

The University of Connecticut Health Center

**GENERAL CLINICAL  
RESEARCH CENTER NEWSLETTER**

**GCRC Resources Enable  
A Rich Ensemble of Clinical  
Studies by School of Dental  
Medicine Faculty**



**J. Robert Kelly, DDS, MS, DMedSc**

Professor, Prosthodontics and Biomaterials  
Director, Dental Clinical Research Center  
School of Dental Medicine

How could there be a relationship between the prophylactic administration of cyclooxygenase-2 inhibitors as an adjunct to cancer treatment and a history of depression as a risk factor for cardiovascular outcomes in diabetic postmenopausal women? What does an improved understanding of the treatment of chronic facial pain patients have to do with highly esthetic, computer-fabricated dental ceramics? These diverse topics are among the many clinical studies that faculty members of the School of Dental Medicine are conducting under the GCRC umbrella. Clinical research activity by dental faculty has been increasing, as reflected in the number of active studies (12), the number of investigators (20), and the number of patient visits in the past year to the Dental Clinical Research Center (440). Many dental faculty are also involved in clinical research activities that bridge the UConn Health Center to other academic medical facilities, both locally and internationally.

GCRC resources, essential to both the feasibility and quality of dental faculty research, are being more broadly employed following the successful creation and funding of the GCRC Dental Core during the 2003 GCRC NIH grant renewal. Besides administering the dental research clinic, the Dental Core is increasingly able to provide assistance in research budgeting, guidance on protocol development and regulatory issues and many elements of study coordination – especially helpful for faculty new to clinical research. Oversight of dental projects by both the GCRC Scientific Advisory Committee and Research Subject Advocate has provided “behind the scenes” input that has improved the program as a whole. Dental faculty are availing themselves of opportunities provided via the Informatics Core, Nursing Core, and the Core Laboratory of the GCRC. Examples of the importance of GCRC resources (not just the Dental Core) to the richness of dental faculty research will become apparent from the details of programs chosen for highlight below.

Dr. Mark Litt, a highly respected behavioral scientist who presented one of the seven “major” projects during the GCRC renewal



**INSIDE THIS EDITION**

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(and which was rated as outstanding), is studying craniofacial pain, termed temporomandibular disorder (TMD), a widespread chronic pain condition. Successful psychosocial and dental treatments for TMD have been developed, but the mechanisms by which these treatments achieve their effects are not well known nor are they applied with consistent results. One goal of his NIDCR-funded project is to elucidate the mechanisms responsible for gains following TMD treatment. Patients are being randomly assigned to receive either (i) a Standard Conservative Treatment (STD) employing an intra-oral splint plus anti-inflammatory agents, or (ii) a Standard Treatment + Cognitive-Behavioral Treatment Program (STD+CBT). The (STD + CBT) group receives standard treatment, as well as focused instruction and counseling on changing self-efficacy and decreasing catastrophization. Dispositional and situational variables derived from a comprehensive model of pain coping are being measured before and after treatment, as well as blood plasma levels of cortisol and selected cytokines. Interactive voice recording (IVR), a research tool that permits "real time" versus retrospective data collection, is being employed for assessment of pain ratings, mood, and coping. This IVR system, developed by Informatics Core Director, Dr. Khamis Abu-Hasaballah, makes four quasi-random outbound calls to patients each day (3000 total calls). Preliminary results have indicated that coping skills acquired in cognitive-behavioral treatment predict a decrease in the pro-inflammatory cytokines IL-6 and TNF $\alpha$ , and an increase in the anti-inflammatory cytokine IL-10, coinciding with decreasing pain levels over time. The results suggest one pathway by which cognitive-behavioral interventions result in a reduction in chronic pain.

Three other dental faculty projects are collecting data using the IVR system. Dr. Robert Aseltine has enabled UHC to serve as the coordinating center of a 14-site national study identifying at-risk alcohol users in emergency room settings and testing the

influence of a brief intervention to reduce drinking. Their hypothesis is that among persons identified with at-risk drinking in this population, brief counseling will reduce alcohol-related risk factors and increased completion of referrals in the intervention group at 3- and 6-month follow-up, compared to a control group that receives only written advice. IVR computers take inbound calls from patients at 3, 6 and 12 months following outbound reminder calls (1921 total calls). Data collection scripts are provided in both English and Spanish.

Dr. Litt, in an NIAAA sponsored collaboration with Drs. Ned and Judith Cooney (Yale University/VA Connecticut) and Cheryl Oncken (UHC), is examining nicotine replacement therapy in alcohol-dependent smokers during the initial phase of outpatient alcohol treatment. Do to its nature, IVR will greatly enhance their ability to examine such issues as whether smoking status mediates drinking outcomes and to determine momentary triggers for nicotine gum self-administration. Patients will receive five quasi-random outbound daily calls assessing alcohol intake, cigarette usage, and mood, representing approximately 278 hours of automated data collection (via 7129 calls).

Dr. Rajesh Lalla, in a pilot project collaboration with Dr. Douglas Peterson, is using IVR to follow medication adherence and adverse events in daily monitoring of cancer patients given a cyclooxygenase-2 inhibitor to suppress radiation-induced oral mucositis. Previous NIH-sponsored results (obtained in collaboration with investigators from Brigham and Women's Hospital, Boston, MA and the Department of Medicine, University of Adelaide, South Australia) indicated an association of critical components of the cyclooxygenase pathway with mucosal injury and pain in chemotherapy-induced oral mucositis. Dr. Lalla won Best Poster and Young Investigator awards at the 2005 meeting of the *Multinational Association for Supportive*

*Care in Cancer/ International Society for Oral Oncology* in Geneva, Switzerland for his presentation "Role of the Cyclooxygenase Pathway in Chemotherapy-induced Oral Mucositis." The GCRC Core Laboratory conducted the laboratory assays for this research and the Biostatistical Core conducted the data analyses. Dr. Douglas Peterson and Dr. Carol Pilbeam collaborated with Dr. Lalla on this research.

In a study to begin this fall, Dr. Litt, in conjunction with Dr. Ronald Kadden, will be using IVR to conduct experience sampling with alcoholics just prior to treatment. Patients carrying a cellphone will be called eight times per day and asked about their thoughts, feelings, behaviors, and surroundings, and about whether they have been drinking or not. The patients' responses will be collated prior to treatment, and these responses will form the basis for a treatment specifically tailored to a patient's strengths and weaknesses. This Individualized Assessment and Treatment Program (IATP) will be compared to a standardized, manual-driven cognitive-behavioral treatment.

Dr. Anna Dongari-Bagtzoglou recognizes that inflammatory processes associated with untreated chronic periodontal infections may contribute to chronic cardiac or renal graft failure in transplant recipients. Compelling evidence has accumulated over the last 5 years associating chronic elevation of serum markers such as serum interleukin-6 (IL-6) and C-reactive protein (CRP) in periodontitis patients with a systemic inflammatory state that may contribute to cardiovascular or cerebrovascular disease. IL-6 accumulates in the chronically infected gingiva at extremely high levels, and both IL-6 and CRP serum levels are elevated as a result of periodontal infections. Dr. Dongari-Bagtzoglou hypothesizes that in transplant patients with extensive periodontal disease, IL-6 may directly (or indirectly via induction of CRP) contribute to chronic allograft failure. Her research, which is NIDCR funded, is being performed in

collaboration with Dr. David Hull, Department of Surgery, Hartford Hospital.

Dr. Dongari-Bagtzoglou has also recently completed NIDCR-funded research examining oral epithelial cell anti-fungal activity in the presence of *Candida albicans*. Oral candidiasis is perhaps the most frequent opportunistic infection experienced by immunocompromised patients. Both *in vitro* and *in vivo* evidence suggest that the neutrophil (PMN) is the primary immune cell type involved in resistance to and eradication of *Candida* fungi. Such PMN functions are activated by soluble proteins known as cytokines, likely derived from cells of non-immune origin such as those comprising the oral epithelium. Her study was designed to test the activation of PMN anti-fungal functions in response to cytokines secreted by oral epithelium cells. In March 2005, Dr. Dongari-Bagtzoglou reported to the *International Association of Dental Research* that oral epithelial cells can activate neutrophil anti-hyphal function, an effect partly attributed to the generation of immunomodulatory cytokines during the interaction of oral mucosal cells with the pathogen.

Dr. Julie Wagner is investigating psychosocial contributors, particularly major depressive disorder, to vascular complications in diabetes and coronary heart disease in postmenopausal women. Her pilot project, titled the "Women's Heart Study," received K12 award support from the UConn Center for Interdisciplinary Research in Women's Health with co-investigators including Drs. Tennen, Mansoor and Malchoff. One specific outcome involves the radiological measurement of brachial artery flow mediated dilation. This measure of endothelial function, known to be markedly attenuated in currently depressed groups, has not been used to investigate the effect of history and duration of major depressive disorder. This project represents one part of a larger program designed by Dr. Wagner to focus on lifetime history of

depression as a risk factor, versus current depressive state at baseline. Her pilot work has led to funding from both the American Heart Association and the American Diabetes Association.

Dr. Ernst Reichenberger has an interest in understand the molecular mechanisms of neoformation of dermal tissue in fibrotic diseases. To achieve this goal, using NIDCR funding, he is studying hereditary keloid formation. Keloids are benign tumors of the skin or cornea caused by overactivity of fibroblasts during abnormal wound repair. The relatively large number of familial cases of keloid formation suggests that it may be possible to identify a gene that is responsible for increased cell proliferation and extracellular matrix expression. Dr. Reichenberger is performing genome wide screening and linkage analysis of suitably large families afflicted with the autosomal dominant form of hereditary keloid formation for subsequent identification and analysis of the chromosomal loci. To date, two possible disease gene loci have been identified. With help of the GCRC, Dr. Reichenberger recently initiated a collaboration with a research group in Nigeria, where heritable keloids are found in large families within the Yoruba tribal area. Other genetic studies involving the GCRC include those examining rare bone disorders such as cherubism, craniometaphyseal dysplasia, forms of aplasia cutis congenita, and tricodontoosseous dysplasia.

Ten dental faculty are examining the clinical performance of emerging materials and surgical techniques for the restoration of missing teeth and tooth structure. Dr. Martin Freilich, with foundation funding and an NIDCR K23 award and in collaboration with Dr. Jonathan Meiers, is using fiber-reinforced plastics developed at UConn by Dr. Jon Goldberg to place implant-supported prostheses in edentulous patients. The fiber-reinforced material is used in place of cast metal substructures that can be difficult to fabricate to the dimensional tolerances desired.

Drs. Kelly, Squier, Arteaga, Rungruanant, and Vogiatzi are placing highly esthetic all-ceramic crowns fabricated, in part, using computer-assisted design and manufacturing technology. This investigator-initiated study at UConn is being sponsored by industry in part due to the researchers' expertise in modeling and predicting clinical behavior of dental ceramics. Drs. Shafer and Vogiatzi are examining issues related to the placement and restoration of dental implants delivered coincident with tooth extraction (termed "immediate implantation"). Drs. Effie Ioannidou and Dongari-Bagtzoglou recently completed a retrospective examination of outcomes from two different surgical bone grafting procedures used in conjunction with the partial placement of dental implants into the maxillary sinus. Dr. Ioannidou has received funding from an implant research foundation for a randomized, prospective study of the immediate loading of dental implants (within 24-48 hours of placement) versus traditional delayed loading (i.e., at 3-6 months).

Overall, the clinical research focus of dental faculty reflects the rich variety of scientific disciplines inherent in the provision of oral and maxillofacial healthcare within the academic environment of the UConn Health Center. Faculty expertise in behavioral science, oral medicine, surgery, inflammation biology, and materials science are being applied to better understand disease processes and optimize treatment outcomes in programs bridging medicine and dental medicine. It is expected that the formal incorporation of the Dental Core within the GCRC (which exists at only four of 78 GCRCs nationwide) will provide an important element in the overall growth of translational research at the UConn Health Center, as well as providing an invaluable resource in the development of clinical research careers for dental faculty.



## NOTES FROM THE GCRC PROGRAM DIRECTOR



**Henry R. Kranzler, M.D.**  
Professor of Psychiatry,  
GCRC Program Director, and  
Assistant Dean for Clinical Research

It is with pleasure and pride that I assume the role of Program Director of the Lowell P. Weicker, Jr. General Clinical Research Center. I began my association with the GCRC as an investigator, served as a member of the GCRC Scientific Advisory Committee, and was appointed Associate Program Director beginning in 1997. Over the past decade, I have had the opportunity to work with many outstanding GCRC staff members and Health Center investigators. As a clinical investigator, the growth and development of the GCRC has provided me with many opportunities to broaden my research and make it more translational in its focus.

Over the past decade, the GCRC has also come to serve as the primary engine for clinical and translational research at the Health Center. With the advent of the Signature Programs, the GCRC has the opportunity to increase its research activity in the areas of cancer, cardiovascular disease, musculoskeletal disease, and public health. Through its growing array of courses and seminar series, the GCRC has come to play a crucial role in educating the next generation of patient-oriented investigators in medicine and dental medicine.

My immediate goal as Program Director is to identify and exploit opportunities for synergy within the Health Center to advance the clinical research mission. A major focus of the GCRC is to assist investigators in their efforts to obtain extramural funding for clinical research. With the advent of the NIH Roadmap, interdisciplinary efforts to translate basic science findings to the clinic and of clinical research findings to the community are being given a high priority. Success in these endeavors will require the involvement of basic science faculty who are interested in the clinical translation of their work. It will also require participation by clinical faculty who recognize that new insights in the etiology, pathogenesis, and treatment of disease are essential to excellence not only in clinical care, but also to the health of the community. Collaborative efforts among basic and clinical investigators will also enhance the Health Center's mission of educating medical, dental, and graduate students.

To continue its success, the GCRC must be efficient, user-friendly, and fully integrated with other UCHC clinical research resources, such as the Clinical Trials Unit. As a regional resource, the GCRC must continue to promote participation in the clinical research mission by other healthcare institutions in the Greater Hartford area. With the renewal application for the GCRC due to be submitted in 2008, we must remain mindful of the efforts that have resulted in two successful renewal applications. Foremost among these is the active involvement of the Health Center community in the growth and development of the GCRC as a key shared resource for clinical and translational research. With that in mind, I invite all interested parties to discuss with me any ideas or concerns that they may have related to the GCRC or clinical/translational research at UCHC. I am confident that the GCRC will continue to prosper through the shared efforts of the Health Center faculty, staff, and students.

## “RESEARCH COORDINATORS COURSE”

By Thomas Kiely, BSN, CCRP

In January 2002, Robin Leger, RN, PhD directed the first course to be offered to study coordinators by the General Clinical Research Center (GCRC) at UCHC. The *Research Nursing Orientation Course* was developed to train nurses in the principles of clinical research through a multidisciplinary team approach using didactic information, identification of available resources, and direct observation. The course evaluations provided valuable feedback on the content and process and were used to revise the course, which was renamed the *Research Coordinators Course* and which debuted over two consecutive days in October 2002. The course has been offered in each of the two subsequent years and has been well received. Since its inception in 2002, a total of 44 individuals have completed the course.

The goal of the course is to promote a conceptual awareness that distinguishes research practice from clinical practice. The participants attend sessions led by staff from the GCRC, Clinical Trials Unit, Human Subjects Protections Office, and Department of Pharmacy. The 16-hour course reviews the research process, with an emphasis on the many facets of coordination that are necessary for safe and effective clinical research. Topics to be covered include subject recruitment, compliance, IRB review, industry-sponsored studies, the drug development process, adverse event reporting, informatics, and fiscal compliance.

Thomas Kiely, having recently assumed the role of GCRC Nurse Manager, will assume organization responsibility for the course beginning in 2005, together with co-facilitator Dr. Leger. Together, they will continue to fine tune the course syllabus to incorporate new materials (e.g., *Financial Compliance in Research*) and update current lectures (e.g.,

*Regulatory Issues and the IRB: What you need to know for a successful submission*) to better prepare the clinical research professional in this rapidly changing field of Clinical Research. In addition, and for the first time, application has been made to provide 17.4 Connecticut Nurse Associations contact hours for full completion of the course.

Below is information on the course location, dates and related issues. To participate in the **fall 2005** program or for more information, please contact Tom or Lynn as indicated below:

**Sponsor:** UCONN GCRC and the Clinical Trials Unit

**When:** October 19 and 20, 2005, 8: 4:30 pm

**Where:** UCONN Health Center,  
263 Farmington Ave., Farmington, CT 06030  
MARB Building, Conference Room N4002

**Target Audience:** RNs, LPNs, APRNs, MDs, other healthcare providers, Clinical Research Technicians Clinical Research Assistants/ Associates, Research Administrators, Dental Assistants, Pharmacists, and students interested in clinical research

### **Continuing Education:**

**CNA CONTACT HOURS:** *17.4 CNA Contact Hours are pending for this program. (John Dempsey Hospital is an Approved Provider of Continuing Nursing Education by the Connecticut Nurses' Association, an Accredited Approver by the American Nurses Credentialing Center's Commission on Accreditation)*

**Registration Fee for the two day course:**  
UCHC employees \$75, Others \$150.

**Contact:** Please contact Tom Kiely 860-679-1707 or email [Kiely@nso.uchc.edu](mailto:Kiely@nso.uchc.edu) for questions on course. For registration and payment, Lynn Bores at 860-679-1751 or e-mail [bores@nso.uchc.edu](mailto:bores@nso.uchc.edu) by September 23, 2005.

## GCRC RESOURCES TO ENHANCE YOUR CLINICAL RESEARCH

The GCRC, which is an outpatient research unit, consists of seven examination rooms, a treatment room with two chairs suitable for extended visits, a consultation room with observation capability, and a sample-processing lab. The associated Dental Clinical Research Center (DCRC) facility consists of three dedicated dental operatories. Use of inpatient beds at John Dempsey Hospital or Connecticut Children's Medical Center can be arranged on an as-needed basis. Specialty inpatient units where GCRC resources help to support clinical research include the neonatal intensive care unit, psychiatry, obstetrics and gynecology, and a range of medical and surgical subspecialties.

**Patient Care Resources.** Skilled, experienced research nurses and other clinical research personnel are available to help facilitate and coordinate your clinical research study. They interact directly with research participants, as well as with ancillary departments, the Institutional Review Board, and the investigator, and help to ensure adherence to federal regulations pertaining to human subjects research.

**Core Laboratory Resources.** The GCRC Core Laboratory has three major components:

1. **Sample Processing** – preparation and shipping of research samples both internal to the Health Center and to external repositories and laboratories.

2. **Molecular Biology** – isolation of DNA and RNA from blood and tissue samples; RT-PCR analysis of specific mRNAs using quantitative TaqMan PCR methods; human gene chip microarray mRNA expression profiling; quantitative DNA copy number evaluation for gene insertion/deletions; PCR based genotyping;

sequence identification of mutations in disease-associated genes; and coordination of peripheral blood lymphocyte transformation by other GCRC core laboratories.

3. **Immunoassay Technologies** – Radio-immunoassay and enzyme-linked immunoassay of hormone, bone marker and cytokine levels; serology; fluorescence activated cell sorting; isolation of peripheral blood lymphocytes and cellular assay of immune competence/reactivity.

**Biostatistical Resources.** Biostatistical support assists investigators with study design, sample size calculations, data analysis and other issues related to the conduct of research and the presentation and publication of research findings.

**Computing Resources.** A full-time Informatics Director is available for consultation and assistance with computerized database management and analysis and with interactive voice response (IVR) technology. The GCRC has set up a state-of-the-art computer system to assist researchers with their informatics needs. Some of the services offered include the design and hosting of database-driven web pages, design and implementation of databases with an interface to MS Access or the web, file serving, hosting of Unix-based proprietary programs, and assistance with complying with HIPAA guidelines and regulations regarding data security.

**Ancillary Resources.** The GCRC supports funding for routine clinical lab tests and routine clinical procedures required for approved investigator-initiated clinical research protocols.

**Research Subject Advocate.** The GCRC offers the services of a Research Subject Advocate (RSA) who can provide guidance in the development of a Data and Safety Monitoring Plan (DSMP) or Data and Safety Monitoring Board (DSMB), which are required for all GCRC studies, depending upon the level of risk to human subjects. The RSA is also the

contact person in the GCRC for all serious adverse events that may occur during a GCRC-supported clinical research study.

**Administrative and Financial Resources.**

Administrative staff is available to facilitate logistical, financial and other grants administration issues. Financial management services include, but are not limited to, initial budget preparation, processing of patient reimbursements, hospital overrides and payments. The GCRC also has specific negotiated prices with John Dempsey Hospital and the University Medical Group for research-related procedures.

If you are interested in applying for GCRC resources, please contact Ms. Lesley Mancini at (860) 679-2880 or [lmancini@uchc.edu](mailto:lmancini@uchc.edu).

**NEW CLINICAL RESEARCH  
IN THE GCRC**

Changing Antiretroviral Therapy Adherence Behavior

*P.I. – Kevin Dieckhaus, M.D.*

Assessing Osteoporosis Risk in Frail Older Adults

*P.I. – Anne Kenny, M.D.*

Prevention of Recurrent Aphthous Stomatitis Using Vitamins.

*P.I. – Rajesh Lalla, B.D.S., Ph.D.*

Individualized Assessment and Treatment for Alcohol

*P.I. – Mark Litt, Ph.D.*

Longitudinal Measurement of Work Stressors in Pregnancy

*P.I. – John Meyer, M.D., M.P.H.*

Lifetime History of Major Depressive Disorder and Endothelial Function in Postmenopausal Women

*P.I. – Julie Wagner, Ph.D.*

Brain Changes and Risk Factors Causing Impaired Mobility

*P.I. – Leslie Wolfson, M.D.*

**UPCOMING  
GCRC SEMINARS**

**Tuesday, October 25, 2005**

**Henry R. Kranzler, MD**

Professor of Psychiatry,  
GCRC Program Director and  
Assistant Dean for Clinical Research  
University of Connecticut Health Center  
Farmington, CT

**“Clinical and Translational Research at  
UCHC: The Role of the GCRC”**

12:00 noon – 1:00 p.m.

Onyiuki Conference Room  
(formerly Faculty/Staff Dining Room)

**Tuesday, December 13, 2005**

**Linda S. Pescatello, PhD, FACSM**

Associate Professor &  
Director, Center for Health Promotion  
School of Allied Health  
University of Connecticut  
Storrs, CT

**“Functional SNPs Associated with *Muscle Size*  
and *Strength*- Findings From the FAMuSS  
Study”**

12:00 noon – 1:00 p.m.

ARB-EG013

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*All GCRC seminars are sponsored by the University of Connecticut School of Medicine Office of Continuing Medical Education. You can receive one hour per session of category 1 credit for attending this educational session.*

## RECENT GCRC PUBLICATIONS

Bauer LO, Ceballos NA, Shanley JD, Wolfson LI. Sensorimotor Dysfunction in HIV/AIDS: Effects of Antiretroviral Treatment and Comorbid Psychiatric Disorders. *AIDS* 19(5):495-502, 2005.

Choudhary D, Jansson I, Stoiliv I, Sarfarazi M, Schenkman JB. Expression Patterns of Mouse and Human CYP Orthologs (Families 1-4) during Development and in Different Adult Tissues. *Arch Biochem Biophys* 436:50-61, 2005.

Covault J, Gelernter J, Hesselbrock V, Nellissery M, Kranzler H. Allelic and Haplotypic Association of GABRA2 with Alcohol Dependence. *Am J Med Genet Part B* 129B:104-109, 2004.

Hernandez-Avila CA, Covault J, Gelernter J, Kranzler HR. Association Study of Personality Factors and the Asn40Asp Polymorphism at the  $\mu$ -opioid Receptor Gene (OPRM1). *Psychiatr Genet* 14:89-92, 2004.

Shan Y, Lambrecht RW, Bonkovsky, H. Association of Hepatitis C Virus Infection with Serum Iron Status: Analysis of Data from the National Health and Nutrition Examination Survey. *Clin Infect Dis* 40:834-841, 2005.



### REMINDER TO INVESTIGATORS

Remember to acknowledge the GCRC grant on all manuscripts and abstracts as follows:

This research was supported in part by a General Clinical Research Center grant from NIH (M01RR06192) awarded to the University of Connecticut Health Center, Farmington, CT

## RECRUITMENTS

### HELP US LEARN MORE ABOUT

### THE EFFECTS OF ESTROGEN AND PROGESTERONE ON THE ANTERIOR CRUCIATE LIGAMENT AND THE ACHILLES TENDON

We are seeking females between the ages of 18-30. Who are:

- Taking a monophasic birth control pill for at least the last 3 months.
- Participants should be active, non-smokers.
- Able to commit to Study duration of 1 month, which includes 9 visits to the GCRC.

In this study, we hope to clarify the effect of birth control pills on both ACL laxity (stretchiness) and the extensibility of the Achilles tendon. Upon completion of the study, participants will receive \$120. If you are interested or know of someone interested in participating in the study please contact Paula Gendreau at (860) 679-8074.

This research is being conducted by Thomas H. Trojian, M.D., Department of Family Medicine

(IRB #04-170)



United States  
National Institute of  
Diabetes & Digestive & Kidney Diseases  
of the National Institutes of Health



### ***Liver Injury Due To Drugs—A Serious Concern***

Liver injury is the main reason drugs do not get approved by the U.S. Food and Drug Administration or get removed from the market after initial approval. In addition, there are increasing reports of liver injury due to taking various nonprescription herbal medicines.

The purpose of this study is to try to understand the reasons why some people have unwanted liver reactions after taking certain drugs and herbal medicines (also called complementary and alternative medications (CAM)), while other people do not. We will look for genetic, environmental, and medical differences to see if we can understand the reasons why these reactions occur.

#### **Inclusion and Exclusion Criteria for Enrollment**

Our research teams *will determine for you* whether or not patients can qualify, but some general criteria are:

##### **Longitudinal Study**

- ANY drug or complementary-alternative medicine EXCEPT acetaminophen
- Onset in the last six months
- Elevation of liver enzymes, with or without elevations in bilirubin, alkaline phosphatase, or PT/INR

##### **Retrospective Study**

- Onset after Jan. 1<sup>st</sup>, 1994
- Total serum bilirubin >2.5 mg/dL, and history of taking:
  - Isoniazid
  - Phenytoin
  - clavulanic acid/amoxicillin

- Or, hospitalization associated with valproic acid
- > 2 years old at enrollment

To find out more information, please contact:

Mariola Smialek, Phone: (860) 679-2996  
E-mail: [smialek@uchc.edu](mailto:smialek@uchc.edu)

Laura Glynn, Phone: (860) 679-4238  
E-mail: [Lglynn@nso.uchc.edu](mailto:Lglynn@nso.uchc.edu)

(IRB #05-010)

### **RESEARCH VOLUNTEERS NEEDED**

Healthy Asian males or females, 18 – 30 years old, are needed for a study of hormonal response to intravenous medication. Participation requires 3 visits, totaling 10 hours. A payment of \$225 is available to volunteers who complete the study.

**Call Dr. Jonathan Covault's office at:  
(860) 679-4186**

(IRB #03-087)

### **RESEARCH VOLUNTEERS NEEDED**

Males or Females, age 21-45, needed for a UConn Health Center study of the effects of approved medication on the response to alcohol. The study involves blood samples, interviews, questionnaires, and three full-day sessions where three large alcoholic drinks will be consumed. \$325 paid for full participation.

**For information call Jessie at: (860) 679-4186**

(IRB #04-108)

#### **GCRC PHONE NUMBERS**

**(860) 679-4145 - ADMINISTRATION**

**(860) 679-3666 - CLINIC**

**(860) 679-1636 - STUDY LINE**

# General Clinical Research Center Newsletter

## GCRC STAFF

### Administrative Services

Lynn Bores	Administrative Assistant
Lisa Godin	Administrative Program Coordinator
Michelle Jones	Administrative Fiscal Assistant
Lesley Mancini, MBA	Administrative Director

### Nursing

Sheila Belber, RN, MS	Research Facilitator
Gloria Borders, RNC, MPH	Research Facilitator
Kathleen Curley, RN	Clinical Research Nurse
Paula Gendreau, BSN, CCRP	Research Facilitator
Thomas Kiely, BSN, CCRP	Nurse Manager
Victoria Odesina, APRN, CS, CCRP	Res. Facilitator
Mariola Smialek, RN, BS	Clinical Research Nurse
Susan Walters, BSN, CCRP	Research Facilitator

### Core Lab

Christine Abreu, MS	Research Associate
Pam Fall, MS	Core Lab Manager
Pam Ferzacca	Research Assistant
Kaitlin Miller, BS	Research Assistant

### Informatics

Khamis Abu-Hasaballah, PhD	Informatics Director
Sophan Iv	Technical Analyst

### Research Support

Theresa George, CCRP	Clinical Research Assistant
Laura Glynn, BA, CCRP	Clinical Research Assistant
Harriet Zawistowski, BGS	Clinical Research Assistant

### Biostatistics

Stephen Walsh, Sc.D.	Biostatistician
Deborah Dauser, MS	Statistician
John Tsimikas, PhD	Statistician

### Dental

J. Robert Kelly, DDS, MS, DmedSc	Director, DCRC
Lisa Burgio	Dental Assistant

**The General Clinical Research Center  
of The University of Connecticut Health Center  
Farmington, CT 06030-3805**

Richard Berlin, MD	Principal Investigator
Henry Kranzler, MD	Program Director
Lawrence Raisz, MD	Associate Program Director
Anne Kenny, MD	Associate Program Director
Cheryl Oncken, MD	Associate Program Director
Jonathan Covault, MD, PhD	Core Lab Director
Lesley Mancini, MBA	Administrative Director
Pam Fall, MS	Core Lab Manager
Thomas Kiely, BSN, CCRP	Clinical Core Dir.
Khamis Abu-Hasaballah, PhD	Informatics Director
Lisanne Cirullo, APRN	Research Subject Advocate



*This Newsletter is a publication brought to you  
by the Staff of the GCRC*

## **General Clinical Research Center Newsletter**

**General Clinical Research Center  
UCONN Health Center, MC-3805  
263 Farmington Avenue  
Farmington, CT 06030**