



# Clinical Trials Network

CTN Bulletin  
April 9, 2008  
Volume 08 – 07

## CTN 0030 POATS



The Prescription Opiate Addiction Treatment Study (POATS) sites continue to work hard recruiting participants. As of February 29, 2008 (the data cut-off date for the March CTN Trial Progress Report), there were 421 participants randomized into Phase 1 for an overall recruitment rate of 101% with the last Phase 1 randomization expected in fall 2008. The next DSMB meeting is scheduled for June 9, 2008. Staffing changes have occurred at the Lead Node team. Kristi Prather left as the CTN 0030 National Project Manager on March 14, 2008. Pearl Zakrofsky and Scott Provost are the new Co-National Project Managers.

This study was recently featured in NIDA Director Dr. Nora Volkow's testimony before the U. S. Senate Committee on the Judiciary on March 12<sup>th</sup>. POATS was given as an example of NIDA's efforts to examine approaches for the treatment of addiction to prescription opiates. CTN 0030 will also be highlighted at CPDD. An abstract entitled, "Methodological issues in designing a clinical trial for opioid analgesic dependence (OAD): defining the population" was accepted for a presentation at the upcoming conference (June 14 – 18, 2008).

## CTN 0032 Update



Site selection activities for the HIV Rapid Testing & Counseling (CTN 0032) protocol continue to move forward. A total of 17 treatment units from 16 CTPs are still potentially eligible to participate in the study. All sites have completed Phase 2B (client survey) of the site selection process to garner more information about their clients' potential eligibility for the study. Phase 3A of the site selection process, involving telephone interviews with CTP representatives and their respective Node Coordinators, continues, and site visits began on April 3, 2008. Subsequently, 12 sites will be selected to participate in CTN 0032 and notified of their status.

## CTN 0028 Adolescent ADHD Protocol



The CTN 0028 study is a randomized control trial of OROS-MPH in adolescents with substance abuse and ADHD disorders. The Lead Team reports that 277 participants have been randomized on the path to 300 ..... almost there!

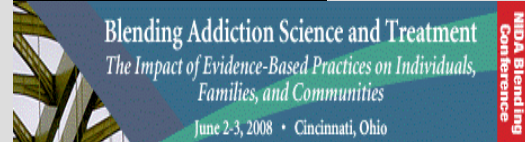
*CTN is a program of the National Institute on Drug Abuse, part of the National Institutes of Health within the Department of Health and Human Services.*

## Next Steering Committee Meeting



The NIDA CTN Steering Committee Meeting will be held June 4-5, 2008 at the Hyatt Regency, Cincinnati, Ohio. The special government rate is \$104 plus tax per night. Reservations must be made by May 5, 2008, in order to obtain the negotiated rate. You may call the hotel directly at (888) 421-1442 and ask for the NIDA CTN room block. *Reservations for the Blending Conference can be made at the same time as the NIDA CTN Steering Committee Meeting reservations under the same 'NIDA' room block.* To register for the Steering Committee meetings, please visit the following link:  
[www.sei2003.com/NIDA/CTN/Meetings/](http://www.sei2003.com/NIDA/CTN/Meetings/)

## NIDA Blending Conference



Don't miss out on this state-of-the-art conference highlighting the science of addiction treatment, *Blending Science and Treatment: The Impact of Evidence-Based Practices on Individuals, Families and Communities*, June 2-3, 2008 in Cincinnati, Ohio. For additional information go to [www.NIDABlendingConference.info](http://www.NIDABlendingConference.info) The Early Bird Conference Fee (\$79) is available through April 15, 2008. After this date the Regular Fee (\$99) will apply.

## Records Retention Guidance



It is the responsibility of each grantee to ensure that study related materials are handled in compliance with the terms of the grant and institutional policies. The need for confidentiality of the documents and participant information does not change over time. Sites should follow the guidance in the Informed Consent and the requirements of their grant or institutional policy.

NIH's general guidance is that grant records be retained for three years after submission of the grant's final FSR. There may also be some instances where an IRB or an Institution's policies require a longer retention period for study records. In those cases, records should be retained for the longer of those periods.

Regarding destruction of files/data, sites must contact their sponsor (via NIDA CPC) prior to destruction of any records. And when these are destroyed, the site must document the destruction (e.g. a receipt from a shredding company).

### **Publications Committee (PC)**



At the Steering Committee meeting in February, the PC distributed a list of CTN publications and copies of the abstracts of each publication, organized by protocol so one can see the outcomes and products of each CTN protocol to date. Forty-three (43) publications were listed; the PC indicated that a similar number of additional manuscripts had been approved for journal submission – some of those others are now accepted and “in press” at the journals. The PC requested updates and corrections to its list. Copies of the list and abstracts may be obtained by e-mailing Quandra Scudder at CCTN ([scudderq@nida.nih.gov](mailto:scudderq@nida.nih.gov)).

In addition to those items already published, manuscripts recently approved by the PC for journal submission include the primary outcome reports for the following CTN studies – congratulations to the study teams:

0003 – Buprenorphine/Nx Two Taper Schedules  
0010 – Buprenorphine/Nx in Youth/Adolescents  
0013 – MET in Pregnant Substance Users  
0015 – Women’s Trtmt for Trauma and Substance Abuse  
0018 – HIV/STD Risk Reduction Behavior (Men)  
0019 – HIV/STD Risk Reduction Behavior (Women)  
0021 – Spanish MET

Other recently published or accepted-for-publication papers include:

Haynes, L.F. Waite-O’Brien, N.; Hubbard, R.L. Can You Hear Me Now? An Innovation to Promote Continued Treatment, Counselor Magazine, June, 2007.

Fussell, H.E.; Kunkel, L.E.; Shannon-Lewy, C.; McFarland, B.H.; & McCarty, D. (2008) Using a standardized patient walkthrough to improve implementation of clinical trials. Journal of Substance Abuse Treatment, in press.

Winhusen, T.; Kropp, F.; Babcock, D.; Hague, D.; Erickson, S.J.; Renz, C.; Rau, L. ; Lewis, D.; Leimberger, J.; Somoza, E. (2008) Motivational enhancement therapy to improve treatment utilization and outcome in pregnant substance users. Journal of Substance Abuse Treatment, in press. [e-pub ahead of print]

### **Topics for CTN Articles in NIDA Notes**

**Please forward ideas for CTN related articles to Jeff Selzer (Long Island Node) at [selzer@lij.edu](mailto:selzer@lij.edu).**

### **CTN Dissemination Library Update**



Three new peer-reviewed articles from the CTN have been added to the Dissemination Library. They are:

- [Blending Addiction Research and Practice: Strategies for Technology Transfer](#) by TP Condon, LL Miner, et al, *Journal of Substance Abuse Treatment* (2008 in press). This article describes the NIDA Blending Initiative, launched in 2001 with the aim of improving the development, effectiveness, and usability of evidence-based practices.
- [What is Usual about “Treatment-As-Usual”? Data from Two Multisite Effectiveness Trials](#) by EJ Santa Ana, S Martino, et al, *Journal of Substance Abuse Treatment* (2008 in press). This article presents data from independent ratings of 379 audiotapes drawn from the "treatment-as-usual" arm of CTN-0004 and CTN 0005 to determine what actually constitutes standard practice in community-based drug abuse treatment.
- [States and Substance Abuse Treatment Programs: Funding and Guidelines for Infection-Related Services](#) by S Krutz, L Brown, RJ Goldsmith, et al. *American Journal of Public Health* (2008 in press). This article reports on a survey done as part of CTN 0012 that explored the relationship between state funding and guidelines and substance abuse treatment program practices.

### **Visit the CTN Dissemination Library:**

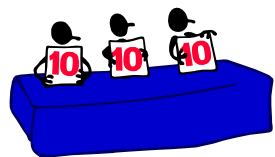
<http://ctndisseminationlibrary.org>. Or, write to the Librarians at [info@ctndisseminationlibrary.org](mailto:info@ctndisseminationlibrary.org) if they can help!

### **Northern New England Co-PI Award**



The Northern New England Node is pleased to announce that Dr. Jennifer Sharpe Potter has received a 5-year Career Development Award (K23) from the National Institute on Drug Abuse. Dr. Potter will focus her research on the important overlap between pain and addiction, with the ultimate goal of developing and studying a treatment approach for substance-dependent patients with chronic pain. Dr. Potter is Co- PI for the Northern New England Node and Co-Lead Investigator on the CTN 0030 (POATS) study. Congratulations!

### Medical Specialty Rankings for 2008



*U.S. News & World Report* just released their annual rankings of Best Graduate Schools for 2008. The top 10 for drug and alcohol abuse medical specialties

are all schools affiliated with CTN Nodes and Regional Research and Training Centers. See the list at:

<http://grad-schools.usnews.rankingsandreviews.com/grad/mdr/drugs>

- 1 [Yale University](#)  
New Haven, CT
- 2 [Columbia University College of Physicians and Surgeons](#)  
New York, NY
- 3 [Johns Hopkins University](#)  
Baltimore, MD
- 4 [Harvard University](#)  
Boston, MA
- 5 [University of California--San Francisco](#)  
San Francisco, CA
- 6 [University of Pennsylvania](#)  
Philadelphia, PA
- 7 [New York University](#)  
New York, NY
- 8 [University of Washington](#)  
Seattle, WA
- 9 [Medical University of South Carolina](#)  
Charleston, SC
- 10 [University of California--Los Angeles \(Geffen\)](#)  
Los Angeles, CA

Congratulations to all ten schools!

### Delaware Valley Node News



The Delaware Valley Node RRTC and Philadelphia Health Management Corporation (one of its CTPs) co-sponsored Motivational Interviewing training on March 19, 2008. Jonathan

Krejci, Ph.D., Director of Training and Research, and CTP Representative of Princeton House Behavioral Health, conducted the one-day training, which was offered to all of our CTP staff. Approximately 50 participants attended.

### Native American Conference on Historical Trauma



The California-Arizona Node is presenting a conference titled, "Historical Trauma: Healing Approaches in Native American Communities" co-sponsored by the Native American Health Center,

San Francisco and Oakland, CA. The conference addresses the role of historical trauma in the treatment of substance use disorders.

The conference is scheduled for Tuesday, July 1, 2008 from 7:30 a.m. - 5:00 p.m. at the Presidio Officer's Club in San Francisco. Keynote speakers will be Maria Yellow Horse Brave Heart, Ph.D, Associate Professor of Social Work at Columbia University; Karina L. Walters, Ph.D, M.S.W., William P. and Ruth Gerberding University Professor and Director of the Indigenous Wellness Research Institute at the University of Washington.

Dr. Brave Heart is viewed as a leading figure in the development of the emerging concept of historical trauma and historical unresolved grief theory, and will discuss the implications of historical trauma for substance abuse treatment among Native Americans. She founded the Takini network, a non-profit organization devoted to community healing from intergenerational massive group trauma among Native Peoples.

Dr. Walters has conducted NIH-funded studies on Native American health, historical trauma, substance use, and HIV risk behaviors. She will review her research findings as they pertain to the treatment of substance use disorders. Other speakers will include Joseph P. Gone, Ph.D., Assistant Professor of Psychology, University of Michigan; Nelson Jim, M.F.T., of the San Francisco Department of Public Health; Michele Maas, M.S.W. and Ethan Nebelkopf, Ph.D. from the Native American Health Center; and Theda New Breast, M.P.H., of New Breast Consultants in Babb, Montana.

There is no charge for this event, but pre-registration is requested. Free parking is available and continuing education credits will be provided for M.F.T.s and L.C.S.W.s. For additional information and to register for the conference, please contact Anna Stevens at [anna.stevens@ucsf.edu](mailto:anna.stevens@ucsf.edu), telephone 415-206-5924.

### Where to Get Information on the CTN



The NIDA CTN website includes information on the CTN Nodes, CTPs, and studies. For more information go to:

<http://www.nida.nih.gov/CTN/Index.htm>

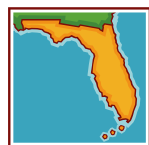
### **Free Motivational Interviewing Training**



Dr. Theresa Moyers of the University of New Mexico's Center on Alcoholism, Substance Abuse, and Addictions (CASAA), is currently conducting a randomized controlled trial funded by the National Institute on Drug Abuse (Grant #1R01DA021227-01A1). This study will provide free motivational interviewing training to healthcare providers (counselors, psychologists, medical doctors, social workers, nurses) who work in the field of substance abuse. They are recruiting providers who have minimal experience with motivational interviewing and work in a not-for-profit setting. One person per agency or setting will be able to participate in this study.

The goal of this study is to test two different strategies for training providers in motivational interviewing. All participants will attend a two-day motivational interviewing training in New Mexico taught by Theresa Moyers, Ph.D. and William Miller, Ph.D. Travel and accommodations will be subsidized. Participants are asked to submit a pre-training audio work sample of a therapy session with an actual client. For additional information on this study, or if you would like to see if you are eligible for the study, please send an email to [mitrainingstudy@gmail.com](mailto:mitrainingstudy@gmail.com) or visit the study webpage at: <http://casaa.unm.edu/elicite.html>

### **Florida Publication News**



Dr. Michael Robbins, at the University of Miami, Miller School of Medicine, is the senior author on a manuscript entitled "The Efficacy of Structural Ecosystems Therapy with Drug Abusing/Dependent African American and Hispanic American Adolescents," which was published in the February issue of the Journal of Family Psychology. This randomized clinical efficacy trial examined the differential impact of family therapy combined with ecological approaches (e.g., interventions to enhance parent-peer and parent-school involvement and supervision) to alternative interventions in a sample of 190 African American and Hispanic drug using adolescents and their families. The results of this study demonstrate that an ecologically-based family treatment is efficacious in improving family functioning for both ethnic/racial groups. However, improvements in drug use (relative to control conditions) were only statistically significant for Hispanic adolescents, which has important implications for treatment research with ethnically/racially diverse populations. Thanks for sharing these findings!

### **New York Node News**



The final proof of the State paper from the Infections and Substance Abuse Study (NIDA CTN-0012) was posted in the 'First Look' section of the American Journal of Public Health (AJPH) website on April 1st. The abstract can be accessed at: <http://www.ajph.org> by clicking on First Look. AJPH members or subscribers can also access the full paper online.

The title of the paper is: States and Substance Abuse Treatment Programs: Funding and Guidelines for Infection-Related Services. Authors are: Steven Kritz, MD, Lawrence S. Brown Jr, MD, MPH, R. Jeffrey Goldsmith, MD, Edmund J. Bini, MD, MPH, Jim Robinson, MEd, Donald Alderson, MS, Patricia Novo, MPA, and John Rotrosen, MD.

Print publication is scheduled for the May issue of AJPH. This is the 3rd paper from this study that has been published. Congratulations!

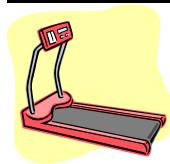
### **Florida Node Update – PI Appointment**



José Szapocznik, Ph.D., has been named chairman of the Department of Epidemiology and Public Health at the Miller School of Medicine. Szapocznik also serves as associate dean for community development and director of the Center for Family Studies at the Miller School. He is considered a pioneer in the national effort to prevent and treat adolescent drug abuse and other behavior problems among Hispanic youth. Szapocznik's Brief Strategic Family Therapy™ has received national and international recognition for its success as a family-based intervention. Szapocznik has a distinguished record of service to the NIH, having been appointed by U.S. Secretary of Health and Human Services Donna Shalala to the national advisory councils for the National Institute of Mental Health and the National Institute on Drug Abuse, and was the first ever behavioral scientist appointed to the NIH-wide AIDS Program Committee (currently the NIH Office of AIDS).

Dr. Szapocznik replaces Clyde McCoy, Ph.D., who served as department chair for more than a dozen years. Dr. Szapocznik said, "Among my immediate goals, in addition to strengthening our current doctorate in epidemiology, is to develop a doctorate in biostatistics which is a great need of the university. In addition, we hope to create several areas of specialty in our master's in public health program as well as a master's in biostatistics and bioinformatics."

### **Exercise for Drug Abuse Concept Update**



The exercise concept team would like to thank all of the CTPs that completed the survey of residential treatment programs. An impressive total of 65 surveys were submitted, and the information compiled from the

questionnaires will be very helpful as the team continues to develop this protocol. Special thanks to the Node coordinators for their timely assistance in distributing and returning the questionnaires, and to everyone who provided feedback on earlier drafts of the questionnaire.

### **Grants Tidbit Corner- New Grants**



The following grant opportunities may be of interest to researchers in the CTN:

- Toxicological Evaluation of Potential Medications to Treat Drug Addiction (NOT-DA-08-025)  
<http://grants.nih.gov/grants/guide/notice-files/NOT-DA-08-025.html>
- Synthetic Peptides & Other Drugs of Abuse/Purity Determination, Stability Testing & Quantitative Analysis (NOT-DA-08-026)  
<http://grants.nih.gov/grants/guide/notice-files/NOT-DA-08-026.html>
- Receptor Profiling and Compound Library Screening (NOT-DA-08-027)  
<http://grants.nih.gov/grants/guide/notice-files/NOT-DA-08-027.html>
- International Research Training and Support (NOT-DA-08-028)  
<http://grants.nih.gov/grants/guide/notice-files/NOT-DA-08-028.html>
- Prescription Drug Misuse (R01) (PA-08-127)  
<http://grants.nih.gov/grants/guide/pa-files/PA-08-127.html>
- Prescription Drug Misuse (R21) (PA-08-128)  
<http://grants.nih.gov/grants/guide/pa-files/PA-08-128.html>
- Prescription Drug Misuse (R03) (PA-08-129)  
<http://grants.nih.gov/grants/guide/pa-files/PA-08-129.html>
- Epidemiology Of Drug Abuse (R01) (PA-08-124)  
<http://grants.nih.gov/grants/guide/pa-files/PA-08-124.html>
- Epidemiology Of Drug Abuse (R21) (PA-08-125)  
<http://grants.nih.gov/grants/guide/pa-files/PA-08-125.html>
- Epidemiology Of Drug Abuse (R03) (PA-08-126)  
<http://grants.nih.gov/grants/guide/pa-files/PA-08-126.html>

### **Clinical Coordinating Center (CCC) at EMMES Training - Webinar Series Catalog Coming in April**

The CCC has teamed up with members in the CTN to provide interactive training sessions via web seminars. These sessions will be described in a catalog which will go to each site and Node. The CCC looks forward to more suggestions for future seminars. Upcoming training includes ASI Booster Training on May 1, Timeline Follow Back on May 15, and Site Management Overview on June 12. If you have any questions or comments please contact Liz Buttrey at [ebuttrey@emmes.com](mailto:ebuttrey@emmes.com) or [ctntraining@emmes.com](mailto:ctntraining@emmes.com).



**Regulatory Facts & Tidbits - Can a clinical investigator be an IRB member?** Yes, however, the IRB regulations [21 CFR 56.107(e)] prohibit any member from participating in the IRB's initial or continuing review of any study in which the member has a conflicting interest, except to provide information requested by the IRB. When selecting IRB members, the potential for conflicts of interest should be considered. When members frequently have conflicts and must remove themselves from deliberating and/or abstaining from voting, their contributions to the group review process may be diminished and could hinder the review procedure. Even greater disruptions may result if this person is the chairperson of the IRB.

*Other CCC related questions and topics-* Robert Lindblad at 301-251-1161, [rlindblad@emmes.com](mailto:rlindblad@emmes.com)

### **Free NIH Workshop**



A day long workshop titled "Partnering with Community Health Care Providers to Translate Research into Practice" will be held May 9, 2008, to explore collaborative ways

to improve and speed research advances into clinical practice. Community partnerships will be the featured topic of the first in a series of planned workshops.

Registration is now open:

<http://www.aptrweb.org/workshops/registration.html>

This is the first in a series of workshops to discuss and share best practices and ways in which researchers can partner with community health care providers to translate clinical research into practice. Participants will develop recommendations for academic-community collaborations and partnerships with other community programs. The contact for information is Dr. Donna Jo McCloskey at [mccloskd@mail.nih.gov](mailto:mccloskd@mail.nih.gov).

## **New SAMHSA Report By State**



A new report providing analyses of substance use and mental health patterns occurring in each state reveals that there are wide variations among the states in problems like illicit drug use and underage drinking. The report by the Substance Abuse and Mental Health Services Administration (SAMHSA) shows that although there are some differences in the patterns of substance use and mental health problems experienced among states, all parts of the country are seriously affected by these problems.

*State Estimates of Substance Use* is based on the 2005-2006 National Survey on Drug Use and Health (NSDUH) and provides state-level estimates for 23 measures of substance use and mental health problems, including underage drinking, use of illicit drugs, serious psychological distress, major depression, and tobacco use. Notable findings in this report include:

### **1) Underage Alcohol Use and Binge Drinking**

Georgia had the lowest level of past month underage binge drinking of alcohol (15.2 percent), and North Dakota had the highest level (28.5 percent).

### **2) Illicit Drug Use**

Past month use of illicit drugs for all persons aged 12 or older ranged from a low of 5.7 percent in North Dakota to a high of 11.2 percent in Rhode Island.

### **3) Tobacco Use**

Utah had the lowest prevalence level for past month tobacco use among persons aged 12 or older (22.1 percent). West Virginia had the highest level for this age group (40.6 percent).

### **4) Substance Dependence and Abuse**

The percentage of persons with a substance use disorder, including either drug or alcohol dependence or abuse, ranged from a low of 7.5 percent in New Jersey to a high of 12.3 percent in the District of Columbia.

### **5) Mental Health Problems**

Hawaii had the lowest level of people age 18 or over reporting at least one major depressive episode in the past year (5.0 percent) while Nevada had the highest rate (9.4 percent).

The full report is available on the Web at <http://www.oas.samhsa.gov/2k6State/toc.cfm>. Copies may be obtained free of charge by calling SAMHSA's Health Information Network at 1-877-SAMHSA-7 (1-877-726-4727). Request inventory number SMA 08-4311.

## **Data and Statistics Center (DSC) at DCRI**

The DSC reminds staff of two key milestones associated with Data and Safety Monitoring Board (DSMB) meetings. The two key milestones are: Clinical Cut-off and All Queries Resolved/All Data Report Issues Resolved.



1. *Clinical Cut-off* – the time point when the sites need to have all data for completed visits entered into the InForm system and Clinical Research Information System (CRIS). This is typically about 2 months prior to the scheduled DSMB meeting to allow time for data cleaning and report generation.
2. *All Queries Resolved /All Data Report Issues Resolved*– once all data are entered, the DSC will perform clinical coding, SAE reconciliation, lab reconciliation etc. The DSC will then generate queries as appropriate for each of these items. All Queries Resolved is the deadline for resolving all of these queries. Additionally, the site should ensure that each Data Status Report meets the level of cleanliness set by the study team. For example, the target cleanliness for DSMB for CTN 0030 is 80-percent.

The DSC will send notifications to the sites via the EDC Helpdesk regarding each of these milestones and will work with sites on each of these milestones to ensure the most current and highest quality data available.

### *Who to Contact:*



You may contact the Site Support Help Desk at 1-888-DSC-SSHD (1-888-372-7743) from 8:00 a.m. to 8:00 p.m. Monday through Friday or send an e-mail to: [nidadsc-help@mc.duke.edu](mailto:nidadsc-help@mc.duke.edu).

### **Data Management Lead:**

Lori Poole, B.A., Phone (919) 668-8238  
[lori.poole@duke.edu](mailto:lori.poole@duke.edu)

### **Lead Statistician:**

Jeff Leimberger, Ph.D., Phone (919) 668-8758  
[leimb001@duke.edu](mailto:leimb001@duke.edu)

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[ccushing@nida.nih.gov](mailto:ccushing@nida.nih.gov), telephone (301) 443-9815

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*Updates for this Bulletin should be sent to Carol Cushing at:*  
[ccushing@nida.nih.gov](mailto:ccushing@nida.nih.gov)