CTN 0021

Motivational Enhancement Treatment to Improve Treatment Engagement and Outcome for Spanish-Speaking Individuals Seeking Treatment for Substance Abuse (METS)

Sponsor: **National Institute on Drug Abuse, Center for the Clinical Trials Network**

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Preface

This is the first CTN protocol to be conducted with a Spanish-speaking population and represents the combined efforts of NIDA, the Florida and New England Nodes, and the participating CTPs. This protocol is in most ways identical to CTN-004, (Motivational Enhancement Treatment to Improve Treatment Engagement and Outcome in Subjects Seeking Treatment for Substance Abuse). Minor adaptations have been made (and indicated in blue text) in order to deliver the treatments and collect data with Spanish-speaking populations. Because of the complexities of conducting a bilingual protocol within the Network, the following is a brief summary of how language issues will be handled.

Issue	***Strategy***	***Language and translation requirements***
Treatment	Treatment will be conducted in Spanish by bilingual counselors (MET and TAU).	• Therapists will be bilingual. • Sections of the MET manual translated into Spanish • PFF and patients worksheets translated into Spanish
Certification and supervision of therapists	Bilingual Node MET experts or CTP supervisors will review and rate session tapes and provide supervision to MET therapists	• Participating Nodes should identify a MET expert or CTP trainer who is bilingual
Supervision	Supervision may be conducted in English or Spanish, depending on the preferences of the CTP supervisor and therapist	•
Tape rating (independent assessment of adherence and competence)	Bilingual tape raters will be trained to reliability rate the instrument using session tapes from both the English and Spanish versions	• Bilingual tape raters will be trained to reliably rate session tapes in both the English (004) and Spanish versions of the MET (0021) protocol
Assessments, CRFs	Most forms has been translated into Spanish; all forms will be administered to participants in Spanish	• Research assistants will be bilingual.
Data management	DMCs participating in this protocol that do not have Spanish-speaking staff should: • Not add any CRFs to the battery that have open-ended questions • Be sure to follow the data dictionaries that are in both English and Spanish • Allow extra resources during active study phase for data monitoring. • Allow extra resources during system start up for handling "different" system. • All back end CRF information will be in English to allow the DMC to audit. • All CRFs will have a field/variable labeled "source document language" with a response code of English or Spanish.	• Data managers need not be bilingual
Quality assurance,	CRFs will show English and Spanish versions.	• Research assistants must be

monitoring	Progress notes and other documentation will be in English	bilingual, but this will not be necessary for QA and monitoring staff.
Regulatory	Consent forms will be in Spanish	• Consent forms have been translated into Spanish; local IRBs may review Spanish and/or English version • Spanish and English versions of Confidentiality Certificate will be obtained

1. Significance

Early dropout, partial attendance and early relapse are common occurrences in most substance abuse treatment programs. Given that (1) the bulk of attrition occurs very early in treatment and (2) retention in treatment has been linked to better outcome in several studies (Ball & Ross, 1991; McLellan et al., 1994; Simpson et al., 1997), identifying effective, practical means of enhancing initial treatment engagement and outcome is an important target for the Clinical Trials Network.

Hispanics are the fastest growing ethnic group in America, and already the largest minority group (US Census Bureau, 2000). Moreover, Hispanics, particularly those whose primary language is Spanish are routinely excluded from a number of clinical trials and are underrepresented in both clinical and research populations (Collins, 1993; Wells et al., 2001; Williams et al. 1996). Therefore, little is known about what treatments work with Hispanic drug users. An important goal of the CTN is to evaluate the effectiveness of treatments with demonstrated efficacy in underrepresented and underserved populations. The unique resources of the CTN will make it possible to evaluate the efficacy of Motivational Enhancement Therapy in Spanish-speaking individuals seeking outpatient treatment for a range of substance use disorders, through an adaptation of an ongoing CTN protocol (004).

This protocol is appropriate for the CTN because:

1. MET is applicable to a broad range of participants and CTPs, including those who treat Hispanic and Latino populations whose primary language is Spanish. The underlying theory of MET and specific interventions are appropriate for a range of Hispanic populations.
2. Multiple trials of MET and closely related approaches with substance using populations have supported its efficacy and durability.
3. There are adequate resources within the CTN to conduct a study where MET treatment is provided in Spanish and compared with standard treatment for Spanish-speaking populations. This includes the availability of Spanish-speaking therapists and research assistants in at least 3 CTPs and in three different Nodes.
4. Provision of training in MET has been identified as attractive to CTP staff members.
5. The focus on brief treatments and initial treatment engagement will allow for the study to be completed comparatively rapidly (e.g., within 1 year). This offers the advantage of rapid dissemination of findings to the academic and clinical communities.
6. The design is simple, straightforward and likely to be feasible within several clinics where Spanish-speaking individuals receive treatment for substance use disorders.
7. This study would be one of the first multisite trials in the United States to address the efficacy of standard and novel treatments when provided entirely in Spanish.
8. This protocol would generate important data about the nature of 'standard treatment' as implemented in CTPs who treat Spanish-speaking individuals and thus set the stage for

future trials evaluating behavioral and pharmacologic treatments with Spanish-speaking individuals.

2. Rationale

Scarcity of Outpatient Treatment Outcome Studies for Substance Abusing Hispanic Adults

Little is known regarding the effectiveness of drug abuse treatment for Hispanic populations. A thorough review of the empirical literature from the past two decades yielded no studies evaluating the effectiveness of outpatient treatment interventions for adult Hispanic clients. Specifically, we examined the PsycINFO and Medline databases from January 1982 to April 2002 searching for the following terms: "treatment", "outcome", "drug", "abuse", "Hispanic", "Latino". Our search was limited to journal articles, book chapter, authored or edited books. Thirty-four records were found in Medline, whereas 184 records were found in PsycINFO, none of which pertained to treatment outcome studies for outpatient substance abuse treatment for Hispanic adults. Most of the literature on adult substance abuse in Hispanic populations involves epidemiological studies and clinical accounts on client characteristics, prevalence of drug use, and cultural considerations for treatment with this population.

Hispanic Adults in Substance Abuse Treatment

Research on drug abuse treatment with Hispanics has documented perceptions about substance use and poor motivation for therapy in this minority group that may hinder participation in substance abuse treatment. Specifically, drug abusing Mexican-Americans have been found to be less likely than Caucasians to say that they need drug abuse treatment and to be more likely to say that they could quit using drugs without help (Longshore, Hsieh, Anglin, Annon, 1992; Longshore, Hsieh, & Anglin, 1993). Similarly, drug abusing Puerto Ricans were found to be more likely than Caucasians and African-Americans to deny a drug problem (Kline, 1996). In addition, when Hispanics do enroll in treatment, they are more likely to dropout. Agosti and colleagues (1996) found that dropout rates among cocaine abusers in outpatient treatment programs were higher among Hispanics than among Caucasian clients. Thus, interventions are needed for Hispanic adult substance abusers to recognize their need for treatment.

Factors that Influence Treatment Enrollment and Attendance of Hispanic Adult Clients

The few studies that are available would suggest that certain factors improve treatment motivation and retention in Hispanic populations. In Mexican Americans, treatment motivation, measured by eight items about the client's willingness to participate in treatment, was improved when clients recognized that using drugs lead them to experience interpersonal problems (Longshore, 1997). In another study, where over one third of the sample was Mexican American, greater pretreatment motivation, measured by the client's problem recognition, desire for help, and treatment readiness before the intake interview, predicted increased session attendance (Simpson et al., 1997). These findings suggest that substance-abusing Hispanics may increase treatment participation if motivation for treatment is increased.

Initial support for MET as an intervention for general and Hispanic populations

One intervention that may be useful with Hispanic adults to engage them into treatment and improve treatment retention may be Motivational Enhancement Therapy (MET). Although its efficacy has not been examined in a large sample of Hispanics, preliminary support for this intervention has been shown in a multisite study including a small number of Hispanics (Babor et al., 1999). Based on the treatment needs of Hispanic substance abusers discussed before, MET, may be a promising intervention to increase Hispanic clients' commitment to change and to reduce their resistance to entering treatment.

Motivational Enhancement Therapy (MET) has a high level of empirical support as an effective, durable treatment for alcohol use disorders and smoking (Bien, Miller & Tonigan, 1993; Babor, 1994; Project MATCH Research Group, 1997; Wilk et al., 1997). Given the comparatively high severity of drug abusing participants, it is unlikely that this typically brief (3-4 session) approach will be sufficient treatment for many treatment-seeking drug-dependent individuals. Instead, MET techniques might be integrated into the early (orientation/ entry/stabilization) phase of drug abuse treatment as a strategy to enhance initial retention and outcome.

Several recent studies have suggested the effectiveness of brief motivational approaches for enhancing engagement among drug abusing populations. For example, Saunders and colleagues (1995) reported that a single session of motivational interviewing for participants entering a methadone maintenance program had greater commitment to abstinence and fewer opioid-related problems over a 6-month follow up period. Both Swanson and colleagues (1999) and Martino and colleagues (2000) reported that a single session of motivational interviewing was associated with better treatment compliance and retention for dual-diagnosis participants compared with treatment as usual in inpatient and day treatment settings, respectively. A multisite trial of 450 marijuana-dependent participants found that 2 sessions of MET was significantly more effective than a delayed-treatment control condition in reducing marijuana use and related outcomes (Babor et al, 1999). A study conducted in a community treatment program found that a single session of MET, delivered by the CTPs staff members who received only brief (single day) training, doubled the rate of treatment initiation compared to the standard evaluation among drug-abusing parents referred to treatment through the child protection system (Carroll, Libby, Sheehan et al., 2001).

Although MET has been shown to be effective in a wide number of populations, its efficacy has not been evaluated in monolingual Spanish-speaking populations or individuals who are bilingual but whose primary language is Spanish. A large multisite study evaluating behavioral treatments for marijuana dependence that included a comparatively large number of bilingual Hispanic individuals (approximately 80 or 17% of the full study population) found (1) good evidence for the efficacy of MET with this population and (2) no differences in outcome by ethnic category (Babor et al., under review).

3. Study Objectives

Primary objectives:

A. To evaluate the efficacy of MET, relative to standard treatment at the participating CTPs, in enhancing treatment engagement and retention as well as in reducing substance use in a sample of Spanish-speaking individuals seeking outpatient treatment for substance use disorders.
B. To evaluate the durability of MET relative to standard treatment at the CTPs through a 3-month follow-up in this population.

Secondary objectives:

A. To explore participant characteristics associated with outcome, as a preliminary step toward understanding the types of participants particularly suited for MET versus those for whom standard treatment is sufficient.
B. To evaluate the ability of clinicians at the CTPs to learn and effectively implement MET techniques.
C. To conduct process analyses which will seek to :(1) assess the discriminability and specificity of each of the treatment approaches, (2) evaluate process (e.g., therapeutic alliance, therapist adherence, therapist skill) and outcome (e.g., participant satisfaction level, participant motivation) measures that relate to successful treatment engagement, retention, and outcome, and (3) to characterize the nature of standard treatment provided at the participating CTPs.
D. To evaluate whether there are systematic differences in outcome, compliance, or process for the Spanish version of the MET protocol compared with the version delivered in English.

4. Study Design

A. Overview of study design

This is a randomized, two arm study comparing individual MET to 'standard treatment" for individuals seeking substance abuse treatment. Spanish-speaking participants at the participating CTPs will be randomly assigned to either 'standard' or "MET" treatment, both delivered in Spanish by bilingual therapists, with a 1- and 3-month follow-up. Primary outcome measures will include (1) treatment retention (e.g., number of weeks in treatment), and (2) substance use (e.g., days of substance use, as confirmed by urinalysis, during the treatment and follow-up period). Secondary outcomes will include motivation, psychosocial functioning, HIV risk behaviors, treatment utilization, and participant satisfaction. Process assessments will include measures of the working alliance as well as therapist adherence and competence ratings. Assessments will also be conducted in Spanish by bilingual research assistants.

This protocol is intended for CTPs that treat large numbers of Spanish-speaking individuals, and where individuals seeking treatment receive several individual sessions, conducted in Spanish, as part of the early phase of treatment. Following initial assessment, participants will be randomized to either 3 sessions of individual standard treatment or 3 sessions of individual Motivational Enhancement Therapy.

B. Participating CTPs

1. CTP characteristics

CTPs participating in this protocol should:

- Deliver treatment in a, non-methadone-maintenance setting.
- Treat large numbers of monolingual Spanish or individuals whose primary language is Spanish patients to meet target recruitment goals (e.g., 80 participants per CTP in approximately one year, or 40 participants per group)
- Have at least 4 bilingual clinicians willing to participate in the protocol (e.g., 2 for MET, 2 for standard treatment)

2. Rationale for CTP selection

We are excluding methadone maintenance (and other agonist treatment) programs because it would be difficult to isolate the effects of any brief behavioral intervention in the context of varying doses of methadone and other interventions typically evaluated with methadone maintenance. Thus, including methadone maintenance programs in this protocol would entail a somewhat different approach (where MET would be used to focus on enhancing compliance and in stabilized patients) and time frame.

Multiple bilingual therapists per condition at each site are needed: (1) to reduce disruptions to the protocol associated with therapist absences (e.g., vacations) or therapist attrition, (2) to reduce scheduling problems and hence delay in assigning participants to clinicians, (3) to reducing the likelihood and magnitude of potential therapist effects, and (4) to permit some exploratory analyses of participant outcome by therapist fidelity or competence levels.

C. Participants

1. Inclusion/exclusion criteria

Individuals will be eligible for the protocol who (see METS Operations Manual for detailed definitions):

a. Are seeking outpatient treatment for any substance use disorder and who have used any substance (cocaine, alcohol, heroin, methamphetamine, marijuana,

benzodiazepines, amphetamines, phencyclidine (PCP), opiates/morphine and barbituates) within the past 28 days.

b. Are 18 years of age or older.
c. Have a sufficiently stable living arrangement.
d. Speak and understand Spanish as their preferred or principal (most commonly spoken) language.
e. Are willing to be randomized to treatment.
f. Are willing to be contacted for follow-up assessments 4 and 12 weeks after treatment ends.
g. Are likely to be in the area for 4 months.
h. Are able to understand and provide written informed consent.

Individuals will be excluded who:

a. Are not sufficiently medically or psychiatrically stable to participate in outpatient treatment. Thus, individuals who have dementia or other organic brain syndromes, who are currently suicidal or have significant suicidal or homicidal ideation, who are facing imminent or likely incarceration for a period of more than 3 weeks, or who has a spouse or close significant other currently participating in the protocol are ineligible, as are individuals who previously participated in the MET protocol.
b. Are seeking detoxification only, methadone maintenance treatment or residential inpatient treatment.

2. Rationale for participant inclusion/exclusion criteria

Broad inclusion criteria are proposed to allow a highly diverse participant sample with a range of substance use and related problems. Participants should be willing and able to participate fully in the protocol (e.g., to accept assignment to either condition, to provide sufficient locator information for follow-up, to allow their treatment sessions to be taped for fidelity/process assessment and supervision). *Participants mandated to treatment **will** be included providing requirements of the protocol and the treatments provided are not incompatible with the conditions of their parole/probation*. Individuals who are not medically or psychiatrically stable (e.g., untreated psychotic disorders, current suicidal or homicidal intent, or those who require detoxification) are excluded because of their need for immediate acute care. Such individuals could be re-evaluated once stabilized, providing stabilization (e.g., acute detoxification) is brief.

3. Feasibility

As of March 2002; four CTPs have indicated they have the necessary resources and are willing to implement this protocol in their clinics. Thus, estimated sample size for this protocol is 320; which, as noted in the section on statistical power below, should be sufficient to address the specific aims.

D. Procedures

1. Initial screening and informed consent.

Individuals seeking outpatient treatment at each of the sites will be offered the opportunity to hear about the protocol using procedures compatible with the standard intake procedures at each CTP. The research assistant will explain the purpose of the study, answer questions, review the consent form, and obtain informed consent from interested individuals. An investigator, sub investigator or their designee should participate in this process OR review all consent forms with the research assistant. If possible, during the same session, the RA will complete the pretreatment assessment battery (see below). Uninterested individuals will be referred to appropriate treatment at the CTP or another agency. The Demographic Form and the Participant Characteristic Form must be completed for all individuals who provide informed consent regardless of whether they meet all inclusion criteria or are randomized.

2. Initial assessment

The research assistant will collect all baseline information from the participant (see section on Assessments, below and Operations Manual). The research assistant will then transfer some of the data collected from the baseline assessment to the Personal Feedback Form for those participants assigned to MET.

3. Randomization

To increase the likelihood that treatment groups are balanced with respect to demographic and key prognostic variables (e.g., gender, education, motivation, principal drug of abuse, whether individual was mandated to treatment), participants will be assigned to treatment conditions through urn randomization. In urn randomization, an algorithm modifies ongoing randomization probabilities based on prior composition of treatment groups, maximizing multivariate equivalence of treatment groups (Stout et al., 1994). Thus, urn randomization offers the benefits of balancing allocation of important prognostic variables in treatment groups, while still retaining other benefits of random assignment (Wei, 1978).

Operationalization of urn variables:

- Gender (male, female)
- Primary drug of abuse (cocaine, methamphetamine, alcohol, opioids, marijuana, benzodiazepene, other) (from ASI lite)
- Mandated to treatment (yes, no)

- Employment status (yes, no)

Urn randomization will take place at the CTP using an Access program (or a comparable procedure using an identical mathematical algorithm) and be done by the research assistant. Data from a sample of 218 alcohol, cocaine, and other drug users in Dr. Jon Morgenstern's recent protocols indicates 88% concordance between participants 'declared' self-reported primary drug problem on the ASI (item 14a) and SCID symptom counts. Because the ASI-lite does not include this item, we will use item DEM008 on the Demographic Form which asks which substance is the major problem (ie. Primary substance of abuse).

4. Treatment phase

Treatment conditions are described in detail below. Study treatments will be delivered in 3 individual sessions in a time 'window' of 28 days from the point of randomization. During this time, participants will meet three times with the clinical evaluator/research assistant for collection of urine and breath specimens, as well as completion of self-report and interview assessments. Participants assigned to either group may also participate in 'regular program activities' as is usual at the CTP (e.g., education or orientation groups, day treatment, intensive outpatient treatment) *provided at least 3 individual sessions are offered* (MET or standard treatment).

Participants will be encouraged to come for treatment and for the evaluation sessions as described in the protocol and the treatment manuals. It will be emphasized to participants during screening that even if they have a relapse they should come to all scheduled appointments. They will be discouraged from using illicit substances, but there will be no protocol-specified penalty for drug use or for missed sessions. Participants who miss scheduled sessions will be encouraged to reschedule them within the 28-day treatment 'window' from the day of randomization.

5. Safety Assessment

Clinical Deterioration: Participants who experience significant clinical deterioration (e.g., suicidal or homicide attempts or significant suicidal or homicidal ideation, significant cognitive or medical deterioration, or significantly increased substance use that requires inpatient treatment or inpatient detoxification) during the 'active' phase of treatment, may require more intensive treatment than the protocol can provide (e.g., hospitalization). In such cases, participants may be regarded as symptomatic failures, withdrawn from the treatment arm of the study, and referred for appropriate treatment at an appropriate facility. *Individuals who experience SAE's and/or those who are withdrawn from treatment due to clinical deterioration should still be interviewed at posttreatment and for follow-ups*

Serious Adverse Events (SAE): Adverse Events will be monitored and logged from the time of randomization through the week 16 follow up. All SAEs requiring expedited reporting will be reported to NIDA/CCTN Medical Monitor, the Lead Node and the Local Node/Site PI within 24 hours of staff notification that an SAE has occurred. Local IRBs must also be informed as per their policy. Initial report should be followed by the full written summary narrative and any accompanying information within 2 weeks of the initial report. Detailed descriptions of AE and SAE reporting are found in the Operations Manual and the AE/SAE reporting plan.

Initial notification of the SAE should be reported to:
NIDA/CCTN Medical Monitor
Phone number: 301-443-6697
Fax Number: 301-443-2317

Kathleen Carroll
Lead Investigator
Phone Number: 203-937-3486 x7403
Fax Number: 860-704-6194

Participating Node PI and Project Coordinator

DSMB: An independent CTN Data and Safety Monitoring Board (DSMB) will examine accumulating data to assure protection of subject's safety while study's scientific goals are met. The CTN DSMB is responsible for conducting periodic reviews of accumulating safety and efficacy data in accordance with the interim analysis plan or established procedures. The DSMB will review data independently from the study sponsor, investigator(s), and IRBs, to determine whether the accumulating data support continuing the trial, whether study procedures should be changed, or whether the trial should be halted, for reasons relating to the safety of the study subjects, the efficacy of the treatment under study, or inadequate trial performance (e.g., poor recruitment of subjects).

Study Medical Monitor: A study medical monitor, or the PI in consultation with a medical monitor, will review all SAEs and provide an assessment of its relatedness to the study intervention. In Addition, NIDA will appoint a medical safety officer to the study to review the safety data, expedite DSMB review and notify all participating IRBs (via Node PI) when necessary. Serious Adverse Events will be reported and handled as defined by current CTN policy.

6. Termination and follow-up

a. At the end of the 28 day treatment period, all participants will be interviewed by the research assistant, who will complete posttreatment assessments as described below and in the Operations Manual.

b. Follow-up interviews will be conducted 4 and 12 weeks after termination of study treatments (e.g., 8 and 16 weeks after randomization). Follow-up interviews will include the full posttreatment battery. A one-month follow-up is included to enhance rates of follow up by contacting participants soon after treatment termination. Because the protocol is designed to focus on strategies for enhancing initial engagement and retention, a 12-week follow-up should be sufficient.

Treatment involvement and follow-up

The MET protocols are using the intention-to-treat principle, that is, we will contact all participants for all follow-ups (posttreatment, FU1, FU2), regardless of their level of participation in study treatments. It may be helpful to remind participants that, even if they decide for some reason to drop out of treatment or not receive their sessions, we will still be interested in reaching them for follow-up interviews.

Thus, once a participant is randomized, that participant should be contacted for posttreatment interviews (28 days) and all follow-ups, *even if they do not receive a single session* of their study treatment (MET or standard treatment).

Also, in the MET protocol, partial involvement is permissible. That is, following randomization, participants have 28 days to receive their 3 sessions. If they only receive 0, 1, or 2 sessions prior to the 28-day point, the posttreatment assessment should still take place at that point as well as the week 8 and week 16 follow-ups.

E. Treatments

1. "Standard treatment" or "Treatment as usual"

Participants assigned to 'standard treatment' would receive three sessions of individual counseling as is usually provided at that CTP, and which should be conducted primarily in Spanish. Other than offering a minimum of three individual sessions over a period of 28 days, standard treatment would not be otherwise constrained or controlled. That is, if it were standard practice at a CTP for patients to attend weekly group sessions in addition to individual counseling, participants in both MET and standard treatment would do so (providing the total number of sessions was equal across conditions and included at least 3 individual sessions of MET or standard counseling). Clinicians providing standard treatment at the sites will meet regularly with a clinical supervisor to review participant progress as is standard at each participating CTP.

As in the MET condition, **all individual sessions will be audiotaped** and a sample will be rated by independent evaluators blind to the participants' treatment assignment for process assessment (see section on process assessment, below). These analyses will address issues such as treatment integrity (e.g., Were MET and standard treatment discriminable? Did

overlap of key MET interventions occur in standard treatment? Was therapist skillfulness different across conditions?) and evaluation of treatment process (e.g., is level of the therapist skill or therapist adherence associated with retention and outcome).

2. Motivational Enhancement Therapy

Grounded in principles of motivational psychology as well as Prochaska and DiClemente's (1992) processes of change theory, Motivational Enhancement Therapy (Miller & Rollnick, 1991 (Miller et al., 1992) incorporates elements found in successful brief intervention strategies, summarized by the acronym FRAMES: **F**eedback regarding personal risk, negative consequences, or impairment related to substance use; emphasis on personal **R**esponsibility to change; the provision of clear **A**dvice to change; presentation of a **M**enu of change options; an **E**mpathic therapist style; and facilitation of the patient's **S**elf-efficacy.

In MET, the clinician seeks to increase the participant's commitment to change their substance use by heightening their awareness of the personal consequences that have resulted from their substance use (e.g., "What bothers you about your substance use?"), expressing empathy ("It must have been difficult for you to come here today"), and avoiding resistance and argumentation ("What you decide to do about your substance use is up to you; if you're willing to go on with the evaluation, we can spend some time talking about how you see the consequences of changing versus not changing your substance use").

Stylistic and technical elements are crucial in MET. The acronym for these skills, OARS, stands for Open questions, Affirmation, Reflective listening and Summaries. These microskills comprise the core of the process of interacting with clients in a motivation enhancing way and can be used at many different stages of the process. They are equally effective with clients from the Precontemplation stage through the Maintenance stage and in both the first and the second phases of motivational interviewing. The OARS are the instruments used by the therapist to move the clients through the change process.

As described in the MET manual (Farentinos, Obert, & Woody, 2000), MET will consist of three carefully planned sessions, with the first session focused on reviewing an individualized Personal Feedback Form, and the second two focused on discussing plans for changing substance use. The Personal Feedback Form will make use of data provided by the participants in their baseline assessment to summarize their view of substance-related problems, consequences, and reasons for quitting. Sections of the manual have been translated into Spanish (therapist/client dialogs, session tasks and key MET terms), to facilitate consistent use of concepts and terms across therapists and CTPs; it is anticipated that a complete version of the MET manual will be available by the end of the protocol.

Personal Feedback Form: A key intervention associated with MET is feedback on consequences of substance use. This occurs during an early MET session (1 or 2) through review of a Personal Feedback Form (PFF), which summarizes objective information (e.g.,

neuropsychological or liver function tests) and the participants' own view of substance use and consequences. Information on negative consequences of substance use will be drawn from the participants' baseline assessment (e.g., sections of the ASI, and the SIP) and summarized by the research assistant on the PFF. All participant worksheets and the PFF have been translated into Spanish.

F. Training, Supervisors, and Therapists

Therapist selection, training, and supervision procedures will be based on those used in previous Stage II multisite behavioral therapy trials (e.g. Crits-Christoph et al., 1998; Carroll et al., 1994; Rounsaville et al, 1983; Woody et al., 1983), but modified to meet the special needs of this protocol and the CTN. This will include a high level of attention to support and ongoing supervision to the therapists (Morgenstern et al., 2001), as well as a Node-centered approach to training and supervision intended to foster greater durability of MET in the CTPs after the trial is completed.

1. METS Supervisor Consultants

a. Selection of METS Supervisor Consultants

To foster greater success and durability of training in METS in the participating CTPs, each participating Node will have one individual *who already has extensive experience in the training, supervision, and/or delivery of motivational interviewing or motivational enhancement therapy serce as the Node's METS Supervisor Consultant*. These clinically experienced individuals together with the CTP supervisors will receive centralized training from the Chief Expert METS Trainer, Dr. Chris Farentinos. Subsequently, they will provide ongoing protocol-focused training, credentialing and consultation to the CTP Supervisors for the duration of this study protocol.

In addition, these individuals will be fully bilingual, because they will be supervising and reviewing sessions conducted in Spanish.

A centralized model for training will be used for the Node METS Supervisor Consultants, CTP Supervisors and CTP Therapists. The purpose of which is to 1) ensure the consistency of training protocols across Nodes and CTPs; 2) provide ongoing supervision and consultation of CTP Supervisors, thereby developing local METS expertise within the CTPs; 3) provide accessible training resources in the event that CTP Supervisor or therapist turnover requires training of new staff.

b. Centralized METS Training

The METS Supervisor Consultants, CTP Supervisors, and CTP therapists will attend a centralized METS training. Before this 2-3 day training meeting, the CTN METS Protocol

Development Team will have distributed the METS treatment manuals. The centralized training will focus on the review of this manual and especially the implementation of a common training curriculum to be used to train the CTP Therapists participating in this protocol. Training will focus extensively on both the stylistic and technical aspects of motivational approaches to substance abusers. The training curriculum developed for the previous CTN MET/MI protocols will be reviewed in detail.

The METS Supervisor Consultants and CTP Supervisors will attend one day of training which will focus specifically on supervising METS as detailed in the treatment manual. The supervisory process and use of the Supervisory Tape Rating Form will also be covered. The procedures and guidelines for providing supervision both during the pilot and randomization phases of the study will be reviewed in detail. In addition to participating in this centralized training, METS Supervisor Consultants and the CTP Supervisors will also attend a two day METS training with the CTP Therapists provided subsequently by the Chief Expert METS Trainer. This training will involve didactic review of motivational interviewing style and techniques, review of videotapes, skill and competency building through completion of several training and role-playing exercises developed by Miller and colleagues.

c. METS Supervisor Consultants role in supervising the CTP Supervisor

Upon returning from the centralized training, the CTP Supervisor will initiate METS treatment with a practice client from their CTP. The METS Supervisor Consultant will review each of the three audio- tapes using the Supervisory Tape Rating Form and begin a supervisory process with the Supervisor that will become a model for how the Supervisor may subsequently work with each of their CTP Therapists. These weekly Supervisor Consultant and Supervisor meetings (face-to-face or phone) should continue through the time that the Supervisor treats a pilot/practice client in order to insure the same level of "credentialing" competence discussed below that is required for Therapists. These meetings should also focus on methods of providing clinical supervision within a manual-guided research protocol, review of the Supervisory Tape Rating Form rating process, and how to use this system to guide the supervision of the CTP Therapists.

The METS Supervisor Consultant's weekly meetings (face-to-face or phone) with the CTP Supervisor should continue while the CTP Therapists are completing their pilot cases and being evaluated for credentialing purposes (see below). During this time, the Supervisor Consultant will review at least one audiotape per therapist using the Supervisory Tape Rating Form with the CTP Supervisor (who will be reviewing all therapists' audiotaped pilot cases) for the purpose of calibrating their ratings. These consultation meetings will also review any supervisory issues the Supervisor is having with the Therapists or more general issues in the implementation of a METS research protocol within an existing clinical operation.

Once the METS Supervisor Consultant and CTP Supervisor determine that all Therapists within a CTP have been 'credentialed' or 'ready' to accept randomized participants, the frequency of phone or face-to-face meetings with the CTP Supervisor will be reduced to a

minimum of at least once a month. The METS Supervisor Consultant will review and rate at least one audiotape prior to this monthly meeting. Each month a different Therapist tape should be rated, except in cases where continued focus is placed on a single Therapist who is showing signs of struggling with protocol compliance.

d. METS Supervisor Consultants Experts Evaluation of Treatment Integrity

A Supervisory Tape Rating Form (using the Tape Rater Guide) is completed by the METS Supervisor Consultant for all pilot/practice cases treated by the CTP Supervisor and at least one session of each pilot/practice case treated by the CTP Therapists. Once all staff are credentialed, the METS Supervisor Consultant reviews one audiotape per month (that has also been rated by the CTP Supervisor) for calibration purposes and to facilitate supervisory consultation with the CTP Supervisor. The STRF instructs the tape reviewer to rate the adherence (frequency and extensiveness) and competence (skill level) with which a Therapist provided prescribed/proscribed interventions within a specific session with a specific research participant based on review of an audiotape. The STRF will be used by the METS Supervisor Consultant during the completion of practice (pilot) cases by CTP Supervisors and Therapists as described above, monthly during the completion of the protocol, and more frequently for clinicians who experience difficulty in adhering to the protocol treatments.

e. 'Credentialing' of Therapists and Supervisors

The METS Supervisor Consultant will 'meet' (face-to-face or phone) with each Supervisor during the time that they and the Therapists are conducting their practice (pilot) sessions. The purpose of these discussions will be to review each practice case, particularly the adherence/competence ratings of specific sessions and provide suggestions on areas of improvement.

Both CTP Therapists and Supervisors will be expected to complete at least three sessions of METS (i.e., typically one METS case) before randomization of participants can begin. The purpose of these practice sessions for the Supervisor is: 1) to insure that supervisors possess sufficient skill as a local METS expert in the therapy they will be supervising; 2) to provide a direct supervisory experience with the METS Supervisor Consultant that may inform the supervisory approach they undertake with the CTP clinicians who will be seeing study participants. The purpose of these practice sessions for Therapists is: 1) to allow an initial try-out of the techniques learned during training under close supervision by the CTP Supervisor and METS Expert Consultant; 2) to insure a level of adherence and competence in following the manual for 'credentialing' purposes.

The METS Supervisor Consultant and CTP Supervisor will listen to the audiotaped practice sessions (as described above) and rate these tapes using the Supervisory Tape Rating Form (with help from the Rating Guide which explains the rating process). The Therapist (and Supervisor) must obtain an average STRF *Frequency and Extensiveness* rating of 'somewhat'

(4) on at least half (5 of 10) of the METS items (i.e., mean of at least 4 for five rated METS items from items 1-10 of the STRF) and all of these rated items need to have a *Skill Level* of at least "adequate" (4). If these criteria are reached for each of the three pilot/practice sessions, then the METS Supervisor Consultant will identify the Therapist (and Supervisor) as 'credentialed' as METS proficient. At this point the CTP Therapists will be 'ready' to accept (or supervise) randomly assigned METS research participants for the protocol. If this minimal credentialing criterion is not achieved on the first practice (pilot) case(s), then additional non-randomized cases will be assigned until the criteria is reached. The CTP Supervisor and METS Supervisor Consultant also will be reviewing and rating the Therapist practice (pilot) audiotapes; this will allow the Supervisor and METS Supervisor Consultant to calibrate their rating decisions and discuss Therapists who are having continued difficulty in the 'credentialing' or 'readiness' process.

f. Supervision of Manual or Protocol "Drifting" Therapists

Primary responsibility for the ongoing supervision of the Therapists rests with the CTP Supervisor except during the pilot or practice case phase of the study, when the Supervisor is away from the clinic for an extended period (greater than two weeks), or when it is decided (jointly by the CTP Supervisor and the METS Supervisor Consultant and Training or Project Coordinator) that a Therapist needs to be removed from the randomization process (see criteria for Re-Piloting Therapists in section below). When this occurs, assuming that the Therapist wants to continue in the protocol, the Supervisor and METS Supervisor Consultant will share responsibilities (when appropriate) for the weekly supervision of the Re-Piloting Therapist while s/he resumes treating one or more practice cases.

g. Summary of the role of the METS Supervisor Consultant:

1) attend the 3 day centralized METS training with other METS Supervisor Consultants and CTP Supervisors, the goal of which is to learn the training protocol and procedures, supervision, and tape rating;

2) have a phone or face-to-face meeting with each CTP Supervisor weekly while s/he and the Therapists are completing practice cases and monthly once cases are randomly assigned;

3) if necessary, provide refresher training for existing staff or initial training for new staff as well as intensified supervision if clinicians are at risk for 'Re-Piloting';

4) rate a sample of METS tapes from each Therapist at the Node for adherence/ competence using the STRF while the study is ongoing to monitor quality and foster greater consistency in treatment delivery across participating Nodes and CTPs

5) serve as a secondary (back-up) Supervisor for CTP Therapists during any CTP Supervisor's extended absence or in cases where it is determined that the CTP Supervisor cannot assume regular supervisory responsibilities or therapists need extra attention.

2. CTP Supervisors

At least one CTP staff from each CTP will serve as a METS Supervisor. Ideally, this Supervisor will be in a clinical leadership position within the CTP, for example, clinical director or coordinator, associate director, or senior therapist. The Supervisor must be willing and have the time to review session audiotapes provided by Therapists, complete adherence/competence ratings on these tapes, keep regularly scheduled individual or small group supervision appointments with Therapists, and have regular phone (or face-to face) meetings with the METS Supervisor Consultant for consultation purposes.

a. Training of CTP Supervisors

The METS CTP Supervisor will participate in the 3 day centralized METS training. Two days of the centralized training will focus on the review of the METS manual, the stylistic and technical aspects of motivational approaches to substance abusers, review of videotapes, role-playing, and implementation issues specific to this METS protocol . One day of training will focus specifically on supervising METS as detailed in the treatment manual. The supervisory process and use of the Supervisory Tape Rating Form will also be covered. The procedures and guidelines for providing supervision both during the pilot and randomization phases of the study will be reviewed in detail.

Upon returning from the centralized training, the CTP Supervisor will initiate METS treatment with a practice client from their CTP. The METS Supervisor Consultant will review each of the three audio- tapes using the Supervisory Tape Rating Form and begin a supervisory process with the Supervisor that will become a model for how the Supervisor may subsequently work with each of their CTP Therapists. These weekly METS Supervisor Consultant and Supervisor meetings (face-to-face or phone) should continue through the time that the Supervisor treats a pilot/practice client in order to insure the same level of "credentialing" competence discussed below that is required for Therapists. These meetings should also focus on methods of providing clinical supervision within a manual-guided research protocol, review of the Supervisory Tape Rating Form rating process, and how to use this system to guide the supervision of the CTP Therapists.

b. Evaluation of Treatment Integrity by CTP Supervisor

A Supervisory Tape Rating Form (using the Tape Rater Guide) is completed by the CTP Supervisor for all of the sessions of the Therapist's pilot/practice cases. Once randomization begins, the CTP Supervisor will rate one session per week, rotating which therapist and session number is rated in any given week. These ratings are used to facilitate supervision with each Therapist, consultation with the METS Supervisor Consultant, and decisions about when a Therapist needs additional supervision or needs to resume a 'Re-piloting' status. The STRF

instructs the tape reviewer to rate the adherence (frequency and extensiveness) and competence (skill level) with which a Therapist provided prescribed/proscribed interventions within a specific session with a specific research participant based on review of an audiotape.

c. Use of Audiotapes and Adherence/Competence Ratings by CTP Supervisor

During the completion of practice (pilot) cases by METS trained Therapists, the Supervisor will listen to all audiotapes and complete a Supervisory Tape Rating Form for each tape using the Rater Guide. For one session per Therapist, the METS Supervisor Consultant will review/rate the tapes for the purpose of calibration of the tape rating process, consultation around supervisory issues to address with the Therapist, and to provide input into the CTP Supervisor's 'credentialing' decision about when the Therapist can begin accepting randomly assigned study participants. This review of audiotapes also provides the foundation for weekly supervisory meetings with the METS trained Therapists during the practice (pilot) phase.

Once all Therapists are 'credentialed' or ready, the Supervisor will rate one audiotape per week by rotating which Therapist and which session number is rated in any given week. This review of audiotapes helps structure the bi-weekly supervisory meetings with the METS trained Therapists during the completion of the study protocol. These ratings are also used to alert the Supervisor (and METS Supervisor Consultant) to clinicians who may need periodic focused supervisory attention or those whose persistent manual compliance problems makes 'Re-Piloting' necessary until the original training performance criteria can be achieved (i.e., mean Frequency and Extensiveness rating of 'somewhat' (4) and minimal Skill Level rating of 'adequate' on at least half of these rated METS items).

d. Supervisory Consultation with METS Supervisor Consultant

During both the credentialing, and main phase of the study, the CTP Supervisors will meet with the METS Supervisor Consultant via conference call (or face-to-face if convenient) regularly to enhance the uniformity of tape ratings, supervision, feedback, as well as to discuss issues arising in supervising community clinicians to use METS. This consultation will occur on a weekly basis during the time the Therapists and Supervisor are completing their initial practice (pilot) cases after training. Once all Therapists and the Supervisor are 'credentialed' or judged to be 'ready' by the METS Supervisor Consultant, this consultation will occur in a monthly meeting

Once all Therapists and the Supervisor are 'credentialed' or 'ready', the METS Supervisor Consultant meetings with the CTP supervisor will shift to monthly and will focus on the review of one audiotape that s/he has rated per month. This consultation would return to a weekly format in the event that a Therapist has been 'Re-piloted' because of persistent (inadequate ratings for three consecutive participants) problems delivering manual-guided METS. This weekly consultation format could also take the form of the METS Supervisor Consultant becoming directly involved in supervising the 'Re-Piloting' Therapist.

e. Supervision of Therapists by CTP Supervisor

(1). Pre-credentialing supervision

After the training, each Therapist will see at least one practice/training case (i.e., three METS sessions) under close supervision by the METS Supervisor Consultant who will review and rate audiotapes using the Supervisory Tape Rating Form. This training case is an opportunity to insure that the METS clinician can adapt his/her usual technique to conform to manual guidelines, to identify the 'boundaries' of the treatment, practice new techniques, and to establish goals for ongoing supervision.

During the pre-credentialing period, the Supervisor will meet weekly with each METS trained therapist. This weekly format should alternate between an individual and a group format. One week, the Supervisor should meet individually (approximately 25-30 minutes) with each Therapist to discuss his/her practice case and raise any issues with the implementation of the manual-guided approach. The Supervisor will use his/her completed Supervisory Tape Rating Form ratings of the practice (pilot) participants to help structure this supervisory process. The alternate week, the Supervisor should meet with all CTP METS trained Therapists as a group (approximately 50-60 minutes). In this group supervision, each Therapist would be allowed time to discuss their specific cases and the success or difficulty they are having implementing the technical or stylistic interventions of the METS manual. When appropriate, the Supervisor would also raise any issues that have been detected in his/her listening to and rating the audiotapes. In addition, it is recommended that some portion of this hour be devoted to the group listening to one of the Therapist's tapes and providing supportive feedback and suggestions to each other. The selection of this tape could either be random or selected by the Therapist or Supervisor as illustrating successful implementation of METS or a problematic patient for whom implementing METS is especially challenging.

During this pre-credentialing period, the CTP Supervisor is also consulting on a weekly basis with the METS Supervisor Consultant about the status of each Therapist's credentialing. The Supervisor Consultant will review one audiotaped session and will calibrate his/her ratings with the Supervisor. The METS Supervisor Consultant has the option to have individual or group supervision sessions with the therapist either in person or over conference call.

(2). Post-credentialing supervision (during randomized trial)

Both CTP Therapists and Supervisors will be expected to complete at least three sessions of METS (i.e., typically one METS case) before randomization of participants can begin. The Therapist must obtain an average STRF *Frequency and Extensiveness* rating of 'somewhat' (4) and on at least half (5 of 10) of the METS items (i.e., mean of at least 4 for five rated METS items from items 1-10 of the STRF) and all of these rated items need to have a *Skill Level* of at least "adequate" (4). If these criteria are reached for each of the three pilot/practice sessions,

then the METS Supervisor Consultant and CTP Supervisor will identify the Therapist as 'credentialed' or 'ready' to accept (or supervise) randomly assigned METS research participants for the protocol. If this minimal credentialing criterion is not met on the first practice (pilot) case(s), then additional non-randomized cases will be assigned until the criteria is reached.

Once all clinicians are 'credentialed' or 'ready,' the bi-weekly individual supervision will stop, but the bi-weekly group supervision will continue. There may be some instances where this individual supervision continues due to scheduling conflicts or time off that prevents all METS Therapists from meeting as a group. Otherwise, regular bi-weekly individual supervision would only be re-instituted when the Therapist has been 'Re-Piloted' (see below) or it is felt that shifting to individual supervision may help prevent the this Re-Piloting process from occurring.

Thus, the bi-weekly group supervision continues from the point of completing training, through the practice case, credentialing process, and through the completion of the study protocol. The goals of this supervision are to ensure that METS is delivered as conceptualized in the manual, to maintain good morale among the Therapists, and to enhance the technology transfer process. The format of these group supervisory meetings is discussed above and should include case discussion by each Therapist, review of adherence/competence rating (both Supervisor and Expert Trainer STRF ratings and the Therapist Checklist self-assessment) issues to reinforce prescribed and discourage proscribed techniques, and review of some portion of audiotapes of different Therapists on a rotating basis.

(3). Supervising Protocol or Manual Drifting (or Re-Piloted) Therapists

Through the routine process of rating Therapist audiotapes, the Supervisor or METS Supervisor Consultant may discover that a particular clinician is experiencing difficulty in providing METS according to the protocol manual. When any given tape rating results in half of the METS items having a mean *Frequency & Extensiveness* rating of less than 'somewhat' (4) or a rated *Skill Level* item below 'adequate' (4), this will trigger off two processes: 1) additional supervisory attention to the issue of prescribed versus proscribed techniques; 2) immediate review of the next available session from a different patient treated by this Therapist. If this second tape review indicates improvement on ratings, then the routine process of Supervisor and METS Supervisor Consultant ratings of audiotapes resumes (rating Therapists and sessions on a random, rotating basis).

If, however, the second tape review and rating indicates that the Therapist is still performing below criteria, this will trigger off three processes: 1) continued supervisory attention to the issue of prescribed versus proscribed techniques; 2) a warning to the Therapist that they are in danger of being 'Re-Piloted' due to their difficulty delivering the manualized METS treatment; 3) immediate review and rating of the next available session from a different patient treated by this Therapist. If this third tape review and rating indicates improvement, then the routine process of Supervisory and METS Supervisor Consultant ratings of audiotapes resumes (rating Therapists and sessions on a random, rotating basis) after reviewing a fourth case.

If, however, the third consecutive tape review indicates that the Therapist is still performing below criteria, this will trigger off three processes: 1) Therapist is (temporarily) removed from the randomization sequence; 2) bi-weekly individual supervision will resume as provided during the pre-credentialing phase; 3) Therapist is assigned regular clinic patients to provide METS. This Therapist will continue in the bi-weekly group supervision throughout the 'Re-Piloting' period. The additional bi-weekly individual supervision can be provided in face-to-face supervision with the Supervisor or phone supervision from the METS Supervisor Consultant or whichever combination of these strategies are felt will return the Therapist to 'credentialed' or 'ready' status most quickly and effectively.

During any 'Re-Piloting' period, Therapists will not accept randomly assigned participants. If they express an interest in returning to this 'credentialed' or 'ready' status, they will be required to provide manual-guided METS to regular clinic patients who are willing to be audiotaped, but are not interested in otherwise being a research participant. These sessions and their adherence/competence Supervisory Tape Rating Form forms will be reviewed within the individual supervision meetings. Continued difficulty will result in ongoing supervision and perhaps some retraining by the METS Supervisor Consultant if it is felt that this would be useful. Once the Supervisory Tape Rating Forms indicate 'credentialing' level ratings for two consecutive clinic patients, then the Supervisor and Expert Rater will make a determination that the Therapist is ready to be re-credentialed and resume treating randomized participants.

Once the Therapist is able to resume taking randomly assigned participants, bi-weekly individual supervision can be dropped if Supervisor and METS Supervisor Consultant agree. However, if a Therapist is 'Re-piloted' and then returns to 'credentialed' criteria on two different occasions, then bi-weekly individual supervision will be required for the remainder of the study protocol. Of course, Therapists can choose at any time to resign their role as study Therapist rather than experiencing some of the extra work and embarrassment that can come with being repeatedly 'Re-Piloted.' In addition, it is always within the purview of the CTP leadership to decide that a particular CTP clinician's performance of routine duties within the clinic is so sub-standard that they can no longer approve of their performing the extra work involved in being a study Therapist.

f. Summary of role of CTP METS Supervisor

Each CTP METS Supervisor will be responsible for:

1) attending the centralized national METS training as provided by the Chief Expert METS Trainer;

2) completing at least three practice sessions of METS and receiving supervision training on these sessions;

3) reviewing and rating audiotapes from each Therapist during Therapist practice cases and while the study is ongoing;

4) meeting with the Therapists conducting METS on a regular basis to review progress and rating forms, identify areas of competence in delivering METS as well as those requiring more work;

5) consulting regularly with the METS Supervisor Consultant about supervisory and adherence/ competence issues of Therapist at CTPs

3. Therapist Training and Assessment

a. Therapist Inclusion Criteria

Clinicians will be individuals currently employed at participating CTPs who are interested in participating in the research protocol, and are:

- Willing to learn a manualized version of METS and follow manual guidelines for the duration of the protocol.
- Willing to be randomly assigned to either the METS or Standard Treatment conditions and participate in any initial and 'refresher' training sessions.
- Willing to have their sessions audiotaped for review by the protocol Supervisor, METS Supervisor Consultant, and independent Raters of adherence/ competence; attend regular supervision sessions; complete process ratings (e.g., ratings of the therapeutic alliance and techniques used during sessions).
- Approved by the CTPs administrative/supervisory staff as appropriate for the study (e.g., sufficiently reliable, performs CTP duties competently).
- Speak Spanish

b. *Therapist Exclusion Criteria*

Clinicians who have received credentialing as a motivational interviewing trainer, have received formal motivational interviewing training within the 3 months prior to protocol training, or who have served as a motivational interviewing or enhancement therapist in a prior clinical trial can serve as on-site METS Supervisors for this study (see previous section), but cannot serve as a Therapist in either condition. Clinicians who have received a less formalized or recent exposure to MET or MI can participate as Therapists.

c. Random Assignment to Conditions

All CTP clinicians who are approved for participation in this protocol will be randomly assigned to be trained to provide METS or Standard Treatment-as-Usual. Random assignment is necessary to ensure that the METS condition does not consist of only those clinicians who are highly motivated for training and supervision (who consequently are likely to be more skilled) while the standard treatment condition consists of clinicians with less interest or motivation.

d. Trainees and Students

Practicum students, interns, residents, and other trainees may, with permission of the Chief Expert METS Trainer, METS Supervisor Consultants and CTP Supervisors, 'sit-in' on the initial METS training or the post-protocol METS training that will be provided to Therapists not randomized to METS. Whether trainees can serve as protocol Therapists will be a Node decision, based on considerations such as the trainee's expected term with the CTP (e.g., will s/he be assigned to the CTP for the full duration of the protocol, whether the trainee's schedule affords the flexibility to be assigned protocol participants, whether the trainee is an employee of the organization), whether the trainee has adequate prior clinical experience (a trainee with very limited clinical experience or with a limited time commitment to the program would be inappropriate), and whether trainee participation might preclude training of a longer-term CTP staff clinician.

e. Therapist Assessments

1. *Clinician and Supervisor Survey*

Several demographic variables will be assessed including therapist gender, age, race, years of experience in substance abuse, years at current CTP, education/degree, certification status, and primary therapeutic orientation. This measure will be completed at baseline, at termination of the study protocol, and 3-months following termination of study protocol.

2. *Practitioner Technique Inventory*

This self-report measures how Therapists see themselves providing clinical care in general. This form asks for a rating of the degree to which (adherence items only) s/he uses a variety of techniques (METS, standard treatment) in the routine individual assessment and counseling s/he provides to clients at his/her clinic. This measure will be used to evaluate changes in practice over time as a function of METS training and regular, year-long supervision. This measure will be completed at baseline, at termination of the study protocol, and 3-months following termination of study protocol.

3. *Pre-training and Post-training Audiotape*

Therapists will be asked to obtain patient permission to tape a recent typical clinical session for which they are providing individual counseling at their CTP. A pre-training audiotape is important to establish a baseline from which the effects of training on practice during the protocol and after protocol completion (for both conditions) can be measured. An independent tape rater will later rate the pre-training and protocol audiotapes using an adherence/competence rating scale. Audiotapes of typical clients also will be collected at termination of the study protocol and 3-months following termination of study protocol.

4. *Protocol Audiotapes*

Therapists will make an audiotape recording of all METS sessions they have conducted. These tapes should be labeled with the study number, therapist ID, subject ID, session date, session number, and the ID number of the Node and CTP. No client names should appear on the audiotape label.

5. *Therapist Session Checklist*

A Therapist Session Checklist is completed by the Therapist after each session with each study participant. It provides a subjective, self-assessment of the degree to which (i.e., adherence items only) the Therapist implemented prescribed and proscribed techniques during each specific session. These ratings are to be completed immediately after a session when the recollection for what transpired should be highest. Although Therapists can listen to their own audiotapes for their own self-improvement, they should not complete Therapist Checklists based on audiotape review but rather their own immediate recollection (i.e., after patient leaves office and before the next appointment or meeting).

f. Training of Therapists

CTP Therapists randomly assigned to provide METS will participate (with Supervisors) in the equivalent of two full days of didactic training, review of videotapes, role-playing, and implementation issues specific to the METS protocol provided by the Chief Expert METS Trainer.

The training will include didactic review of motivational interviewing style and techniques and skill and competency development, including completion of several training and role-play exercises developed by Miller and colleagues. The training also will include an overview of the study aims and procedures and extensive review of the METS manual. This portion also will cover issues that present initial challenges for many therapists delivering manual-guided therapy in the context of a clinical trial (e.g., adhering to manual guidelines with a diverse study population, supervision and rating via audiotapes, guidelines for supervision, randomization, roles of research assistants versus therapists, time-limited nature of the approaches).

g. Supervision of Therapists

1. Pre-credentialing supervision

Because an important aim of the CTN is to understand the processes which best facilitate the most cost-effective methods of training and supervising real-world clinicians working in real-world settings, credentialing will be an individualized process involving the completion of as many training cases as are needed to reach an acceptable criteria. Therapists will not

automatically be excluded if they cannot rapidly adhere to the manual guidelines, but instead be provided additional training and supervision.

After training, each Therapist will complete one practice/training case (i.e., three METS sessions) under close supervision by both the METS Supervisor Consultant and Supervisor, both of whom will review audiotapes and rate tapes using the Supervisory Tape Rating Form. This training case is an opportunity for the Therapist to learn to provide METS and adapt his/her usual technique to conform to manual guidelines, to learn the 'boundaries' of the treatment, practice new (prescribed) techniques, and avoid using (proscribed) techniques that are antithetical to METS. This training case(s) provides practice in providing METS under highly supportive conditions with close supervision.

During the pre-credentialing period, the Therapist will meet weekly with his/her METS Supervisor. This weekly format should alternate between an individual and a group format. One week should consist of an individual meeting (for approximately 25-30 minutes) with the Supervisor to discuss the practice case and receive feedback regarding any issues with his/her implementation of the manual-guided approach. The other week should involve a group supervision meeting with the Supervisor and other METS trained Therapists at the CTP (for approximately 50-60 minutes) to discuss specific cases, including successes and frustrations with implementing the METS interventions. In the group supervision, all Therapists will be expected to provide and receive feedback to and from other Therapists to support each other's ongoing development in the use of these techniques.

2. Post-credentialing supervision.

Both CTP Therapists and Supervisors will be expected to complete at least three sessions of METS (i.e., usually one METS case) before randomization of participants can begin. The Therapist must obtain an average STRF *Frequency and Extensiveness* rating of 'somewhat' (4) and on at least half (5 of 10) of the METS items (i.e., mean of at least 4 for five rated METS items from items 1-10 of the STRF) and all of these rated items need to have a *Skill Level* of at least "adequate" (4). If these criteria are reached for each of the three pilot/practice sessions, the Therapist will be 'credentialed' as METS proficient or 'ready' to accept (or supervise) randomly assigned METS research participants for the protocol. If this minimal credentialing criterion is not met on the first practice (pilot) case(s), then additional non-randomized cases will be assigned until the criteria is reached. The CTP Supervisor will be reviewing and rating all Therapist practice (pilot) audiotapes; the Supervisor Consultant will review one session for each Therapist practice (pilot) case. This process will allow the Supervisor and METS Supervisor Consultant to calibrate their rating decisions and discuss Therapists who are having continued difficulty in the 'credentialing' or 'readiness' process.

Once all clinicians are 'credentialed' or 'ready,' the bi-weekly individual supervision will stop, but the bi-weekly group supervision will continue. There may be some instances where this individual supervision continues due to scheduling conflicts or time off that prevents all METS Therapists to meet as a group. Otherwise, regular bi-weekly individual supervision would only

be re-instituted when the Therapist has been 'Re-Piloted' (see below) or it is felt that shifting to individual supervision may help prevent this 'Re-Piloting' process from occurring.

Thus, the bi-weekly group supervision continues from the point of completing training, through the practice case, credentialing process, and through the completion of the study protocol. The goals of this supervision are to ensure that METS is delivered as conceptualized in the manual, to maintain good morale among the Therapists, and to enhance the technology transfer process. The format of these group supervisory meetings is discussed above and should include case discussions by each Therapist, review of adherence/competence rating (both Supervisor and METS Supervisor Consultant ratings and the Therapist Session Checklist self-assessment) issues to reinforce prescribed and discourage proscribed techniques, and review of some portion of audiotapes of different Therapists on a rotating basis.

3. Supervision Protocol or Manual Drifting (or Re-Piloted) Therapists

Through the routine process of rating Therapist audiotapes, the Supervisor or METS Supervisor Consultant may discover that a particular clinician is experiencing difficulty in providing METS according to the protocol manual. When any given tape rating results in more than half of the METS items having a mean *Frequency & Extensiveness* rating of less than 'somewhat' (4) or a rated *Skill Level* item below 'adequate' (4), this will trigger off two processes: 1) additional supervisory attention to the issue of prescribed versus proscribed techniques; 2) immediate review of the next available session from a different patient treated by this Therapist. If this second tape review indicates improvement on ratings, then the routine process of Supervisor and METS Supervisor Consultant ratings of audiotapes resumes (rating Therapists and sessions on a random, rotating basis).

If, however, the second tape review and rating indicates that the Therapist is still performing below criteria, this will trigger off three processes: 1) continued supervisory attention to the issue of prescribed versus proscribed techniques; 2) a warning to the Therapist that they are in danger of being 'Re-Piloted' due to their difficulty delivering the manualized METS treatment; 3) immediate review and rating of the next available session from a different patient treated by this Therapist. If this third tape review and rating indicates improvement, then the routine process of Supervisory and Expert Trainer ratings of audiotapes resumes (rating Therapists and sessions on a random, rotating basis) after reviewing a fourth case.

If, however, the third consecutive tape review indicates that the Therapist is still performing below criteria, this will trigger off three processes: 1) Therapist is (temporarily) removed from the randomization sequence; 2) bi-weekly individual supervision will resume as provided during the pre-credentialing phase; 3) Therapist is assigned regular clinic patients to provide METS. This Therapist will continue in the bi-weekly group supervision throughout the 'Re-Piloting' period. The additional bi-weekly individual supervision can be provided in face-to-face supervision with the Supervisor or phone supervision from the METS Supervisor Consultant or whichever combination of these strategies are felt will return the Therapist to 'credentialed' or 'ready' status most quickly and effectively.

During any 'Re-Piloting' period, Therapists will not accept randomly assigned participants. If they express an interest in returning to this 'credentialed' or 'ready' status, they will be required to provide manual-guided METS to regular clinic patients who are willing to be audiotaped, but are not interested in otherwise being a research participant. These sessions and their adherence/competence Supervisory Tape Rating Forms will be reviewed within the individual supervision meetings. Continued difficulty will result in ongoing supervision and perhaps some retraining by the METS Supervisor Consultant if it is felt that this would be useful. Once the Supervisory Tape Rating Forms indicate a 'credentialing' level rating for two consecutive clinic patients, then the Supervisor and METS Supervisor Consultant will make a determination that the Therapist is ready to be re-credentialed and resume treating randomized participants.

Once the Therapist is able to resume taking randomly assigned participants, bi-weekly individual supervision can be dropped if Supervisor and METS Supervisor Consultant agree. However, if a Therapist is 're-piloted' and then returns to 'readiness' criteria on two different occasions, then bi-weekly individual supervision will be required for the remainder of the study protocol. Of course, Therapists can choose at any time to resign their role as study Therapist rather than experiencing some of the extra work and embarrassment that can come with being repeatedly 'Re-Piloted.' In addition, it is always within the purview of the CTP leadership to decide that a particular CTP clinician's performance of routine duties within the clinic is so sub-standard that they can no longer approve of their performing the extra work involved in being a study Therapist.

4. Audiotaping Procedures

All METS and Standard Treatment sessions will be audiotaped using standard 120-minute audiocassettes which will allow for the taping of one (of the three) sessions of the METS intervention. Blank tapes and cassette recording equipment will be kept in the Project offices. Research staff will be responsible for obtaining informed consent for the study as a whole and audiotaping specifically. Therapists will be responsible for taping each session and giving the tape to the Research Assistant. Therapists will label each tape with the following information:

1) node number
2) CTP number
3) study number (NIDA-CTN-0021)
4) participant ID number (supplied by Research Assistant)
5) therapist ID number (supplied at training)
6) session date
7) session number

No patient names, initials, clinic medical record numbers or other potentially identifying information will be included on the tape

All audiotapes received by the Research Assistant from the Therapist will be stored initially in locked cabinets at each CTP. The Node Project Coordinator, or their designee, will select from

these tapes, a sub-sample of sessions that will be given to the Supervisor and/or METS Supervisor Consultant for supervisory review and adherence/competence rating (for quality control) purposes. This subsample of tapes may also be used within individual or group supervision of Therapists for instructional purposes. Once the tape has been rated and used in supervision, it will be returned immediately to the locked cabinet in the Research Assistant's office. Other than the Therapist, Supervisor, other METS Therapists, and the Node METS Expert, no one within the CTP or Node will have access to these taped sessions.

Every three months, the Node Project Coordinator, or their designee, will be responsible for sending all tapes that have been stored in the cabinet (unrated tapes and returned tapes) to the Lead Investigator's RRTC (Yale University) with a log. Here the tapes will be catalogued and the independent Tape Rater review of these tapes will be coordinated.

5. Summary

Each CTP METS Therapist will be responsible for:

1) attending the two-day training provided by the Chief Expert METS Trainer and participate in the group discussion and role plays involved in training to provide this treatment protocol;

2) completing Therapist assessments before, during, and after completion of the study protocol;

3) meeting with the CTP METS Supervisor and other Therapists conducting METS on a regular basis to review progress and rating forms, identify areas of competence in delivering METS as well as those requiring more work;

4) making every effort to schedule the necessary number of treatment sessions within the time allowed for the intervention;

5) ensuring that all sessions are audiotaped and given to the research assistant or coordinator.

NOTE: *To enhance the buy-in of all CTP staff, it is recommended that the non-METS assigned clinicians and all CTP staff who have elected not to participate in this protocol (or whose CTP Supervisor has not approved) be offered some alternate form of psychosocial treatment training that does not overlap with METS and is unlikely to be part of a CTN study in the next two years (e.g., Stage I study treatments being conducted at RRTCs). In addition, all clinicians who are randomly assigned to the Standard Treatment condition and remain employed at the CTP should be offered the METS training once subject recruitment has been completed for this study and the post-study audiotapes have been completed.*

G. Assessments

1. Overview

Assessments will address the following domains: (1) screening and description of the study sample, (2) predictors of outcome, (3) detection of response to treatments, and (4)

assessment of the treatment process. The assessment battery was developed with the following principles in mind:

a. Brevity: It is important keep the time between recruitment, randomization and the first session to a minimum and to keep participant burden low, particularly with a very brief intervention. A ceiling of two hours total time for the pretreatment assessment has been adopted. It is estimated that the intake will take 2 hours.
b. Evaluation and operationalization of primary and key secondary measures
c. Linkage with 'core' CTN assessment battery.
d. METSpecific measures for Personal Feedback Form. Measures of intensity and consequences of substance use are included for preparation of the Personal Feedback Form.
e. Use of assessment instruments that have been validated in Spanish-speaking populations whenever possible. For example, a validated, widely used version of the ASI in Spanish already exists and will be used for this protocol. Similarly, because the SDSS (which is being used in the English version of this protocol) does not have an equivalent Spanish version, the CIDI, which has a validated Spanish version, will be substituted.

   These measures have been examined by CTP staff to determine the appropriateness of the Spanish translation to capture the common uses of Spanish words used by Hispanic clients in their region. If the CTPs indicated other common uses for Spanish words in their region, alternative translations for specific items were added in parenthesis. Other interview- and self-administered assessment instruments from the English version of the MET protocol that do not have an equivalent Spanish version have been translated under the supervision of Dr. Lourdes Suarez of the University of Miami.

   Four University of Miami IRB-approved translators completed these translations. Two translated from the original English version to Spanish. The Spanish versions were reviewed by all participating CTPs and adjustments were made. The Spanish version with CTP specific adjustments have been translated into English by two translators that have never seen the English form. The two English versions were compared by Dr. Suarez. Discrepant items were resolved by a committee comprised of the translators, Dr. Suarez, and CTP representatives familiar with the patient population.

2. Substance use severity, consequences, and frequency

a. Type, frequency, and intensity of alcohol and illicit drug use will also be determined by **urine and breath specimens** collected pretreatment, three times during treatment, posttreatment, and at follow-ups. All urine specimens will be collected under staff observation and/or using temperature controlled monitoring and screened for illicit amphetamines, barbiturates, benzodiazepines, cannabinoids (THC), cocaine metabolites, methadone, methamphetamines, opiates/morphine, and phencyclidine (PCP) using the SureStep 10, which have the added advantage of on-site analysis and may reduce the need to collect multiple samples for research and clinical purposes.

b. Severity of substance use and substance-related problems will also be measured by composite scores of the Spanish version of the Addiction Severity Index (ASI) (Gonzalez-Saiz, Carulla, Martinez-Delago, Lopez-Cardenas, Ruz-Franzi & Guerra-Diaz, under review) of the Addiction Severity Index-Lite (McLellan et al., 1992). To parallel the English version of the ASI-Lite, items pertaining to the extended version of the ASI were deleted from the Spanish version and the sections will be reorganized as needed to duplicate the version of the ASI-Lite that is being used in the CTN. The ASI is the most widely used instrument for assessment of substance use and related problems and its psychometric properties are well established (Cacciola et al., 1997).

c. Presence and type of DSM-IV substance use disorders will be assessed via the Spanish version of the Composite International Diagnostic Interview (Robins, Wing, & Helzer, 1983). The CIDI is brief (the substance abuse module of the CIDI, the CIDI-SAM, takes about 20-30 minutes to administer) and has been shown to be reliable in a number of populations (Cottler et al., 1997; Cottler, Robins, & Helzer, 1989). A Spanish version that has been used in several international protocols is available (Cottler et al., 1991). Moreover, the CIDI has been used successfully in large-scale surveys of community treatment programs (e.g., Simpson, Joe, Fletcher, Hubbard, & Anglin, 1999) and requires less specialized knowledge of drug abuse nosology than other instruments.

3. Psychiatric disorders and symptoms

The prognostic significance of concurrent psychopathology in substance dependent populations has been noted in several investigations (McLellan et al, 1983; Rounsaville et al., 1986, 1987; Woody et al., 1984, 1985) and may be particularly relevant to treatment response in the CTN, given its emphasis on treatment outcome among diverse populations. A continuous rating of psychiatric severity will be available through use of **the Psychological Severity Composite Score of the ASI** (McLellan et al., 1992).

4. Other domains

a. Readiness for change

As the participant's motivation, or readiness for change, may be an important predictor of response to treatment and is particularly relevant to this protocol (Prochaska et al., 1992), the **University of Rhode Island Change Assessment**, (DiClemente & Hughes, 1990) which assesses the participant's current position regarding readiness for change (e.g., precontemplation, contemplation, commitment), will be administered pre- and posttreatment and at follow-up. This version has been translated using the procedures outlined above.

b. Consequences of use

To assess the participant's perception of the adverse consequences of their substance use, a short version of the **Short Inventory of Problems (SIP-R),** will be administered before treatment and at posttreatment. The SIP is modified from the Drinker Inventory of Consequences **(DrINC)** (Miller et al., 1995), for use with drug users. Its psychometric properties have been found to be acceptable in previous trials (Miller et al., 1995). This instrument, with the ASI, will form the foundation of the Personal Feedback Form for MET. This version has been translated using the procedures outlined above.

c. Treatment attitudes and expectations

Greater congruence of participant's expectations of treatment and beliefs regarding the causes and nature of substance use with those of the treatment they receive may result in improved outcome over participants whose treatment expectations contrast with study treatment received (Hall et al., 1991). The **Treatment Attitudes and Expectation form**, a self-report of treatment attitudes, adapted from the NIMH TDCRP (Elkin et al., 1985), has been modified for use with drug dependent individuals. This version has been translated using the procedures outlined above.

d. HIV risk behaviors.

Baseline level of HIV risk behaviors and change in those behaviors during treatment will be assessed using **the HIV Risk Behavior Scale (HRBS**), a 12 item **interview** adapted from Darke *et al.* (1991) that includes a question regarding participant's knowledge of HIV status. This version has been translated using the procedures outlined above.

e. Measure of biculturalism

Historically, acculturation has referred to the process of change experienced by individuals of a minority group during the adoption of the majority group's culture (Berry, 1980). Szapocznik & Kurtines (1993) have suggested that acculturation can occur in a more complex fashion that involves both the retention of the behaviors, customs and values of the culture of origin as well as the acquisition of the behaviors, customs and values of the host culture. To assess this process in Hispanic immigrants, Szapocznik and Kurtines developed the **Bicultural Involvement Questionnaire** that permits the separate measurement of Hispanicism

and Americanism (Szapocznik, Kurtines, and Fernandez, 1980). This 24-item self-report measure assesses comfort of Hispanic and English language, as well as enjoyment of cultural customs and behaviors associated with the Hispanic and American cultures using a 5-point Likert scale (1 = Not at all Comfortable to 5 = Very Comfortable). Scores for three subscales are calculated, including Americanism, Hispanicism, and Biculturalism. Adequate internal consistency has been reported, ranging from .89 to .94 (Gomez & Fassinger, 1994; Szapocznik, Kurtines, & Fernandez, 1980). Acculturation (Rogler, Cortes, & Malgady, 1991) and Biculturalism (Szapocznik, Kurtines & Fernandez, 1980) levels have been related to psychological adjustment in Hispanic groups.

5. Assessment of Primary Outcomes (retention in treatment and substance use)

a. Alcohol and Urine samples are collected at baseline, each treatment session, post treatment, follow-up 1 and follow-up 2.

b. Self-reports of substance use (marijuana, cocaine, alcohol, methamphetamine, benzodiazepenes, opioids, and other illicit drugs) will also be documented at each contact by the research assistant via the **Substance Use Calendar**. Similar to the Form-90, which has been shown to be a reliable and valid instrument for monitoring substance use and other outcomes in longitudinal studies (Miller & DelBoca, 1994), the Substance Use Calendar instrument assesses substance use on a daily basis and allows a flexible, continuous evaluation of substance use. It also allows for collection of data points for participants who miss evaluation sessions and thus prevents missing data and problems associated with gaps or overlap of datapoints. The use of the calendar format prompts participants to remember key dates.

c. Other information on substance use and substance-related impairment will be assessed at monthly intervals via the ASI (Gonzalez-Saiz et al., under reviewMcLellan et al., 1992).

d. Other outcomes

1. **Participant Satisfaction**: At the end of treatment, a self-report form (**Posttreatment Attitudes and Expectations)**will be completed by all participants, with ratings of participant's satisfaction with treatment, the degree of change of their condition, and perception of helpful or harmful aspects of the treatments received. This has been adapted from forms used successfully in Project MATCH and the CSAT multisite marijuana treatment trial (Donovan et al., under review). This version has been translated using the procedures outlined above.
2. Treatment compliance: Number and duration of scheduled treatment sessions and post-study treatment involvement after completion of study treatment will be monitored via the **Treatment Utilization/Health Services Form**.
3. Treatment compliance will also be monitored by the therapists, using the **Therapist Session Report and Technique Checklist**, which documents events

such as major changes in the participant's condition, as well as the specific interventions delivered in a given session.

6. Measures of Treatment Specificity

To evaluate the specific effects of the different types of treatments being compared, we will assess aspects of treatment outcome that are theoretically likely to be differentially affected by the study treatments: For example, the specificity of MET, which is intended to increase participants motivation for change will be assessed through the University of Rhode Island Change Assessment (URICA*)*.

7. Process Assessments

a Overview

Extensive assessments of the psychotherapeutic process are intended to: (a) evaluate the extent to which treatments were implemented as intended and the validity of the independent (treatment) variable was protected, through assessment of treatment discriminability, (b) therapist adherence and competence in performing the treatment, and (c) assess the patient-therapist relationship as well as the extent to which the nature of the therapeutic alliance and other aspects of the therapeutic process are related to outcome.

b. Integrity of the independent (treatment) variable

To assure the study treatments (MET versus standard treatment) are discriminable and delivered in a manner consistent with manual guidelines, all therapy sessions will be audiotaped and selected sessions (estimating one session from each participant) will be evaluated by raters who are blind to type of treatment received, using the adherence/competence rating scales described above, which have been adapted from validated instruments for assessing adherence and competence in delivering MET, supportive interventions, and other treatments in previous trials (e.g., Barber et al., 1996, 1997; Carroll et al., 1998, Carroll, Nich, Sifrey et al., 2000).

c. Therapeutic alliance

Defined by Bordin (1979) as consisting of agreement on goals, agreement on tasks, and development of bonds between therapist and participant, the therapeutic alliance has proven to be a promising variable for predicting outcome from psychotherapy for substance abuse (Connors, Carroll et al., 1997) and other disorders (Horvath & Luborsky, 1993). In this study the working alliance will be assessed through the revised Helping Alliance Questionnaire (HAq-II, Luborsky et al., 1996), a well-validated measure of this construct, from both the

therapist and participant perspectives, after the first session. This version has been translated using the procedures outlined above.

H. Data Management & Analysis

1. Data Management

The New England Node will coordinate data management activities and provide ongoing consultation and assistance to participating nodes through out the study.

a. Specific Considerations for the Bilingual Aspect of this Protocol

Because the vast majority of CRFs in both the Spanish and English version of the protocol are closed ended and numerical, we anticipate it will NOT be necessary for Data Management staff to be bilingual.

Therefore, DMCs participating in this protocol that do not have Spanish-speaking staff should:

- Not add any CRFs to the battery that have open-ended questions.
- Be certain that any responses that are given in Spanish are recorded in the manner consistent with GRP guidelines for translating source documents.
- Be sure to follow the data dictionaries that are in both English and Spanish.
- Be sure that all back end CRF information is in English to allow the DMC to audit.
- All CRFs will have a field/variable labeled "source document language" with a response code of English or Spanish.
- The DMC should be given extra time for system start up.
- Allow extra resources during system start up for handling "different" system.
- Allow extra resources during active study phase for data monitoring.

b. Standard Data Management Procedures

1. Study Assessments and Data Collection

All study assessments are listed in the Assessments/Case Report Forms (CRF) Procedural Table included in this Protocol. Each Assessment is listed with the corresponding CRF name. The table also includes information of when each Assessment is to be completed and the responsible person. Within the table, acceptable windows of collection times for each Assessment are labeled with a footnote.

The New England Node Data Management Center will provide final CRFs for the collection of all data required by the study. There will be an English version of each CRF and an additional Spanish version of each CRF that has been translated by the Florida Node. It is understood that CRFs may be modified for incorporation into each Node's automate data acquisition and

management system as appropriate. However, the study data content of the CRFs cannot be changed. *The wording on the Spanish translated CRFs must be exactly like the final copies provided by New England.* It is possible to add comments to the CRF in the specific dialect of the node's population for clarification purposes. All CRFs will be designed in accordance with standards established by the Case Report Form and Data Dictionary Development Standards SOP developed by the CTN Data Management and Analysis Subcommittee. Form Completion Instructions for each CRF can be found in the Spanish MET Operations Manual. The New England Node will provide other necessary documentation for the CRFs as needed.

Each Node will collect the study data at the study sites on either electronic (paperless) or paper CRFs. Each Node's data management center will coordinate the preparation and the distribution of the CRFs to participating Community Treatment Programs (CTPs) within their Node. These CRFs are to be completed on an ongoing basis during the study and should be in accordance with the detailed CRF Collection Schedule, which will be provided by the New England Node. Paper CRFs must be completed legibly with permanent ink. Any corrections should be made by striking through the incorrect entry with a single line using permanent ink and entering the correct information adjacent to the incorrect entry. Corrections to paper CRFs must be initialed and dated by the person making the correction. Corrections to electronic CRFs shall be tracked electronically with time, date, individual making the change, both the old data and new data and the reason for correction.

2. Data Submission, Editing and Error Detection

Completed forms/electronic data will be submitted to each node's data management center in accordance with Data Timeliness and Completeness Standard Operating Procedure (SOP) published by the CTN Data Management and Analysis Subcommittee. Each node data management center will implement comprehensive error checking and data management procedures as per the Error Tracking SOP published by the CTN Data Management and Analysis Subcommittee. An automated error checking procedure will be programmed based on validation rules specified in the data dictionary. An error log will be produced for tracking all errors and documenting their resolution. Each node is responsible for developing and implementing a Standard Operating Procedure for identifying and resolving all data errors. This SOP will also include the tracking of all errors from initial identification through resolution.

3. Data Monitoring

The New England Node Data Management Center expects each node to monitor all data in accordance with the Data Management and Analysis Subcommittee Data Monitoring SOPs. Each node is responsible for maintaining accurate, complete and up-to-date records and for

tracking CRFs for each participant in accordance with the Data Timeliness and Completeness and Data Accuracy and Auditing SOPs published by the CTN Data Management and Analysis Subcommittee. Data completeness and error rate monitoring will be conducted on at least a monthly basis The total number of fields with missing data should be less than 5% for each CRF and the total CRFs in the study. Any CRF with missing data greater that 5% must be reviewed and a corrective plan of action documented and implemented. The total number of errors found should be less than one half of one percent (.5%). If the error rate exceeds one half of one percent (.5%) for any CRF, the cause(s) of the error rate should be evaluated and a corrective plan of action documented and implemented.

One hundred percent (100%) of the data for the first 8 participants for each participating Community Treatment Program (CTP) will be audited. A random sample of additional 16 participants should be audited during the course of the protocol. Recruitment of the 80 participants is expected to take one year. Therefore, 4 participants per quarter should be audited to achieve the 16 participant quota when 80 participants are entered. If recruitment is less than expected, a minimum of 2 cases per quarter should be audited until the protocol terminates recruitment. The data audit process will be done on the complete chart or 100% of the participant data will be audited. The data audit will compare data on the CRFs with the data processed and stored in the study database. All safety data found on the Serious Adverse Event CRF, for all participants, will have a 100 % data audit. If the error rate of any data audit exceeds one half of one percent (.5%) for any CRF, the cause(s) of the error rate should be evaluated, and a plan of corrective action documented and implemented. Each Node will be responsible for developing and implementing a Standard Operating Procedure for resolving any CRF with greater than one half of one percent (.5%) error rate for any CRF.

4. Recruitment Reporting

Each Node will be entering specific recruitment and retention data into the NIDA Clinical Trial Portfolio System (CTPS) on a weekly basis:

- Number Screened
- Number Eligible
- Number Completed Pretreatment Assessments
- Number Randomized
- Number Started
- Number Currently in Active Phase
- Number of Drop outs
- Number of Completers
- Number Eligible for Post Treatment Interview
- Number Completed Post Treatment Interview
- Number Eligible for Follow-up 1 Interview
- Number Completed Follow-up 1 Interview
- Number Eligible for Follow-up 2 Interview

- Number Completed Follow-up 2 Interview
- Number of Serious Adverse Events

This information will be used by the New England Node to monitor Node and Site recruitment and retention. Documentation of all the elements and their definitions will be provided by the New England Node in collaboration with the NIDA Protocol Manager. In the event that the CTP System is unavailable for this protocol, each node will be responsible for collecting and forwarding the required information to the New England Node Project Coordinator on a weekly basis.

In addition, the following reports as specified in the Participant Recruitment, Progress and Monitoring SOP will be produced on a monthly basis to monitor participants through out the study. These reports will be sent to the New England Node Data Manager on a monthly basis:

- Screened to Randomized Participant Comparison
- Reasons for Non-Randomization of Participants
- Targeted, Actual and Projected Randomizations
- Treatment Phase Status of Participants
- Reasons for Early Termination of Participants – Treatment Phase
- Follow-up Status
- Reasons for Early Termination of Participants – Follow Up Phase
- Participant Demographics
- Number of QA visits and reports
- Number of protocol violations and resolution

In addition, the following should be reported to the Lead Node Data Manager on a monthly basis:

- Number of Data QA visits
- Urn Randomization Log

Each Node is responsible for developing and implementing a Standard Operating Procedure for reviewing and resolving any issues that arise from the participant recruitment, progress and retention reports.

5. Automated Data Acquisition and Management Systems Development

Each node is responsible for the development of a comprehensive automated data acquisition and management system in accordance with guidelines and SOPs published by NIDA and the CTN Data Management and Analysis Subcommittee. The New England Node Data Management Center will provide data dictionaries for each CRF that will comprehensively define each data element. The data dictionary will specify missing, illogical, out of range, and inconsistent value checks for each data element as well as within CRF logic checks and across CRF logic checks. The data dictionaries provide the specifications necessary for each node to develop an automated data acquisition and management system. The data dictionaries will be

designed in accordance with standards established by the CTN Data Management and Analysis Subcommittee. The Data Dictionaries developed for the Spanish CRFs will have the Spanish translation of the Question and the response labels, in addition to the regular English information.

6. Central Data Repository

A data extract program will be programmed, tested and ready for transmitting data to the NIDA central data repository. The transmission of data will be in accordance with the guidelines published in the CTN Data Management and Analysis Subcommittee Data Transmission SOP. Written approval will be received from the NIDA central data repository vendor indicating that the node has been approved for transmitting data to the central data repository prior to the implementation of the study. Data will be transmitted by the data management center of each participating node to the NIDA central data repository on the 1st day of every month .The New England Data Management Center will receive data from the NIDA central data repository on a monthly basis for data completeness, timeliness and accuracy quality assurance review. The New England Node will provide a database locking timeline and requirements checklist. At the completion of the study and after all node databases have been locked, all data will be transmitted from the NIDA central data repository to the New England Data Management Center for data analysis and the development of the final study report. The New England Data Management Center will send the final analysis dataset back to NIDA for storage and archive.

2. Data Analysis

Outlined below is the general strategy for data analyses that will address determination of the relative efficacy of treatments, analysis of potential participant predictors of outcome, and process analyses. Notes: The MET (CTN004) and METS (CTN 0021) protocols will be treated and analyzed as two independent protocols, although patient characteristics and outcome data will be compared.

a. Determination of Treatment Outcomes

1. Data reduction

Primary outcome variables have been defined a priori to reduce the risk of Type I error. As there is no single recognized indicator of outcome in substance abuse treatment, supplementary analyses will evaluate reliability, validity, and relationships between outcome variables (e.g., between retention in treatment and frequency of drug use, between drug use and psychosocial outcomes). Other preparatory analyses will include examination of distributions of outcome variables, validation of randomization through comparison of key demographic and drug use variables across treatment groups both within and across CTPs**,** as well as analysis of correspondence of self reports and biological indicators of drug use.

Since many statistical models have an assumption of normal distribution (Glass & Hopkins, 1984), all primary outcome variables will be assessed for normality. Any dependent variable found to violate the assumption of normality will be transformed to reduce skewness. Documentation of all transformations, including statistical program and rationale, will be archived in the central data repository.

Operationalization of primary outcome variables:
Retention: Weeks in treatment at CTP through 3-month follow up.
Substance use: Days of substance use, validated with urine and breath specimen results.

2. Evaluation of treatment effects

The proposed study follows a single factor, two cell design in which psychotherapy condition constitutes the primary independent variable. All analyses will be conducted on the sample of all participants randomized to treatment regardless of actual exposure to treatment to avoid bias associated with analyzing more compliant subsets (i.e., compliance bias), with data pooled across sites (CTPs). The primary means of assessing retention will be a survival analysis using "week of termination" as the dependent variable and treatment group as the independent variable, with the addition of site and site-by treatment terms to assess site effects. Survival analysis does not require normal distribution of the dependent variable. Additional tests may include simple ANOVAs with the dependent variables "session completed" with treatment group as the independent variable, with additional terms added to evaluate site as well as site by treatment interactions.

These same statistical models will be applied to the substance use outcome evaluation. In addition, longitudinal analyses involving repeated assessment of the same variable (such as frequency of drug use by week over a 4-week period) may be evaluated using random effect regression analyses (Bryk & Raudenbush, 1987), with treatment as the primary independent variable. Like ANOVA, the random effect regression model allows for use of many independent variables and interactions, with the additional benefit of modeling outcomes for all participants, regardless of whether there is missing data or data collected off schedule.

3. Adequacy of sample size

A conservative approach to sample size calculation has been adopted that will permit, in addition to addressing the primary aims, undertaking several exploratory analyses that can be uniquely addressed through the CTN or are special interest for the CTN: First, for example, given that significant site- or site by treatment interactions may be more likely in the CTN than in other Stage II multicenter studies (due to diversity in patient samples, therapists, and 'standard treatment' across participating CTPs), it is advisable to have adequate power to conduct secondary within-site analyses, should significant site effects or interaction be detected through the principal analyses. Thus, the power calculations presented below are based on the most conservative case; that is, if the pooled analyses reveal significant site or site by treatment interactions, it may be necessary to have adequate power to conduct some within-site analyses

for the primary outcomes. These power calculations suggest that the estimated sample size will be adequate to detect moderate effects within sites.

Second, an important secondary aim of the protocols will be to conduct a series of analyses using therapist, rather than participant, as the unit of analyses (e.g., evaluating outcome as a function of therapist skill in delivering MET or MI, evaluating level of training needed for different types of therapists). Thus, there are clear advantages to having larger number of therapists treat a 'meaningful' number of participants that can only be achieved through a comparatively large sample.

Finally, a larger sample size will allow analyses which can take advantage of the anticipated diversity of participants in CTN protocols; for example, evaluating treatment response by particular patient characteristic of high interest to the CTPs and the clinical community (e.g., response by level of psychiatric severity, whether participants are mandated to treatment, and so on).

H1: MET will be more effective than standard treatment in engaging and retaining participants and in reducing substance use within treatment.

Outcome Type	Var Type	Statistical Method	Est. Effect Size	Sample Size
Engagement	categorical	chi-square	Genesis, .71	26
Substance use	continuous	t-test	.80	70

Thus, to detect significant effects in categorical outcomes (e.g., retention), based on estimates of effect size from available studies (Wilk et al., 1997; Carroll et al., 2001), power would be adequate (.95) given a sample size of 80 at each CTP, should the primary analysis indicate within-site analyses are necessary. To detect significant effects in continuous outcome measures (e.g., drug use by week), the sample size of 95 is sufficient to detect moderate-to-large (.80) effect sizes within CTPs, should within-site analyses be necessary. This is consistent with the effect size on MET compared with directive counseling on substance use outcomes in the Miller et al. (1993) study.

H2: MET will be more effective than standard treatment in fostering continued retention in treatment and in reducing substance use through the 1 and 3 month follow up.

Outcome Type	Var Type	Statistical Method	Est. Effect Size	Necessary Sample Size
Engage/drug use	dichotomous	chi-square	Large (.50)	52

For the follow-up data, the sample would be adequate to detect medium to large effects.

4. Analysis of treatment specificity and process variables

a. Treatment specificity:

Analysis of treatment specificity data (e.g. change in motivation for MET) will be done through random effects regression models for continuous variables with multiple data points and repeated measures ANOVA models for measures collected at pre- and post-treatment only.

b. Process analyses:

Using data obtained from the independent observer rating scale of the audiotaped psychotherapy sessions, several steps will be taken to establish the psychometric properties of the assessment. First, the raters will be evaluated for consistency by having the session raters observe and rate the same subset of at least 15% of the sessions. Intra-class correlation coefficients will then be run on each of the variables to assess reliability of the raters. Once rater reliability has been established (and/or less reliable items have been eliminated from the subscale), the factor structure of the intended subscales will be assessed using confirmatory factor analysis. Once factor/subscales have been shown to be valid (and/or less correlated items have been eliminated from the subscale), treatment discriminability will be evaluated first with simple t-tests of subscale scores by treatment group by week. The second, more precise evaluation of treatment discriminability involves running a multiple groups profile analysis (Harris, 1985) to evaluate all possible systematic effects and interactions (therapist, session, site within node, node, treatment, session by treatment, site within node by treatment, node by treatment, session by node, etc.). This completes the psychometric component of the process analyses.

Finally, our general model for analyzing the impact of specific adherence and competence ratings for each treatment will be to evaluate the effect of measured treatment delivery on outcome. Tests will include simple regression models with the dependent variables "weeks completed" or “percent days abstinent” with treatment score as the independent variable.

c. Interim Analyses

This trial will not involve over 1000 participants, will not involve treatments of 6 months duration or longer, will not be measuring deaths or serious adverse events as an efficacy measure, or evaluate a behavioral intervention for which published information supporting efficacy in the treatment of the addiction under study is considered limited or inconsistent. Moreover, this protocol is not considered likely to provide evidence of “overwhelming efficacy” of one treatment over another. Accordingly, interim analysis of accumulating efficacy data by treatment assignment is not planned.

Rather, in accordance with the Data Safety Monitoring Board’s SOP, presentation of primary and secondary efficacy outcome data and other data not intended to evaluate safety will be presented for all treatment groups combined, further broken down by study node and, if feasible, by CTP. No statistical penalty will be taken for this blinded interim analysis of efficacy data that will be conducted for the sole purpose of assessing the acceptability of safety results.

Adverse event data and other data intended for the monitoring of safety will be presented to the DSMB in an unblinded fashion. Since the trial is not considered to be powered to demonstrate statistically significant differences in adverse events or other safety outcomes, p-values will not be calculated for any differences observed unless specifically requested by members of the Board to assist in the evaluation of a potential safety concern. No adjustments will be made for the number of interim analyses in the final report.

Although interim analysis of efficacy data is not planned, the DSMB may feel that such analysis is necessary to permit proper evaluation of safety data. Should an unscheduled interim analysis of efficacy be necessary, the Board will specify the question, the analysis required, the critical values for a decision and the statistical procedures necessary to control the overall type 1 error at $p<0.05$. A protocol amendment will be included in the DSMB report of the analysis describing necessary changes in the statistical plan that result from the analysis.

I. Regulatory and Reporting Requirements

1. IRB Approval

Prior to initiating the study, the Principal Investigator at each study site will obtain written IRB approval to conduct the study. Should changes to the study protocol become necessary, protocol amendments will be submitted in writing to the IRB by the investigator for IRB approval prior to implementation.

2. Informed Consent

All potential candidates for the study will be given a current copy of the Informed Consent Form to read in Spanish. The investigator, sub-investigators or their designee will explain all aspects of the study in lay language and answer all of the candidate's questions regarding the study. If the candidate desires to participate in the study, s/he will be asked to sign the Informed Consent. No study procedure will be performed prior to signing Informed Consent. Participants who refuse to participate or who withdraw from the study will be treated without prejudice. Consent forms will be translated into Spanish by the University of Miami English/Spanish translators or local translators.

3. Clinical Monitoring

All investigators will allow representatives of NIDA to periodically audit, at mutually convenient times during and after the study, all CRFs and corresponding source documents for each participant. These monitoring visits provide the opportunity to evaluate the progress of the study and to inform NIDA of potential problems at the study sites. The monitors will assure that submitted data are accurate and in agreement with source documentation; verify that study treatments are properly provided, verify that participants' consent for study participation has

been properly obtained and documented, and confirm that research participants entered into the study meet inclusion and exclusion criteria.

4. Study documentation and records retention

Study documentation includes all case report forms, data correction forms, workbooks, source documents, monitoring logs and appointment schedules, sponsor-investigator correspondence, and signed protocol and amendments, Ethics or Institutional Review Committee correspondence and approved consent form and signed participant consent forms.

Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study. Whenever possible, the original recording of an observation should be retained as the source document; however, a photocopy is acceptable provided that it is a clear, legible, and exact duplication of the original document.

5. Confidentiality

a. Confidentiality of Data

The investigator affirms to NIDA that information furnished to the investigator by NIDA will be maintained in confidence and such information will be divulged to the Institutional Review Board, Ethical Review Committee, or similar or expert committee; affiliated institution; and employees only under an appropriate understanding of confidentiality with such board or committee, affiliated institution and employees.

b. Confidentiality of Participant Records

The investigator agrees that within local regulatory restrictions and ethical considerations NIDA or any regulatory agency may consult and/or copy study documents in order to verify case report form data.

6. Site Management and Coordination

Participating Nodes and CTPs will agree to adhere to all current CTN Data Management, Regulatory, Quality Assurance and Training subcommittee policies and procedures. Sites will forward a *weekly* report of participant recruitment, randomization, follow-up, supervision, and QA activities to the Lead Node.

Table 1: MET protocol: SCHEDULE OF CLINICAL ASSESSMENTS , SOURCE OF RATINGS

Instrument			Purpose/domain	Time estimate		Rater	When rated			
Name	**Translate into Spanish?**	**Times done**		**Interview**	**Self-report**		**Pretx**	**Weekly (1x/week x 4)**	**Posttx 28 days**	**Follow-up 1 & 2**
Inclusion/exclusion criteria (IEC)	No	1	Establish eligibility, document reasons for ineligibility			RA	x			
Demographic Form (DEM)	Yes	1	Characterize sample, obtain variables for urn randomization	5 min		RA	x			
Participant Characteristic Form (PCF)	Yes	1	Characterize sample	5 min		RA	x			
Randomization form (RAN)	No	1	Urn randomization							
URICA	Yes	4	Motivation measure, predictor of outcome		5 min	P	x		x	x
Biculturalism scale	Yes	1	Measure of biculturalism		5	P	x			
Treatment Attitude & expectations (AEQ)	Yes	1	Predictor of outcome		5	P	x			
CIDI **Spanish version to be used		1	Diagnostic, characterize sample	20		RA	x			
Urine monitoring (UMR)	No	7	Outcome measure	5		RA	x	x	x	x
Breathalyzer (ABR)	No	7	Outcome	2		RA	X	X	X	X
ASI 'lite' (ASIP, ASI F) Spanish Version		1,3	Baseline assessment/ outcome/component of Personal Feedback Form	25		RA	x		X	X
Substance use calendar (SUP, SUA, SUF, SUF2a, SUF2b)	No	1,1,1,1,1	Self report of frequency of substance use, treatment tracking	10		RA	x		X	x
HRBS (HRB)	Yes	4	HIV risk behaviors, component of PFF, secondary outcome	5		RA	X		X	X
Short Inventory of Problems-R (SIP)	Yes	2	Personal Feedback Form for MET, secondary outcome		5	P	X		X	
Treatment Utilization TUA, TUF, TUF2	No	(3,1),1,1	Treatment utilization, compliance, estimates for cost evaluations	5		RA		X	x	x
Posttx Attitudes & Expectations (PAE)	Yes	1	Satisfaction with treatment			P			x	
Client disposition (CDE)	No	1	Participant response and disposition, including Serious Adverse Events			RA			x	
Helping Alliance Questionnaire (HAQC, HAQT)	Yes (HAQC only)	1,1	Treatment process, rating of therapeutic alliance			P,T		Session 2		
Adherence/competence Rating Scale (STR)	No	1/week S, 1/month E	Quality control of treatment delivery/Process rating system/treatment integrity			**E, S & R versions**		X		
Therapist Session Report & Technique Checklist (TSC)	No	3	Treatment process/quality control			T		x		

Instruments in Blue are CTN Core Assessments (CAB)
Note: RA=Research assistant, P=Participant, T=Therapist, S=Supervisor, R=Process rater, E=Node MET Expert

J. *HUMAN SUBJECTS*

1. Subjects

Individuals will be eligible for the protocol who:

1. Are seeking outpatient treatment for any substance use disorder and who have used any substance (cocaine, alcohol, heroin, methamphetamine, marijuana, benzodiazepines, amphetamines, phencyclidine (PCP), opiates/morphine and barbituates) within the past 28 days.
2. Are 18 years of age or older.
3. Have a sufficiently stable living arrangement
4. Speak **and understand** Spanish as their preferred or principal (most commonly spoken) language
5. Are willing to be randomized to treatment
6. Are willing to be contacted for follow-up assessments 4 and 12 weeks after treatment ends
7. Are likely to be in the area for 4 months
8. Are able to understand and provide written informed consent.

Individuals will be excluded who:

1. Are not sufficiently medically or psychiatrically stable to participate in outpatient treatment. Subjects who have dementia or other irreversible organic brain syndromes, who are currently suicidal or have significant suicidal or homicidal ideation, who are facing imminent or likely incarceration for a period of more than 3 weeks, or who has a spouse or close significant other currently participating in the protocol are ineligible, as are individuals who previously participated in the MET protocol.
2. Are seeking detoxification only, methadone maintenance treatment or residential inpatient treatment.

2. Consent Procedures

After routine screening, all participants will receive an explanation of the study, risks, benefits, treatments, procedures and options for alternative treatment by the research assistant. Participants will be asked to sign the consent form if they wish to participate following resolution of any questions and clear indication that the participants understand the nature of the study and the consent.

3. Risks

a. Psychotherapy

The treatment evaluated here, Motivational Enhancement Therapy (MET), has been used safely in multiple trials with a range of substance-using populations in the past. Psychological risks are minimal and not different from those of equivalent non-study psychotherapeutic interventions, including the comparison condition (standard treatment at the CTP). For each treatment condition, frequent monitoring (at least weekly) of the participant's clinical status by therapists and research staff will insure identification and withdrawal from

the study of participants who show significant psychological or symptomatic deterioration. Women of childbearing age will be included in the study, as there is no known negative interaction of psychotherapy with pregnancy.

b. Urine and Breath Specimen Collection

Urine and breath specimens are collected at each interview as measures of outcome and as safeguards to participants. They should add no risks other than those normally associated with these procedures.

c. Rating Scale and Questionnaires.

These are all non-invasive, should add no risk, and have been used without difficulty or any adverse events in similar, previous studies with substance-abusing populations. The major disadvantage is the time taken to complete them and we have made extensive efforts to minimize the length of time needed to complete the battery as well as its overlap with assessments routinely conducted at the participating CTPs. Past experience with these and closely related measures indicates that they are acceptable to participants. Careful efforts aimed at maintaining confidentiality have been effective in previous research, and only participants' code numbers will be recorded on the forms themselves to protect confidentiality.

d. Audiotaping of Therapy Sessions

Audiotaping of therapy sessions is necessary to assure that the therapists administer the study treatments within explicit manual guidelines and to evaluate the degree to which overlap between conditions occurs. To assure the confidentiality and protection of participants with respect to audiotaping, the following steps will be taken:

(1) Participants have the right to refuse audiotaping. Participants who consent to audiotaping will be informed that they have the right to stop taping at any time during any session. Participants also have the right, at any point during participation, to request that all existing tapes be erased.
(2) Each therapist will conduct the taping him/herself. All taping will take place in the office of the participating CTP.
(3) Each tape will be labeled with the participant's study identification number, the therapist's identification number, the CTP number, the study number (NIDA-CTN-0021), the Node number, the the session number (e.g., 1-3) and the session date.
(4) The therapist will then give the completed tape recording to the Research Assistant. Tapes will be stored in locked files in secure research offices in the participating CTP.
(5) To evaluate treatment integrity (e.g., whether the therapists followed the manual guidelines) and discriminability (e.g., to what extent motivational interventions were present in the 'standard treatment'), it is necessary that a portion of all session tapes be rated for therapist adherence and competence. For these ratings, the tapes and log to be sent to the Lead Node Coordinating Center (LNCC) via a traceable mailing system (ie. UPS, FedEx). The research assistant at the LNCC will document that the tapes have been received by the CTP, and distribute the tapes to the tape raters. Following the completion of the ratings, the tapes will be destroyed at LNCC and the CTP coordinator will be notified that this has been done.

(6) Access to the audiotapes will be limited to the CTP supervisors and the specially trained tape raters, who will rate the tapes in order to evaluate therapist adherence and competence in implementing treatment. All ratings will be done in secure research offices.

(7) Upon completion of these ratings, the audiotapes will be destroyed at both sites (CTP and Lead Node Coordinating Center).

4. Protection of Participants

Confidentiality in regards to collected materials will be maintained via a numbered reference system maintained by the research assistant. Participants' names will appear only on a consent form and "key" form kept by the Node project coordinator in a locked cabinet. Participants will be withdrawn from the study if they show severe psychological or symptomatic deterioration if clinically necessary for ethical or safety purposes. Participants dropped from a study for these reasons or because they wish to withdraw from a study will be offered treatment as usual at the CTP.

To further safeguard confidentiality, we have applied for/received a Federal Certificate of Confidentiality. Participation in the study will involve no increased risk to participants beyond that which would be incurred through seeking and entering treatment at the participating CTP. Prospective participants will be informed that their decision to participate in the study or to drop out of the study will have no impact on their relationship with the CTP or their ability to obtain treatment at the CTP in the future.

5. Potential Benefits

Benefits to participants include significant psychotherapeutic exploration through the provision of study psychotherapies. All participants will be offered a material inducement for participation in study evaluations including $10 for each assessment completed. The major potential benefit in this study is in reduction of substance use via the study treatments, which may, in turn, foster improvement in participants legal, medical, interpersonal, psychological and occupational functioning. ***Note that individual Nodes may determine the amount of financial incentive for completion of research instruments. The local IRB must be informed of any change in level of incentives and this should be forwarded to the lead node.***

6. Risk/Benefit Ratio

Purely psychotherapeutic approaches are standard treatment in the majority of participating CTPs and treatment centers in the US. The study psychotherapies carry minimal risks and are likely to be of benefit. The psychological and laboratory assessments also confer minimal risks and these are minimized through confidentiality procedures and the used of skilled personnel. We believe we have included adequate safeguards for participants to address the ethical questions, including exclusion of participants at significant risk for suicide, regular contacts with program staff and close monitoring of symptoms, procedures to withdraw from study treatments participants who show significant deterioration, and minimization of coercive aspects of treatment and research participation. Thus, the potential benefits for individuals and society at large are great; and the risk/benefit ratio appears favorable toward the proposed study treatments.

Sample consent form: Yale HIC format

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY DEPARTMENT OF PSYCHIATRY

**Name of CTP*

Invitation to Participate and Description of Project

You are invited to participate in a study of ways to increase treatment involvement for substance use. You have been offered this choice because it is our understanding that you are seeking treatment for a substance use problem at this clinic

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study that a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, and any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

This study will last for 4 weeks. Each participant will be assigned to one of the two following treatments:

1). Standard individual drug counseling.

This is identical to the treatment you would normally receive at this clinic. It will include at least three individual weekly sessions that will focus (***describe in terms of Standard Treatment at the CTP, such as) on *orienting you to the treatment program, teaching you important concepts of recovery, increasing your self-awareness of specific problems you may be experiencing related to your addiction and demonstrating new ways of coping with skills designed to fit your lifestyle, as well as…..* You will also be asked to complete a brief questionnaire and to provide urine and breath specimens for drug and alcohol testing. Each weekly session will require about one hour.

OR

2). Motivational Enhancement Therapy

This therapy will also take place in three individual weekly sessions and will focus on reviewing what you see as problems associated with your substance use and developing a plan to change your behavior You will also be asked to complete a brief questionnaire and to provide urine and breath specimens for drug and alcohol testing. Each weekly session will require about one hour.

We will decide what treatment you will receive by random selection. This means that your treatment will be decided by luck of the draw and not selected deliberately because of any special characteristics or problems you have.

When you enter the study you will be interviewed by study staff and asked to fill out questionnaires and provide a urine and breath specimen for drug and alcohol testing. This will require about one and 1/2 hours. At the end of the four weeks you will be asked to fill out more questionnaires, provide a urine and breath specimen for drug and alcohol testing, and be interviewed again. At the end of this part of the study, you may continue treatment at this, or if you wish, be referred elsewhere or leave treatment.

We request your consent to audiotape the treatment sessions. This taping is being performed in order to make sure your therapist is carrying out the treatment properly. Members of the research team will review the audiotapes only. . You also have the right to stop taping at any time during the evaluation. You also have the right, at any point during participation, to request that all existing tapes be erased. Audiotapes will not be used for training or any other purpose and identification of tapes will be by code number only. Following review of the audiotapes by members of the research team, the tapes will be erased.

We will contact you one and three months after you leave the study and ask you to come in for a brief interview, to fill out questionnaires, and to provide a urine and breath specimen for drug and alcohol testing. This will take about an hour each time.

You will be paid $xx for completing each of the assessments (pretreatment, each week during treatment, posttreatment, and each of the two follow-ups. Therefore, if you complete each assessment as scheduled, you would be paid a total of $xx.

We will ask you to provide the names and telephone numbers of several individuals in your life who are likely to know of your whereabouts in order to help us locate you for the follow-up interviews. These individuals will be contacted only if we cannot locate you directly first; we will ask them only about where we may contact you (we will not ask about drug use or other problems); and we will not reveal to your locators any information about this study or your participation in it.

Risks and Inconveniences

We can foresee no known risks to participating in this treatment. We would like you to tell us about any times you use alcohol or illegal drugs while you are in the study. It is not illegal to report past substance use. Also, we know that stopping substance abuse can be quite difficult. In order to be helpful to you we simply need to know about your substance use. The urine drug tests and the breathalyzer tests for alcohol enable us to be certain of our results. The only way you might be dismissed from the study is if you repeatedly do not come to treatment. Your obligation to the study is to do your best to stop using drugs, to be honest about yourself and your problems and to be available at your appointment times for both the research assistant and your counselor.

Benefits

This program may help you control your drug use. However, there is no guarantee that you will benefit from participating in this program. Further treatment will be arranged at the end of the study (at the end of the four weeks) if you wish. If this involves this clinic, you will be charged for subsequent treatment as is usual.

Economic Considerations

All evaluations you receive as part of this study are provided free of charge. You will be paid for the time it takes to complete assessments. If you attend all seven interviews as scheduled that you will receive a total of $xx.

Alternative Treatments

Should you decide not to participate in this study, you will be referred to the regular evaluation and intake procedures and be referred to treatment as is usual at this clinic.

Confidentiality

We will make every effort to insure your confidentiality. In all records of the study you will be identified only by a number. Your name will not appear in any publication or be released to anyone without your written consent. Participation in the study will involve no increased risk to you. However, you should understand that there is a risk that you will be recognized by other participants or staff involved in the study, but this is no greater than the usual risk of identification that occurs in our usual treatment in this clinic. If you find this risk unacceptable you should not sign this consent form.

In order to further safeguard your confidentiality, we have applied for a Certificate of Confidentiality from the Secretary of the US Department of Health and Human Services. As a result, the investigators and anyone else involved in this project cannot be compelled to reveal your name, urinalysis results, and other identifying characteristics to anyone without your written consent. This certificate protects investigators from being forced to release any research data in which you are identified, even under a court order or subpoena. This protection, however, is not absolute. It does not for apply to any state requirement to report certain communicable diseases, to report cases of physical or sexual abuse, or to disclosure of medical information in cases of medical necessity. These types of reports will not be made without your knowledge. The results of this research project may be presented at meetings or in publications; however, your identity will not be disclosed in these presentations.

Voluntary Participation

You are free to choose not to participate, and if you do become a participant, you are free to withdraw from the study at any time. If you withdraw it will not adversely affect your relationship with this clinic or the clinicians or doctors here. If you decide to withdraw, arrangements will be made with you to receive further treatment as needed.

Please feel free to ask about anything you do not understand and please consider this research and the consent form carefully before you decide whether or not to participate. You may take as much time as necessary to think it over.

Summary:

This study will compare two types of treatment to determine which is most useful in increasing engagement in treatment. The study will take place in three individual sessions of approximately one hour over a four-week period. These sessions will be audiotaped. At the end of the four weeks I will be asked to complete research assessments and I will be contacted for a follow-up evaluation one and three months later.

Authorization: I have read this form and decided that:

_____(name of participant)
will participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

_____
(Signature)

_____
Relationship (Self, patient, guardian)

_____
Date

_____ _____
Signature of Person Obtaining Consent Telephone

If you have further questions about this project or your rights as a research participant, please contact the principal investigator, Kathleen Carroll, Ph.D at 203.937.3486 x7403.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING
BOX HAS BEEN COMPLETED IN THE HIC OFFICE:

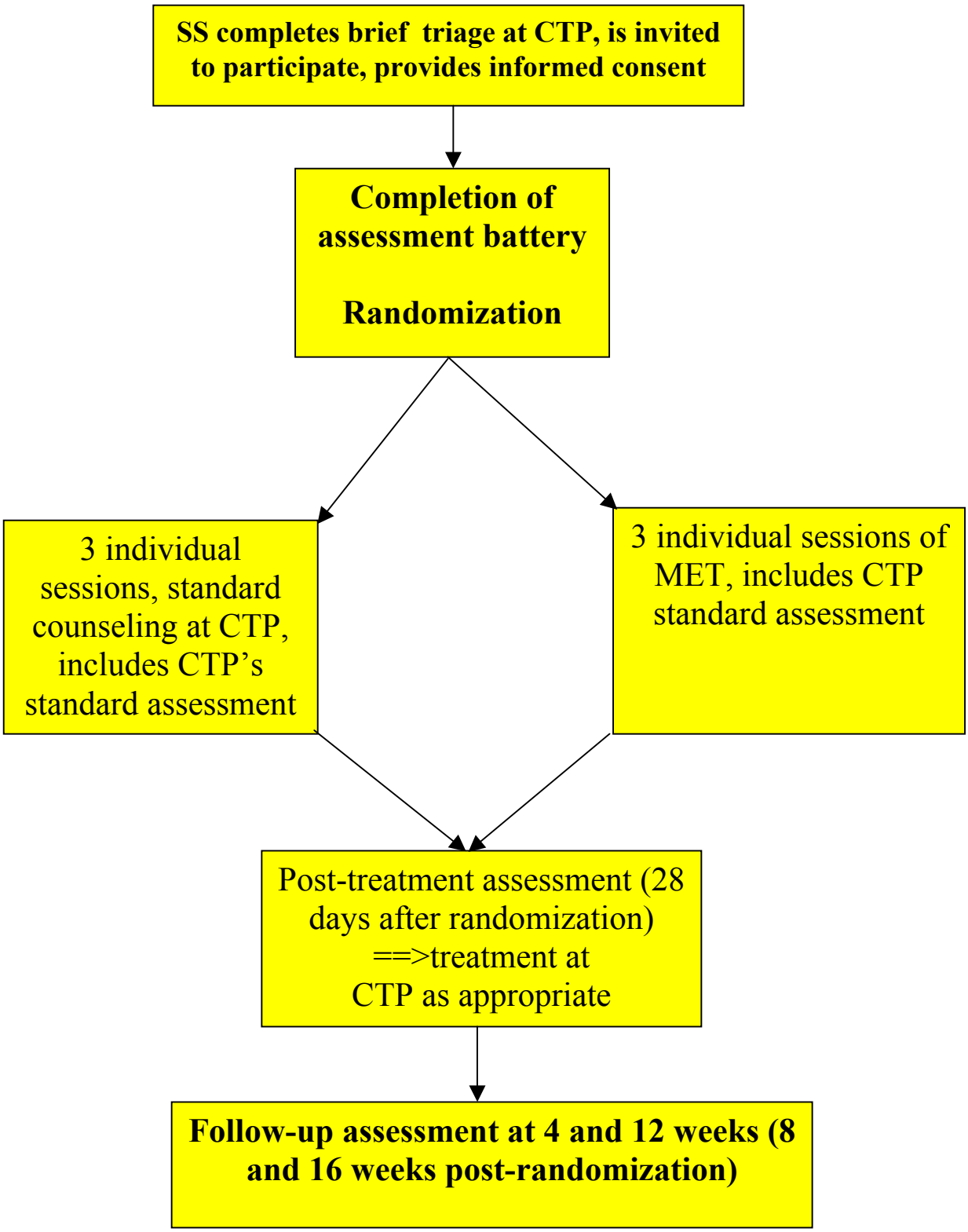
THIS FORM IS ONLY VALID UNTIL:

_____(date)

HIC Protocol #_____

Initialed:_____

MET protocol: Does incorporating MET into the treatment entry process enhance engagement, retention, outcome?



K. *Literature cited*

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