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Strategies for Maintaining Compliance

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One of the greatest challenges for alcoholism treatment outcome studies is assuring the availability of participants throughout the entire followup period. To date, the focus in most projects has been on recruiting participants and not on successfully maintaining them in the study (Twitchell et al. 1992). If study participants are missing, refuse to continue, or are difficult to contact, there is a potential loss of internal validity. Selecting only compliant participants—those who are likely to complete subsequent followup procedures or interviews—is one way to ensure better participation. However, using a selected group of participants may affect the external validity of the study and limit the generalizability of results only to groups that have the same characteristics as the selected sample.

In either case, data quality depends largely on the availability and cooperation of the participants (Searles and Alterman 1992). Typically, noncompliance has been judged the fault of the participant. In Project MATCH, we viewed compliant and noncompliant behaviors as stemming from the participants' unique backgrounds and life circumstances, and we developed procedures to take those circumstances into account.

The purpose of this chapter is to introduce strategies that enhance the likelihood that a person will not only consent to join a research project but also complete the followup interviews. Perhaps the single most important aspect of this is recognizing that participants in a study involving alcohol are not one-dimensional people nor are they the disorder they present with. They are individuals with different cultural backgrounds, coping skills, and family, financial, educational, and environmental concerns.

This chapter presents step-by-step procedures that can be used to develop a firm foundation for successful followup compliance. It describes procedures that begin prior to recruiting the first participant and continue until the final interview of the last one. They are the day-to-day procedures used to engage participants, maintain their compliance, and detect problems that may inhibit their ability to comply with the task demands of the research. These strategies include locating a clinical site; educating, orienting, and training the staff at both the clinical and research sites; and educating participants as to the purpose, procedures, and expectations of the study.

These procedures are easily initiated during the planning phase of a project and can also be applied to studies that have already begun. The chapter also serves as a guide for standardizing contact with participants, thereby clarifying roles and responsibilities between the research staff and the participant.

Select the Site

The selection of a recruitment site for a study deserves the same level of attention as that given to the development of the treatment and research protocols. Many site characteristics should be considered.

Prevalence of Alcoholism

Alcoholism treatment agencies typically attract clients from a definable geographic area. Epidemiological surveys conducted by State health and welfare agencies typically contain estimates of the prevalence of alcohol and other drug disorders by county and usually include separate estimates for metropolitan areas. An agency located in an area with low prevalence is, all else being equal, a poor choice. The amount of effort required to recruit clients from a low-prevalence area as compared to a high-prevalence area will be roughly similar, but the yield (the recruitment-to-effort ratio) will be small.

Institutional Stability

A history of continuous operation and the absence of large, rapid variations in client base size are indicators that allow you to assess the likelihood that an agency will be stable over the course of a study.

Staff Professionalism

Fielding a research protocol typically means introducing changes in the usual way clients are handled, and resistance to change is a common reaction of agency staff. If staff are resistant to the presence of a research study, it can negatively affect client retention. Usually, but not always, staff with professional credentials adjust to change more rapidly.

Client Characteristics

Client characteristics affect the generalizability of the study results; in treatment-matching studies, it is advantageous to maximize heterogeneity. An agency whose clients are white, middle-class men between 30 and 45 years of age is less attractive than an agency that serves an ethnically diverse population with nearly equal proportions of men and women aged 18 to 70. On the other hand, for a small-scale efficacy trial, the former agency, with its homogeneous participant base, might be the better choice.

Community Reputation

Agencies often have reputations in the communities they serve, and those reputations need to be taken into account. For example, an agency's reputation for providing service only to minorities and low-income individuals might make it difficult to attract middle- and upper-income clients. Likewise, minority and lower income individuals might feel unwelcome in a private, for-profit agency. In either case, the agency's reputation can be a barrier to recruitment.

Site Accessibility

Access by public transportation, sufficient parking for private vehicles, and adequate hours of operation reduce common barriers to participation. In addition, potential clients should be able to find it easily.

Security

Well-lighted parking areas, the presence of security police, easily accessible telephones, and restricted building access during evening hours will also reduce barriers to participation.

Confidentiality

A private office in which to conduct the assessments and a clear explanation of confidentiality procedures will assure participants that the information they are providing will be kept in confidence.

Physical Comfort

Interview rooms need to be furnished in such a way that clients are comfortable over the course of the assessment period. Desk space for filling out questionnaires and adequate lighting impress clients favorably and remove sources of irritation that can become excuses for not participating in followups.

Laboratory Access

Many alcohol treatment outcome studies collect blood and urine samples. Participants deserve to have these collections done by trained, competent professionals. They also need to find the laboratory. Choosing a lab that is physically convenient or arranging to have a trained professional obtain the specimens at the site where the assessments are conducted enhances compliance in this aspect of a protocol.

Childcare

Whenever possible, childcare should be provided free of charge to potential participants to increase their likelihood of showing up for scheduled appointments.

Language

Given that English may not be the first language of potential clients, it is useful to have signs in Spanish as well as English. In addition, giving potential participants the opportunity to speak with bilingual staff is helpful.

Warm, Friendly Environment

Participants are more likely to continue with the study when they feel welcome. Simply having coffee and snacks available and offering a smile can make individuals feel at home.

Define the Population

While the majority of research participants report that they had very little trouble completing the followup requirements, persons with substance abuse problems are typically difficult to follow (Rumptz et al. 1991). Some of these difficulties are the result of structural barriers, while others are the result of personal idiosyncrasies. Research has shown that obtaining the full cooperation of clients depends in part on the ability of the research staff to minimize barriers and maximize the satisfaction the client derives from participation (Thornton et al. 1982).

By giving some thought to population characteristics, you will be able to anticipate the major barriers faced by identifiable groups of participants. Efforts to minimize those barriers will increase participant satisfaction and, in turn, help to maintain and enhance client participation. In order to accomplish this, an understanding of common situational needs of the service population is a must. A good place to begin is by analyzing the demographic characteristics of the sites' service population, as it will provide the clients for the study.

Gender

Alcohol treatment studies have too often been unable to recruit or retain women and minority participants. Women with children often need childcare, either at the site or in their home in order to get to the site for appointments. Single mothers with small children often live on fixed incomes and may also need transportation. Arranging for onsite child sitters or a voucher system for women participants is a simple way of attracting and retaining women in the study.

Ethnic/Cultural Issues

The cultural sensitivities of minority peoples often go unrecognized in majority-dominated health service agencies. Being a person of color amid a sea of white faces can be discomfiting.

Language barriers also can be problematic and lead to noncompliance. In busy agencies, staff members who are not sensitive to ethnic and cultural issues can easily be misperceived as being indifferent or callous. Cultural sensitivity training and hiring minority staff can help retain minority participants.

Income Level

Lower socioeconomic status, which cuts across gender, age, and culture, can be a barrier to full participation. Low income is often concomitant with transitional housing, loss of telephone and utilities, no health insurance, and lack of transportation. A voucher system is a good start, but a high proportion of low-income individuals in the study sample requires a system to provide cash for transportation to assessment appointments, as some participants cannot afford even bus fare.

Paying participants cash for their interviews is an easy process if the project uses an ATM card with its cash account. This enables project staff to give the participant cash for the completed interview, obtain a signed receipt for the money, and get cash to prepay the cab driver if one is used. Purchasing marked route maps for the public transportation system is another convenient way to offset transportation problems. Setting up a toll-free 800 number allows participants to call the research staff without charge. Finally, flexibility (to the extent allowed by the research design) in permitting assessments to be conducted offsite can make the difference between a completed interview and a lost participant.

Incorporate the Research Into the Site

Involve Site Staff

Site staff play an integral role in conducting the research. They can provide archival records for client information, support services for recruitment, an environment for the clinical needs of participants, medical services, laboratory services, and general support for the scheduling of assessments. Establishing role parameters early and developing formal and informal channels of communication between the site and research staffs helps to create an atmosphere of cooperation that will have a positive impact on research participant compliance.

Orienting the clinical staff to the goals, objectives, and progress of the research project is a worthwhile undertaking, particularly if the institutional affiliations of the recruitment site differ from that of the research staff. It is particularly important to the integrity of the research protocol to explicitly describe the role of each individual within the project. This should be an ongoing process, because people tend to become lax in adhering stringently to research protocol, and in any extended research project, there are

personnel changes. In addition, as clients become familiar with the process and procedures of a research project, their perceptions of their role and that of the research assistant may become altered.

When working with the site staff, who may be involved only peripherally with the research project, it is helpful to conduct regularly scheduled interstaff meetings with handouts. Liaisons from the site and research staffs can be nominated to attend these meetings. This keeps the project visible and informs the staff of the status of the project. It is also a forum for newly hired personnel to be oriented to the project. Reinforcing the importance of confidentiality regarding project participation, reviewing the process of recruiting, and reviewing the procedures for followup interviews refresh their memories about this work. Reminding them that the clinical treatment always has priority helps site staff recognize the respect given them by the researchers.

Following is an overview of what to include when preparing clinical site staff.

Engage site management:

- Establish goals and set boundaries
- Schedule orientation for line staff
- Identify staff liaisons
- Establish interstaff meeting schedules

Conduct orientations to research protocol:

- Explain purpose of research
- Introduce research staff
- Delineate staff involvement in:
  - Screening
  - Recruiting
  - Treatment
  - Followup
  - Emergency protocols for participants (e.g., for suicide risk, intoxication, clinical deterioration, legally mandated reporting incidents)

Clarify expectations and identify concerns:

- Define site staff involvement in research
- Discuss boundaries
- Address concerns and solicit suggestions
- Define participant confidentiality
- Establish information exchange protocols

Respond Rapidly to Site Problems

It is unrealistic to expect that difficulties will not arise between the clinical and research staffs at a site. It is likewise unrealistic to expect that such difficulties will have no impact on research participants. Certain types of difficulties can be anticipated, and protocols can be established to effectively deal with them prior to their occurrence. For instance, a joint effort between the site and research staffs can establish protocols for dealing with research participants who come to assessments inebriated. Sometimes, however, situations arise with clients that require the joint efforts of site and research staff but fall outside established protocols. Without a mechanism built into the liaison structure for reacting to such cases in a rapid, flexible manner, the end result is often a disgruntled participant who finds a ready-made excuse for dropping out of the study. Following is an example of a participant who presented with specific questions about suicide to the research assistant.

> During a scheduled followup interview with Raymond L., the research interviewer was asked about the incidence of suicide with participants who were in the study. Raymond L. proceeded to talk about how he sometimes thought it would be so much easier for those people who opted for suicide, because they would no longer be a burden to their friends and families. The research assistant suggested that they talk with one of the counselors on site about the incidence of suicide with alcohol-troubled participants. Raymond L. requested a particular counselor with whom he had a professional relationship. The counselor contracted with Raymond L. for safety until they could meet the following day. The integrity of the followup interview was maintained, because the research assistant did not disclose information specific to the participant with the counselor but linked the participant with a trained professional who could assess the situation.

Ensure Confidentiality

When clients are recruited into a research protocol, part of the informed consent form provides assurance that their participation in the research will be held in confidence. However, the research followup protocols often entail interviews in the same agency that provided the treatment. This could compromise the client's confidential participation if site staff not involved in the research but with whom the client has had prior contact are not appraised of the protocols ensuring confidentiality.

During Project MATCH, for example, an employee of one of the sites inquired about becoming a participant. The employee assistance counselor at the agency had recommended the MATCH protocol as an opportunity to obtain aftercare.

> Joan J. liked the idea of participating in an innovative type of treatment for her alcohol dependence, and preliminary assessment found that Joan would be eligible to participate in MATCH.

Her initial enthusiasm dropped abruptly when she realized that she would need to come to the agency where she was an employee for both the treatment and followup assessments periodically over the course of the study. Joan was quite concerned that certain of her coworkers would have occasion to antagonize her if they found out that she was participating in the research project. In Joan's case, only minimal assurance that her participation would escape the notice of her coworkers could be given. However, the fact that research staff could speak for themselves and also for the site staff and assure Joan that her participation would be kept confidential helped persuade her that these structural safeguards reduced her risk of exposure. It also helped to be able to schedule weekend appointments for Joan. Typically, the site staff were not those with whom she worked closely during the week.

This case illustrates the advantage of training the site staff in the requirements of participant confidentiality. It would have been all too easy for a naive agency employee to casually mention that Joan was participating in Project MATCH. Such a disclosure would have breached Joan's confidentiality and may have led her to drop out of the study. It also could have tarnished the reputation of the study.

Maintain a Presence at the Site

If the clinical site and research site are at two different locations, actual time spent at the clinical site by research staff will be reduced as the study moves out of the recruitment phase and into the followup phase. Limiting site time to periods of scheduled assessments certainly has advantages when research staff have responsibilities other than interviewing (e.g., data entry). Particularly in the later phases of followup, scheduled assessments at a given site might taper off dramatically. The end result could be that the clinical site staff loses awareness of the research project.

Under these circumstances, it becomes all the more important to maintain established liaison contact. Doing so will help to avoid and minimize confusion for the clients, site staff, and research staff. One awkward situation could occur when a participant appears at the site for a scheduled assessment only to find that the research staff is not there. If the site staff is up to date on the activities of the research staff, they can explain the situation as an unanticipated problem and offer to reschedule at the client's convenience. Conversely, if the site staff is unfamiliar with the research staff and does not know how to contact them, the client has an excuse for refusing further participation. Late in the followup protocol is a time for paying close attention to details that will enhance client participation, not for growing complacent.

Select and Train Research Staff

Few studies consider the impact of the research assistant on the outcome of followup. While the importance of maintaining interest in the project by both the client and the staff has been addressed in the literature (Meinert 1986), little has been written about the training required for the research assistants to ensure that they adequately locate and recruit participants as well as complete followup interviews and accurately manage data. Involving staff in the planning and development stages of a project increases their understanding and enthusiasm (Thornton et al. 1982; Meinert 1986).

Select Staff

Although a variety of skills are necessary to be an effective research assistant, many of those that are specific to a particular project can be taught. What follows are general characteristics of a competent, professional, motivated research assistant:

- Team player
- Effective communicator
- Problem solver
- Skillful interviewer

Further, such a person should be able to demonstrate the following behaviors:

- Respects individual participants
- Adheres to ethics and confidentiality of project
- Follows research protocols
- Adheres to protocol of data management
- Is prompt for appointments
- Displays sense of humor
- Shows willingness to stay with the project until completion
- Does not take on more clients than can be handled effectively

Develop and Improve Staff Skills

Perhaps the greatest commitment when starting a research project is setting aside time to train staff well. In order to promote an atmosphere that enhances the participant completion rate, the project must make a concerted effort to train staff in effective methods of establishing and maintaining contact with clients. Training must include a standardized approach to conducting the interviews, scheduling followup appointments, and sending letters for intermittent contact with the client. This alleviates the possibility that something in writing may be misconstrued by the

participant. Research assistants need to develop skills in effective interviewing, creating a standardized system of maintaining contact with participants, handling data management, and problemsolving for the difficult situations that can arise in any study. Additional training may also be needed for those research assistants who handle blood or urine samples.

Training should include a solid base of information about the population to be enlisted in the study as well as guidance for understanding the process that participants undergo during the followup period. The interaction with clients is enhanced when staff can anticipate common participant needs (Vlahov et al. 1991). With a good understanding of the population, the project staff can initiate and design protocols that eliminate ineffective contact procedures and concentrate on promoting procedures that will enhance followup completion rates.

Working through possible scenarios of interaction during contacts with the participants, such as tearful clients, playboys who use sexual innuendo, and hostile, fearful, or relapsed clients, helps to proactively address uncomfortable situations. It also provides a decision tree of choices to make under given or similar situations. Research assistants are usually relieved to know they are not expected to handle all situations.

Roles

Staff members within a project are typically assigned different roles and tasks. Understanding the interaction of the different roles enables them to identify how each staff member affects the success of the project. It is also important that all research assistants be able to do all the jobs in addition to their specialty. Teaching them about the tasks involved with each position in the project helps them work effectively, and such flexibility helps during unforeseen absences and holidays.

There are two schools of thought about single versus multiple interviewers. Rapport can be established between a client and a single research assistant that may not be as easily attainable with several assistants. Thus, maintaining continuity of contact between a participant and a single research assistant across multiple followup interviews may be the goal of the research protocol. However, research assistants leave, personalities clash, and participants may feel so strongly about not working with a particular person that it is necessary to provide an option.

The main argument against having one interviewer for each followup point is the potential for bias, both positive and negative. Although we would like to believe that those issues would be handled with ongoing supervision, personal issues could still interfere with clean data collection. Establishing a system for

Research Roles	
Screener	Locates potential participants using exclusion/inclusion protocol
Recruiter	Engages eligible applicants Obtains informed consent
Interviewer	Conducts baseline assessment
Treatment provider	Conducts treatment (a separate function with a separate staff); overlap occurs in tracking participants through treatment phase
Followup interviewer	Tracks participants Schedules appointments Conducts followup assessments
Collateral interviewer	Conducts telephone interviews with collaterals Confirms information obtained from the participant
Data entry/ manager	Codes interviews Enters and verifies data

sharing client identifiers, such as birthdays, anniversaries, and so forth, among research assistants can help to maintain the personal touch while involving several interviewers.

Monitor and Supervise Staff

Allotting time for individual and group meetings between research assistants and supervisory staff is important for keeping research staff abreast of participant monitoring, disseminating information, and anticipating problems. The meetings are a forum for soliciting suggestions for increasing participant compliance and discussing difficult cases under the guidance of the supervisors, who are well versed in research. They also facilitate a sense of belonging to the larger research group.

Having an established monitoring and supervision structure provides a forum for addressing such participant behaviors as sexual innuendo, intimidation, or threats to the research staff. Providing direction on reestablishing contact, conducting home visits, and working with known difficult participants, reduces the possibility that research assistants will provide more than they are qualified to give. Monitoring likewise allows supervisory staff to deal with inappropriate research staff behavior toward participants.

Staff morale is affected by a variety of influences, and helping research assistants maintain a high level of interest in the progress of the study may decrease turnover. Reduction in turnover translates into higher continuity for the study participants. If clients can expect to find a familiar face among the research staff each time they appear for an assessment, their willingness to continue will be enhanced.

For safety, offsite interviews should always be conducted by two research assistants, and the supervisor should know where the interview is being conducted and the estimated timeline. Other safety precautions, such as a telephone call while there, can also be utilized. Once again, if research assistants are given strict guidelines to follow, it reduces the possibility that they will succumb to inappropriate requests by the participants.

Finally, research assistants should be encouraged to monitor and evaluate their particular sites. An evaluation created by team members themselves helps maintain enthusiasm for the study and also enables research assistants to detect possible problems and begin intervention.

Reports of Abuse

Mandated reporting laws, which vary from State to State, address physical and sexual abuse. In the course of a clinical trial for substance abuse, it is common for research assistants to learn about such abuse. Participants can be either the victims or perpetrators of reportable events. Research assistants must be made familiar with the laws and helped to feel comfortable with handling these circumstances. Reviewing the laws and establishing a protocol that clarifies roles for each research staff member is important for both legal and professional purposes.

Establish and Maintain Boundaries

Delineating the boundaries between research and clinical care is important. While establishing and maintaining rapport with clients is fundamental to keeping them in the study, a research assistant can become overly involved with them, especially during the followup period. When research assistants witness the suffering of participants, they may feel compelled to address their clinical needs. Many express the concern that they should be doing more for the client. However, the requirements of the research design circumscribe the type of assistance that a research assistant can provide, and such situations require the attention of the supervisory staff.

Training research assistants to recognize and respond appropriately is the key to enhancing the odds that participants in these situations remain in the study. When working with the research staff, establishing and reminding them of boundaries for the research protocol and patient interaction is a daily exchange.

Establish a System for Tracking Participants

The purpose of a tracking system is to provide enough information to contact participants throughout the followup phase regardless of whether they are compliant. Prevention, early intervention, and reengagement of noncompliant participants are only possible (for prevention and early intervention) or greatly simplified (for reengagement) if background information is readily available. This strategy avoids the panic of having to obtain information about clients after they have missed a scheduled appointment or, worse, refuse to continue to participate. The ability to quickly assess the situation is more desirable than having to wait until several days or weeks have elapsed and the participant is beyond a standard followup procedure.

A computerized system creates a quick and convenient way for the research assistant and the supervisor to locate, identify, and follow up on the progress of participants. The basic procedures of the followup (mailing contact letters, conducting telephone calls, notifying participants of changes in their appointments) can then be conducted by one person with a computer and a printer. The following guidelines describe the development of a cohesive plan for retaining participants and for increasing followup completion rates.

Collect the Data

The basic foundation of an effective system for monitoring and tracking participants is the standard intake questionnaire. One that includes demographic information can be used in maintaining contact and in relocating a participant. The information on the demographic form should include the following:

- Participant identification number
- Participant name, address, and day and evening telephone numbers
- Name under which the telephone numbers are listed
- Time of day client is available for contact, appointments
- Permanent address if different from above
- Date of birth
- Ethnic background
- Social Security Number
- Locators: two people who know the participant and will forward a message; preferably one of the locators does not live with the participant
- Personal identifying information such as hobbies, interests, and unique physical traits

When the followup phase is entered, additional information should be tracked.

- Data about the followup process: time, date, location of interview, when completed, by whom
- Documentation of followup procedures

Identify Potential Problems

Attending to cues that may otherwise be overlooked provides a means of obtaining anecdotal information about participants. These cues include information about anticipated life changes, such as change in marital status. Documenting this information is invaluable if contacting the participant becomes a problem.

Telephone Information that should be documented includes when telephone calls were made and the results. For instance, if a call is made at 3:00 p.m. and an answering machine picks up the call, it may be a good idea to attempt another contact at a different time. If someone other than the participant answers, ask that person's name and relationship to the participant, and record the information. For example, indicating that a message was left with a babysitter at 7:00 p.m. enables all workers to know what has been done and to determine the feasibility of leaving another message with the same person. It also helps pinpoint times that may be inconvenient for the client or may indicate a change in the client's schedule. This approach places responsibility for returning telephone calls with the participants.

Mail Another method of identifying potential problems is to mail brief, informational letters or postcards at predetermined intervals. Ideally, the letters should have an easily identifiable logo, the same as the one on the business card. These letters or postcards can include anything, from notes on how far along the study has progressed to the names of newly hired research assistants who have been assigned to the study. Including brief, informative blurbs of interest to the participants helps them realize they are part of a larger unit. However, if postcards are used, be sure that they do not include information that will compromise the client's confidentiality.

Always include a return address on the envelope along with the letters ACRDNF. This message to the post office means Address Correction Requested, Do Not Forward. The post office will return the unopened piece of mail with a new address listed, if one is available. The post office will forward first class mail for 12 to 18 months, provided an address has been given. They will notify the sender of a new address for 1 year. They will forward second class mail for 60 days. If there is no forwarding address available, it will be noted as Moved No Forwarding Address.

Requesting notification has several advantages. If the participant has left a forwarding address, mail can be sent to the correct address. This also lets the client know that the research assistant is maintaining accurate records, thus enhancing the professionalism of the study. Sending mail at regular intervals, preferably biannually, has the additional advantage of early notification by the postal system if the client has left no forwarding address. This allows the research assistant to begin looking for the participant before too much time has passed. This makes relocation less time consuming.

Update Information at Each Contact

Each contact between the research staff and the participant is an opportunity to ensure that the information contained in the tracking system is current. It takes only a few moments to ask if there are any changes in the following:

- Address
- Day and evening telephone numbers
- Name under which the telephone numbers are listed
- Time of day client is available for contact, appointments
- Locators

This is also an excellent time to obtain anecdotal information on the participants' level of enthusiasm for continuing in the study.

Learn About the Client's Support Systems

All participants will have some formal or informal support systems. These include people or places they may be involved with in their community or daily lives, such as a bowling league, bingo group, support group (such as AA or Parents Without Partners), or senior citizen travel club. Many neighborhoods have community mental health centers that double as meeting places for people who share similar cultural or ethnic backgrounds. Health clinics or emergency room departments in neighborhood hospitals are also frequented by area residents. There are also clubs, community centers, and senior centers where clients may be located. Knowing about such support systems is useful, because very often it is possible to use them to get a message to the participant. When accessing these facilities, it is important to remember to maintain ethical and confidentiality standards.

Educate Potential Participants

An important component of the recruitment phase is the clear and concise explanation of the project to potential participants. For instance, completing the baseline assessment battery, completing the treatment as directed, and completing followup interviews as scheduled are all part of the procedures that should be explained.

Many research projects hand out a printed brochure during the initial contact. Add-on incentives will not be necessary for the majority of participants, but they are concerns for some individuals. Once all benefits have been explained, it is also necessary to explain the importance of the client's role in and responsibility to the study. This process helps to establish the rules, boundaries, and confidentiality of the project and to address reservations or concerns the participant may have. A Participant's Guide to Alcoholism Research (appendix A) is a handy take-away summary of this discussion for the potential participant. Be sure to—

- Describe the assessment and followup procedures. It is much easier to explain the followup process initially than to surprise the participant with this information during the followup phase.

- Describe the notification process, emphasizing that it is important to notify the researcher if an appointment must be changed. This is especially true if the participant's circumstances change, since any change, positive or negative, can make it difficult to contact the client for an appointment.

- Review the procedures for laboratory work that may be necessary on specific target dates during the followup.

- Indicate that some or all of the interviews may be audiotaped or videotaped.

- Explain the importance of a collateral person in maintaining contact with participants if they move or become otherwise unavailable.

- Obtain informed consent to use enhanced measures, including but not limited to public access locator services if the participant moves with no forwarding address. This may include naming a locator or person who can be trusted to forward a message in the event the research assistant is not able to reach the participant by the usual means.

- Describe the nature of the release of information to others in an effort to locate the participant. The ability to go outside the common methods of contact should be discussed and written consent obtained, preferably in the informed consent form.

- Reassure participants that research assistants will not disclose the nature of their inquiry except to say that it is "personal business." On the rare occasion when someone refuses to answer questions regarding the whereabouts of

the participant, the research staff will leave a telephone number for a return call. If that call is returned, confidentiality is maintained because the telephone is answered simply with "Good afternoon, this is (Name)." That way, people who may want to gather more information than the staff is able and willing to divulge are prevented from retrieving it in unscrupulous ways.

A standardized letter informing participants that the clinical phase is complete and that the followup research phase will begin with the research assistant during the next scheduled interview helps to orient participants. The research assistant can remind them that during these interviews, specific questions will be asked for research purposes only.

The research assistant should also specify that if unusual circumstances arise that do not fall into the researcher's purview, the help of another team member, who is better equipped to handle the situation, will be requested while maintaining confidentiality. This keeps things in perspective for participants and enables them to realize that the research assistant is not a therapist and is part of a team.

Establish Appropriate Incentives

Often clients do not want to continue participating in a research study because of barriers that make it difficult to meet the requirements of the protocols. In acknowledging these barriers, the research staff usually finds a tangible problem that is relatively neutral and that can, in many instances, be eliminated. Identification and removal of such barriers is a form of positive social reinforcement that encourages participants to complete the research.

The following are examples of ways to meet general needs, reduce barriers, and increase participant satisfaction.

Transportation

- Make free parking passes available.
- Reimburse for cab or bus fare.
- Provide local bus schedules and telephone numbers for taxi service.
- Make home visits an option. There may be times when a person is unable to leave home for an interview. However, for personal safety reasons, two research assistants should go on home visits.

Childcare

- Arrange prescheduled childcare during assessments.
- Reimburse for babysitting.

Assessment schedule

- Make early morning and evening appointments available.
- Have weekend appointment slots available.
- Be willing to schedule assessments on holidays.

Culture

- Have bilingual staff available for assessments.
- Provide cultural sensitivity training to all staff.
- Have waiting areas for family who accompany participants.

Gratuities

- Provide simple snacks after the assessment.
- Arrange for participation milestone giveaways.
- Develop a periodic newsletter for all participants that describes study progress.

Be Proactive Toward Compliance

Much as in the business world, clinical researchers must realize that the goodwill of its customers—the participants—keeps it in business. Promoting this goodwill means that "the customer is always right." Rapid, courteous attention to client concerns promotes client satisfaction. Conversely, participants can become irritated when their time is wasted or their questions go unanswered. Amid the demands of multiple responsibilities, research staff can easily overlook a participant's request, tune out complaints, or simply overlook a waiting client. This combination of circumstances generally has a negative impact on participants and reinforces any reservations they might have about continuing with the trial. Preventing this type of reactive circumstance requires adequate numbers of research staff that have been trained in customer relations. The following are healthy habits to promote among the research staff.

Appointments

- Have a staff member greet the participant upon arrival for an appointment.
- Begin the assessment on time and finish on time.
- Give adequate lead time if an appointment must be rescheduled.

- Arrange for a substitute interviewer if rescheduling is not possible.

Participant queries

- Return participant telephone calls promptly.
- Show flexibility where possible or offer explanations when participant requests violate protocols.
- Offer to obtain information when you do not know.

Personality clashes

- Avoid arguing with a participant.
- Respond positively to participants even if they are wrong and you are right.
- Offer to have participants air their complaints with a higher authority.
- Discuss conflicts with supervisory staff in a timely manner.

Understand the Circumstances

By the very fact of needing treatment for alcohol involvement, the lives of participants are disrupted. Often participants tell research staff about events in their lives that affect their ability to continue in the trial. One of these is deciding to seek additional treatment. In this case, the response of staff should be guided by the research protocol. Usually, participants seeking nontrial treatment are referred to the project manager, who then follows the protocol established for these situations. The research staff member receiving such a request can explain this process to participants and reassure them that the matter will be addressed.

At other times, participant requests might be unrelated to the conditions of the trial but influence the participant's ability or motivation to continue.

> Harry G. arrives at the assessment appointment clearly having a bad day. You remark on his obvious agitation and are greeted with a string of expletives directed at Harry's car, which apparently failed for the third time in 2 weeks. In sympathy for Harry's fate, you attempt to soothe troubled waters, acknowledging that Harry overcame a difficult irritation and kept his appointment. You then offer to reimburse Harry for the cab fare he spent getting to the appointment. The offer surprises Harry, and he calms down. He apologizes for his outburst and declines the offer, stating that he would settle for the name of a good mechanic. You remark that another interviewer on the project who lives in his part of the city recently had his car repaired. You offer to call the interviewer after completing the assessment and see if the interviewer would recommend his mechanic to Harry. Harry looks hopeful, and you begin the interview.

The type of situation illustrated above has the potential for taking a more negative turn than described here. Recognizing the strain on a participant is a skill to promote among your research staff. Usually, but not always, reflective listening to allow participants to clarify what you are hearing will defuse their agitation. Sometimes, as in the example above, the research assistant can offer helpful suggestions. The principle to remember is that adopting a positive regard for clients can avoid further aggravating the situation and promote satisfaction with the clients' decision to participate.

Use Prompts and Reminders

Most people today have demanding schedules. For people in an alcohol treatment study, their usual routine may be further complicated by the time they spend addressing their alcohol problems.

It is not only important but also indicates the professional nature of a study to schedule followup appointments with participants' input. They become a partner in the followup process when they schedule times and dates that are convenient for them. As with any appointments that are scheduled, be they with a dentist, doctor, or other professional, appointment cards are issued. Reminder notes (that can easily be personalized with a computerized system) and telephone calls reinforce the importance of notifying the participant and the agency of changes.

- Time is an important factor for most people. Ask participants what time is best for them to be reached at home or at the location of their choice.

- Setting the next followup appointment while the participant is with the research assistant helps ensure compliance with that time and date. For instance, if the target date for the next interview is in 6 months, the research assistant could say: "I have Tuesday morning, April 4, open and Friday afternoon, April 6. Is it easier for you to come in during the morning or the afternoon? I'll pencil you in now so I'll be sure to have plenty of time to see you."

- It is important to allow participants to have limited control over the scheduling of interviews. Give the choice of what time and date the interview will be conducted but not the choice *that* it will be scheduled, although participants always have that option. Respecting participants' time is demonstrated by scheduling their next appointment, even if it is a telephone interview. Of course, there will be times when either the participant or research assistant needs to reschedule. However, since the appointment is clearly set and the

best times to reach the participants are recorded, it is easy for either party to reschedule by telephone.

- An advantage to making appointments well in advance is that the coordinator and staff can set up their work schedules accordingly and thus ensure the necessary coverage. Once the interview time and date are determined, write the information down in the appointment book or enter it into the computer tracking system.

- Give a business card, preferably with a distinct logo specific to the study, to the participant with all the necessary information about the next interview. This includes the time, date, location, and whether it will be conducted over the telephone, as a home visit, or on site. Also include the name and telephone number of the person who will be conducting the next interview or a person to contact in the event the participant has a question or problem. This technique minimizes the possibility of participants making excuses about not knowing when or where the interview was to be conducted or whom to contact to notify of a change.

- Approximately 2 weeks prior to the scheduled interview, mail a target-date-specific confirmation letter (appendix B). This letter should include which interview this is—for example, the second followup interview; a reminder of the compensation, if any, to be paid; and the importance of completing the interview. Include any pertinent information discussed at the time the interview was scheduled.

- Three days prior to the interview, telephone the participant to confirm the appointment. This provides a pleasant transition to the interview, and it allows the research assistant to quickly assess any significant changes in the participant's life and motivation to continue with the study. It also alerts the research assistant if the telephone has been disconnected or the number changed. Appropriate actions can then be taken to locate participants while they are still in range.

Negotiate an Explicit Contract

It is important to gain participants' consent in advance for the research team to go to great lengths to relocate and reconnect them to the study if normal procedures break down. The idea is to raise participants' awareness that problems do occur and that it is critical to the integrity of the study to keep them involved, no matter what happens in their lives. It is helpful to talk about other people who have experienced circumstances similar to the individual being interviewed. This is usually framed as "some people" and serves to normalize compliance problems as well as to educate

the participant about common reasons for noncompliance and how the noncompliance was resolved.

> *Interviewer*: Let's talk about how we should handle it if you become concerned about your privacy in the next 2 years and decide that you don't want to be interviewed.
>
> *Participant:* That's just not going to happen. If you do what you say you are going to do, then I shouldn't have to be concerned.
>
> *I*: I think you are saying that if we follow our own procedures, the information you give us will be kept confidential. Is that right? ("Yes, that's correct.") The laws are clear about what official information we can release to outside parties. But I'm more concerned about the informal breach of privacy that participants sometimes complain about. For example, research assistants calling you at home, leaving messages at work, or interviewing a family member as a collateral informant for the study. We get complaints about these things even though we have your permission to call and leave messages. For instance, I remember one case where a guy nearly dropped out because he told his wife he had come for an interview. She discovered it when we called to reschedule the appointment, and they got into a big fight.
>
> *P*: I guess I can just be up front about what I'm doing, to you and my wife.
>
> *I*: So, you'll tell us if you have any concerns about confidentiality rather than break the research agreement?

Early Warnings

Gilbert and Maxwell (1987) suggest an "early warning system" that alerts researchers when a participant is at high risk for dropping out. They indicate that knowledge of an individual's status in treatment can substantially reduce the error in predicting attendance at followup evaluations. This is important, since early dropout from treatment is most predictive of difficulty completing the followup evaluation at 3 to 6 months postdischarge. An early warning system for increased risk of attrition will allow followup efforts to focus on preventing attrition.

The following lists some indicators of potential problems that can arise with participants and eventually lead to noncompliance. Although these indicators do not always signal a problem, they are often precursors and demand attention.

- Early dropout from treatment
- Expressed dissatisfaction with some aspect of treatment (e.g., treatment assignment, therapist style)
- Clients who were court ordered to participate in the treatment program from which they were recruited

- Negative experience with facility (e.g., broken appointment, car theft)
- Expressed dissatisfaction about some aspect of the research study
- Participant is hard to schedule, misses a followup, or does not return calls when messages are left on the answering machine
- Relapse or other manifestation of clinical deterioration (e.g., comes to appointments intoxicated)
- Participant has stopped drinking
- Unexpected social, occupational, or health event (e.g., filing for divorce, loss of job, detection of cancer, job promotion, transfer)
- Participant has temporary living conditions or does not have a permanent address (e.g., may be living with relatives or in a shelter)
- Disconnected or unlisted telephone
- Undelivered mail

Discuss Noncompliance

Certain interactional factors can easily be overlooked by an investigator not attuned to subtle cues, such as participant expectations, that influence compliance. These factors can be teased out in the process of determining eligibility, so that appropriate decision-making can occur. This approach highlights the importance of staff/participant interaction in maintaining compliance. In the following example, the investigator explores the client's specific expectation about the reward he will gain through participation. It becomes clear that he has not considered some of the potential costs of participating. Identifying this provides an opportunity to discuss a solution to this potential source of noncompliance:

I: Tell me about why you are interested in participating.

P: I think I'll get something different, hopefully something better than what I got the last time I was in treatment.

I: So you were disappointed with what you received when you were treated before? Is that right?

P: You bet. I knew that I had a drinking problem, but they wanted me to totally change my life. The hardest part was asking me to spill my guts to a total stranger! No way am I going to walk into a room full of strangers and talk about my business.

I: How do you think this study will be different? You will still have to talk about very personal matters with a variety of our staff members.

P: That's the point, they will be staff members. I know it will be confidential. I don't mind owning up to what I've done; I just don't want this to get back to anyone outside this office.

I: I understand it is important for you to protect your confidentiality. We have built many safeguards into the design of the study for just that reason: to protect your confidentiality. However, there are some things we can't guarantee. For instance, some people will need to find out about the fact that you are here because we ask you to give us the names of some individual who will know about your status and your whereabouts. The other thing is that this is a big hospital. You may run into some people who know you when you come in for an appointment. How will you handle that?