Dr. Woody participated in the 5th European Conference on Clinical and Social Research on AIDS and Drugs, held in Vilnius, Lithuania during the week of April 28. During a one-day NIDA meeting prior to the beginning of the conference, he gave a presentation that summarized findings from international addiction studies that have in St. Petersburg, Russia; Kiev, Ukraine; and Porto Alegre, Brazil. He also discussed plans for possible new studies in St. Petersburg, Russia; Tbilisi, Republic of Georgia; Porto Alegre, Brazil; and Reykjavik, Iceland. Each of these studies takes advantage of unique opportunities that are available at each site as a result of local drug use patterns, treatment facilities, and qualified investigators. For example, naltrexone studies are much easier to do in Russia than the U.S. because most patients begin treatment with inpatient detoxification, thus making induction onto naltrexone easy because all get detoxified and receive 2-6 weeks of residential treatment. Kiev has a very high proportion of injecting drug users with HIV, thus pointing to a great need to study the impact of methadone maintenance on HIV risk behavior. Porto Alegre has large numbers of adolescents that are abusing or dependent on marijuana and also have ADHD thus making it possible to study Concerta as a HIV risk reduction strategy in adolescents with marijuana use disorders. The Republic of Georgia has a high proportion of persons who are injecting buprenorphine, thus providing an opportunity to compare daily observed Suboxone vs methadone as treatments for this problem, which we are beginning to see in the U.S. Iceland has an outstanding national health system with parity for persons with substance use disorders, many of whom have amphetamine dependence, thus presenting an excellent opportunity to study the impact of sustained release naltrexone on relapse to amphetamine dependence. In addition to these scientific opportunities, it is very interesting to collaborate with colleagues in other cultures as it provides additional perspectives to what we are doing in the U.S.

Sabrina Poole, M.S., Project Manager, University of Pennsylvania, Department of Psychiatry, Co-Director of the NIDA Summer Program, spoke at the Summer Research with NIDA: Mentoring the Next Generation of Drug Abuse Researchers Conference in Bethesda on May 11, 2009. The NIDA summer program has been a wonderful way to introduce minority students to the field of medicine, especially to the methods of treatment of substance abuse. Some of them have gone into health careers. Dr. Charles O’Brien, Vice Chair, Department of Psychiatry at Penn is the PI on this project.

Regulatory Q&A: Research Involving Children

**Q:** What happens if a child reaches the legal age of consent while enrolled in a study?

**A:** The Office for Human Research Protections (OHRP) notes that informed consent should be viewed as an ongoing process throughout the duration of a research project. When a child who was enrolled in research with parental or guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the subject’s participation in the research is no longer regulated by the requirements of 45 CFR part 46.408 regarding parental or guardian permission and subject assent.
Unless the Institutional Review Board (IRB) determines that the requirements for obtaining informed consent can be waived, the investigators should seek and obtain the legally effective informed consent, as described in 45 CFR 46.116, for the now-adult subject for any ongoing interactions or interventions with the subjects. This is because the prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult subject. However, the IRB could approve a waiver of informed consent under 45 CFR 46.116(d), if the IRB finds and documents that the required conditions are met.

Similarly, if the research does not involve any ongoing interactions or interventions with the subjects, but continues to meet the regulatory definition of “human subjects research” (for example, it involves the continued analysis of specimens or data for which the subject’s identity is readily identifiable to the investigator(s)), then it would be necessary for the investigator(s) to seek and obtain the legally effective informed consent of the now-adult subjects. The IRB may consider, if appropriate, a waiver under 45 CFR 46.116(d) of the requirements for obtaining informed consent in order for the subjects to continue their participation in the research.

NIDA/SAMHSA
Thomas Brown, LPN attended the NIDA/SAMHSA Chicago Training of Trainers on Buprenorphine Treatment on May 11-12, 2009. The training was conducted by Thomas E. Freese, Ph.D. and Susan A. Storti, Ph.D., RN. The course covered Buprenorphine Awareness and Short-term detox as well as training and practice presentations by the students. The course development was a Blending Initiative of NIDA and SAMHSA. The sponsor of this training was the Great Lakes ATTC.

DelVal Node Trial Progress:
CTN 0027 - START
Study Update by: Edgar Weiss, Assoc. Project Manager; Site: NET Steps, Phila, PA
We have entered into the cleanup phase of the study. Devlin Hart has moved out of the clinic and over to TRI. The study charts have also been moved over to TRI for easy access until such time as they can be archived. Devlin is in the process of verifying their completeness and accuracy. Tom Brown is working on cleaning up the dosing records at the clinic. Lin Denton continues with her meticulous monitoring as we wind down. Ed Weiss is combing through the regulatory binders and EMMES is planning a site visit for the end of May.

CTN 0028 – ADHD - Charlotte Royer-Malvestuto, Project Manager, Site: RAW Paoli, PA
The Lead Node final data lockdown was completed on February 13, 2009. The Rehab after Work site is fully closed and the IRB was notified that data will reside at Treatment Research Institute until archival at Penn. Lin Denton, local CTN QA monitor, is conducting a “final” review of all Regulatory and IRB binders; she plans to complete her closeout report later this week.

CTN 0037 Exercise Study – As part of the site selection process, Harold Imber, Director of Special Projects and Jim DeSanto, Clinical Director from Firetree, Ltd., have participated in several conference calls with Dr. Woody, Delaware Valley Node Project Managers, and members of the Lead Node (University of Texas Southwestern Medical Center).

CTN 0046 Smoking Cessation and Stimulant Treatment.
The plan is to have all 12 CTN-0046 sites selected by early August and to initiate the Wave 1 sites in January 2010. A 3-step process being used to select sites.

1) Call for nominations from the Node PIs, with nominations due by May 15th, 2009.
2) Lead Node will request and evaluate more specific information directly from the nominated sites.
3) Phone "interviews" with the prospective sites before the final selection is made.
Step 1: Del Val Node nominated two sites: Thomas Jefferson IOP Rehab After Work, Center City. Firetree, Ltd., Reading, PA
The University of Pennsylvania IRB reviewed and approved the proposed LAX Pilot study on April 16, 2009. The LAX Center IRB will review changes recommended by the UPenn IRB later this month. Allen Howell, LAX Outreach Coordinator, is in the process of completing the CITI training requirements regarding Human Subjects’ protections.

**Upcoming Meetings/Conferences**

**CPDD, 71st Annual Meeting** • June 20-25, 2009 • Reno/Sparks, Nevada

The Headquarters hotel will be John Ascuaga’s Nugget Casino Resort in Reno/Sparks, Nevada. All scientific sessions will be held there. Rooms are assigned on a first-come, first-served basis, so make your reservations early, using the electronic forms: [http://www.cpdd.vcu.edu/Pages/MeetingRegist.html](http://www.cpdd.vcu.edu/Pages/MeetingRegist.html)

**APA 117th Annual Convention**

Toronto Canada

August 6-9, 2009.

You can register for the convention online, by mail or on-site in Toronto.

Register early and save!

APA has secured a large block of rooms at headquarters hotels and supplemental hotels in convenient locations and at competitive prices. To take advantage of special APA rates, reserve a room through APA's housing service, Experient. Rooms fill up quickly, so make your reservation early. Visit: [http://www.apa.org/convention09/register.html](http://www.apa.org/convention09/register.html)

**NIDA SC Meeting**

The NIDA CTN Steering Committee Meeting is scheduled to take place at the Hyatt Regency Bethesda on October 20-22, 2009. More information, including registration, agenda and logistics, will be available once registration is open on August 10, 2009. A notice will be sent to SC Members once registration is open.

**SAVE THE DATE**

**September 11, 2009**

“New Developments in Addiction Treatment” Conference to be Co-sponsored by the Delaware Valley Node of the Clinical Trials Network, PHMC and IRETA - NeATTC. Keynote speaker: A. Thomas McLellan, Ph.D. Details coming soon.

**SAVE THE DATE**

**November 3, 2009**

Delaware Valley Node Steering Committee

The next meeting of the Delaware Valley Node Local Steering Committee is scheduled for 11/3/09 at 2 p.m. in the Multi-Purpose Conference Room at the Treatment Research Institute. See you then!

**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](http://ctndisseminationlibrary.org)

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

For additional information, contact Ed Weiss, Assoc. Project Manager, Delaware Valley Node [eweiss@tresearch.org](mailto:eweiss@tresearch.org) or call 215-399-0980 x145.
Grants Corner

The following grant opportunities may be of interest to researchers:

Physician Outreach: Research to Practice (NOT-DA-09-028)

Recovery Act Grand Opportunities GO Grant Submission Deadline Moved to May 29, 2009 (NOT-OD-09-090) National Institutes of Health American Reinvestment and Recovery Act of


Women's Mental Health in Pregnancy and the Postpartum Period (R01) (PA-09-174)

Women's Mental Health in Pregnancy and the Postpartum Period (R21) (PA-09-175)
http://grants.nih.gov/grants/guide/pa-files/PA-09-175.html

Sudoku Puzzle

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