



Clinical Trials Network

CTN Bulletin

May 22, 2009

Volume 09 – 10

Trial Progress – Over 10,000!



Trial enrollment is taken from the official Trial Progress Report prepared by the Data and Statistics Center (DCRI) each month. These enrollment numbers reflect information in the database through **April 30, 2009**.

Open Studies (5)

- CTN 0027 – Randomized 1095
- CTN 0027A (Genetics) – Randomized 648
- CTN 0031 – Randomized 301
- CTN 0031A – Randomized 141
- CTN 0032 – Randomized 1,138

Total Randomized All Studies: 10,962

CTN 0032 Reaches Enrollment Goal!



The HIV Rapid Testing & Counseling (CTN 0032) team is pleased to announce that they have met their recruitment goal! On May 20, the combined randomization was 1,272. The Lead Team would like to thank all sites and their corresponding Nodes for their hard work and dedication to the study, which led to a remarkable recruitment rate:

- **Appalachian Tri-State Node**
CPCDS Addiction Medicine Services (WPIC)
- **California/Arizona Node**
La Frontera Center, Inc.
- **Florida Node**
Daymark Recovery Services, Inc.
- **Mid-Atlantic Node**
Chesterfield CSB Substance Abuse Service
Glenwood Life Counseling Center
- **New England Node**
MCCA (Midwestern Connecticut Council on Alcoholism)
Wheeler Clinic
- **Ohio Valley Node**
Gibson Recovery Centers
- **Oregon/Hawaii Node**
CODA, Inc.
- **Southern Consortium Node**
LRADAC (Lexington/Richmond Alcohol and Drug Council)
Morris Village Alcohol and Drug Treatment Center
- **Southwest Node**
The Life Link

Additionally, all sites are engaged in 1-month follow-up activities. As of May 21st, 972 1-month follow-up visits have been completed with only 1% having been lost to follow-up (two due to death).



Sarah Essex of Gibson Recovery Center (Ohio Valley Node) was selected as the “**CTN STAR**” for **April 2009!** Sarah is the Lead RA at Gibson Recovery. She has shown

herself to be a very dedicated member of the team. Over the course of this study, Sarah has been instrumental in helping to develop local SOPs, making sure their regulatory binder is consistent with EMMES standards and playing an essential role in recruitment and retention. She is very meticulous in her work and has become a leader within the team. Congratulations to Sarah for joining the ranks of CTN 0032 stars!

As a reminder, please send nominations for the “CTN 0032 Star of the Month” for May to the Lead Investigator, Dr. Lisa Metsch, at L.Metsch@med.miami.edu by Thursday, May 28th.

CTN 0030 (POATS Main Trial) - The Prescription



Opiate Addiction Treatment Study (POATS) has fewer than 20 participants who remain active for follow-up visits.

The last research follow-up visit is projected to occur in July, and database lock is anticipated for early September.

CTN 0030A3 (POATS: Long-Term Follow-up Project)

Progress continues with the follow-up extension to the CTN 0030 trial. The extension study will examine long-term outcomes for individuals dependent on opioid analgesics and extends the follow-up period by three years from study randomization. Nearly all of the sites have begun contacting and consenting participants for this project. As of May 11th, staff from the Lead Node at McLean Hospital had completed 27 telephone assessments with participants from the McLean Hospital (Northern New England), ADAPT (Oregon/Hawaii), ISAP (Pacific), EITC (Ohio Valley), and BHS (Southern Consortium) sites. Thank you to the participating CTN 0030 sites for all their efforts in helping to launch the Long Term Follow-up extension project!

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.

Southern Consortium CTP News



Behavioral Health Services of Pickens County (BHSPC), located on Main Street in Pickens, is quite a distance from the Medical University of South Carolina both geographically and culturally. This distance has not prevented a productive relationship.

Beginning in 1999 BHSPC was chosen as a Community Treatment Program for the MUSC-centered Southern Consortium Node of the Clinical Trials Network.

Successful performance was demonstrated as Pickens was the only Community Treatment Program that succeeded in recruiting and retaining participants in an earlier smoking cessation study. More recently, the BHSPC Research Department has been a top performing site in the CTN on the Prescription Opiate Analgesic Treatment study (CTN 0030 POATS). Due to their success in CTN research projects, Pickens has been selected as a site for several other National Institutes of Health and private industry trials.

As research became one of BHSPC's priorities, a new stand alone center was built to house the research department. On May 1, 2009, South Carolina's Attorney General, Henry McMaster, and Dr. Kathleen Brady of MUSC cut the ribbon, officially marking the grand opening of Behavioral Health Services of Pickens County's new research office. Local legislators, Southern Consortium members, and supporters were also in attendance.

The research and treatment work being done at Behavioral Health "is very, very important," McMaster said. "We're all working for a common goal," Bob Hiott, Executive Director of Behavioral Health and the Site Investigator for clinical trials said. "We're making the lives of our citizens better by reducing drug use." Ten years ago, an opportunity came, through the National Institutes of Health, to form alliances with community providers to "bring evidence-based practice into the community in the area of drug abuse," said Dr. Brady. "Those alliances are important, as they take research out of the "ivory towers" of academia and place it in the areas where they're needed most," she said. "This group has done just a fabulous, knockout job," Dr. Brady stated.

The research staff at Behavioral Health Services would like to thank everyone who came out to support their grand opening, as well as MUSC and their fellow research sites for their support. Congratulations!

New Grant Opportunities



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

Notice of Intent to Publish a Request for Applications for The Human Connectome Project (U54) (NOT-MH-09-010) <http://grants.nih.gov/grants/guide/notice-files/NOT-MH-09-010.html>

NIH Clinical Trial Planning Grant Program (R34) (PA-09-186) <http://grants.nih.gov/grants/guide/pa-files/PA-09-186.html>

Pacific Northwest (PNW) Node News



Meg Brunner, one of the CTN Dissemination Librarians, was named Chair-Elect of the organization [Substance Abuse Librarians & Information Specialists](#), at the recent SALIS

conference in Halifax, Nova Scotia. SALIS is an international association of individuals whose work focuses on the exchange and dissemination of alcohol, tobacco, and other drug information, and both Meg and Nancy Sutherland (the other CTN Librarian) are active members. Meg obtained her MLIS from the University of Washington School of Library and Information Science in 1998, and has been working at the UW Alcohol and Drug Abuse Institute -- home of the PNW Node -- ever since. She specializes in web and database development, including special projects such as the [CTN Dissemination Library](#). Meg ran on a platform of Total World Domination, and was pleased that she was not defeated by a write-in campaign for Stephen Colbert. Congratulations Meg!

News from the New York Node



A fifth paper from the Infections and Substance Abuse Study (NIDA CTN 0012) will be published in the June issue of the Journal of Addiction Medicine: *Disparities in Health Services for HIV/AIDS, Hepatitis C Virus, and Sexually Transmitted Infections: Role of Substance Abuse Treatment Programs.*

Authors are Lawrence S. Brown, Jr., MD, MPH (Lead Investigator), Steven Kritz, MD (Project Manager), Adashima Muhammad, MPH, Edmund J. Bini, MD, MPH, R. Jeffrey Goldsmith, MD, Jim Robinson, MEd, Donald Alderson, MS, Deborah S. Hasin, PhD, and John Rotrosen, MD (NY Node Principal Investigator).

CTN Dissemination Library Update



Four new journal articles about CTN platform/ancillary investigations have been added to the Dissemination Library. Don't have access to professional journals? Did you know you can e-mail the Library to request a copy of items in the CTN Dissemination Library? Look for the "E-mail CTN Library (free)" link on the article display page.

- [Evaluating Motivational Enhancement Therapy Adherence and Competence among Spanish-Speaking Therapists](#) by Santa Ana, Carroll, Anez, et al. *Drug and Alcohol Dependence* (2009 in press). This report provides data on the psychometric properties of a therapist adherence/competence rating system adapted from MET trial CTN 0004 and used in the Spanish MET trial, CTN 0021.
- [Heterogeneity of Stimulant Dependence: A National Drug Abuse Treatment Clinical Trials Network Study](#) by Wu, Blazer, Patkar, et al. *American Journal on Addictions* (2009 in press). In this study, the presence of DSM-IV subtyping for dependence on cocaine and amphetamines was investigated among outpatient stimulant users enrolled in CTN 0006 (MIEDAR).
- [Correspondence of Motivational Enhancement Treatment Integrity Ratings among Therapists, Supervisors, and Observers](#) by Martino, Ball, et al. *Psychotherapy Research* 2009;19(2):181-193. This paper examines the correspondence of treatment integrity ratings (adherence and competence) among community program therapists, supervisors, and observers for therapists using MET in CTN 0004.
- [The Construct and Measurement Equivalence of Cocaine and Opioid Dependences: A National Drug Abuse Treatment Clinical Trials Network \(CTN\) Study](#) by Wu, Pan, Blazer, et al. *Drug and Alcohol Dependence* 2009 (in press). This study examined the construct and measurement equivalence of diagnostic criteria for cocaine and opioid dependences using data from public-use files from patients enrolled in CTN 0007 (MIEDAR).

Also new: The [2009 CTN Directory](#) in PDF format, with handy bookmarks to make searching for names and Nodes easy.

Visit the CTN Dissemination Library:

<http://ctndisseminationslibrary.org>, or write to the Librarians at: info@ctndisseminationslibrary.org.

Conflict of Interest – Proposed Regulations



NIH Requests "Comments on Proposed Amendment of Regulations on the Responsibility of Applicants for Promoting Objectivity in Research,"

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-099.html>

NIH is requesting public comment on possible revisions to the PHS regulations regarding conflict of interest. The NIH believes that the complex and controversial issues surrounding FCOI warrant a carefully considered, open dialogue with all affected parties to enhance regulatory compliance and effective oversight. Consequently, NIH is seeking public comments on all aspects of potential regulation in this area, and particularly on the following issues:

- Expanding the scope of the regulation and disclosure of interests;
- The definition of "Significant Financial Interest";
- Identification and management of conflicts by Institutions;
- Assuring Institutional compliance;
- Requiring Institutions to provide additional information to the PHS; and
- Broadening the regulations to address Institutional conflicts of interest.

Addiction Science Award at 2009 Intel ISEF



A resourceful study into the effect of third hand smoke upon the risk for genetic mutations in fruit flies won the top Addiction Science Award at this year's Intel International Science and Engineering Fair (ISEF), the world's largest science competition for high school students. The Intel ISEF Addiction Science Awards were presented at an awards ceremony May 14 by the National Institute on Drug Abuse (NIDA) and Friends of NIDA, a group that supports NIDA's mission, and educates policy makers, health professionals and the general public about advances achieved from the investments in biomedical and behavioral research related to finding a cure for and eliminating drug dependence. More than 1,500 students from 50 countries participated in the ISEF competition at the Reno Sparks Convention Center. Winners of the Addiction Science Award received cash awards provided by Friends of NIDA with a \$2,500 scholarship for the first-place honoree. "What impressed us most about these young scientists was their ability to design and complete an extremely successful scientific project without having access to a college-level laboratory," said NIDA Director Dr. Nora D. Volkow.

Federal Offices Closed



The CCTN office and NIDA will be closed on Monday, May 25, 2009, for the Memorial Day holiday observance.

Clinical Coordinating Center (CCC) at EMMES



CTN Training on LiveLink News Channel
CTN Training News is now scrolling on LiveLink news channel under the CTN project area. Visitors may click the scrolling update for complete training information.

Site Management Tools and Practice Workshops



The CCC thanks Frankie Kropp and Gloria Miele for the excellent training and resources provided during the Site Management Tools and Practice Series held on April 2, April 23, and May 7.

Each workshop gathered 80 CTN members who were very pleased with the information and resources available from Gloria, Frankie, and fellow project managers. The entire Site Management series is available on LiveLink or on CD through the Node Coordinators, who received a shipment of seminar CDs for distribution to sites within their Node.

Project Management Tool Kit Available on LiveLink



the tool kit.

This tool kit was created to help CTN members share documents and ideas on project management best practices. Feel free to send your helpful tools to ctntraining@emmes.com for inclusion in

LiveLink Discussion Board is Available in



CTN\CCC\Training
Participants of the Site Management workshop requested a mechanism for continued communication and

collaboration. This discussion board is open for all CTN members wishing to collaborate with colleagues on study or site related issues.

Informed Consent Regulations Q and A

Question: The informed consent regulations [21 CFR 50.25 (a)(5)] require the consent document to include a statement that notes the possibility that FDA may inspect the records. Is this statement a waiver of the subject's legal right to privacy?

Answer: This is not a waiver of the subject's legal right to privacy. FDA does not require any subject to "waive" a legal right. Rather, FDA requires that subjects be informed that complete privacy does not apply in the context of research involving FDA regulated products.

Under the authority of the Federal Food, Drug, and Cosmetic Act, FDA may inspect and copy clinical records to verify information submitted by a sponsor. The FDA generally will not copy a subject's name during the inspection unless a more detailed study of the case is required or there is reason to believe that the records do not represent the actual cases studied or results obtained.

The consent document should not state or imply that FDA needs clearance or permission from the clinical investigator, the subject or the IRB for such access. When clinical investigators conduct studies for submission to FDA, they agree to allow FDA access to the study records, as outlined in 21 CFR 312.68 and 812.145. Informed consent documents should make it clear that, by participating in research, the subject's records automatically become part of the research database. Subjects do not have the option to keep their records from being audited/reviewed by FDA.

When an individually identifiable medical record (usually kept by the clinical investigator, not by the IRB) is copied and reviewed by the Agency, proper confidentiality procedures are followed within FDA. Consistent with laws relating to public disclosure of information and the law enforcement responsibilities of the Agency, however, absolute confidentiality cannot be guaranteed.

- **Drug and lab supply orders** - ctnsupport@emmes.com
- **Safety related issues/adverse event follow-up** - ctnsafety@emmes.com
- **Training information, comments or requests** - ctntraining@emmes.com

Other CCC related questions and topics- Robert Lindblad at 301-251-1161, rlindblad@emmes.com

NIDA Project Officer, Steve Sparenborg, at:
sparenborgs@nida.nih.gov, telephone (301) 496-4844.

Southern Consortium Baby News



Congratulations to Elizabeth Chapman, Director of Research at Behavioral Health Services of Pickens County on the birth of her son, Elijah Russell Chapman.

Site to Remember



Good Clinical Practice training is available online for all CTN members at www.nihtraining.com/ctn.

Recovery Corner



In 2008 more than 1,900 women received treatment at Nexus Recovery Center, a Community Treatment Provider in the Texas Node. *Thanks to Abby Foster for sharing this story.* Each of these women has a story. This is Stephanie's.

After years of being chronically homeless, addicted to crack, in and out of jail, and prostituting to support her habit, Stephanie saw her life take an unexpected turn. It was a July night in 2008, and Stephanie, once again, had been picked up by the police for prostitution. This time, however, instead of being hauled off to jail, she was brought to a parking lot staging area. There the Dallas Police Department, in partnership with various service providers, intervened in the lives of women engaged in prostitution and offered treatment as an alternative to incarceration. The DPD called this initiative New Life Opportunities. Nexus staff had recently begun accompanying the police on these monthly round-ups, and a Nexus representative was present the night Stephanie was picked up. That fact would change her life.

But Stephanie was not looking for help for her addiction; in fact she was celebrating her 30th birthday and was headed to get high. After an assessment, Stephanie was court-ordered to 45 days in treatment at Nexus. Recalling that night, Stephanie admits that "I didn't want to stop using drugs at all." So she entered the Adult Women program, and in its safe environment, away from the clamor of the streets, she began to reflect on her life. "I was living on the streets in Oak Cliff. I'd wake up every morning and the first thing I would think of is how to get an early morning hit. For ten years I had lived to use crack cocaine. I slept on bus stops and in abandoned houses. Wherever I was, I got high. I became a prostitute."

Stephanie fit the profile of the kind of woman New Life Opportunities wants to reach: a woman on the periphery of society. And Nexus is uniquely equipped to meet the complex needs of these women. While substance abuse is their primary issue, many women enter treatment with histories of sexual abuse and trauma, domestic violence, homelessness, and involvement with the justice system. That mandated 45 days in residential treatment allows Nexus counselors time to address many of the underlying reasons for substance abuse.

Of those 45 days at Nexus, Stephanie says, "Being at Nexus really helped me. I learned how to respect myself and others, too. For the first time in a long, long time I

could eat all I wanted for free and didn't have to steal anything from anyone. That may sound like normal life for some people, but it was a different way of living for me. Very slowly I learned how to trust others, open up and talk and share with other women there." As her stay in residential treatment was nearing completion, Stephanie was planning to step down into the Outpatient program, but wondered what was next and how she would handle her new life. Like many clients, Stephanie had spent years devoted only to her addiction. Now she was faced with real issues about safe housing and employment - issues that had to be addressed while being newly sober. Once again Nexus was able to help. Nexus collaborates with transitional housing programs in the community; however, many programs require the first month's rent in advance - a difficult hurdle to overcome for a woman just leaving residential treatment. Nexus paid Stephanie's first month's rent so she could transition safely into the next phase of her new life.

The day Stephanie left residential treatment she moved directly into Vision House, a transitional living home for women in Dallas. Stephanie says about her transition, "When I arrived at Vision House, a lady named Tabitha was there to greet me with a smile saying, 'Come on in. There is a place for you to begin your journey to recovery after death to street life.' My first day there I started working at the Rangers Ballpark in Arlington. I did it just to have money in my pocket. Here we are, four months later, and I'm still working through Vision House. I'm a manager in training at American Airline Center. I love to work. Now I'm paying my own rent from working. But in the beginning I had a lot of help."

Stephanie celebrated six months sobriety recently and is still a resident at Vision House. She stays in contact with the staff at Nexus, and when asked about her journey so far she had this to say: "What I'd like people to understand is that just because you're on the streets doing God knows what doesn't mean that you don't want help. It takes that right person to break that wall down and get into our comfort zone and do whatever it takes to help us. Most of us women with a prostitution history are crying out in that way for help, and that's the only way we can get someone's attention. I thank God for the people who gave me a second chance at life. You can live life on life's terms or be known in society as a bum on drugs, always begging, stealing, or doing something that's not right. I did it all. But look at me now. I'm a changed woman today."

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