



Clinical Trials Network

CTN Bulletin
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Reminder - Steering Committee Meeting



The NIDA CTN Steering Committee Meeting will be held Monday, February 25 thru Wednesday, February 27, 2008 at the Bethesda North Marriott Hotel & Conference Center in Bethesda, Maryland.

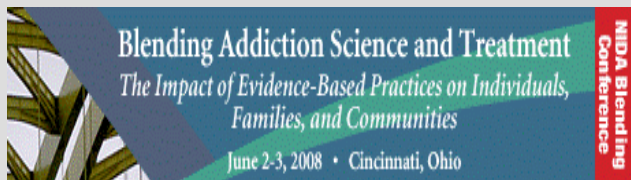
To register for the Steering Committee meetings through the contractor web site, please visit the following link:
www.sei2003.com/NIDA/CTN/Meetings/

Federal Offices Closed



The CCTN office and NIDA will be closed on Monday, February 18, 2008, for the Presidents Day holiday observance.

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. Join your colleagues in bi-directional dialogue while examining the most current drug abuse and addiction findings and their application to clinical practice. It is a wonderful opportunity to learn more about the Blending Team Products and how they may be utilized to improve addiction treatment so more people recover from addictive disorders. For additional information go to www.NIDABlendingConference.info

Please note that the Early Bird Conference Fee (\$79) is available through April 15, 2008. After this date the Regular Conference 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 simply 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.

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.

CTN 0027 START Protocol



The START Study (Starting Treatment with Agonist Replacement Therapies) Lead Team sends "Congratulations!" to the Bi-Valley site for completing their 100th randomization! The Bi-Valley site finished off a huge week for randomizations (5 randomizations in all) by randomizing their 100th participant (actually participant 1150) on Friday, January 25, 2008.

All the CTN-0027 sites continue to do a phenomenal job with recruitment. A total of 611 participants have been enrolled in this study to date.

CTN 0032 Update



The HIV Rapid Testing & Counseling (CTN 0032) protocol seeks to evaluate the most effective testing strategy to ensure that persons in drug treatment programs get HIV tested, receive their results, and reduce their HIV risk behaviors. Site selection activities continue to move forward. Node Coordinators of sites that are still potentially eligible to participate and who had not previously supplied client-level data were asked to move forward with Phase 2-B (client survey) to garner more information about their clients' potential eligibility. Phase 3-A of the site selection process, involving telephone interviews with CTP representatives and their respective Node Coordinators, is scheduled to begin on February 11, 2008. Phase 3-B, involving site visits, is scheduled to begin in late February and last through March 2008. Subsequently, 12 sites will be selected to participate and notified of their status.

While site selection activities are underway so are many other behind-the-scenes activities, including development of SOPs, training materials, assessments and CRFs. The CTN 0032 Kick Off meeting was held at the DCRI on January 29 – 31, 2008 and much progress was made toward the development of these materials.

Design and Analysis (D&A) Workshop at SC Meeting

Reminder - a workshop on "Simple Trials versus



Comprehensive Assessments" is scheduled for Monday, February 25, 2:00 PM - 4:00 PM, in conjunction with the CTN Steering Committee meetings in Bethesda, Maryland. The purpose of the workshop is to discuss tradeoffs between keeping CTN trials simple and adding assessments to allow for additional secondary analyses and ancillary studies, or adding common assessment instruments for future cross-study analyses.

New England News – Training Offered



Another Training of Trainers in the MIA: STEP Blending product (Motivational Interviewing Assessment: Supervisory Tools for Enhancing Proficiency) will occur

immediately following the NIDA Blending Conference in June in Ohio. The training will occur June 4-6, 2008. The New England Node is in the process of identifying individuals from each of the Nodes who may be interested in applying to the training. These individuals should have prior training in MI and be able to demonstrate their proficiency in the approach in a recorded session sample.

Please send Julie Mathews and Steve Martino the name and contact information of people who may be interested in this opportunity. As in the prior MIA: STEP training of trainers, each Node is expected to cover the lodging and travel expenses of their candidates. If you have any questions about the training or MIA: STEP, please contact Julie Mathews (jmatthews@abhct.com) or Steve Martino (steve.martino@yale.edu). Please respond by February 21st, either to let them know who wants to apply or to inform them that nobody from your Node will participate. Thanks to the New England Node for setting this up!

Southern Consortium Update



Royce Sampson, MSN, CRA, Node Coordinator of the Southern Consortium Node, recently passed the Research Administration Certification Council exam to become a Certified Research

Administrator. Congratulations Royce!

Florida CTP Adopts the Trauma Intervention



Having completed the data collection phase of the Women and Trauma (CTN 0015) clinical trial, the Village adopted and is implementing Seeking Safety in its residential treatment programs. Women from

any of the programs who report PTSD symptoms of moderate to severe frequency and/or severity may avail themselves of this service. Of adult women admitted to residential treatment, 68% experienced a sexual assault, 80% a physical assault. The Village has started its third group of clients, and begins a new group every 6-8 weeks. Therapists receive regular supervision, and pre and post-treatment data is being collected to evaluate the effectiveness of the treatment delivery. This is an example of practice being changed as a result of participation in a CTN trial. Thanks for sharing this news!

NARCH Grants



The 5th round of Native American Research Centers for Health (NARCH V) Funding, Announcement # HHS-2009-IHS-NARCHV-0001, was published January 24, 2008. Application Receipt date is May 16, 2008 and further information can be found at: <http://www.ihs.gov/medicalprograms/research/narch-V.cfm>

What is a NARCH?

Federally-recognized Tribes, Tribal Organizations (including Tribal Colleges) and Tribally authorized Indian Health Boards are eligible to form partnerships with research institutions and apply for funding to create a Native American Research Center for Health (NARCH). The NARCH initiative provides funding to AI/AN Tribes or Tribally based organizations to create partnerships with research institutions and conduct high quality biomedical, behavioral and health services research that will be relevant to the needs of the Tribes. In FY 2007, over \$7 million went to NARCH grantees in grants ranging from about \$100,000 to over \$1,000,000.

If you are a university-based (or other non-Tribal) researcher: You are not directly eligible to apply for a NARCH grant. To be eligible to participate in the NARCH program, you will have to become a subcontractor for an eligible Tribe or Tribal organization (or consortium of such eligible applicants). The Tribe(s) or Tribal organization(s) must determine the Tribal priorities for health research projects and research training. The university role is then to provide technical and educational expertise and assist in the development of the NARCH application to be submitted by the Tribe(s) or Tribal organization(s). At least 30% of the budget submitted with the application must remain within the Tribal organization(s) involved in the NARCH. Contact information for the federally recognized Tribes can be found at:

http://www.ncai.org/Tribal_Directory_3.0.html. Information on Indian Health Boards can be found at: <http://www.nihb.org/staticpages/index.php?page=200403301344375598>. And information for the Tribal colleges can be found at: http://www.aihec.org/tribal_college_roster.cfml.

If you represent a Tribe or Tribal organization considering a NARCH application: Please send an e-mail to narch@ihs.gov with a subject heading “**Technical Assistance**” and your contact information, including your e-mail address in the body of the e-mail. You will be added to a listserve that receives all the information on additional technical assistance.

What's New in the CTN Dissemination Library?



Have you heard about the NIDA Networking Project (<http://nnp.drugabuse.gov/>)? It currently consists of 11 networks and more than 150

sites involved in research and data collection sponsored by NIDA. The site provides access to network locations, people, expertise, and resources intended to help synergize efforts, improve efficiency, and accelerate scientific discovery.

A link to the NNP has been added to the Library's [Resources & Policies](#) page, where you can also find links to CTN Data Share, the National ATTC Blending Initiative, Livelink, the National Treatment Study Center in Georgia, and a variety of other useful sites.

Also new in the Library this month is a series of articles from the latest issue of *Journal of Psychoactive Drugs* (v. 39(4), 2007). This issue, edited by **Joseph Gydish, Ph.D.** of CTN's California/Arizona Node, focused on Smoking, Mental Disorders, and Substance Abuse Treatment, and features four articles that used the CTN Platform to investigate issues related to smoking in addiction treatment centers. The articles discuss [staff smoking and other barriers to nicotine dependence interventions](#), [smoking among adolescents in treatment](#), [addressing tobacco use through organization change](#), and [how nicotine addiction is addressed in substance abuse counselor certification in California](#).



As always, the latest items in the CTN Dissemination Library can be found on the *What's New* page at <http://ctndisseminationlibrary.org/new.htm>. If you're an RSS user, don't forget to subscribe to the RSS feed to see new additions as soon as they are posted! The library is maintained by the Pacific Northwest Node of the Clinical Trials Network. The address is: <http://ctndisseminationlibrary.org>

Avant Garde Award

This 5-year, \$2.5 million award, is designed to support individual scientists of exceptional creativity who propose cutting-edge and transformative approaches to major challenges in research on drug abuse and HIV/AIDS. Additional information including frequently asked questions and a link to the RFA are available at: <http://drugabuse.gov/avgp.html>



Data and Statistics Center (DSC) at DCRI



CRIS Visit Cache Table Description ("The BLOB")

Visit Cache Table

The CRIS (Clinical Research Information System) survey application utilizes a "save as you go" feature which records the participant's responses and activity as they navigate through the questions. If the participant happens to stop before the questions are completed (i.e. before they reach the "Done" button), the system stores the responses, including the question flow that was used to get to the current point in the assessment. All of this data is stored in a *visit cache table* (also called "BLOB" table). This process allows the Research Assistant to bring the visit screen back up in the exact condition it was discontinued.

When a new release of CRIS is deployed and there are entries in the *visit cache table*, the new system does not recognize the *visit cache table* created in the older version of the application. Therefore an error appears when an attempt is made to access the previously incomplete assessments. The data is still stored in the database, but the new application cannot present the assessments on screen.

To avoid this problem, it is always best practice to encourage participants to complete individual assessments prior to leaving a CRIS session. If all assessments required within the visit window can not be completed in one sitting, it is recommended to encourage participants to get to the closest "Done" button so that assessments are not left partially complete.

Upgrade Utility

To resolve any problems that could occur with the *visit cache table* as a result of a CRIS upgrade, a new upgrade utility will be deployed in the near future. The upgrade utility will allow DCRI to extract the saved but incomplete data and restore it in the new format. This will permit the patient to complete the assessment and save it to the appropriate database table.



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.

NIDA Project Officer, Carol Cushing, at: ccushing@nida.nih.gov, telephone (301) 443-9815.

Clinical Coordinating Center (CCC) at EMMES



Drug and Supply Orders:

Please let the CCC know if you need to re-order drug and/or lab supplies for your site. Send an e-mail request to

ctnsupport@emmes.com.

Training:

The CCC recently completed a Training Needs Analysis and is working on identifying training topics and possible events for 2008. Any training ideas or topics that the Network would like to propose are always welcome. Please send any ideas you have to Liz Buttrey at ebuttrey@emmes.com.

The Regulatory Corner

What's an "assurance" or a "multiple project assurance"? An "assurance," is a document negotiated between an institution and the Department of Health and Human Services (DHHS) in accordance with DHHS regulations. This is also commonly referred to as a Federal-wide Assurance (FWA). For research involving human subjects conducted by DHHS or supported in whole or in part by DHHS, the DHHS regulations require a written assurance from the performance-site institution that they will comply with the DHHS protection of human subjects regulations [45 CFR Part 46]. Once an institution's assurance has been approved by DHHS, a number is assigned to the assurance. The assurance may be for a single grant or contract (a "single project assurance"); for multiple grants ("multiple project assurances" - formerly called "general assurances"); or for certain types of studies such as oncology group studies and AIDS research group studies ("cooperative project assurances"). The Office for Protection from Research Risks (OPRR) is responsible for implementing the DHHS regulations.

Currently, FDA regulations do not require an assurance. When research studies involving products regulated by FDA are funded/ supported by HHS, the research institution must comply with *both* the DHHS and FDA regulations. For more information, go to www.hhs.gov/ohrp/. OHRP also offers the FWA required training module, which is located at <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>.

Who to contact:

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

NIDA Project Officer, Ron Dobbins, at:
rdobbins@nida.nih.gov, telephone (301)451-9575

Summer Institute on Randomized Clinical Trials – Extended Due Date



The NIH Office of Behavioral and Social Sciences Research (OBSSR) has organized a summer training on randomized clinical trials. The classes will be held July 13 - 25, 2008, at the Airlie Conference Center, Virginia. The objective is to provide a thorough grounding in the conduct of randomized clinical trials to researchers and health professionals.

Costs: The NIH OBSSR will pay for travel, room and board, and course materials. *There are no additional fees.* **Applications are now due February 8, 2008.** These must be submitted electronically. The application instructions and forms are posted at: <http://www.blswb.net/app2attend/>

Contact: Ronald P. Abeles, Ph.D., 301.496.7859
E-mail: abeles@nih.gov

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

System Down Time



DCRI seeks to minimize disruption of services by using a standard process to communicate and implement changes. Planned maintenance occurs during the standard DCRI scheduled change window, beginning Thursday at 8:00 PM and continuing until 2:00 AM Friday. There may be times when planned maintenance may require a longer maintenance window due to the type of maintenance being performed. The following describes the various changes that can occur to an IT environment and how the Users will be notified.

	User notification	Example
Planned	EDC Help Desk will advise Users at least two business days in advance.	Monthly client OS patch.
	EDC Help Desk will advise Users at least two business days in advance.	Replacing network router or installing patch on InForm.
Unplanned (Emergency)	EDC Help Desk will advise Users while change is being implemented.	Inform server is down.

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