

**Assessment of the National Drug Abuse Clinical Trials Network:
A Baseline for Investigating Diffusion of Innovation
("Baseline Study") – Version 5.1**

Protocol Team

Co-Lead Investigators: Mitch Greenlick Oregon Health Sciences University
Dennis McCarty Oregon Health Sciences University

Project Manager: Eldon Edmundson Oregon Health Sciences University

Coordinating Center: Pierre LaChance KP Center for Health Research

Collaborators: Cynthia Arfken (GL) Wayne State University
Bill Cornely (DV) Fresh Start
Richard Drandoff (OR) ChangePoint
Bob Forman (DV) Treatment Research Institute
Roy Gabriel (OR) RMC Research
Diane Hague (OV) Jefferson Alcohol & Drug Center
Paula Horvatich (MA) Mid-Atlantic ATTC
Yih-Ing Hser (PN) UCLA
Bob Hubbard (NC) Duke University
Kathy Magruder (SE) Medical University of South Carolina
Jo Neal (GL) Chelsea Arbor Treatment Center
Eileen Pencer (NY) Lower Eastside Service Center
Elizabeth Reid (LI) Columbia University
Jody Sindelar (NE) Yale University
Nancy Vuckovic (OR) KP Center for Health Research

Data Management Reesa Laws KP Center for Health Research
Regulatory Affairs Lynn Kunkel Oregon Health Sciences University
Quality Assurance Sara Lamb Oregon Health Sciences University
Training Eldon Edmundson Oregon Health Sciences University

NIDA Liaison: Ivan Montoya National Institute on Drug Abuse

Consultants: Ben Bowser U. C. Hayward
Lee Kaskutas ARG, Public Health Institute
D. Dwayne Simpson Texas Christian University

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Summary

The National Drug Abuse Clinical Trials Network is developing a clinical trials system that works, has measurable outcomes for determining success or failure, and can be realistically implemented within the prevailing addiction health care system. The Network includes 100 or more unique community- based treatment programs (CTPs). It is essential to understand the beliefs, attitudes, treatment interventions and philosophy of treatment of the CTPs in order to increase the likelihood of acceptance and utilization of scientifically proven interventions over a broad array of addiction treatment modalities.

The "Baseline Study" protocol is designed to help the CTN understand the characteristics of the CTN network. Organizational, treatment unit and workforce surveys are used to collect information about the CTPs. The protocol is designed to ...

- Describe the organizations and practitioners delivering drug abuse treatment services within the CTN using organizational and workforce surveys.
- Build a data collection and monitoring infrastructure that has the potential to track changes in programmatic and staff characteristics
- Produce reports that allow treatment program management to review their data and assess their program relative to comparable programs within the CTN and with national treatment program data.
- Create, document, and archive a data set that promotes studies of organizational change, organizational culture, and the organization and staff attributes associated with the diffusion of evidence-based innovations within the CTN participants.

The results of the data collection will assist the CTN to identify the inherent strengths as well as the potential barriers to the successful dissemination and use of effective treatment interventions in real world treatment settings.

The scientific investigators and collaborators of this protocol understand a successful protocol requires a partnership between all of the CTPs in the CTN and the research scientists. This alliance can assist the CTN build an infrastructure for efficient dissemination and use of proven, effective and innovative treatment interventions.

1.0 Significance

The National Institute on Drug Abuse has invested substantial resources in the development of empirically based behavioral and pharmacological therapies for the treatment of dependence on opioids, cocaine and other drugs of abuse. It is critical to construct a comprehensive understanding of variables that facilitate or inhibit the adoption and use of these treatment innovations. The National Drug Abuse Clinical Trials Network (CTN) includes one hundred or more community-based treatment programs (CTPs) across 14 (or more) nodes throughout the country and provides an extraordinary opportunity to investigate the diffusion of research findings. These CTPs reflect the specialized drug abuse treatment services in the United States. The characteristics of individual treatment programs including attributes like size, organizational affiliations, staffing patterns, and the attitudes and beliefs of staff and supervisors are likely to have substantial influence on the clinical implementation and adoption of CTN research findings. The CTN needs a clear description of the heterogeneity of its participating treatment partners.

The CTPs participating in the CTN are not representative of the universe of drug and alcohol treatment programs throughout the US. Programs are over-represented who (a) are interested in improving their services by means of adopting evidence-based practices, (b) are able to make a commitment to do so, and (c) are willing to incur some tangible and intangible costs to do so. Nonetheless, the CTPs who are leaders in their communities are likely to be opinion leaders and reflect the leading edge of improvement in substance abuse treatment services. Systematic investigation will greatly improve chances of success with the national treatment research network and with the communication of the evidence-based innovations that flow from the CTN.

An investigation of organizational characteristics can also provide valuable information to the participating treatment programs. Confidential reports allow the programs to gain knowledge about their strengths and areas of needed growth, particularly with regard to research-readiness, training and education needs of clinical staff, and awareness of agency culture. Additionally, it is anticipated that community treatment programs and scientists will learn a great deal more about each other to facilitate a much-needed bi-directional approach to research readiness.

Assessments of organizational environments and cultures ultimately provide a foundation for more comprehensive assessments of the adoption and diffusion of behavioral and pharmaceutical therapies in drug abuse treatment programs. Subsequent studies can use the data to identify organizational factors that facilitate and inhibit more successful and less successful implementation of new therapeutic technologies. As Clinical Trials Network protocols evolve, studies can assess the influence of the broader social and policy environments on service delivery and the adoption of new technologies for the treatment of drug abuse.

2.0 Introduction (Background and Rationale)

Many hypotheses have been advanced about factors that enhance or hinder implementing the fruits of treatment research in drug abuse. The IOM report that recommended development of a CTN suggested that, in addition to other factors, the culture that

dominates a program contributes to the likelihood that a treatment program will apply research results (Lamb, Greenlick & McCarty, 1998). This hypothesis suggests that there are different cultures in programs linked to a medical care system or behavioral science oriented program, in programs dominated by persons in recovery, and in those linked to religious programs. The mechanism for “knowing” is different in the three cultures, with only the first characterized, primarily, by a cultural element that says one learns from doing scientific research.¹

We need to learn to understand the nature of the CTN programs in order to increase the probability of acceptance of research findings within CTN and other community-based treatment programs. The characteristics of programs and practitioners are likely to influence the adoption and diffusion of pharmacotherapies and behavioral therapies in community treatment settings. Classical diffusion theory suggests that at least four sets of influences affect adoption of new technology (Banta & Luce, 1993; Office of Technology Assessment, 1994; Rogers, 1995):

- a) the nature of the technology,
- b) the organizational and financial structures in which the technology is disseminated,
- c) characteristics of the providers and patients, and
- d) the communication methods (by whom, and through what channels).

Factors associated with earlier adoption of innovation include larger size, academic affiliation, system openness, organizational slack, a more competitive marketplace, and favorable reimbursement for the innovation. To assess the influence of these factors on the adoption of technology, this protocol proposes to characterize dimensions of the corporations and affiliated services providing care, record characteristics of the women and men providing direct care services, and observe the delivery of care.

Understanding the nature of the treatment programs, however, is only half of the challenge. The other half is to understand how best to translate science into the different treatment programs’ cultures. One of the dissemination challenges of the network is to make sense of its findings for therapists in recovery and for treatment people in a variety of other types of programs (Altman, 1995; Nurco & Hanlon, 1996). This brings an added and applied dimension to this research. Learning how programs with a culture that is not based within behavioral or medical science see the science may very well provide us with new insights and hypotheses about treatment, as well as information about how to translate the fruits of science into multiple realities.

¹ Some of this argument follows a perspective first put forth by Robert Merton in Merton, RK, “Patterns of Influence, Local and Cosmopolitan Influentials,” *Social Theory and Social Structure*, Glencoe: Free Press, 1957 and refined by Edward Suchman. In discussing different world views among consumers of health care, Suchman argued that some people had, what he called, a “cosmopolitan” view of the world, while others had a “local” view. And he proposed ways to differentiate those approaches to and explanations of life. He suggested that people with a “cosmopolitan” view of the world were more likely to have, what he referred to as, a “scientific” orientation to health and disease. Those with a “local” life view would be more likely to have a “parochial” orientation to health and illness. See, for example, Suchman, E. “Health Orientation and Medical Care,” *American Journal of Public Health*, 56 (January): 97-105, 1966.

Many other hypotheses have been offered to explain the diffusion of innovation within treatment programs of various kinds (Rogers, 1995; Wallack, 1999). This protocol suggests a plan to develop a comprehensive data set that could (and perhaps, should) be used to address these different hypotheses and other critical practice research questions during the early development of our network.

Finally this research activity will provide a basic data set that can be used to help the program managers improve their services and should also provide data for the ultimate evaluation of the National Clinical Trials Network. These two uses will be carefully monitored as the project develops.

3.0 Objectives

This multi-faceted project gathers data to describe the clinical treatment programs and the practitioners participating in the Clinical Trials Network. Initial objectives emphasize the design and collection of information on the treatment organizations, component treatment units and the workforce in each unit. The data collection system that comprises the total protocol has four objectives in advance of undertaking the ultimate research analysis; specific research questions are outlined in Section 4.4 and in Table 1.

- Describe the organizations and practitioners delivering drug abuse treatment services within the CTN using organizational and workforce surveys.
- Build a data collection and monitoring infrastructure that has the potential to track changes in programmatic and staff characteristics
- Produce reports that allow treatment program management to review their data and assess their program relative to comparable programs within the CTN and with national treatment program data.
- Create, document, and archive a data set that promotes studies of organizational change, organizational culture, and the organization and staff attributes associated with the diffusion of evidence-based innovations within the CTN participants.

4.0 Study Design and Measures

The study design includes descriptive and comparative facets. During the first round of data collection descriptive analyses are emphasized to characterize and describe the treatment organizations participating in the CTN. Initial data collections (those supported in this protocol) provide baseline measures of organizational and staff variables. Subsequent rounds of data collection (to be proposed in future protocols or investigator initiated applications) will update the descriptive elements and permit comparisons overtime within the same agencies and comparisons between agencies at the same point in time. Comparisons between agencies will identify differences and similarities among programs participating and not participating in specific CTN protocols. Participation in

protocols may amplify differences with nonparticipants and suggest variables that may influence organizational change and adoption of treatment innovations.

Three separate types of data collection activities are planned with this protocol: 1) corporate surveys, 2) treatment unit surveys, and 3) workforce surveys. The protocol may also include site visits and ethnographic observations but details for the qualitative facets will be developed later. Organizational surveys characterize each program at a macro level, focusing on characteristics of the treatment units and the sponsoring agencies. Data are obtained from existing data sources and web-based interviews with program management. Data include type of corporation, work environment and setting, program philosophy and orientation and staffing patterns. Web and paper-based workforce surveys describe the clinical and medical staff in terms of their education, training, experience, gender and race/ethnicity. Staff attitudes and beliefs are also assessed. The organizational and workforce surveys will permit a characterization of the CTPs and their constituent treatment units. **The qualitative aspects of the protocol will be developed later and are not included in the current version of the protocol.**

Subsequent rounds of data collection may be coordinated with separate investigations funded as investigator initiated applications (R01s). The data collected in the baseline study can be available, with masked ID information, to projects approved to undertake research in the CTN. The protocol design team has been working with several research groups with proposals under review. The expectation is that downstream phases of the work begun in this study will be done in conjunction with some or all of those projects. Data sharing agreements will be executed to assure adherence to CTN confidentiality requirements. To facilitate anticipated collaborations, this design nests a panel study of the workforce within a cross-sectional design. If subsequent workforce surveys are supported, a panel study permits examination of how individual therapists react to working within a research/practice context at the same time we study how programs change over time.

4.1 Organizational and Treatment Unit Surveys. The first wave of data collection uses previously published surveys and validated methods and instruments to characterize the treatment programs enrolled in the CTN. The organizational survey collects information on type of corporation, service delivery setting, individual treatment units and sources of revenue. In addition, data will be integrated from other existing sources. This protocol collects descriptive data and provides a framework for subsequent follow-up data collections. Follow-up surveys are likely to be supported through collaborations with investigators with funding from investigator-initiated awards.

The organizational assessment builds on the instrumentation and data collection methods developed in prior investigations. Program characteristics are recorded using items from SAMHSA's Uniform Facility Data Set (Substance Abuse and Mental Health Services Administration, 1999), the Addiction Treatment Inventory (Carise, McLellan & Gifford, 2000), and the New England Outpatient Survey (McCarty, Levine, Steenrod, Prost & Meredith, 1998). Program philosophy is assessed using the Social Model Philosophy Scale (Kaskutas, Greenfield, Borkman, & Room, 1998). The scale is a 34-item checklist

that reviews six domains: physical environment, staff role, authority base, view of substance abuse problems, governance, and community orientation. Versions are available for both residential and outpatient facilities.

The treatment unit survey includes a count and listing of treatment program staff (number and job titles). This information provides the list of staff used for the workforce surveys.

4.2 Workforce Surveys. The Staff Survey provides data on staff characteristics and perspectives using two survey instruments focusing on clinical and management staff. A second tool will be developed for use with research staff under a supplement to this protocol. As part of the treatment unit surveys, program management provide a roster of staff (medical, clinical, management and other staff with direct patient contact). A brief web-or paper-based questionnaire (Staff Survey see Appendix C) elicits data from staff on their training and education, certification, years of experience and recovery status (Mulligan, McCarty, Potter, & Krakow, 1989). Questions from the instrument developed by the Delaware Valley Node for its baseline assessment of staff opinions are included that provides information on staff treatment attitudes and beliefs (Forman, Bovasso, McLellan & Woody, 2000). Respondents are also asked to complete an instrument developed by the Institute for Behavioral Research at Texas Christian University (Simpson, et. al, 2000) to assess attitudes and information about current practices and utilization of research-based findings – the Organizational Readiness for Change instrument. This questionnaire addresses agency and counselor characteristics and readiness to change practices including adoption of research based findings. Management and clinical supervisors receive a slightly different version of the Organizational Readiness for Change instrument.

4.3 Qualitative and Site Visit methods. (*Note: the qualitative aspects of the protocol will be developed and submitted for review later and are not included in this version of the protocol.*)

4.4 Study Questions, Variables and Hypotheses. The Baseline Study instrumentation addresses specific research, management and evaluation questions. Study dimensions are based on hypotheses about change factors in organizations and issues relevant to program managers. Table 1 outlines potential questions and variables related to the three quantitative instruments: organizations, facilities, and workforce. Hypothesis testing will be used to assess the strength of these potential relationships.

5.0 Participants (Subjects)

This protocol will collect data from drug abuse treatment organizations, drug abuse treatment units, and the workforce in the programs (and later in the regional research and training centers). Patient data are neither solicited nor collected. All of the treatment organizations participating in the National Drug Abuse Clinical Trials Network are invited to participate. Treatment organizations with multiple treatment units may limit participation to the units that are participating or are most likely to be participants in CTN activities. Each organization will identify the distinct treatment programs and facilities

Table 1: Outline of Study Questions by survey: Organizations, Units and Staff

| Questions and Variables | Survey A: Organization | Survey B: Treatment Units | Survey C: Workforce |
|--|-------------------------------------|-------------------------------------|-------------------------------------|
| Organizations and facilities | | | |
| Do organizational attributes affect adoption? | | | |
| A. Size (Staff and patient load) | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| B. Organizational setting or sponsorship | | | |
| 1. Medical setting, mental health setting, free-standing AOD | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| 2. Residential, outpatient, day treatment | | | |
| 3. For profit/not for profit | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 4. Board composition | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C. Nature of clients | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 1. drug use | | | |
| a. drug of choice | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| b. drugs used and poly-drug use | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 2. gender, age, race/ethnicity | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 3. housing stability – homelessness | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 4. employment | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| D. Treatment approaches, models, services | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| E. Regulatory environment | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| F. Accreditation and certification | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| G. Use of automated databases | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| H. Assessment tools and guidelines | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| I. Urine and breath testing | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Workforce | | | |
| Do workforce characteristics affect adoption? | | | |
| J. Age, experience, staff retention rates | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| K. Training, education, credentials | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| L. Personal recovery | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| M. Participation in a clinical trial | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| N. Staff attitudes and beliefs | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| O. Treatment orientation and philosophy | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Revenues and Costs | | | |
| Do revenues and costs affect adoption? | | | |
| P. Sources and methods of reimbursement | | | |
| 1. private and public revenues | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. participation in managed care | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

they manage and operate that are eligible to participate in the surveys. The program director, administrator, or manager at each of program site will be asked to complete a program survey that provides site-specific information. The protocol also surveys the clinic’s workforce to assess their characteristics and their attitudes and beliefs about specific drug abuse treatments.

6.0 Study Procedures

A three-faceted assessment of program attributes is planned. Initial efforts develop an inventory of organizations and programs participating in the CTN. Workforce surveys are the second emphasis and will be in the field about the same time as organizational surveys. A study implementation plan is outlined and summarized in Table 2. Finally, as mentioned previously, qualitative site visits will be conducted at a later date (as outlined in a separately reviewed supplement to the Baseline Protocol). Organizational and workforce data will guide the design of that phase of the overall baseline study.

6.1 Organizational and Program Surveys. Node Baseline Coordinators will list the treatment organizations and executive directors participating in the Clinical Trial Network and provide email and telephone contact information for each. As with any CTN project **participation will be entirely voluntary** for both Nodes and their individual treatment programs, and CTP staff. But with participation rates closer to 100%, the likelihood the CTN and its participants will benefit from the results increases. Everything possible will be done to reduce the difficulty of participating.

The Center for Health Research (the Oregon Node's Coordinating Center) will prepare a code number to identify the treatment organization and the lead respondent. The number will be enclosed in a sealed envelope addressed to the respondent. The envelopes will be distributed to node baseline coordinators who will in turn distribute to each respondent. In addition to the identification code, the envelope contains a password to access a secure website where the respondent can complete the survey. To facilitate responses and minimize duplicative efforts, recipients (i.e., Executive Directors or their designees) will be able to complete the survey in steps and data will not be finalized until the completed survey is submitted. A completed summary of the responses will be generated for each organization and treatment unit and the respondent will be asked to review the answers for accuracy. Training and detailed instruction manuals will be provided. Hard copy versions of the survey will be available to facilitate collection of agency data and may be used, if desired, to complete the survey. Hardcopy will be returned directly to the Center for Health Research.

The survey provides information on the corporation (e.g., name, address, contact person), the ownership status (e.g., not-for-profit, for-profit, government), primary service setting (e.g., hospital, mental health center, free-standing addictions treatment program), and information on size of the corporation (e.g., total revenues, number of employees, number of facilities). In addition, respondents note the distinct substance abuse treatment programs / facilities that the corporation operates, provide information to categorize the programs (e.g., inpatient, outpatient), and list a program contact. Submissions enter a database maintained by the Oregon Node. The Oregon Node's Coordinating Center

Table 2

Baseline Study Implementation Plan -- Task Description

Version 1.02 May 10, 2001 La Chance

1 Identify Node Baseline Coordinator (NBC)

Get node, name, address, phone number for each Node Baseline Coordinator (NBC).

2 Create web accounts for NBCs

Create web accounts for NBCs that includes their username and password and a table that links these to their name, web ID, and database ID, Node ID

3 Create form 1 for NBC to enter CTP information

Create simple web based form to be filled out by NBCs for their nodes. The data elements are :
CTP Name, CTP Owner/Manager -- node name will be implied by Node Baseline Coordinator

4 Distribute NBC account information to NBCs

Send an envelope to each NBC with a letter inside giving them their username and password
Include instructions on how to enter the data to the web form.

5 Collect data from NBC re: Node CTPs

The web form will take care of this.

6 Extract Owner/Manager data from form 1

Go into the database that the web form enters data to and extract the information needed to create the materials we will mail to CTP Owners/Managers

7 Prepare materials to distribute to CTP Owner/Manager via NBC

Take the data from step 6 and create an envelope with the CTP Owner/Manager's name on the outside. Create a letter to be stuffed inside the envelope that shows the CTP Owner/Manager's name, userid, and password. Include instructions on how to access the website (URL) and how to enter data and/or download a paper copy of the form.

8 Create CTP web accounts

Create web accounts for CTPs that includes their username and password and a table that links these to their name, web ID, and database ID, Node ID

9 Send materials to NBC

Send to the NBCs the envelopes with each CTP Owner/Managers user account information.

10 Create form 2 for CTP Owners/Managers to enter survey data

Acquire final form 2 from OHSU and design both a web based form and a paper form that is downloadable from a browser in a stable format that is independent of printer configuration (PDF from Publisher?)

11 Collect data from CTP Owners/Managers on form 2

The web form will take care of this. For paper forms create a receipt system and a modified web based entry form for use by CHR entry staff that, unlike the regular web based form, includes field numbers for entry reference.

12 Create report summarizing completeness of data from form 2

Create a report that shows rate of return to date in terms of percent. For form 2 this will be dichotomous -- Done or not done.

13 Create report summarizing data from form 2

Create a report summarizing basic frequencies and univariates for initial data review. Create SAS data auditing reports for more detailed review.

14 Extract Supervisor data from form 2

Go into the database that the web form enters data to and extract the information needed to create the materials we will mail to CTP Supervisors at each CTP facility

15 Prepare materials to distribute to CTP Supervisors via NBC

Take the data from step 14 and create an envelope with the CTP Supervisor's name on the outside. Create a letter to be stuffed inside the envelope that shows the CTP Supervisor's name, userid, and password. Include instructions on how to access the website (URL) and how to enter data and/or download a paper copy of the form.

16 Send materials to NBC

Send to the NBCs the envelopes with each CTP Supervisor's user account information.

17 Create CTP Supervisor web accounts

Create web accounts for CTP Supervisors that includes their username and password and a table that links these to their name, web ID, and database ID, Node ID

18 Create form 3 for CTP supervisors to enter facility data

Acquire final form 3 from OHSU and design both a web based form and a paper form that is downloadable from a browser in a stable format that is independent of printer configuration (PDF from Publisher?)

19 Collect data from CTP Supervisors

The web form will take care of this. For paper forms create a receipt system and a modified web based entry form for use by CHR entry staff that, unlike the regular web based form, includes field numbers for entry reference.

20 Create report summarizing completeness of data from form 3

Create a report that shows rate of return to date in terms of percent. For form 3 this will be a percent. The denominator will be the total numbers of supervisors as identified by the CTP Owner/Manager. The numerator will be the number of completed forms received multiplied by 100.

21 Create report summarizing data from form 3

Create a report summarizing basic frequencies and univariates for initial data review. Create SAS data auditing reports for more detailed review.

22 Extract Employee data from form 3

Go into the database that the web form enters data to and extract the information needed to create the materials we will mail to CTP staff at each CTP facility

23 Prepare materials to distribute to CTP Employees via NBC

Take the data from step 22 and create an envelope with the CTP Staff name on the outside. Create a letter to be stuffed inside the envelope that shows the CTP Supervisor's name, userid, and password. Include instructions on how to access the website (URL) and how to enter data and/or download a paper copy of the form.

24 Send materials to NBC

Send to the NBCs the envelopes with each CTP Staff user account information.

25 Create CTP Employee web accounts

Create web accounts for CTP Staff that includes their username and password and a table that links these to their name, web ID, and database ID, Node ID

26 Create form 4 for CTP Employees

Acquire final form 4 from OHSU and design both a web based form and a paper form

that is downloadable from a browser in a stable format that is independent of printer configuration (PDF from Publisher?)

27 Collect data from CTP employees

The web form will take care of this. For paper forms create a receipt system and a modified web based entry form for use by CHR entry staff that, unlike the regular web based form, includes field numbers for entry reference.

28 Create report summarizing completeness of data from form 4

Create a report that shows rate of return to date in terms of percent. For form 4 this will be a percent. The denominator will be the total numbers of supervisors as identified by the CTP Owner/Manager. The numerator will be the number of completed forms received multiplied by 100.

29 Create report summarizing data from form 4

Create a report summarizing basic frequencies and univariates for initial data review. Create SAS data auditing reports for more detailed review.

30 Create training materials for data collection

31 Conduct training for data collection

32 Transfer Data to NIDA monthly

Duplicate data transfer process used for other protocols for monthly data transfer to NIDA

tracks responses and asks Node Baseline Coordinators to follow-up with organizations that fail to respond and encourage participation. See Appendix A for a copy of the instrument.

Similar procedures will be used for the treatment unit survey. The Organizational Survey provides information on specific treatment units including the name of the contact person. For each treatment unit identified in the Organizational Survey, a respondent identification code will be generated, enclosed in a sealed envelope, and addressed to the respondent. In order to reduce delays waiting for completed organizational data, treatment unit envelopes will be mailed directly to the respondent as soon as the contact information is provided. Node baseline coordinators will be notified as envelopes are mailed. Envelopes include a description of the study, the respondent identification code and the password for accessing the secure web site. The instrument may be filled out in stages but once submitted to server it cannot be accessed again. Hard copy versions of the instrument and may be used to complete the survey. Completed hard copy will be returned directly to the Center for Health Research. The Treatment Unit Survey collects more specific program information: the types and levels of care, accreditation and licensure, patient characteristics, sources of revenue, staffing, staff retention, and program environment and philosophy. A copy of the instrument is included in Appendix B.

6.2 Workforce Survey

6.21 Survey Overview. Workforce surveys elicit information from the individuals working in each treatment program or facility. Clinical, medical, other staff with direct patient contact (e.g., reception, case management) and program management staff are asked to participate. In addition, research staff working with the regional research and training centers will also have an opportunity to complete the instrumentation (this material will be ready later). Staff surveys provide data on job titles, demographics, training and education, credentials, and attitudes and beliefs about the pharmacotherapies and behavioral therapies being tested in the Clinical Trials Network. Part II of the survey includes the TCU Organizational Readiness to Change instrument (Dwayne Simpson, <http://www.ibr.tcu.edu/pubs/datacoll/coresetforms.html#Form-ORC>). Management and supervisors receive a slightly different version of the instrument.

Respondents are identified in the Treatment Unit Survey. Identification codes will be generated for each potential respondent and enclosed in sealed envelopes along with a unique password to access the secure web site. The envelope includes instructions, a study description and a form to indicate participation consent. The Staff Survey may be completed using the Internet. Nodes and CTPs have indicated that Internet data collection may not be feasible or efficient in many treatment units. Specific distribution and completion strategies are likely, therefore, to vary from among treatment units. If the hard copy (paper) format is used, the identification code will be preapplied to the survey, sealed in an envelope and addressed to the respondent. Node baseline coordinators will distribute to each treatment unit unless they opt for direct distribution from the Center for Health Research. Respondents seal completed surveys in a postage paid envelope and

mail directly to the Center for Health Research. Respondents may also choose to mail directly to the Center for Health Research. All eligible employees will be asked to complete the Workforce Survey – the goal is 100 percent participation. Appendix C includes a copy of the instrument.

6.22 Procedures to Protect Confidentiality. In addition to assuring that the web sites and servers provide security, logistical processes used to support data collection, linking and analysis will be applied to assure the confidentiality. Staff names for each CTP within each node will be provided to CHR through the treatment unit survey. These staff names and their CTP/NODE will be linked within a secure MS SQL database at the study coordinating center (Center for Health Research) to two separate and arbitrarily assigned identifiers that contain no embedded meaning (for example the triplet John Q. Modern [NAME] MX107CL [WEBID] CD114GR [Analysis ID]). No one, other than a very few and select CHR IT staff will have access to this database. Prior to data collection, CHR will mail to each Node Baseline Coordinator a sealed envelope for each staff member within each CTP for his or her Node. On the outside of the envelope will be the staff person's name and CTP/Node. Within the sealed envelope will be the staff person's Web ID and password. The staff will use these to authenticate their access to the site's web pages that allow survey data collection. Here, they will enter their data. As data are entered to the database this Web ID will be replaced within the CHR database with the staff person's Analysis ID. Thus, even if a staff person is careless and leaves their Web ID and password out for public view, when data are later released and shared for analysis, it will be impossible to tie these data to that individual. Furthermore, when follow up data are needed, this process will be repeated allowing us to confidentially tie together an individual's data across time, even if they forget their Web ID and password.

6.3 Site Visits. Note, the qualitative aspects of the protocol will be developed later and are not included in the current version of the protocol.

6.4 Informed Consent and Confidentiality

6.41 Informed Consent. The protocol is basically an investigation of organizational characteristics and attributes (community treatment programs participating in the Clinical Trials Network). As such, the Organizational and Treatment Unit Surveys do not involve human subjects and should be exempt from IRB review. The Workforce Survey, however, may be viewed as involving human subjects (direct care workers in the participating treatment programs). Administration of the Workforce Survey is designed to protect confidentiality and to minimize potential risks to participants. Institutional Review Boards are likely to vary in their judgments about the need for formal informed consent procedures. The protocol team has developed a model consent package. The Oregon Node will work with individual nodes to address any unique IRB concerns. See Appendix D for a copy of the consent package which provides a memo to the Node PI and model informed consent materials. See discussion in the Regulatory section for more detail.

6.42 Confidentiality. Because the protocol uses web technology to administer some of the surveys and collect data, electronic safeguards are an important aspect of confidentiality protections. The Center for Health Research hosts secure websites that contain sensitive information. Multiple layers of security work together to ensure that only authorized users can access project files and information appropriate to their role on a project. Although no web site is 100% secure, the precautions offer a high level of protection against unauthorized access, and in fact, are more secure than more traditional data handling methods routinely used – anonymous FTP, email, and physical mail of hard copy or diskettes. The areas of primary concern when dealing with sensitive information on the Internet are:

- User Authentication
- Encryptions of information over the Internet
- Storage of information in a secure environment

Forms filled out on paper will also have confidential codes so that names cannot be tied to results.

User Authentication. Each project's website on the secure servers (including those for the CTN protocols) requires that users log in with a valid account (username/password combination) to gain role-based access to the contents of the site. Each project manages its own list of user accounts and role-based access via a web based administration interface. This assures that those who understand the project's security needs manage these accounts rather than systems staff who might be limited to a technical understanding of the project. For this protocol, Reesa Laws (chair of the CTN Data Management and Statistics Subcommittee) will manage these accounts. To improve the security of the accounts, CHR administration interfaces impose minimum requirements on the length and complexity of usernames and passwords.

Once a user has logged into a particular project's website, they are only allowed access to content and files related to that specific project. Furthermore, within the project's website, users are only allowed access to content and files based on their role within the project. Thus, a project's coordinator may have access to different parts of the project website than a project clerk. Again, these roles are defined and managed by the project staff. This authentication is enforced at the file system level using a combination of NT Groups and NTFS permissions.

Encryption of Information transmitted over the Internet. All communication between the client browser and our secure servers is protected using SSL (Secure Socket Layer) encryption. CHR's servers use SSL certificates issued by Verisign Corporation, which is the top certificate authority in the industry. The encryption strength required for a project can be set to a minimum of either 40 or 128 bits, depending on the requirements of the project. Any attempt to access a project on our secure servers without using the minimum level of encryption results in the display of an error page.

Storage of information in a secure environment. The web servers are physically secured in racks in a locked server room, and only authorized CHR personnel are allowed access. They are connected to a secure Extranet (External Network), which is protected from the Internet by one of the leading Firewalls on the market. Finally all communications are logged by both the Firewall and the web servers, and stored for tracking and reporting purposes.

6.5 Pretest and Pilot Studies

Study methods and procedures will be tested using pretest and pilot procedures in order to be more confident that the instrumentation works as desired and that the methods are feasible and efficient.

6.51 Pretest. A thorough pilot study is essential to the success of the national baseline assessment of CTPs. The pretest is designed to provide a sense of response burden, clarity of individual items, and the feasibility of collecting the requested information. To minimize bias the lead investigators will not participate in the pretest. The Oregon Node will contract with RMC Research to conduct the pretest. Pretest activities will be completed under the direction of Roy Gabriel from RMC Research and results will be described in a written report. CTPs currently engaged in the Oregon node will not be included in the pretest. Agencies will be chosen that have similar characteristics as the CTPs currently engaged in CTN activity. Three diverse treatment agencies volunteered to participate.

A diverse sample of pretest participants will maximize learning opportunities. The sample includes a large, multi-site and multi-faceted treatment agency; a relatively small agency with one or two programs (treatment units, in the parlance of the survey design); and a small stand-alone chemical dependency treatment agency. Agencies will offer a variety of treatment modalities (residential, outpatient) and serve diverse client populations (racial/ethnic, criminal justice, youth, adults).

Protocol data collection procedures will be mimicked and surveys will be completed sequentially. The executive director or director of substance abuse treatment services will complete the Organizational Survey (survey A) and RMC Research staff will interview him or her in person to debrief on the survey experience. Research staff will review the director's survey responses prior to the interview to ensure that the intent of the items was understood. The interview will include questions on how long it took to complete the survey, how easy or difficult it was to answer the questions accurately (e.g., did the director have to consult other staff for any of the questions?), how clear the instructions were in setting up the second tier of the survey process, and how exhaustive the questions on the survey were in representing key considerations that will relate to effective implementation of CTN goals (i.e., a mutually beneficial researcher/practitioner partnership in the improvement of treatment practice).

The Treatment Unit Survey (survey B) will be distributed to all treatment unit directors in the agency. Again, their completion of the surveys will be followed by a review of the

responses and a debriefing interview that probes response burden, item clarity, and feasibility. RMC will conduct this debriefing with the full group of respondents simultaneously to allow for differences in perception to be aired. There is a synergistic benefit to discussing these ideas as a group rather than one on one.

A sample of two or three staff within each unit will be selected by the unit director to complete the Workforce Survey (survey C). There is no attempt to select a randomly representative sample of unit staff at this stage in the pilot. Rather, as with the agency selection, the goal is to maximize the opportunity to learn by requesting a heterogeneous sample. The pretest is not interested in the data *per se*, but simply in the experience of completing the surveys. At this stage, the target population is not limited to practicing or certified clinicians, but anyone who has direct contact with clients. For example, in a residential treatment facility there are staff who tend to many essential, albeit non-therapeutic, needs of clients beyond the “normal” working hours. Their attitudes and philosophies are often considered integral to the success of treatment in those agencies and are thus important to this baseline assessment. Following the completion of these surveys, RMC staff will review the responses and facilitate a group discussion for feedback purposes. Multiple group discussions will be held in large agencies to keep the group size down to a manageable number.

With permission of respondents, debriefing interviews will be audiotaped for future reference. This will eliminate or at least minimize any interviewer bias in recording the impressions of the respondents. Data obtained from these interviews will be summarized in a report of the pretest. Both quantitative data (length of time to complete surveys, percent of respondents who had difficulty with a given item) and qualitative data (reasons for confusion, differing perceptions within the agency not sufficiently clarified in the existing items) will be included in the report.

The pretest report will guide modifications to Baseline instrumentation and methods.

6.52. Pilot. In addition to the pretest activity, the Oregon Node will be used to pilot the final versions of the methods and instruments. The first implementation of the Baseline study will occur in the Oregon Node. A Node Baseline Coordinator will be trained to oversee data collection and instrument distribution. Internet methods will be tested and paper and pencil measures will also be tried for the Workforce Survey. Implementation problems will be identified and methods modified as necessary. If needed a second node will be sought to continue the pilot process.

6.6 Data Collection

Each node will be asked to identify a Node Baseline Coordinator. The Baseline Coordinator will be the node liaison and the individual with whom the Oregon Node will coordinate study implementation. Baseline Coordinators will be responsible for facilitating data collection and communication with node CTPs. They will confirm contact individuals at each CTP, facilitate survey distribution if the CTP cannot access the web-based survey, and coordinate distribution of passwords to staff with direct

patient contact for completion of the web-based workforce survey. In addition, they will work with the Oregon Node to monitor response rates and promote participation. The Oregon Node will provide training for the Baseline Coordinators and support their efforts to promote survey participation. Nodes may also elect to identify a more senior investigator to supervise and support the Baseline Coordinator.

The Oregon Node will provide both a traditional paper-based distributed or centralized web-based data collection and management system as well as providing a web based data collection and management system to be used during the Baseline protocol. Using the web-based system will allow other CTN nodes to participate in this protocol with minimal technical development and minimal costs if their CTPs have access to the Internet. In addition to these cost savings, the time from collection to insertion into the master database will be minimized and data quality will be enhanced. Additionally, it is likely that some CTP staff will perceive the web based system as preferable to the paper based method due to perceptions of enhanced confidentiality. Web-based data collection also provides an opportunity to test the feasibility of using these procedures. We may be able to improve the quality and cost-efficiency of our data collection and management systems by avoiding costly development duplication, but may also dramatically shorten the time from data collection to final analysis.

If CTPs do not have Internet access or choose not to use Internet access, the paper surveys will be sent to Oregon Node for processing. Processing at Oregon Node strengthens confidentiality protections and relieves participating nodes and CTPs of the processing burden.

We plan to build the data collection and management system using a secure Internet client/server architecture. This design will incorporate a mix of HTML, ActiveX controls, Dynamic HTML, XML, Visual Basic Script, custom Visual Basic components, Internet Information Server, and SQL Server database management system in a multi-tiered configuration. This web based model has been designed, fully tested, and is currently in use in the Oregon node for the MET/MI protocol.

Using Internet-enabled data entry and verification components, the system will identify and highlight, in real time, any data that violate range and/or logic checks both within and across forms. Many of these checks will occur field by field by using client side validation. When the survey respondent is satisfied with the data that has been entered for the entire form and submits the form's data, the validated data are automatically updated and validated in Oregon node master database via a secure transaction. If other exceptions exist at this time, they are immediately reported to the survey respondent for editing or confirming.

The Oregon node will take a multi-faceted approach to ensure absolute data security from the point of entry to the master database. Security steps will include a combination of certificate authentication for field center connection to the host server, custom programming to secure individual access to forms and other documents, and data packet encryption to ensure that confidential data cannot be revealed even if packets are

intercepted in transmission. Additional security for data entry transactions will be applied by using the role-based security model in Microsoft Transaction Server. The Oregon node server will sit behind the CHR's standard configuration of firewall/proxy server with access via encrypted Virtual Private Network (VPN) connections.

6.61 Participation Incentives. Discussions with CTPs and with Nodes suggest a range of opinions on the value and need for participation incentives. Many program directors indicate that they will complete the forms because of their participation in the CTN and do not expect additional incentives. Moreover, they also intend to direct staff to participate as part of their workday and will not offer participation incentives. On the other hand, the director of a large program reported that participation incentives were essential to facilitate enthusiastic participation from all treatment units. The Protocol leaves the decision to the Nodes and their participating treatment programs. Node baseline coordinators will record the use or nonuse of incentives and, if used, the value of the incentives. Information on incentives will be examined to determine if response rates were affected by the use of incentives.

6.7 Quality Assurance

Quality assurance focuses on four primary areas:

- User registration and authentication
- Web-based entry
- Paper-based collection
- Paper-based entry

User registration and authentication quality is assured by providing each user with a user-specific username and password. This assures that only this individual has access via the web to their web-based form for either entry. These usernames and passwords are mailed by CHR to the node baseline coordinators and distributed directly to the users in sealed envelopes. If a user loses or forgets their username and/or password, new ones will replace the existing ones and be distributed, as were the originals, by mail to the node baseline coordinator for personal distribution to the user. Usernames or passwords will not be distributed by phone or email.

Web-based entry forms possess real-time intelligence for range, logic, and skip checks, which will minimize entry error. These checks make it difficult to enter most types of "bad" data. For fields that are deemed vital for analysis, confirmation boxes are used to assure the entered value is what the respondent intended. However, certain errors may occur, for example someone may type in 14 years of education instead of 15. These types of errors persist in this system as they would in traditional entry systems. Other types of errors may persist given the impossibility of creating real-time processes to control for every conceivable error or exception. Confidentiality requirements for the protocol prevent direct respondents contact for verification.

Using simple, clear, and user-friendly paper forms enhances paper-based data collection quality. The survey instruments possess virtually no skip patterns and very little variance

in formatting, in keeping with this goal for simplicity and clarity. Unlike web-based collection, it is not feasible to use real-time QA to assist the respondent and enhance quality. Some errors and exceptions will leak through and persist. Confidentiality requirements for the protocol prevent contacting respondents for verification. However, some types of errors and exceptions are handled by using standard procedures such as accepting the first answer when two categories are chosen, or accepting the data as missing when it is illegible.

Double verification for all forms will assure the quality of data entry from paper-based forms. Additionally, CHR data entry staff have substantial experience (typically 10 years or more of experience) and routinely meet the department quality goal of 99.99% accuracy.

7.0 Statistical Analysis

This baseline study has multiple objectives, which complicates the development of an analysis plan. Consequently, an analysis plan is presented in developmental components. Specific research and management questions illuminated the study design, including a set of questions about how treatment decisions are made within treatment programs (both at the program and at the individual client level). Opportunity is also present to collect data in a parsimonious manner for a variety of future (and as yet, unknown) research and CTN management objectives.

Therefore the analysis is organized both to answer immediate needs and to facilitate the ability to get data that serves other needs. A great deal of work will need to go into pre-analysis data preparation and reporting to enhance the ability of this effort to serve a variety of analytical objectives. Early activities focus the creation of a data dictionary, specifying the large number of variables and producing a catalog of the simple descriptive data on each of the variables. Careful examination of those reports is a part of the data processing activity and also facilitates the analysis design and conduct.

7.1 Program Reports. An early analysis objective is to create a set of program reports that allows CTP management to compare their program to all of the other programs in the CTN and to programs in the CTN that are similar in important characteristics to their own program. The baseline study requires a significant commitment on the part of the treatment programs. It is important to provide some specific payoff to the treatment program management. In addition, this facet of the analysis will create a unique inventory of the CTPs of the CTN that will provide a great deal of descriptive information about the CTP for a variety of CTN purposes.

Program-specific reports will present the data in a readily accessible form, protecting the confidentiality of the treatment programs, but focusing on key questions that are specified by the treatment personnel as the study develops. The process for developing these questions is well under way and includes in its focus many manpower issues, as well as issues that reflect on treatment program effectiveness.

7.2 Descriptive Analysis. Table 1 provides an outline of the variables to be addressed in various facets of the study. The descriptive analysis phase provides frequencies and cross-tabs on each of the critical variables, focusing on the distribution of the variables across the treatment programs in the study. The first set of descriptive analyses will allow examination of the treatment program universe of the CTN on the elements that characterize treatment programs, including their personnel, patients, and the environment within which they practice. This aspect of the analysis begins the effort needed to characterize the programs. While looking at the data across the individual variables in this phase, it is critically important to begin to create indices and scales upon which to characterize the programs. Responses will differentiate among the treatment programs and the unique dimensions that differentiate programs can be specified. This begins with the analysis of the descriptive data sets.

Once the questionnaires and other data gathering instruments are finalized, intermediate analysis plans are developed including specifying the sets of dummy tables that will guide that plan.

7.3 Multivariate Analysis. The purpose of the multivariate analysis of the baseline study data is to examine the underlying concepts that will be used as independent and dependent variables in the study of factors affecting the adoption of treatment methods. This will be an ongoing analysis activity that is initiated during the organizational and treatment unit surveys (see Table 1), but during the preliminary multivariate analysis activities we will be in hypothesis generation, rather than hypothesis testing mode.

The critical question for multivariate analysis is specifying a manageable number of variables that define the constructs under study. The study of organizational factors that determine the way treatment is delivered in substance treatment programs is in its infancy and we don't have too much prior work to guide us, although we scanned the literature to provide scales and indices for our questionnaires. What we need to undertake in the analysis is to parsimoniously characterize treatment programs on critical dimensions of organizational culture, mission, and environment. We will be undertaking the preliminary analyses and then will be testing the interpretation of the preliminary findings during the intensive visits to the treatment programs in qualitative facet of the study. The analysis of the qualitative data will provide insights into the ultimate analytical design for the data gathered in the program and workforce surveys.

8.0 Training and Regulatory Issues

8.1 Training. The baseline study requires that Node Baseline Coordinators and staff completing forms have specific information to carryout their responsibilities. Training for the baseline survey will assist Node Baseline Coordinators to understanding the purpose of the surveys and how to instruct respondents to the organizational, treatment unit and workforce surveys.

Node Baseline Coordinators need to have completed GRP training prior to attending the baseline study training. Specific study procedure issues that require training will be

covered in a 3-4 hour training session. Each survey includes specific instructions on how to complete the questionnaire. These instructions include definitions for terms. The Node Baseline Coordinators serve as a resource to survey respondents. Note, this is not an intervention study and instruments in the Common Assessment Battery (ASI-Lite, Demographics, HRBS, or other assessments) are not included in the protocol so these tools will not be discussed.

8.11 Personnel to be Trained. Node Baseline Coordinators will receive the study training (see job description in Appendix D) so they understand the baseline survey process and their roles in that process.

8.12 Trainers. Five people will lead the training for Node Baseline Coordinators. Eldon Edmundson will facilitate and coordinate the training activities. Mitch Greenlick and Dennis McCarty, co-PIs for this study, will provide the overview about the study and review the questionnaires with the baseline node coordinators. Reesa Laws and Pierre LaChance from the Oregon Node coordinating center will provide training on data collection and web-based entry. The Trainers will facilitate discussions on ways to market the study to node and sites.

8.13 Study Training Topics. Training topics are outlined below.

a. Baseline Study:

- baseline study purpose and process,
- effective liaison with the protocol management team and node participants,
- ways to assist employees in completing the workforce survey, and
- data collection, data management, and quality assurance methods.

b. GRP Related Training. GRP training for baseline node coordinators is necessary and the GRP training provided by nodes for other protocols should provide these coordinators with the necessary information about research, human subjects, data collection, quality assurance and related issues.

c. CAB Training: The baseline study does require CAB training.

d. Data Collection Training: Data entry uses both web-based and paper methods. The Training includes a review of the web-based and paper versions of the instruments. The baseline node coordinators will be available to help people at the sites complete the forms.

8.14 Implementation of Training Activities. Baseline node coordinator training will occur during the month prior to initiation of the baseline study. Currently, we anticipate a September or October date for the training. It is possible that a west coast and east coast training session may occur or an early fall and late fall session, to better time training with node implementation.

8.15 Training Costs. Nodes are responsible for travel costs related to participation in the training for Node Baseline Coordinators. No other training costs should be incurred, except those associated with the time and travel for the baseline node coordinators to provide training related information sessions about the questionnaires to their site staff.

8.2 Regulatory.

The major regulatory issue in the Baseline Study is the IRB approval process. The Oregon Node will seek approval for the treatment program surveys and the workforce survey. We anticipate that the program surveys will qualify for IRB exemption and that the workforce surveys may be considered minimal risk and require an information sheet rather than a formal informed consent process. While many nodes expect the Oregon IRB approval to be sufficient, some nodes plan to request IRB approval from their sponsoring institutions. The Oregon Node will collaborate in preparing the IRB applications and provide as much support as possible.

8.21 FDA Form 1572. Not applicable; the protocol is not a clinical intervention and does not use investigational drugs.

8.22 IRB Approval. The Oregon Node will submit the protocol package to the Kaiser-Permanente IRB for review and approval (because the CHR Coordinating Center has primary responsibility for data collection). The package will be shared with the Clinical Trials Network after IRB approval. The package will include information sheets in lieu of informed consents because we anticipate that a full informed consent will not be required. Individual nodes may also elect to request IRB review from the local RRTC board and CTP boards as necessary. Oregon node will work with each node to facilitate IRB review and approval. See Appendix D for a model IRB submission package.

8.23 Informed Consent. A project description is included in the sealed envelope distributed to each potential respondent. Study procedures will not require written consent beyond the participants' agreement to answer some or all of the questions on the questionnaire. There will also be an opportunity to record a refusal at that point of the survey. The introductory material includes all of the elements of an informed consent. See Appendix D for a copy of a draft IRB submission. If a local IRB requires a formal informed consent, a paper version of the study information sheet will be provided and a signature line will be added to record informed consent.

8.24 Adverse Events and Serious Adverse Events. This study is not a clinical intervention. Survey completion is not likely to lead to Adverse Events and Serious Adverse Events. Procedures are in place to protect confidentiality. Any adverse events that are observed will be reported to the sponsor and to appropriate IRBs.

8.25 Record Retention. All records (paper and electronic) will be stored at the Center for Health Research. Individual Nodes will not retain records. Records will be retained for at least five years.

8.26 Investigator Qualifications. Curriculum vitae and other statements of qualifications for participating investigators will be kept in the regulatory binder at Oregon Node.

9.0 Resources and Coordination with Investigator Initiated Research

Data from this protocol can facilitate a research agenda, for internal and external studies, on the factors leading to the successful adoption of the fruits of the CTN research into treatment programs. We may be able to identify key factors in the successful diffusion of innovation, within CTPs, both those who were specifically involved in the protocols and the other CTPs of the CTN. An estimate of the total cost of the project to the node, including cost to the CTPs and the RRTC, is provided in Table 3. The study is relatively inexpensive and we do not anticipate substantial differentials in costs in nodes with larger numbers versus smaller numbers of CTPs. A budget justification follows.

Table 3
Node Budget Estimate for Baseline Study

| Personnel or Expense | Base Pay | % Effort | Estimated cost |
|---|---|---------------------------|--|
| Personnel costs | | | |
| Node Baseline Coordinator (a research associate who handles day to day details) | \$4,000 per month | 3 months @ 20 per cent | \$2,400 |
| | | 4 months @ 50 per cent | \$8,000 |
| Science Collaborator (more senior investigator to oversee study implementation) | \$10,000 per month | 7 months @ 10 percent | \$7,000 |
| Fringe | | 30 percent of salary | \$5,220 |
| CTP costs (estimates assume the Org and Trt Unit Surveys require two hours to complete and the Workforce Survey is completed in 30 minutes) | Org Survey = 2 hr/CTP Trt Unit Survey (10 units/CTP) = 20 hr/CTP Workforce (25 staff/CTP) = 250 hours/CTP | | \$50/hr = \$ 100 \$40/hr = \$ 800 \$15/.5 hr = \$ 3,750 Total = \$4,650 per CTP 6 ctps per node = \$27,900 |
| Study supplies, incentives, telephone, etc | | | \$10,000 |
| Total Direct | | | \$60,520 |

9.1 Budget Justification

Background: During the review process, it became apparent that nodes use a variety of methods to reimburse CTPs for the time spent on CTN activities. Some nodes use direct time-reimbursement (CTPs are paid for time spent on specific CTN activities). At the other end of the scale are nodes who budget a percent of staff time for general CTN activities and provide additional reimbursement for time spent on protocol specific activities. There was also variation among CTP's about whether or not counselors or the agency should be reimbursed for time the staff spend completing the workforce questionnaire. These decisions must occur at the Node and CTP level. Oregon Node will record the decisions made in each node and CTP to assess impact on participation rates.

The preceding budget is an estimate of what direct-time reimbursement could be. It also includes possible costs for a senior investigator to oversee the project, if a node wanted such coordination, and potential costs to pay the workforce for the approximately 30 minutes to complete the workforce questionnaire.

Node Baseline Coordinator: A research associate is responsible for the administrative and implementation details for the node – IRB materials, contacts with CTPs, follow-ups with non-respondents, etc. Annualized salaries will vary from node to node and we estimate a high of about \$48,000 per year. Actual salaries may be lower. Separate time estimates are provided because the organizational and treatment unit surveys should require less time and energy than the workforce survey. Organizational and treatment unit surveys should be completed in three months or less and require about 1 day per week of oversight and attention. The workforce surveys will require more time and effort. We estimate 4 months at about 50 percent time.

Science Collaborator: A senior investigator or CTP director to provide oversight for the node and to facilitate study implementation and data collection. The Science Collaborator may also serve as the node lead investigator for IRB purposes. Estimated as 10 percent time for 7 months.

Fringe. Estimated at 30 percent of salaries.

CTP Costs. These costs are the estimated costs for the time required to complete the survey. For purposes of the budget estimate, we assume two hours per survey for the organizational and treatment unit surveys and 30 minutes for the workforce survey.

- Each CTP Executive Director completes one Organizational Survey (two hours x \$50 per hour Ex Dir time = \$100).
- Each Treatment Unit Director completes one Treatment Unit Survey (two hours x \$40 per hour Trt Unit Dir time x 10 trt units per CTP = \$800).
- Each direct care worker completes one Workforce Survey (.5 hour x \$30 per hour direct care time x 25 workers per treatment unit x 10 treatment units = \$3,750)
- Cost per CTP is \$4,200 (50 + 400 + 3750)
- Cost per node assuming 6 CTPs per node is 25,200 (4200 x 6)

These are probably high estimates. If Nodes reimburse CTPs differently, it may be much less expensive.

Study Supplies, incentives, telephone, etc. Estimated costs of study participation – supplies, telephone and potentially incentives to the CTPs and their workforce.

This is meant to be a rough guide. Salaries and staffing patterns will vary from node to node. Some nodes may choose not to have both a science collaborator and a node baseline coordinator. We assume that most nodes will not add staff to oversee the distribution and collection of baseline data but will assign the task to someone already on staff. Thus, the staff costs represent funds already allocated and we are estimating the share of those expenses attributable to the baseline study. We believe that the organizational and treatment unit surveys will require three months or less to complete and about 1 day per week of attention from the node study coordinator. The workforce survey is likely to be more labor intensive and may take up to 50 percent time for four months. The Science Collaborator provides oversight and supervision as necessary. . The total direct cost is estimated at about \$60,000 per node.

9.2 Services Research RFA. An important resource for this initiative is NIDA RFA DA-01-003: Services Research on the National Drug Abuse Treatment Clinical Trials Network. Investigations funded under this mechanism can be synergistic with the Baseline Protocol and may provide the resources for qualitative site visits, cost-effectiveness analysis and continued data collection in Years 3, 4 and 5 of the CTN. The Lead Investigators have discussed the study with a number of individuals who prepared applications in response to the RFA. All expressed strong support for collaboration and an interest in minimizing burdens on participating treatment programs.

9.21 Data Sharing. To facilitate, the sharing of data from the Baseline Study with other CTN investigations and investigations funded through R01 mechanisms, study consent materials will identify the investigations and specify the data to be shared with each investigation. Respondents will have the option to opt out of sharing their data with subsequent investigations. The collaborating investigators will be required to only report aggregated data and not to identify data from specific programs.

9.3 Timeline. The time for each node to complete the three surveys is estimated to be five to six months from the submission of an IRB package. Table 4 outlines the study tasks and an estimated elapsed time.

Timeline for Baseline Protocol

| | Study Task | Elapsed Time |
|----|---|--------------------|
| | | |
| A | Identify Node Baseline Coordinator | Completed |
| B | Complete Baseline Protocol Training | To be scheduled |
| B | Prepare Node IRB Submission | 0 |
| C | Provide updated list of CTPs and CTP contacts to Oregon Node using OrNode web-site | Week 1 |
| D | Receive CTP instructions and user account information from OrNode | Week 3 |
| E. | Receive IRB approval | Week 4 (estimated) |
| F | Distribute materials to CTP Executive Directors | Week 4 |
| G | CTPs complete Organizational Survey | Week 5 – 7 |
| H | Node Baseline Coordinators follow-up with nonrespondents | Week 7 – 8 |
| I | OrNode extracts Treatment Unit and Contact Information from Organizational Survey and sends user account information to Node Baseline Coordinator | Week 6 – 8 |
| J | Node Baseline Coordinators distribute instructions and user account information to Treatment Unit Contacts | Week 7 – 9 |
| K | Collect Treatment Unit Surveys | Week 8 – 10 |
| G | Follow-up with nonrespondents | Week 10 – 12 |
| H | Extract Workforce names and create user accounts and / or user numbers and paper forms | Week 9 - 13 |
| I | Distribute workforce materials to Node Baseline Coordinator | Week 10 – 14 |
| J | Distribute materials to CTP workforce | Week 11 – 15 |
| K | Collect workforce data if paper forms are used | Week 12 – 16 |
| L | Ship forms to OrNode Coordinating center | Week 13 – 17 |
| M | Follow-up to assure high response rates | Week 14 - 20 |
| M | OrNode Coordinating Center transmits data to NIDA monthly | ongoing |

10.0 References

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