

## **A structural model of Twelve-Step group process**

## A. Specific aims

For over 20 years criminal courts have mandated alcohol and drug-related offenders to attend Twelve-Step meetings as part of the criteria for probation. Depending upon the history of the offender, and seriousness of the offense, the frequency of meeting attendance varies (Green, et al, 1991; O'Callaghan, 1990; Fair, 1986). Many justice systems around the country view these programs as at least one efficacious alternative treatment solution (Speiglman, 1997). Many in-patient and out-patient treatment facilities utilize Twelve-Step oriented therapy as one of their primary treatment procedures in both group and individual formats. Some 90 percent of residential and outpatient treatment programs draw directly on its principles (Lampman, 2004). Attending Alcoholics Anonymous is free. Meetings are in abundance worldwide, AA/NA local phone numbers are available in any phonebook, and there is always someone to refer the caller to the closest meeting. There is no patient co-payment; there is no deductible. Indeed, research suggests that AA/NA may financially relieve the healthcare burden in the U.S. markedly (French, 2000; Humphreys and Moos, 2001). Millions of former alcoholics and addicts insist that attending Twelve Step meetings, and following the program set forth there, has played a major role in helping them to lead sober and productive lives.

AA and its sister group meeting formats are similar internationally, and contain most of the same elements with variations only in meeting types, length, and in local and cultural nuances (Makela, et al, 1996). If the purpose of treatment manualization or "best practices" procedures were to define and operationalize treatment structure, format, and content more rigorously in the name of empirical reliability and therapeutic uniformity (Carroll, 1997), then Twelve-Step programs potentially provide a stable reference platform toward these ends. A research-based or "empirical" bridge is required between the academic and Twelve-Step communities. Some writers have attempted to describe constructs in terms of cognitive-behavioral psychology in order to map Twelve-Step programs to empirical, researchable therapeutic paradigms, but they seem to have fallen short on specifically how the Twelve-Step paradigm intervenes therapeutically (Kadden, 2001; Project MATCH, 1998; Fuller, 2000).

Our primary aim is to demonstrate and confirm a general model that will describe the twelve-step group process with or without the participation of a group facilitator or therapist, a model that accounts for the therapeutic factors associated with participating in a twelve-step oriented, professionally led therapy group, or simply going to AA/NA meetings. Based upon Yalom's Curative factors, and other research findings (Beutler, et al, 1993; Getter, et al, 1992; Stone, et al, 1994), we propose to demonstrate such a model. It is a structural model with four interrelated factors: Information (Factor 1), Social Support (Factor 2), Cognitive Restructuring (or Defense Mitigation) (Factor 3), and Therapist Effects (Factor 4) (Figure 1-D).

Cognitive Restructuring (Factor 3), or "breakdown of defenses", is strongly associated with addicted individuals becoming committed to addiction recovery and abstinence (Marlatt & Gordon, 1985; Larimer, et al, 1999; Steigerwald, et al, 1999; Wolburg, et al, 1999). It is to this factor we postulate that all other factors of the therapeutic group process contribute, and to which they continue to maintain. Our proposed model positions the factor Cognitive Restructuring so that it is mediated directly by therapist effects ( $C_{43}$ ) through his/her therapeutic directiveness and skill. Through the therapist intervention the group members combine to confront misaligned beliefs (an indicator of Factor 3) and perceptions, and facilitate a process of blame reduction, thus promoting a process of taking responsibility for one's own actions and decisions, i.e. "attribution redirection" (another indicator for Factor 3).

We propose that Cognitive Restructuring is also mediated by paths from Information ( $C_{13}$ ,  $C_{31}$ ) and Social Support ( $C_{23}$ ,  $C_{32}$ ). The reciprocal effects of these factors vary depending upon the presence of a therapist group leader, but the coefficient valence is positive. That is, Information acts positively on Cognitive Restructuring, and Cognitive Restructuring acts reciprocally positively on Information. When the Therapist Effect factor (Factor 4) is removed by simple absence of a professional group leader, as is what occurs at an AA/NA meeting (AA's Twelve Traditions, 1978), the Cognitive Restructuring factor remains (Figure 2-D). However, in order for the model to continue to fit, the effects of Information and Social Support must compensate for the lost therapist effects. Reciprocal effects from Social Support and Information become more prominent, but the combined coefficients do not account for the loss of the therapist. Hence, the reciprocal effects between Information and Cognitive Restructuring and Social Support and Cognitive Restructuring vary proportionally when the factor of Therapist Effects is removed. Figure 2 represents this general nested model.

The measures to which the related factors are causal agents are each differentially associated with patient characteristics of coping style and resistance. They are also modified parameters of Yalom's curative factors. Coping style is measured along a dimension of externalizing to internalizing. Examples of externalizing include "acting out", blaming, avoiding, and projection; examples of internalizing include excessive worry, rumination, introversion, and compartmentalization. Resistance is a dimension ranging from accepting and docile to argumentative and passive-aggressive. We propose that the factor loading of each measure will differ relative to the general type of Twelve-Step meeting. The relative weights of the independent variable indicator coefficients ("oval" to "rectangle" arrows) will similarly align corresponding to the meeting category (i.e. speaker, step study, participation, beginner, etc).

It is to this phenomenon that we postulate AA/NA becomes even more differentially effective depending upon different individuals' predisposing characteristics. One explanation could be that there is a reliance of fewer contributing factors of change, so the overall potency of the therapeutic process becomes less effective. The independent indicator variables on which the remaining factors of Information and Social Support load must be optimized by aligning them to a patient's characteristics, his/her coping style and level of resistance to change.

Our secondary aim is to optimize the change process (Figure 3-D), thereby optimizing positive outcomes (fewer relapses, less time within each relapse, more time between relapses, and greater well-being over a period of four years). The independent latent variable, Outcomes, is acted on directly by the independent latent variables via  $C_{25}$  from Social Support,  $C_{15}$  from Information, and  $C_{35}$  from Cognitive Restructure (Figure 3-D). Optimization of outcomes is based on assumptions regarding differential loading of independent latent variable indicators across Twelve-Step group categories: (1) nested models that are less directive and less expressive will be more facilitative to positive outcomes for reactant and internalizing patients; (2) nested models that are less directive and more expressive will be more facilitative to positive outcomes for reactant and externalizing patients; (3) nested models that are more directive and less expressive will be more facilitative to positive outcomes for nonreactant and internalizing patients; (4) nested models that are more directive and more expressive will be more facilitative to positive outcomes for nonreactant and externalizing patients (all derivatives of Figure 3-D).

To summarize this section, our objectives are:

1. Identify the model for professionally led Twelve-Step group therapy illustrated in Figure 1 (Section D).
2. Identify the model for community Twelve-Step meetings (no therapist or facilitator leader) in Figure 2 (Section D).
3. Confirm fits for nested models of different types of meetings based upon differential loading of the independent factor indicators (i.e. the indicators will load differently for Speaker meetings than for Step Study meetings).
4. Confirm that meeting category differentially facilitates outcomes relative to individual predisposing characteristics of coping style and resistance, thereby improving outcomes over a four year period.

## **B. Background and significance**

### Research and Twelve-Steps

Theories and anecdotal diatribes abound as to why and how Alcoholics Anonymous (AA) and its sister groups (NA, CA, etc) work, or don't work, as the case may be (Ellis and Velten, 1992; Peele, et al, 2000; Tonnigan, 2001). However, research exploring the group dynamics and factors internal to Twelve Step meetings is scant. Indeed, the effects of inclusion of Twelve Step concepts into professionally led group therapy reveals a paucity of compelling research data. Any statistically relevant factor variations in meeting dynamics could aid in transitioning substance abusers to more personally facilitative meetings and social support networks after release from inpatient facilities. If the components of Twelve Step groups were operationalized, then perhaps variation in some of these factors across individuals or groups would help to systematically optimize treatment outcomes. Identifying salient factors in professionally led Twelve Step groups would lead to greater definition and reliability of the process through manualization.

Beutler and his colleagues (1993) observed some of the constraints imposed on research in Twelve-Step programs because of the distinctive philosophies of AA (Alcoholics Anonymous) as compared to conventional

group psychotherapy methods. They proposed "philosophical assumptions and misconceptions" that distinguish the mechanism through which change is assumed to occur in AA. Indeed, it could be reasonably postulated that there are mechanisms of change that AA may or may not share with conventional group therapy. An examination of these effects would require varying the formats used to evoke change processes by Twelve-Step and other group therapy models, and exploring some of the more practical methods of measuring group processes. An examination of the therapeutic processes and outcomes that both characterize and distinguish AA relative to other group methods is necessitated.

Our research proposes a practical method for examining these kinds of group processes. This study is a correlational design using structural equation modeling and nested models. Not only do we believe it is the most appropriate design approach for this particular study, but it also circumvents many of the methodological confounds and barriers inherent in Twelve-Step research (specifically, AA does not "engage in or sponsor research", [http://www.alcoholics-anonymous.org/default/en\\_about\\_aa.cfm?pageid=25](http://www.alcoholics-anonymous.org/default/en_about_aa.cfm?pageid=25)). Based on the stated unavailability of twelve-step groups for research, random selection of participants, randomly assigned groups with a control group, or single/multiple subject experimental designs are impractical and disruptive approaches when researching twelve-step oriented addiction recovery programs, and especially AA /NA and other community-based groups.

Some of the more obvious and directly observable differences between institutionally sponsored Twelve-Step group therapy and community-based Twelve-Step (Alcoholics Anonymous, Narcotics Anonymous) meetings should first be considered before the more subtle nuances are embraced. Community meetings are not professionally led or guided. The leader is "invisible", and does not provide "therapeutic guidance" or direction. Rather, the leader is chosen before the beginning of the meeting, and adheres to a previously defined format. Second, there is no personal confrontation. Meetings adhere to a specific topic or theme, and the guidelines for individual comments are established from there. A person speaks when selected by the leader or in turn, and in almost all cases directs his/her comments to the group, and very seldom to a particular individual. Indeed, some "speaker meetings" only have 1-3 selected speakers, and they speak "podium-style". Third, meeting attendance is essentially free. A nonobligatory collection is taken close to the end of the meeting time, and attendees usually contribute one dollar (AA Forum Group website).

A considerable body of research which compares professional treatment based on Twelve-Step philosophy with other professional treatment modes shows no superior outcomes (Galanter, 1987; Montgomery, et al, 1995). This lackluster evidence may be based on several overlooked factors. Many non-Twelve-Step treatment programs do not use abstinence as an outcome measure, whereas the primary (but not the only) goal of Twelve-Step philosophy is sobriety, i.e., abstinence (AA Grapevine; Nathan, et al, 1987; Orford & Alistair, 1986; Marlatt, 1985). Secondly, some of the components of Twelve-Step programs may indeed not be best suited for certain individuals. Certainly atheists do not bode well with a program that requires them to "turn their will and life over to the care of God.." (Peele, et al, 2000; Ellis & Velten, 1992). Thirdly, any treatment that includes Twelve-Step content and facilitates going to AA/NA meetings can call itself treatment with twelve-step orientation. Nevertheless, Twelve-Step content, or allusion to Twelve-Step philosophy is not necessarily "Twelve-Step treatment". The construct lacks operationalization and definition, which makes any empirical examination futile. The first part of this study proposes to define and clarify the components of Twelve-Step treatment common to both professionally guided and community groups.

Findings differ on whether self-help, professional, or a combination of the two contribute more concisely to outcomes. Timko (Timko, Moos, et al, 2000) compared four groups of previously untreated problem drinkers: AA only, formal treatment only, formal and AA, and no treatment at all. They found that individuals who received some intervention (AA, professional, or both) were more likely to be abstinent at eight year follow-up than were individuals who received no treatment, but they also found that formal treatment plus AA was better at one and three year follow-up than formal treatment only. Similarly, Galanter and his colleagues (2001) compared two ambulatory alcoholism treatment programs, a control program operated solely by professional staff and an experimental program based on peer-led self-help (SH), and found that although the self-help patients scored significantly higher on social adjustment, their drinking rates and utilization of Alcoholics Anonymous were no different from controls. Humphreys and Moos (2001) conducted a prospective, quasi-experimental comparison of five Twelve-Step-based and five cognitive-behavioral (CB) inpatient substance abuse treatment programs. They found patients treated in Twelve-Step programs had significantly greater

involvement in self-help groups. In contrast, patients treated in CB programs averaged almost twice as many outpatient continuing care visits after discharge, and received significantly more days of inpatient care.

Frequency of AA meeting attendance is often touted as a surer and reliable road to recovery, and could be a possible contributory factor to better outcomes (Brown, et al, 2001). Findings suggest, however, that higher frequency of Twelve-Step meeting attendance alone does not seem to contribute to positive outcomes (Watson, et al, 1997). The evidence upon which research has seemed to agree so far is that occasional and moderate AA attendance appears to be associated with better outcomes than nonattendance, but frequent participation does not appear to be associated with better outcomes than occasional or moderate participation.

### Elements of group process

Research into the evaluation of group process and dynamics has steadily advanced. Constructs associated with group change on salient variables that affect the outcome of groups and group interventions have consistently evolved over the past century. Traditionally these theories and associated evaluative mechanisms have focused on the individual within the social group situation, rather than on the group as a unit (Smith & White, 1983). There are a number of factors thought to influence group outcomes. These are generally referred to as “therapeutic” or “curative” factors in the literature (Reid, 1997; Toseland & Rivas, 1995; Yalom, 1995). They have been the subject of both clinical and empirical research and provide a conceptual basis for group evaluation.

Yalom (1985) lists eleven therapeutic factors in group therapy: instillation of hope, universality, imparting of information, altruism, corrective recapitulation of the primary family group, development of socializing techniques, imitative behavior, interpersonal learning, group cohesiveness, catharsis, and existential factors. The scale has been shown to have adequate stability in an extensive factor analysis (Stone, 1994). If Yalom’s factors map to groups with Twelve-Step orientations, then it is reasonable to infer that these factors are recapitulated in professionally provided Twelve-Step group therapies. Taking the inference one step further, if one adjusts for the absence of therapist effects, these factors could be the active therapeutic ingredients in varying proportions in self-help Twelve-Step groups (AA, NA, etc). Our research purports to demonstrate just this concept. How much relative weight each “curative factor” bears in the treatment, how each maps to Twelve-Step philosophy, and how each factor differentially impacts individual patient characteristics represent a systematic alignment of treatment to outcomes.

Factors in addition to Yalom’s should be considered in the group therapy process. Self-understanding, reality testing of members, group acceptance, freedom to self-disclose, and the degree of perceived guidance offered by the group are also worth consideration as group evaluative constructs (Reid, 1997). Some of Yalom’s constructs could be unwieldy to operationalize and measure, like recapitulation of the primary family group, catharsis, and existential factors, and will not be considered in the present study.

### Addiction Treatment Groups

There is a very commonly heard adage in Twelve-Step programs: “Keep coming back.” (ref). The phrase is enduring and ubiquitous within AA, and two possible explanations could be offered. One possibility is that through continued repetition and exposure one’s attributions eventually shift away from those which are addictively predisposing, to “healthier” attitudes and outlooks. There is yet another possible explanation of alignment and match. If the addicted individual continues to persistently and unwaveringly navigate her way through the myriad of various meetings, she will eventually find one or more regular groups that distinctively align with her personal characteristics. The alignment will facilitate continued and deeper exposure and involvement, and the patient will become more committed and entrenched in the process of remaining substance free. Furthermore, this process will shift from one of resistance and “fighting the urge” to drink/use, to one of attraction to a restructured thinking pattern in which drinking/using is simply unacceptable and undesirable.

However, the process of “discovery” is random, one of trial and error, and lends itself to frustration and premature dropout. The “one size fits all” mentality may not apply to Twelve-Step oriented substance abuse treatment, anymore than it applies to the treatment of other mental disorders (Beutler & Clarkin, 1990; Beutler

& Williams; Fuller & Allen, 2000; Harwood & Williams, 2003). Patient variables and pre-disposing qualities must be considered and co-factored into outcomes ((Beutler & Clarkin, 1990; Beutler & Williams). Co-morbid depression and other disorders, chronicity, organic degeneration, alcohol/drug-centered social support, as well as potentially compromising reasons for being in treatment effect outcome (Beutler & Harwood, 2000). Previous findings in this area support continued research for prescribed or systematic approaches to matching treatments to patients, especially in the area of Twelve-Step treatment where the number of different groups abound and the variation is marked but definable.

### *Treatment Alignment*

Project MATCH (Matching Alcoholism Treatments to Client Heterogeneity- was a large multi-site trial that tested whether outcomes can be improved by matching subgroups of patients to treatments. Three psychosocial treatments were tested for potential to match to over 20 attributes among 1,726 participants: Twelve-Step Facilitation Therapy, Motivational Enhancement Therapy, and Cognitive Behavioral Therapy. Only four out of the 20 patient characteristics produced statistically significant matches: psychiatric severity (number of psychological symptoms), anger, network support for drinking (outpatients), and alcohol dependence (aftercare patients). There was a 10% advantage for Twelve-Step Facilitation Therapy over the other treatments in twelve month follow-up (Project MATCH, 1998). Findings appear somewhat consistent for better outcomes for inpatient programs to transition to outpatient programs with Twelve-Step focus with patients higher in dependence severity (Fuller and Allen, 2000). Other research suggests that addiction severity alone (without Twelve-Step intervention) is a sufficient alignment variable for predicting outcomes (Satre, et al, 2003). Individual coping style and resistance were not included in the matching attributes, however.

Cognitive attribution or coping style could be important treatment alignment components to treatment for the addicted individual. Thornton and his colleagues (2003) explored whether pretreatment levels of learned helplessness (LH) were related to outcomes for substance-dependent individuals receiving high-structure, behaviorally oriented (HSB) or low-structure, facilitative (LSF) treatment. They found significant and comparable reductions in symptoms occurred for both the HSB and LSF patients both during treatment and at follow-up. Specifically, the more "helpless" patients did significantly better in treatments with more structure and direction, whereas the less "helpless" patients had better outcomes with less structure. In another study that used level of patient psychiatric severity as a matching dimension, high level patients were matched to cognitive-behavioral therapy (high), and low level patients to interactional therapy. Prospective matching did not produce superior drinking outcomes compared to patients receiving random treatment assignment (Kadden, et al, 2001).

### *Coping style*

The behaviors defining different "Coping styles" are well defined and broadly accepted as being trait-like. Personality research (e.g., Widiger, & Trull, 1991) has bifurcated individuals into extroverted and introverted groups. The former group is characterized by acting out, stimulation seeking, and impulsive behavior (external coping styles) and those in the second group are characterized by emotional restriction, stimulation avoidance, and indecisiveness (internal coping styles) (Beutler, & Clarkin, 1990). Research by Beutler, Engle, Mohr, et al., 1991; Beutler, & Mitchell, 1981; Beutler, Mohr, Grawe, et al, 1991; Calvert, Beutler, & Crago, 1988 has consistently supported the hypothesis that externalizing, depressed individuals do best with a skill-building, behavioral contracting, and symptom-focused therapies while internalizing depressives do best with an insight or relationship-oriented therapies.

Similar aspects of coping style have been studied widely in the alcohol literature. Impulsive and aggressive patients ("externalizers") have been found to respond better to cognitive-behavioral (Longabaugh, et al, 1994) and behavioral (Kadden, Cooney, Getter, & Litt, 1989; Litt, Babor, et al, 1992) interventions than they do to interpersonal or relationship enhancing therapies. Less impulsive and aggressive patients, on the other hand, have responded well to interpersonal and relational therapies.

### *Resistance Level*

Patient resistance can be differentiated into state and trait qualities (Brehm & Brehm, 1981). As a pre-treatment trait, it has been widely observed to be a predictor of poor treatment response (e.g., Miller, et al, 1993). It has also been identified as a differential marker for the use of directive and non-directive procedures (Beutler & Mitchell, 1981; Dowd, Wallbrown, Sanders, & Yesenosky, 1994) as well as an indicator for using

paradoxical interventions (Horvath, & Goheen, 1990; Shoham-Salomon, & Hannah, 1991; Shoham-Salomon, Avner, & Neeman, 1989) among depressed patients.

Among chemical abusing patients, trait-like resistance has also been found to be indicative of a poor treatment response (Crits-Christoph, et al., 1999; McLellan et al., 1983; Miller, et al., 1993; Karno, 1997; Karno, et al, 2002). However, there have only been a few studies (e.g., Karno, 2002) of resistance traits as differential indicators for directive and non-directive interventions among these patients. In a multi-site cross-validation study of patients with depression and chemical abuse problems, a match of patient resistance traits and treatment directiveness level emerged as a significant predictor of outcome, both when the patient dimension was defined by standardized self-report measures (Beutler, Clarkin, & Bongar, 2000) and when these patient characteristics were defined by external clinicians (Beutler, Albanese, et al., 1999).

### Twelve-Step Meeting Classifications

There are broad Twelve-Step meeting (AA and NA) classifications: Speaker meetings; Twelve-Step study meetings; “specific book” format meetings (e.g., “Big Book”, “As Bill Sees It”, “The 12 and 12”); discussion meetings; newcomer/question-answer meetings; demographic-specific (men, women, Hispanic, gay, etc) (Alcoholics Anonymous website). Not only will there be variations across the meeting types, there will also be a between groups difference between Alcoholics Anonymous and Narcotics Anonymous. Furthermore, within each meeting classification there will be consistency that correlates to specific group therapeutic factors. There are relatively few basic classifications or factors of AA/NA meetings, and within these we believe there is considerable consistency, with unique loading from each meeting classification to Yalom’s curative factors. It is reasonable to postulate that these specific factors can be matched to patient variables that will best facilitate their treatment perseverance during the early stages of recovery.

Tonigan, et al (1995) examined differences in three Alcoholics Anonymous (AA) groups in perceived social dynamics, emphasis on, and completion of the Twelve steps of AA. Participants responded to questions regarding “group environment and the frequency with which each of the twelve steps was used”. Results show that the three groups differed in perceived group cohesiveness, independence, aggressiveness, expressiveness, and in how frequently members reported that twelve steps were discussed in meetings. Step discussion was lowest in the group with highest aggressiveness. The group with highest cohesiveness and step discussion reported having completed the fewest “surrender” steps (1-3 steps...basically, “I’m out of control, and I admit it; a “higher power” can manage my life better than I can; and I’m going to let a higher power take care of me in lieu of my own “will power”). These findings suggested that AA groups differ not only in perceived social environment characteristics, but in AA implementation of the twelve steps.

Manualized approaches to chemical dependence incorporating Twelve-Step treatment programs appear to be scant, if not nonexistent. There are many other manuals for individual and couples formats for the alcoholic patient that address both treatment and relapse prevention (Luborsky, et al, 1995; Marlott & Gordon, 1985; Rohrbaugh, et al, 1995; Wakefield, Williams, et al, 1996). These manuals provide the professional clinician with a template for a particular approach to the treatment of alcohol/drug dependence by discussing an overview of treatment, treatment goals, the therapist’s role, procedures, interventions, and a suggested timeline. Since Twelve-Step treatment principles are in such wide-spread use, it would seem fitting that the same rigors of manualization and treatment schematicism apply to it as well.

### C. Preliminary Studies

Oliver Williams, Ph.D. – Dr. Williams has been a researcher and research data director at the University of California at Santa Barbara (UCSB) for the development of two of the primary instruments to be used in this study, the STS [Systematic Treatment Selection] Clinician Rating Form (STS) and the STS Therapy Process Rating Scale (STRS). Dr. Williams is currently the CEO and founder of the Center for Behavioral HealthCare Technologies, Inc., which provides treatment planning consultation services and software to HMO’s and clinical centers nationwide. Of particular importance for the present study, he was an associate researcher on NIMH and NIDA grants with Dr. Larry Beutler as Principle Investigator. Both studies were conducted at the University of California, Santa Barbara. The NIMH grant was designed to examine matched treatment planning with

alcohol dependent individuals in committed relationships, the Couples Alcoholic Treatment Project (CAT). The NIDA grant had similar treatment alignment goals, and examined the effects of treatment matching for individuals dual-diagnosed with addiction to cocaine and/or amphetamines, and depression. The abstracts for these two studies are listed below.

**Prescriptive Therapy of Depressed Cocaine/Methamphetamine Addicted Individuals  
University of California, Santa Barbara (NIDA Grant, Dr. Larry E. Beutler, P-I)**

**Dr. Oliver Williams, Researcher and Director of Statistics and Data Management**

This study was designed to test the clinical efficacy of Prescriptive Therapy (PT), an integrative psychotherapy that we have been developing over the past four years. PT draws procedures from relationship, contingency management, self-directed, and cognitive therapies using empirically established algorithms for matching four patient and treatment qualities. This proposal rests on several assertions: (1) that stimulant abuse is a major problem in north America; (2) that treatment outcomes are significantly limited by high drop out, failure to respond, and relapse rates; (3) that depression significantly complicates the treatment of these disorders; and (4) that fitting multiple patient qualities to corresponding classes and types of interventions, in a theoretically neutral treatment program (PT) will enhance treatment effects and durability.

**Couples Alcoholism Treatment Project**

**University of California, Santa Barbara (NIMH Grant, Dr. Larry Beutler, P-I)**

**Dr. Oliver Williams, Associate Researcher**

In the field of alcoholism treatment, as in mental health treatment more generally, no one treatment model is equally effective for all patients and problem types. Literature in both alcohol treatment and in psychotherapy research suggests some relationships in common between treatment efficacy and patient coping style, drinking patterns, and family dynamics. This literature suggests that "internalizing" alcoholics, whose drinking tends to be steady and to be functionally interwoven with family dynamics, will benefit more from family systems oriented treatments than from symptom- or individually focused treatments. Conversely, "externalizing" alcoholics may derive more benefit from symptom-focused cognitive and behavioral treatments than from family systems treatment. This research project was designed to test these hypotheses and to develop treatment manuals that may increase differential treatment efficacy.

Dr. Williams' s previous research has also included studies in the differential effects of parental pathology on their adult children. One study examined the adult children of alcoholics, and adult children of parents identified with a major mental disorder other than substance dependence.

**The differential effects of parental alcoholism and mental illness on their adult children  
Journal of Clinical Psychology, May 1992**

In this investigation, we examined whether growing up in a household with alcoholic or mentally ill parents is more likely to produce lower self-esteem, greater dysphoria, and more anxiety in adulthood. 139 undergraduate and graduate students completed measures of anxiety, depression, social avoidance, self-esteem, and social support. Results show that adult children of alcoholics, *adult children* of *mentally* ill parents, and adult children of substance-abusing mentally ill parents had lower self-esteem and were more socially anxious than normal controls. Also, *adult children* of *mentally* ill parents were more depressed and showed greater trait anxiety than did adult children of alcoholics and controls. The impact of parental pathology was diminished when the adult child had a large and/or satisfactory social support network.

**The mediating effects of shame and social Support on distress and attributional processing in adults  
abused as children: A structural model**

**Williams, Oliver B. – Dissertation, 1995**

We compared psychodynamic and behavioral models of the effects of child sexual and physical abuse on adult functioning. The constructs of each model were represented using structural equation modeling techniques. The mediating effects of distress, shame, current social support, and perceived childhood social support were incorporated in a psychodynamic model. It was hypothesized that a latent factor, shame, mediated between distress and social support. The behavioral model did not include shame as a mediator, and exemplified a direct interaction between social support and distress. Social support, distress, and shame were structured to interact in order to organize an individual's internal and external attributions of personal expectancies for success or failure. Childhood sexual abuse, physical abuse, and combined physical and sexual abuse were

examined for differential effects on shame, and thus on levels of distress. Treatment implications from these findings were explored for behavioral strategies for adult childhood abuse victims. The model supported interventions with programmed augmentation of an individual's social support size. Interactively, attributions should change to a more internal and positive perspective. Preventative treatment procedures for children were supported by the model. Since there was a strong and significant link between childhood social support and current social support, the intervention of abused children by providing social support augmentation skills should positively effect adult functioning.

Listed below are Dr. Williams's published peer-reviewed contributions to the development of treatment planning and outcomes testing, both of which are crucial to the application of the present study.

### **Use of psychological tests/instruments for treatment planning**

**Beutler, Larry E.; Goodrich, Ginger; Fisher, Daniel; Williams, Oliver B. In Maruish, Mark E. (Ed). The use of psychological testing for treatment planning and outcomes assessment (2nd ed.). (pp. 81-113). Mahwah, NJ, US: Lawrence Erlbaum Associates, Publishers (1999)**

Psychological tests have been used widely in the prediction of response to treatment. This chapter summarizes the status of research on some of the more promising of these dimensions and their associated measures. Seven dimensions appear to be promising for use in planning treatment: Functional Impairment, Subjective Distress, Readiness for (or stage) of Change, Problem Complexity, Resistance Potential or Inclination, Social Support Level and Coping Style. Also, this chapter reported the initial development of a clinician-based measure that promises to tap a multitude of relevant treatment planning dimensions that can be used to plan a treatment with the potential to enhance the efficiency of treatment.

### **Identifying Treatment Relevant Assessment: The STS**

**Harwood, T.M. and Williams, O.B. (2003). In Beutler, L.E. and Groth-Marnat, G. (Eds.), Integrative Assessment of Adult Personality (2<sup>nd</sup> rev). New York: Guilford Press**

This book chapter follows the treatment progress of a specific patient whose initial intake and collection of baseline pathology and characterological indices were conducted by computer-driven Systematic Treatment Selection. It discusses the 18 principles of Systematic Treatment Selection, and how these are applied to prescriptive treatment relative to client predisposing characteristics and presenting problems. Initial assessment of patient coping style and resistance are important, but constant vigilance of distress indicators to induce or reduce arousal to optimize therapeutic efficiency is stressed as well. Clinical decision making is presented as a dynamic process throughout therapy, and not a static diagnostic step as a result of intake decisions. The internet-distributed application for administering STS is discussed in detail. Charts, graphs, treatment plans, and "best practices" models are graphically presented based on a real patient. Differences in "projected outcomes" at intake vs. actual outcomes over a 12 week period are compared and examined.

### **STS Clinician Rating Form (STS) (Appendix).**

There are a variety of established instruments that can be used to measure the patient dimensions targeted in this proposal (e.g., Beutler & Berren, 1995; Beutler, Clarkin, & Bongar, 2000; Carey, Purnine, Maisto, & Carey, 1999), but there are decided limitations inherent in these instruments: (1) Most are self-report and thus, require a good deal of patient motivation and insight; (2) managed care companies do not generally support the use of routine psychological assessment as a treatment planning procedure; and (3) these instruments are too general for efficient use, supplying a great many scores that are unrelated, empirically, to improving the decision process. Clinicians require focused, time-efficient measures and typically are more positively disposed to rely on their own judgment and observations than on the results of formal tests (e.g., Garb, 1997). The STS (Fisher, Beutler, & Williams, 1999; see Appendix 2) was designed to help clinicians consolidate their observations into reliable and valid treatment relevant decisions.

The STS is a clinician-based instrument that taps the patient variables that we (Beutler, Clarkin, & Bongar, 2000) have found to be predictors of treatment response. The STS is comprised of 226 items, 130 of which are used to ascertain the four treatment planning dimensions used in PT. The other items are used to assess various problem areas that are tracked over time The STS is administered by interactive computer after the clinician has interviewed the patient and reviewed all available supportive materials. The clinician first identifies the most salient problem areas (e.g., drug abuse, depression, thought disorder, etc.) and a branching

program then circumvents those questions that are not relevant to the problems identified. The STS requires from 20 to 40 minutes to complete, depending on the number of problem areas identified.

The STS computer output includes a full intake report and a specific treatment plan based on the four PT dimensions. It also suggests representative interventions, provides a graphic representation of patient treatment planning characteristics based on outpatient norms, presents a graphic display of major symptom areas, and a projects expected treatment course based on a similar outpatient case mix. This information is used as feedback on patient progress. The STS compares very favorably to other procedures used to assess patients at intake and to track change across time, and is the only method that provides an up-front treatment plan (Harwood & Williams, 2003).

The STS has good interrater reliability, construct validity, and criterion validity (Fisher, Beutler, & Williams, 1999). The mean kappa coefficients across five experienced clinical raters range from .77 to .99. The mean kappa's across various rater pairs for the four dimensions of focus in this project are .82 (subjective distress), .88 (functional impairment), .86 (coping style), and .80 (resistance).

Convergent validity studies demonstrated the predicted patterns of inter-relationships both among the four patient constructs and in comparisons of depressed and chemical abusing patients (Fisher, Beutler, & Williams, 1999). Intercorrelations of the various STS dimensions with the same constructs extracted from standardized self-report measures also showed the predicted pattern and direction of relationships. Predictive validity assessment demonstrated that each of the four pairs of patient-treatment dimensions was significantly related to the subsequent development of either a good therapeutic alliance or of clinical improvement (Beutler, Clarkin, & Bongar, 2000; Beutler, Albanese, et al, 1999 and in Appendix 2).

#### **The STS Therapy Rating Scale** ( Appendix ).

The STRS is a rating scale that was initially conceptualized by Beutler, Patterson, et al., (1993) for use with alcohol dependent patients. It was refined on the multi-site archival study by Beutler, Clarkin, & Bongar (2000) in which the patient-treatment variables that related to outcomes were defined. The four targeted dimensions were judged both by tabulations of objective aspects of the intensity of treatment (e.g., frequency and length of treatment) and the in-session activities of the therapist (e.g., high vs. low directiveness, insight vs. symptom focus, abreactive vs. supportive interventions). The STRS also incorporates a rater-based measure of the therapeutic alliance (Luborsky, et al, 1983). When completed for various subsamples of patients by at least two advanced graduate student raters, interrater reliabilities were consistently high (Kappa >.70). Two advanced and criteria-trained graduate students rated one randomly selected treatment session from each of the patients in the Phase #1 study. Interrater reliabilities (kappa's) consistently remained above .70. Validity assessment (Malik, Beutler, & Moleiro, 2000) has confirmed that different treatments provide distinctive profiles. CT, for example, is consistently found to be directive, symptom focused, arousing, and moderately intensive, and this profile generalizes across sites, therapists, and formats of delivery. Predictive validity studies have indicated that all dimensions are related either to treatment outcome or to the therapeutic alliance (Beutler, Clarkin, & Bongar, 2000; Beutler, Albanese, et al., 1999). Estimated effect sizes were also good, suggesting adequate clinical utility.

## **D. Research Design and Methods**

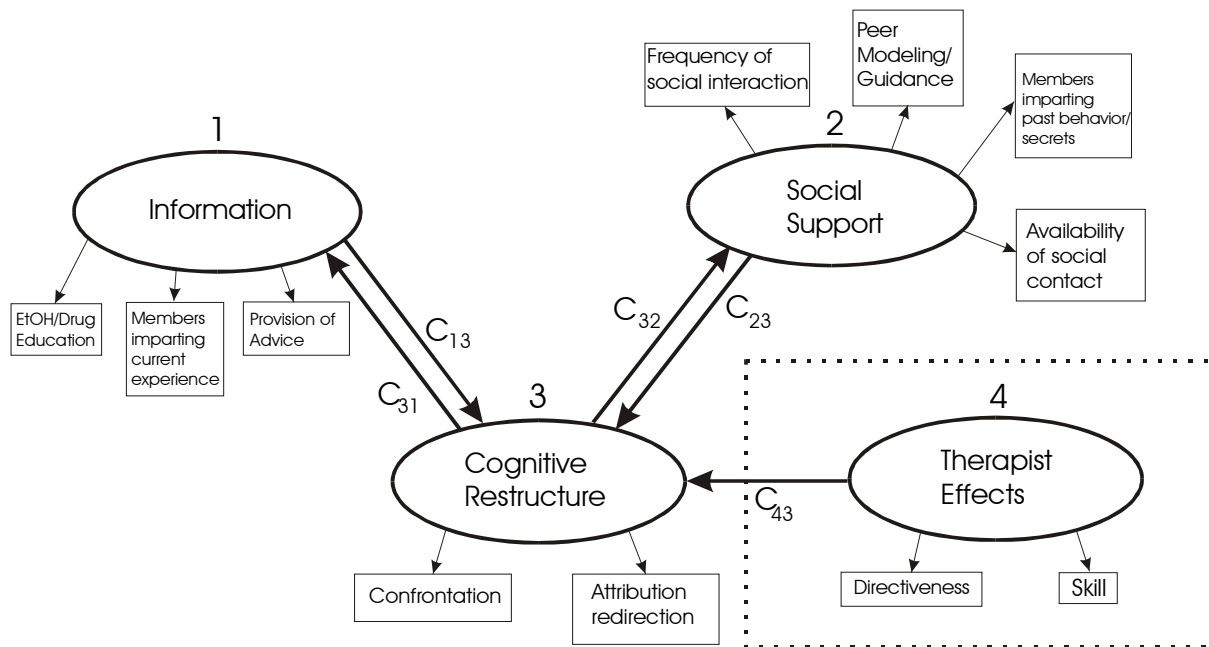
### **Experimental Design**

Structural equation modeling (the LISREL model) (Joreskog & Sorbom, 1989) will be used to estimate the fit of the interrelationships between Information, Social Support, Cognitive Restructuring, and Therapist Effects factors. Specifically, the computer program AMOS will perform an analysis for maximum likelihood parameter estimates and overall maximized goodness of fit for our hypothesized model. The fit of alternate models will also explored. Nested models will be of primary interest in the analysis. Significant differences in goodness of fit based on the equality or nonequality of certain parameters in the model will be key to this investigation.

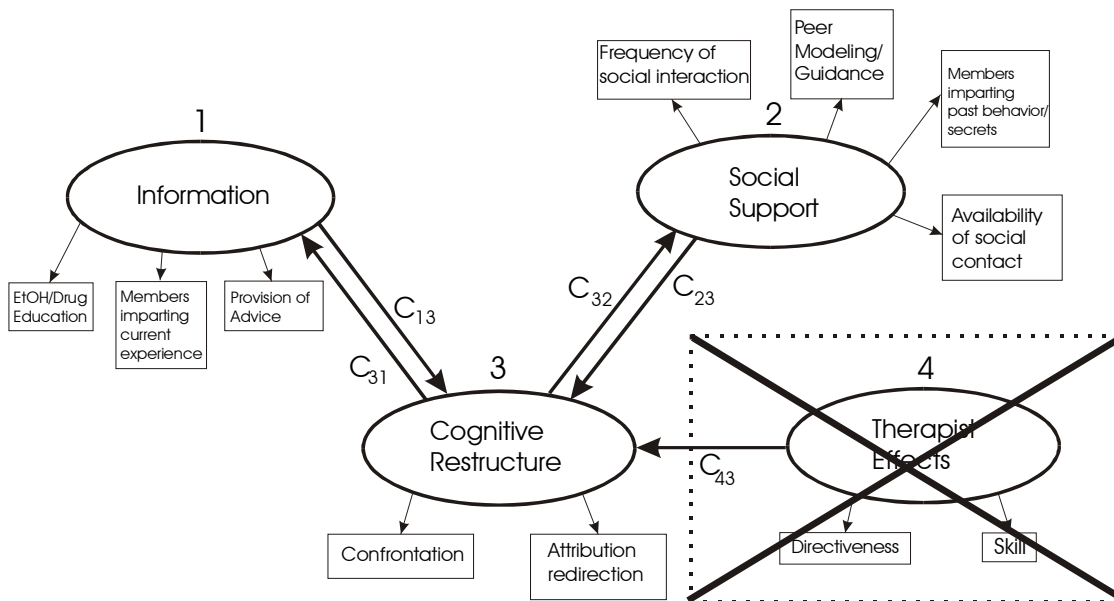
Generally the LISREL model assumes that a causal structure is specified among a set of latent dependent and independent variables. There are a set of observed variables that are related to the latent variables. Hence, the latent variables appear as underlying causes of the observed variables. These latent variables can also be

treated as intervening variables in a causal chain. The full LISREL model consists of two sub-models: the measurement model and the structural model. The measurement model specifies how the latent variables are measured in terms of the observed variable indicators. The structural model specifies the causal relationships among the latent variables. Figures related specifically to our hypotheses models are below.

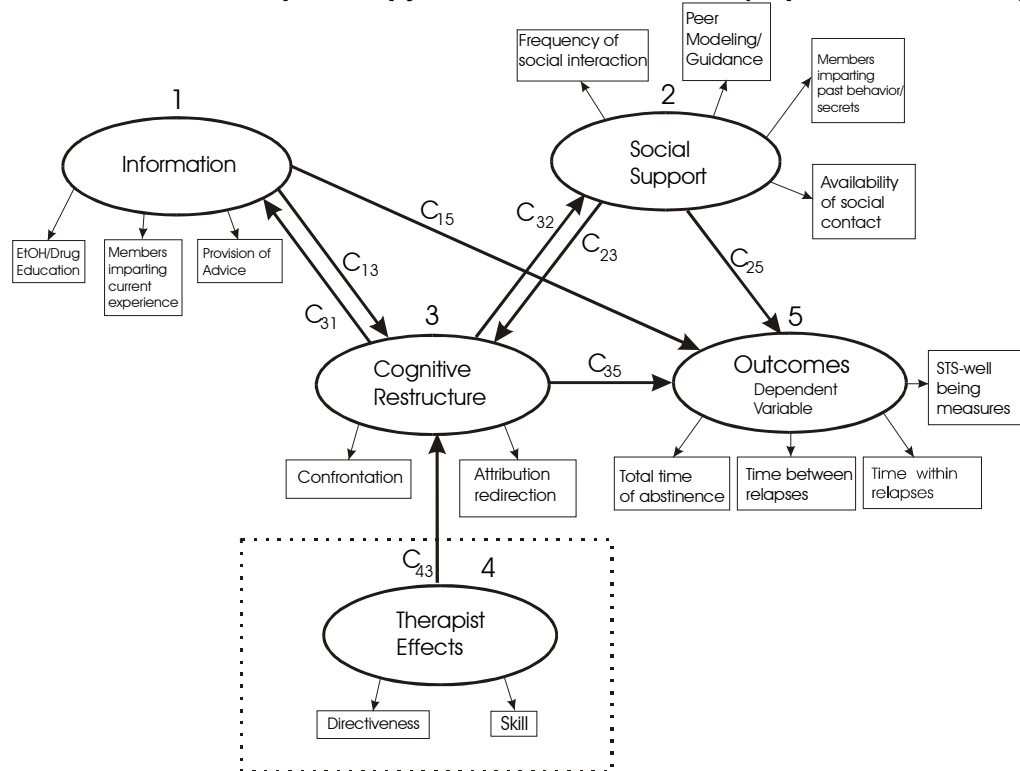
**Figure 1**  
**Case 1: General Twelve-Step Group Therapy Model (with Therapist Intervention)**



**Figure 2**  
**Case 2: General Twelve-Step Group Therapy Model (without Therapist Intervention)**



**Figure 3**  
**Case 3: Twelve-Step Therapy Model with Outcomes (dependent variable)**



## Study Sites

### Residential Setting

The in-house portion of the study will be conducted at the Pflieger Center of Cri-Help, Inc., a 120 bed 40,000 square foot residential and outpatient treatment facility for alcoholics and other drug addicted individuals in North Hollywood, CA . Cri-Help has been in operation since 1971, and is licensed and certified by the State of California Department of Alcohol and Drug Programs. Cri-Help, Inc.'s residential program is divided into clinical phases which range from a period of restriction to a gradual re-integration into the community. They primarily utilize the treatment philosophies found in the programs of Alcoholics and Narcotics Anonymous. Other services include twenty-four hour supervision, ongoing individual and group counseling, daily Twelve-Step study groups, daily attendance of Narcotics Anonymous and/or Alcoholic Anonymous meetings, drug use detection testing. (random and monthly), individualized therapies as determined by the treatment team, recreation, and family support groups. The outpatient program is designed for those individuals who need a structured recovery program for substance abuse but don't require 24 hour supervision.

### Community Setting

Most community groups examined are within a 10-mile radius of North Hollywood, CA, and in the San Fernando Valley of Los Angeles, CA.

## Participants

### Individual Participants

Participants for this research will be selected from patients attending the Pflieger Center of Cri-Help. All persons attending the outpatient program are at least 18 years of age and have a primary diagnosis of substance abuse/dependency. Clients with co-existing psychiatric diagnosis who are medically stable, medication compliant and able to participate in the treatment milieu are case managed with the assistance of the consulting psychiatrist or therapist. All patients will be offered the opportunity to participate in the research. Typically there are 111 residential patients, and 60 individuals participating in outpatient or continuing care.

Based upon admissions data from 1/1/2003 to 12/31/2003 the following demographic and severity data represent the expected participant pool:

Participant pool characteristic	Male	Female
Average age	36.8	37.1
Average number of lifetime arrests	3.1	2.7
Average number of treatment facility enrollments	5.3	4.3
Number of patients enrolled due to court mandate	60.0	26.0
Average number of years drinking	25.4	25.3
Average number of years using other drugs	25.0	24.9

There will be no reward or retribution for participation or nonparticipation.

### Residential Groups

There are various types of Twelve-Step oriented professionally led groups conducted at the Cri-Help weekly. These group types include "Step Study", "Spirituality and Recovery", "Relapse Prevention", and "Brief Therapy", all of which yield an average of ten in-house meetings per week (N=10). The "Step Study" group has as many as 100 attendees, and is held in the cafeteria, while the other groups have smaller numbers. All meetings are facilitated by Cri-Help staff, although leader credentials may vary from Ph.D./MD to certificated alcoholism counselor.

Unless a patient has express exemption from attending a meeting, all meetings are mandatory. Permanent and unobvious recording equipment placement in the cafeteria could be more problematic than placement in the more standard group meeting rooms. We will monitor and record group interaction and process. Individual participants are not the focus, and identities will not be recorded, nor are they relevant to this evaluation process. Unless the mechanics of room selection and equipment placement are prohibitive, all groups are subject for data collection. Another problem that may lead to group exclusion is that all attendees must consent to being video taped. Hopefully, this problem can be averted through pre-research conferences with the patients in order to ease potential anxiety and distrust about the research.

### Community Groups

Vans transport patients to a variety of community Alcoholics Anonymous and Narcotics Anonymous meetings daily. Most of these meetings are within a 10 mile radius of the Cri-Help Pflieger Center in North Hollywood. Meeting classifications include, but are not restricted to, "Speaker Meetings", "Discussion Meetings", "Participation Meetings" (usually these differ from 'discussion meetings' since the attendee wishing or chosen to 'share' must stand at a podium for no longer than a predetermined amount of time), various "Study" meetings, and meetings restricted to one sex (usually called 'Stag' meetings).

Meetings from which to gather data will be selected weekly by a randomizing computer program several weeks in advance. The schedules will be given to the raters so that accompanying schedules can be determined. We will attempt to have more than one rater available for any given meeting time so that raters can be randomly selected. This process may have restrictions imposed by rating therapists' personal and professional schedules. However, part of the initial rater selection will be availability for meeting attendance.

### **Study Procedures**

#### Rater and Rater Recruitment

Six therapists with clinically relevant credentials of Ph.D., MFCC, MSW, or Master of Nursing will independently evaluate measures for the independent variables of this study. They will not engage in individual or group therapy, and will only serve as group process and therapy process evaluators.

We will post advertisements in the Los Angeles/North Hollywood community for qualified therapists to be trained in our group and therapist rating processes for both in-patient and community environments. The initial screening will be done by phone, and they will be provided with information about the study. They will be required to submit vitas, background information forms, blocks of times available for meeting attendance. They will be ranked based on these criteria, plus their own professional and personal Twelve-Step group involvement. Our screening will reduce the final number of therapist/raters to six. Raters are hold academic

credentials of Ph.D., MFCC, MSW, or Master of Nursing. Therapists will be selected based on the judged fit of the therapist's previous training and experience with group settings, past research experience, relative bias to Twelve-Step programs, and their ability to attend meetings and conduct surreptitious evaluations. Therapist/raters will be provided with twelve hours of training in evaluation of the professionally-led group, therapist evaluation using the STS Therapist Rating Form, and the Twelve-Step Process Evaluation Scale. Videotapes of sessions other than those to be used for data collection will be used for training and establishing inter-rater reliability.

#### Rater training

In order to establish interrater reliability, all raters will meet with the research team during a training seminar to establish consistent rating parameters for the Group Sessions Rating Scale, Twelve-Step Meeting Process Evaluation Scale, and the STS-TRS. During that time the group will observe a series of 15 minute taped group session segments. Specific reference will be made to each item on the rating questionnaires, and how each item should be rated relative to viewed group process and therapy process. Raters will then team up in pairs, view a tape segment simultaneously, then independently and simultaneously rate the viewed segment. After each rater completes his/her evaluation, each will compare his/her results with one another. This training seminar should take eight hours.

#### Group Process Evaluation (in-house)

Groups led by Cri-Help staff will be videotaped in full. Two cameras will be mounted in the meeting room, each in opposite upper corners so as to provide a panoramic view from two sides. Taping will not be obvious to the group participants so as to avoid observation reactance. Taping equipment will be in a separate control room. The taping will be initiated clandestinely by a research assistant so as to not cue the group facilitator or patients.

Taping will occur over a 12 week period. The number of taping events will be 30% of the total number of group sessions during a week over 12 weeks. Each tape will be identified by date, time of day, group type, and therapist/facilitator name. The tapes will be stored in a secure and locked location, available only to therapists and qualified research staff. Tapes will be destroyed 12 months after recording

#### Group Process Evaluation (community)

Meeting attendance scheduling for raters will have been predetermined. Each rater will attend all meetings independently. The rater must not announce his/her presence as a rater or observer, and participants from Cri-Help must not know the rater's identity. Since only group process is observed, and personal identities are neither recorded, nor are they the focus of the evaluations, then this sort of surreptitious or undercover operation seems to be well within ethical boundaries. Surreptitious and "blinded" observation is a common and mostly accepted procedure for data collection among cultural anthropologists, educational, and social psychologists (Klesges, et al, 1990; Kirsch, et al, 1989; Berry and Hansen, 1996; Koocher, 1977)

The rater should fill out the Twelve-Step Group Process Evaluation within two hours of the meeting's end. The evaluations should not be completed during the meetings, and notes should not be taken. Personal and clinical impressions of the meeting must be committed to memory only during the meeting. Each form will be identified by the name of the rater, and the time/place/date of the meeting to which it refers.

In order to establish interrater reliability, during the pilot testing, each rater will individually attend and rate the same meetings. All raters will have rated each meeting in pairs. Variable and rater consistency will be evaluated based on normal distribution of each scale. Any scale with outliers beyond 1.5 s.d. will be reexamined.

#### Group Leader/Facilitator Rating

In order to factor out therapist effects on the group process and dynamics, the Cri-Help staff leader/facilitator of each in-house evaluated group will also be rated by the STS-TRF. This rating is not a personal assessment of the group facilitator, nor does it imply or record any type of quality accountability. Indeed, the name or other identifying information need not be on the form. The data is strictly to include in the model analysis in order to account for generic therapist effects.

## Participant Self-Report

### *Baseline*

Patients will complete the STS before the research commences. The STS can be completed either by telephone via an automatic voice system (Interactive Voice Response/IVR), or directly online within 20 minutes for most individuals. The system will automatically assign a number to the patient requesting intake access. It will not ask names or other identifying information. Personal identifying data must be associated with the automatically assigned STS number by attending staff at the Cri-Help facility, and stored in a safe and secure location.

### *Outcomes Tracking*

#### STS

Outcomes will be measured by number of relapses, length of each relapse, and length of abstinence between each relapse. Patients outcomes will be tracked and monitored through the use of telephone or online access to the STS. Patients can call an 800-number and respond to voice-prompted questions within five minutes, or log on to a user-friendly website, enter their confidential id number, and respond directly. During months 4-12 we will request two follow-ups per month. During years two through four we will request one follow-up per month.

#### Twelve-Step Meeting History Questionnaire

This measure will be accessible via the internet (with STS), but will not have an IVR feature. For individuals without internet access, mail-in forms will be available. Also, a system will be established through which participants can email the responses. Again, names will not be used or connected with the forms or responses.

### Screening and Informed Consent Procedures

Participants in this project will all be asked to supply written informed consent. We will have taken steps to minimize the ethical issues with informed consent that have been identified with chemically abusing populations (Beutler & Kendall, 1991; McCrady, & Bux, 1999). There will be no deception and all treatments, recording, and evaluation procedures will be explained to all participants, therapists, and evaluators beforehand. They will also be invited to have a representative of their choosing available to explain and assist them when the consent procedure is discussed. Treatment risks include stress from the completion of baseline and follow-up procedures, breach of confidentiality, and the observation and recording process. Risks to confidentiality will be minimized by coding all records and securing them in code-activated computer files. We will also seek an FCC protection against court subpoena. Until they are destroyed, tapes will be kept in locked file cabinets within the Cri-Help central office.

Participants about whom a question is raised, either by the therapist, the Case Manager, or one of the Investigators, about their continuing appropriateness for this program will also be referred to the project psychiatrist for independent evaluation. Patients who fail to follow up with treatment will be contacted by the therapist or the Case Manager.

This project will actively solicit and recruit members from all ethnic groups and both sexes who meet the intake criteria. While we cannot justify the inclusion of children in this study because of the diverse definitions and methods of measurement required to assess depression and chemical abuse among them, we will extend the age range to include both adolescents and older adults.

Participants will be assessed with self-report measures. Their participation in the group process is coincidental to the group evaluation observations, and personal performance or identity will not be the focus. There are no invasive procedures to be used.

The fear of being coerced will be addressed by discussing this issue at the time the informed consent procedure is presented. Participants, along with their representative (if selected), will be reminded that participation is voluntary. The observations and recordings, themselves, pose few risks. Since this is a group process and outcomes study not using randomized selection and group assignment, the risk is essentially the same as if the study did not exist. Data will be examined after the fact, so participants will conduct their group residential and community group selection as they usually would.

## Data Collection Procedures

Data will be collected from two sources:

1. Patient participant data will come from entries they provide through the STS interactive voice response (IVR) system and/or directly through a web browser accessible data entry screen. There will be no data that identifies a participant specifically. There are no names, social security numbers, or other public or private means of identification handled or transmitted through this system.

2. All therapist/rater data will be collected from completed evaluation forms, and entered via a secure workstation into a central database residing on a secure server at Cri-Help, Inc.

All data entry personnel will be post bachelors' degree level research assistants with interest and experience in clinical trial research.

**Figure 4**

Measure	Pilot/3 Months	Baseline	Month 4-9	Month 10-12	Year 2	Year 3	Year 3	Year 4
STS Self-Report (Telephone or Internet)		X		2/month	2/month	1/month	1/month	1/month
Meeting Attendance Questionnaire (Internet or mail)				2/month	2/month	2/month	2/month	2/month
Group Process Evaluation (inhouse-per rater, 6 raters)	1/week	n/a	2/week					
Group Process Evaluation (community-per rater, 6 raters)	1/week	n/a	2/week					
STS TRS (per rater, 6 raters)	1/week	n/a	2/week					

## **Study Measures**

### ***Independent Variables***

#### Twelve-Step Meeting Process Evaluation Scale

The Twelve-Step Meeting Evaluation Scale is a ten item Likert scale measure. It is based on Yalom's Curative Factors, with the "recapitulation of family group" item removed. The questions are rewritten so as to apply specifically to AA/NA groups. It is designed so that a undercover observer can attend a meeting, and respond to the scale shortly thereafter. It was developed solely for the purpose of this proposed study. Hence, part of the Stage 1 exploration is to pilot test this scale.

Study measures will be administered according to the Data Collection Schedule in Figure 4. All patient participant data can be entered conveniently and directly via telephone touch pad response, in-house Internet-connected workstation, or through the participant's personal PC Internet browser via a secure 128-bit encrypted site.

#### Meeting Attendance Questionnaire

This forms simply asks the respondent to list the types and/or specific names of AA, NA, or other Twelve-Step meetings attended within a specific period of time. In order to make responding more convenient, the form will be available online.

#### STS Therapy Rating Scale (STRS)

The STRS is a rating scale that was initially conceptualized by Beutler, Patterson, et al., (1993) for use with alcohol dependent patients. Since the measure was developed for individual therapy evaluation, for the purpose of the present study, we will modify it only by conceptualizing the group as a separate patient. The reliability of this process will be determined during the pilot study.

The STRS was refined in a multi-site archival study by Beutler, Clarkin, & Bongar (2000) in which the patient-treatment variables that related to outcomes were defined. The four targeted dimensions were judged both by tabulations of objective aspects of the intensity of treatment (e.g., frequency and length of treatment) and the in-session activities of the therapist (e.g., high vs. low directiveness, insight vs. symptom focus, abreactive vs. supportive interventions). The STRS also incorporates a rater-based measure of the therapeutic alliance (Luborsky, et al, 1983). When completed for various subsamples of patients by at least two advanced

graduate student raters, interrater reliabilities were consistently high ( $Kappa > .70$ ). Validity assessment (Malik, Beutler, & Moleiro, 2000) has confirmed that different treatments provide distinctive profiles on the four dimensions of interest to the current proposal. CT, for example, is consistently found to be directive, symptom focused, arousing, and moderately intensive, and this profile generalizes across sites, therapists, and formats of delivery. Predictive validity studies have indicated that all dimensions are related either to treatment outcome or to the therapeutic alliance (Beutler, Clarkin, & Bongar, 2000; Beutler, Albanese, et al., 1999). Estimated effect sizes were also good, suggesting adequate clinical utility.

## **Dependent Measure**

### **STS Clinician Rating Form (STS) – Self-report Computer version**

The STS (Fisher, Beutler, & Williams, 1999; see Appendix ) was designed to help clinicians consolidate their observations into reliable and valid treatment relevant decisions. The STS is a clinician-based instrument that taps the patient variables that have found to be predictors of treatment response (Beutler, Clarkin, & Bongar, 2000). The STS is comprised of a total of 226 items which branch into smaller subgroups depending upon response scenario. The STS is administered by interactive computer online or through telephone touchtone response. A branching program circumvents those questions that are not relevant to the problems identified. The computer version of STS requires from 15 to 20 minutes to complete the baseline (intake), and only five minutes or less for each follow-up.

The STS computer output includes a full intake report and a specific treatment plan. It also suggests representative interventions, provides a graphic representation of patient treatment planning characteristics based on outpatient norms, presents a graphic display of major symptom areas, and a projects expected treatment course based on a similar outpatient case mix. This information is used as feedback on patient progress. The STS compares very favorably to other procedures used to assess patients at intake and to track change across time, and is the only method that provides an up-front treatment plan.

The STS has good interrater reliability, construct validity, and criterion validity (Fisher, Beutler, & Williams, 1999). The mean kappa coefficients across five experienced clinical raters range from .77 to .99. The mean kappa's across various rater pairs for the four dimensions of focus in this project are .82 (subjective distress), .88 (functional impairment), .86 (coping style), and .80 (resistance).

Measures specific to the present study derived from the STS include questions about current substance use, levels of distress and self-esteem, resistance, and coping style. The coping style and resistance measures are trait-like, and are assessed only at baseline. Continued follow-ups with the STS establish a timeline which will reveal length of abstinence, number of relapses, and time and behavior within each relapse.

## **DATA ANALYSIS**

### **General Data Analysis Strategy**

The path parameters between measures (boxes) and factors (ovals) are depicted by coefficients. They are the path parameters between latent factors and their associated loadings. Relative factor loadings between independent and dependent latent variables and their associated measures will also be analyzed. The coefficient of each path will be tabularized along with significance of each path will be shown by the associated t-value.

The "C" parameters show direction and strength of effect between factors (latent variables). The significance of each path will also be represented by the associated t-value in parentheses. Parameters with values of zero will be fixed in the model, and will not be estimated. Typically, values not estimated will be statistically insignificant, and will be subsequently fixed in order to provide more degrees of freedom to the model.

All data will be stored in SPSS format, or in Microsoft Access, and converted to SPSS at a later time. Analyses will be conducted using SPSS and AMOS software. We will establish an integrated network system for entering and checking data to reduce error and to track patient adherence. Trained research assistants under the direct supervision of the project director will collect and monitor data according to the Data Collection Schedule in Figure 4. The expertise of the data management/data analysis group, and the quality assurance and data monitoring routines developed by this group, will allow for quick access to the database from

workstations connected to a central data server. The completeness of the data set being collected can be measured at any point in time during the trial using this resource and the data will be available immediately following completion of data collection activities.

### **Missing Data**

To minimize missing data, our primary strategy will be to aggressively collect data when participants are available. The amount and patterns of attrition will be carefully tracked and necessary interventions with staff will be made promptly to resolve attrition problems early. Research staff will be trained in approaches for follow-up procedures with substance abusers. However, our online and telephonic (IVR) access streamline follow-up procedures, which will minimize the potential for missing data.

### **Baseline Characteristics**

Retention of participants is a consideration in every study. In one sense retention is an interesting outcome and it will be analyzed with chi-square and survival analysis methodology. However, sample attrition has two other effects. Even random attrition reduces statistical power somewhat. Systematic attrition threatens the external validity of the results (e.g., if a subgroup such as more dependent participants tend to drop out of the study across all groups roughly equally, generalizability may be compromised). Differential attrition may produce serious bias when comparing conditions if baseline variables correlate with outcome. Multivariate equivalence resulting from the urn randomization procedure will allow us to measure the effect of systematic and differential attrition prior to making conclusions about efficacy.

### **Primary aims**

1. The model representing a general twelve-step group with therapist effects (Figure 1) will be confirmed using AMOS structural equation modeling software.
2. The model representing a general twelve-step group without therapist effects (Figure 2) will be confirmed using AMOS.
3. Data from specific meeting categories will be identified by groups. Each group type will represent a nested model in an AMOS analysis. We anticipate differential factor to indicator loading based on meeting category.
4. The model depicting group effects on outcomes (Figure 3) will be confirmed using AMOS. There will be four nested participant subgroups based on a coping style X resistance matrix. Coefficients from the independent factor variables (1-3) are expected to be stronger for matched meeting category to participant subgroup nests.

### **Other outcome measures**

Secondary aims of this study are to assess the impact of these interventions on psychosocial functioning, To accomplish these ends other "quality of life" variables of the STS will be analyzed. We expect to see a reduction in measures of psychological distress, and an increase in overall "well-being" as measure by STS follow-up sessions.

### **Additional Analyses**

Exploratory factor analysis of the data will be used to compile alternate group process models other than those the study aims to confirm. Structural equation modeling aims to confirm the null hypothesis. Thus, a model presented for analysis is test for a maximum likelihood of it parameter,  $\chi^2$ , with a corresponding number of degrees of freedom so that ideally  $p > .4$ .

### **Power Analysis**

Bollen (1989) suggests a minimum of 5-10 subjects for each free model parameter in a structural model. The full outcomes model represented in Figure 4 offers the greatest potential number of degrees of freedom. A full and unrestricted model of Figure 4 would be unwieldy and indecipherable. The maximum number of free paths included between indicators and factors, paths between factors, and error perturbation paths where there is more than one observed measure for a factor is a free and unrestricted model. Any model with few restricted paths is considered a nested model. Our study requires a minimum of five subjects per free parameter estimate. Since there were 32 free parameters in the base group model (confirmatory model without outcomes, Figure 3), a minimum of  $N=320$  independent variable observations will be required for Aims 1-3. There are 12 free parameters on the outcomes (dependent) side of the full model which would call for 120 participants completely baseline and follow-up reports.

## **E. Human Subjects Research. Protection of Human Subjects**

### **1. Risks to the subjects**

Human subjects involvement and characteristics. Participants will be patients enrolled in residential and outpatient services at Cri-Help, Inc. It is expected that the demographics of participants who participate in this project will reflect the overall gender and ethnic characteristics of the clientele in the current client population. The racial/ethnic composition of clients currently enrolled in similar treatment programs is as follows: 65% Caucasian, 25% Hispanic, and 7% African American. Forty percent of those treated are women. Participation of women and minorities in this project will be encouraged.

Participants randomized into the study must meet all of the following inclusion criteria: (1) 18-65 years of age, (2) meet DSM-IV criteria for substance dependence, (3) willing and able to comply with study procedures, and (4) willing and able to provide written informed consent. Participants must not meet any of the following exclusion criteria: (1) have a medical condition that, in the study PI's judgment, may interfere with safe study participation, (2) have a recent (past 30 days) history of suicide attempts and/or current serious suicidal intention or plan, (3) any other circumstances that, in the opinion of the PI, would interfere with study participation.

### **Sources of Materials**

Research materials obtained from participants will include, data derived from psychological questionnaires and drug and alcohol use information. These records and materials will only be available to authorized staff. All electronic or paper forms with information concerning an individual participant will be marked with a unique code and not the participant's name. The link between the code and the name will be kept by the PI or Co-PI under lock-and-key.

### **Potential Risks**

The anticipated physical, psychological, social, or legal risks are all minimal. However, as in all trials of this nature, there is the possibility of unauthorized disclosure of confidential information; discomfort or embarrassment related to questionnaires dealing with personal habits, lifestyle, and drug or alcohol use.

### **2. Adequacy of Protection against Risks**

Informed consent will be obtained, in writing, from all potential participants before research participation. Potential participants will be scheduled to meet individually with a member of the research staff and informed consent will be obtained during that meeting. Research staff will receive extensive training in the appropriate way to obtain informed consent and they will all be videotaped conducting a "mock" consent interview. This tape will be reviewed by Dr. Williams and staff to ascertain the adequacy of the consent process and to ensure consistency in the process across individuals. Participants will have the opportunity to ask questions during this session. We will emphasize that there is no pressure to participate, and that they are encouraged to speak to the PI or his staff about issues or concerns related to study participation. Candidates will be quizzed on their understanding of the protocol using a 10-item true/false written test. Incorrect answers will be used to determine areas of the protocol in need of further clarification. The issues of confidentiality will be discussed in detail. Two forms will be signed, one for the participant to keep and another for the PI's records. This signed consent form along with the test will be kept in a separate, locked file. Participants who have any questions regarding their informed consent or any aspects of the program at any time will be directed to the principal investigator.

Protection against Risk. All staff will be trained to be sensitive to issues surrounding confidentiality and other forms of participant risk. If at any time a participant expresses discomfort over any aspect of the treatment program, staff will be told to discontinue the distressing activity and seek consultation so as to minimize risk. Applicants will be thoroughly screened to eliminate candidates with disorders or conditions that are may be considered contraindicated, e.g., excessive paranoia. In addition, the study will be conducted in a site with licensed mental health professionals who will deal with psychological problems or distress. Social risks from participation are expected to be minimal, since sensitive material is unlikely to be divulged. We will emphasize

the confidential nature of all data collected in this study to potential participants. We will also explain thoroughly our safe guarding procedures. Finally, we will obtain a certificate of confidentiality for the study.

### **3. Potential Benefits of the Proposed Research to the Subjects and Others**

The minimal risks to participants are reasonable in relation to the anticipated benefits because identification of more effective treatment of substance dependency through group process and meeting attendance may provide the current treatment system with useful information and thereby benefit others. Furthermore, the data collected in the proposed study will have a high level of external validity and may serve to render other 12-step oriented programs for other types of substance abuse more pragmatic.

### **4. Importance of Knowledge to be Gained**

The results of this proposed research might produce more effective and pragmatic treatment associated with 12-step oriented group therapy, and help direct future patients to more personally effective meeting types. Established treatment facilities may choose to modify their approaches in light of information gleaned from the proposed study. Modified treatment approaches may facilitate long-term behavior change.

### **Collaborating Site**

The Friends Research Institute will be collaborating (see letter of agreement). The protocol will be reviewed by both the Friend's Research Institute and the UCLA IRBs.

### **Inclusion of Women**

This study will include women who meet inclusion criteria. Based on prior research at the proposed site with alcohol/drug abusers, women should comprise approximately 40% of the sample. We will be able to compare the efficacy in men and women as we are including gender as one of the characteristics in our analysis procedures.

### **Inclusion of Minorities**

Recruitment efforts will make an effort to inform minority communities of the opportunity for participation in this research. The study will be inclusive of alcohol/drug abusers from all racial and ethnic groups.

### **Composition of Study Population**

In order to be eligible for this study, patients will be required to have met the DSM-IV criteria for alcohol or other drug dependence as determined by a diagnostic evaluation with a mental health professional. Patients come from a wide range of socio-economic levels, representing ages from 18 through 65, from all races and sexual orientations. Participants will be 120 healthy substance dependent individuals enrolled in services at Cri-Help, Inc. It is expected that the demographics of participants who participate in this project will reflect the overall gender and ethnic characteristics of the clientele within the community. The racial/ethnic composition of clients currently enrolled in a similar treatment program is as follows: 65% Caucasian, 25% Hispanic, and 7% African American. Forty percent of those treated are women. Participation of women and minorities in this project will be encouraged.

### **Prior experience in recruitment and retention of target population**

The Friends Research Unit, which will oversee the proposed study, has been the study site for numerous research projects involving substance abusers. Recruitment goals have generally been met and systems have been established for tracking referrals and monitoring the usefulness of various recruitment sources. Linkages have been established and continue with a variety of agencies, which service women and minorities. Typically, we are able to reach a satisfactory number of participants for follow up interviews.

### **Time Line**

The clinical and research staff at this treatment center have had considerable experience with the delivery of similar services and have participated in other research projects. Therefore, we are confident that this project can be effectively conducted within the timeline described.

The project is scheduled to take place over the course of four years. Staff will be hired and trained as needed over the first 60 days of the project and recruitment of appropriate participants will begin in month three. In

month three, participants will begin entry into the project. By the end of month 24, a minimum of 120 patients will have completed follow-up procedures.

Timeline:

Months 1-2: Hire and train staff as needed and secure regulatory approvals.

Months 3-6: Collect pilot data to establish procedural reliability and reduce Hawthorne effects.

Month 7: Collect participant baseline data

Months 7-12: Collect residential and community group observation data

Months 12-14: Analyze data for Aims 1-3

Months 12-24: Collect follow-up data and perform first round outcomes evaluation

Months 25-36: Continue to collect follow-up data and perform second round outcomes evaluation

Months 37-48: Continue to collect follow-up data and perform third round outcomes evaluation

Months 45-48: Write-ups and final analyses

**Justifications for Exclusion of Children**

Participants who are at least 18 years of age will be included. Although those who are 18 to 20 years old qualify as “child” by the definition provided by NIH, applicants younger than 18 years will be excluded. The justifications for this are: substance dependence is less common in young children; the material in the counseling groups is directed towards adults; material discussed in groups would often be inappropriate or irrelevant to children; the risks of involving children in a research intervention which does not address children’s issues and provide more comprehensive clinical care do not outweigh potential benefits.

**Data and Safety Monitoring**

***Reporting SAEs***

The Safety Monitor for this study will be Heather Meschery., phone: (818) 985-8323 x141, e-mail: heatherm@cri-help.org.

Ms Meshery, in conjunction with Dr. Williams and Mr. Bernstein will be responsible for evaluating all Serious Adverse Events (SAEs) and for preparing and sending the pertinent expedited reports to the appropriate persons, as detailed below. In addition, she will help to evaluate whether an active participant should be discontinued from further participation in the study, for safety reasons. At least annually, Dr. Williams, Ms Meschery, and Mr. Bernstein will prepare a summary report of all Adverse Event (AE)s.

***Reporting of Serious Adverse Events***

Each AE will be classified by a study investigator as serious or non-serious and appropriate reporting procedures followed For purposes of this specific data safety plan, serious adverse events are defined as any fatal event, any immediately life-threatening event, any permanent or substantially disabling event, any event that requires or prolongs inpatient hospitalization, or any congenital anomaly. This category also includes any other important medical event that a study investigator judges to be serious because it may jeopardize the participant or require intervention to prevent one of the above reportable outcomes, or which would suggest a significant hazard, contra-indication, side effect, or precaution.

The investigators in this study will promptly report all Unexpected, Serious AEs to the Friend’s Research Institute’s Institutional Review Board.

As required, expedited reporting of SAEs to NIDA will adhere to the following guidelines:

1. Apply regardless of the investigator’ s assessment of the relatedness of the Serious Adverse Event to the intervention under study.
2. Apply to any Serious Adverse Events that occur during the post-treatment observation period defined by the protocol.
3. Apply to suicidal or homicidal behavior that causes a serious adverse event in the participant or someone else (e.g., hospitalization or death).
4. Any Unexpected, Serious AE that occurs during the course of this study and during the follow-up period, whether or not related to the study procedure, will be reported within one working day (M-F) to Dr. Cecelia McNamara (this contact may change at the discretion of NIDA) at NIDA.

The telephone report will be followed within two working days by sending a SAE report including demographic information and a narrative explanation of the event. The narrative will also provide details of relevant screening measures. Attached to the SAE Form will be photocopies of relevant source documents (Case Report Forms). The investigators will address whether there is a need to redesign or amend the protocol, and/or to inform current and future participants of a change in description of risk, either in the consent form and protocol, or by other written or verbal communication.

#### ***Reporting of All Adverse Events***

In accordance with local IRB reporting requirements, all AEs occurring during the course of the clinical trial will be collected, documented, and reported by the investigators to the IRBs at the time of their continuing reviews.

An AE is defined as any unexpected reaction, side effect, or untoward event that occurs during the course of the clinical trial. A new illness, symptom, unfavorable and unintended sign, or worsening of a pre-existing condition or abnormality is considered an AE. Stable chronic conditions that are present prior to clinical trial entry and do not worsen are not considered AEs. For this study, AEs will include symptoms reported by the patient and abnormal measures of clinical importance noted by study staff.

A summary report of all Adverse Events will be prepared at least annually, by the investigators, to be submitted to NIDA. The analysis of all adverse events accumulated-to-date will include a listing of all AEs. Participants' descriptions of adverse events will be grouped, counted, and compared by treatment groups. A designation of 'more-common' will be given to events occurring at an incidence of at least 5% in participants assigned to a treatment group, and for which the incidence is at least twice that observed in the control, or standard treatment, group.

#### ***Reporting Changes or Amendments to the Protocol***

Changes that may be made to the protocol will be discussed with the NIDA Project Officer. Agreed upon changes will be submitted as an amendment to our main human subjects application to the Friend's Research Institute's Institutional I Review Board for approval. Such changes will be reported in the annual progress report to NIDA.

#### ***Trial Stopping Rules***

The processes being studied pose zero to minimal safety risks to study participants. A decision to stop the study would be jointly determined by either the safety monitor, Dr. Petry, or by the involved IRBs.

#### ***Conflict of Interest***

The researchers involved in this study do not have any known conflict of interest issues in this Data and Safety Monitoring Plan.

### **Trial Safety**

#### ***Potential Risks and Benefits for Participants***

Overall, the risk in this study is minimal. During the consent process, clients are informed that they have the right to refuse to answer any question or to stop their participation in the study at any time. The procedures to be used in this project are conventional procedures that are routine for a study of this nature. None of the procedures will present physical or legal risks to the subjects. Some client interviewees may experience anxiety or embarrassment when answering sensitive questions about drug use history, treatment history, and related behaviors. The interviewers will be/have been trained to respond appropriately and reassure the participants that no harm will come to them as a result of answering the questions and that all responses will be kept confidential. On the rare chance that a client interviewee becomes unusually distressed, the interviewer will be instructed to call in the Principal Investigator or Project Director to provide further reassurance and, with the interviewee's permission, contact the client's counselor for further consultation and discussion. At follow-up, when most clients will be out of treatment, all interviewers will have a copy of local hotline and referral phone numbers where immediate help is available. Information derived from the study could help improve other contingency management programs. This may benefit society and other clients of treatment programs. Participants in the study may see improvement in the physical, psychological, occupational, familial, and economic problems associated with their drug/alcohol use.

#### ***Collection and Reporting of AEs and SAEs***

See above.

#### ***Management of SAEs or Other Study Risks***

See above.

## **Trial Efficacy**

### ***Interim Analysis***

After approximately one-half of the participants have completed the baseline and one year of follow-ups of the study, we will conduct preliminary analysis of the primary outcome variables to assess the initial validity of the hypotheses.

## **DSM Plan Administration**

### ***Responsibility for Data and Safety Monitoring***

Primary responsibility for monitoring the data and safety of the study will be Oliver B. Williams, Ph.D., Principal Investigator, with the assistance of Mr. Jack Bernstein, Co-Principal Investigator and President/CEO of Cri-Help, Inc.

### ***Frequency of DSM Reviews***

The data will be reviewed every six months over the course of the study.

### ***Content of the DSM Report***

The DSM report, to be submitted with the annual progress report, will include information organized into the following sections: study description, sociodemographic characteristics of the accumulated participants at baseline, data on the status of study participants, quality assurance issues, regulatory issues, data on AEs and SAEs, and efficacy.

## **F. Vertebrae Animals. N/A.**

## **G. Literature cited**

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