

**CONSUMER  
OPERATED  
SERVICES**

**Logistics Procedures Manual**

**Logistics Subcommittee**

Consumer Operated Services (COS) Multi-Site

Center for Mental Health Services

Table of Contents

	<u>Page #</u>
<b>Recruitment Materials and Procedures and Demand Characteristics.....</b>	<b>4</b>
<b>Data Collection Schedule .....</b>	<b>4</b>
<b>Data Collection Window.....</b>	<b>4</b>
<b>Spanish Version of Common Protocol.....</b>	<b>5</b>
<b>Confidentiality Certificate .....</b>	<b>5</b>
<b>Exclusion and Inclusion Criteria.....</b>	<b>5</b>
<b>Guardianship.....</b>	<b>5</b>
<b>Recording Diagnosis for the Data Repository .....</b>	<b>7</b>
<b>Screening for Exclusion and Inclusion Criteria.....</b>	<b>7</b>
<b>Randomization Procedures.....</b>	<b>6</b>
<b>Intention to Serve Analysis .....</b>	<b>6</b>
<b>Mode of Data Collection.....</b>	<b>8</b>
<b>Place of Data Collection.....</b>	<b>7</b>
<b>Tracking of Participants .....</b>	<b>9</b>
<b>Definitions for Tracking and Quarterly Reports.....</b>	<b>9</b>
<b>Common Induction and Sampling Procedures.....</b>	<b>9</b>
<b>Reviewing Informed Consents after Baseline .....</b>	<b>10</b>
<b>Position of Site Specific Measures in the Common Protocol .....</b>	<b>11</b>
<b>Interviewer Observation Rating at End of Each Interview.....</b>	<b>10</b>
<b>Pledge of Confidentiality .....</b>	<b>11</b>
<b>Study Blind Policies.....</b>	<b>11</b>
<b>Recruitment/Enrollment and COS Utilization .....</b>	<b>11</b>
<b>Implementation Problems .....</b>	<b>12</b>

**Adverse Events and Notification.....12**  
**Appendices**

## **Overview**

The purpose of this manual is to summarize the logistical and implementation concerns addressed by the Logistics Subcommittee. For a full discussion of the issues and concerns leading up to the final decisions made by the Steering Committee, please refer to the SC teleconference and face-to-face notes.

## **Recruitment Materials and Procedures and Demand Characteristics**

All recruitment materials and procedures (brochures, flyers, information provided in group or individual orientation sessions, common induction materials and IRB or consent materials) should be developed with caution so as not to alert potential participants to the hypotheses under study. Potential participants must be fully informed about the study, its risks and benefits and the intent of the data collection. But it is important not to alert them to the specific hypotheses under study in any written materials, group presentations, screening meetings, or subsequent contact. Doing so could create demand characteristics that subtly suggest to the participants that they answer the questions in the CP in a particular way. It is also very important that there not be an imbalance between the experimental condition (COS + TMHS) and the control condition (TMHS only) in terms of this information or these demand characteristics. For example, we would not want one group to be singled out and have high expectations for the gain communicated to them.

## **Data Collection Schedule**

The baseline version of the Common Protocol (CP) will be administered to all participants who sign an Informed Consent and agree to be in the study. The date of the baseline interview becomes the index date from which all subsequent interview appointments should be calculated. The target dates for data collection should not be altered if the intervention does not start in a timely way, as it may not in at least one site. The Follow-up version of the CP should be re-administered at 4 months, 8 and 12 months post the baseline date of administration. The 12 month follow-up is optional but highly recommended.

## **Data Collection Window**

A one-month window around data collection points for follow up is acceptable. Sites can conduct the follow-up interviews anywhere between one month before the collection period to one month after the collection period. For example, for the 4-month data collection point, sites can collect data from month 3 to month 5. If interviews take place after the one-month window, the site should still collect the data. Calculations can then be made from the date of the baseline to the date of any particular follow-up to determine what percentage is outside of the acceptable window.

Some respondents may be unavailable for interviews within the follow-up window time frame. For example, a person may have been unavailable in the 4-month follow-up window but then become available between 6-7 months (prior to the 8-month follow-up window opening). We want to get as much data as possible but we should make sure that there is at least 2 months between assessments. If an interview is conducted late in one assessment period and early in the next, 2 months may not have elapsed between assessments. The following procedures were decided upon.

Conduct the late interview up until the point that you have entered the next follow-up window. If that point has been reached, record the previous assessment as missed and conduct the assessment in the currently open window. For example if a person becomes available for the 4-month assessment at 6-1/2 months, go ahead and conduct the 4-month Follow-up Protocol. If a person becomes available for the 4-month assessment at 7 months (when the 8-month FUP window is also open), mark the 4-month FUP as missed and conduct the 8-Month FUP interview.

Note that the index date from which to calculate future assessments is always the baseline interview. If there are any instances that do not seem to conform to these procedures, bring them to the attention of the Logistics Subcommittee.

### **Spanish Version of Common Protocol**

Two sites may need for translation of the common protocol into Spanish: Connecticut and Florida. Any site having concerns about needing the Common Protocol in a language other than English should contact the Coordinating Center. Since we are presently unsure of the demand for the Common Protocol in a language other than English, the CC will not translate it at the present time until contacted by a site.

### **Confidentiality Certificate**

Every site should apply for a Confidentiality Certificate from SAMSHA. Appendix A contains information about the Confidentiality Certificate. The Certificate provides some protection for participants in research studies to help keep the information they provide confidential and prevent it from being summoned by a court of law if the research participant is involved in a criminal justice proceeding. Each site must apply for the Confidentiality Certificate when their local IRB's have signed off on the project and on the Informed Consent. *Please note that there is specific language that is required in an Informed Consent to obtain a Confidentiality Certificate.*

### **Exclusion and Inclusion Criteria**

#### **COS Involvement**

More than minimal involvement in the past 6 months in a COS similar to the ones under study (i.e., drop-in centers, education and advocacy programs and peer support programs) results in

exclusion from the study. “Minimal involvement” is defined as more than three visits/meetings at COSP like those under study. In order to qualify as a COS, the program has to meet the definition of COSP using the first three common ingredients structural criteria (see Appendix B).

### **TMHS Involvement**

In order to be included in the study, the GFA states a potential participant must be a recipient of traditional mental health services for at least one year. The individual does not need to be a recipient of services with the same TMHS provider, but must have been on a TMHS roster during that period. The traditional mental health services involvement must meet three core criteria: recency, longevity, and intensity.

- 1) **RECENCY OF INVOLVEMENT** (an individual coming into the study would have to have had received services within the past 4 months prior to the date of “application” to the study);
- 2) **LONGEVITY** (an individual coming into the study would have had to be involved with a TMHS provider for a full 12 months prior to the date of application to the study);
- 3) **FREQUENCY** (an individual coming into the study would have to have received services at least 4 times in the past year, for example, 4 visits with a case manager, 4 visits for medication checks, etc.).

### **TMHS Diagnosis**

Participants in this study must meet the diagnostic criteria in the GFA which states that the target population for this grant is individuals with a serious mental illness. Therefore, applicants to the study must have a DSM-IV Axis I or Axis II diagnosis that implies a serious mental illness. Co-occurring substance abuse disorders are acceptable for entrance as long as the person has a mental health diagnosis in addition to their substance abuse diagnosis. Severe mental illness is usually defined as meeting three criteria: diagnosis, duration, and disability. Certain DSM-IV diagnoses are usually associated with severe disability: schizophrenia, schizoaffective disorders, any diagnosis with psychotic features, major depression, and some personality disorders (Axis II diagnoses). In addition, duration is usually a factor in determining disability, with two years being the commonly accepted cutoff. Finally, functional impairment (disability) as a result of the diagnosis is needed. Criteria two and three (duration and disability) are difficult to ascertain when simply screening for entry. Therefore, we must rely primarily on diagnosis for inclusion.

Sites may impose additional inclusion and exclusion criteria as long as they do not conflict with these basic criteria.

In their recruitment, sites should target the programs and people within the TMH system that serve people with major mental illness. Baseline data on diagnosis and functional impairment (e.g., employment status) should be examined by individual sites and by the multi-site study after 3 months of data collection, and periodically thereafter to insure that we are reaching our intended population for the study in conformance with the GFA.

## **Guardianship**

We recognize that the ability to give informed consent and to successfully participate in this project is not necessarily limited by guardianship status (that is, some individuals without guardians may not be able to give full and knowing consent while some individuals with guardians may). Unless an individual site's IRB has required that they exclude individuals with guardian's, every attempt should be made to include those individuals in their recruitment process. At the time of this draft manual, two sites planned to exclude individuals with guardians (FL possibly, and ME) but they will revisit their procedures. The TN tracking database will allow us to track the number of individuals with guardians who apply for the study.

## **Recording Diagnosis for the Data Repository**

The collection of an individual's mental health diagnosis will not be made during the face-to-face interviews with the participants in the study. Each study site must make arrangements to collect diagnosis from the TMH provider. Each site should use the data entry structure created by the Data Repository committee to enter diagnostic information. This will allow merging of the diagnostic information with the data from the CP. Every attempt should be made to obtain the most complete and up-to-date diagnosis possible. All Axis I and Axis II diagnoses should be recorded. Three fields for Axis I and three fields for recording Axis II diagnoses using the numbering nomenclature found in the DSM-IV (e.g., 395.80) will be available.

## **Screening for Exclusion and Inclusion Criteria**

Appendix C contains a copy of a Screening Questionnaire that can be used by sites to insure that they are screening in and screening out people who might not be eligible for the study based on the criteria in the GFA. Use of this Screening Questionnaire is not mandatory, however, each site must have a way of tracking the screening criteria on the last page of the Questionnaire for reporting to the CC. All sites should send a copy of their final, complete inclusion/exclusion criteria to the CC.

## **Randomization Procedures**

Randomization to the experimental (COS + TMHS) and control (TMHS only) will occur after the baseline CP is administered.

A multi-site randomization process was not agreed upon: sites will block on gender and will generate their own randomization schedules based on gender. Sites are free to add blocking variables to the randomization process as long as they document their randomization procedures for the CC. Sites should guard against any attempts to influence the random assignment of participants by having the PI closely monitor the process, by taking the random assignment out of the hands of the interviewers, and by developing procedures that are "game-proof".

Appendix D contains a summary of the randomization procedures across sites and an example of a randomization schedule that can be generated by Proc Plan using SAS software. Any site

needing technical assistance to carry out their randomization procedures should contact ROW Sciences. Any site needing a randomization schedule can contact Sally Rogers at Boston University.

### **Intention-to-Serve Analysis**

The overall study approach agreed upon was an “intention-to-serve” (a.k.a., Intention to Treat) design where all individuals enrolled in the study will be tracked regardless of the amount of each condition they receive. This approach has power implications. (That is, the more individuals who are randomized to the COS condition that don’t participate in it, the less likely we will see a difference between the COS + TMHS and the TMHS group alone.)

Therefore, it is important that each site emphasize strategies to maximize the retention of study participants in the respective conditions. Secondly, whatever each site can do within ethical constraints to keep crossover to a minimum will help preserve the power of the study. If individuals refuse to participate in a scheduled follow-up interview, the interviewer must assess whether the individual simply does not want to participate on that day, or is refusing participation for the duration of the study. The interviewer should make several attempts (being sensitive to the individual’s wishes and rights as a research participant) to complete a follow-up interview, unless the individual emphatically refuses.

“Administrative withdrawals” are individuals who cannot participate in the study condition to which they are assigned (e.g., they are arrested shortly after random assignment and would not be able to receive either COS or the TMH service). For these individuals we can do early replacement of them in the study, meaning we can treat them as though they were never in the study and randomly assign someone else to take their place. We cannot do any other kind of replacement of participants since we are using an “intention to serve” approach. Some sites may over-sample to insure they have sufficient power, but they will still track every person entered into the study.

If individuals want to re-enter the study after an administrative withdrawal they will not be allowed to. If an individual withdraws from the service component, they will still be a research participant. If a participant wants to withdraw from the research *and* the services, he or she can do that and request that their data be destroyed. In that case, locally held data should be destroyed and Matthew Hile should be instructed to delete data from the repository.

Any withdrawal or re-entry scenario that does not fit the above description should be posted to the Logistics Subcommittee listserv for comment and final decision making so that we can keep a log and a protocol for these unusual situations.

### **Mode of Data Collection**

All interviews be conducted in a face-to-face mode rather than self-administered because of concerns about literacy. The paper-and-pencil CP instruments provided by the CC can be used, or computer-assisted interviewing (CAI) can be performed. Tom Summerfelt, PI of the TN site

has the Access program for the computer-assisted interviewing. Using computer-assisted interviewing conserves resources for data entry, but special steps need to be taken to preserve and back up the data and to verify the data entry. Data entry verification will not be necessary with CAI. Contact Matthew Hile at the CC at MIMH for the data verification protocol for regular data entry.

### **Place of Data Collection**

The baseline interview with the Common Protocol should not be held at the consumer operated program for any participants. Because randomization occurs after baseline, we do not want individuals who will be randomly assigned to the control condition to be “exposed” to the experimental condition, nor do we want any particular demand characteristics of the setting to influence the baseline data collection. The Follow-up protocols can be conducted at the COS for the E participants only.

### **Tracking of Participants**

The tracking of study applicants needs to occur to provide the information that will be requested by the CC each quarter. Tom Summerfelt, PI of the TN site has developed an Access database and screen program that will track these data elements and generate the reports needed to CMHS. This tracking software can also be used as a tickler system to help plan and manage the interviews. Managing the interviews and interviewer resources is critical for having complete datasets.

Each site is strongly encouraged to use the Tennessee tracking software. Sites that adapt the TN software or develop their own should insure that they can generate reports that provide the information required in the quarterly report and/or any other tracking needs that the CC may have. Rise Goldstein at ROW is the contact person for questions pertaining to tracking.

We will not track any demographic items on potential participants because they will not have given their permission at that point. It was generally agreed that people who refuse to participate in the study not be asked “why” they refuse. They might be asked if they are willing to share why they refused, and then if the information is volunteered, it can be used to help improve future recruitment. Sites can keep track of that information if they choose, but it is not mandatory.

### **Definitions for Tracking and Quarterly Reports**

- 1. Date of first attendance at COSP.** *Defined as the first time an individual comes to the COS drop-in center, class, meeting, or group, as documented in attendance records of the COS.*

This field will be added to the Cost data collection worksheet and recorded there, or transferred there in the case of sites collecting it from other sources.

- 2. Date of last attendance at COSP.** *Defined as the last time that an individual attends the COS drop-in center, class, meeting, or group, as documented in attendance records of the COS.*

This field will be added to the Cost data collection worksheets and recorded there, or transferred there in the case of sites collecting it from other sources.

We recognize that this field will not be accurate until the end of the data collection period for any one participant. Therefore sites may wish to monitor this field quarterly, but it will only be required after the end of a participant's 12-month assessment point.

- 3. Withdrawal from COSP:** No definition attempted. We decided that this would be inferred from Date of First and Last Attendance because "Withdrawal from COSP" is not consonant with how certain programs are run. Sites may want to add this on a site-specific basis.

**4a. Four-month Follow-up Missed:** *Defined as any one with whom a FUP cannot be completed for the 4-month assessment.*

**4b. Eight-month Follow-up Missed:** *Defined as any one with whom a FUP cannot be completed for the 8-month assessment.*

**4c. Twelve-month Follow-up Missed:** *Defined as any one with whom a FUP cannot be completed for the 12-month assessment.*

Recommendation: That we track reasons for being lost to follow-up at *each* FUP. The following checklist was suggested

- Death
- Moved out of geographic area
- Hospitalized and unable to interview
- Physical or mental health problems prevent participating
- Incarcerated and unable to interview
- Unable to locate
- Refused (use just when participant refuses this assessment, and not when he/she withdraws from study)
- Other

Refusing to participate in the study permanently would be recorded under "Withdrawal from Study"

**5. Crossover to E:** *Defined as anyone randomized to C who goes to the E COS program.*

**6. Withdrawal from research aspect of study:** Participant informs research team that they no longer wish to participate in the assessments.

## **Common Induction and Sampling Procedures**

The sampling procedure we agreed upon was a modified II sampling proposal (given the three sampling procedures discussed at the August, 1999 face to face meeting). That is, we will sample/recruit consumers who are receiving services at a TMH provider who express sufficient interest in motivation for project and who go through a common induction procedure.

The common induction process will fully inform prospective study participants about randomization and what is expected of them. We agreed that all sites would have a common induction process as voted on in the 11/23/99 and 11/29/99 SC calls. The essential elements of a common induction process are the following: a) that potential participants be informed that this study involves 8 sites and is funded by the CMHS, b) that they have a 50-50 chance of being randomized into each of the two conditions; c) that these conditions be described briefly and neutrally; d) that language discouraging crossover be included in the common induction in a positive way (e.g., "If you are randomized to the TMHS condition, the COS will not be available to you for a period of one year"). This language will need to be tailored to fit site-specific situations. Whether this language appears in the Informed Consent or in a separate stand-alone document will be determined by each site. Sites may overlay their own induction process upon this common induction process.

As a method of record keeping, all sites should submit a final version of their induction procedures and materials (e.g., handouts, fliers, etc) to the CC. This will allow for follow-up/fidelity checks, and will facilitate future summaries for articles regarding methods.

## **Reviewing Informed Consents after Baseline**

Some sites are required by their local IRB to review the original informed Consent document, or an abbreviated one at each data collection point. Other sites are not required to do so. Whether the Informed Consent is reviewed at each assessment point will be left to the discretion of each individual site and the requirements of their local IRB's (at present, Missouri, Connecticut, Tennessee, and Pennsylvania will not review the Informed Consent after the initial signing; Maine and Illinois must review annually and Florida will orally review consent at each follow-up). Sites may wish to bring the original signed informed consent to the follow-up interviews in case the participant wishes to review it.

## **Position of Site Specific Measures in the Common Protocol**

Sites may add site specific measures to the Common Protocol with the following guidelines: a small number of site-specific items may be added at the end of any one section. The maximum number of site-specific questions to added by any one site can be 20. If an entire scale is to be added by a particular site, it must be added at the end of the Common Protocol.

## **Interviewer Observation Rating at End of Each Interview**

At the end of each baseline and follow-up interview, the person conducting the assessment will complete a brief questionnaire designed to record any difficulties with the validity or the reliability of the participant's answers to the questions in the Common Protocol. The comments/notes taken by the interviewer throughout the CP interview should be perused prior to completing the observation scale. See Appendix E for a copy of that interview. Any interview judged unreliable should be reviewed by the interviewer's supervisor.

Note that this rating was voted as optional by site during the SC call on 5/19/2000.

## **Pledge of Confidentiality**

Sites should instruct every interviewer about the importance of maintaining information obtained during the interview in the strictest confidence. Interviewers should be verbally instructed about the importance of confidentiality and should also sign a pledge of confidentiality. Appendix F contains a sample pledge (from Tennessee).

## **Study Blind Policies**

1. No one will be permitted to publish or publicly present multi-site outcome data or site outcome data or to discuss such data with anyone outside of their site or outside the CC until the multi-site data collection is complete at all sites. Comparisons across sites (that is, comparing data from one site to another), comparisons of the experimental to the control conditions, or examination of any multisite outcome data by anyone outside the CC will not be permitted until the study is concluded.
2. After a site's baseline data are complete, a site may publish/present from these data.
3. Sites will not have direct access to the complete multi-site database until one year following completion of all multi-site data collection and cleaning, and after the core papers have been written. Multi-site baseline data will be made available to sites by the CC when data collection of that data is closed (that is, when no new entrants to the study will occur) and the data have been cleaned. Analysis of baseline data can proceed under the guidelines put forth in item number 4.
3. Presentations of preliminary findings of multisite baseline aggregate data (that is, with E and C combined) is permitted with the approval of the Publications Workgroup. It is permissible for the site variable to be included in the baseline multisite database only before the study blind is removed and for publication workgroups to examine site differences. These analyses are only for the purpose of examining and understanding site differences at baseline and not to examine differences in site outcomes.

4. Examinations of data over time, in the aggregate, may be permitted as long as, in the opinion of the Coordinating Center, the basic integrity of the E vs. C comparisons is not compromised and no comparisons are revealed by site. Decisions about presentation of preliminary findings are made by the Publications Workgroup.
5. Any analysis of multi-site data by an individual site must be turned over to the Coordinating Center for verification and storage to maintain the consistency of the data (for example, so that similar re-coding, collapsing, and subscales are used). Once the funding of the Coordinating Center ceases, this submission will no longer be required.
6. Research staff should be cautioned that preliminary examinations of the data could be misleading and could result in demoralization among staff at a site or changes in the way that services are delivered. Although the Study Blind policies cannot prohibit the PI or research staff at a site from examining and interpreting their own data, such interpretations should be made cautiously and circumspectly.

### **Recruitment/Engagement/COS Utilization**

The Logistics Sub-committee has promoted discussions of strategies for recruiting and enrolling individuals in the study, as well as promoting utilization of the COS after randomization. We have compiled a document of those on-going efforts (See Appendix G).

We have also attempted to address what we mean by “engagement” in the COS. Because engagement implies that some kind of relationship has been developed between the person and the COS, we have decided to use the term “rate of COS utilization” to refer to a participant’s use of COS services, or attendance at the COS. The Logistics Committee notes of 2/15/01 describe these discussions more clearly.

Information on COS utilization will come from the Cost study attendance data. *All sites other than PA define a “COS visit” as the consumer’s one-time physical presence at the COSP site or a COSP activity.* PA presently includes phone contacts in their tally of visits so their data are not presently comparable to the other sites. We did agree, however, that telephone contact could be significant and could be considered having received the COS service. COS attendance data will be reported on the quarterly reports to Coordinating Center.

### **Implementation Problems**

There has been some confusion about the section of the Follow-up Protocol that is designed to measure satisfaction with the COS under study. The instructions in the protocol itself are misleading and don’t specify that the satisfaction should be rated with the COS under study in mind. The Q X Q does spell this out, but interviewers have been under the impression that they should not use the Q X Q unless the interviewee is confused or needing clarification. Therefore, the data from this instrument to date will be muddled for at least several sites. Henceforth (January, 2001), interviewers have been instructed to specify that these questions are for rating the COS under study. Reviewing this problem site-by-site we found the following sites will not

have a problem: FL and CA, ME. The remaining sites feel that there was some confusion on the part of the interviewers and/or there are other COS in the area that the interviewee could be rating.

### **Adverse Events and Notification**

IRBs require that they be notified in the event of an injury due to participating in a study, or new or unanticipated risks of participating in the study that become known to the researcher. Many IRBs do not require that they be notified about death from natural causes, however, IRBs differ in the way that they interpret rules related to adverse events. Since the IRB policies are not uniformly applied within this multi-site study, it is best to notify the Coordinating Center and your own IRB whenever a participant death is discovered, even if it is not related to the conduct of the study. Also, you can check with your IRB coordinator about the particular reporting requirements followed by your University or organization.

Appendix A  
Confidentiality Certificate material

## **SAMHSA CONFIDENTIALITY CERTIFICATE (CC) INFORMATION** (updated 2/2/00)

APPLICATION INSTRUCTIONS (for General Information, please see page 3):

The principal investigator (PI) of the research project (e.g., of the evaluation segment of a demonstration) applies for a Confidentiality Certificate. We suggest that the PI apply for his/her CC after the project is entirely planned and the final consent form is written. She/he would have to apply again if the consent form or anything else substantial changed, since by signing the application, he/she is legally affirming that description of the study. That is, the consent form and protocol in the actual study have to be as presented in the application. Please let Dorita Sewell know by a call or e-mail if you need your certificate very quickly--that is, if you're about to recruit participants in the next week or two--and please don't hesitate to call with questions or status checks. Applications are filed by PI name, so please identify your application by PI name in any communications about your application.

An example of an application is attached to these instructions. An example of consent-form text related to the Confidentiality Certificate is in these instructions. We try to comply with the regulations perfectly in case your Certificate faces a legal challenge.

A CC application is a letter from the principal investigator to SAMHSA (to Dorita Sewell, Ph.D., SAMHSA OPPC, 12C-26, 5600 Fishers Lane, Rockville, MD 20857 301-443-7023; FAX 301-594-6159. E-mail [dsewell@samhsa.gov](mailto:dsewell@samhsa.gov)). The LETTER MUST PROVIDE the following (as required in the regulations--it may save time to respond very literally and exactly):

- a) Name & address of person primarily responsible for the conduct of the research [the principal investigator], and of the sponsor or institution with which that person is affiliated (Please have the PI's name on the front page with the address.)

Name and contract or grant ID number of the project

Documentation of institutional approval in the form of a copy of notice of a valid Institutional Review Board's (IRB's) approval (IRB with SPA or MPA) if IRB approval is required for the project, or other documentation of institutional approval if IRB approval is not required

- b) Location of the research project and description of the facilities available for conducting the research, including the name and address of any hospital, institution, or other facility to be used in connection with the research

- c) Names, addresses, and summaries of the scientific or other appropriate training and experience--of all personnel having major responsibilities in the research project, and the training and experience requirements for major positions not yet filled. (The PI's resume or summary bio is the least we can get away with.)

d) An outline or summary of the research protocol, including a concise statement of the rationale and purpose of the research project and the general research methods to be used (Ideally, these should include summaries of criteria and procedures for subject selection, study variables, procedures for data collection and analysis, any treatment/intervention provided, and informed consent procedure. Subject selection and informed consent procedures are especially important.)

e) Start date and estimated end date (CC will expire then) for the project

f) Specific request (e.g., "I request authority to withhold..."), signed by the individual primarily responsible for the conduct of the research, for authority to withhold the names and other identifying characteristics of program participants, and the reasons supporting that request

g) through k) are assurances that each application must provide. The application might say: "As principal investigator, I assure you of the following:

g) that my colleagues and I will comply with all the requirements of 45 CFR 46, "Protection of Human Subjects" [IRB regs]

h) that the CC will not be presented as endorsement of the research by the Secretary, DHHS, or used to coerce or pressure subjects to participate

i) that the Certificate will be used by all those covered by it, to refuse to disclose identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects

j) that all research participants under the CC will be informed that:

1) A CC has been issued

2) The persons authorized by the Certificate to protect the identity of research subjects may not be compelled to identify research subjects in any civil, criminal, administrative, legislative, or other proceedings, whether State, Federal, or local  
LIMITATIONS

3) Under any of the following conditions, the CC does NOT authorize any person to refuse to reveal identifying information concerning research subjects:

i. If the subject (or guardian) consents in writing to disclosure of identifying information

ii. If release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or regs thereunder (21 CFR)

iii. If authorized DHHS personnel request identifying information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors

4) The Certificate does not prevent voluntary disclosure of identifying information

5) The Certificate does not represent an endorsement of the research by the Secretary, DHHS

k) that all research subjects entering the study after termination of the Certificate will be told the protections do not apply to them

We ask for all these assurances. Only those that are relevant to your project, however, have to be reflected in your consent forms or other information you give to project participants.

The application letter must be complete and provide all of the information requested.

The following documents should be attached to the letter:

1. A copy of the original grant application or research protocol (not necessary if the project is described well in the application)
2. Documentation of IRB review and approval of procedures for the protection of human subjects if IRB approval is required. The IRB must have an SPA or MPA from the Office for Protection from Research Risks.
3. Sample consent forms

## GENERAL INFORMATION ABOUT CONFIDENTIALITY CERTIFICATES

The Substance Abuse and Mental Health Services Administration (SAMHSA) has responsibility for issuing Confidentiality Certificates for projects it sponsors. This document is intended to help project directors develop their requests for Confidentiality Certificates. It is based on the Federal regulations for implementing the authorizing legislation regarding Confidentiality Certificates: 42 CFR 2a.

Confidentiality Certificates (CCs) are issued under the authority vested in the Secretary, DHHS, by section 301(d) of the Public Health Service Act, 42 U.S.C. §241(d), as amended. A CC authorizes "persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not directly connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals." In other words, a CC protects researchers from having to comply with things like subpoenas and court orders. SAMHSA works to protect participants in its projects and SAMHSA's issuance of Confidentiality Certificates incorporates this aim. CC's were tested successfully in a Supreme Court case soon after they were enacted.

If an IRB grants approval contingent only on the project's having a CC, then SAMHSA can proceed as if the project had IRB approval. A CC applies to research, and does not cover services or services components. CCs do not apply to research requiring an Investigational New Drug exemption or to research related to law enforcement activities within the purview of 502(c) of Controlled Substances Act and 21 CFR 1316.21. A CC applies to one project; separate application is required for each project.

## CONSENT FORMS

A consent form that leads to genuine and realistic informed consent is a key element of adequate participant protection. A consent form should truly inform readers, in language they understand. In some cases, consent forms should be read out loud. If there will be questions about drug use, mental health or substance abuse treatment, sexual activity, or any other sensitive issue, this should be explicit in the consent form. If risks are discussed, the risk of confidentiality breach must be mentioned for participants to consider. Many consent forms follow this statement of confidentiality risk with information about how confidentiality is being protected, to reassure prospective participants.

Consent forms should not, however, over-promise the degree of protection or be vague or misleading. For example, stating that “participant information will be kept in strictest confidence” is vague and false since DHHS can audit and you may be reporting child abuse. “Only researchers will have access to your data” is similarly false. SAMHSA has had to turn down many consent forms with statements like these.

Better than such general (and false) statements is to tell people about the specific steps that have been taken to protect participants’ confidentiality, such as training staff to keep information private, keeping the code file locked or encrypted, and getting a CC. Thanks to a policy change, SAMHSA now allows statements on the order of, “Information you give us will be kept private to the extent permitted by law,” but SAMHSA still does not pass consent forms with false statements.

SAMHSA CC projects’ consent forms (or other pre-consent information forms) must have 1) CC information required by the regulations and mentioned in the assurances, and 2) information related to requirements that are based on department and agency requirements. HHS and SAMHSA require researchers to report communicable diseases (if they are testing for them; most SAMHSA projects do not do this), and SAMHSA requires reporting of child abuse as legally required by States. We also ask researchers to take appropriate steps, including reporting confidential information, if they discover that there is danger that someone will harm him/herself or others. Researchers must notify participants (usually in consent forms) in advance about any reporting they will do. Another way to put this is, DHHS CCs do not protect information about communicable diseases in projects that routinely seek this information in States that require reporting, and SAMHSA CCs do not protect information about evidence of child abuse or imminent harm to self or others where States require reporting. If imminent harm or child abuse might be discovered in the research setting, researchers should establish a reporting policy that conforms with State law, to deal with this. Participants must be told in advance (in consent forms or information sheets) that this information may or will be reported, if that is the case.

The laws about reporting child abuse and other information differ from State to State. For example, it may be illegal for some researchers to volunteer information about child

abuse, or it may be illegal for some researchers not to report child abuse in your State. Please make sure your child-abuse and other statements are consistent with applicable laws.

Consent forms may leave out what is not germane. For example, if a project does not fall within the purview of the FDC Act, then SAMHSA does not require consent forms to include information about the CC limitation regarding the FDC Act, even though you will have signed all the assurances, including the one about including it.

Consent forms differ, but the following is an example of consent-form language about CCs that was approved as suitable for some projects:

To help keep information about you confidential, we have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). This Certificate does not imply that the Secretary, DHHS, approves or disapproves of the project. The Confidentiality Certificate will protect the investigators from being forced, even under a court order or subpoena, to release any research data in which you are identified. This protection is not absolute, however. For example, it does not apply to disclosure of medical information in cases of medical necessity, reporting if you are likely to harm yourself or others, or reporting child abuse under State law. Also, because this research is sponsored by SAMHSA, staff from that and other DHHS agencies may review records that identify you.

More information about adequate informed consent forms and other aspects of participant protection can be found in the regs published by the Office for Protection from Research Risks (OPRR) (301-496-8101) under the title "Protection of Human Subjects."

#### AMENDMENTS/EXTENSIONS OF SAMHSA CCs

CC protection is permanent for information on participants in a covered study while the CC is in effect. CC protections do not extend to a research project that changes significantly from its description in the original CC application, or to participants who join a project after its CC has expired. An amended application or application for extension must be made and approved if protection under the CC is to continue in force.

To extend a CC, the principal investigator on the original CC sends a signed request for an extension, with the new expiration date, the justification for the extension, a copy of the current IRB approval, and a statement that the project has not changed in any significant way since the original CC was issued. That is, the primary staff, consent form, scope and direction, instruments, and other significant features must be the same as when the certificate was issued. A copy of the original CC should accompany the request. If there have been changes, a full new application must be submitted.

## **An Example of a SAMHSA Confidentiality Certificate (CC) Application:**

Dorita Sewell, Ph.D.  
SAMHSA OPPC  
12C-26, 5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Sewell,

I am writing to request a confidentiality certificate for the project described below.

a) Principal investigator's name and address:

John Doe, Ph.D., Director of Studies, Services Research Institute, Suite 400, 3300 Dupont Avenue, Fremont, MD 20999.

I can be reached at 301-123-4567 (voice), 301-123-8910 (fax), jdoe@SRI.org.

My study is CSAT grant no. TI01234, "Evaluation of Project HEALTH."  
Our project officer at SAMHSA is Ken Ncadi.

b) Location and description of study sites:

The study sites are residential substance abuse treatment facilities in three Oklahoma counties. Treatment will be provided and all interviews will be conducted at these sites. Data analysis is housed at University Research Institute. The project sites are as follows: [Please give names and addresses of any hospital, institution, or other facility to be used in connection with the research. Your cooperating agencies also are covered by your CC, and it's probably good to identify them in the application. If their nature isn't obvious, please also give a brief description.]

c) Information about investigator(s):

[Resumes or brief summaries, including names and addresses, of the scientific or other appropriate training and experience--of all personnel having major responsibilities in the research project, and the training and experience requirements for major positions not yet filled. At least the PI's resume or summary should be attached or included.]

d) An outline or summary of the research protocol:

[This should be a half-page or shorter clear, concise statement of the purpose of the research project and the general research methods to be used. Generally, this should include criteria and procedures for subject selection, study variables, procedures for data collection and analysis, any treatment/intervention provided, and informed consent procedure. Subject selection and informed consent procedures are especially important.

In addition, please include a paragraph summarizing the purpose of the research and the other key characteristics in one or two paragraphs, such as the following:]

The purpose of the study is to evaluate the effectiveness of ... and .... by comparing their outcomes over a period of .... years. Using a quasi-experimental research design, the researchers will conduct baseline and three follow-up interviews, at 3, 6, and 12 months after discharge. We will also use information from .... The following outcome categories will be studied: ....A total of 200 adult clients and 300 of their children are expected to participate. Some of the data will be used in a wider cross-site study.

e) Start date and estimated end date (CC will expire at end date) for the project:

The project began 10/1/97 and will end 9/30/2000. We expect to begin recruiting participants by 12/1/97, pending receipt of the CC and final IRB approval. [Knowing when your CC must be done helps me plan the work on it. Please note also that CC coverage isn't retroactive, but starts only when your CC starts. If you recruit before the date of your CC, information you get before the CC date won't be protected by your CC.]

f) Signed specific request with reasons:

I request authority to withhold the names and other identifying characteristics of the participants in my study, "Evaluation of Project HEALTH." My reasons for this request are [reasons you want authority to protect your participants should very briefly be summarized here. This should include how the Certificate will benefit participants in your project.]

\_\_\_\_\_[signature]\_\_\_\_\_  
John Doe, Ph.D.

g) - k) Assurances:

I assure you of the following:

g) that my colleagues and I will comply with all the requirements of 45 CFR 46, "Protection of Human Subjects";

h) that the CC will not be presented as endorsement of the research by the Secretary, DHHS, or used to coerce or pressure subjects to participate;

i) that the Certificate will be used by all those covered by it, to refuse to disclose identifying characteristics of research subjects in any Federal, State, or local civil,

criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects;

- j) that all research participants under the CC will be informed that:
- 1) A CC has been issued
  - 2) The persons authorized by the Certificate to protect the identity of research subjects may not be compelled to identify research subjects in any civil, criminal, administrative, legislative, or other proceedings, whether State, Federal, or local
- LIMITATIONS
- 3) Under any of the following conditions, the CC does NOT authorize any person to refuse to reveal identifying information concerning research subjects:
    - i. If the subject (or guardian) consents in writing to disclosure of identifying information
    - ii. If release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or regs thereunder (21 CFR)
    - iii. If authorized DHHS personnel request identifying information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors
  - 4) The Certificate does not prevent voluntary disclosure of identifying information
  - 5) The Certificate does not represent an endorsement of the research by the Secretary, DHHS;
- k) that all research subjects entering the study after termination of the Certificate will be told the protections do not apply to them.

[We ask for all these assurances. Only those that are relevant to your project, however, must be reflected in the content of consent forms or other information given to project participants.]

I include copies of the notice of final approval from all IRBs that must approve our project and of every consent form that will be used in the project.

Sincerely yours,

John Doe, Ph.D.  
Principal Investigator

Enclosures

Appendix B  
Common Ingredients  
Criteria for qualifying as a COS

INGREDIENT	DEFINITION	EXTRACTED ISSUES
<b>Structure</b>		
Consumer operated	<p>Consumers constitute the majority (at least 51%) on the board or group which decides all policies and procedures.</p> <p>With limited exceptions, staff consists of consumers who are hired by and operate the COSP.</p> <p>Consumers have control of the operating budget.</p> <p>Role opportunities for participants may include board and leadership positions, volunteer jobs and paid staff positions.</p>	<p>Board of Directors or decision-making group</p> <p>Staff composition</p> <p>Budget control</p> <p>Leadership roles for participants</p>

Appendix C  
Draft Screening Questionnaire

## **SCREENING QUESTIONNAIRE**

**Person completing form:** \_\_\_\_\_

**Applicant Name:** \_\_\_\_\_

\_\_\_/\_\_\_/\_\_\_ **Date Form Completed**

**INSTRUCTIONS TO PERSON COMPLETING FORM:** This form is designed to be completed using information from the applicant directly, using information from available records, your general knowledge about the applicant's circumstances, or any combination of these sources. By "applicant" we mean an individual who has expressed interest in participating in the COSP study. The purpose of this form is to determine if the individual meets the requirements for coming into the study. If there are any questions about the applicant's eligibility, please contact:

\_\_\_\_\_.

1. *Is the applicant over the age of 18?*                    \_\_\_Yes            \_\_\_No

2. *Is the applicant already a participant of the study, or has he/she applied to the study in the past?*

\_\_\_Yes            \_\_\_No

If yes, please explain: \_\_\_\_\_

3. *Is there a compelling reason to believe that the applicant cannot give informed consent?*

\_\_\_Yes            \_\_\_No

4. *Is there a compelling reason to believe that the applicant cannot give reliable or valid responses to questions on the CP?*

\_\_\_Yes            \_\_\_No

5. *Does this person have a guardian?*                    \_\_\_Yes            \_\_\_No

If Yes, be sure to include guardian (as needed by local laws and regulations) in the informed consent process.

6. *Does this person's current diagnosis meet the inclusion criteria for the study (i.e., the applicant has a diagnosis of major mental illness)?*

\_\_\_Yes            \_\_\_No

If Yes, what is the applicant's diagnosis: \_\_\_\_\_

7. *Does the applicant meet the TMHS inclusion criteria:*

7a. Does he/she currently receive mental health services such as case management, residential services, or help with medications?

\_\_\_Yes            \_\_\_No

7b. Write in the applicant's mental health provider (or providers if there is more than one provider)? \_\_\_\_\_

7c. How many times in the past year (one year from today) has the applicant received services from this mental health provider(s) (that is, how many times have they had a visit with a case manager, or any mental health provider. If applicant lives in a residential program that is run by a mental health provider, check that option)?

- 1) \_\_\_ Not at all
- 2) \_\_\_ 1-3 times
- 3) \_\_\_ 4 times or more
- 4) \_\_\_ Applicant lives in a residential program that is run by a mental health provider
- 5) \_\_\_ Information not available or applicant does not know

7d. Estimate how long ago applicant's last contact was with someone from the mental health provider/program?

- 1) \_\_\_ No contact
- 2) \_\_\_ more than 4 months from today
- 3) \_\_\_ less than 4 months ago
- 4) \_\_\_ Applicant lives in a residential program run by a mental health provider or goes to day treatment and has contact almost every day
- 5) \_\_\_ Information not available or applicant does not know

7e. How long has applicant been involved with this program (or any other mental health provider)?

- 1) \_\_\_ Never involved
- 2) \_\_\_ for the past 1-6 months from today
- 3) \_\_\_ for the past 6-11 months from today
- 4) \_\_\_ for more than the past year
- 5) \_\_\_ Information not available or applicant does not know

8. *Does the applicant meet the COSP inclusion criteria?*

8a. Has the applicant participated in a COSP program (that is a peer support program, a drop in center, or an education and advocacy program that is run by consumers and meets other CI structural criteria) in the past 6 months?

\_\_\_ Yes      \_\_\_ No

If Yes, please record the name of the program(s): \_\_\_\_\_

8b. If yes, how many times in the past 6 months has the applicant participated in/visited this program?

- 1) \_\_\_ Not at all
- 2) \_\_\_ 1-3 times
- 3) \_\_\_ 4 times or more
- 4) \_\_\_ Information not available or applicant does not know

**Summary of Inclusion/Exclusion Criteria:**

1. Applicant is at least 18 years of age?  Yes  No
2. Individual is currently enrolled in the study/or has been in study  Yes  No
3. Is there a compelling reason to believe that the individual cannot give informed consent?  Yes  No
4. Is there a compelling reason to believe that the individual cannot participate in the research interviews?  Yes  No
5. Does this individual have a guardian?  Yes  No
6. Individual has a diagnosis of major mental illness?  Yes  No
7. Individual meets THMS criteria for inclusion?  Yes  No  
*(Individual has been involved with a Traditional Mental Health service provider in the past 12 months and demonstrates recency, longevity and intensity of involvement-that is has had at least 4 services in the past 12 months with any traditional mental health provider; the most recent contact had to be 4 months ago or less)*
8. Individual meets COSP criteria for exclusion?  Yes  No  
*(Individual has had more than minimal involvement in a COSP program, that is, he or she has had more than 3 visits/meetings in the past 6 months)*

A Yes to Questions 1, 6, and 7 and a No to Questions 2, 3, 4, and 8 are necessary for the applicant to be enrolled in the study.

*(For Question 5, either a Yes or a No answer is acceptable for study entry. If the person has a guardian, however, specific steps should be taken for Informed Consent.)*

Was the individual enrolled in the study?  Yes  No

Screening Form Reviewed by Research Staff Person: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Appendix D  
Randomization Descriptions by Site

COSP Randomization Procedures

<i>Issue</i>	<i>SITE</i>							
	<b>CA</b>	<b>IL</b>	<b>FL</b>	<b>PA</b>	<b>TN</b>	<b>ME</b>	<b>CT</b>	<b>BU</b>
<b>Plans for stratification</b>	Gender	Gender, race	Gender, number in E vs C	Gender	Gender	Gender	Gender	Gender, race, level of involvement in TMHS
<b>Who oversees RA process</b>	Interviewer who does baseline has sealed packet with interview materials and RA number generated by PI; packets monitored	Interviewer who does baseline uses program in laptop interview	Project Manager uses sealed, numbered envelope for each recruitment appointment	Interviewer calls PD to get random assignment for interviewee	Interviewer using program in laptop interview	Administrative Assistant prepares envelope using random assignment table numbers under direction of PI/Co-PI; controlled in that RA only done per interview	Random numbers generated centrally	Research Specialist at BU has random assignment; interviewers call in to receive RA
<b>Who informs participant of RA outcome</b>	Interviewer	Interviewer	Project Manager	Research Assistant (?Interviewer) informs participant	Interviewer	Interviewer opens envelope after baseline and informs participant	Interviewer	Interviewer
<b>How is RA made</b>	Random number table with random start	Random number program in laptop	Random number simulator with blocking	Computer generated random number list	Random number program in laptop	Random assignment tables numbers with even # for E and odd # for C; different envelopes for M vs. F	Computer generated random numbers	Random number sequence generated by SAS Proc Plan; 3 stratification variables built in to plan

	<b>CA</b>	<b>IL</b>	<b>FL</b>	<b>PA</b>	<b>TN</b>	<b>ME</b>	<b>CT</b>	<b>BU</b>
<b>If there is more than one recruitment site within the site, how is RA handled</b>	Two sites, RA conducted centrally	RA will be conducted independently within 3 sites (Tinley PK, Rockford, Champlain)	One site	One site	One site	One site	One site	One site
<b>Is assignment to groups intermittent or continuous</b>	Continuous	Continuous	Continuous	Continuous	In waves with start of classes	Continuous	In waves with start of classes	Continuous

*Note: For BU, stratifying by race includes white, non-white; stratifying by TMHS involvement will be done using three levels: minimal involvement, moderate involvement, intensive involvement (using definitions of this).*

RANDOMIZATION SCHEDULE FOR STUDY

Page 1 of 2

=====MALE - WHITE=====						=====MALE - NON-WHITE=====						
I..	I.D.	Minimal	I.D.	Moderate	I.D.	Intense	I.D.	Minimal	I.D.	Moderate	I.D.	Intense
_____	C	_____	E	_____	C	_____	C	_____	E	_____	E	_____
_____	E	_____	C	_____	E	_____	E	_____	C	_____	C	_____
_____	E	_____	C	_____	C	_____	C	_____	E	_____	E	_____
_____	C	_____	E	_____	E	_____	E	_____	C	_____	C	_____
_____	C	_____	E	_____	E	_____	E	_____	E	_____	E	_____
_____	E	_____	C	_____	C	_____	C	_____	C	_____	C	_____
_____	C	_____	E	_____	C	_____	C	_____	E	_____	C	_____
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_____	C	_____	C	_____	C	_____	E	_____	C	_____	E
_____	E	_____	E	_____	E	_____	E	_____	C	_____	C
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_____	C	_____	E	_____	C	_____	E	_____	C	_____	E
_____	E	_____	C	_____	E	_____	C	_____	E	_____	C
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_____	E	_____	C	_____	E	_____	C	_____	E	_____	C
_____	C	_____	E	_____	C	_____	E	_____	C	_____	E
_____	E	_____	E	_____	E	_____	E	_____	C	_____	

Appendix E  
Interviewer Observation Scale

Interviewer: \_\_\_\_\_

Date: \_\_\_\_\_

**INTERVIEWER RATINGS- Do not ask the following of the respondent.**

**1. Circle One:**

**IC** = Interview Completed

**IT** = Interviewer Terminated Interview

**RT** = Respondent Terminated Interview

**2. How reliable do you think the respondent's answers were?**

- a. **Unreliable:** respondent appeared consistently confused, unwilling to answer many questions, had interfering symptoms, was intoxicated, was distracted, was unable to understand English--go to #2a.
- b. **Mixed:** respondent appeared occasionally confused or unwilling to answer significant number of questions; had interfering symptoms, was somewhat distracted, was unable to understand many questions, or was intoxicated but was generally able to participate in interview--go to #2a.
- c. **Reliable:** respondent was able to fully participate in interview; understood the questions being asked and was not hesitant to answer questions.

**2a. Briefly describe why you question the reliability of this person's responses (i.e. very anxious, intoxicated, someone else present, fatigued by interview, could not understand English, etc.)**

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**3. Did the respondent have difficulty understanding or completing any particular segment of the interview?**

**0** No (skip to #4)

**1** Yes (go to table below-#3a)

**3a. Check which segments were difficult:**

Section	<input type="checkbox"/>	Section	<input type="checkbox"/>	Section	<input type="checkbox"/>
Demographics		Empowerment		QOL	
Employment		Making Decisions		Symptoms	
Finances		Personal Empowerment		Hopkins	
Satisfaction-TMHS		Reduction in Chance		Health Status	
Outcomes-THMS		Organizationally Med. Emp.		Colorado	
Satisfaction-COS		Service Utilization		Recovery	
Outcomes-COS		Program Activities		Meaning of Life	
Recent Service use		Social Inclusion		Religion/Spirituality	
Side Effects		Social Acceptance		Herth Hope Index	
Substance use		Discrimination			

**3b. Any other comments about difficult sections?**

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**4. What other comments would explain responses during this interview?**

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Appendix F  
Pledge of Confidentiality  
(Sample)

**CONFIDENTIALITY CONTRACT  
BETWEEN EMPLOYEE AND BRIDGES EVALUATION PROJECT**

As an employee of the BRIDGES Evaluation Project, you are working on a nationwide study of supportive services provided by mental health care consumers operated in conjunction with traditional mental health services providers compared to traditional mental health services alone. As part of your role in the research process, you have access to information about people receiving services and their feelings about their services received. This information is considered by our project to be strictly confidential. By agreeing to work on the project, you agree to respect the privacy of persons who are involved as study participants or are otherwise affiliated with the study by not sharing any identifying information about them with anyone unless you learn that they have active thoughts of danger to themselves or someone else. Breaches of confidentiality will be met with disciplinary action and can result in termination of employment.

Statement of contract: I understand the above policy and agree to abide by it.

Signed Employee \_\_\_\_\_ Date \_\_\_\_\_

Supervisor \_\_\_\_\_ Date \_\_\_\_\_

## Appendix G

### Summary of Recruitment/Enrollment/COS Engagement Procedures and Activities



## ***SITE RECRUITMENT/ENROLLMENT SUMMARY***

*Revised 2/15/01*

*This document is a summary of key points made in recruitment/enrollment checklists and related reports submitted to the CC by all COSP sites. It also contains information shared on Logistics Subcommittee teleconferences on 12/12/00 and 2/15/01. No sites are identified by name. This summary has two purposes. The first purpose is essentially information sharing: each site can get a sense of what others have found helpful in the process of enhancing recruitment and enrollment numbers. The second purpose is to provide background information for members of the logistics committee as they initiate a multi-site discussion of COSP recruitment/enrollment issues.*

### ***Recruitment/Enrollment Enhancement Planning at the Site Level***

All sites appear to be holding recruitment/enrollment enhancement meetings regularly. Meetings are variously attended by COS, Research Team, local CAP, and TMHS representatives. Most seem to focus on a) site-level brainstorming re: recruitment and enrollment techniques and b) logistics of carrying out new ideas. Meetings are held fact-to-face, via teleconference, and e-mail.

### **Strategy Development at the Site Level**

#### **Recruitment Strategies:**

Several sites are holding more regular meetings with TMHS staff at the administrative AND line level in order to:

- 1) be sure that accurate and up-to-date information gets to all important players.
- 2) be sure that everyone remembers/has opportunity to be reminded of COSP eligibility requirements.
- 3) facilitate referrals from Case Management staff to research staff.
- 3) engage TMHS staff in brainstorming meetings and focus groups focused on how best to reach potentially eligible and appropriate consumers.

Due to difficulty contacting folks who have expressed consent to be contacted, several sites have instituted local policies that research staff attempt to reach potential COSP participants Many, Many, MANY times before giving up. Sites doing this also note that it is important, when encouraging frequent and repeated follow-up, to keep in mind the risk of being perceived as harassing. One site is also enlisting the assistance of TMHS Case Managers to facilitate initial contact with consumers who have given consent for contact. Another site is sending interviewer/recruiters to “hang out” in areas where persons may be reached face-to-face (i.e. TMHS lobbies, group homes, clubhouses, etc.).

Due to high numbers of interview no-shows, several sights have become more flexible about where interviews take place (i.e. doing interviews at group residences /consumer homes,

restaurants, etc). Some are also providing transportation to/from interviews (rides w/interviewers, taxi coupons, bus tokens, etc.).

*Several sites are considering the TN approach of directly recruiting off TMHS rolls via the “uncompensated employee” technique.*

Several drop-in sites are considering recruiting people at the front door. This approach has raised a variety of concerns, however, and does not appear to have been implemented yet. (See Meeting notes of 12/12/00 for further discussion on this topic).

*Several sites are considering ways to provide direct on-site information about the study to TMHS participants. Examples of approaches used thus far include:*

- Setting up Info booths in TMHS lobbies on days when consumer traffic is high. This is most effective when used intermittently so that the booth’s presence is Perceived as novel and curious – novelty draws people’s attention.
- Holding informational meetings at TMHS-sponsored group homes. This approach has proven successful at one site but less so at another site.
- Placing colorful, attractive posters/fliers in TMHS waiting areas. Distributing same material to TMHS staff. It may be particularly useful to change the colors and format of fliers/posters occasionally to attract people’s attention.
- Sending out mass-mailing to potentially eligible TMHS consumers. Mass mailings typically have had two parts: 1) A cover letter from the TMHS &/or study PI and, 2) an informational recruitment letter or flier from the research team. The mailing labels are produced & the mailing is sent out by the TMHS for purposes of maintaining TMHS consumers’ confidentiality.

One site has held focus groups at the COSP to learn more about what draws people to attend and to gather consumers’ perspectives on how to improve recruiting strategies.

Several sites have reallocated staff resources to expand time for TMHS- and community-based recruiting efforts. This has most often involved expanding the roles of interviewers to include a variety of recruitment & outreach efforts.

Several sites have revisited their original lists of potentially COSP eligible TMHS participants to see if any persons who were originally ineligible may now have become eligible (i.e. people who may have recently passed their 18<sup>th</sup> birthday, people who may have earlier been new to TMHS but now have now utilized TMHS services for over 1 year, etc.).

Several sites have initiated a kind of “Snowball” approach to recruiting whereby current COSP participants are given blank Consent to Contact forms with SASE. They can then forward these forms and envelopes to friends who may be interested in the study. Due to the likelihood that

persons recruited in this manner are very similar to one another, it may be particularly important to track random assignments of persons recruited in this manner.

### **Strategies to Promote COS Utilization:**

- Over the course of providing background on the study for purposes of informed consent, several sites are putting extra effort into helping potential participants to understand random assignment, and the possibility of being assigned to the COSP. Theoretically this will weed out persons who, in the event of “E” group assignment would not be willing to participate in the COSP.
- Several sites are sending letters to study participants, reminding of group assignment. ‘E’ group members are receiving calendars of COSP activities and invitations to special COSP-sponsored events. Special events thus far have included COSP open houses, COSP-newcomer socials, and monthly COSP-wide socials. Some sites have the interviewers attend these events so that there is always at least one familiar face to greet new ‘E’ group members.
- Upon random assignment to “E” group, participants are given engagement packets (packets include a bus pass, a COSP welcome letter, photos of COSP, list of current activities, and personal testimonies from COSP attendees). Duplicates of these packets are also sent out via monthly mailings to the ‘E’ group and at 4 month follow-up interviews.
- Placing follow-up phone calls to “E” group 2 weeks post-random assignment. Calls made by research staff. Names of COSP contacts given so that participant has an individual at the COSP to contact.
- Upon randomization to “E” group, asking research participant if it is ok for RA/Interviewer to give his/her contact number to a COSP representative. If yes, COSP representative then follows up with the person directly to invite them to attend upcoming COSP events.
- A couple sites are revisiting their methods for tracking COSP attendance to be sure that no research participant COSP-visits are missed.
- Several sites are inviting persons assigned to the ‘E’ group to visit the COSP with the interviewer immediately after random assignment. The interviewer acts as a familiar guide and introduces the new ‘E’ group member to COSP personnel and activities.
- One site has begun to over-sample from the demographic group known to be most likely to use the COSP.
- One site has begun holding follow-up interviews for E-group members next door to the COSP and then taking the respondent on a COSP tour immediately after the interview is complete.

- A couple sites have set up weekly times/days for COS tours. Persons newly assigned to the 'E' group are informed of the tour schedule and encouraged to attend.
- One site is experimenting with the type of language they use to describe the COSP to 'E' group members. For example given that some folks may initially be intimidated by information on support groups, it may be better to begin by drawing their attention to more emotionally neutral activities such as coffee, meals, etc.
- Sites are looking into using pre-existing COSP transportation services to provide rides to persons randomly assigned to the 'E' condition.
- One site is considering expanding their van service to include round trips to/from areas where consumers are most likely to live. This service can assist both current COSP members and new members affiliated with the research. Other sites are using taxicab coupons to facilitate transportation.
- Computer email access at COS attracts people to attend.
- Developed special classes and/or outreach for subpopulations such as women.

#### **Suggestions to Improve Follow-up Rates:**

- Attempt contact between interviews.
- Incentivise consumers to call us, i.e., report in one time per month.
- Provide bonus \$25 if consumer makes it to all follow-up interviews.
- Track returned mail and follow-up right away by going to Case Manager to try to find consumer. Also, in some places may be able to go to post office with former address and ask to be given the new address.
- Send monthly mailings to keep in touch with participant.
- Send letter in advance of call to arrange FUP so that the FUP call is not perceived as a surprise or "cold call."
- Drive by participant's residence and drop off "tried to contact you" letter.
- Ask for an update for participant's contact person(s) list at each FUP.
- Get interviewer business cards that can be personalized with interviewer's name and printed with "call our office to arrange your next interview."

- Impress on interviewers how important FUP interviews are to data analysis and the study.

**Common Themes:**

*It is VERY challenging and time consuming (but certainly not impossible) to balance the following:*

- The need to proceed in a manner that is consistent with the Logistics Manual.
- The needs to proceed in a manner consistent with the GFA.
- The needs to proceed in a manner acceptable to all local collaborating parties: CAP, Researchers, TMHS, COSP.
- The slow pace of change given need to obtain IRB approval for new procedures prior to implementation.
- The natural ebb and flow of recruiting successes (at some sites this is programmatic) and associated stresses and strains on project staff and resources.

Delay in start-up related to finalizing the CP initially resulted in a shortened period for recruiting. Several sites expressed concern that they would not be able to meet their recruiting goals under these unexpected circumstances. As a consequence of negotiations held in January, 2001 between the Federal Representatives, the CC, and members of the Research Committee, recruiting may now be extended through September, 2001 by those sites who need extra time to meet their recruitment goals. Persons recruited into the study between June and September, 2001 will be followed for multi-site data collection purposes for a total of 8 months. All persons recruited into the study prior to May 31, 2001 will continue to be followed for 12 months as originally planned.