

**Clinical Research Center
Vanderbilt University Medical Center
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"CRC...the Center where people Really Care."

Newsletter or database inquires may be sent to:

**Clinical Research Center
AA-3223 MCN, Nashville, TN 37232-2195
(615) 343-2532 or 343-8649 (fax)**

Volunteers Studies Newsletter



*The following studies are currently enrolling. Please note the descriptions, CRC numbers and contact persons if you are interested in participating. For additional copies or inclusion on our mailing list and/or database of volunteers, please call the number on the front page of this newsletter. If you know your address or phone number has changed since you first began receiving the newsletter, **PLEASE** call with that new info so we can update our files. **THANKS!***

FOR WOMEN ONLY

Effect of Bayer Aspirin on Levels of C-Reactive Protein in Postmenopausal Women Who Initiate Hormone Replacement Therapy; David Kerins, M.D., Principal Investigator (CRC #1022)

Subjects: Healthy postmenopausal women age 44 and up.

Description: 12 week study.

Contact: Barbara Roberts, R.N. or Kathy Steinson, R.N. (615) 936-1945

Compensation: Upon completion of study.

Pharmacokinetic Interaction Studies of Amprenavir, Efavirenz, and a Second Protease Inhibitor in HIV-Seronegative Volunteers; David Haas, M.D., Principal Investigator (CRC #1034)

Subjects: Women age 18 and older who are either surgically sterile or post-menopausal and are within 20% of ideal body weight. Must also have no history of hypertension, coronary disease, arthritis, diabetes or chronic gastrointestinal condition.

Description: This study will last approximately one month and include 3 separate 12 or 24 hour admissions to the CRC.

Contact: Victoria L. Harris, Ed.D. (615) 467-0157 (ext. 109)

Compensation: Provided upon completion of study.

Treatment of Systemic Lupus Erythematosus with Raloxifene; Nancy Olsen, M.D., Principal Investigator (CRC #1002)

Subjects: Postmenopausal females with a diagnosis of systemic lupus erythematosus.

Description: Subjects are treated with the selective estrogen modulator raloxifene (Evista) for a period of 6 months. Visits for blood work and evaluations are every 2 months. Patients may not be taking any estrogen-containing hormone for 3 months prior to study. Subjects with a history of thromboembolic disease or with positive tests for the lupus anticoagulant are excluded. All regular medications are continued throughout the study.

Contact: Nancy Olsen, M.D. (615) 343-4208

Compensation: No charge for visits, tests, or study medication.

Laboratory Monitoring of Hot Flashes; Janet Carpenter, Ph.D., Principal Investigator (CRC #959)

Subjects: Older women who are having hot flashes but taking **NO** medications other than Tamoxifen.

Description: The purpose of this study is to obtain information regarding the use of a non invasive portable monitoring device that can be used to measure hot flashes. It will also compare the experience of hot flashes for peri- and post-menopausal women. The study will last approximately 5 hours. Four hours of that time participants will be monitored in a hospital bed and will refrain from as much movement as possible.

Contact: Janet Carpenter, Ph.D. (615) 322-0831

Compensation: Reimbursement will be given to participants for their time and effort in participating in this study.

OLDER ADULTS

Failure to Thrive Treatment Study; Harry Gwirtsman, M.D., Principal Investigator (CRC #992)

Subjects: Adults age 65 or older. May or may not have failure to thrive but if diagnosed with FTT, must be currently receiving nutritional therapy and have had a recent unintentional weight loss of more than 10% of body weight.

Description: This study involves an overnight stay in the metabolic chamber (a room which is fitted with instruments to measure metabolic rate) at the CRC.

Contact: Lynne McFarland, RN (615) 343-0843

Compensation: Reimbursement for time spent on study.

Shingles Prevention Study; Peter F. Wright, M.D., Principal Investigator (CRC #890)

Subjects: Adults, age 60 or older, who have had chickenpox but have **not** had shingles (herpes zoster).

Description: This study is to determine if varicella vaccine decreases the incidence and/or severity of shingles and its complications in older adults. It requires one hour of time in the CRC for education and vaccination. There is no compensation for vaccine. However, persons in the study who develop shingles will be seen until the rash resolves and will receive compensation for these visits.

Contact: Carol Meisch (615)343-8800

ADOLESCENTS

Energy Balance in Adolescents with Sickle Cell Disease; Mac Buchowski, M.D., Principal Investigator (CRC #1010)

Subjects: African American adolescents ages 12 to 18 years old. Need teenagers **without** sickle cell disease and **with** sickle cell disease. Parental consent is **REQUIRED!**

Description: Determine how sickle cell disease affects the body's ability to make and to break down protein and to process energy from food eaten. This study requires that you stay **one 24 hour period** in the metabolic chamber. You will be required to keep an activity and diet log. You will also collect urine for a total of 4 days. This is a safe and drug-free study.

Contact: Mac Buchowski, Ph.D. (615) 327-6906 or 343-4192

Compensation: Available upon completion of study.

ASTHMA

Study of the Effect of Albuterol, Levalbuterol, and S-albuterol on the Late Phase Response to Segmental Allergen Challenge; John Murray, M.D., Principal Investigator (CRC #1025)

Subjects: Men or women 18 years of age or older, diagnosed with asthma.

Description: If you've been diagnosed with asthma, you may be eligible for a currently available asthma medication. This study will compare the effects of medications and placebo in asthmatics.

Contact: Suzanne Tilley (615) 936-5764

Compensation: Physical exams and study medications are provided, as well as compensation for your time.

Medication Use in Assessing and Improving Asthma Control; Tina V. Hartert, M.D., Principal Investigator (CRC #839)

Subjects: Age 18 years and older, admitted to VUMC for asthma exacerbation. Must have access to a working telephone and transportation.

Description: This study is researching physiologic, biochemical, and behavioral aspects of hospitalized asthmatics. Patients will complete a questionnaire, and have blood, urine and sputum samples collected. There is no medical intervention; however, patients will receive basic asthma education. They will return to the CRC for a 3 month out-patient follow-up visit.

Contact: Lesa Wood, RN (615) 343-4441

Compensation: Available upon completion of study.

CARDIOVASCULAR & HYPERTENSION

The Effect of Genetic Variation on Aldosterone Production; Jay Gainer, M.D., Principal Investigator (CRC #951)

Subjects: Men and women, African Americans and Caucasians, ages 18 to 65, with and without high blood pressure.

Description: Studies may require special diets that are prepared by the CRC.

Contact: Tami Neal, R.N. (615) 322-3371

Compensation: Participants will be compensated.

Evaluation of New Blood Pressure Drug in Hypertensive Patients; Nancy Brown, M.D., Principal Investigator (CRC #1024)

Subjects: Healthy men and women with high blood pressure.

Description: Study requires patients to come off regular blood pressure medications.

Contact: Tami Neal, R.N. (615) 322-3371

Compensation: Participants will be compensated.

Vascular Disease in Patients with High Blood Pressure; Douglas Vaughan, M.D., Principal Investigator (CRC #870)

Subjects: Men and women age 18 to 60.

Description: Study will look at high and low salt diets.

Contact: Barbara Roberts, R.N. (615) 936-1945 or Kathy Steinson, R.N. (615) 936-2165

Compensation: Reimbursement upon completion of study.

CHRONIC BACK PAIN

Pain Regulatory System Dysfunction in Chronic Pain; Stephen Bruehl, Ph.D., Principal Investigator (CRC #1018)

Subjects: Males and females between the ages of 18 and 50, chronic low back pain of at least 3 month duration who are not taking daily narcotics and who have no history of hypertension. Also, healthy pain-free males and females between the ages of 18 and 50, without history of hypertension or chronic pain.

Description: Two sessions lasting approximately two and a half hours each. This study is designed to better understand the mechanisms that the body uses to manage pain, and to determine whether individuals with chronic pain have problems with these natural pain control systems.

Contact: Pamela Ward (615) 936-2499.

Compensation: Upon completion of study.

DIABETES

Non-Invasive Glucose Monitoring in Diabetic and Normal Humans; Stephen N. Davis, M.D., Principal Investigator (CRC #808)

Subjects: Healthy males and females between the ages of 18 to 55 with or without diabetes.

Description: The purpose of this study is to test a new investigational device to determine if it can accurately measure blood sugar without a needle stick. This study involves an overnight stay in the CRC and the placement of two IV's - one in each hand or arm. Saline, potassium, insulin and glucose will be infused and blood sugar measurements will be taken over the length of the study (appx. 8 hours). Bedrest and immobility of both arms is required during the study. Health screening, urine test and bloodwork will be done prior to the study.

Contact: Antoinette Richardson, RN (615) 936-3447

Compensation: Reimbursement upon completion of study.

Metabolic Adaptation to Diabetes; Alvin Powers, M.D., Principal Investigator (CRC #965)

Subjects: Healthy males and females between the ages of 18 to 40 **with** Type 2 diabetes **OR** without diabetes.

Description: Visits for initial screening and lab work with one overnight stay in the CRC.

Contact: Linda Balch, RN (615) 327-4751 ext. 6642

Compensation: Reimbursement upon completion of study.

Metabolic Adaptation to Diabetes; Stephen N. Davis, M.D., Principal Investigator (CRC #1013)

Subjects: Healthy adults between 18 and 45 years of age either **without** diabetes **OR** with a minimum of five year history of Type 1 diabetes (with no diabetic complications)

Description: This study involves an overnight stay in the CRC with the placement of two IV's and the infusion of saline, potassium, glucose, insulin, and labeled sugar. Blood samples will be drawn over a 4 hour period and the study will end with a muscle biopsy of the leg. Patients will return for a second study

approximately two months later that will include the same procedures including a repeat muscle biopsy and the infusion of epinephrine. Patients are screened prior to the study with blood work, an EKG and measurement of body composition.

Contact: Deanna Aftab-Guy, M.D., (615) 936-1824 or Linda Balch (615) 327-4751 ext. 6641

Compensation: Reimbursement upon completion of study.

Metabolic Adaptation to Diabetes #2; Stephen N. Davis, M.D., Principal Investigator (CRC #747)

Subjects: Post-menopausal women either on estrogen therapy or not on estrogen therapy and healthy men ages 45 to 65.

Description: Treadmill stress test, blood draw and one overnight stay in CRC.

Contact: Antoinette Richardson, RN (615) 936-3447

Compensation: Reimbursement upon completion of study.

GENETICS

Effect of CYP3A4 of Polymorphisms on Basal & Induced Enzyme Activity; Grant Wilkerson, Ph.D., Principal Investigator (CRC #921)

Subjects: Healthy non-smoking African American men and women ages 18 to 45.

Description: This 2 1/2 week study is investigating how people with different genetic makeups break down medications in the intestine and liver.

Contact: Gail Mayo, RN (615) 322-7072

Compensation: Reimbursement upon completion of study.

Genes & Fibrinolytic Capacity of Human Endothelium; Nancy Brown, M.D., Principal Investigator (CRC #968)

Subjects: African Americans & Caucasian smokers and non-smokers ages 18 to 65.

Description: This is a one day study.

Contact: Tami Neal, RN (615) 322-3371

Compensation: Reimbursement upon completion of study.

HIV/AIDS

HIV Vaccine Trials Unit at Vanderbilt; Peter Wright, M.D., Principal Investigator (CRC #938)

Subjects: Healthy uninfected adults between the ages of 18 and 60.

Description: National Institutes of Health (NIH) sponsored potential preventive HIV vaccine studies. Vaccines do **not** contain any killed or live AIDS virus. People **cannot** get infected from these vaccines.

Contact: Mary Braeuner, RN (615) 343-6957

Compensation: Payment for study participation.

METABOLISM

Screening for Drug Transporter Polymorphisms & Drug Clearance; Richard Kim, M.D.,

Principal Investigator (CRC #962)

Subjects: Healthy, non-smoking individuals age 18 and up who are on **NO** medications.

Description: This study involves a screening visit and 1 outpatient visit to take an Allegra capsule and have a blood sample taken 3 hours later.

Contact: Gail Mayo, RN (615) 322-7072

Compensation: Reimbursement given after outpatient visit.

Fexofenadine (Allegra) Study; Richard Kim, M.D., Principal Investigator (CRC #880)

Subjects: Healthy African American and Caucasian men and women ages 18 and up. Must be nonsmoker and on **NO** medications.

Description: Study drug will be given; involves one inpatient visit

Contact: Gail Mayo, RN (615) 322-7072

Compensation: Reimbursement upon completion of study.

PEDIATRICS

Wyeth-Lederle Pneumococcal Vaccine Study; Kathryn Edwards, M.D., Principal Investigator

(CRC #1017)

Subjects: Children age 2 to 7 months.

Description: This vaccine is used to help prevent ear infections, meningitis and pneumonia.

All currently recommended licensed immunizations will be given at no cost. Children do not need to be part of the vaccine practice to participate.

Contact: Kitty Miller, R.N. (615) 322-2477

Compensation: Compensation provided.

RSV in Healthy Adults, Children and Infants Study # 1; Peter Wright, M.D., Principal Investigator

(CRC #608)

Subjects: Health infants 4 to 12 weeks old.

Description: RSV is a serious respiratory illness that causes pneumonia and wheezing in infants and children. This investigational vaccine against RSV is given by nose drops.

Contact: Kitty Miller, R.N. or Alice O'Shea, R.N. (615) 322-2477

Compensation: Compensation is given for each study visit.

RSV in Healthy Adults, Children and Infants Study # 2; Peter Wright, M.D., Principal Investigator

(CRC #608)

Subjects: Health infants and children 6 to 59 months old.

Description: RSV is a serious respiratory illness that causes pneumonia and wheezing in infants and children. This investigational vaccine against RSV is given by nose drops.

Contact: Kitty Miller, R.N. or Alice O'Shea, R.N. (615) 322-2477

Compensation: Compensation is given for each study visit.

Functional Ovarian Hyperandrogenism Study: Revi Mathew, M.D., Principal Investigator
(CRC #847)

Subjects: Girls between the ages of 4 and 11 who are **not** on hormone or steroid treatment. We will include 10 girls who are not in puberty and, if African American, less than 6 years old; or if Caucasian American, less than 8 years old. We'll also include 10 girls in early puberty between the ages of 9.5 & 11.

Description: This study will help us learn to diagnose polycystic ovary syndrome in girls with early onset of pubic hair. It requires two separate visits to the CRC on two consecutive mornings for the tests, as well as taking one steroid pill at bedtime each evening beforehand.

Contact: Revi Mathew, M.D., (615) 322-7427, pager: 736-4158

Compensation: Upon completion of study.

PULMONARY

Efficacy & Safety of Mometasone Furoate Dry Powder Inhaler in the Treatment of Patients with Chronic Obstructive Pulmonary Disease (COPD); John J. Murray, M.D., Principal Investigator
(CRC #982)

Subjects: Participants must be at least 40 years old and a current or former smoker.

Description: This study will evaluate the effectiveness of a treatment for smokers' lung disease.

Contact: Jill McHenry (615) 936-5764.

Compensation: Participants will be compensated for their time.

The Vanderbilt General Clinical Research Center (CRC), operating since 1957, is funded by the National Institutes of Health (NIH) to promote ethical and responsible medical research. The CRC has created a volunteer database to allow our researchers access to potential volunteers. We support patient-oriented research of high quality in both children and adults and have more than 125 projects active at any given time.

If you have not already done so, and are interested in your name being added to our database where you may receive additional information about other research studies, please complete the information below.

Due to the large number of studies performed, there is the possibility that you will get numerous calls. Please update us on any change of address or phone numbers. If at any time you choose not to remain in our volunteer database, please call us at (615) 343-2532.

Thank you!

VOLUNTEER QUESTIONNAIRE

Name _____

Address _____

Zip code _____

Email address: _____

Home Phone (____) _____ Work Phone (optional) (____) _____

Date of Birth _____ Male _____ Female _____

Race (mark one please) American / Alaskan Indian _____ Black _____

Hispanic _____ Asian / Pacific Island _____ White _____ Other _____

Height _____ ft. _____ in. Weight _____ lbs.

Please mark any of the following areas of interest about which you would like more study information. You do not have to have any condition that you mark. However, if you do have a condition (such as diabetes, high blood pressure, asthma, etc.), **PLEASE** make note of that and any medications in the “**Conditions**” section below.

Volunteers without a specific condition (**General volunteer**) are also needed for the areas listed. **Complete this form and mail or fax to: Denise Owens, GCRC Vanderbilt University Medical Center, MCN AA-3223, Nashville, TN 37232-2195; fax number (615) 343-8649.**

General volunteer _____ Are you a twin? ____ yes ____ no

Diabetes _____ Parkinson’s disease _____ (Tremors) _____ Alcoholism _____ Sickle Cell disease _____

Allergy _____ Arthritis _____ Geriatrics _____ Smoking _____ (Do you smoke? Yes ____ No ____)

Alzheimer’s disease _____ Asthma _____ Heart disease (Arrhythmia Angina, Congestive heart failure, etc.) _____

Vaccine trials (Pediatric ____ or Adult ____) _____ Hypertension (High blood pressure) _____ Cancer _____

AIDS (Prevention _____ or Treatment _____) _____ Hypotension (Low blood pressure) _____ Depression/Anxiety _____

Obesity/Diet _____ Exercise _____

***Conditions you have or would like to participate in research on:**