



Clinical Trials Network

CTN Bulletin

March 7, 2008

Volume 08 – 05

Executive Committee (EC)



The EC approved 2 guidelines to move forward: interim review of concepts and final study report. These documents will be ready for distribution within the next couple of weeks. The EC will be reviewing the Trial Progress Report on a regular basis. Lead Investigators are encouraged to update the timelines found in the report.

The EC has formed two ad hoc work groups. The first group will address lessons learned in the previous CTN trials. A “lessons learned” workshop was proposed and approved. It is tentatively planned for the Fall 2008 Steering Committee Meeting. The group members include: Roger Weiss, Jim Sorenson, Paul Wakim, Louise Haynes, Mary Ellen Michel, and Dennis McCarty. A second subcommittee was formed to identify and acknowledge outstanding service to the CTN. The following members were identified: Dennis McCarty, Joan Zweben, and Al Cohen.

CTN 0031 STAGE –12 Is Randomizing!



The STAGE-12 (Stimulant Abuser Groups to Engage in 12-Step) began enrolling patients on February 11. Three Wave 1 sites will be active in this first phase. At the end of February, 5 participants had been enrolled in the study, 3 at Maryhaven in the Ohio Valley Node and 2 at RCKC in the Pacific Northwest Node. The study will be carried out at 9 sites with a planned enrollment of 400 participants.

CTN 0032 Update



Site selection activities for the HIV Rapid Testing & Counseling (CTN 0032) protocol continue to progress. A total of 26 treatment units from 18 CTPs are potentially eligible to participate in the study. Several sites are currently participating in 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, is also ongoing and several interviews have already been conducted. Phase 3B, involving site visits, is scheduled to begin this month. Subsequently, 12 sites will be selected to participate. While site selection activities are underway, the Investigative Team, various work groups and collaborators continue to develop SOPs, training materials, assessments and CRFs.

CTN 0031A Neurotoxicity Gains Momentum!



CTN 0031-A is a CTN-funded ancillary study to the CTN 0031 (STAGE-12 Stimulant Abusers Group to Engage in 12 Step) trial. Six of the nine CTN 0031 study sites will participate.

The CTN 0031A Neurotoxicity Study has enrolled its first participant and opened its second site for enrollment. The Lead Team is pleased to announce that Maryhaven in Columbus, Ohio, had the distinction of enrolling the first participant in the study on February 26, and has since enrolled additional participants. Recovery Centers of King County in Seattle, Washington, received endorsement to begin enrolling participants on February 28, and has scheduled the first study participant at that site. Drs. Theresa Winhusen and Eugene Somoza and the entire Lead Team would like to thank study teams at both sites for their hard work to ensure that the study had a great start!

The Study Team would like to clarify the target study enrollment. In the last CTN Bulletin, it was reported that the study would enroll approximately 164 participants. This is the number of participants expected to be enrolled from the pool of participants in the CTN 0031 STAGE-12 study. While multiple studies have revealed neurocognitive deficits in METH/Cocaine abusers relative to normal controls, this is the first study to evaluate oxidative stress/damage in this population and, thus, oxidative stress/damage will also be assessed in 30 normal comparison participants, bringing the total enrollment target to 194.

Daylight Savings Time Begins Early!



Reminder- Daylight Savings Time Begins Sunday, March 9. Turn your clocks ahead 1 hour on Saturday night, March 8.

START Protocol - CTN 0027



The START (Starting Treatment with Agonist Replacement Therapies) has randomized 648 participants. A few sites have switched to the new 2:1 randomization allocation (Bup/Nx: Methadone). The remaining sites are awaiting IRB approval but expect to be approved this month. The next DSMB will meet by teleconference on April 15.

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.

Travel Awards for CPDD Meeting



NIDA is again offering the Director's Travel Award to help offset the cost of attending the annual College on Problems of Drug Dependence (CPDD) meeting in

San Juan, Puerto Rico in June. This award is open to NRSA trainees, NRSA fellows, and Minority Supplement recipients, and is contingent upon attendance of the Tutorials—a workshop that is intended to provide junior investigators with fundamental information from a variety of disciplines representing the breadth of drug abuse and addiction research. The application deadline for this award is April 4, 2008.

There is a Grant-Writing Workshop for junior investigators within 5 years of their doctoral or medical degree. The application deadline for this workshop is May 1, 2008. The application for the travel award and Tutorials workshop and additional information can be found on NIDA's training homepage (<http://www.drugabuse.gov/researchtraining>).

Mid-Atlantic Node Science Event



The Mid-Atlantic Node will host their sixth annual science-to-practice symposium on March 28, 2008. The topic for this year's day-long event is Sex and Drugs: Reducing Risky Behavior for Men, Women and

Adolescents. The morning plenary will include an overview by James Sorenson and presentations by Donald Calsyn, Susan Tross, and Lesley Cottrell. Afternoon workshops will provide participants with interventions appropriate to their population. The event, which is co-sponsored by Maryland's Office of Education and Training for Addiction Services, will be held at their Spring Grove Campus. The Central East ATTC will provide CEU credits. For more information and to register for this free event, go to www.mactn.org.

Bup/Nx CTN 0010 Hand Off Meeting



Drs. Woody, Subramaniam, Bogenschutz, McNicholas, Mercer, Connery and Freese, along with staff from Mountain Manor, the New Mexico programs and Mercy Hospital, participated in the Young Adult

Buprenorphine Treatment Hand-Off Meeting that was held on February 28, 2008, at the Bethesda North Marriott Hotel and Conference Center. Drs. Condon, Tai and Stein provided introductions and an overview of the purposes of the meeting followed by Dr. Woody who presented study findings. Issues regarding protocol training, lessons learned, and proposed dissemination strategies involving the ATTCs were discussed by other participants.

Free Training in Motivational Interviewing (MI)



NIDA has funded a research study through the University of New Mexico focusing on training front line substance abuse clinicians in MI. If you have clinicians in your programs who treat substance abuse

clients and are interested in learning more about motivational interviewing, please contact the researchers at mitrainingstudy@casaa.unm.edu. Eligible clinicians will participate in a 2-day MI training in Albuquerque, NM. William Miller, Ph.D., Theresa Moyers, Ph.D., Jennifer Knapp Manuel, M.S., and Brian Burke, Ph.D., will provide workshop-training instruction. For additional information, go to their web page at <http://casaa.unm.edu/elicite.html>. Study costs, including transportation to New Mexico, are covered by this research grant. One person per agency or setting will be able to participate in this study.

Award to Pacific Northwest CTP



Congratulations go to Residence XII (<http://www.residencexi.org/>), a women's treatment program in Kirkland, across Lake Washington from Seattle, and a charter CTP

member of the Pacific Northwest Node! The agency has been selected to receive the James W. West, M.D., Quality Improvement Award from the National Association of Addiction Treatment Providers (NAATP). The award, which was named after James W. West, M.D., the medical director emeritus of the Betty Ford Center, in recognition of his pioneering efforts and support of quality improvement, is given annually to one or more member programs to recognize their efforts in the area of quality improvement. Residence XII is receiving the award for its adaptation and implementation of Seeking Safety following its participation as one of the CTPs involved in CTN 0015 - the Women and Trauma protocol. The award will be presented at the NAATP Annual Addiction Treatment Leadership Conference in Indian Wells, California, on May 20, 2008. There will be an article about the program featured in Behavioral Health Magazine.

Request for Information



NIDA needs to keep track of the number of grants that use CTN as a platform. Our current information is limited. Please let us know of any funded R01, K23, R03, R21, or other grants using CTN as a platform. Send the information to Quandra Scudder at: ScudderQ@nida.nih.gov. Thanks!

Updates from the Oregon/Hawaii Node



CTN Results Highlighted in Counselor Magazine - A feature article in the February 2008 issue (Volume 9, Issue 1) of Counselor Magazine (The Magazine

for Addiction Professionals) is based on research completed within the Clinical Trials Network. Bret Fuller (Oregon/Hawaii Node) and Joseph Gudysh (California/Arizona Node) collaborated on the paper ("No Smoking Allowed: Integrating Smoking Cessation with Treatment" p. 22 - 27) and summarized results previously published in the Journal of Substance Abuse Treatment (Fuller, Gudysh et al., 2007, Attitudes toward the integration of smoking cessation treatment in drug abuse clinics, JSAT, 32, 53 * 60). The research examines the characteristics of drug abuse treatment programs that promote smoking cessation and the workforce characteristics associated with support for integrating smoking cessation into addiction treatment. The paper will soon be available electronically at www.counselormagazine.com after the next issue of Counselor Magazine is mailed to subscribers. Papers of broad interest to the Counselor Magazine readership are selected from the Journal of Substance Abuse Treatment; authors are invited to prepare an abbreviated and simplified version of the study. This is one more facet of the efforts to promote the blending of practice, policy and research.

Staff Retreat - The Oregon/Hawaii Node conducted a one-day retreat for all of the protocol teams within the Node. Since the protocols are being conducted at different locations in the state, the teams were not familiar with each other. The daylong event included introductions, an overview of each protocol by study coordinators, discussions of the IRB, an overview of drugs used by our participant population, monitoring guidelines, review of Good Clinical Practices and an open discussion. The night before the retreat a dinner was held by Lynn Kunkel, Node Coordinator, where all the CTP Site Coordinators, protocol monitors and research assistants gathered for an informal evening. The dinner established a nice informal feeling that led to the next day's development of collaboration and collegiality.

Congratulations Dr. George Woody



Dr. George Woody, PI of the Delaware Valley Node at University of Pennsylvania, has been selected to appear on ISI HighlyCited.com because of his exceptional citation count in the field of Social Sciences. Less than one percent of all publishing authors meet the criteria for inclusion on this website. Congratulations!



Grants Tidbit Corner- New Grants

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

The Funding Opportunity Announcements (FOAs) for the CBPR (Community-based Participatory Research) for underserved populations are in the NIH guide at: http://grants.nih.gov/grants/guide/search_results.htm?scope=pa&year=active&text_curr=PAR-08-076&Search.x=31&Search.y=5

These have special panel reviews, but the submission dates are once a year in the next 3 years. Letters of intent are due April 16 and applications are due May 16.

Another FOA is for R01 only, http://grants.nih.gov/grants/guide/search_results.htm?scope=pa&year=active&text_curr=PA-08-074&Search.x=32&Search.y=9 This one is reviewed along with the rest of NIH proposals, and can be submitted during the regular R01 cycles.

CPDD Mini-Conference on Women and Smoking

The College on Problems of Drug Dependence (CPDD) is holding a conference on Women and Smoking:



Understanding Socioeconomic Influences April 9-10, 2008 at the Westin Annapolis Hotel in Annapolis, Maryland. This conference offers a single-track, two-day, interdisciplinary program in which internationally recognized scholars will present on current research advances relevant to the problem of cigarette smoking among disadvantaged women. A plenary session involving two distinguished experts on social factors as fundamental causes of disease and the history of smoking will be followed by a series of five paper sessions on: (1) epidemiology & etiology; (2) genetic factors; (3) behavioral, pharmacological, and neurobiological factors; (4) prevention and treatment; and (5) tobacco-control policies. Following completion of all paper sessions each day, one of two distinguished leaders in smoking and women's health will act as Discussants with the charge of integrating and critically considering the knowledge shared during the meeting on that day. Conference registration is \$250, which includes continental breakfast each morning and afternoon refreshments. More information is available on the CPDD website (<http://www.cpdd.vcu.edu/>). Conference, travel and hotel registrations can be made through Sailair at 800-759-5800 or thaslett@sailairtravel.com.

What is Research Misconduct?

Per NIH Grant Policy, research misconduct is "fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. The term does not include honest error or honest differences of opinion.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit."



What should I do if I suspect there is misconduct at my site? Allegations of misconduct should be kept confidential at all times. You should only report to those in "a need to know" basis. Contact your

supervisor for further advice on how each site should handle these cases. Just remember to keep the allegation strictly confidential and do not discuss the events in conference calls or meetings. Questions or comments, please contact Carmen Rosa.

NCI Course on Human Subjects



On March 1, 2008, the NIH Office of Extramural Research (OER) on-line tutorial [Protecting Human Research Participants](http://phrp.nihtraining.com) (<http://phrp.nihtraining.com>)

replaced the NCI Human Participant

Protections Education for Research Teams course. Like the previous course, the OER tutorial is a free, web-based course that presents information about protections for human participants in research. The tutorial is designed for those involved in the design and/or conduct of research involving human participants. It satisfies the NIH human subjects training requirement for obtaining NIH awards, but it is not the only way to satisfy this requirement. Information on satisfying the requirement and answers to commonly asked questions about the education requirement may be found on OER's Frequently Asked Questions on the Requirement for Education on the Protection of Human Subjects (http://grants.nih.gov/grants/policy/hs_educ_faqs.htm).

Topics for CTN Articles in NIDA Notes

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

Clinical Coordinating Center (CCC) at EMMES



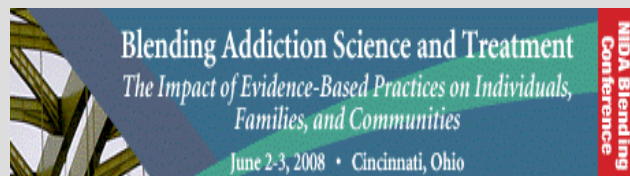
Webinars Coming Soon! The Clinical Coordinating Center has teamed up with members in the CTN to provide interactive training sessions via web seminars. Seminars include site

management, recruitment and retention, adverse events, informed consent, IRB and regulatory documents, HIPAA, and an overview of good clinical practice. A catalog of seminars is reaching completion and should be distributed by the end of March. This web seminar format provides the most cost effective and accommodating way to continue learning through collaborative discussions with network colleagues from the comfort of your own office. No travel, no travel expenses, and no time away from your office!

We welcome your suggestions for future seminars. If you have any questions or comments please contact Liz Buttrey at ebuttrey@emmes.com.

Other CCC related questions and topics- Michele Straus 301-251-1161, mstraus@emmes.com

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

The Early Bird Conference Fee (\$79) is available through April 15, 2008. After this date the Regular Fee (\$99) will apply. The room block at the Cincinnati Hyatt is set-up for travelers to make a single reservation to stay for the Blending Conference as well as the Steering Committee Meetings which follow June 4-6. You may make your reservation on-line by [clicking here](#) or you may call reservations (888) 421-1442 or the hotel at (513) 579-1234. Be sure to ask for the "NIDA" room block to receive the negotiated rate when you call.

Updates for this Bulletin should be sent to Carol Cushing at: ccushing@nida.nih.gov