

# Clinical Trials Network

CTN Bulletin

July 26, 2011

Volume 11 - 11

## Trial Progress – Over 13,000!



Trial enrollment numbers reflect study information as of July 25th.

### Open Studies

- CTN 0037 – Randomized 161 (N=330)
- CTN 0044 – Randomized 459 (N=500)
- CTN 0046 – Randomized 401 (N=528)
- CTN 0047 – Randomized 730 (N=1,285)

**Total Randomized All Studies: 13,369**

**CTN GO Grant Study (AWARE) – Randomized 5,013**

## 2011 Steering Committee (SC) Meeting



The Fall Steering Committee Meeting will be held in Bethesda, Maryland, on September 26-28, 2011. The hotel is the Bethesda North Marriott, one block from NIDA Headquarters.

Registration is open for the CTN Steering Committee Meeting. To register and obtain logistical and program information, please visit

(<http://www.seiservices.com/NIDA/CTN/meetings/index.asp>). For further program information, please contact Ron Dobbins, M.A., at [rdobbins@nida.nih.gov](mailto:rdobbins@nida.nih.gov) or (301) 451-9575.



There will be a Design and Analysis Workshop on Monday, September 26, from 3 to 5 p.m. before the SC meeting. The workshop is titled *Determining Stimulant*

*Drug Use by Combining Results from Timeline Follow-Back and Urine Drug Screening*. Many CTN trials collect self-reports on drug use via the Timeline Follow-Back (TLFB) as well as urine samples for drug screening (UDS). The primary outcome is based on UDS results alone, on TLFB alone, or on a combination of results from both methods. This workshop will compare several algorithms for combining TLFB reports and UDS results, and will offer a recommended approach for future CTN trials. All are welcome!



### Poster Session at September SC Meeting!

A poster session will be held at the Steering Committee Meeting in September. CTN investigators with posters presented at national conferences during 2011 are encouraged to consider displaying them for the CTN. Please notify Ron Dobbins at [rdobbins@nida.nih.gov](mailto:rdobbins@nida.nih.gov) by close of business on August 26<sup>th</sup> if you're interested in submitting a poster.

## Regulatory – Human Subject Research



The U.S. Department of Health and Human Services (DHHS) announced today that "the federal government is contemplating various ways of enhancing the regulations overseeing research on human subjects.

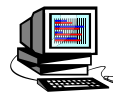
Before making changes to the regulations – which have been in place since 1991 and are often referred to as the Common Rule – the government is seeking the public's input on an array of issues related to the ethics, safety, and oversight of human research."

For background info and details on how to submit comments, please visit <http://1.usa.gov/rjeqr3>.

The current regulations governing human subject research were developed years ago when research was predominantly conducted at universities, colleges, and medical institutions, and each study generally took place at only a single site. Expansion of human subject research into many new scientific disciplines and venues (including community-based organizations, which are cited in the advanced notice of proposed rulemaking released today by HHS) and an increase in multi-site studies have highlighted ambiguities in the current rules and have led to questions about whether the current regulatory framework is effectively keeping up with the needs of researchers and research subjects.

Revisions to the current regulations are now being considered because HHS believes these changes will strengthen protections for research subjects in a number of important ways.

## Live Link Changes Coming!



The function of Live Link Administrator will be transferred to the Data and Statistics Center 2 at EMMES as of July 31st. Live Link is the document

management system used to store and share files across the Network. The transition to the new Live Link should be seamless with all files and folders remaining intact. Study specific documents should be kept in the protocol folders to ease any problems during transitioning. If it becomes necessary to re-assign passwords, a notice will be sent to current users before the end of the month. Any concerns or questions should be sent to Carol Cushing at [ccushing@nida.nih.gov](mailto:ccushing@nida.nih.gov).

*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.*

## Ohio Valley Node News



Here are some recent items from the Ohio Valley Node (OVN) group –

1. Kathy Burlew, Ph.D. from The Crossroads Center CTP, has received the APA Award for Mentorship of Ethnic Graduate Students (see announcement below). Additionally, she received an internal grant from the University of Cincinnati to fund a project entitled “Safer Sex for African American Substance Abusing Women” which will utilize data from the NIDA CTN (<http://www.uc.edu/news/NR.aspx?id=13799>). Congratulations Kathy!
2. The OVN is involved with several projects in response to the prescription opiate epidemic in Ohio:
  - Drs. Somoza and Winstanley spent two days in Portsmouth (OH), an area of the State hardest hit by the prescription drug epidemic. On July 7<sup>th</sup>, they presented an overview of addiction and evidence-based treatment for opioid use disorders that was open to the community. On July 8<sup>th</sup>, they facilitated a PCSS-B Half-and-Half course on buprenorphine open to physicians and clinicians.
  - OVN staff are working with the Ohio Department of Alcohol & Drug Addiction Services to expand access to medication-assisted treatment (MAT) in the State, in particular expansion of MAT for the criminal justice population in response to the recently passed sentencing reform in Ohio.
  - The OVN, the Great Lakes Addiction Technology Transfer Center, the American Osteopathic Academy of Addiction Medicine, and the American Academy of Addiction Psychiatry are sponsoring a one-day training for all professionals interested in learning more about buprenorphine on September 22<sup>nd</sup> in Cincinnati, OH. This will be a two-track training event on the same day and at the same location whereby physicians will be able to attend the PCSS-B Half-and-Half course and non-physicians can attend the “Buprenorphine Treatment: A Training for Multidisciplinary Addiction Professionals” course. Please contact Teresa Latham at 513-487-7883 or at [latham@carc.uc.edu](mailto:latham@carc.uc.edu) for additional information. This buprenorphine training is being planned in conjunction with the “2011 CeTREAD University of Cincinnati Health Addiction Update” conference on September 23<sup>rd</sup>. For additional information and to register for this

conference, please contact Madelyn Milner at 513-475-6568 or [Madelyn.milner@va.gov](mailto:Madelyn.milner@va.gov).

- The OVN is facilitating a panel presentation, in collaboration with the Prairielands ATTC, on medication-assisted treatment at the South Dakota Association of Addiction & Prevention Specialists conference on September 28<sup>th</sup> in Mitchell, South Dakota.

## Publications Committee (PC) Update



The PC discussed CTN policy on publication plans and recommends changing the guidelines to the following: *"The study team will submit a publication plan to the PC when 50% of the target sample is enrolled. Within six months after data lock, the study team will review and revise the publication plan and resubmit the plan to the PC. Thereafter, the publication plan will be reviewed and revised semiannually."* The PC felt the prior guidelines required publication plans too early.

## Published

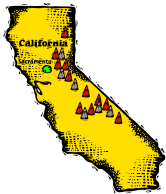
1. Covey et al, "Divergence by ADHD Subtype in Smoking Cessation Response to OROS-Methylphenidate," Nicotine and Tobacco Research, published on-line June 2011

**AJDAA Special Issue Update:** The American Journal of Drug and Alcohol Abuse CTN special issue entitled, "Methodology of Multisite Effectiveness Trials," guest edited by Ned Nunes, anticipates publication in mid-August 2011.

## Acceptances for Publication:

1. Riggs et al, "Randomized Controlled Trial of Osmotic-Release Methylphenidate with CBT in Adolescents with ADHD and Substance Use Disorders," Journal of the American Academy of Child and Adolescent Psychiatry; this is the primary outcome paper of CTN 0028.
2. Tamm et al, "Attention-Deficit/Hyperactivity Disorder Subtypes in Adolescents with Comorbid Substance-Use Disorder," The American Journal of Drug and Alcohol Abuse.
3. Robbins, et al, "Results of a Multi-Site Randomized Trial comparing Brief Strategic Family Therapy and Treatment as Usual for Drug Using Adolescents," Journal of Consulting and Clinical Psychology; this is the primary outcomes paper of CTN 0014, "BSFT".
4. Svikis, et al, "Randomized Multi-site Trial of the Job Seekers' Workshop in Patients with Substance Use Disorders," Drug and Alcohol Dependence; this is the primary outcome paper of CTN 0020.

### News from the Western States Node



The Western States Node is collaborating with the Mountain West ATTC, the Pacific Southwest ATTC, and the Northwest Frontier ATTC to offer a free training on **Promoting Awareness of Motivational Incentives (PAMI)**. The webinar, scheduled for

Tuesday August 16 from 9:30 a.m. to 11:30 a.m. (PDT), will be presented by Beth A. Rutkowski, M.P.H. of the Pacific Southwest Addiction Technology Transfer Center.

This Blending Initiative focuses on informing the field about successful approaches in the use of motivational incentives. Research has shown that motivational incentives programs using low-cost reinforcement (prizes, vouchers, clinic privileges, etc.), delivered in conjunction with onsite urine screening, promotes higher rates of treatment retention and abstinence from drug abuse. This Blending Team focused their efforts on informing the field about successful approaches in the use of motivational incentives (also referred to as contingency management).

This webinar has been approved for a total of 2.0 contact hours through the National Association of Alcoholism and Drug Abuse Counselors (NAADAC). Certificates indicating the number of contact hours earned are issued to all participants within 10 days of the training. Please note, to receive a certificate you will have to register. To register, go to the link below:

<http://mwattc.wufoo.com/forms/pami-webinar-registration-august-16-2011/>

The University of California, San Francisco (UCSF), part of the Western States Node, is hosting four summer interns in the Summer Research with NIDA program this year. The students, each of whom is paired with a faculty mentor, also participate in the UCSF Graduate Division's Summer Research Training Program, which offers GRE test preparation and Professional Development Workshops, among other activities. This year's students are Danielle Bohmer, who is currently a junior at Gloucester County College, NY and is pursuing a major in psychology; Melissa Gasser, a junior at the University of Virginia studying psychology and cognitive science; Krystal Parra, a junior at the University of San Francisco, with a major in psychology and a minor in neuroscience; and Stacy Songco, a senior at UC Berkeley with a double major in molecular and cell biology and sociology. The students are actively involved in research projects, which they will present at a poster presentation session in early August.

### Florida Node Alliance News



SAMHSA-HRSA Center for Integrated Health Solutions (CIHS) has selected Operation PAR for the New Integrated Health Provider Learning Collaborative.

The Integrated Health Provider Learning Collaborative is a nine-month project involving 15 community mental health and addiction provider organizations that were chosen through a competitive application process. The Collaborative creates a platform for participating organizations to effectively bridge the traditionally distinct primary care and behavioral healthcare practices in their communities. Congratulations Operation PAR!

### Tips from the CTN 0037 STRIDE Study Team



The STRIDE (Stimulant Reduction Intervention Using Dosed Exercise) Lead Team would like to recognize the creative retention approaches that their study sites

are implementing. Retention is a critical issue for any clinical trial, and their sites are continually striving to identify novel approaches to increase study retention. On the study conference calls, they frequently discuss key retention issues that the team believes are critical for good retention. We hope that these ideas may be beneficial to other studies as well:

- 1) **Carefully consider potential barriers at the point of recruitment.** Explicitly discuss possible barriers with participants prior to randomization. Strongly consider having the local study PI or Project Manager hold this discussion. Talk with participants about their daily schedule and how the study visits would fit into their schedules, discussing the time commitment and envisioning any changes to their schedules.
- 2) **Develop excellent rapport.** Talk to participants often, in a personable and supportive way. Make sure they are comfortable going to the site and interacting with the study staff. Let them know you appreciate their participation in the study.
- 3) **Compromise.** Try to be as flexible and accommodating as possible with participants' needs while maintaining the goals of the study.
- 4) **Obtain comprehensive and accurate locator information.** Obtain a variety of locator information from the participant. Discuss with the participant that you would like to call the contacts they provide to make sure the numbers are operational. The site staff can call the numbers or the site staff can dial the number and the participant can converse with the contact if preferred. (*continued page 4*)

- 5) **Focus on transition points.** Be sure to obtain updated Locator Information during important transition points during treatment as usual or study participation (e.g., transition from one type of treatment to another, transition from study acute phase to follow-up phase). Discuss possible barriers and ways to work around them as participants are dealing with new issues in their lives (e.g., new job, new living arrangement, etc.).
- 6) **Review barriers as a team.** Participants may share different information with different study staff (e.g., RA and interventionist). Discuss these issues as a team to be sure that all study staff are aware of potential barriers for each participant and brainstorm possible resolution to those barriers.
- 7) **Consider telephone or off-site assessments.** Of course, study and local approvals must be in place for these to occur, but they can assist in maintaining contact and collecting data for participants who may not be able to come to the study site.
- 8) **Perseverance.** Keep up frequent attempts to contact participants if they become out of touch. Have a variety of staff members attempt contacts. Our sites have consistently attempted to contact non-adherent participants and have successfully re-engaged them in study activities.

Thanks to the STRIDE team for sharing this information!

### What's New in the CTN Dissemination Library?



First off, a big "thank you!" to those of you who submitted your posters and presentations from CPDD this year to the Dissemination Library! You can see the list of posters and presentations from that conference on the Library's **What's New** blog here:


<http://ctndisseminationslibrary.wordpress.com/2011/06/27/college-on-problems-of-drug-dependence-cpdd-2011-posterspresentations/>.


If you have a CTN presentation from CPDD or another conference to add, e-mail the librarians at [info@ctndisseminationslibrary.org](mailto:info@ctndisseminationslibrary.org).


All the articles from *Journal of Substance Abuse Treatment's* special 10-Year CTN Anniversary issue are now available for **free** in PubMed Central! Find links to informational pages about each article, as well as links to the free PMC manuscripts here:


<http://ctndisseminationslibrary.org/display/jsatsuppl.htm>.

### New in the Library This Summer:

 [Improving Drug Abuse Treatment Delivery Through Adoption of Harmonized Electronic Health Record Systems](#) by Udi Ghitza, Steven Sparenborg, and Betty Tai. *Substance Abuse and Rehabilitation* 2011;2:21-28. This article, a product of the CTN Electronic Medical Records Special Interest Group, attempts to illuminate the urgent public health need to develop and implement harmonized EHR at the national level, including data fields containing standardized vocabulary/terminologies relevant to substance abuse treatment.

 [The Potential Impact of Recruitment Method on Sample Characteristics and Treatment Outcomes in a Psychosocial Trial for Women with Co-Occurring Substance Use Disorder and PTSD](#) by Theresa Winhusen, Erin Winstanley, Eugene Somoza, and Greg Brigham. *Drug and Alcohol Dependence* 2011 (in press). This article reports on an analysis of data from a site participating in **CTN-0015** (Women & Trauma) that recruited participants for the protocol using newspaper ads and clinic intakes, finding that recruitment methods may impact both sample composition and treatment effects.

 [Divergence by ADHD Subtype in Smoking Cessation Response to OROS-Methylphenidate](#) by Lirio Covey, Mei-Chen Hu, Judith Weissman, and colleagues. *Nicotine and Tobacco Research* 2011 (in press). This article reports on an ancillary investigation of data from protocol **CTN-0029** that examined smoking cessation response by ADHD subtype to OROS-MPH. The study's results supported the hypothesis that ADHD subtypes are distinct clinical entities and may indicate the need for personalized treatments for smokers with ADHD.

 [An Investigation of Substance Use Patterns and Associated Issues in Urban Treatment-Seeking Northern Plains American Indians](#) by Frankie Kropp and Michelle Moore. Presented at the Native Health Research Network National Conference, Niagara Falls, NY, June 27-30, 2011. This presentation, the first item in the Library specifically about **CTN-0033-Ot-4**, reports on an exploratory study examining the epidemiology of methamphetamine use and co-occurring problems and disorders in diverse Native American communities from the Aberdeen area of North Dakota. The importance of elements of Native culture were found to differ for some Native Americans seeking treatment for substance use in urban (*continued page 5*)

settings, and urban providers should consider cultural identification, as well as health and economic disparities, when developing individual treatment and referral plans for this population.

The CTN Library is web-based, and includes a catalog with descriptive records for each item in the Library. The web site is maintained by the Pacific Northwest Node of the Clinical Trials Network. The address is: <http://ctndisseminationlibrary.org>.

**CTN Website:**  
<http://www.drugabuse.gov/CTN/index.php>



**Clinical Coordinating Center (CCC) at EMMES**  
***2011 Web Seminar Series***



Upcoming webinars! Mark your calendar:

- **August 10** Certificate of Confidentiality
- **September 14** Integrated Treatment of Co-Occurring Disorders
- **October 12** Informed Consent
- **December 7** A New Look at Manual of Procedure (MOP) Development

Those interested in registering may contact [ctntraining@emmes.com](mailto:ctntraining@emmes.com) or Liz Buttrey at [ebuttrey@emmes.com](mailto:ebuttrey@emmes.com)



All webinars are available free online on the CTN Dissemination Library. Go to <http://ctndisseminationlibrary.org/ctntraining.htm>. Non-CTN members have been welcomed to our webinars since 2010.

Those interested in registering may contact [ctntraining@emmes.com](mailto:ctntraining@emmes.com) or Liz Buttrey at

[ebuttrey@emmes.com](mailto:ebuttrey@emmes.com).

***Other CCC related questions and topics- Principal Investigator, Robert Lindblad, at 301-251-1161, [rlindblad@emmes.com](mailto:rlindblad@emmes.com), or Eve Jelstrom, Project Director, at 301-251-1161, [ejelstrom@emmes.com](mailto:ejelstrom@emmes.com).***

**CTN INVEST Program - Correction**



The CTN INVEST Drug Abuse Research Fellowships are awarded to non-U.S. scientists who will work with a mentor affiliated with one of the **13 CTN Nodes**.

(Not 16 Nodes as reported last issue.) For more information on the CTN INVEST program, please visit <http://international.drugabuse.gov/fellowships/postdoctoral-training/investctn-drug-abuse-research-fellowship> and/or contact Carmen Rosa at [crossa@nida.nih.gov](mailto:crossa@nida.nih.gov).

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