow-up is kept to a minimum, usually ≤ 3-6 months, depending on the endpoint of the study. A listing of our open, soon-to-open, and developing studies is provided later in the newsletter.

The Learning Curve

New registration forms!

All of the Research Base protocols have new, easier to use Eligibility Checklist / Registration Forms. Once you have completed the hard copy of the Eligibility Checklist / Registration Form, you will be ready to register your patient on-line. The written forms were created to match the on-line registration form for your convenience. When the patient is registered, remember to print a copy of the confirmation for your records. The written Eligibility checklist / Registration Form, Consent /HIPAA forms, pathology report, required scans and labs per protocol should be faxed to Research Base Data Management at 336-713-6476.

CCCWFU RB Protocol 71103: Phase II Study of Single Agent Depsipeptide (FK228) in Metastatic or Unresectable Soft Tissue Sarcomas

Cardiac Requirements-
NCI recommended several cardiac changes for patients receiving Depsipeptide. The protocol has been amended to reflect these new cardiac requirements for eligibility. Please review carefully.

GIST Patients
Gastrointestinal stroma tumors (GIST) patients may now receive up to 3 prior treatment regimens before enrollment into the Depsipeptide study. These patients must have received Gleevec as front line therapy. In addition GIST patients may have received Imatinib and/or Sutent. These are the only 3 chemotherapy treatments permitted prior to enrollment in the study for this patient population.

CCCWFU RB Protocol 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

Why is the transferrin level needed?

Transferrin is normally associated with its use in iron metabolism and transport. In protocol 97102, the transferrin level is used as a parameter to monitor the patients nutritional status. Frequently used values of albumin (half-life approximately 3 weeks) or pre-albumin (half-life days) are affected by inflammation, infection, and fluid status more than the transferrin level. Also in a number of settings in cancer bearing patients and in animal studies, albumin has a shorter than normal half-life with increased degradation. Therefore, this may not reflect nutritional or protein anabolic status in some patients. Specifically, nutritional and protein status may be improving but may not be able to elevate serum albumin levels. Transferrin is the only NCI approved "nutrition" lab test required in this protocol. When transferrin levels are low it may be an indication of not only malnutrition but also liver disease and nephrotic syndrome.

Robin Rosdhal RN, OCN

Sixth Annual Meeting

The Research Base sixth annual meeting will be held this year on October 27 & 28 at the Charleston Place Hotel in Charleston, SC. A block of rooms will be held at the Charleston Place until September 12, 2006 at the special rate of $299 per night (double occupancy).

The format of the Research Base meeting has changed this year. On Friday afternoon, all open and developing protocols will be presented by the principal investigators, followed by a reception Friday evening at Sticky Fingers Restaurant (located just around the corner from the Charleston Place). Saturday will begin with a breakfast buffet business meeting followed by a morning of round table sessions for the physicians, nurses, CRAs and data managers. The meeting will end by noon. Online registration is available for the meeting at www.wfubmc.edu/cancer/researchbase, or you can fax your registration to Lisa Hawkins at 336-716-6275, or mail it to:

Lisa Hawkins
CCCWFU CCOP Research Base
Protocol Information Office
2000 West First Street, Suite 401
Winston-Salem, NC 27104

Registration Form

Friday

- ☐ 1:00 pm Afternoon Protocol Review
- ☐ 6:30 pm Reception at Sticky Fingers
  Number attending _____

Saturday

- ☐ 7:15 am Breakfast Buffet
- ☐ 7:30 am Research Base Business Meeting
- ☐ 8:00 am Round Table Session (CRA)
- ☐ 8:00 am Round Table Session (Physician)

There are no registration fees associated with the Research Base Meeting.

Name: _____
Job Title: _____
Specialty: _____
Guest Names: _____
Business Address/City/State/Zip: _____
_____
Email: _____
Credential(s): _____
Business Phone: _____
Fax: _____
SS# last 4 digits/AMA#: _____
CCOP/Non-CCOP/Hospital Affiliation:
_____

Please fax registration form to (336) 716-6275 or mail to:
Protocol Information Office
Attn: Lisa Hawkins
2000 W. First Street, Suite 401
Winston Salem, NC 27104

Registration Deadline: October 13, 2006

Feel free to contact Lisa with any meeting related questions at 336-716-0891 or lhawkins@wfubmc.ecu.

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, PI

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, 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

Soon-to-Open Studies (Fall 2006)

Cancer Control and Prevention

97405 Phase III Study of Soy, Venlafaxine (Effexor), and Soy + Venlafaxine on Hot Flush Symptoms in Men with Prostate Cancer

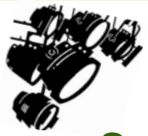
Mara Vitolins, RD, PhD, PI

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

Steven Rapp, PhD, PI

97106 Phase III Double Blind Placebo Controlled Study to Determine Whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors

Kathryn Greven, MD and Brigitte Miller, MD, coPIs



Spotlight on: Virginia Deaton and Kathy Reid

Kathy Reid is currently the Oncology Research Coordinator at High Point Regional Health System. She has been a nurse for 23 years. Initially Kathy began her nursing career in the United States Navy and proudly served our country for 8 years through active duty and reserves. After discharge from the Navy, Kathy entered the research world as the coordinator for an international cardiac study for the National Heart, Lung and Blood Institutes. Little did she know that she would get the opportunity to return to the research world on the "other side "as a community member in High Point, North Carolina years later. Kathy helped start a community research program in Oncology at the High Point Regional Health System in September, 2002 and remains there today! During the 2004-2005 grant year, Kathy was presented an award by SCCC (Southeast Cancer Control Consortium) for having the highest accruals in CCCWFU cancer control trials.

Virginia Deaton (left) and Kathy Reid (right) are on the research staff at High Point Regional Health System in High Point, NC.

In her spare time, Kathy happily enjoys following her three active teenagers from the basketball court to the baseball diamond to the soccer field. She enjoys working out, reading great novels, seeing movies, travel and cooking.

Virginia Deaton joined the High Point Regional Health System research team one year ago as a Clinical Research Assistant. Virginia has worked in the medical field for 14 years as a Nationally Certified Pharmacy Technician. She conducts daily screening and is prompt and complete with her data submissions. Virginia's interests include working with children and gardening.

Kathy says the physicians now joke that if you walk through the doors of the High Point Re-

For article ideas and comments, please contact Sarah Hahne at shahne@wfubmc.edu.