Dr. Woody is part of a panel along with other CTN members who will present at the 10th Annual International Society of Addiction Medicine (ISAM) Conference, which is being held on November 13-21, 2008 in Cape Town, South Africa.

ISAM annual meetings focus on the diagnosis, management & research in the domain of addiction medicine. This is encapsulated in the theme of the 10th ISAM Annual Scientific meeting, “Understanding Addictions and Providing Comprehensive Care”. The theme is resonant with the need to provide knowledge to those affected by addictions and making care accessible to all who need it. ISAM, in collaboration with national and international organizations, hopes to make the 10th Annual Scientific meeting a memorable experience for you in terms of delivering evidence – based information on how to manage addictive disorders; how to plan community and hospital services and how to promote advocacy for education and skills development in management of substance abuse and other addictions.

**TRI International ASI Trainings**

June 23rd through 26th, 2008, Charlotte Royer-Malvestuto conducted a three-day Treatnet ASI Training for clinicians in Orenburg, Russia. Treatnet is an international network similar to the CTN which represents twenty centers dedicated to the dissemination of information and good practices in a partnership with providers to improve the quality of drug treatment and rehabilitation in United Nation member countries. Dr. Deni Carise, TRI, provided consultation regarding the design of a research study with Opiate dependent clients in the Orenburg region in response to an increase in clients seeking help for heroin addiction.

A contract was negotiated with the United Nations Office of Drugs and Crimes (UNODC) for training and consultation, which includes assistance with design of outcome studies research and the implementation of evidence-based practices. Training is scheduled for mid-September for clinicians at the Treatnet center for the Baltic States, in Riga, Latvia.

**Hope for the Republic of Georgia**

We are troubled about the political situation in Republic of Georgia as Georgia is openly invaded and destroyed by Russian military forces. We express our hope that Russian aggression would be stopped and that Russian troops would leave Georgian territories soon.

Our international NIDA/CTN/INVEST fellow, Gvantsa Piralishvili MD PhD, who is from the Republic of Georgia, has been active in gathering information and practical insights which she hopes to directly apply to her home country of Georgia. She has attended the CPDD, presenting a poster and gaining a much wider perspective on addiction research. Adding that experience to her interviews of staff at the START project’s Net-STEPs clinic, she has come away with a much greater appreciation for the systems we have in place.

Therefore, much of Dr. Piralishvili’s current work and training is with very specific goals in mind. She has taken Power Point instruction to be able to best disseminate information gleaned from seminars and better train staff in anticipating a new research protocol being implemented. She is training in DCRI’s Inform/CRIS systems so that she can work with computer technologists in Georgia to set up their own web-based interfaces for data collection.

With some luck, considering the recent Russian ‘adverse event’, and her diligence, she will return to Georgia to start her own clinical trial, now being proposed. After her stay with us, she will have a much more global understanding of what needs to be accomplished in order to have a successful clinical research study.
First Look. Two NIDA Programs Share Initiatives.

On Tuesday, August 5, 2008, several NIDA Minority Supplement Program Students and several START NIDA Clinical Trial staffers visited the NIDA Cell & DNA Repository at Rutgers University in Piscataway, New Jersey. The RUCDR, as it is formally called, was established in late 1998 and hosts a major state-of-the-art facility on the scenic Busch Campus. The RUCDR began when scientific and managerial leadership re-located to New Jersey and transferred several cell lines and DNA collections from Indiana University’s School of Medicine to the Busch Campus. Soon after, the National Institute of Mental Health (NIMH) transferred its Center for Genetic Studies to RUCDR. Since then, RUCDR has become the hub of collections for processing cell lines for DNA explorations on initiatives such as families and schizophrenia, bipolar disorders, Alzheimer disease, ADHD, and substance abuse. In 2000, the National Institute on Drug Abuse (NIDA) established the NIDA Center for Genetic Studies. The NIDA Repository collection is used by such on-going studies such as START to examine DNA from subjects enrolled in addiction studies.

By: Sabrina A. Poole (START) Manager.

Regulatory Q & A

Question: What are the categories for permissible research involving prisoners?

Answer: Research involving prisoners is permissible only if the research involves one or more of four permissible categories, or if the research meets the criteria described in an HHS Secretarial waiver that applies to certain epidemiological research (68 FR 36929, June 20, 2003):

The first two categories are (i) the study of the possible causes, effects, and processes of incarceration, and of criminal behavior, and (ii) the study of prisons as institutional structures or of prisoners as incarcerated persons. Research in these two categories is permissible only if the study presents no more than minimal risk, and no more than inconvenience to the subjects (45 CFR 46.306(a)(2)).

The third category (iii) is research on conditions particularly affecting prisoners as a class; the regulations list as examples vaccine trials and other research on hepatitis, which is much more prevalent in prisons than elsewhere, and research on social and psychological problems such as alcoholism, drug addition, and sexual assaults. Research in this category may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research (45 CFR 46.306(a)(2)).

The fourth category (iv) is research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In this category, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research (45 CFR 46.306(a)(2)). OHRP interprets control groups which may not benefit from research to include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.

The HHS Secretarial waiver for certain epidemiological research conducted or supported by HHS functions as a fifth category of permissible research. The criteria for this category are that the research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. The institution still must review the research under subpart C and certify to OHRP that an appropriately constituted IRB has reviewed the proposal and made all other required findings under HHS regulations at 45 CFR 46.305(a) and receive OHRP authorization prior to initiating any research involving prisoners. All of the other requirements of subpart C apply to research in this category.
DelVal Node Trial Progress:

CTN 0027 Study Update by:
Edgar Weiss, Assoc. Project Manager, NET Steps, Phila, PA

START at NET-STEPS is now a well oiled machine, but with fewer moving parts. Without recruitment, we rededicate our energies to clients already in the pipeline and that has allowed us to improve our retention. Plans are now being made to cross-check all of our documentation, maintain our 100% data cleanliness rating, and verify dosing records for all of our clients before the end of the study. We got past a bolus of blood draws for the Genetics add-on study to find that there aren’t any folks left. Kudos to Tom Brown, as he has now completed that effort with remarkably good participation rates.

One NIDA-CTN objective is to favorably influence the community clinics when they host a research project. It is gratifying to see NET-STEPS begin to change from a methadone-only clinic to including Suboxone as a viable alternative. They have a Suboxone arm supported by counselors with additional training and specialists working to pry support out of ‘third party payers’ whenever possible.

To prepare for current changes and future projects, staff development is ongoing. Devlin Hart, RA, is cross-training Tom Brown, RN, in various assessments and data entry. Tom, Devlin and Ed Weiss are all taking ASI training this month with Charlotte Royer-Malvestuto. “And the beat goes on.”

CTN 0028 Study Update by:
Gretchen Friedberger, RN
Laura Scott, Research Assistant,
Rehab After Work, Paoli, PA

CTN 0028 – ADHD in Adolescents, Site: Rehab After Work, Paoli, PA

Since June, the team has focused their efforts on the active study participants and the close-out process. Currently, the team is addressing the needs of one active participant and one participant in follow up. To date, the team has pre-screened 66 potential participants, consented 33 and randomized 15.

The EMMES monitor visited the site June 17-20, 2008, and the team greatly appreciates the feedback. Gretchen and Laura have been working on cleaning up all data. The team would also like to thank Lin Denton who continually provides the team with guidance.

The team would like to thank Charlotte Royer-Malvestuto for her leadership!

Upcoming Meetings/Conferences
Delaware Valley Node Steering Committee
Mark Your Calendars:

The next meeting of the Delaware Valley Node Steering Committee is scheduled for Tuesday, November 4, 2008 at 2 PM in the large conference room at TRI. Hope to see you then!

SAVE THE DATE!
Collaborative Innovations In Public Health
Forming A More Perfect Union

November 17-19, 2008
Loew’s Hotel
Philadelphia, PA

Conference sponsored by
Pennsylvania Public Health Association
Pennsylvania Department of Health, Public Health Institute

For more information please visit:
http://www.ppha.org/

Congratulations and best wishes to Ellen Fritch, Senior RA, Delaware Valley Node, who accepted a new position as a research coordinator at the University of Pennsylvania Center for the Study of Addictions earlier this month. Ellen worked on CTN-0005, MET, at both NET and Rehab after Work sites; CTN-0006-7, Motivational Incentives, at Thomas Jefferson and ACT II (JEVs) clinics; CTN-0018-19, Safer Sex Skills, M/F, at Consortium and Jefferson Methadone clinics; 0028, Adolescents w/ADHD and SUDs, Rehab after Work, Paoli; and most recently, 0027, START, at NetSteps. Ellen's willingness to assist across protocols and siters and her commitment to quality data has been an asset to our team and she will be missed. Best of luck, Ellen- and thank you!
Recovery Walks!
Register, Sponsor a Walker, or Donate

Please support PRO-ACT and the recovery movement by participating in this show of “living proof” that recovery is real. We are asking you to be a part of this dramatic fundraising event. Our goal is to display, celebrate, and support recovery! Come help us open new doors and remove barriers to recovery for those still struggling with alcohol and other drug addictions.

This event is our 7th annual walk and Southeastern Pennsylvania’s largest walk for recovery from alcohol and other drug addictions. A free Barbeque will follow the walk for all registered participants. A children’s area hosted by the Please Touch Museum will also be available.

Sunday, September 21, 2008 from 10am to 4pm. Registration begins at 10am. Walk begins at 12pm
register:http://proact.org/calendar/recovery_walks/register/

Recovery Works! Phillies Game
Friday, September 26, 2008; 7:05 PM

The federal agency SAMHSA (Substance Abuse and Mental Health Services Administration) developed and supports this annual baseball game initiative, held in ballparks across the country, to show the nation that Recovery Works! Join us for a night out with the Phillies as they take on the Washington Nationals at Citizens Bank Park.

To purchase tickets, go to:
http://proact.org/calendar/recovery_works/cart/

Tickets cost $10 each. Tickets will be mailed Monday, September 15. If you prefer, you may also make arrangements to pick up your tickets. To do so, please contact ProAct telephone: 1-800-221-6333 before September 15. The proceeds from this fundraiser directly support PRO-ACT’s recovery support programs, services, and events. Thanks in advance for your support!

CTN Dissemination Library
The CTN Library is web-based, and includes all the CTN related publications (under What’s New). The web site is maintained by the Washington Node of the Clinical Trials Network. The address is:
http://ctndisseminationlibrary.org

For a detailed list of upcoming conferences, click on “Upcoming Conferences” under “Dissemination Opportunities”

Links to DelVal Node CTPs/Collaborators
Caron Treatment Centers http://www.caron.org/
Consortium http://www.consortium-inc.org/
Jonathan Lax Center http://www.fight.org/
NET http://www.net-centers.org/
PHMC http://www.phmc.org/
Presbyterian http://pennhealth.com/behavior_health/addiction/presby/
PRO-ACT www.proact.org
RAW http://www.rehabafterwork.com/contact.htm
Seabrook House http://www.seabrookhouse.org/
Thomas Jefferson University http://www.jeffersonhospital.org/psychiatry/article4821.html
Treatment Research Institute www.tresearch.org
The University of Pennsylvania, Center for Studies on Addiction http://www.uphs.upenn.edu/trc/
Van Horn Consulting http://www.vanhornconsulting.com

Grants Corner
The following grant opportunities may be of interest to researchers:

Criminal Justice Drug Abuse Treatment Studies 2 (CJ-DATS 2) (U01)
RFA-DA-09-006 (U01) - [Receipt Date: August 28, 2008]
Pilot Clinical Trials of Pharmacotherapies for Substance Related Disorders (R01)
RFA-DA-09-005 (R01) - [Receipt Date: October 23, 2008]
Functional Characterization of Genetic Variants and Interactions: The Genes, Environment and Health Initiative
RFA-DA-09-003 (R21), RFA-DA-09-004 (R03) - [Receipt Date: October 17, 2008]
Medications Development for Cannabis-Related Disorders (R01)
RFA-DA-09-001 (R01) - [Receipt Date: September 10, 2008]
It's Labor Day...take a break.
Have a safe holiday!

The History of Labor Day

Labor Day: How it Came About; What it Means

Labor Day, the first Monday in September, is a creation of the labor movement and is dedicated to the social and economic achievements of American workers. It constitutes a yearly national tribute to the contributions workers have made to the strength, prosperity, and well-being of our country.

Founder of Labor Day

More than 100 years after the first Labor Day observance, there is still some doubt as to who first proposed the holiday for workers.

Some records show that Peter J. McGuire, general secretary of the Brotherhood of Carpenters and Joiners and a cofounder of the American Federation of Labor, was first in suggesting a day to honor those "who from rude nature have delved and carved all the grandeur we behold."

But Peter McGuire's place in Labor Day history has not gone unchallenged. Many believe that Matthew Maguire, a machinist, not Peter McGuire, founded the holiday. Recent research seems to support the contention that Matthew Maguire, later the secretary of Local 344 of the International Association of Machinists in Paterson, N.J., proposed the holiday in 1882 while serving as secretary of the Central Labor Union in New York. What is clear is that the Central Labor Union adopted a Labor Day proposal and appointed a committee to plan a demonstration and picnic.

The First Labor Day

The first Labor Day holiday was celebrated on Tuesday, September 5, 1882, in New York City, in accordance with the plans of the Central Labor Union. The Central Labor Union held its second Labor Day holiday just a year later, on September 5, 1883.

In 1884 the first Monday in September was selected as the holiday, as originally proposed, and the Central Labor Union urged similar organizations in other cities to follow the example of New York and celebrate a "workingmen's holiday" on that date. The idea spread with the growth of labor organizations, and in 1885 Labor Day was celebrated in many industrial centers of the country.

Labor Day Legislation

Through the years the nation gave increasing emphasis to Labor Day. The first governmental recognition came through municipal ordinances passed during 1885 and 1886. From them developed the movement to secure state legislation. The first state bill was introduced into the New York legislature, but the first to become law was passed by Oregon on February 21, 1887. During the year four more states — Colorado, Massachusetts, New Jersey, and New York — created the Labor Day holiday by legislative enactment. By the end of the decade Connecticut, Nebraska, and Pennsylvania had followed suit. By 1894, 23 other states had adopted the holiday in honor of workers, and on June 28 of that year, Congress passed an act making the first Monday in September of each year a legal holiday in the District of Columbia and the territories.

Taken from http://www.dol.gov

DON’T FORGET TO VOTE ON NOVEMBER 4th

Updates for this newsletter should be sent to Doreen Cardillo dcardillo@tresearch.org