

The University of Connecticut Health Center

GENERAL CLINICAL RESEARCH CENTER NEWSLETTER

RESEARCH ON THE ETIOLOGY AND TREATMENT OF SUBSTANCE DEPENDENCE



Back Row (L-R) Howard Tennen, Ph.D.; Lynn McLaughlin, R.N.; Cheryl Oncken, M.D.; Henry Kranzler, M.D.; Christine Calusine, M.S.; Jonathan Covault, M.D., Ph.D.; Front row:(L-R): Kristen Tremblay, M.P.H., CCRP; Cristina Goncalves, B.S.; Michelle Slivinsky, M.A.; Roberta Gline, L.P.N.; Richard Feinn, Ph.D.

Featured PI

Henry R. Kranzler, M.D.
Professor, Department of Psychiatry
GCRC, Program Director

Alcohol use disorders (i.e., alcohol abuse and dependence) are common in the United States. Data from a recent epidemiological study in which more than 43,000 individuals from the U.S. general population were interviewed show that, during a one-year period, nearly one in 12 individuals has an alcohol use disorder (Grant et al. 2004). In addition to being highly prevalent, these disorders are associated with a variety of adverse medical, psychiatric, family, legal, and work-related problems. The estimated annual cost of alcohol use disorders in the United States is \$185 billion (Harwood et al. 1998). Despite the adverse effects and high cost, less

than 15% of individuals with a lifetime alcohol use disorder report ever having received alcohol treatment (Cohen et al. 2007). This includes participation in Alcoholics Anonymous, the most widely available and commonly used resource for problem drinkers.

During the past 20 years there has been considerable research aimed at increasing the efficacy of alcohol treatment and the dissemination of new findings to patients and clinicians, thereby promoting evidence-based treatment approaches. One particular focus of this research has been the identification and evaluation of medications to treat alcohol dependence. These efforts have resulted in the approval by the U.S. Food and Drug Administration (FDA) of three products to treat the disorder: oral naltrexone (approved in 1994), acamprosate (approved in 2004), and extended-release naltrexone (approved in 2006). These are the only treatments approved by the FDA since the aversive agent disulfiram (so named because it causes an unpleasant reaction when combined with alcohol) became available for clinical use in 1949.

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Since the late 1980's, our research group at UConn has studied medications to treat alcohol dependence. Current investigators in the group include Drs. Cheryl Oncken, an internist; Howard Tennen, a clinical psychologist; Jonathan Covault, a psychiatrist and biochemist; Albert Arias, a psychiatrist; Grace Chan and Richard Feinn, statisticians; and Stephen Armeli, a social psychologist (and collaborator at Fairleigh Dickinson University). Over the past decade, we have broadened our research focus to include studies of the pharmacogenetics of alcohol, which represents the convergence of our longstanding interest in pharmacology with work that we initiated in the early 1990's on the genetics of alcohol and drug dependence.

To date, we have completed more than 20 trials of medications to treat alcohol dependence, and three studies are currently in progress. Funding for these studies has come from the National Institute on Alcohol Abuse and Alcoholism [NIAAA; both through the UConn Alcohol Research Center (ARC), which has been continuously funded since 1978, and individual research grants to Dr. Kranzler], with additional support from the GCRC and the pharmaceutical industry. The UConn ARC played a key role in the FDA approval process for oral naltrexone, funding one of the required pivotal studies, which was directed by an ARC investigator at Yale, Dr. Stephanie O'Malley (O'Malley et al. 1992). We were the first group to test the safety and efficacy of a long-acting naltrexone formulation to treat alcohol dependence (Kranzler et al. 1998) and to conduct a multi-center trial with the formulation (Kranzler et al. 2004). Our group also participated in the multi-center trials that led to the approvals of acamprosate and long-acting naltrexone (Garbutt et al. 2005). We have also evaluated medications to treat alcohol dependence with co-occurring psychiatric disorders (such as major depression, which is commonly associated with heavy drinking;

Hernandez-Avila et al. 2004, Kranzler et al. 2006).

Building on work conducted in the UConn ARC, which examined empirically derived subtypes of alcoholism (Babor et al. 1992), we demonstrated that clinical features in alcoholics can be used to predict their response to selective serotonin reuptake inhibitors [SSRIs, including Prozac® (fluoxetine)], which are among the most widely prescribed medications in the world (Kranzler et al. 1996). One of the clinical trials currently underway in the Clinical Research and Evaluation Unit, an ARC research clinic located on the first floor of UConn Health Center, is "Sertraline Pharmacotherapy for Alcoholism Subtypes," which is funded by NIAAA. That study, an effort to prospectively replicate and extend the earlier findings with SSRIs, is nearing completion. Two other current studies ("Zonisamide versus Placebo in the Treatment of Alcohol Dependence," and "Topiramate Treatment of Problem Drinkers") reflect a growing interest in the use of anticonvulsant medications to treat alcohol dependence. These studies are funded as part of the competitive renewal of the UConn ARC, which runs through November 2012.

Our pharmacogenetic research has included the examination of genetic moderators of the response to medication in treatment trials and in human laboratory studies. The clinical pharmacogenetic studies (Oslin et al. 2003, Gelernter et al. 2007, Arias et al. 2008) have focused on the moderating effects of a functional polymorphism in *OPRM1*, the gene encoding the mu-opioid receptor, on the response to treatment with the opioid antagonists naltrexone and nalmefene. In the laboratory studies, healthy individuals are administered a drug alone or in combination with alcohol, and their physiological responses (e.g., changes in hormone concentrations and body sway) and subjective responses (e.g., feelings of intoxication, pleasurable and sedative effects of alcohol) are measured. A

blood sample is also obtained for genotyping. These human laboratory studies have examined the moderating effects of the functional *OPRM1* polymorphism on the cortisol response to naloxone (an opioid antagonist; Hernandez-Avila et al. 2003, 2007). Another focus of these studies has been on the interaction of finasteride, a drug that blocks the synthesis of neurosteroids (which have been implicated as mediators of alcohol's effects), with genes encoding subunits of the gamma-aminobutyric acid, type A (GABA-A) receptor on the subjective responses to an acute dose of alcohol (Pierucci-Lagha et al. 2005). Dr. Jonathan Covault is currently conducting a study that uses a similar paradigm (in which dutasteride, an analog of finasteride, is being examined) entitled "Pharmacogenetics of Alcohol: Treatment Implications." That study is being conducted in the CREU and the GCRC through a grant to Dr. Covault from NIAAA.

In summary, our research, which began with the conduct of clinical trials to develop medications to treat alcohol dependence, has broadened to include pharmacogenetic studies and other mechanistic approaches. The existence of the UConn GCRC has made these studies possible by providing space suitable for the conduct of human laboratory studies and clinical, informatics, and core laboratory support. These resources have made it possible to expand our research into basic studies of alcohol's effects in humans and the etiology of alcohol use disorders.

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NOTES FROM THE GCRC PROGRAM DIRECTOR



Henry R. Kranzler, M.D.
Professor of Psychiatry,
GCRC Program Director

The Lowell P. Weicker, Jr. General Clinical Research Center (GCRC) is currently in its fifteenth and last year of funding from the National Institutes of Health (NIH). The GCRC Program at NIH has been replaced by the Clinical and Translational Science Award (CTSA) Program, so competitive renewal applications are no longer being accepted for GCRCs. This has led to some uncertainty as to the continued existence of the GCRC at UCHC, which was compounded by uncertainty as to the GCRC's location on the UCHC campus. Fortunately, the situation has stabilized on both fronts and we continue to support clinical and translational research efforts at UCHC. The Health Center has committed to support the GCRC for years 16 and 17, ensuring that the GCRC can play a central role in the institution's efforts to secure a CTSA. In addition to a stable financial picture, a commitment was made to maintain the GCRC in its current location on the main floor of the main building at UCHC.

A CTSA application was recently submitted to NIH by the Health Center for review early in 2009. Congratulations go to all involved in that effort, which was led by Drs. Judith Fifield and Peter Albertsen. The focus will now be on implementing the extensive plans outlined in the CTSA application, which involve the creation of the Connecticut Institute for Clinical and Translational Science (CICaTS). These efforts will be outlined by Drs. Fifield and Albertsen in a GCRC seminar scheduled for February 10, 2009.

In view of these positive developments, the GCRC continues to invite requests by investigators for resources to support clinical and translational research. All of the GCRC cores remain intact and fully functional, so investigators who may need assistance from the clinical, informatics, or biostatistics cores or the core laboratory should submit an application requesting such resources. In addition, the educational programs of the GCRC, including the twice monthly seminar series, the summer student seminar series, the Introduction to Clinical Research course, the research coordinators' course, and the Master's Program in Clinical and Translational Research will continue to be offered. Please consult the following website for more information: <http://gcr.uchc.edu/Training-Education.html>. Inquiries regarding these and any other issues related to clinical and translational research are welcome.

CHARGE-BACK CENTERS

By Lesley Mancini, MBA
GCRC Administrative Director

Change to the underlying funding of our GCRC comes as our NIH/NCRR grant ends. This motivates us to review the cost of Scientific Advisory Committee (SAC)-approved resources for investigator protocols and to develop or refine tools to estimate and

track the use of resources for individual studies while they are underway. Over time, we will transition to having investigators co-pay for clinical research resources on a "fee-for-service," charge-back basis, the resource funding model of the new Clinical and Translational Science Award grant program. Our rollout of the "charge back" model will be informed by the work of the Office of Clinical and Translational Research on the Clinical Trial Budget Workbook and that of Research Finance on its Research Store.

Below is an overview of the development of GCRC Charge-Back Centers and what this will mean for investigators. In our Spring 2009 newsletter we will describe the Charge-Back Centers, their current/planned capabilities, and how to access these resources.

What is a Charge-Back Center?

Operating a research Charge Back center assumes that a unit/core has capacity to provide products and/or services that are valuable to investigators, there is demand (i.e., investigators know what is available to them, want it and can afford it), and there is a business system for setting rates, requesting/providing work and billing/paying for the work. The terms for this functionality, which are often used interchangeably, include: Charge Back Center, Fee-For-Service, Recharge Center and Service Center.

A Charge Back center has designated leadership, staff, equipment and space, exists within a UCHC department or center, and has a separate FRS account set up to segregate its revenues and expenses. An example of a Charge Back center is Reprographics within Information Technology, which provides copy services and then charges back expenses for those services to users. Charge Back centers may serve external and internal customers or only internal customers. Charge Back centers

are expected to “break even” (the revenues and expenses are about the same) including planned accumulation of cash to replace equipment or expand capabilities, as needed. These characteristics are important for customers who are federally funded and must comply with OMB Circular A-21 (which addresses allowable costs).

Volumes can be written about product development, marketing, and cost accounting related to Charge Back centers -- more than investigators typically want or need to know. Regarding the business mechanics, there are four key components that are necessary for a Charge-Back center to function. The GCRC has many of these components in place and continues to automate functions and improve data reliability:

- a standard set of products and/or services
- a utilization estimation and tracking mechanism
- a series of cost accounting steps to assign “price tags” to products and/or services
- a billing and payment process

What Does This Mean for Investigators?

Through the end of our NIH/NCRR funding GCRC investigators who have been allocated resources by the SAC will not experience any difference in how their studies are supported. Costs for staff, space and equipment will be covered by the GCRC grant. Currently, investigators whose grants include funds for certain “cash” items, such as patient care ancillary services, pharmaceuticals, IVR telephone lines and minutes, core lab supplies, advertising and subject payments are asked to help pay for their use of these items. With the transition to a Charge-Back model, investigators will have to bear a greater proportion of the costs for staffing, space, equipment and “cash” items for their studies as the resources are used. Investigators will need to plan for these expenses when developing project proposals and budgets for future grant submissions,

similar to what is now required for industry-initiated studies.

Not all projects have external sources of funding, and options are being considered for supporting new investigators, junior faculty and pilot studies in the future. The Connecticut Institute for Clinical and Translational Science (CICaTS), of which the GCRC will be a part, will be launched in the Spring of 2009. More information about UCHC sources of funding will be shared when it becomes available.

CLINICAL RESEARCH STUDY INVESTIGATOR’S TOOLBOX

There was a recent publication by the National Institute on Aging of a Clinical Research Study Investigator's Toolbox, which can be found on the NIA public webpage. The purpose of the Toolbox is to provide a Web-based information repository for investigators and staff involved in clinical research. The Toolbox contains templates, sample forms, guidelines, regulations and information materials to assist investigators in the development and conduct of high quality clinical research studies. The link is: <http://www.nia.nih.gov/ResearchInformation/CTtoolbox/>

Please note that, although NIA is the source of this information, it applies to all clinical investigation and the materials can readily be tailored to research with all age and patient groups. Please share it with your staff and feel free to contact Dr. Henry Kranzler (Kranzler@psychiatry.uchc.edu) if you have questions about these materials.



REGISTERING CLINICAL TRIALS WITH CLINICALTRIALS.GOV

ClinicalTrials.gov is a directory of federally and privately supported research trials (national and international) that are testing the effects of experimental drugs, devices and procedures for many diseases. All clinical trials must be registered.

Clinical investigators are being encouraged to consult with www.ClinicalTrials.gov to ascertain what other clinical studies are being conducted in their areas of interest. We encourage investigators to review this site prior to submitting a proposal to the GCRC Scientific Advisory Committee. Pamphlets describing ClinicalTrials.gov are available in the GCRC.

RECENT STAFFING CHANGES

In August 2008, Dr. Stephen Walsh left the Health Center to accept a position in the School of Nursing at Storrs. While at the Health Center, Steve worked in the Department of Community Medicine. He also provided biostatistical support to the GCRC Scientific Advisory Committee (SAC) and GCRC investigators. We thank Steve for his many contributions and wish him all the best in his new position.

We are pleased to announce Dr. Richard Feinn, an epidemiologist at Yale University, has assumed the position of GCRC Biostatistician. In that capacity, Dr. Feinn will provide statistical support to the SAC and to clinical investigators. In addition to proficiency in study design and general linear modeling, Rich has considerable strengths in multilevel modeling and meta-analysis. Rich is currently

working part-time and is in the GCRC on Wednesdays and Fridays and it is anticipated that his availability will increase to four days per week in the new year.

Dr. Khamis Abu-Hasaballah, Informatics Director, is leaving the GCRC effective December 19, 2008. Khamis accepted a position as Assistant Vice President – Research Informatics in the Department of Information Technology at the Health Center. This position will enable him to work at the institutional level to advance all research, including clinical research. We thank him for his many contributions to the GCRC, will miss working directly with him, and wish him all the best in his new position.

Mr. Kenneth Dugas has joined the GCRC staff half-time as the new Informatics Director. Ken comes to us from the Department of Psychiatry, where he will continue to work as the Informatics Director. We look forward to working with Ken, a highly experienced and effective informatics professional.

UPCOMING GCRC SEMINARS

Tuesday, January 13, 2009

Julian D. Ford, Ph.D.

Associate Professor of Psychiatry
University of Connecticut Medical School
University of Connecticut Health Center
Farmington, CT

“Are a Complex Post Traumatic Stress Disorder (cPTSD) Diagnosis and Specialized Treatments Justified?”

12:00 noon – 1:00 p.m.
Academic Research Building - EG-013

Tuesday, January 27, 2009

Michael A. Lynes, Ph.D.

Professor
Associate Head for Research and Graduate
Education
Department of Molecular and Cell Biology
University of Connecticut
Storrs, CT

**“Grating-Coupled Surface Plasmon
Resonance: A Real Time, Multiplexed
Microarray System for Biomarker Signature
Detection and Diagnosis”**

12:00 noon –1:00 p.m.
Academic Research Building - EG-013

*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.*

NEW CLINICAL RESEARCH IN THE GCRC

Predicting Treatment Outcome in Adolescent
Alcohol Use Disorder
P.I. – Lance Bauer, Ph.D.

Does Colostrum Application To Oral Cavity
Increase Serum Epidermal Growth Factor in
Premature Neonates? A Pilot Randomized
Controlled Trial
P.I. – Naveed Hussain, M.D..

Naltrexone and CBT for Problem Drinking
P.I. – Henry Kranzler, M.D.

Oral Mucositis Research Registry/Repository
P.I. – Rajesh Lalla, BDS, Ph.D.

T-Cell Responses Predict Influenza Risk in
Older Adults *Sub-study '08*
P.I. – Janet McElhaney, M.D.

Comparison of Zoledronic Acid Dosing at
yearly or at Longer Intervals for the
Treatment of Osteoporosis
P.I. - Faryal Mirza, M.D.

Healthy Activities for Prize Incentives
P.I. - Nancy Petry Ph.D.

Pilot Study on Transient Bacteremia and Blood
Stream Infections after Invasive Dental
Procedures in Cancer Patients with Central
Venous Catheters
P.I. – Robert Bona, M.D..

RECENT GCRC PUBLICATIONS

Arias AJ, Armeli S, Gelernter J, Covault J,
Kallio A, Karhuvaara S, Koivisto R, Mäkelä
R, Kranzler HR. Effects of Opioid Receptor
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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 (M01RR006192) awarded to the University of Connecticut Health Center, Farmington, CT

STUDIES THAT ARE ACTIVELY RECRUITING PARTICIPANTS

INDIAN MEN NEEDED FOR BONE HEALTH STUDY

Osteoporosis is a condition that results in weakening of the bones in your body. It can cause bone fractures. In the United States and in many European countries, it is most often seen in elderly women. However, there are reports that suggest that East Asian (Indian) men may be susceptible to this condition.

The University of Connecticut Health Center is conducting a study to examine the status of bone health and vitamin D and calcium metabolism in East Asian Indian men. The aim of the study is to determine whether Indian men who have immigrated to the United States are also susceptible to osteoporosis.

If you are an East Asian Indian male age 50 or older, and are interested in finding out more about your current bone health, please contact Dr. T. V. Rajan at the University of Connecticut Health Center (Tel: 860-679-3221; rajan@neuron.uhc.edu) or Ms. Harriet Zawistowski (Tel: 860-679-1658; zawistowski@nso.uhc.edu) for further information.

(IRB #08-303)



HEALTHY ADULT MEN NEEDED FOR ALCOHOL STUDY

Healthy males, 21-45 years old, with no history of substance dependence or psychiatric illness, are needed for a UConn Health Center study to evaluate an FDA approved medication, dutasteride, and common genetic variation on the effects of a moderate dose of alcohol. Dutasteride (Avodart™) is not FDA approved for the purpose of this study.

Participation involves blood samples, interviews, questionnaires, 7 brief study visits and 4 full day laboratory sessions where you will be asked to consume placebo or alcohol drinks based on your body weight. \$555 paid for full participation.

For information call 860-679-4186
or go to www.uchcalcoholstudy.com
(refer to study #2)

(IRB# 06-218-2)



GCRC PHONE NUMBERS

(860) 679-4145 - ADMINISTRATION
(860) 679-3666 - CLINIC
(860) 679-1636 - STUDY LINE

INFORMATION FOR WOMEN STARTING ANASTRAZOLE (ARIMIDEX) OR LETROZOLE (FEMARA) FOR THE TREATMENT OF BREAST CANCER

Newer medications for breast cancer such as anastrozole (Arimidex) and letrozole (Femara) are increasingly being used for the treatment of breast cancer. These medications lower the levels of the female hormone estrogen and as a result may result in bone loss and increased risk of fractures. We are studying the early effects of this treatment on bone health. Benefits for participants include monitoring of their bone health during the first year of treatment with anastrozole or letrozole.

There are 6 study visits over 1 year.

If you, or someone you know, is considering taking anastrozole (Arimidex) or letrozole (Femara) and would like to know more about participation in this research study, please contact the principle investigator, Dr. Pamela Taxel at (860) 679-4743.

(IRB# 07-043-2)



General Clinical Research Center Newsletter

GCRC STAFF

Administrative Services

Lesley Mancini, MBA	Administrative Director
Lynn Bores	Administrative Assistant
Lisa Godin	Administrative Program Coordinator
Kathy Lapierre	Records Clerk
Marsha Murray	Administrative Assistant
Jayne Roman	Clinic Office Assistant

Nursing

Thomas Kiely, BSN, RNC	Nurse Manager
Gloria Borders, RNC, MPH, CCRP	Research Facilitator
Kathleen Curley, RN, BS, CCRP	Research Facilitator
Paula Gendreau, BSN, CCRP	Research Facilitator
Mariola Smialek, RN, BS, CCRP	Clinical Research Nurse
Susan Walters, RN, BSN, CCRP	Research Facilitator

Core Lab

Jonathan Covault, M.D., PhD	Core lab Director
Pam Fall, MS	Core Lab Manager
Christine Abreu, MS	Research Associate
Pam Ferzacca, CCRP	Research Assistant
Kaitlin Miller, BS	Research Assistant

Informatics

Kenneth Dugas, MBA	Informatics Director
Robert Piangozza	Technical Analyst I
Harriet Potts	System Coordinator

Research Support

Paul Appleton, MD.	Clinical Research Assistant
Nancy Dean, BA, CCRP	Clinical Research Assistant
Harriet Zawistowski, BGS, CCRP	Clinical Research Assistant

Biostatistics

Richard Feinn, MA, MS, PhD	Biostatistician
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Dental

J. Robert Kelly, DDS, MS, DmedSc	Dental Director
Megyn Clement, CDA	Dental Assistant

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

Bruce Koeppen, MD, PhD	Principal Investigator
Henry R. Kranzler, MD	Program Director
Anne Kenny, MD	Associate Program Director
Cheryl Oncken, MD, MPH	Associate Program Director
Lawrence G. Raisz, MD	Associate Program Director
Kenneth Dugas, MBA	Informatics Director
Jonathan Covault, MD, PhD	Core Lab Director
J. Robert Kelly, DDS, MS, DMedSc	Dental Core Director
Pam Fall, MS	Core Lab Manager
Thomas Kiely, BSN, RNC	Nurse Manager
Lesley Mancini, MBA	Administrative Director
Kathleen Salomone, 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**