



The Northern New England Clinical Trials Network



Volume 2, Issue 2
June 2004

Protocol Concept Update

Special points of interest:

- *Upcoming Meeting Calendar*
- *CTP News*
- *Clinician Tips*
- *Protocol Updates*

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The quarterly meeting of the CTN's National Steering Committee convened on May 12th, 2004, in Gaithersburg, Maryland. At this meeting, members of the committee carefully reviewed forty-two Wave 5 concept submissions, of which thirteen were approved. The Northern New England node is proud to report that two of the thirteen concepts approved were submitted by NNE researchers, Dr. David Gastfriend and Dr. Steven Safren. Not

only did their concepts survive a highly competitive approval process, but their submissions were two of the top six proposals accepted. Dr. Gastfriend's concept, "Effectiveness of Patient Placement Criteria for Drug Abuse Outcome," will examine whether the use of a formal decision tree, a structured interview, and a technology tool improves the intake process for drug abuse treatment. Dr. Safren's concept, "Brief

Cognitive-Behavioral Therapy (Life-Steps) for HIV Medication Adherence in Drug Users," tests a cognitive-behavioral intervention designed to increase medication adherence in HIV-positive patients who receive substance abuse treatment.

Concepts which were approved at the May 12th meeting will be reviewed this summer by an ad-hoc, external committee.

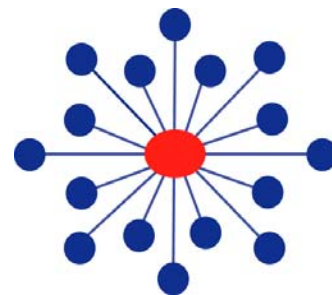
3R Workshop: Recruitment, Retention, and Return for Follow-Up

The first of two workshops on Clinical Trials recruitment and retention was held in Gaithersburg, MD in May. The workshop provided strategies for identifying research participants within clinical programs and maintaining their participation throughout the study. Jennifer Sharpe Potter of McLean Hospital presented on strategies to enhance recruitment.

Northern New England Node was well represented.

Participants included: Derek Moore, Director of Outpatient Services, at CAB Health & Recovery Services; Michelle Rapoza, Project Coordinator for CTN-0017 at SSTAR of Fall River; and Kate Della-Porta, Kate McHugh, Kate Szilagyi, Kristi Prather, Scott Provost, Alan Shields, and Bill Jaffee from McLean Hospital.

Another workshop is scheduled for September 13th and 14th, 2004, in Albuquerque, New Mexico.



Northern New England Sites are encouraged to send a participant if a member of their program did not attend the Gaithersburg training. For information contact the CTN member at your program or Jennifer Sharpe Potter at 617-855-3215.

This newsletter is designed to help everyone in our quickly expanding Node stay up-to-date with CTN news. If you have questions, comments, or suggestions for the newsletter please contact Marge Maxwell (mmaxwell@mclean.harvard.edu).



College on Problems of Drug Dependence Conference

June 12th-17th: San Juan, Puerto Rico

The Annual Meeting for the College Problems of Drug Dependence (CPDD) convened on June 12th-17th in San Juan, Puerto Rico. A number of Northern New England members presented:

- Roger Weiss presented results from his research, entitled *A Randomized Controlled Trial of Integrated Group Therapy for Patients with Bipolar Disorder and Substance Dependence*
- Jennifer Sharpe Potter presented results from her research on pain and substance use disorders, entitled *Moderate to Severe Physical Pain and Associated Characteristics in Persons Seeking Treatment for Substance Use Disorders in Four Treatment Modalities*
- CTN researchers presented a symposium, entitled *CTN COMMUNITY-BASED TREATMENT EVALUATION: RESULTS OF WAVE 1 STUDIES*
- Hortensia Amaro chaired a symposium, entitled *Prevalence, Correlates, Comorbidity and Consequences of Substance Use Disorders Among 4 groups of U.S. Latinos: Results of the National Latino and Asian American (NLAAS) Study*



Upcoming Meetings

- **CTN 0017 National Training for Research Staff:**
June 23-25, 2004
Denver, Colorado
- **Research Society on Alcoholism Conference**
June 26-30, 2004
Vancouver, Canada
- **Composite International Diagnostic Interview (CIDI) Training:**
June 28, 2004: 9am-5pm
Paul Howard Room, Admin. Building, McLean Hospital
June 29, 2004: 9am-5pm
Brain Imaging Center, Room 188, McLean Hospital
- **CTN 0020 National Training for Job Seekers Workshop Interventionists:**
June 28-30, 2004
Cambridge, Massachusetts
- **CTN 0020 National Training for Research Staff:**
July 13-16, 2004
Portland, Oregon

Research Society on Alcoholism Conference

June 26th-30th: Vancouver, Canada

The 27th Annual Meeting for the Research Society on Alcoholism (RSA) will convene on June 26th-30th in Vancouver, Canada. The following researchers from the Northern New England node will be making presentations:

- Dr. Alan Shields: *Characterizing the reliability of scores among alcohol screening tools via meta-analytic integration* (June 29th)
- Dr. Alan Shields: *Reliability reporting practices among alcohol screening tools in published reports* (June 29th)
- Dr. David Gastfriend: *A Phase III Study of Vivitrex® (Naltrexone for Injectable Suspension) in Alcohol-Dependent Adults*
- Dr. David Gastfriend: *Developing a Baseline Assessment Battery: Balancing Patient Time Burden with Essential Clinical and Research Monitoring*
- Dr. Joseph LoCastro and Dr. Domenic Ciraulo: *The Atypical Antipsychotic Quetiapine for the Treatment of Alcohol Dependence*

David Gastfriend's Treatment Matching Book



Dr. David Gastfriend (Massachusetts General Hospital/Harvard Medical School) is the editor of a recently released book entitled, "Addiction Treatment Matching: Research Foundations of the American Society of Addiction Medicine (ASAM) Criteria" published by the Haworth Medical Press. Dr. Gastfriend is chair of the CTN treatment matching interest group and is working on a Treatment Matching concept for a future CTN protocol.



CTP News



CAB Health & Recovery Services

By Michael Levy/CAB Health & Recovery Services

AdCare Hospital

By Patrice Muchowski/AdCare

CDC Grant Award

CAB Health & Recovery Services was just awarded a grant through the Center for Disease Control to decrease the incidence of HIV/AIDS. The grant is for five years and the funding will be used to provide prevention case management to individuals at very high risk for HIV. Prevention case management will be provided to homeless women who are living in temporary housing and to women who are initially engaged through CAB's current street outreach activities.

Workshops and Meetings

Michael Levy gave a two-day workshop at the New England Institute of Addiction Studies Summer School in Vermont on June 14th-15th, 2004. The workshop was on Assessment and Treatment of clients with co-occurring disorders.

Michael Levy was also invited to the Center for Substance Abuse Treatment's Partners for Recovery Workforce Development Meeting of Clinical Directors and Supervisors in Washington on May 19th.

AdCare Hospital recently completed a five-day JCAHO Survey which involved the new patient tracer methodology. The survey was focused on current direct patient care activities and how such treatment flows throughout the organization. This required much more involvement from staff than during previous surveys. AdCare is happy to report that the survey went extremely well, and that it resulted in three minor recommendations.

In other news, the Boston AdCare Outpatient staff has officially begun the Patient Feedback study. Staff is very excited. Finally, AdCare Educational Institute was recently awarded a five-year contract from the Bureau of Substance Abuse to continue to provide training for Bureau and Department of Public Health funded programs.

SSTAR

By Nancy Paull/SSTAR

On Saturday, May 22nd, SSTAR hosted a physician training in conjunction with the American Society of Addiction Medicine. The training, *Buprenorphine & Office Based Treatment of Opioid Dependence*, was held in the SSTAR Ambulatory Clinic's new state-of-the-art training center. Approximately 50 physicians from New England & New York attended the eight-hour training, that will entitle them to apply for a DATA 2000 waiver. SSTAR psychiatrist Dr. Greg Etter was one of the presenters.

What is the Clinical Trials Network?

The National Institute on Drug Abuse (NIDA) Clinical Trials Network mission is twofold:

- 1. Conduct studies of behavioral, pharmacological, and integrated behavioral and pharmacological treatment interventions of therapeutic effect in rigorous, multisite clinical trials to determine effectiveness across a broad range of community-based treatment settings and diversified patient populations; and*
 - 2. Transfer the research results to physicians, providers, and their patients to improve the quality of drug abuse treatment throughout the country using science as the vehicle.*
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Clinical Trials Network Dissemination Library



The door to the new **CTN Dissemination Library** is open! The Library is a digital repository of documents created for and about the NIDA Clinical Trials Network, with articles, presentations, manuals, and other documents. Its purpose is to provide a single point of access to research findings and other materials that are *approved for dissemination* throughout the CTN and to the larger community of providers, researchers, and policy-makers. This last point differentiates the contents of the Dissemination Library from Livelink, which contains many internal documents not intended for use outside of the CTN.

The Library is web-based, and includes a catalog with descriptive records for each item in the Library. It can be searched by author, subject keyword, source, date, CTN Protocol, Node, CTP, and a number of other indexes. Other features include a 'What's New' page, and links to relevant Web Resources and CTN Policies.



The CTN Dissemination Library is located at the following URL: <http://lib.adai.washington.edu/ctnlib>.

The Library opened with only a few documents, so Lead Investigators and Sub/Committee Chairs are encouraged to submit new items to be added to the collection. Send electronic copies (in Word, PDF, PPT or other formats) to ctnlib@adai.washington.edu. Librarians Nancy Sutherland and Meg Brunner can answer questions and help put your work into the Library. Updates about documents added to the Dissemination Library will appear regularly in future issues of the CTN Bulletin.

CTN Northern New England Training Sessions

By Scott Boruchow/McLean Hospital



On Monday, May 3rd, CTN staff from McLean, SSTAR, and CAB Health & Recovery Services attended the Good Research Practice Training Session at McLean Hospital, led by Jennifer Sharpe Potter, Ph.D., M.P.H. The training was intended to provide a guiding framework for CTN staff members to follow while conducting research. In addition, the Common Assessment Battery training sessions are currently in progress.

CTN-certified trainer Alan Shields, Ph.D. conducted a two-day workshop at McLean on preparing staff to administer the Addiction Severity Index. Dr. Shields also held a Risk Behavior Survey (RBS) training session at McLean Hospital on June 7th, 2004. Upcoming CAB training events aim to certify staff to conduct the Composite International Diagnostic Interview (CIDI), and will take place June 28th and 29th at Mclean.



Protocol Updates

CTN-0008 **Baseline Survey**

This study, implemented in May 2003 at the Northern New England node, has been completed. The Regional Research and Training Center (RRTC) is finalizing a preliminary report containing basic findings, which will be disseminated on June 1st, 2004. Additional data will be distributed as it is released by the lead node.~

CTN-0012 **Infections & Substance Abuse**

This is a cross-sectional, exploratory survey of CTP attributes regarding the spectrum of care delivered for HIV/AIDS, HCV, and STIs that began in our node in September 2003. Two respondent groups, chief administrators and front-line clinicians, from each CTP have been surveyed with regards to opinions, policies, procedures, patient characteristics, staffing, and funding at the individual clinic level. After 10 months of survey distribution and completion, CTN-0012 within the Northern New England Node is set to close on June 15th, 2004. To date, the CTP administrator response rate has been 100% and over 80% for CTP clinicians. Excellent work!

Data gathering will likely be complete within the next six months across nodes and the findings of this study will be used to describe current practices and fuel hypotheses for health services research, health outcome studies, and other scientific endeavors.~

CTN-0016 **Patient Feedback**

Patient Feedback officially kicked off on March 22nd with the collection of attendance data at AdCare Hospital's Outpatient clinic in Boston. Participating clinicians began the distribution of feedback surveys to their group members the week of April 26th. The feedback surveys consist of seven items designed to measure therapeutic alliance, as well as items measuring demographics and substance use. Both individual and clinic-wide reports detailing data from the feedback surveys are available, and response rates to-date look promising: response rates for the first two weeks of data collection average 91%. During the first team meeting at the end of May, clinicians as well as the local PI's and the clinic supervisor discussed strategies to make any potential improvements in the treatment they provide.~

CTN-0017 **HIV/HCV Interventions**

CTPs for this study have received IRB approval and are on schedule according to the lead node's recommended timeline for implementation. Thanks to the hard work of the CTP directors and staff, the target start date for this study is August 1st, 2004.

CTP staff are currently in the process of completing CTN Common Assessment Battery training in preparation for two national training sessions in Denver, Colorado. The first of these sessions, which took place on June 2-4, is for the Counseling and Education (C&E) and Therapeutic Alliance (TA) interventionists. The second session, on June 23-25, is for research staff. Training with the NKI data team is scheduled for summer of 2004.~

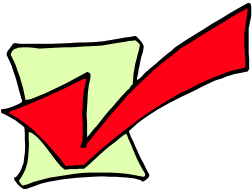
CTN-0020 **Job Seekers**

This study examines whether additional occupational training helps outpatient drug users find and maintain employment. Sites are on track according to the lead node's recommended timeline for implementation, and CTPs have received IRB approval (amendments in progress). At present, the target start date is September 1st, 2004.

CTP staff are currently being trained on the CTN Common Assessment Battery, and will be attending one of two national trainings. The first, on June 28-30 in Cambridge, Massachusetts, is for clinicians in the experimental condition who will be implementing Job Seekers' Workshop with their clients. The second training, on July 13-14 in Portland, Oregon, is for research staff associated with this study. Training with the NKI data team is scheduled for summer 2004.~



Quality Assurance Update



Scott Provost recently became Chair of the CTN Quality Assurance Subcommittee's Administration Workgroup during the January 2004 Steering Committee Meeting in Tucson, Arizona. The QAS Administration Workgroup is charged with developing procedures for analyzing Quality Assurance-related processes throughout the CTN and maintaining a system for organizing QAS documents on Livelink.

Biopharmaceutical Research Consultants, Inc. (BRCI) Update

Biopharmaceutical Research Consultants, Inc. (BRCI), of Ann Arbor, MI, is the company contracted by NIDA for providing external Quality Assurance Monitoring for the Clinical Trials Network. Scott Bailey from BRCI has been assigned to cover the Northern New England Node and will be conducting site initiation visits for CTN protocols starting at SSTAR and CAB Health and Recovery Services, Inc.

Conference Information

AHRQ TRIP Conference

By Scott Provost/McLean Hospital

Dr. Patrice Muchowski (AdCare Hospital) was part of a team led by Dr. Robert Forman (Delaware Valley Node) that submitted a presentation proposal for the upcoming conference, "Translating Research Into Practice (TRIP): Advancing Excellence from Discovery to Delivery" sponsored by the U.S. Agency for Healthcare Research and Quality (AHRQ) in Washington, D.C., July 12-14, 2004. The AHRQ TRIP conference examined the state-of-the-art and next horizons in implementing research in clinical practice and health policy. Dr. Forman's proposal described the clinical and quality improvement implications of the performance monitoring and feedback system examined in the Patient Feedback Protocol (CTN-0016) for improving engagement and attendance in outpatient addiction treatment.

Dr. Michael Levy (CAB, Inc.) was also involved in the development of a proposal for the AHRQ TRIP conference along with Dr. Joseph Gudysh (California/Arizona Node) and Ray Daw (Southwest Node), reviewing strategies to encourage adoption of evidence based practices in substance abuse treatment.



Harvard Medical School Addictions Conference

By Scott Provost/McLean Hospital

A number of node members attended the 27th annual Harvard Medical School/Cambridge Hospital Addictions Conference at the Park Plaza Hotel in Boston, MA on March 5-6, 2004. Two researchers affiliated with the Northern New England Node were presenters at the conference, including Dr. Dominic A. Ciraulo (Boston University) and Dr. David R. Gastfriend (Massachusetts General Hospital/Harvard Medical School). Dr. Gastfriend, chair of the CTN Treatment Matching Interest Group, delivered a presentation entitled, "Patient Treatment Matching: What Works for Whom and Why", which focused on the clinical and policy implications resulting from his research examining the ASAM placement criteria.



Clinician Tips

Beginning with this edition of the Northern New Englander, we will include a section on “Clinician Tips” that we hope you will find useful. The goal of this section is to provide new materials to clinicians that work with clients in group sessions. Please feel free to send us feedback or suggestions for future topics!

Drink/Drug Refusal Training

One of the most disturbing circumstances the newly recovering person can find him or herself in, is having to turn down drinks or the opportunity to use drugs. Too many people have relapsed into their addictions because they had not properly prepared themselves for how they would handle this type of situation.



Refusing drinks/drugs can actually be simple. Remember these points:

1. You do not have to give any explanation why you are not drinking/using drugs.
2. You can turn down the offer to drink or use drugs by simply saying:

“No thanks, not today.”

You do not have to tell them about your alcoholism/addiction. Chances are they would not understand.

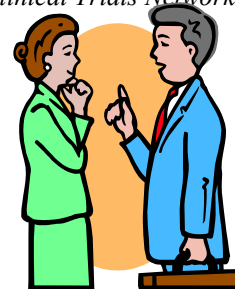
- Remove yourself from the situation as soon as possible. There’s no need to prove anything to anyone – don’t leave yourself in dangerous situations. Even if you don’t drink or use drugs, simply being around people who are drinking/using may cause you unnecessary discomfort.
- Avoid trouble altogether. If at all possible, don’t place yourself in situations where drinking/drug use is taking place. A long time ago someone said: “I can resist anything except temptation!” Don’t go to slippery places if you don’t want to slip.

Group Exercise:

1. Have the group count off by 2s (“1, 2, 1, 2...”).
2. Begin with the “1s” offering a drink or drug to the “2s”. The “1s” should “set the stage;” in other words, they should find out from the “2s”:
 - What would you be offered? (e.g., beer, coke, pot)
 - Who would offer you the drink/drug?
 - Where would you be?
 - Who else might be there?
3. Once the “stage” has been set, the “1s” should begin a conversation with the “2s” by offering him/her a drink or drug (depending upon what would normally be offered). The “2s” get to practice saying “no”. After 5 minutes, switch roles (“2s” first find out from the “1s” how to set the “stage”).
4. After both “1s” and “2s” have had a chance to practice, discuss how you felt about refusing.



ATTC-NE Science to Service Library



In the 2003 fiscal year, the National Institute on Drug Abuse partnered with the national Addiction Technology Transfer Center (ATTC) network to improve the dissemination of addiction research to the treatment field. The goal of the project is to build on NIDA's efforts within the Clinical Trials Network to enhance the transfer of science to chemical dependency treatment providers.

ATTC-NE Principle Investigator/Project Director Susan Storti, Ph.D., R.N., and ATTC-NE/NIDA Liaison, Stephen J. Gumbley, M.A., L.C.D.P. designed a two-pronged pilot project to diffuse evidence-based treatment practices throughout New England, based on a number of foundational concepts. The goals of these efforts are to:

- Facilitate a change *initiative* involving a three tiered approach – individual, agency and system; to build an *infrastructure* that will support on-going adoption of evidence-based practices [EBPs]
- Focus on technology transfer *process* rather than a particular evidence-based practice
- Facilitate *bi-directional communication* between provider agencies and researchers
- Provide *post-exposure support* through consultation with ATTC-NE trained Technology Transfer Specialist

From the beginning, our belief has been that we would best serve the system if, rather than focusing on teaching specific evidence-based interventions, we focused on helping agencies learn the “how to” of adoption. This has been a difficult sell: many agencies and practitioners seem to assume that if they learn the particulars of the intervention, the adoption process “just happens” by itself.

Using a technology transfer model articulated by Dwayne Simpson, Ph.D., the ATTC-NE developed a New-England-wide initiative (the Science to Service Laboratory [SSL]) and a state-specific pilot program in Rhode Island. Simpson's model identifies four stages of technology transfer: exposure, adoption, implementation and practice.

As an important part of facilitating bi-directional communication between the researcher and the treatment community, we contracted with Nancy Petry, Ph.D. to provide training to the participating agencies in both projects. Based on her extensive research, she taught the details of Contingency Management [CM] so that the agencies could actually practice the implementation process by adopting a specific intervention.

In both the SSL and the state-specific model, we worked with six agencies. The SSL began with a four-day training at the 2003 New England Advanced School of Addiction Studies, where three participants from each of the six agencies received information (exposure stage) on the technology transfer process and contingency management. Participants then developed plans (adoption stage) around the use of the CM intervention within their treatment setting. The ATTC-NE hired experienced clinicians/trainers to be Technology Transfer Specialists. They participated in the 4-day training and provided on-going support to the agencies following the initial exposure trainings (implementation stage). Coincidentally, Dr. Petry engaged five of the six agencies in another NIDA-funded research project on the adoption of CM in community agencies.

The state-specific project in Rhode Island had similar efforts, with the ATTC-NE/NIDA Liaison acting as the Technology Transfer Specialist for the six agencies. A significant difference was that these agencies met frequently as a group which, based on participant report, has had a beneficial effect on the implementation process. This was also a cost-effective strategy to providing consultative support.

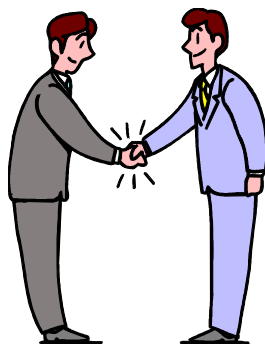
Both projects are currently in process; the ATTC-NE and the agencies have learned important lessons throughout the project. Some of these lessons have affected the new design for this year's Science to Service Laboratory which will focus on training Technology Transfer Specialists rather than agencies. This change is in line with the ATTC-NE's goal of developing a regional infrastructure to support on-going and diverse efforts to enhance the adoption of evidence-based treatment interventions.

For further information on this project, contact Mr. Gumbley at Stephen_Gumbley@brown.edu (401-444-1892) or Dr. Storti at Susan_Storti@brown.edu (401-444-1805).



New Faces/ New People

Researchers at CTN's Northern New England node have begun collaborating with staff at Stanley Street Treatment and Resources (SSTAR), a CTP with participating locations in Fall River, MA, and North Kingstown, RI. We would like to take this opportunity to welcome and recognize the following staff at SSTAR:



- ◇ **Michelle Rapoza:** Study Site Coordinator for both Fall River and Rhode Island locations
- ◇ **Bob Hitt:** Supervisor covering both Fall River and Rhode Island for the Counseling & Education Intervention arm of CTN-0017
- ◇ **Ula Ward:** Supervisor in Fall River for the Therapeutic Alliance arm of CTN-0017
- ◇ **Claire Smith:** Supervisor in Rhode Island for the Therapeutic Alliance arm of CTN-0017
- ◇ **Jonathan Paull:** Research Assistant at SSTAR Fall River
- ◇ **Maryann Sullivan:** Research Assistant at SSTAR Fall River
- ◇ **Chuck Sullivan:** Research Assistant at SSTAR Rhode Island
- ◇ **John Bois:** Research Assistant at SSTAR Rhode Island

In addition, the Northern New England node welcomes the following new staff at McLean Hospital:

- ◇ **Kate DellaPorta:** Research Assistant for CTN 0020 (Job Seekers Protocol)
- ◇ **Kate Szilagyi:** Research Assistant for CTN 0017 (HIV/HCV Interventions) and CTN 0020 (Job Seekers Protocol)

Call for Submissions: "Notes From The Field"

Upcoming editions of the Northern New Englander will include "Notes from the Field." This new section of the newsletter is intended to be a forum for CTN clinicians to share and benefit from each others' ideas, knowledge and experiences. Any interested readers should submit a few paragraphs to Marge Maxwell at: mmaxwell@mclean.harvard.edu.

Northern New England Node Webpage

The Northern New England Node now has a website! This site provides information about the Clinical Trials Network, the Northern New England Node and its affiliated Community Treatment Programs, and contact information for node staff. It also provides updates on current research protocols, a list of publications and presentations, and contains links to other CTN-related websites, including a link to the portal for the Northern New England folder on Livelink. Visitors can also access the online version of the NNE Newsletter.

The node's website is located at the following URL: <http://www.mclean.harvard.edu/research/clinicalunit/adatp/ctn.php>.

Glossary of CTN Terms

- **Clinical Trials:** A clinical trial is a research study that aims to answer specific questions about new treatments or vaccines for a health-related condition such as drug addiction. Clinical trials are used to determine whether new drugs or treatments are both safe and effective. Clinical trials are also used to determine the best way to use a standard treatment.
- **Community Treatment Programs (CTPs):** Each RRTC is affiliated with five to eight Community Treatment Programs. The Northern New England Node RRTC works in collaboration with five CTPs: AdCare Hospital in Worcester, Massachusetts; Center for Addictive Behaviors (CAB) Health and Recovery Services, Inc. in Danvers, Massachusetts; Faulkner Hospital's Addiction Recovery Program (ARP) in Jamaica Plain, Massachusetts; Mercy Recovery Center, Westbrook, Maine; and Stanley Street Treatment and Resources (SSTAR) in Fall River, Massachusetts.
- **Protocols:** All clinical trials are based on a set of rules called a protocol, which describes what types of people may participate, the schedule and doses of the treatment, and the length of the study.
- **Node:** The combination of a RRTC and the CTPs associated with the RRTC. The CTN currently has 17 Nodes.
- **Regional Research and Training Center (RRTC):** RRTC refers to the academic research center within the Node. The Northern New England Node RRTC is based out of McLean Hospital. The Northern New England RRTC works in collaboration with its affiliated Community Treatment Programs and with the other nodes in the CTN. ~