Trial Progress – Over 9,000!

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 July 31, 2008.

Open Studies (5)

- CTN 0027 – Randomized 797
- CTN 0027A (Genetics) – Randomized 434
- CTN 0030 – Randomized 565
- CTN 0031 – Randomized 61
- CTN 0031A – Randomized 37

Total Randomized All Studies: 9,224

2008 Steering Committee Meetings

The Fall Steering Committee Meeting will be held in Bethesda, Maryland, from October 21-23, 2008. The hotel is the Bethesda North Marriott, one block from NIDA Headquarters. Registration is now open at www.sei2003.com/NIDA/CTN/Meetings/. The hotel can be contacted directly at 301-822-9200. Ask for the NIDA CTN room block. The deadline for making reservations at the negotiated government room rate of $201 per night plus tax is September 22, 2008. Here is a preliminary schedule for the meetings:

Tuesday, October 21

1:00 p.m. - 5:00 p.m. American Indian Workshop
3:00 p.m. - 5:00 p.m. Electronic Medical Records Workshop
6:00 p.m. - 8:00 p.m. CTP Caucus
6:00 p.m. - 8:00 p.m. PI Caucus

Wednesday, October 22

8:00 a.m. - 12:30 p.m. Steering Committee
1:30 p.m. - 3:30 p.m. Executive Committee
2:30 p.m. - 4:30 p.m. Research Development Committee
2:30 p.m. - 4:30 p.m. Research Utilization Committee

Thursday, October 23

8:30 a.m. - 1:00 p.m. Steering Committee

American Indian/Alaska Native Workshop

The CTN plans to conduct a workshop on October 21, 2008, titled: Conducting Research with American Indian/Alaska Native Communities in the CTN: Challenges, Opportunities and Best Practices.

This very important workshop will be part of the upcoming Steering Committee week (same hotel). It is designed to address a number of issues related to conducting community-based participatory research in American Indian/Alaska Native communities. The major topics include: 1) health disparities/substance abuse issues; 2) history of research in American Indian communities; 3) building relationships within the community; 4) ethical and regulatory issues; 5) study implementation issues; 6) publication and dissemination of the research; and 7) future research directions and funding opportunities. All interested staff are welcome to attend. Contact Carmen Rosa at crosa@nida.nih.gov for further details.

EC Elections

Congratulations to the following CTNers who have been elected to the Executive Committee (EC):

(In alphabetical order by last name)

- Becca Crowell, CTP Director, Texas Node
- Dennis Daley, PI, Appalachian Tri-State Node
- Ron Jackson, CTP Director, Pacific Northwest Node
- John Rotrosen, PI, New York Node
- Roger Weiss, PI, Northern New England Node

Thank you for your votes and to those who have previously served on the Executive Committee! All EC member terms will expire in August 2010 with the award of the new CTN RFA. Please contact Carol Cushing if you have any questions.

CTN 0031 STAGE-12

Members of the STAGE-12 (Stimulant Abuser Groups to Engage in 12-Step) protocol team met in Rockville, MD on August 6-8 for Wave 2 training of clinical and research staff. More than 50 counselors, clinical supervisors, research assistants and researchers attended from all ten of the STAGE-12 study sites. The three Wave 1 sites have been enrolling since February, and the first of the seven Wave 2 sites are expected to begin enrollment in September. Welcome aboard to everyone!
**SBIRT Meeting**
The Clinical Trials Network Working Group on Screening, Brief Intervention and Referral to Treatment (SBIRT) for Substance Use convened a workshop on SBIRT in Emergency Medicine and Integrated Health Care Systems on July 31 at NIDA. Twelve invited experts in SBIRT in medical settings met with NIDA Director Nora Volkow, NIDA Deputy Director Tim Condon, CCTN Director Betty Tai, other CCTN and NIDA staff, and CTN members. The workshop’s goals were to discuss several critical issues on SBIRT for substance abuse and advise NIDA on future planning. Some of the questions discussed were:

- What obstacles exist to employing SBIRT for substance abuse?
- What aspects of SBIRT can be realistically conducted in the EMS (Emergency Medical Services) and IHCS (Integrated Health Care Systems) environments?
- What challenges are posed in each of these environments in the delivery of each phase?
- How should we focus CTN research in these settings?
- Where can CTN’s uniqueness be most effective?
- How can we most fully and effectively engage Community Treatment Programs?

CTN members in attendance included Carol Luna-Anderson, Jeff Selzer, Ann Uhler, John Rotrosen, Marc Gourevitch, Patsy Novo, Dennis McCarty, Michael Bogenschutz, and Tom McLellan. A summary of the workshop is being prepared and will be posted for CTN members.

**CTN Data Share Web Site**
Data from CTN 0021 (Motivational Enhancement Treatment in Spanish Speaking Substance Users) are now available to the public on the CTN Public Data Share web site (www.ctndatashare.org). The web site also contains data from the following thirteen studies: CTN 0001, 0002 - 0009, 0011, 0012, 0013 and 0016. The next protocol to post will be CTN 0018 (HIV Risk Reduction in Men) in September.

The data share web site is also undergoing some major improvements including a more dynamic design, additional protocol descriptions, a searchable list of validated assessment instruments, and more documentation to help download data and navigate the web site’s content. We are planning to launch the new web site in early September.

If you have suggestions or questions about the web site contents, please contact Cindy Green at cindy.green@duke.edu or Carol Cushing at ccushing@nida.nih.gov.

**Grants Tidbit Corner – New Grants**
The following NIH grant opportunities may be of interest to researchers in the CTN:

- Drug Abuse Prevention Intervention Research (R01) (PA-08-217)  
- Drug Abuse Prevention Intervention Research (R21) (PA-08-218)  
- Drug Abuse Prevention Intervention Research (R03) (PA-08-219)  
- Drug Testing for Clinical Trials (NOT-DA-08-030)  
- Notice of Availability of Administrative Supplements for Drug Abuse Research on GALT and HIV/SIV Pathogenesis (NOT-DA-08-036)  
- Notice of Availability of Set-Aside Funds for FY 2009 for PAR-08-081 (NOT-DA-08-038)  
**CTN Dissemination Library Update**

The CTN Library is web-based, and is maintained by the Pacific Northwest Node of the Clinical Trials Network. The address is: [http://ctndisseminationlibrary.org](http://ctndisseminationlibrary.org).

Four items were recently added to the CTN Dissemination Library:

- **Infrequent Illicit Methadone Use among Stimulant-Using Patients in Methadone Maintenance Treatment Programs: A National Drug Abuse Treatment Clinical Trials Network Study** by Wu, Blazer, Stitzer, Patkar, and Blaine. American Journal on Addictions 2008;17(4):304-311. Using data from protocol CTN-0007 (MIEDAR: Methadone Clinics), the authors sought to determine the prevalence, patterns, and correlates of past-month illicit methadone use and history of regular illicit use among stimulant-using methadone maintenance treatment patients.

- **Community Program Therapist Adherence and Competence in Motivational Enhancement Therapy** by Martino, Ball, Nich, Frankforter, and Carroll. Drug and Alcohol Dependence 2008;96(1-2):37-48. This article is about the extent to which clinicians in addiction treatment programs can implement empirically validated therapies like MET with adequate fidelity.

- **The Contingency Management (CM) Checklist** by Christine Higgins. Mid-Atlantic Node, Unpublished manual, 2006. This 11-page document, developed as part of a training manual that drew on the results of the CTN MIEDAR protocols (CTN-0006 and -0007), provides a set of recommended guidelines with examples for community treatment programs interested in implementing a contingency management program in their clinics.

- **Trauma and Intravenous Drug Use among Pregnant Alcohol/Other Drug Abusing Women: Factors in Predicting Child Abuse Potential** by Erickson and Tonigan. Alcoholism Treatment Quarterly 2008;26(3):313-332. This article is about an ancillary investigation of protocol CTN-0013 that examined associations between trauma, route of drug administration (IV use), and child abuse potential in pregnant substance abusers.

Find out what else is new at our [What’s New page](#), and add your own posters, presentations, articles, and other CTN-related documents to the Library by e-mailing them to: info@ctndisseminationlibrary.org. If you have questions or comments, please ask!

**Florida Node Highlights**

On July 18, 2008, CTN Florida Node PI Dr. José Szapocznik delivered the opening keynote address at the annual meeting of the American Mental Health Counselors Association (AMHCA) in San Diego, California. Consistent with the conference theme of “Embracing Diversity,” Dr. Szapocznik spoke about “Demystifying Diversity”. Dr. Szapocznik and CTN-0014 Lead Investigator Dr. Michael Robbins also presented an invited full-day workshop on Brief Strategic Family Therapy™ (BSFT™) to AMHCA during this annual meeting. The emphasis of the workshop was on discussing videotaped BSFT™ sessions.

**NIH Minority Health Conference**

The National Center on Minority Health and Health Disparities is sponsoring a conference titled “NIH Summit: The Science of Eliminating Health Disparities” on December 16-18 at the Gaylord Hotel, National Harbor. [The call for abstracts has been extended to September 15.](http://www2.blsdev.com/blsmeetings/h1288/v11/index.cfm) Information is available at [http://www2.blsdev.com/blsmeetings/h1288/v11/index.cfm](http://www2.blsdev.com/blsmeetings/h1288/v11/index.cfm).

A workshop on grants titled “Mastering the NIH Grants Process and Research/Training Mechanisms – A Roadmap Toward Successfully Funded NIH Applications” is offered on Dec. 15 (information available at the above referenced site). There are sessions for junior investigators and mid-senior investigators. The program will end with a mock scientific review panel including critiques as for an IRG study session.

**New York Node Update**

A paper from the Infections and Substance Abuse Study (NIDA CTN 0012) has been accepted for publication as a Rapid Communication by the Journal of Addictive Diseases. It is titled “Substance Abuse Treatment Clinician Opinions and Infectious Disease Service Delivery.” The lead author is Kathlene Tracy from NYU. Co-authors are: Lawrence S. Brown, Steven Kritz, Donald Alderson, Jim Robinson, Edmund J. Bini, Michael Levy, Donald Calsyn, Traci Rieckmann, Bret Fuller, Pat McAuliffe, and John Rotrosen.

This is the fourth paper from this study to be accepted. The Lead Investigator was Dr. Brown from Addiction Research and Treatment Corporation. Dr. Rotrosen from NYU is the Principal Investigator for the New York Node. The publication date will be forthcoming.
Sad News – New England Node

It is with sadness that we announce the loss of our beloved friend and colleague Patrick McAuliffe. Pat was one of the original members of the CTN when it was established in 1999. Pat was Chief Executive Officer of Connecticut Renaissance, Inc., a community treatment program in the New England Node. He will be remembered for his dedication and joy which embodied the best of the CTN. Julie Matthews (Node Coordinator) will be compiling people’s remembrances of Pat for a future special Bulletin. Please send Julie pictures of Pat and special memories to: jmatthews@abhet.com.

Publications Committee (PC)

Three publications have been accepted recently. Kathlene Tracy, Ph.D. has received word that her paper, "Substance Abuse Treatment Clinician Opinions and Infectious Disease Service Delivery" was accepted for publication as a Rapid Communication in the Journal of Addictive Diseases. This is another publication from the CTN-0012 Infectious Diseases protocol. Congratulations to Dr. Tracy and to the whole CTN-0012 study team.

The primary outcome paper for CTN 0019, HIV Risk Reduction in Women Substance Abusers, entitled "Effectiveness of HIV/STD Sexual Risk Reduction Groups for Women in Substance Abuse Treatment Programs: Results of a NIDA Clinical Trials Network Trial," has been accepted for publication in the Journal of AIDS. Susan Tross was the Lead Investigator and lead author. Congratulations to Susan and her team.

A paper examining the occurrences of serious adverse events (SAEs) reported in multicenter psychosocial trials in the CTN was accepted for publication: “Individual and Organizational Variables Influence Serious Adverse Events in Randomized Psychosocial Treatment Studies: Safety or Arbitrary Edicts?” by Nancy M. Petry, John M. Roll, Bruce J. Rounsaville, Samuel A. Ball, Maxine Stitzer, Jessica M. Peirce, Jack Blaine, Kimberly C. Kirby, Dennis McCarty, and Kathleen M. Carroll. Congratulations!

Abstracts of these three published papers are provided at the end of this newsletter.

Federal Offices Closed

The CCTN office and NIDA will be closed on Monday, September 1, 2008, for the Labor Day holiday observance.

NIDA Networking Website: A Bridge to Transdisciplinary Research

Have you wondered how you can find an expert in genetics for your new grant application? Looking for speakers for an interdisciplinary panel? Considering ways to ensure that your prevention or treatment intervention works with diverse populations? The NIDA Networking Project (NNP) website has been designed to help you do that at http://nnp.drugabuse.gov. It allows you to: search a directory of addiction researchers or practitioners to find an expert in genetics; identify scientists from across the addiction spectrum to complete the panel; or, locate network sites with access to diverse populations across the country. Crossing networks, disciplines or geography, the NNP website is designed to connect addiction scientists, practitioners, and policymakers to research-based information and resources.

The NNP website features 14 networks sponsored by NIDA or in partnership with other Federal agencies. The website includes:

- An interactive map with close to 300 NIDA-supported network sites;
- Network descriptions and resources;
- Links to network websites to access research teams, scientific protocols and papers, procedural policies/manuals;
- NNP colleagues’ directory with close to 400 members participating; and
- NIDA news and events of interest to scientists, clinicians, addiction specialists, policymakers.

For more information on the NNP website, please contact Susan David, NNP Coordinator at: davids2@nida.nih.gov; telephone: 301-435-0640.

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

Long Island Node News

This summer the Long Island Node has been busy having babies! Anna Rodriguez/Fernandez (Assistant Node Coordinator) had a baby girl, Hailey Ann on July 3rd. Eva Kourniotis-Turgiano (Protocol Coordinator) also had a baby girl, Sophia, on August 11th. Congratulations to both women and their families!
Conflict of Interest

In order to address the increasing complexity of the financial interests held by biomedical researchers, the Public Health Service (PHS) and the Office of the Secretary of Health and Human Services (HHS) published a regulation establishing standards and procedures to be followed by Institutions that apply for research funding from PHS granting agencies, including the NIH. The regulation is aimed at ensuring that the design, conduct, or reporting of research funded under grants and cooperative agreements will not be biased by any conflicting financial interest of the Investigators responsible for the research.

The NIH has compiled answers to the most frequently asked questions regarding the implementation of this regulation by the NIH and hopes these will clarify issues that may arise.

1. **What does the regulation require of institutions who receive federal funding?** The regulation requires that each Institution maintain a written, enforced policy on conflict of interest that conforms with the following requirements:
   - Complies with the regulation;
   - Informs each Investigator of the Institution's policy as well as the regulation;
   - Informs each Investigator of his or her reporting responsibilities;
   - Provides adequate guidelines for enforcement mechanisms and sanctions where appropriate.

2. **Does this regulation apply to all grants/research contracts awarded by the NIH?** No. This regulation does not apply to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) program applications or awards.

3. **Does the regulation apply to subgrantees, collaborators of grantees (e.g., consortia) or subcontractors?** Yes. The regulation is applicable to each Institution that applies for NIH grants or cooperative agreements for research or submits a proposal for a research contract whether in response to a solicitation or otherwise and, through the implementation of the regulation by each Institution, to each Investigator participating in such research. Accordingly, Institutions carrying out NIH-funded research through subrecipients (e.g., contractors, collaborators) or subcontractors must take reasonable steps to ensure that Investigators working for such entities comply with the regulation, either by requiring the Investigators to comply with the awardee Institution's policy or by requiring the entities to provide appropriate assurances to the awardee Institution.

Here is the NIH website for more information and a list of frequently asked questions and answers: [http://grants.nih.gov/grants/policy/cope/](http://grants.nih.gov/grants/policy/cope/)

Data and Statistics Center (DSC) at DCRI

**What are critical variables?**

Critical variables are those data points that are integral to efficacy, safety analyses and regulatory requirements. These variables include all that are involved with primary and secondary analyses. Under this definition, any dependent variables (such as outcome variables) and any independent variables (such as study treatment) as well as key covariates (age, gender, baseline drug use or site) related to the primary or key secondary hypotheses are considered critical variables. For efficacy analyses, the list often includes primary and key secondary outcomes, treatment assignment, variables to identify analysis populations, key demographic data, and key subgroup identifiers. For regulatory/safety reports, the critical variable list often includes Serious Adverse Events and inclusion/exclusion variables. It is strongly recommended that a 1st draft of all proposed critical variables be identified prior to building the electronic trial database. In general, critical variables comprise 5 – 10% of the total variables in the study.

**Who to Contact:**
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.

**Data Management Lead:**
Lori Poole, B.A., Phone (919) 668-8238
lori.poole@dcri.duke.edu

**Lead Statistician:**
Jeff Leimberger, Ph.D., Phone (919) 668-8758
leimb001@dcri.duke.edu

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

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

Substance Abuse Treatment Clinician Opinions and Infectious Disease Service Delivery. Lead author is Kathlene Tracy, Ph.D. from NYU. Co-authors are: Lawrence S. Brown, M.D., M.P.H., Steven Kritz, M.D., Donald Alderson, M.S., Jim Robinson, M.Ed., Edmund J. Bini, M.D., M.P.H., Michael Levy, Ph.D., Donald Calsyn, Ph.D., Traci Rieckmann, Ph.D., Bret Fuller, Ph.D., Pat McAuliffe, M.B.A., L.A.D.C., and John Rotrosen, M.D.

Objective: Substance abuse treatment programs are an important platform for delivery of services for infectious diseases (ID) associated with drug and alcohol use. However, important components of ID care are not universally provided. Clinician training often focuses on information about ID. Less attention is paid to provider opinions and attitudes that may be barriers to providing ID services. In a national multi-site trial conducted by the National Drug Abuse Treatment Clinical Trials Network (CTN), we investigated the relationship between clinician opinions and the delivery of services for human immunodeficiency virus, hepatitis C virus, and sexually transmitted infections in substance abuse treatment settings. Survey data were collected from 1,723 clinicians at 269 CTN treatment programs. Clinician opinion was found to be significantly related to infectious disease service delivery. Implications for training are discussed.

Effectiveness of HIV/STD Sexual Risk Reduction Groups for Women in Substance Abuse Treatment Programs: Results of a NIDA Clinical Trials Network Trial By Susan Tross, Aimee N. C. Campbell, Lisa R. Cohen, Donald Calsyn, Martina Pavlicova, Gloria Miele, Mei-Chen Hu, Louise Haynes, Nancy Nugent, Weijin Gan, Mary Hatch-Maillette, Raul Mandler, Paul McLaughlin, Nabila El-Bassel, Paul Crits-Christoph, and Edward V. Nunes

Objective: Since drug-involved women are among the fastest growing groups with AIDS, sexual risk reduction intervention for them is a public health imperative. Test effectiveness of HIV/STD safer sex skills building (SSB) groups for women in community drug treatment. Design: Randomized trial of SSB versus standard HIV/STD Education (HE); assessments at baseline, 3- and 6- months.

Participants: Women recruited from 12 methadone or psychosocial treatment programs in NIDA’s Clinical Trials Network. 515 women with one unprotected vaginal or anal sex occasion (USO) with a male partner in the past 6 months were randomized.

Interventions: In SSB, five 90-minute groups used problem-solving and skills rehearsal to increase HIV/STD risk awareness, condom use and partner negotiation skills. In HE, one 60-minute group covered HIV/STD disease, testing, treatment, and prevention information.

Main Outcome: Number of USOs at follow up. Results: A significant difference in mean USOs was obtained between SSB and HE over time (F=67.2, p<.0001). At 3 months, significant decrements were observed in both conditions. At 6 months SSB maintained the decrease, HE returned to baseline (p<.0377). Women in SSB had 29% fewer USOs than those in HE.

Conclusions: Skills building interventions can produce ongoing sexual risk reduction in women in community drug treatment.

Individual and Organizational Variables Influence Serious Adverse Events in Randomized Psychosocial Treatment Studies: Safety or Arbitrary Edicts? By Nancy M. Petry, John M. Roll, Bruce J. Rounsaville, Samuel A. Ball, Maxine Stitzer, Jessica M. Peirce, Jack Blaine, Kimberly C. Kirby, Dennis McCarty, and Kathleen M. Carroll

Objective: Human subjects protection policies developed for pharmaceutical trials are now being widely applied to psychosocial intervention studies. This study examined occurrences of serious adverse events (SAEs) reported in multicenter psychosocial trials of the National Institute on Drug Abuse Clinical Trials Network. Substance abusing participants (N=1,687) were randomized to standard care or standard care plus either contingency management or motivational enhancement. Twelve percent of participants experienced one or more SAEs during the 27,198 person-weeks of follow-up. Of the 260 SAEs recorded, none were judged by the Data Safety Monitoring Board to be study related, and there were no significant differences between experimental and control conditions in SAE incidence rates. These data underscore the need to reconsider the rationale behind, and appropriate methods for, monitoring safety during psychosocial therapy trials.