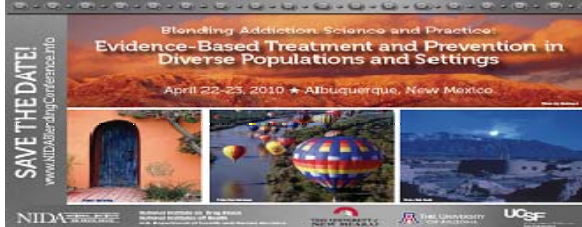




Clinical Trials Network

CTN Bulletin
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Reminder – NIDA Blending Conference



The NIDA Blending Conference website is now active – please go to www.NIDABlendingConference.info for information on the two day event entitled *Blending Addiction Science and Practice: Evidence-Based Treatment and Prevention in Diverse Populations and Settings*. The Early Bird conference registration is \$79 and includes all applicable sessions, continental breakfast, refreshments, lunch and course materials. To get this reduced rate, register by March 1st, 2010. The Student Rate is \$49 if registered by April 5th. Please see the web site for hotel and logistical information as well as the conference sessions.

CTN 0027 START Reaches Enrollment Target!



After months of hard work, the CTN 0027 START (Starting Treatment with Agonist Replacement Therapies) protocol team has met its recruitment goal, ending recruitment on October 30! The end of the randomization phase came roughly 7 weeks ahead of earlier projections. Three and one-half (*short*) years after Evergreen Treatment Services consented the very first START participant, the study team has reached the bittersweet close of recruitment! The sites randomized 1,269 opioid-dependent individuals (Bup/Nx: 740 Methadone: 529) of the record 1,920 participants consented and screened. There is still a distance to travel (32 weeks, plus at least 30 days post last dose) to finish out the final participant follow-up assessments. Sites are continuing to work diligently to retain as many of their active participants as possible. The latest Recruitment and Retention Report indicates that there will be more than enough Bup/Nx and Methadone participants in the pipeline to reach the target of 300 evaluable patients in each arm of the study. On behalf of the study Executive Committee and the entire Lead Team we appreciate your outstanding efforts on this study! Congratulations all!

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.

News from the California/Arizona (CA/AZ) Node



The University of California San Francisco Department of Psychiatry and the Kaiser Permanente Northern California Division of Research co-sponsored the 2009 Addiction Health Services Research Conference, which was held in San Francisco at the Sir Francis Drake Hotel, October 28-30. Drs. Carmen Masson, James Sorensen, and Michael Shopshire of the California-Arizona Node of the CTN served as Co-Chairs for this event. Several investigators affiliated with the CTN participated on the program planning committee, including Steven Batki, Audrey Brooks, Valerie Gruber, and Joseph Guzy (CA-AZ Node), and Dennis McCarty and Traci Rieckmann (OR/HI Node). The conference has become a major annual event in the intersecting fields of drug/alcohol abuse and health services research. It attracts attendees from across the nation and provides an opportunity for senior and junior investigators to interact with other investigators and program officials at NIDA and other institutes and centers within NIH. These interactions allow investigators to shape and advance the nation's policy and research agenda for drug/alcohol abuse and health services.

The theme of this year's conference was "Health Care Reform, Parity, and Continuing Care Models: A Forum for a New Era in Addiction Health Services Research." The conference was one of the first forums to address the implications of the Domenci/Wellstone Parity Law and health care reform for addiction treatment. Keynote speakers included nationally recognized investigators in health services research, Philip R. Lee, UCSF Institute for Health Policy Studies; James R. McKay, Director of the Center on the Continuum of Care in the Addictions and Professor of Psychology in Psychiatry at the University of Pennsylvania; and Keith Humphreys, Senior Policy Advisor at the White House Office of National Drug Control Policy, and Stanford University. The invited speakers represented the great breadth and depth of this field, from well-known leaders to emerging young scientists. The conference drew the largest number of attendees ever in its history, with nearly 300 individuals attending this two-and-a-half day continuing education event.

Federal Offices Closed



The CCTN office and NIDA will be closed on Thursday, November 26, 2009, for the Thanksgiving Day holiday observance.

New York Node News



The New York Node of the National Drug Abuse Treatment Clinical Trials Network and the Center of Excellence on Addiction at the NYU Langone Medical Center

hosted a symposium on “Advances in Addiction Research and Practice” on Thursday, November 5th, 2009 to honor Professor Eric J. Simon on the 36th anniversary of the identification of the opiate receptor and to celebrate, respectively, the 10th and 1st anniversaries of the Node and the Center.

Dr. Nora Volkow, Director of the National Institute on Drug Abuse and a graduate of NYU’s Residency Program in Psychiatry, was the keynote speaker. Other presenters included Drs. Eric Nestler, George Koob, Chris Evans, Kenneth Carr, John Rotrosen, Clare Kelly, Laurie Brotman, Donna Shelley, Mary Jeanne Kreek, Joshua Lee, Lawrence Brown and Brigitte Kieffer. The program highlighted CTN work and translational multidisciplinary themes that are the focus of the Center. Presentations covered epigenetic and other mechanisms of drug addiction, animal models of vulnerability, opioid systems and drugs, methadone, resting state functional connectivity, clinical and public health approaches to tobacco control, opioid and alcohol treatment in medical primary care and criminal justice settings, early childhood prevention, and addiction-related infections.

The event brought together over 300 participants representing basic and clinical scientists, clinicians, medical, nursing, and dental students, residents, post-doctoral fellows, other health professionals and representatives of local community-based treatment programs and city and state agencies.

Implementation Research Institute (IRI)



New NIMH funded training institute invites applications

The Implementation Research Institute (IRI) is funded by a five year grant from the National Institute of Mental Health (NIMH). This unique training program will help launch a research career in implementation science. The IRI will provide experiential learning, didactic training, faculty mentoring, and support for pilot research and grant writing—all focused on helping participants shape a research project for competitive external funding.

What is the IRI? The IRI was established to advance the field of implementation science in mental health by enhancing the career development of early to mid-career investigators. Implementation research is the study of processes for integrating empirically supported treatments (ESTs) into usual care, and holds high promise for reducing

the gap from treatment discovery to community practice. IRI participants will join a collaborative of implementation researchers for two years, spending one week each summer at a week-long institute at the [Center for Mental Health Services Research](#) (CMHSR) at Washington University in St. Louis.

Who should apply? Applications from ambitious PhD/MD investigators, with demonstrated experience and enthusiasm in the study of mental health services, **who wish to conduct ground-breaking research in the area of implementation science, are invited to apply.** The 2010 IRI will support a cohort of eight participants, who seek expert mentoring and collaboration to advance their research capacity in areas referenced by NIH PARs on “Dissemination and Implementation Research in Health” <http://grants.nih.gov/grants/guide/pa-files/PAR-07-086.html>. Topics include, but are not limited to, the “uptake” or spread of evidence-based treatments for specific disorders, the implementation of mental health interventions in novel settings, or organizational or policy issues associated with implementation. Applicants must have graduated from medical school or hold a Ph.D. from such fields as social work, psychology, health services, nursing, anthropology, public health, or management.

IRI benefits. Eight IRI Fellows will be appointed each year for two-year terms. They will join a network of peer Fellows and IRI faculty with expertise in implementation science. Each Fellow will receive:

- One week on-site training in June 2010 and June 2011 at Washington University in St. Louis.
- Travel support to the annual NIH conference on Dissemination and Implementation Research.
- Bimonthly, long-distance mentoring with an expert implementation researcher associated with this Institute to help craft a competitive research proposal in mental health implementation research.
- Travel funds to support each Fellow’s visit, up to 5 days, to the site of a funded implementation research project, relevant to their research interests.
- Pilot project funding for each Fellow’s mentored study of real-world implementation, to shape preliminary studies for their grant application.

Click here to learn more about this opportunity, qualification requirements, and deadlines:

<http://cmhsr.wustl.edu/Training/Pages/ImplementationResearchTraining.aspx>

CTN Dissemination Library -- Check it Out!



<http://ctndisseminationlibrary.org>

Has it been a while since you visited the CTN Dissemination Library? Then you may have overlooked the wealth of

information and resources that can be found on the public web site.

First, the Protocol pages have been updated to include a snapshot of published outcomes data, plus links to the primary outcomes article and the CTN Public Data Share – a great resource for anyone planning ancillary investigations. The complete list of protocols, including the newest studies like CTN 0048 (CURB) is found here: <http://ctndisseminationlibrary.org/protocols.htm>.

Another treasure is the calendar of [Upcoming Conferences](#) (under “Dissemination Opportunities” on the home page). The calendar lists dozens of conferences, with abstract submission deadlines, links to conference web sites, and contact information. The calendar is kept up-to-date, so check back often for the latest in upcoming opportunities, and let the librarians know if you’re planning an event to list there.

You’ll also find a new page of [Training Resources](#) for CTN clinical staff and others. These resources include the videos and slides from the 2009 Clinical Coordinating Center courses, as well as slides and videos from other selected NIDA trainings of interest to CTN members and other clinicians. The [Implementation Page](#) describes a set of free implementation tools recommended by the Research Utilization Committee, links to all the NIDA Blending products and past Blending conferences, and other resources like the ATTCs, Network for Improvement of Addiction Treatment (NIATx), and the National Conference of State Legislatures.

There’s a lot to find in the CTN Dissemination Library! Help us keep it growing by sending your CTN-related posters, presentations, manuals, or articles to the Library at: info@ctndisseminationlibrary.org.

Florida Node News



NHSN 9th Annual International Scientific Conference, Miami, Florida, October 29-31, 2009

The National Hispanic Science Network on Drug Abuse (NHSN) 2009 Annual International Scientific Conference titled "*Advances in etiologic and intervention models in Hispanic addiction research*" welcomed over 150 participants and a stellar group of scientists in the field of drug abuse research to Miami, Florida on October 29-31. Drs. Terry Pechacek and

Lourdes Baeznod-Garbanati opened the conference with a presentation that focused on the role of Hispanic/Latino culture in tobacco use and exposure to second hand smoke.

Dr. Thomas McLellan, Deputy Director of the Office of National Drug Control Policy, discussed the administration's strategy in demand reduction with an emphasis on reaching the millions of individuals who have diagnosable drug abuse and dependence who are not currently in treatment, but may be reached through medical settings.

NIDA Director Dr. Nora Volkow provided an overview of how drug abuse and addiction involves complex interactions between a wide array of biological, developmental and environmental variables. Volkow’s presentation highlighted scientific advances in knowledge of the etiological factors known to play a role in drug abuse and addiction and described examples of strategies that can promote positive outcomes. In addition to presenting her own studies, Dr. Volkow also led a town-hall type session dedicated to young investigators. Set in an informal round-table style, Volkow asked the meeting participants to share their research interests, ambitions, and concerns and also offered them her own expertise and wisdom in the field of research and scientific careers in the drug abuse field.

Dr. Rafael Maldonado, Professor at the University of Pompeu Sabra in Spain, presented on “New Advances in the Neurobiological Mechanisms Underlying Nicotine Addiction” which focused on how the endogenous opioid system plays an important role in the behavioral effects of nicotine. His studies found a dissociation between nicotine rewarding properties and physical dependence and suggest a differential implication of β -endorphin in these addictive related responses.

Dr. Sharon Milgram, NIH Director of the Office of Intramural Training and Education, hosted a mentoring luncheon, which gave students and early career participants a chance to meet with senior scientists in small groups. Like Volkow’s round-table discussion, this session provided young researchers with an opportunity for valuable advice for their futures. In particular, this discussion addressed mentoring relationships and provided resources to help NHSN students find mentors and mentored lab experiences at the NIH, how to maximize mentoring interactions, and share perspectives on what makes a good mentor.

For more information about the conference or about the NHSN, please visit their website at www.hispanicscience.org

New Grants

The following grant opportunities may be of interest to researchers:



- [NOT-RR-10-001](http://grants.nih.gov/grants/guide/pa-files/PA-10-020.html) NIH Announces the Availability of Recovery Act Funds for Administrative Supplements to Support Core Consolidation
- Drug Abuse Dissertation Research: Epidemiology, Prevention, Treatment, Services, and/or Women and Sex/Gender Differences (R36) (PAR-10-020) <http://grants.nih.gov/grants/guide/pa-files/PA-10-020.html>
- AIDS-Science Track Award for Research Transition (R03) (PAR-10-021) AIDS Application Due Date(s): September 7, 2010, September 7, 2011 and September 7, 2012 <http://grants.nih.gov/grants/guide/pa-files/PA-10-021.html>
- Accelerating the Pace of Drug Abuse Research Using Existing Epidemiology, Prevention, and Treatment Research Data (R01)(PAR-10-018) <http://grants.nih.gov/grants/guide/pa-files/PA-10-018.html>



Correction to October 30th Bulletin

This is the grant (PA-08-263) which Bennett Fletcher referred to in his comments at the CTN Cost Analysis

Workshop last month:

<http://grants.nih.gov/grants/guide/pa-files/PA-08-263.html>

<http://grants.nih.gov/grants/guide/pa-files/PA-08-264.html>

<http://grants.nih.gov/grants/guide/pa-files/PA-08-265.html>

NNP Website



The NIDA Networking Project (NNP) provides opportunities for information sharing and research collaboration among NIDA's networks across the country. The

NNP gives researchers and clinicians access to networks' locations, people, expertise, and resources to help synergize efforts, improve efficiency, and accelerate scientific discovery.

Read more and check out the NNP Website at:

<http://nnp.drugabuse.gov>.

We Get Questions!



1. How long do I have to keep the research records at my site?

The short answer is 3 years from data lock or longer if specified by the local IRB. Here is the language from the CTN SOP

Manual:

"2.21 Record Retention and Storage

Each Node is responsible for storing the research records for the studies in which they participate. The RRTC will establish policies and procedures for the archiving of research records at study closure, in compliance with their state, local, institutional and IRB regulations and with the minimum standard for CTN protocols. In all CTN sponsored studies, study records must be maintained for three years (after data lock) or longer if specified by local institutions/agencies or FDA regulations. Clear, written documentation of record location should be forwarded to the study team and NIDA CCTN. The site PI noted in the 1572 and Investigator's Agreement must be notified of the disposition and retrieval process for site records.

Each Node must contact CCTN before records are destroyed."

2. How can I order CTN Brochures and Directories?

CTN brochures, directories, and other CTN related trial materials are available free of charge from Synergy Enterprises Inc. (SEI) at CTNSupport@sei2003.com. Send an e-mail with your request and the number of items needed. They will be mailed to your site.

3. Who do I call about getting access to Live Link?

Contact the DSC 1 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. Please copy your Node Coordinator on this request. You will receive log in instructions with a password by e-mail.

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

