



# Clinical Trials Network

CTN Bulletin

June 30, 2008

Volume 08 – 11

## Protocol Numbers?



Many CTN protocols have included ancillary (add-on) studies to the main study. In order to keep track of these projects, we have added an indentifying letter starting with “A” to the main protocol number for each ancillary study. In addition, some smaller studies have been awarded under NIDA’s Minority Supplement Program. These projects have been given numbers starting with CTN 0033 – CTN 0036. Here is a listing of the current ancillary and supplemental studies:

Study Number	Study Title
CTN 0030A	Collection of economic data for Prescription Opioid Addiction Treatment Study (POATS)
CTN 0030B	Effects of chronic opioids on the brain
CTN 0031A	An evaluation of neurocognitive function, oxidative damage, and their association with treatment outcomes in methamphetamine and cocaine abusers
CTN 0031B	The role of alcohol consumption in classifications of alcohol use disorders
CTN 0031C	Organizational and practitioner influences on implementation of STAGE 12 (CTN 0031)
CTN 0033	Methamphetamine use among American Indians (National study)
CTN 0033A	Methamphetamine use among American Indians – Oregon/Hawaii Node
CTN 0033B	Methamphetamine use among American Indians – Southwest Node
CTN 0033C	Methamphetamine use among American Indians – Pacific Northwest Node
CTN 0034	Developing research capacity and culturally appropriate research methods: community-based participatory research manual for collaborative research in drug abuse for American Indians and Alaska Natives
CTN 0035	Access to HIV and Hepatitis screening and care among ethnic minority drug users in and out of drug treatment
CTN 0036	Epidemiology and ethnographic survey of “cheese” heroin use among Hispanics in Dallas County, Texas

## Methadone Research Tutorial!



NIDA’s website is the online source for information about NIDA’s International Program, which coordinates this Institute’s collaborative activities with scientists and government agencies in other countries and with international organizations. A new link on the site is a tutorial on methadone research. The Methadone Research Web Guide is divided into four subject areas, and each question links to a section for more information. Readers can answer questions to test their knowledge about methadone maintenance treatment (MMT). The flexible design permits users to decide the best way to use the tutorial.

- Answer the questions before you review the full Web Guide to identify subject areas where you need more information.
- Answer the questions after reviewing the full Web Guide to assess your understanding of the material.
- Concentrate on the section of the Web Guide that is most relevant to you.
- Answer all of the questions correctly to obtain your personalized Certificate of Completion.

The tutorial’s four subject areas include:

- [Efficacy of MMT \(6 questions\)](#)
- [MMT program design \(6 questions\)](#)
- [MMT as an HIV/AIDS risk reduction strategy \(3 questions\)](#)
- [Gender issues in providing MMT \(3 questions\)](#)
- [Methadone and buprenorphine \(2 questions\)](#)

To access the International Program, go to <http://international.drugabuse.gov/index.html>

## Federal Offices Closed



The CCTN office and NIDA will be closed on Friday, July 4, 2008, for the Independence Day holiday observance.

## Upcoming Events



The Investigator Training for CTN 0031 (STAGE 12) is scheduled for August 6-8 in Rockville, Maryland. The Investigator Training for CTN 0032 (HIV Rapid Testing) is planned for September 10-12 in Bethesda, Maryland. The fall Steering Committee will be held October 21-23 in Bethesda, Maryland. Hotel and meeting information will be sent out later this summer.

*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.*

### **Florida Node Highlights**



Drs. Michael Robbins, Viviana Horigian, and José Szapocznik, Associate Professor, Assistant Professor, and Chair, respectively, in the Department of

Epidemiology and Public Health, recently 'went international' with the German-translated publication of their article, "Brief Strategic Family Therapy: An Empirically Validated Intervention for Reducing Adolescent Behavior Problems" in *Prax. Kinderpsychol. Kinderpsychiat.*, which is the German journal, *Practice of Child Psychology and Child Psychiatry*.

Brief Strategic Family Therapy™ is the nationally renowned intervention model developed by Dr. José Szapocznik and colleagues at the University of Miami Center for Family Studies which has the most widely recognized program of intervention research with Hispanic families in the nation. The Center is the premiere training facility in the U.S. for teaching family-based intervention research with minority populations. Its award-winning Brief Strategic Family Therapy™ (BSFT™) model has been empirically validated and shown to reduce adolescent drug use, conduct problems, association with deviant peers, and improve family functioning. The Center has established a National Training Institute to provide training and certification in BSFT™, in Spanish or English, to agencies around the country. BSFT™ has previously received recognition as a Model Program of the U.S. Substance Abuse and Mental Health Services Administration, the Presidential Award from the International Society for Prevention Research, and the Research Award of the U.S. Center for Substance Abuse Prevention and is the first adolescent treatment manual included in the National Institute on Drug Abuse's treatment manual series. In addition, Dr. Robbins led an eight-site national study on BSFT for the treatment of adolescent drug abuse (CTN 0014) funded by the Clinical Trials Network.

Dr. Rüdiger Retzlaff, Director of the Clinic of Marital and Family Therapy at the Institute for Collaborative Psychosomatic Research and Family Therapy at University Hospital in Heidelberg, Germany, commented on the Robbins, et al article, "It is a fine piece of work and I am sure it will make an important contribution to the field." Below is the complete citation:

**Robbins, M.S.,** Horigian, V., & Szapocznik, J. (2008). Brief Strategic Family Therapy: An Empirically-Validated Intervention for Reducing Adolescent Behavioral Problems. *Practice of Child Psychology and Child Psychiatry (Prax. Kinderpsychol. Kinderpsychiat.)*, 57, 381-400.

### **Awards Available for International Program**



NIDA seeks to enhance international collaborative research on drug abuse through the Distinguished International Scientist Collaboration Program (DISCA).

The competitive DISCA and the DISCA for U.S. Citizens and Permanent Residents (USDISCA) invite senior researchers from other countries and NIDA grantees to work together for their joint research. The Program allows participants to choose the travel option that works best for their research. If the project would best be conducted outside the United States, NIDA grantees should apply for a USDISCA award to visit their partner's home country. If the project would best be conducted in the United States, international drug abuse researchers should apply for a DISCA award to visit their U.S. partners.

Applicants must propose an innovative approach to projects that fall within the NIDA research mission, clearly define their expected product or outcome, and submit a final report to NIDA.

#### *What Do the DISCA and USDISCA Awards Include?*

DISCA and USDISCA awards provide a research exchange visit lasting from 1 to 3 months, depending upon the project requirements; a monthly allowance of up to \$6,500 to cover short-term living expenses in the host country; and one round trip between the home and host cities for the scientist only. Visas and health insurance are the responsibility of the awardee.

#### *Who Is Eligible for the DISCA Award?*

Applicants must –

- Be citizens or permanent residents in a country other than the United States.
- Team with a current NIDA grantee.
- Have a minimum of 7 years of experience in drug abuse research beyond the postdoctoral level.
- A scientific record that includes peer-reviewed publications.

#### *Who Is Eligible for the USDISCA Award?*

Applicants must –

- Be U.S. citizens or permanent residents.
- Be current NIDA grantees.
- Have a minimum of 7 years of experience in drug abuse research beyond the postdoctoral level.
- A scientific record that includes peer-reviewed publications.

#### **How Should I Apply?**

Application forms and instructions can be downloaded from this website in Microsoft Word and Adobe PDF format:

<http://international.drugabuse.gov/research/fellowships/disca.html>

### **CTN 0032**



The first national call for HIV Rapid Testing & Counseling (CTN 0032) was held on June 23, 2008, to introduce sites and personnel and discuss project implementation. Representatives from all 12 community treatment programs were in attendance. Future calls will be held bi-weekly on Tuesdays at 3:00 PM EDT. The initial CTN 0032 protocol is being reviewed by the central IRB, Western IRB. After being approved, site-specific protocols will be submitted and reviewed on a rolling basis. The Investigative Team, various work groups and collaborators continue to develop the manual of operations, and intervention materials and training materials.

### **Delaware Valley News**



Schering Plough, the European distributor of Subutex and Suboxone, invited Dr. Woody (Delaware Valley Node PI) to present findings from study CTN 0010 (Bup/Nx in Adolescent Drug Abusers) to the Department of Addiction Psychiatry at the Karolinska Institute in Stockholm and at the 3<sup>rd</sup> Annual Nordic Opioid Treatment meeting in Helsinki during the week of June 9. The meetings were interesting from several points of view. The Scandinavian countries are strongly endorsing Suboxone for treating opioid addiction. Alcoholism and amphetamine addiction continue to be the most prevalent addictions; however opioid addiction causes substantial harm and expense to patients, families, and society in the same way it does as in the U.S. These countries were late to endorse methadone and more recently began using buprenorphine with Subutex. However they had problems with injecting Subutex that was smuggled into the country from other sources and are in the process of switching to Suboxone. (In Norway it was done in less than a week!).

Another interesting fact had to do with the treatment system in Norway. They provide a very high level of psychosocial services and report excellent results that seem to emerge over a period of 1-2 years with methadone. The Norwegian presenter mentioned that part of the treatment involves changing the patient's living environment if needed. When someone asked how that was done, she said that the State will relocate the patient into a new apartment in a better part of town and pay for it if necessary. When asked about their annual per patient/per year costs, she said it was between 20 and 30,000 US dollars. She added that the government finds their treatment cost-effective because most patients return to work and pay taxes, and use fewer other medical and legal services. Nevertheless, this level of support for substance abuse treatment seemed to be on the high side, even for the Scandinavian countries.

### **Fun Facts from the CTN Dissemination Library**



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>.

#### *Statistics from the first half of 2008:*

Items in the Library: 224

Authors represented: 375

Journal with most CTN articles: *Journal of Substance Abuse Treatment*

Visitors: 5,085

Page views: 14,435

Top 5 countries of origin for visitors: U.S., Turkey, Canada, United Kingdom, and India.

Top 5 terms "Googled" that led to the Library: CTN Dissemination Library (or some variation thereof), NIDA CTN, Nancy Petry, 2006 NIDA Blending Conference, CTN 0031.

Top 5 pages viewed: [Home page](#), [What's New?](#), [Record 146](#) (MIA:STEP Blending product), [Protocol List](#), [Protocol CTN-0003](#).

A quick way to see everything in the Library's digital collection is the [CTN Dissemination Library Catalog](#). This full-color PDF is updated regularly with additions to the Library, including over a dozen presentations from the 2008 CPDD conference and a new article from Steve Martino, Steve Gallon, Sam Ball, and Kathy Carroll entitled, "[A Step Forward in Teaching Addiction Counselors How to Supervise Motivational Interviewing Using a Clinical Trials Training Approach](#)" (J Teach Addict 2008;6(2):39-67).

For questions & submissions, e-mail the librarians at [info@ctndisseminationlibrary.org](mailto:info@ctndisseminationlibrary.org)

### **Morrison Award**



Congratulations to Dr. Betty Tai, Director, CCTN, for being selected for the CPDD J. Michael Morrison Award. The J. Michael Morrison Award is given annually in recognition of outstanding contributions in the area of scientific administration related to drug abuse. Dr. Tai, along with Dr. Rita Liu from NIDA, will share the award jointly this year. Dr. Tai is being recognized for her untiring devotion to the development and successful implementation of the Clinical Trials Network.

## NIH Announces New CTSA Awards



Fourteen academic health centers in 11 states are the latest members of the National Institutes of Health's Clinical and Translational Science Award (CTSA) consortium. Creating a unique network of medical research

institutions across the nation, the consortium is working to reduce the time it takes for laboratory discoveries to become treatments for patients and to engage communities in clinical research efforts. It also is fulfilling the critical need to train the next generation of clinical and translational researchers. The consortium is led by the National Center for Research Resources (NCRR), a part of the NIH.

These 14 academic health centers join 24 others announced in 2006 and 2007. Total funding for these new awards is \$533 million over five years. The 2008 CTSA grants expand state representation in the consortium to Alabama, Colorado, Indiana, Massachusetts, and Utah. They also support pediatric research at 13 dedicated children's hospitals; expand research in genetics and genomics; enhance research in behavioral immunology and infection risk; and increase outreach into local communities. The new CTSA Centers include:

- Albert Einstein College of Medicine of Yeshiva University (New York City)
- Boston University (Boston)
- Harvard University (Cambridge, Mass.)
- Indiana University School of Medicine (Indianapolis)
- Northwestern University (Chicago and Evanston, Ill.)
- The Ohio State University (Columbus, Ohio)
- The Scripps Research Institute (La Jolla, Calif.)
- Stanford University (Palo Alto, Calif.)
- Tufts University (Boston)
- The University of Alabama at Birmingham (Birmingham, Ala.)
- University of Colorado Denver (Aurora, Colo.)
- The University of North Carolina at Chapel Hill (Chapel Hill, N.C.)
- The University of Texas Health Science Center at San Antonio (San Antonio)
- The University of Utah (Salt Lake City)

A major goal of the CTSA initiative is to develop a national consortium of CTSA institutions that will work together to transform the discipline of clinical and translational research across the country. The web site for more information is: <http://www.ctsaweb.org/>

## What are queries?




Queries ask questions about the data in clinical trials. The queries can be manual queries, generated by monitors or by data management staff during audits, or automatic queries created by pre-programmed checks in the data system.

Both types of queries need to be addressed, and the data must be corrected, if necessary, in order to close the queries and permit data cleaning and locking at the end of the trial.

Queries exist in three different states in the InForm system: Open, Answered, and Closed. An Open Query is one which has not been addressed. An Answered Query is one in which the data was confirmed "as is" but not changed. This type of query will remain Answered until a monitor or site personnel verify the data entry is correct. A Closed Query is one in which the data was changed to satisfy the pre-programmed checks in the system, or where the monitor or DCI has reviewed and moved the query from a previously Answered state.

Starting July 1, the Data and Statistics Center at DCRI will begin working with the local sites to address resolving the Answered Queries. A backlog of these queries will be addressed by DCRI on a site by site basis. In some cases, the data auditor will make a site visit to close out the Answered queries still outstanding. DCRI will be setting up webinar training sessions for staff who are assigned these responsibilities. Any questions please send to Debbie Drosdick at [Debbie.drosdick@duke.edu](mailto:Debbie.drosdick@duke.edu).

### Sites to Remember

 Here are some useful CTN and federal sites for reference:  
*CTN Data Share* – download public data sets, study information at [www.ctndatashare.org](http://www.ctndatashare.org).

*Good Clinical Practice* training is available on-line for all CTN members at [www.nihtraining.com/ctn](http://www.nihtraining.com/ctn).

*Federal Per Diem Rates and GSA Forms* at <http://www.gsa.gov/Portal/gsa/ep/home.do?tabId=0>.

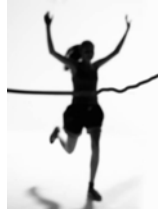
*CRISP Data Base* is a searchable database of federally funded research projects. <http://crisp.cit.nih.gov/>.

*CTN brochures, directories, conference calls* from Synergy Enterprises Inc. (SEI) are available at [CTNSupport@sei2003.com](mailto:CTNSupport@sei2003.com).

### Topics for CTN Articles in NIDA Notes

*Please forward ideas for CTN related articles to Jeff Selzer (Long Island Node) at [selzer@lij.edu](mailto:selzer@lij.edu).*

### **A Success to Remember – START Feedback**



A special thanks to Tom Hill (BiValley CTP) for sharing this success story –

*I know that those of us who have been working in the field of addictions studies and treatment have been witness to many success stories over the years. Some of those stories come from the total abstinence treatment models and many have come from medically assisted treatment modalities, such as methadone maintenance.*

*Most recently one of our START participants successfully completed the study. The wonderful thing about her successful completion is that, at her final interview, she spoke with me about the fact that she had been on methadone for the past 15 years, off then on again, and using the entire time. She has been trying to attain abstinence and ultimately recovery. She described 15 years worth with relapse, program after program and in a nutshell, a life of addictive hell.*

*The participant then went on to tell me that since being enrolled in the START study and being assigned to receive buprenorphine, she quickly attained abstinence and has not turned back since. This individual speaks of buprenorphine as if it has been a miracle in her life. She has found what she has been seeking for a decade and a half. As she was telling me this, tears welled up in her eyes and “thank you” crossed her lips. I believe that she was thanking us all for the work we are doing!*

*Within the last couple of months, she found out that she most likely has thyroid cancer. With the help of buprenorphine, counseling, and the support she received while on START, she is walking forward, one step at a time, into a better life and now completely drug free.*

### **Clinical Coordinating Center (CCC) at EMMES**



**Training** – The CCC thanks Jennifer Sharpe Potter and Lynn Kunkel for their contribution to the Recruitment and Retention Seminar held on June 18, 2008. Web Seminars conducted thus far have been recorded and are available on CD. Please send requests for

CDs to the address provided below. The next seminar is scheduled on July 8 at 2pm ET and will cover Adverse and Serious Adverse Events. Registrations are welcome via e-mail. The CCC also thanks CTN members who have provided valuable feedback. Training ideas, requests, or comments are welcome and appreciated. Training related communications may be addressed to [ctntraining@emmes.com](mailto:ctntraining@emmes.com) or [ebuttrey@emmes.com](mailto:ebuttrey@emmes.com).

**Regulatory Facts & Tidbits** – If an IRB disapproves a study submitted to it, and it is subsequently sent to another IRB for review, should the second IRB be told of the disapproval?

Yes, the subsequent IRB should be informed of the disapproval. When an IRB disapproves a study, it must provide a written statement of the reasons for its decision to the investigator and the institution [21 CFR 56.109(e)]. If the study is submitted to a second IRB, a copy of this written statement should be included with the study documentation so that it can make an informed decision about the study. 21 CFR 56.109(a) requires an IRB to "... review ... all research activities [emphasis added] ...." The FDA regulations do not prohibit submission of a study to another IRB following disapproval. However, all pertinent information about the study should be provided to the second IRB.

*Other CCC related questions and topics-* Bob Lindblad at 301-251-1161, [rlindblad@emmes.com](mailto:rlindblad@emmes.com), [ctnsupport@emmes.com](mailto:ctnsupport@emmes.com) for laboratory and/or medication supplies, and [ctnsafety@emmes.com](mailto:ctnsafety@emmes.com) for safety related issues/adverse event follow-up.

***NIDA Project Officer – Steve Sparenborg at (301) 496-4844, [sparenborgs@nida.nih.gov](mailto:sparenborgs@nida.nih.gov).***

### **Data and Statistics Center (DSC) at DCRI**



Please notify the DSC of any changes in staffing, whether additions or attritions. Upon notification of these changes, the DSC will provide or remove access as appropriate.

#### **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](mailto:nidadsc-help@mc.duke.edu).

#### **Data Management Lead:**

Lori Poole, B.A., Phone (919) 668-8238  
[lori.poole@dcri.duke.edu](mailto:lori.poole@dcri.duke.edu)

#### **Lead Statistician:**

Jeff Leimberger, Ph.D., Phone (919) 668-8758  
[leimb001@dcri.duke.edu](mailto:leimb001@dcri.duke.edu)

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

---

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