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STRATEGIES FOR FACILITATING PROTOCOL COMPLIANCE IN ALCOHOLISM TREATMENT RESEARCH

PROJECT MATCH MONOGRAPH SERIES

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Project MATCH Monograph Series
Volume 7

Strategies for Facilitating Protocol Compliance in Alcoholism Treatment Research

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While the authors of this monograph were intimately involved in designing the methods and procedures described here for facilitating compliance with research protocols, the issues and content represent the combined wisdom of the investigators and support staff involved in Project MATCH. We have drawn upon their knowledge and expertise in presenting the compliance strategies found to be effective in that study. We also wish to express our appreciation to Carolyn Kott Washburne, whose assistance with planning, organizing, and editing was enormously helpful. Special thanks to Cathy Nelson for her hard work and dedication in helping to pull together the final draft.

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Contents

Preface

Clinical trials typically require attention to two aspects of subject compliance: (1) compliance with the intervention being tested, for example, attending psychotherapy sessions and taking medications, and (2) compliance with the requirements of the research protocol, that is, attending data collection sessions and completing questions, providing biological specimens, and naming collaterals. Maximizing subject followup rates and completeness of the data base is essential to the internal validity of a trial. Volume 6 of the Project MATCH Monograph Series, *Improving Compliance With Alcoholism Treatment*, provides strategies for enhancing client compliance with psychosocial treatments, as well as therapist compliance with treatment protocols. This monograph describes methods for facilitating research compliance in a multisite clinical trial. Practical strategies are offered for retaining participants in trials and for gathering accurate data in a timely manner. Specific examples from Project MATCH are used to illustrate methods of enhancing research compliance.

The monograph begins with Zweben's discussion of how our experience with Project MATCH prompted us to write a volume on compliance with research. Then Carty, Rice, and Barrett discuss, in detail, practical strategies that have been used effectively to address common sources of noncompliance in alcoholism treatment outcome research. Such difficulties might be related to resource needs of clients (e.g., lack of transportation) or pressures that interfere with continuing with followup assessments and related matters (e.g., relapse). Also, this section examines how staff are trained to address compliance issues such as identifying early warning signs of noncompliance.

Barrett and Morse focus on developing a customized compliance strategy to deal with the individualized needs of participants. They discuss the different circumstances and needs of participants who require special handling. Particular focus is placed on how the worker can tip the decisional balance in favor of continued participation.

Next, Morse and Barrett address methods for maintaining collaterals in the research protocol. This is an important issue in alco-

holism treatment research since these data are necessary to validate self-report data on alcohol use and related measures.

Rice, Freda, and Lawson deal with setting up and maintaining an electronic data base for monitoring activities of participants. At issue is how to use these data to enhance compliance with the protocol. For example, they demonstrate ways to flag certain events that might be indicative of potential compliance problems, such as death in the family, marital separation, or loss of a job.

McRee discusses the role of the coordinating center in the organization of the trial. Emphasis is placed on how the training and supervisory activities of the MATCH Coordinating Center helped to maintain boundaries between data collection and therapy in Project MATCH. Specific examples from Project MATCH demonstrate how coordinating activities directly and indirectly promoted compliance with the research protocol and facilitated the accuracy of research reporting,

This volume is aimed at a wide audience of clinical researchers, including individuals planning to become investigators and those already involved in conducting clinical trials, research assistants, and practitioners in general. We recognize that the strategies presented in this monograph may be familiar to researchers especially those having extensive experience in conducting outcome research. What is new is the organizing framework for addressing compliance problems, the detailed description of the compliance strategies, and the systematic way in which these strategies are delivered. The authors hope this volume will be useful as a reference guide for researchers dedicated to enhancing research compliance in a problem-drinker population.

Why We Wrote This Monograph

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Background

Our motivation for developing this monograph on research compliance grew out of our involvement in a multisite treatment-matching study called Project MATCH (*M*atching *A*lcoholism *T*reatments to *C*lient *H*eterogeneity). In 1989, the National Institute of Alcohol Abuse and Alcoholism initiated a large-scale clinical trial to validate and extend prior matching hypotheses. It involved nine clinical research units throughout the United States. Individuals recruited into the study represented a heterogenous population as seen in typical inpatient and outpatient treatment facilities around the country.

These participants were randomized to one of three types of treatment: Cognitive-Behavioral Therapy, Motivational Enhancement Therapy, or Twelve-Step Facilitation. Clients were seen in two types of settings: outpatient and aftercare. In the latter settings, participants (N=1726) were assigned to one of the three MATCH treatments following a regimen of inpatient or intensive day treatment. They were followed for 15 months after the initiation of treatment (Project MATCH Research Group 1993, 1997, in press). In the continuation study of Project MATCH (1994–97), only participants in the outpatient settings (N=954) were followed up at 3 years after the initiation of treatment (Project MATCH Research Group, submitted).

In Project MATCH, as in any clinical trial, maintaining participants in followup was particularly critical to the success of the study, since losing a substantial proportion of subjects could result in having particular subgroups disproportionately represented. This would cause serious difficulties not only in testing the matching hypotheses but in interpreting treatment outcomes as well. The investigators would not be able to assert with any assurance that a specific treatment could account for differences found among clients (Flick 1988). Thus, any conclusions drawn about the study would be weakened by having a substantial number of participants dropping out.

Challenges to Compliance

Matching studies are specifically designed to answer questions about what kinds of treatments are suitable or not suitable for certain kinds of participants or situations (Carroll et al. 1994). Thus, it is necessary to include a large, heterogenous sample population that varies in problem severity, demographics, and individual social and coping resources while employing treatments that vary in philosophy, theoretical orientation, treatment goals, and treatment intensity (Donovan et al. 1994). The high degree of variability in the client population and the contrasts across treatments usually result in various subsets of clients deriving important benefits from particular treatments (i.e., matching) while others do not (i.e., mismatching). More specifically, this means that sizable proportions of clients will likely be assigned to treatments that are unrelated to their particular needs, capabilities, and resources.

Clients' aversive reactions to treatment often carry over to followup, since participants do not routinely distinguish between them. Research has shown that such negative reactions on the part of participants often lead to future compliance problems (Stout et al. 1996). Thus, as in all outcome studies, but perhaps more so in matching studies, investigators are continually confronted with the daunting task of obtaining valid outcome data from a sizable number of clients who have aversive reactions to their treatment assignments.

Moreover, contrary to conventional wisdom, it cannot be assumed that all compliance problems in alcoholism treatment research stem from the negative experiences of participants in the treatment setting. Increased work and family responsibilities resulting from an improvement in the drinking behavior can account for some individuals having difficulties remaining committed to the research. These persons may become less motivated as they become increasingly involved in day-to-day activities. Not surprisingly, they may want to forget that time in their lives when they engaged in excessive alcohol use. Evidence suggests that individuals refusing further contact (in contrast to those lost at followup) do as well as those who remain in the study (Silverman and Beech 1979).

At the same time, there is an ongoing concern that the high task demands placed upon clients could contribute to low attrition rates, especially among individuals residing in socially unstable settings. This was a concern in Project MATCH, since clients had to undergo extensive testing on a regular basis, and much of the information was not used for treatment purposes.

In addition, the length of the followup period in Project MATCH (15 months for aftercare clients and 39 months for outpatient

clients) was seen as creating potential compliance problems. A rule of thumb in outcome research is that the longer the posttreatment period, the greater the number of difficulties in maintaining participation. Studies have shown that the number of hardships stemming from drinking (e.g., family problems) is a significant predictor of noncompliance (Zweben et al. 1988). Given the day-to-day pressures experienced by clients, the length of time between intake and the final followup appointment could conceivably have a negative impact on the research.

Thus, it became apparent in Project MATCH that much thought and preparation would be needed to deal with compliance problems. Without an adequate plan, there was a strong possibility of substantial numbers of participants dropping out from both treatment and followup. Therefore, it was deemed necessary to devise a trialwide strategy for addressing compliance issues. The investigators and staff drew upon their knowledge of the compliance literature and experience in conducting outcome studies to develop a coherent framework for dealing with compliance problems across different clinical research settings. The next section describes the conceptual framework that guided trial investigators in their attempts to define, measure, and maximize compliance with the protocol.

Research Compliance Model

In Project MATCH, as in many alcohol treatment outcome studies, compliance problems were viewed from a multidimensional perspective. That is, how well participants fulfill the research task demands is related to a combination of individual, interactional, and contextual issues.

- *Individual.*—Participants may be so frustrated or dissatisfied with their prior treatment experiences that they may be unable to engage in the research protocol. Or, because of problems associated with drinking, their lives may be too disorganized or stressful to meet the demands of the study.

- *Interactional.*—A lack of consensus between worker and participant about the latter's roles and responsibilities could lead to future compliance problems. For instance, a participant's uncertainty or ambivalence about undertaking the necessary research task demands may not have been adequately addressed in the pretreatment interview. It is not uncommon for participants to initially give lip service to carrying out the study requirements in order to gain access to innovative and free study treatments or reimbursement for the initial assessment interview. Others may participate to look good for an upcoming court appearance.

- *Contextual.*—Participants may encounter barriers in the setting that interfere with their commitment to the research, such as poor transportation, inconvenient office hours, and other obstacles (e.g., no Spanish-speaking workers, no childcare arrangements).

Recognizing that a number of issues affect participant involvement, the general approach undertaken in Project MATCH was to use information generally known about individuals afflicted with alcohol problems and the unique cultural, social, and personal circumstances of the individual client to develop a plan for maintaining the participant's involvement with the research protocol. The aims of these compliance strategies are to address concerns that arise during the course of the study *before* they result in serious noncompliance behaviors. This gives researchers a head start in reducing potential barriers (e.g., client resistance) that could eventually interfere with obtaining accurate data, thereby improving the efficiency of the research enterprise.

Practical Strategies

Alcoholism is a chronic disorder with unexpected relapses, family disorders, and social upheavals. Consequently, individuals afflicted with alcohol problems may require help at unexpected times. This dynamic interplay of personal, social, and situational factors requires a continuum of strategies to maintain participant involvement in and commitment to the research protocol. These strategies may involve reducing task demands on participants, such as administering a questionnaire via telephone rather than in person, or increasing support for participant involvement through a variety of outreach activities, such as conducting interviews in a participant's home instead of at the trial site.

Many of these strategies are geared to creating what has been termed a user-friendly environment. This usually entails choosing a site that is readily accessible, having flexible appointment times, and providing important amenities such as transportation vouchers, childcare, and emergency referrals. Such an approach helps participants balance concerns of everyday living with the demands of the research. This is especially important for those with limited resources.

Other strategies may involve the use of prompts, reinforcers, and incentives to facilitate client participation. This means that participants routinely receive brochures or pamphlets explaining followup procedures, letters or phone calls reminding them about appointment times, and trinkets such as mugs, tee shirts, and pens with the study logo on them. Also, clients are offered remuneration for providing blood and urine samples and for participating

in followup interviews. Together, these strategies help to reinforce commitment to the research.

Dealing with Difficult Clients

For most participants, the above strategies are sufficient to address anticipated or potential compliance problems in alcoholism treatment research. However, despite careful planning, some participants do not remain committed to the research protocol; their idiosyncratic circumstances have a negative impact on their involvement in the study. This requires adapting the protocol to address these particular circumstances or events and developing new strategies to deal with the unique concerns of these participants. For example, some clients may want to withdraw from the study after a period of heavy drinking. They may experience a great deal of guilt about their drinking and feel embarrassed about sharing this information with a followup worker. Some clients may be isolated from their family and friends and consequently lack the requisite support to continue in the study. Conventional strategies such as offering financial incentives for completing assessment interviews usually prove to be futile or counterproductive with such participants. Thus, innovative and creative methods are needed to maintain high followup rates.

A review of procedures employed in Project MATCH indicated a commonality in efforts made across the settings in responding to special needs or circumstances of participants. It is important to point out here that tailor-made or customized strategies were typically used when the commonly employed strategies were not successful in maintaining participants in the study. In this monograph, we have tried to integrate these experiences to show how the various strategies can be used differentially to deal with various kinds of compliance issues.

Finally, time and financial constraints of a study dictate an efficient use of strategies by tailoring the approach to reflect the capacities, needs, and resources of hard-to-reach participants. Using customized strategies does not necessarily mean you are working *harder* but rather working *smarter*.

Maintaining Boundaries Between Data Collection and Therapy

Obtaining subjects' compliance with the research protocol without compromising the integrity of the study has been a troublesome issue in outcome research. Research staff are expected to work at rapport building and help confirm a clients' commitment to the research protocol. Such involvement is expected to facilitate obtaining accurate and complete data from the client population. However, participants often fail to distinguish between research and clinical activities during the course of the study even though efforts are made to separate the different functions. Clients often

consider frequent followup interviews as equivalent to aftercare treatment (Sobell and Sobell 1982), and such blurring of clinical and data-collection roles may contaminate the results. If clients believe that the interviewers are more committed to helping them change their drinking behavior than to obtaining accurate and complete information, they may enhance their self-reports in order to give the interviewers what they think they want to hear.

Therefore, how to maintain the boundaries between research and therapeutic components is given serious attention in this monograph. The question is not whether social interaction between participants and research staff could become therapeutic but, rather, how to minimize this therapeutic component in followup. The concern is that research staff might cross over the boundary of data collection and serve in an active helping capacity with participants. To address this issue, Project MATCH established a coordinating center that was responsible for (1) the training, monitoring, and supervising of staff that collected the data generated in the trial and (2) the conduct and monitoring of the study treatments. These two functions were carried out in separate settings employing different staff members. Separating these functions helped to prevent the blurring of roles related to data gathering and therapy.

High Compliance Rates in Project MATCH

In Project MATCH, research compliance was simply defined as the extent to which a participant met the requirements of the followup protocol (Mattson and Delboca, submitted). This was measured by a variety of indicators such as attendance at followup sessions, timeliness of attendance, accuracy and completeness of data, provision of urine and blood specimens, and the identification of a collateral informant.

At the 15-month followup, 92.5 percent of Project MATCH participants were interviewed. Complete followup data were obtained on 95 percent of the participants at 15 months, and 85 percent at 39 months. The latter group included outpatient clients only. Further, the mean number of followups attended for the 15-month period was 4.45 (out of a total of 5 appointments); 83 percent of blood and urine samples were obtained at 15 months; and collateral information was collected on 75 percent of the sample. At the same time, the self-report data were found to be highly accurate, as evidenced by the reliability and validity studies conducted during the course of the study (Project MATCH Research Group 1997).

Project MATCH compliance rates for the research protocol are excellent when compared with those reported in other studies. For example, Miller et al. (1994) in reviewing alcoholism treatment

outcome literature discovered that only 57 percent of studies could account for 85 percent of the cases at one or more followups. Moreover, in a large-scale study conducted by the National Institute on Drug Abuse, the average followup completion rate among the various research sites was 49 percent (Desmond et al. 1995).

Thus, our positive experiences in Project MATCH provided the impetus for developing this monograph on research compliance to share what was learned with other researchers.

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?

Handling Noncompliance

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This section focuses on procedures developed to maintain study participation for individuals who become lost or resist followup interviews. These methods were employed in Project MATCH when information could not be obtained by other means. Because many of them represent a deviation from standard interviewing techniques and may result in incomplete data, it is important that they be closely monitored.

Although all of these methods were used for Project MATCH to some degree, it seemed that the more organized and skilled the staff became, the less we had to rely on customized followup strategies. Nevertheless, no matter how well a staff organizes and anticipates, there will be some situations where they will need to adapt the followup in order to achieve high compliance rates. Some of the strategies described in this chapter may not be appropriate or feasible for every research study. We suggest that each research project prioritize its efforts and employ the strategies that are likely to offer the largest return in terms of complete and accurate data and high rates of continuation. Remember, *the goal is to minimize lost or contaminated data and maintain the active involvement of the participant.*

Addressing Compliance: A Balancing Act

As in other areas of health care, the practitioner is often the most important factor in preventing compliance problems (Meichenbaum and Turk 1987; Blackwell 1997). Many factors impinge on the participant's decision to cooperate with followup, and these factors must be considered in attempting to resolve noncompliance. Our approach reflects the belief that the research staff can take proactive steps to reduce noncompliance among clients who are having difficulties or expressing dissatisfaction with some elements of research participation.

Understanding Noncompliance

Adopting a proactive stance requires an understanding of the multidimensional causes of noncompliance and skill in negotiating the conditions of participation. The treatment outcome literature tells us that noncompliance does not necessarily mean that an individual has relapsed or is doing poorly. Missed appointments, or even a refusal to schedule a followup, do not necessarily indicate that someone is dissatisfied with the study.

Researchers have concluded that there is a role for persuasion in clinical research. While "persuasion" is not explicitly defined, it seems to incorporate elements of listening, encouraging, and using contingent rewards (Capaldi and Patterson 1987; Mackenzie et al. 1987; Robles et al. 1994; Strohmetz et al. 1990). These studies suggest that resistance can be overcome by procedures that establish and maintain rapport. The process of obtaining informed consent is critically important as well, as it not only educates the individual on the roles and responsibilities of participation, but also sets the stage for addressing later concerns.

Research teamwork has been found to be the best way to identify and resolve issues affecting participation (Young and Dombrowski 1989). Project MATCH achieved impressive compliance rates in part by establishing guidelines for the research staff to follow, setting up boilerplate letters for staff to use to fashion a personalized letter to someone refusing to schedule, and providing ongoing supervision and support. For instance, clients who were unable (or unwilling) to come to the research site for a followup interview were offered a home visit or an interview by telephone. Accordingly, two telephone versions of the primary assessment instruments on alcohol consumption were developed for special situations. Form 90-Q was used to obtain essential followup data from the participant. If participants were successfully engaged, they were invited to complete the more detailed Form 90-T.

Adapting the Protocol

Sometimes it becomes necessary to adapt the followup protocol in order to prevent attrition. This means that either some data elements or the standardization of collection procedures must be sacrificed in order to preserve the research agreement so that future interviews can be conducted. Deciding when and how to adapt the protocol requires an understanding of how missing data affect data analysis and good judgment regarding when to scale back the demands of participation in order to overcome resistance. "Some data are better than no data" is a reasonable rule of thumb for a clinical researcher.

Provisions should be made to allow research staff to adapt the followup protocol in order to prioritize the data elements and focus on obtaining the most important information when complete data are not possible. Regular meetings of the entire research

team can maximize opportunities for creative problemsolving about difficult situations and cases and provide mutual support, encouragement, and advice on how best to address noncompliance. They also allow the research investigator an opportunity to monitor the drift that can occur as staff adapt the protocol in order to engage resistant participants.

Flexibility and Timing

As George Vaillant (1983) so aptly said, "The alcoholic, like the unconscious, has little sense of time" (p. 308). Individuals whose lives are disorganized and chaotic are often not used to making and keeping appointments (Capaldi and Patterson 1987). Followup is given a low priority by these individuals, who are likely to be experiencing significant life events. During times of stress, they often need additional time and concrete support in order to follow through on their commitment (Robles et al. 1994). Flexibility with respect to the demands that the study places on clients increases the likelihood that they will complete the followup.

Research staff also need flexibility in the amount of time they are given to locate, schedule, and complete followup interviews with participants. Desmond (1995) points out that high followup rates are impossible to achieve when the staff faces strict time constraints. High rates of compliance with his group of highly unstable "lost" participants required more staff time to complete the interview (mean of 36 days from due date versus 3 days for controls), more travel to sites other than the treatment center (66 percent offsite versus 5 percent offsite for controls), and more flexible interviewing procedures because of the likelihood of meeting clients in a site not conducive to the exact protocol. Desmond states, "Doubling the size of the followup staff will not necessarily cut the time required [to obtain the data] in half." In other words, a research assistant may simply have to wait it out until the problem is resolved (or the participant sobers up) before the followup interview can be completed.

It is also important to remember that, at any moment, the participant's status may change. This can work for or against compliance. Sometimes postponing data collection results in lost data. Other times, postponing an interview is wise because it reduces the demands on an overloaded life and allows participants the time they need in order to resolve life problems. The client who is unable to comply given his present situation will often be able to meet his commitment later. It is important to communicate that the issue is not "if" but "how and when you are going to do the interview."

Develop a Plan

Often, compliance issues can be resolved by talking through participants' complaints or concerns about their role in the study.

This could be considered a "reinduction," because the initial experience of noncompliance provides an opportunity to review the informed consent and to reestablish an understanding about the costs and benefits of research participation as well as the importance of continuing in the study despite personal problems. In many cases, noncompliance can be easily resolved, and the participant will be no more likely than others to have further compliance problems. In other cases, however, compliance problems are ongoing, and high rates of data collection are achieved only with a considerable expenditure of staff time and energy directed at maintaining contact and persuading reluctant participants to continue.

This section describes three steps or stages for developing a plan to address serious or persistent noncompliance. Step 3 represents the most serious threat to the methodological integrity of the study, because in this stage the staff engage participants in a discussion of their problems and adjust the demands of the study in order to overcome their resistance. Staff are instructed to employ such specialized or customized strategies to resolve compliance problems only when routine procedures have failed.

A Plan to Address Compliance Problems

STEP 1	STEP 2	STEP 3
Categorize the noncompliance by *type*:	Construct a working hypothesis about the probable *source(s)* of noncompliance:	Construct a *plan* to resolve the noncompliance:
■ Lost	■ Situational factors	■ Locating strategies
■ Resistant	■ Interactional factors	■ Interactive strategies
• Difficult to schedule	■ Individual factors	■ Adaptive strategies
• Difficult to interview	• Relapse	
■ Refusing		

Step 1: Categorize

Moos and Bliss (1978) found a clear correlation between difficulty of followup and treatment outcome. They distinguished between *lost* and *resistant* participants and developed indexes of "locatability" and "cooperation," defined by both the number and the type of followup activities required to complete an interview. The two groups represented different potential sources of bias in the findings, and different approaches were required to retain them in the study. These results are consistent with other researchers (Armor et al. 1978; Sobell et al. 1984; Mackenzie et al. 1987), who state that the two groups of noncompliers are different on important dimen-

sions and require different followup strategies. Using Moos' typology, we have categorized participants into three types: lost, resistant, and refusing.

- *Lost* participants cannot be located. They have moved, disconnected or changed their telephone numbers, or taken other steps to make it difficult to locate them. Issues associated with lost participants have received considerable attention because they represent a major reason for missing followup data. Moos and Bliss (1978) define "locatability" by the number and type of information sources needed to find the current location of a lost participant. Thirty-six percent of their lost sample were found using institutional information sources in addition to, or instead of, known (baseline) information sources. More than half of this group required multiple other-agency contacts in order to be located. Lost participants tended to be more deteriorated than resistant subjects, but once found, they could usually be interviewed.

- *Resistant* participants are difficult to schedule and interview. They seem to want to be lost, but their location is known. They often cannot be reached, do not return telephone calls, or are very busy and resist efforts to engage them in scheduling or completing the interview. Some do not schedule or keep appointments because they are doing well and perhaps do not want to be reminded of a painful past (Sobell and Sobell 1981). For others, their condition has deteriorated. They are preoccupied with serious life problems, or they are reluctant to admit their "failure" to the research team with whom they have developed a relationship.

- *Refusing* clients have made a decision not to participate. This may be an impulsive decision, or it may have been carefully thought out, such as when they are doing well and want to distance themselves from anything to do with treatment or their alcoholic past. One approach to this refusal would be to accept it at face value as a decision to drop out and make no further attempts to reinvolve that person in the study. This may, in some instances, be appropriate. However, the circumstances behind these decisions are so varied that we recommend first trying to address these participants' problems with the study so that they may reconsider and continue participation.

The type of noncompliance determines the initial thrust of the customized approach. Obviously, a lost participant needs to be found before staff can determine whether there is a problem with cooperation. Clients who have not responded to repeated attempts to engage them are either experiencing significant life problems

or are ambivalent about continued participation in the study (Howard et al. 1986). In either case, the participant will need to be persuaded to become reinvolved with the study, and this may require some adapting of the followup.

Step 2: Construct A Working Hypothesis

The next step is making an informed guess (i.e., a working hypothesis) about the factors associated with the noncompliance based on a careful review of the history and circumstances of the case and developing a realistic plan for addressing the problem. By considering the wider context of the individual's social, cultural, and environmental surroundings, staff may be able to identify the factors that are blocking compliance. This often suggests ways to persuade the individual to continue in the study.

Factors That May Hinder Compliance

- *Interactional*: The participant is having a communication problem with a member of the research team.
- *Situational*: There are barriers to participation, such as the client not having money for transportation or childcare, or being in jail, hospitalized, or homeless.
- *Individual*: The participant's personal circumstances (e.g., depression, medical illness, wanting to forget the past) interferes with participation.
- *Relapse*: The participant has started drinking or using drugs and so is unwilling or unable to complete a followup interview at this time.

Noncompliance usually results from a confluence of factors that affect the participant's decisionmaking about continued involvement in the study (Strohmetz et al. 1990). It is helpful to be mindful of the instability of most participants' lives. They may be doing well or doing poorly. Do not rule out a possible source of trouble because it has not characterized the participant up to that point, and explore all potential sources of noncompliance. Remember what has been learned from other participants. Be creative. Ask questions such as—

- Are there small children and perhaps no one to babysit while she comes for her appointment? (*situational*)
- Has there been a domestic fight and he's no longer living at home? (*individual*)
- Is she drinking and afraid that she has let us down? (*interactional*).

Step 3: Construct A Plan

An adapted followup can include any combination of the strategies directed at relocating or gaining cooperation. While it may be possible to identify characteristics at intake that might lead to problems at followup, it is difficult to say which strategies will ultimately be successful in resolving a given situation (Moos and Bliss 1978). Therefore, the research team's approach needs to be flexible and persistent in the use of a range of available strategies. Documenting the incidents of noncompliance, and how they were resolved, will provide important clues for planning the approach.

Assuming the participant has been located, adapting the followup is usually a two-stage process that begins with trying to uncover the sources of the noncompliance and then offering to adapt (as necessary) the protocol to meet the individual circumstances. For someone who is about to drop out of the study, this may be the one and only chance to reconnect, so plan the approach carefully.

Plan for Resolving Noncompliance

- *Locate*

  Find the participant.
- *Interact*

  Engage the participant in a discussion about the problem with participation looking for possible solutions.
- *Adapt*

  Change the rewards or demands of the research to increase its attractiveness, paying attention to flexibility and timing.

Interactive strategies allow staff to learn how participants' circumstances and attitudes may have changed and provide an opportunity to remind them about the importance of their contribution to the study. If interactive strategies are not sufficient, then adaptive strategies should be employed. Listening to participants' concerns about the study and offering a choice from a range of mutually acceptable alternatives often results in their choosing to give the personal interview with no lost data.

Locating Lost Participants

At some point, this will surely happen to any followup researcher—an attempt to telephone a participant results in a recording that the number has been disconnected or changed to an unlisted number, or a letter is returned stamped "Return to sender. No forward order on file." The research assistant calls the locator, who is (or was) the participant's girlfriend, and she says they broke up and she has no knowledge of his whereabouts. The

research assistant feels particularly frustrated because she is fairly certain she could complete the interview if she could just find the participant. But for the moment, he is *lost.*

This is not an uncommon experience in longitudinal research. The longer the time in followup since treatment, the more difficult it is to locate the participants (Moos and Bliss 1978; Twitchell 1992). Yet every lost client represents a potential bias in the study and limits the generalizability of the data because the treatment outcome is unknown (Sobell et al. 1984; Strohmetz et al. 1990; Twitchell et al. 1992). Thus, we stress the importance of procedures to track and locate participants over time and in spite of their negative life events. Efforts put into locating lost participants generally pay off; once they are relocated, they can almost always be persuaded to continue in the study.

Useful information can be gathered from anyone who may be able to shed light on the participant's whereabouts or attitudes about involvement in the study. Consideration must be given to privacy and confidentiality, but there are many sources of information that can be tapped without revealing sensitive data about the participant.

Getting Started

The best way to proceed is to start by thinking about the possible sources of noncompliance. The reason why clients cannot be located may relate to a number of factors that have come to affect their status. This can include social and economic circumstances as well as beliefs, perceptions, and expectations. Review this participant's file to see if there has been a pattern of noncompliance or any new information that may shed light on his frame of reference. Is he trying to hide from someone or avoid the research team? Has he improved or has his situation deteriorated? Might he be institutionalized, homeless, or deceased?

Individual Factors

A research team may be unable to locate participants because they are trying to hide from someone, such as friends, family, business acquaintances, the police, social service agencies, or collection agencies. Keep in mind the natural history of alcoholism, with its ups and downs and many life events. Avoidance as a coping mechanism is common with this population and can be associated with either improved or deteriorated status. Given this fact, it should not be surprising to encounter avoidance behavior in the course of followup. The following case is an example of hiding from someone.

> At intake, Ed had asked to be contacted at his office for scheduling followup interviews. He gave his secretary as his collateral, saying he had no family or friends in the area. All went well for the five followups scheduled over the period of a year after treatment.

However, when the 3-year followup was due, Ed could not be located. The office telephone was disconnected; mail was returned with no forwarding address. His apartment address and telephone number were obtained through a locator service, but upon calling the number, we discovered that the telephone was no longer in service, and our letter sent to the new address was returned. We called Directory Assistance and were given another telephone number, which turned out to be the telephone number for Ed's ex-wife, who informed us that Ed had left the country to avoid making child support payments. We enlisted her help and were eventually able to call Ed at his European location and complete the interview by telephone.

Interactional Factors

It should be no surprise when clients have trouble communicating with others in their life, including the research team. Participants may be trying to hide from people, and these same people may be reluctant to help you find them.

Participants often drop out of sight because of a problem related to the study. Reasons for avoiding the research staff can be complex. Two of the most common causes are dissatisfaction with some aspect of the study (e.g., treatment assignment) and concern about confidentiality. Interactional factors are a challenge to overcome, but once the participant is located, skilled negotiation can almost always work out the issues so that data are not lost.

Situational Factors

If participants are not avoiding someone and cannot be reached through a collateral or locator, then it is likely that they are homeless, in a hospital or prison, or deceased. Given the unstable life of substance abusers, any of these situations is possible. Or the participant may be doing well and does not want to be reminded of bad times in the past. If clients can be found, there is a high probability that they will agree to be interviewed, although the followup protocol may need to be modified for their situation. Following are three common scenarios when a person cannot be located.

Doing well. Participants may be doing well and very busy with their new lives and may have put the project out of their minds. Silverman and Beech (1979) examined data on dropouts from treatment at a community mental health center and found that 80 percent who dropped out said that their problem had been resolved. While the percentage for substance abuse treatment dropouts doing well is likely to be far smaller, it still represents an important source of contamination of the data.

Finding someone who is doing well presents its own problems, because clients are less likely to show up at an institution such as an alcohol detoxification center where they could be located. They may have moved, changed their friends, changed jobs, and

changed the telephone number to an unlisted one. The following case is an example of doing well.

> Robert was lost for 11 months. Scheduling had always been an issue with him. He had moved several times but had always been willing to come in for the interview. His collateral was Sue, a long-time girlfriend who had been very cooperative in the past. He had no other family in the area but had assured us that Sue would always have his current location. This time was different. Sue had not spoken to or heard from him in almost a year. There was no forwarding address or telephone number. Robert was finally found through a Locator Service that provided a current address and telephone number. When contacted, Robert reported that he had married, started his own business, and was doing well. He stated that with all of the positive events in his life, he had "forgotten about the study." He had left no forwarding address because he was trying to avoid Sue. When assured that his current location would remain confidential, he was happy to provide an interview.

Not doing well. Participants in this category may be drinking heavily, seriously ill and hospitalized, or in jail, homeless, or in a detoxification or treatment facility. Locators may know the participants' location but may not be willing to say how to find them. They may be upset and disappointed with the participant or may even blame the research team for the relapse. Certain populations (e.g., veterans) with access to medical and social services often live in close proximity to the institution on which they depend. The good news is that this may help in locating the individual and complete the followup. The bad news is that research staff must weave their way through the red tape of an institution and act quickly to interview the clients before they leave. Since many of these places do not give out any information about residents and clients, and staff are not likely to have a valid consent for release of information, they may need to overcome some hurdles in order to contact the participant.

Deceased. Individuals with a history of alcohol problems have a high mortality rate due to accidents or alcohol-related medical problems. If the staff knows that participants' status has deteriorated or they had a history of severe medical problems, consider that they may be deceased and check with the coroner's office.

Relocation Strategies

Relocation efforts comprise a major part of the specialized activities within the compliance model. Twitchell et al. (1992) provide guidelines for followup structure and strategies to relocate lost participants. These guidelines emphasize obvious sources of information, such as family and friends, as well as official records and directories (motor vehicle and Social Security records, reverse telephone directories, marriage and death certificates).

In a longitudinal study with an unstable group of patients on methadone maintenance, Desmond et al. (1995) reported impressive compliance rates by incorporating strategies that emphasized institutional information sources and field work. A significant proportion (49 percent) of the sample was prematurely discharged from treatment and at risk for attrition from the study. These individuals required considerably more staff time and effort to locate and complete the interview because they were likely to have left the area, severed contact with the sponsoring agency, and encountered new problems secondary to their substance abuse. Forty percent of this group was found and interviewed in jail or prison, necessitating knowledge of and coordination with other institutional policies.

Sources of Information for Relocation

Known Sources	Institutional Sources
■ Last telephone number	■ Public data bases
■ Directory assistance and telephone directories	■ Locator service
■ Last address	■ Institutions
■ Mail service and directories	■ Field work
■ Collateral/locators and known informants	
■ Known associations	

Finding a lost participant requires that staff pull together all the information that has been gathered, especially that provided at intake. Membership in a fraternal organization (e.g., Moose Lodge) or another group in the community (e.g., a church) or inclusion in a special population (e.g., ethnic group, Vietnam Vets) may help to narrow the search. The more information that has been documented, the more leads staff will have to build on. Begin with the information provided by the participant at the last contact and, if this does not work, proceed to the more time-consuming strategies, such as institutional data bases and field work.

Known Sources of Information

Relocation starts with information that is already known, such as the last telephone number and address, the telephone number at work, the collateral or locator provided at the last contact, and other associations that are known about through their contact with the participant. In our experience, collateral informants have been the most productive sources of information about the status and location of a lost client. These individuals have often partici-

pated in collateral interviews and have a basis of trust and cooperation with the research staff.

Phone Directories

If the individual has moved and established telephone service at the new location, it will generally be given when you call the old number. If the new number is not given, try Directory Assistance under the full name and the last name with first initial (e.g., John Doe and J. Doe). The amount of help obtained from the operator depends on how the request is phrased. For instance, we called and said, "I'd like the telephone number for Lonnie Smith." The operator said, "There is no listing for that person." We called again and said, "I called the telephone number listed for Lonnie Smith at 159 Main Street and received a message that the number was no longer in service. Do you have a new listing for that address?" "The operator said "No, but I have an L. Smith at 13 Elm Street," and gave us the telephone number we were seeking. Perhaps giving more information sounded more credible, so the operator was more willing to try to help.

Another option is using an automated telephone directory. With the explosion of telemarketing, there are now CD-ROM telephone directories for sale that can be updated several times a year for an additional fee. Such directories are also available on the Internet. These automated directories can be very helpful *except* when the participant has an unlisted telephone number. Otherwise, staff can enter the telephone number and get the address, or enter the address and get the telephone number as well as addresses and telephone numbers of persons nearby. Reverse telephone directories, which are available at the library, are a hard-copy resource that lists the telephone subscriber (including unlisted numbers) by consecutive addresses within a given community. This can be a help if the staff knows clients' approximate address and suspect that they may be avoiding contact.

Mail Service and Directories

If the participant has moved, send a letter to the last known address and write on the envelope ACRDNF (address correction requested, do not forward). The letter will usually be returned with a new address or with "No forwarding address." We say "usually," because the postal service is now cutting back on the information it gives out. If a new address is received, note this in the file and send a new letter to the new address. Once the current address has been obtained, try to get the new telephone number from Directory Assistance or the CD-ROM telephone directory program.

Collaterals and Locators

When asked to name collateral informants, participants usually identify individuals who know them intimately and are invested in the outcome of their treatment. Usually, collaterals are involved in the study as an additional source of information about how the

participant is doing, so they will understand why staff is calling when a participant cannot be located. Thus, these individuals are the best source of information at any time in the study *unless* they are angry at the participant or the study itself or are no longer involved in the participant's life.

Locators are individuals who are likely to know the participant's whereabouts. Depending on the protocol for the study, there may or may not be a release of information for these persons on file. Without signed consent from the participant, staff will not be able to say why they are trying to locate the participant, and this often creates problems. Do not lie, and do not say things like, "Well, I can't say why I'm calling," which would create an air of suspicion, but give out only the most basic of information.

> Hello, this is Jan Smith from the West Haven VA Medical Center. I'm trying to get in touch with Joe Jones about completing a survey that he had agreed to do. He is no longer at the same address, but gave your name and number as a trusted friend who would know how to reach him. Is it possible that you could give me his new number or get a message to him that I am trying to reach him?

Locators may not trust you and may incorrectly suspect your reasons for trying to locate the participant. For instance, they may think that you are from a collection agency. The *most* important thing is to protect the anonymity of the participant. If the locator is suspicious and uncooperative at this moment, it is likely that a carefully crafted letter will dispel the questions. Better to be patient and have a later opportunity to contact the lost individual than to violate confidentiality. Staff should always try to end a telephone call asking for permission to contact the locator again. For instance, you might say, "If I don't hear from [participant] in a few days [or weeks, if appropriate], would you mind if I call again to see if you have heard from him?" This maintains a communication link with the locators and, while they might not bother to call you with information, they are usually more receptive to talking with you on another occasion.

Institutional Sources of Information

Institutional sources of information are more important with less socially stable population groups and with individuals who have few close relationships. This may influence how unique identifiers are collected and information is tracked at intake. It is important to obtain identifiers such as Social Security Numbers in order to use public data bases to seek lost participants. It is also important to obtain consent to use these sources of information. This section describes how to obtain information from sources other than what the client provides at intake.

Public Data Bases Historically, researchers have used the most readily available sources of information, such as telephone directories, and public records, such as those at the Veterans' Administration, the Social Security Administration, and the Department of Motor Vehicles (DMV). However, recent rulings on the confidentiality of public domain information as well as concerns about individual privacy and safety jeopardize these relocation tools. For instance, when Project MATCH began, we expected to rely on DMV records to track lost participants. However, during the course of the study, a change in public policy made these records off limits in some states without specific consent from the individual to access this information. Obtaining consent at the beginning of the study to access public data bases will simplify your job if someone becomes lost.

Locator Services Locator services provide another way to access comprehensive, updated information. These services are routinely used by business, marketing, and credit firms to verify information or track the location of individuals in the United States. They can be helpful when other sources have failed to produce a current address or telephone number.

Locator services create a data bank using a number of public domain directories, such as Social Security Administration files, U.S. Post Office National Change of Address files, telephone directory files, and credit information from banks, credit unions, and other sources of commercial credit. Access to the more sensitive information in the data bank (such as credit history) is restricted to qualified credit agencies.

Gaining access to the locator data base requires a contract with the host agency, which then links up computer access via personal computer and modem located at the research site. This process does not compromise confidentiality, because the research staff conduct the search. The identity of the participant is not revealed to any outside entity.

A limitation of this service is its reliance on credit history, telephone directories, and so forth. It is unlikely that participants will be applying for credit, and they may not even have a telephone. Try repeating the query every 6 months for a persistently lost participant. For more information on locator services, contact any credit agency.

Jails or Prisons If staff know or suspect that the participant is in jail, they can call a correctional facility telephone number for that State (in the blue pages) and ask them to check their computer to see if the participant is an inmate and, if so, at what location. For instance, by

calling the central correctional facility in New Haven, Connecticut, we located a participant in the Bridgeport facility.

Given the security concerns in prison institutions, staff will need to follow certain procedures to gain access to an incarcerated individual. These adaptations are time consuming and, therefore, expensive. However, a participant who is incarcerated is usually happy to have a visitor. In addition, staff has relative assurance that the individual will be sober at the time of the interview. Do not delay in arranging an interview, since the incarcerated person may be moved to another facility or released without notice.

The first contact at the institution will probably be a switchboard operator who will refer the caller to a supervisor or the counselor in charge of the inmate. It is unlikely that the project will have a release of information for this institution, so the research assistant will need to ask the counselor to inform the participant that the project is attempting contact and needs verbal consent so the

Locating and Scheduling Individuals in Correctional Facilities

- Call the correctional facility (phone number in blue pages of telephone directory).
- Introduce yourself as a professional associated with a university or hospital study.
- Ask the person who answers to check their computer to confirm that your participant is incarcerated and at what facility.
- Call the appropriate facility and explain that you would like to arrange a professional interview. (You will be referred to a supervisor or counselor.)
- Ask the supervisor or counselor for the appropriate procedure for arranging a professional interview and follow that exactly. You will probably need to call again at a prearranged time or send an individualized letter to the participant to request permission to conduct the interview. Get exact instructions on how to set or confirm the interview date and time.
- Ask participants how they want the payment handled. Cash may need to be checked with the cashier. Obtain a receipt and send a copy to the participant.
- For an interview conducted on site, leave your purse or brief case in your car, dress professionally, and carefully follow the institution's regulations for visitors.
- Bring photo identification and a letter of introduction with the participant's full name and date of birth.

research assistant can explain the reason for a visit. The research assistant then calls back at a designated time and finalizes arrangements for the interview. An alternative method is to write to the participant or to leave a message for the participant to call the project. Inmates are generally allowed to place collect telephone calls for a limited period of time.

Prison interviewing environments vary considerably, from the inmate's cell to the prison cafeteria to private interviewing rooms. The person doing the followup should be someone who will feel comfortable in a prison environment. For example, an interviewer may have to walk by inmates who will call out rude or sexual comments or ask for favors. It is also advisable to do these interviews in teams. Certain institutions, such as federal prisons, do not allow inmates to have personal contact with anyone outside of immediate family. In such cases, the protocol must be adapted so that followup data can be collected entirely by mail.

Institutions

Hospitals, recovery centers, halfway houses, and so forth usually have rules to protect the confidentiality of the residents. If the project does not know the name of the client's health care provider, contact the agency's administrative or social service department. Since it is unlikely that either the research project or the institution has consent to release information, research assistants can only say that they have spoken to the person in the past and that the person would probably be interested in knowing that they were calling. One method that works is to assume that the participant is a resident there and request that a message or a letter be forwarded.

Field Work

Drive-bys, canvassing a neighborhood, and networking with people who may know the whereabouts of an individual are last-resort measures to take when other, simpler strategies do not work. These strategies are time consuming and have some inherent risk, but they can pay off when other methods have failed. When doing field work, keep in mind that the personal safety of the researcher is a primary concern. Use a buddy system by working in pairs. Staff should also let their supervisor know where they are going and when they plan to return. If possible, have staff carry a cellular telephone so they can call in if a problem arises. Have current, detailed street maps of the area, and find out the kind of neighborhood the research assistant will be going into by asking a social worker, visiting nurse, or police officer. If necessary, schedule the trip in the morning when the streets are quieter and carry "pepper spray" (if legal in that State) as a deterrent for dogs or other unwanted confrontations.

Driving by the last known address can sometimes provide clues for finding the participant. If the residence is a house, the research

assistant can see if it is occupied or for sale. If people are out and about, she can say she is trying to get in touch with the participant and is wondering if perhaps he has moved. In our experience, people are more willing to provide information to someone in person, especially if that person looks and acts friendly. If the project is affiliated with an institution such as a university or hospital, an identification badge may help credibility. Leave pocketbook or wallet locked in the trunk and dress in clothing appropriate for the setting.

If the participant lived in a rental home or apartment, the research assistant can try contacting the landlord to see if he knows the location of the participant. Usually a telephone call to the city or town tax collector will generate the name of the owner of the property. If there has been a problem with the participant, the landlord will often be more than willing to share the story. If he refuses to share information but indicates some knowledge of the participant, the research assistant can ask to leave a message. If he agrees, then he is probably in contact with the participant. If the landlord questions the reason for the call, explain that it is a personal business call from the organization represented, for instance Brown University or Rhode Island Hospital. Very often, the mention of a well-known facility is enough for a landlord to offer information about the participant. The research assistant can also go to the apartment building and look at the listing of names on the mailboxes to see if the participant is listed there.

If the research assistant suspects that clients are homeless, she can check around to discover where they tend to hang out, such as local food pantries or free meal programs. Go there and ask staff or other homeless persons to deliver a message to call the project. Homeless persons have an amazing communication network, and they appreciate the tangible rewards of research participation.

The following case is an example of a homeless participant who was literally living in a tree house. The case describes the research staff's step-by-step strategy for locating the participant.

> Mike presented at intake with a history of instability in both employment and residence, having lived as a homeless person for extended periods of his life. His characterization of those time periods was "a hobo's life." He had also been imprisoned at one time for a drug offense and received alcohol/drug treatment while incarcerated. He did not have a driver's license, worked for a temporary employment agency, and had no family in the area. He named one person, Leon, as both collateral and locator. During treatment, Mike had difficulty with abstinence, but he completed his treatment and the first two followup interviews without any problem. He was cooperative and seemed to want to be responsible. However, he frequently missed appointments and seemed oblivious to the importance of schedules. When he was

lost to followup, his locator reported he had not spoken to him and did not know of his whereabouts.

Working Hypothesis: Based on his history, it is likely that Mike is experiencing problems. He may or may not be in an institution. However, it is possible that he is simply homeless and in no particular crisis. The most promising plan for relocating him is to use his locator/collateral in the hope that Mike is still in the area and will turn up again. We assume he will cooperate with the interview if we can find him. Travel money may be necessary.

Strategies: (1) Send a letter to Leon asking his help locating Mike. (2) Consider a finder's fee if Leon helps us locate and interview Mike [if the IRB allows this]. (3) Assign a followup worker to call Leon periodically to update the status of the case. (4) Be prepared to canvas a neighborhood, or conduct the interview in the community, if Mike is sighted.

Outcome: Leon agrees to notify us if he sees or hears of Mike. The followup worker places routine calls on a monthly basis. On one occasion, Leon reports that a mutual friend has seen Mike, who is apparently living in the friend's son's tree house. This is likely to be temporary, however, because cold weather is coming, and Mike is likely to move to Florida. A drive-by is arranged in the area where we suspect Mike is living. Two research assistants are prepared to complete the interview if they can find him. Mike is sighted at a local convenience store getting a cup of coffee. The research assistants approach Mike and say, "Mike! We're from Project MATCH. We've been trying to find you to do your last followup. We have the money with us to give you when you complete the interview. How about we buy you breakfast and do the interview right now?" Mike agrees and completes the missing interview. Anticipating that he will move soon, the research assistants give Mike several stamped postcards to update his location, and a card with instructions to call the office collect if he moves.

Comment: In most instances, updated or additional locators would be the preferred strategy to maintain contact with a participant whose living situation is unstable. However, Mike has no enduring relationships and is likely to be lost again if steps are not taken to track his location between interviews. Cash incentives and the personal relationship with the research team are likely to be the best reinforcement for maintaining contact.

Deceased Participants

Large, longitudinal studies are certain to experience some deaths among the people enrolled. Information about the date and cause of death is important for the study as well for the alcohol field in general, because alcohol-related deaths are often underreported, leading to a misrepresentation of the true social costs of alcohol abuse (U.S. Department of Health and Human Services 1993). Notice of a participant's death most often occurs when a routine

letter or telephone call is returned by a family member. Other sources of information about mortality include obituaries and official death records.

When staff has determined that someone in the study has died, they must plan to obtain information for project records about the date and cause of death. Family, friends, or another person who was named by the participant as a collateral are the people most likely to provide the needed information. These individuals may have had previous contact with the research staff and, if so, will likely be happy to answer a few questions about the circumstances surrounding the death. It is important to inform the person that the information related to the death is needed in order to complete your record. Recognize that the family member may be grieving and not feel like talking about the cause of death. Appropriate concern and empathic telephone manners will help. Ask family members if they feel prepared to answer some questions. It is always possible to call again later if the person is emotionally distraught. The following case is an example of a conversation initiated after a letter was returned marked "deceased."

I: Hello, Mrs. Smith. This is Sue Miller from Project MATCH. I have spoken with you in the past. I just heard the sad news that your son Jim died.

L: Yes, he died October 7. I was out of town on vacation, and he was supposed to have dinner with his sisters. When he didn't show up or answer the telephone, they went over to his apartment and found him dead.

I: I'm so sorry. I was surprised at the news. Had he been sick?

L: Well, he had pneumonia and then an infection in his heart. I think it was his drinking. He kept promising me he would go for more treatment, but then he'd put it off.

I: I understand how that is. People with alcohol problems sometimes have such a hard time deciding to get help. How are you doing?

L: Not so good. I'm upset that I didn't get a chance to see him before he died.

I: That's hard, his dying suddenly like this. (Pause) I called mainly to express my condolences for your loss, and to thank you for your past help and your support of Jim while he was involved in the study. It has meant a lot to us. We're very sad to lose him. I need to ask you a few questions about the time and cause of death, but I know this may not be the best time. What do you think? Do you want me to call you back some other time?

L: No. I suppose this is as good as any. Is it going to take a long time?

Comment: This represents a sensitive handling of a difficult situation. The collateral is informed why she is being called and offered a choice about responding now or being called back later. Information obtained should be kept to a minimum, asking only what is needed for the data base. We have found that common courtesies help the grieving family feel that we are interested in more than just the facts. Following up the interview with a sympathy card is a good idea.

Another way to get needed information is to contact the local newspaper and ask for the obituary department. Give them the name of the deceased, and they will give the date of death. If it is known that the death was violent, contact the police department, using the project's letterhead. For a slight fee, they will honor a request and provide last known address and date of death. Another way to confirm the death is through the bureau of vital statistics in the city in which the person died. However, some cities require a relative of the deceased to request a death certificate.

Resistant or Refusing Participants

Once a lost participant is found, the goal is to schedule and complete the necessary interview and to obtain a renewed commitment to continue with the research study. For some individuals, the interaction is straightforward: the staff reminds them of their commitment, emphasizes the importance of their input, and proceeds with the routine protocol. For individuals easily reengaged, it is important that staff reinforce the participant's renewed commitment (such as, "That's great! We're really glad to have you back on board again! This will help us a lot!") and obtain additional information to prevent the participant from being lost again. These positive interactions should be a routine part of the social reinforcement that clients receive for their involvement.

For other individuals, relocation raises the more fundamental problem that they do not want to schedule an interview at this time. Many factors impinge on the participant's decision to cooperate or not with the followup. Staff will probably have to ask about the difficulties they are having in providing the requisite data and attempt to talk through the issues with them. What research assistants uncover may seem trivial or irrelevant, and they may feel annoyed by participants' actions or words. This reaction is normal. However, these actions are probably not directed at the research assistants personally, so they should approach each situation unencumbered by personal biases and avoid arguing or moralizing.

Remind staff that their job is to collect the data, not to provide therapy. They should focus on completing the interview and collecting the necessary data. If not successful in that regard, it is very important that they keep the door open to future contact and continued involvement in the study.

Interactive Strategies

This section is intended as a guide to use as staff negotiates the conditions of continued participation with resistant participants. The interactive strategies describe an attitude as well as a set of concrete steps to follow. They are designed to elicit important information about the participant's beliefs, expectations, and preferences, with the hope of identifying the source of the problem and a possible solution. The style of interaction is person-oriented as opposed to data-oriented.

Interactive Strategies

- Meet resistance with understanding, empathy, and respect
- Normalize or legitimize problems with the study
- Provide a rationale for involvement and a range of possible solutions

In practice, it is impossible to collect data and avoid at least some discussion of current problems or personal concerns (Maisto et al. 1985). However, it is imperative that the research assistant who engages a resistant participant recognize the importance of avoiding giving unnecessary support, advice, or referrals for treatment even when the client is in distress. Attentive listening to the personal experiences of the participant may result in the interviewer being perceived in a helping role. Regular clarification of the roles and responsibilities of research staff helps research assistants adhere to the research protocol.

Meet Resistance With Understanding, Empathy, and Respect

Numerous studies have cited the importance of empathy and understanding in promoting compliance with various health-care regimens (Chafetz et al. 1964; Meichenbaum and Turk 1987; Miller 1985). Robles et al. (1994) indicate that in their longitudinal study, resistant subjects were likely to be depressed, harried, and overwhelmed by recent events in their lives. These factors were associated with noncompliance, and their resolution was contingent on staff taking a posture of support and encouragement until the resistance dropped.

In Project MATCH, we found that acknowledging the difficulty that participants were experiencing was an effective way of communicating respect for their situation. That can be conveyed in a

simple phrase such as, "I understand. That must be hard for you." If the discussion reveals a fundamental problem with the study, it is important to know the nature of the complaint. Understanding the participant's perspective on the problem may provide an opportunity to influence the situation in question.

Normalize or Legitimize Problems

The research assistant should communicate to participants that other people in the study have experienced life problems that interfered with followup or have expressed reservations about continued involvement. In their longitudinal research, Capaldi and Patterson (1987) described the importance of legitimizing the experiences of subjects. They trained their research staff in communication skills, stressed that families are diverse in their lifestyles, and urged staff to communicate a sensitivity to the many problems facing families. This posture allows the research staff to empathize with the participant and avoid an adversarial relationship. It is also important that the staff member communicate that, while problems do occur, they can be resolved by coming to some compromise that meets the participant's needs while obtaining the necessary data.

Provide a Rationale

Providing a rationale for involvement is a highly individualized process that needs to reflect the context of the person's life and values. This represents the element of persuasion in the specialized strategies. The goal is to help the person decide to continue as an active research participant. It helps to know the previously identified motives for participation. For instance, it will make a big difference if participants initially identified "free treatment" as the primary reason for involvement. They may or may not be responsive to appeals to altruism.

People often express the belief that "my data won't help you." Somehow, they come to believe that if they never improved,

Rationale for Continued Participant Involvement

- Participation may not directly benefit the participant, but it will help others with the same problem.
- Dropping out diminishes the quality of information for the study and makes it hard to draw conclusions about the helpfulness of treatment.
- Many participants report some difficulty following the exact protocol. Some adjustments can be made to accommodate the individual's special circumstances.
- It is better to lose some data (i.e., miss an interview) than to have people drop out just because they cannot complete the interview at this time.

dropped out of treatment, or relapsed, they would not be able to provide helpful information. These individuals need encouragement and a reorientation about the value of their contribution. They need to be reminded that a research study learns as much from what does not work as it does from what does work for different individuals.

The following case demonstrates the importance of eliciting data from a man who had been lost and who is clearly discouraged.

> Jim had experienced many problems during the course of the study. He relapsed during the treatment phase and was hospitalized twice during followup. His wife left him and filed for divorce, and for some time we could not locate him. During periods of relative stability, Jim lived with his mother, whom he named as both locator and collateral. She had cooperated with past attempts to contact Jim. This time, however, he is lost and she says that she does not know his whereabouts. The research staff think that Jim's mother is hiding him. This represents a change of behavior on her part and suggests that something about Jim's status has changed. The staff question whether he is really lost, but will accept her statement at face value until new information surfaces.
>
> *Plan*: (1) Call Jim's mother regularly to check on Jim's whereabouts. (2) Send a collateral letter to Jim's mother thanking her for past assistance and asking for her help getting a letter to Jim. Enclose with the collateral letter a letter addressed to Jim. Explain to the mother that participants generally want to be interviewed if we can locate them. (3) In the letter addressed to Jim, offer a plausible guess about why he was lost; remind him of the rewards of participation and reinforce the importance of knowing what happens to people over time. Also inform him of everything that has gone on between us and his mother, explaining that these steps are consistent with the research agreement he had signed at intake.
>
> *Outcome*: Contact is made with Jim's mother. We ask if she has received our letter, and she says yes. We ask if she would be able to help us get in contact with Jim. She says, "Why don't you ask him yourself, he's right here." The staff expresses appreciation to Jim for agreeing to talk to us and reminds him of the importance to the study of complete information on all participants. Jim's telephone demeanor is brusque, gruff, and guarded.
>
> *Working Hypothesis*: Based on Jim's history and his demeanor with the interviewer, it seems that he is not committed to continuation and needs to be persuaded to remain in the study.
>
> *Strategies*: (1) Ask about the noncompliance (assuming he is lost and not resistant or refusing) and explore his thinking about continuation. (2) Offer a rationale for his continued involvement that may address some of his concerns. (3) Use financial incen-

tives or adapt the task demands to fit Jim's current situation. The following is an excerpt from the conversation.

I: So, you received our letter. We appreciate the help your mom has given us in reaching you. Are you able to set an appointment?

P: Yeah, I suppose so, but this is going to have to be the last one.

I: Is there a problem with you continuing after this appointment?

P: I just got out of the hospital, and I'm spending all of my time going to meetings so I don't go back to drinking.

I: It seems like you are busy and you don't have the time to come for an interview. We can make some adjustments to make it less demanding of your time. We can come to you, or even do it over the telephone. What do you think?

P: That's not the point. I just don't have anything new to tell you. I don't know if you know how it is, but it's hell to recover from this disease. I do okay for awhile, but it seems I can't get very far away from my next drink. The only thing I know to do is go to meetings. I don't see any point in coming in and going over the same questions. Anything I have to say, I've already said.

Comment: It is disheartening for Jim to come in repeatedly and tell us of his failures. The research assistant communicates empathy and understanding, while asking for information about his problem. Still, it seems he will need another reason to continue in the followup.

I: You've been through a lot trying to overcome your problem. I understand that you're getting the help and support you need. Other people in the study have had similar experiences, and we've had to work with them so that they can take care of themselves. I hope you will give us a chance to do the same thing with you. We can learn a lot from people like yourself about how hard it is, and to what lengths people have to go to recover. I can understand why you say you don't have anything new to tell us, but from my viewpoint, you still have something important to contribute. We hate to lose you when you are so close to being finished. We could do a short telephone interview now, it would only take us about 5 minutes to answer some basic questions. We still want you to do the last scheduled followup interview in 6 months. That would give you some time to take care of your affairs.

Comment: As the investigator incorporates a number of specialized strategies in this case example, it is hard to say which strategy is successful. Jim's primary need is to be reassured that he is still valued and has something of importance to contribute. It seems that this is accomplished in a straightforward and respectful fashion that persuades Jim to continue despite his discouragement and his own belief that he has failed.

In cases like this, where the risk of attrition is high, it is helpful to educate the participant about the cost of attrition. Many people, like Jim, are not aware of the problems that occur when someone does not complete the followup. The message we give is "dropout diminishes our ability to draw conclusions about the helpfulness of treatment for people like yourself." This by itself may not dissuade an angry or disappointed participant to continue, but it may be enough to encourage a resister to reconsider or to consider another option (such as a call-back at another date) that preserves the research relationship.

Adaptive Strategies

If interactive strategies are unsuccessful, the next step is to attempt adaptive strategies. These can be added incrementally, because each represents a greater deviation from the standard protocol. This might involve removing aversive elements, increasing financial or other incentives to make participation more attractive, or, for cases of persistent refusal, encouraging the participant to delay decisionmaking until later. These steps provide an opportunity for the staff to review the case and influence the participant's decisionmaking about continued involvement. It may also give the client time to resolve the problems that are blocking participation. Identifying a range of options (all of which incorporate a *yes* to participation) and allowing the client to choose, is a highly effective approach to overcoming resistance. For most clients, it is the *perception* of choice that increases cooperation.

Adaptive Strategies

- Offer financial incentives
- Remove aversive elements
- Obtain partial data
- Delay decisionmaking
- Defer to a higher authority
- Accept no as temporary and situational
- When all else fails, accept the decision gracefully

Financial Incentives

While many participants identify altruistic motives for participation, it is clear that tangible rewards, including money, are an important part of the incentive package. We routinely remind clients about the benefits of participation, such as by saying, "I know you're not doing this for the money, but you will receive $25 for doing this followup." We present this as reimbursement for the time, travel, and service (feedback, data, opinions) provided. Institutions' human subjects committees usually have strict rules regarding participant reimbursement, so financial incentives must be in keeping with these.

Remove Aversive Elements

Some individuals object to certain elements of the protocol that they perceive as aversive. These may include giving laboratory specimens, completing the self-report forms, or traveling to a distant research office. Initiating a discussion about such issues may uncover reservations about an aspect of the protocol that, if eliminated, will resolve the problem.

Cooperating with the participant's preference communicates an attitude of respect and responsiveness, which seems to enhance the mutual, reciprocal nature of the research agreement. This interaction can also provide important feedback to the investigator about conditions that impact on the participation of other individuals. For instance, at one MATCH site, we heard complaints about a phlebotomist who was performing the blood specimen draw at the time of enrollment. Several people indicated that they were bruised by this staff member's technique. This problem represented considerable risk to compliance with the study because we were informing participants that we would be collecting blood samples every 3 months. We addressed the problem with the laboratory and then assured these participants that they would not have to worry about a recurrence of the problem. Listening to the complaint and recognizing that giving blood is very aversive for some individuals resulted in effective problem-solving.

Obtain Partial Data

Another option is to obtain only partial data when the participant is unwilling (or unable) to complete the entire interview. For instance, Project MATCH protocol called for a telephone version of the main drinking data interview (FORM 90-T), and a quick version of the daily drinking calendar (90-Q) for use when it was unlikely that the participant would schedule an inperson interview. When it appears that only partial data can be obtained, prioritize the measures for the interview so as to obtain the most critical information first. Sometimes, after participants have provided some basic information, they will feel reengaged with the study and agree to provide more complete data.

Delay Decisionmaking

If talking through the problem or adapting the research protocol does not resolve the compliance problem, it is best to delay the decision about continuation. Support for the technique of delayed commitment to change is well established (Kelman and Hovland 1953; Zweben et al. 1988). A participant who has relapsed may not feel like doing anything, but when sober again is likely to want to cooperate. Removing pressure to decide upon study participation will decrease the likelihood that individuals will drop out of the study as a means of resolving their current discomfort.

Defer to a Higher Authority

Sometimes, despite use of these strategies, a research assistant will be unable to obtain the participant's cooperation and agreement

to continue in the study. If clients refuse to do the interview, research assistants can indicate that they do not have the authority to "dissolve the research agreement" and request that they talk with the Principal Investigator. This emphasizes the importance of the decision and the value of the participant's contribution to the study. It also provides clients with another opportunity to rethink their decision. Also, a person of greater authority may be able to more effectively address the issues that concern the participant. In our experience, the Principal Investigator and Project Coordinator typically have the most success persuading resistant participants to continue.

Accept No as Temporary and Situational

Individuals have the right to decline continued involvement, and this right must be respected by the research team. However, a participant's no may be due to a temporary situation, such as a life crises or heavy drinking, and may not reflect an exact preference. In a sense, the process of engaging participants in a discussion about the problems with the study clarifies their thinking and allows a more careful decision about an important commitment. There is an ethical fine line here, because it may be difficult to determine if the decision to drop out is a current state of mind or a decision arrived at through a more intentional process. The research assistant can set the tone of cooperation by acknowledging the participants' perspective and respecting their choice but still offering another option.

The following statements are examples of adaptive strategies; the word in parentheses after each statement describes the type of adaptive strategy.

- I understand what you're saying about not wanting to continue in the study. (*acknowledgment*)

- This has come up with others, but it often is a matter of being *really* inconvenient to do the interview now. (*normalization*)

- I know that you understand how important it is to the integrity of the research to not lose participants, especially after so much time and energy on your part and ours. I know that the information you have to share may not seem helpful to you, but it will help others like yourself in the future. (*education*)

- I wonder if you would consider skipping this interview and allowing us to call you in 3 months to see if things have changed for you. If you still want to drop out of the study, you can let us know, and we will close your case. (*delaying decisionmaking*)

- If your situation is different and you are willing to do the interview, we can make an appointment. There won't be any problem making up the data we missed. (*providing a rationale*)

- We would pay you for both interviews because we would be covering the two full periods in one interview. (*offering financial incentives*)

The following case describes a surprising turnaround after the staff used several adaptive strategies.

Tori, a 40-year-old woman, participated in Project MATCH but dropped out of treatment, placing her in a high-risk category for research attrition. The research team had difficulty scheduling her for the first research followup, which further reinforced the tenuous nature of the relationship. Tori finally agreed to a home visit, but when the research assistant arrived, Tori refused to allow the interview to take place in the house. She denied any drinking and angrily declined to answer certain questions in the interview. She wrote on one self-report inventory, "NONE OF YOUR BUSINESS." This was interpreted as a clear message that the participant was not interested in continuing. She also declined to have her husband be interviewed as a collateral. Our guess was confirmed at the next scheduled interview. The participant said, "I don't want to continue."

Working Hypothesis: Staff suspect that Tori is drinking and that there is some conflict between her and her husband. A letter is sent, acknowledging her decision.

Strategies: Another letter is sent prior to the due date for the 15-month interview inviting Tori to reconsider her decision (appendix C). Tori responds by calling the investigator and requesting information about the interview. This is an opportunity to reinvolve her in the study. She is told: (1) We understand that she had her reasons for deciding to drop out 12 months ago; (2) she is welcomed back into the study and has a significant contribution to make; and (3) the missing information could be captured without much difficulty. We offered her several options, including another home visit, which she chose.

New Hypothesis: Tori has resolved the unknown obstacle to compliance and wants to complete her commitment and regain her sense of integrity. Providing a rationale for reinvolvement and reinforcement for her decision is critical.

Outcome: Upon arrival, the interviewers are invited in and shown the home Tori and her husband have built. When the discussion about the research agreement begins, Tori volunteers that she refused previously because of her heavy drinking. Her husband had been angry, refusing to allow her to drive because of the risk of an accident. He had refused to participate as collateral because

of her relapse. She had sobered up 8 months after that time and decided "to tell her story in the hope that it might help the alcoholic who is still suffering."

Comment: Respecting the participant's decision without interpreting her no as an absolute decision provided an opportunity for both the client and the researcher to end as winners. The source of her noncompliance was a combination of contextual, individual, and relapse factors: she cannot drive to the office for the interview, feels ashamed about her relapse, and does not want to acknowledge her drinking for fear it might further hurt her marriage. The particular approach used in this instance required the investigator to both respect the client's no and persist in a creative fashion with a variety of compliance strategies.

Accept the Decision Gracefully

It is inevitable in longitudinal research that some participants will not respond to attempts to reinvolve them and will assert their intention to withdraw from the study. This is their right, and it must be respected. When attempts to deter participants from dropping out do not work, it is important to express gratitude for their contribution to the study. We have found it helpful to follow this verbal exchange with a personalized letter from someone in authority (appendix C). This letter acknowledges the decision to quit and thanks the individual for contributing. It also identifies the means for getting reinvolved in case there is a change of heart at a later date. In some instances, this may include a statement informing the participant that there will be a notification of the due date of the last interview to provide an opportunity for reconsideration. This procedure should be cleared by each institution's IRB before using it.

Other Issues

No Treatment

One of the more difficult scenarios for the followup team occurs when a participant is enrolled in the study but receives no treatment. These participants feel less connected to the study and may even think that they are no longer part of it. The two most likely reasons why treatment is not received are (1) the participants are doing worse than expected or (2) they decide that alcohol treatment is not necessary. From the client's perspective, the reason may not matter. The fact remains that they received no treatment as part of their participation in the study, so one condition of the research agreement was not fulfilled.

When clients are doing worse than expected, it is likely that they cannot stop drinking and are in need of detoxification or hospitalization. They may have underreported their drinking at intake or relapsed to heavy drinking once enrolled in the study or the motivation for change may have decreased even though they

initially sought treatment. If participants have changed their minds about wanting treatment, staff is faced with the challenge of engaging them in a meaningful research relationship. It is likely that they will have to work hard throughout followup to reinforce participation and instill a sense of responsibility toward completing the study.

In such cases, staff should start by reviewing the research agreement. The case should be flagged as nonroutine and extra attention given to tracking and monitoring. Often these participants require help with concrete problems (for example, a treatment referral) in order to stabilize their condition. The factors behind the lack of treatment may not emerge for some time into the followup period. We have found the following steps to be helpful when no treatment was received.

- Inform the participants in writing that the decision to drop out of treatment does not invalidate their agreement to participate in followup (appendix C).
- Follow the letter with personal contact. Ask participants what they intend to do about followup appointments. This is best done by the Project Coordinator or Investigator.
- Be prepared to carry out various outreach activities to complete the first followup. Participants who comply with one interview are more likely to comply with others even if their condition deteriorates.

Clinical Deterioration

It is inevitable that some participants will suffer setbacks in their personal or interpersonal functioning. It is imperative that accommodations be made to provide support or referral services for medical, psychological, or substance abuse services when they are needed. Offering referral services when clients express a need is an informal incentive to participation that seems important to some individuals. However, many participants who make requests for additional help may not follow through on the referral given.

Treatment Referrals

Staff training and active involvement in the staffing of noncompliant cases provide vehicles for balancing personal relationships between staff and participants with methodologically sound ways of conducting followup. It is difficult for a research assistant to listen to a client's woes and not offer advice, encouragement, or active support. Thus, initiating treatment referrals is a topic that needs to be addressed in staff training and in the establishment of policies and procedures for all staff involved in the research. These policies and procedures may be influenced by the practices

of the host agency (for example, a VA hospital) or by criteria identified for the protection of human participants (IRB). Establishing clear policies for responding to clinical deterioration will prevent staff from undertaking an active helping role with clients. Several strategies are helpful in this regard.

- Inform participants that a treatment referral is available if required. This should be done at the same time that staff are reviewing roles and responsibilities for study participation.
- Give participants requesting a referral a list of treatment resources so they can call directly. However, research staff should take the initiative on a referral only if there is concern about the participant's personal safety or in another such emergency.
- Identify one staff member, perhaps the Project Coordinator, who is not involved in data collection as the person to contact if a referral is needed.

Mandatory Reporting Laws

Mandatory reporting laws pose a unique and special challenge for the research team. All individuals entering treatment need to be educated about the circumstances in which their confidentiality may be breached. This includes participants in a research study that provides treatment, because the same laws mandate that the therapist report certain crimes or events. In addition, information obtained outside the treatment relationship can create a situation that increases the likelihood of noncompliance because disclosure of some facts may result in unwanted social or legal consequences (for example, reporting suspected child abuse to protective services). Clients should be routinely reminded of the risks of reporting certain behaviors (such as planning to hurt themselves or someone else) and the protections in place for their privacy (such as a blind file, statements of confidentiality). Research assistants should also be required to report any problems or complaints that a participant voices. These should be carefully documented along with what action, if any, was taken.

Involving and Maintaining Collaterals

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Collecting data from collaterals to help substantiate the self-reports of participants is a component of many research protocols. In the absence of a specific biological test for current alcohol consumption and with concerns about the validity of self-reports, the use of collaterals increased from 54.1 percent during 1976-80 to 81.3 percent during 1980-84 (Sobell et al. 1987). However, surprisingly little has been written on how to *succeed* with collateral interviews. If collateral data are part of the research design, then we must assume its importance and attend to collateral interviews with the same care given to participant interviews.

Obtaining data from collaterals is often a problem in research studies that otherwise are progressing very well. If we consider the collaterals' perspective, we realize that they gain little, if anything, from the call. They are not being paid for the time involved. They are not the ones with the problem. They may not keep close track of the participant's drinking. Thus, they may not know the answers to some questions and feel as though they are not being helpful or that they should know and feel bad that they do not. They may also feel uneasy about "ratting" on a friend or family member. All of these reasons and perhaps others account for the evasions, unreturned calls, and sometimes outright hostility that research assistants confront when conducting collateral calls.

Collateral calls are difficult from the research assistant's perspective as well. Calls often need to be made in the evening after a long work day, and the collateral is usually a total stranger. There are many unknowns to face, such as the possibility that the collateral will be unpleasant or ask questions that make the research assistant uncomfortable. Also, there is the frustration of getting an answering machine with every call. This may cause the research

assistant to postpone making collateral calls or to be less persistent if the collateral does not answer the telephone on the first try. The problem compounds over time, diminishing the chances for completing the interview or obtaining accurate information.

In addition, a research assistant making collateral calls may decide that the data from a collateral is not as important as the rest of the data collected in the study and, being extremely busy anyway, may make only a minimal effort to pursue collaterals who are not easy to contact. Research assistants sometimes complain that doing the collateral telephone call is a waste of time, because often the person named by the participant does not know the answers to many of the questions asked. It is not surprising then that research assistants are often reluctant to undertake collateral telephone interviews.

Sometimes the job of doing collateral interviews is given to part-time people who may be less well trained in research techniques. This means they may be less prepared to negotiate with a collateral who wants to refuse an interview or less trained in how to contact hard-to-reach collaterals. Also, part-time people may not have a strong enough commitment to the project to make the extra effort needed for a high collateral compliance rate.

Consider the Many Dimensions

A multidimensional perspective works well as an approach for collateral interviews. Situational, interactional, and individual factors all come into play and interact during collateral data collection. For instance, a collateral interview is not completed because the collateral is hardly ever home (*situational*). The research interviewer is uncomfortable doing telephone interviews, so makes few attempts at contact (*individual*). When contacted, a collateral is angry at the research staff because the participant continues to drink, and the interviewer lacks the skill to negotiate the completion of the interview under these difficult conditions (*interactional*). Attention to these factors in designing the protocol, in staff selection and training, and in dealing with problems that occur will result in high collateral compliance rates.

This chapter presents methods for involving and maintaining collaterals in research according to the tasks to be accomplished by the various members of the research team: (1) the enrollment interviewer who obtains permission from the participant for collecting collateral data, (2) the Principal Investigator and Project Coordinator who will be setting the standard for adherence to the protocol, training the collateral interviewer, and providing support and incentives for doing the job, and (3) the collateral interviewer (usually a research assistant) who will be conducting the interview.

The Enrollment Interview

The first step for research that involves collateral interviews is to set the stage for these calls when participants enter the study. Taking some extra time in helping participants select a good collateral in the beginning is important, because it will help prevent problems later on. The interviewer should make it clear that "this should be someone who knows you well and knows about your drinking habits." Participants will need to sign a release of information that allows a member of the research staff to contact the collateral.

It is also important to clarify for participants that information they give will not be shared with the collateral, and information given by the collateral will not be shared with the participant. There are two reasons for this: (1) assuring confidentiality puts the participant at ease and thus more willing to name a collateral, and (2) most likely the participant will pass the information about confidentiality along to the collateral, which will later reinforce the interviewer's explanation to the collateral about confidentiality. A script for asking the participant's permission to contact a collateral will assure that everyone is asked in the same way.

To avoid bias and maintain independence of collateral data, the collateral interviewer should be different from the person who interviews the participant. Furthermore, the collateral interviewer should be kept blind regarding information obtained from the participant. Explaining this to participants will underscore the fact that no information about them will be shared with the collateral. The research assistant might say, "Another person on the research staff, who is not familiar with the information you've given me about yourself, will be making this call," once again reinforcing the policy about confidentiality. Going over the details relating to a collateral takes a bit of extra time at an intake session, but the effort will save time in the long run.

The research assistant should also inquire about the best time to call the collateral. Also ask "Is there anything else we should know about this person?" For instance, the collateral may speak a different language, and a bilingual person will need to do the interview. Or the collateral may have a drinking problem and be intoxicated at times. Make a note of pertinent information for the person who will be contacting the collateral. For instance, the participant might say, "My wife knows the most about my drinking habits, but she drinks too, so call her before noon, because after that she may be drinking."

Participants need to speak with their potential collaterals to tell them what to expect. The research assistant should ask participants to explain how much time will be involved and remind them that if the collateral is not willing to participate, they should

contact the research staff without delay to relay this information and provide another collateral.

Training Collateral Interviewers

Adequate training of the staff who will be doing the collateral interviews is essential. Collateral interviews and participant interviews are different, so research assistants trained for interviewing one group may not do as well with the other without additional training. For one thing, participant interviews are usually done in person, while collateral interviews are usually conducted by telephone. Also, collaterals have not made the commitment to the study that participants have (nor are they usually compensated for their time), so the research assistant has less leverage in making appointments with them.

Some interviewers have a tendency to accept "don't know" responses more readily from a collateral than from a participant. This may occur because collaterals often have more "don't know" responses, and the interviewer gets into a set of just accepting them. Training should include role plays and other techniques for helping interviewers explore the delicate balance of probing without annoying the collateral.

The Importance of Collateral Data

The Principal Investigator or Project Coordinator needs to convey to the research staff that collateral interviews are an important part of the protocol. Even though the day-to-day supervision of staff and monitoring of interview completion rates may be delegated to a senior research assistant, the Principal Investigator needs to show interest in the collateral component of the protocol; otherwise, the staff may conclude that collateral data collection is relatively unimportant and give it low priority. Training should stress the importance of collecting these data in a timely fashion, maintaining a research perspective, and adhering carefully to the research protocol. In addition, the training should emphasize the importance of research staff being polite, friendly, honest, and empathic during the collateral interview.

Written Guidelines and Scripts

As when interviewing participants, the collateral interviewer needs to understand that the job is to collect data, not to provide therapy. Interviewers should be reminded that hostility or bad behavior on the part of the collateral is not a personal reflection on them, nor is it their job to correct the collateral's irresponsible or obnoxious behavior. While this may seem obvious, in reality it is sometimes given inadequate attention by investigators.

In training, interviewers should be provided with clear guidelines for dealing with situations that typically arise during a collateral interview. These guidelines, which will depend somewhat on the

protocol for the particular study, should be discussed during a research team meeting and practiced during role-playing sessions. Knowing how to deal with difficult situations will put collateral interviewers more at ease and will allow them to focus on what the collateral is saying. This, in turn, will make the interviewer more willing to pursue hard-to-reach collaterals. If interviewers are concerned that reading a script will sound unnatural and annoy the collateral, they can say, "I'm reading this to you so that I can be sure everyone gets the same information and is asked the same questions."

Collateral interviewers should be encouraged to prepare for each call. This includes sending a letter to the collateral explaining the purpose of the interview, time involved, and the date and time the research assistant plans to call. The letter should have a telephone number where the research assistant can be contacted if the collateral wishes to change the interview date (appendix D.)

When it is time to make the call, the research assistant should assemble the relevant information, select a place where the call can be made in privacy, and be prepared for resistance, suspicion, and complaints from the collateral. After the interview, the research assistant should thank the collateral for the time spent and also perhaps send a thank-you note. If there is to be another interview, have the research assistant set the stage by negotiating a plan to schedule the next one.

Throughout training, the overriding message to interviewers should be that confidentiality must be enforced. All telephone interviews, for example, should be conducted in a room where the caller will not be disturbed or overheard by nonresearch staff persons. It should be made clear to the interviewers that no information from a collateral may be shared with the participant.

In addition, guidelines need to be spelled out for collateral calls made offsite. Some would argue against allowing confidential information or information that could link a participant or collateral to a study to be taken outside of the immediate research site. Thus, if calls are to be made offsite, appropriate precautions need to be taken. First, no files should be removed from the research site. Instead, the research assistants should copy the minimal information needed in order to make the call. They could, for example, memorize the collaterals' and participants' full names, use only the first names or initials on the interview form, and carry the telephone number separate from the interview form.

For the interviewers' protection, have them block the Caller ID telephone feature by entering *67 on the telephone before dialing the collateral's number. The problem with this, however, is that the person being called may not accept a Caller-ID-blocked call. In

that case, the research assistant can call the operator and ask to have the call put through. Issuing a calling card to the collateral interviewer will facilitate doing evening and weekend telephoning offsite.

Supervise Initial Calls

After the interviewers have become familiar with the process, have them call and interview a member of the research team who is experienced with telephone interviews. This role-play can be repeated several times with different staff members until the interviewers feel comfortable.

Next, the trainee should listen while an experienced caller does a collateral interview. As the trainee makes the first few collateral phone calls, the supervisor should sit in on them or have the trainee tape them (with the collateral's permission) for later review. This is especially important, since many collateral calls are made during evenings and weekends when the supervisor is not available to respond to difficulties.

Support and Incentives for Staff

One helpful approach is to stress that the research team is in this together, truly as a team, so if someone cannot reach a collateral, this becomes the problem of the entire staff. Difficulty with a collateral interview can be discussed during research team meetings, and members can offer encouragement and suggestions for success.

For example, if one caller is having difficulty with a collateral, a different caller may have more success. A woman collateral may feel more comfortable talking with another woman, or another caller may have more free time to try to telephone after hours. Designating a "Collateral Specialist" who will be entirely responsible for the collateral interviews is one approach to helping solve the collateral problem. This could be a part-time person, such as a graduate student, who is willing to work evenings and weekends.

Another option is to allow staff members who do collateral interviews to have flexible hours. Since many calls have to be made during evenings and weekends, staff making these calls can be allowed to take time off during the week. Most staff appreciate having this flexibility.

Finally, since it is generally recognized that conducting collateral interviews is not enjoyable, ongoing support for staff assigned to do them is needed. It is helpful to designate someone to listen to the frustrations of contacting problem collaterals and empathize. A kind ear and a big thank you go a long way, as does a special celebration during milestones of the project. Recognition for a job

well done, perhaps in the form of a memorandum, is another way of showing appreciation.

Responding to Special Situations

It is common in substance abuse research that friends and family members, who are likely to be collaterals, have many concerns about the participant. They may see this call as an opportunity to find out how the participant is doing or to express their concerns, and maybe anger, and ask the interviewer to do something. In other words, they would like to make the research call a clinical event. The interviewer's task is to get the research data according to the protocol without aggravating the collateral, breaking confidentiality, or overlooking the potential for a participant to harm himself or others.

This section presents some common situations that interviewers may confront and suggest responses for handling them.

What if someone other than the collateral answers the telephone?

Imagine this scenario:

> *Interviewer*: Hello, this is Mary Smith. May I please speak with Ben Gray?
>
> *Voice*: May I tell him why you're calling?
>
> *I*: Well, it's confidential.
>
> Person answering hangs up the telephone.

The person hung up because saying, "It's confidential" aroused suspicion, so to be on the safe side, he hung up. What might you have said in this situation? Try to remain calm and confident and give a simple response. You might have started out with, "Hello, this is Mary Smith from Brown University...." (You would not say, "This is Mary Smith from Brown University Addiction Treatment Program.") This safe name dropping gives some importance to your call without giving any information that would break confidentiality. What you want to avoid is being asked, "May I tell him why you are calling?"

If this does happen, try saying something low key and innocuous and end it with a question such as, "Well, I have a message here to call him. Is he available?" This sounds like Ben knows why you are calling. You can explain to Ben later when you talk with him. By asking a second question right off, you can probably avoid having the person answering ask you for more information. If the person answering says Ben is not available, then say, "Well, I'm in

and out all the time, so I'll try calling back. When do you think would be a good time to call?"

At this point you no doubt realize that an ounce of prevention might have saved you from this difficult situation. More probing of the participant at intake as to who is likely to answer the telephone, getting a release of information for the person, or sending a letter ahead of your telephone call to the collateral stating the date and time you plan to call might have avoided this situation. But sometimes these things happen anyway, so it is good to be prepared and know ahead of time what you are going to say.

What if you feel that the collateral cannot talk openly for some reason?

For instance, if the collateral is a spouse, the participant may be within hearing distance of the telephone. If you do the interview while the participant or someone else is listening, the collateral may not feel free to give accurate information. If you suspect this situation, take time to ask the collateral if anyone is listening. If so, hold the line while the collateral takes the call in another room or suggest rescheduling the interview.

What if the collateral sounds intoxicated when you call?

You cannot say to a collateral, "Gee, you sound as if you've been drinking, so let's do this later," which you could say to a participant. You will have to say something like, "This is not a good time for me to ask you these questions, so could we possibly plan another time to do it?" Try to reschedule the interview for another time of day. At the same time, remind yourself that someone needs to probe about these things at intake and note it under "Best time of day to call." For instance, the note might say, "Collateral drinks in the evening, so make the call in the morning between 8:00 and 10:00 a.m."

What if the collateral starts asking you questions?

The following scenario is not uncommon:

I: "I'd like to ask you some questions about how Teddy has been doing over the past 3 months."

C: "I know Teddy is lying to you about how much he drinks. He lies to me all the time. He thinks I don't know he's drinking. But I can smell it on his breath, and I find his bottles tucked away all over the house. Did he tell you about getting that DWI last weekend? I don't think he's getting enough treatment in your study. I think he needs to go to an inpatient program. Don't you agree?"

> *I:* "I understand your concerns about Teddy, but to protect confidentiality, I can't talk about that, just the way I can't tell Teddy anything you say to me. I'm sure you understand. I can, however, ask our Project Coordinator to call you. Would you like me to do that? Okay, fine. Now to get back to the questions..."

How the Project Coordinator is going to handle the call to this person is not your problem. Leave that to the Coordinator, who knows what to do in these situations, and get on with collecting the data.

What if the collateral asks advice on how to deal with the participant and his substance abuse problem?

This is a frequent occurrence. Instead of giving advice, empathize and use reflective listening to convey your appreciation of the difficulties. Then defer the collateral to a higher authority, usually the Project Coordinator, who can deal with the situation according to the research protocol. The conversation might go something like: "You say you're at the end of your rope [or whatever the collateral said]. Alcohol problems put such a strain on the family. Would you like to speak with the Project Coordinator?"

What if the collateral states that he is dissatisfied with the study or that it is not helping the participant?

This does happen, and it would be easy to become defensive at this point, so it is important to be prepared. A possible response is, "We [or the investigators] are interested in any comments you would like to make about the study, and I would be happy to relay your concerns to the Project Coordinator and have him call you. Or you could call him yourself."

What if the collateral reports that he is afraid the participant is going to harm himself or others?

Make sure to take the proper steps for homicidal or suicidal ideation risk according to the protocol for your institution and defer the interview to a later date. Usually this would include having the collateral speak with the Project Coordinator or Principal Investigator immediately if possible. If you are making your collateral call offsite, which is often the case, and you feel a person is at risk, you will need to call 911 and give the operator the information. This means that when making calls offsite, you should remember to bring all the information you might need (such as the address of the collateral or participant) with you. In the situation of suicidality or homicidality, confidentiality may be broken in order to obtain help.

What if the collateral asks for a treatment referral for the participant, or the collateral asks for a treatment referral for himself?

Collaterals can be assured that the project has a list of possible sources for treatment and be told that they can call the office or the Project Coordinator will call them if they prefer. A suggested response is, "We do keep a list of sources for treatment that hopefully could be helpful for you, but the Project Coordinator is the best person to speak with about this. Would you like him to call you?"

What if the collateral is just generally angry for reasons unknown?

He may say, "How long is this going to take anyhow?" or "This research is a waste of the taxpayers' money." At this point, you need to remind yourself that the collateral probably is not angry with you personally and proceed politely. A proper response would be, "I appreciate the time you're giving me, and there are only two questions left, but maybe you'd prefer to finish the interview at a later date. That would be fine with me." Of course, it would not be fine, because you want to complete the interview right then and there, but by turning control over to the collateral, he will usually decide to finish the interview.

What if the collateral is a talker?

Let's say the collateral is a woman with apparently a lot of free time who is really enjoying the chance to tell you her whole life history. Shape the interview along by saying, "Uh huh" with the proper intonation to let the person know you understand what has been said. Then, without pause, ask the next question.

What if the collateral balks at the questions?

For instance, one collateral said, "How do I know if he's happy with his living situation? I'm not going to pass moral judgments on my friend." Normalize the collaterals' statements and reassure them by saying, "Sometimes the people we call find these questions hard to answer, but ____ gave us your name because he thought you were the best one for us to ask about how he's doing. Either you could try to answer as best you can or if you prefer, I could ask ____ to provide a different collateral." Very often the collateral will continue with the interview. If not, then you need to ask the participant to name another person.

What if you always get the answering machine when you call?

A common problem that arises in doing collateral telephone interviews is that the caller always gets an answering machine. Because of problems that might arise about confidentiality, careful consid-

eration should be given before leaving a message. If the collateral is a spouse and the participant has said it is all right to leave messages, then leaving a message may help. But leaving repeated messages may seem like badgering. Try calling at different times and on different days.

If you have been having the answering machine problem and call and get a busy signal, immediately try calling every few minutes, because often after people hang up the telephone, if it rings again soon, they will answer the call rather than leaving it to the machine. Also, if you again get the answering machine, a message may get results. The collateral may pick up the telephone or may call right back.

If you continue to get only an answering machine and do not make contact with the collateral, this may be a sign that the collateral does not want to cooperate with the interview. Sending collaterals a letter saying that you were unable to reach them and asking them to call you at their convenience may be helpful. If none of these approaches works, the participant should be contacted again to ask for suggestions on how to reach the collateral or to name another person.

Setting Up and Maintaining an Electronic Data Base

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Conventional strategies for monitoring participant compliance place the burden of adhering to the research protocol on the participant. There may be no theoretical formulation for this, nor does the current empirical evidence indicate that participant-centered compliance is the most effective strategy. The convention appears to stem from the notion that an interactive strategy that anticipates rather than simply reacts to protocol participation barriers is too costly. To interactively monitor each participant's progress through the research protocol requires staff time over and above the essential tasks of assessment and data entry. Hence, efforts to enhance participant compliance usually involve adding staff. However, the accompanying cost increase makes this solution unattractive.

A computerized, participant-tracking data base easily fits into the working technology of the staff of a research project. It allows the staff to shift from a reactive perspective that puts the burden of compliance solely on the participant to a proactive position that anticipates barriers, standardizes participant contact, and limits intensive efforts at reengaging participants to those few who do not react favorably to the routine.

Yet this is only the tip of the iceberg. Many other opportunities remain to move clinical trials toward full automation of administrative and logistical procedures. Along that path lies the ability to reduce staff tedium and focus their attention on the human contact that it takes to enhance the participation of research clients.

Computerized Tracking

It might seem too obvious in this age of microcomputers to promote the use of a computerized data base program for information storage during a clinical trial because it allows for more efficient compilation, organization, tracking, and retrieval of data.

However, many research projects still use file cabinet systems for managing participant compliance. The disadvantages of these low-tech systems are not always appreciated, particularly since the bulk of the trial's resources and attention is devoted to establishing sophisticated systems for the collection of data for the planned research analyses.

Project MATCH took a different approach. We reduced the contextual barriers to developing a participation enhancement strategy by developing specialized client data bases that allowed staff to—

- Minimize the amount of time it took to track client status.
- Easily retrieve client-specific information.
- Modify client contact tactics to achieve maximum response with minimal effort.
- Allow standardization and automation of frequent client reminder mailings.
- Continually update client information.

This data base tool allowed the research staff time to develop a routine approach to all participants as well as devote extra time to the small percentage of participants who required additional attention.

The Low-Tech Alternative

The basic difficulty with file cabinet systems is that they must be physically organized. Since the primary purpose of collecting data is to address the research questions, the file cabinet is usually organized to provide the most efficient access to the data for that purpose. However, organizing the file cabinet in a way that is efficient for data analysis might not be suitable for other important project tasks.

For example, it is often necessary to maintain copies of portions of the assessment batteries as separate information files for each ancillary purpose. This typically hampers the timely retrieval of the bits and pieces of information that are required when project staff are attempting to reengage a recalcitrant participant. They are less likely to use routine methods for enhancing participant compliance if they need to rummage through the physical records in order to retrieve information to compile assessment due dates, draw up mailing lists, or send personalized form letters. Continually updating physical files is time-consuming, confusing, and prone to error. In addition, when there are several distinct second-

ary files, it is more likely that some information will not be updated at all.

There are two typical methods of physically organizing participant data, by case and by assessment instrument. The case organization method uses participants' folders as the repository of all data collected on each client recruited into the research project. Most often the case file is marked by a participant identification (PID) number.

One major drawback of this method relates to data entry. Computerized files are generally constructed for each specific instrument, so a natural way to enter data into such programs is by assessment across individuals. This is especially true if data are entered and then reentered in a verification pass. When physical

Common Methods of Organizing Data Files

Case Organization	Participant ID	000001
	Assessment 1	
	Assessment 2	
	Assessment 3	
	Assessment *n*	
	Participant ID	000002
	Assessment 1	
	Assessment 2	
	Assessment 3	
	Assessment *n*	
	Participant ID	00000*n*
	Assessment 1	
	Assessment 2	
	Assessment 3	
	Assessment *n*	
Assessment Organization	Assessment 1	
	Participant ID	000001
	Participant ID	000002
	Participant ID	000003
	Participant ID	00000*n*
	Assessment 2	
	Participant ID	000001
	Participant ID	000002
	Participant ID	000003
	Participant ID	00000*n*
	Assessment 3	
	Participant ID	000001
	Participant ID	000002
	Participant ID	000003
	Participant ID	00000*n*

records are filed by case, the data entry task begins with retrieving a given assessment from each client's folder, entering and verifying the data, and then refiling that assessment across participants. So the case organization structure is inefficient when the data needed are assessment specific.

The second method of organizing participant data is by assessment instruments used. Retrieving information from physical files organized in this way, however, poses other problems. When data are collected and stored by instrument, it can be tedious and inefficient to find specific participant information. For instance, a research assistant preparing to do a followup interview may need to get the participant's identification number from one instrument, telephone number from another, and target date of the interview from a third.

Further, file cabinet data storage systems are often idiosyncratic, in that only those staff people who have developed or who heavily use it know how to locate a particular piece of information. Although it is possible for a research team to become familiar with a particular file cabinet system and to make it work for the project, this is not an efficient use of staff time. A complicated system that requires staff to have a lot of knowledge about the research project in order to perform relatively simple tasks, such as data entry or filing, makes it difficult to hire part-time or student help.

In addition, using paper files sometimes poses confidentiality problems. Locking up paper files is one solution to this problem, but there is a good chance that files may be left open or unattended. Also, it may be difficult to organize paper files so that some information is not available to "blind" research staff.

Thus, storing and retrieving data from a file cabinet is time consuming and increases the chance of making data transfer errors. Although most projects need to store huge quantities of data, they typically retrieve discrete bits of information at any one time. Given the widespread availability of personal computers, it becomes obvious that computerized data base storage is the better way.

The remainder of this chapter focuses on the general principles involved in constructing a data base and describes the type of data base that can be used to monitor and enhance participant compliance with the research project protocol. Because several computer platforms are available (e.g., DOS, Windows, UNIX, Macintosh), and for any given platform, several data base programs might exist, the material is presented as platform/program independent.

Determine Your Needs

Before deciding on the structure of the data base program, consider the requirements of each phase of the study, such as screening and recruitment, randomization and assignment to treatment conditions, monitoring treatment attendance, conducting and monitoring posttreatment assessments, and conducting analyses that address the trial hypotheses. Each of these phases involves data collection or manipulation. Although most of the data are collected to address some aspect of the scientific research questions, other data are used to support the process necessary to conduct the trial.

In order to preserve internal validity and conform to the expectations of rigorous scientific practice, the data collected for assessing the trial hypotheses are usually maintained in a distinct data base or as a parent data base with restricted access. This practice allows you to limit information that might influence a research staff member conducting participant assessments. It also helps ensure the confidentiality of the data collected. However, retrieval of selected bits of information from these parent files is both necessary and desirable for monitoring and enhancing client participation. Without cooperative participants, there can be no data with which to address research hypotheses.

Basic Information

The first design consideration in constructing a participant-monitoring data base is to review the data that are routinely being collected for the research project. When staff know what data are available, they can determine which bits of information will be helpful for monitoring participants.

Participant Data

The basic information needed to contact a participant is usually obtained in the initial interview: demographic and residential information such as age, sex, ethnicity, marital status, address, and telephone number along with information that allows staff to determine whether the client is suitable for the study. This type of information is also required to monitor client participation. A Note section allows staff to store anecdotal information concerning those idiosyncracies that they have found helpful in their attempts to contact the participant.

Locator Data

For each participant, the project will also need basic information about at least one locator, that is, a person named by the clients as someone with whom they have a well-established relationship who would likely know their whereabouts at all times. Participants must agree to grant the research staff permission to contact the locator; particulars of the conditions under which contact with the locator can be made are detailed in the informed consent.

Minimal Client Management Data

PID _____ Initial Interview _____ Target Interview _____

Last Name _____ Home Phone _____

First Name _____ Employer _____

Address _____ Work Phone _____

City _____ Work Title _____

State _____ Zip Code

Name of Collateral Source and Relationship _____

Soc. Sec.# _____ M F (circle) Ethnicity _____

D.O.B. _____ Yrs of Education _____ GED _____

Interests _____

Student Y N Where _____ FT/PT/NA Major _____

Locators:

Name _____ Name _____

Address _____ Address _____

City _____ State ___ Zip _____ City _____ State ___ Zip _____

Home Phone _____ Home Phone _____

Relationship _____ Relationship _____

Target interview date _____ Comments _____

Scheduled date/time _____

Site (onsite/home visit/telephone/other) _____

Date letter sent _____

Telephone confirmation due date _____

Last date called _____

Outcome of contacts _____

_____

Interviewer ID# _____ Amount paid _____

Interview complete _____ Date of last drink/drug _____

The interviewer should collect sufficient information about the locator to be able to actually contact the person who is named. Also, the information should be verified while the participant is available to make corrections. Keep in mind that life circumstances do change. It is good practice to verify the information on the locator at each contact staff has with the participant. Oftentimes, it is useful to separate the locators from the collaterals, especially when soliciting names from the participant. Someone who may serve well as a locator may know nothing about the participant's drinking (e.g., the grandma with whom the participant keeps in touch).

Collateral Data

Many trials of alcoholism treatments use collateral sources to verify the participant's self-report of drinking. Some check body fluids (blood and urine); others interview someone close to the participant who is likely to know. As with locators, participants must grant the research staff permission to contact the collateral; particulars of the conditions under which contact with the collateral can be made are detailed in the informed consent.

Upon initial contact with the collateral, the research staff should obtain that person's permission to conduct interviews; these are usually conducted over the telephone. As with locators, enough information should be collected on collaterals to actually contact them, and the collateral contact information should be verified with the participant at each contact.

In a file cabinet system, the information identified so far could be considered a hanging file folder. Within this hanging file, which could be labeled "Basics," there are now three folders: participant information, locator information, and collateral information. Thus, similar information of three distinct types is needed, and this information is collected as a routine aspect of the trial. Once it is computer readable, this information is available for monitoring participant compliance. Usually there is no need to collect the data in a separate effort.

Define the Tasks

After basic information on the participant has been collected in the screening interview, the next step is to determine what information will help keep track of where the participant is in the research process. Monitoring the participant's progress over the course of a treatment study begins with the initial contact. Often the most obvious details are the ones that are neglected but prove to be the most useful.

The obvious details here center on the participant's progress from initial contact (which is sometimes over the telephone) to screening, recruitment, baseline assessment, and randomization. Given the complexity of multitreatment service centers, the comprehen-

siveness of research assessments, and participant availability (or lack of it), it is not unusual for this initial process to take several days. Although the completion rates of screening and baseline assessments are usually very high, assuming that a participant will get through the process in a timely manner can lead to several lost applicants during the recruitment phase. It is a better practice to exercise prudence and begin the tracking process at the point of initial contact. Likewise, continue the monitoring process with each participant right through the final exit interview. Doing so will ensure that the trial has sufficient current information available to recontact a former participant should the trial receive additional funding to extend the followup period.

There are many ways to organize information that is useful for monitoring client participation. The method presented here is partitioned along the lines of tasks within the phases of the study and applies to each type of person monitored: participants, locators, and collaterals. The concept is to recognize that people other than the participant are important to track, and that the monitoring activity requires several separate tasks.

Scheduling Appointments

One identifiable task is the scheduling of participant appointments. A file can be created for each phase of the research, that is, baseline, treatment, and followup. Each file would contain four fields: participant identification number (this is the primary key variable that allows linkage to other files in the data base), scheduled date, scheduled time, and completed date.

One advantage of forecasting target dates and times for appointments is that it provides the staff and participants with tangible evidence of the clients' commitment to the project. From a research management perspective, a projected schedule of contact with each participant is an invaluable tool in organizing staff monitoring efforts. Projected schedules allow staff to assess upcoming workloads and plan their activities accordingly. For the staff, such schedules serve as prompts to send participants reminders of upcoming appointments. With a computerized data base, it is possible to automate a considerable amount of the effort involved in routine participant contact. This frees staff time for the specialized techniques designed to reengage noncompliant participants.

For example, treatment attendance is a leading indicator of subsequent participation in posttreatment assessment (Del Boca et al. 1995). Thus, a file that summarizes client participation in the treatment phase of the study is important. In the case of treatment dropouts, such information can be used to flag the need for specialized text in the letter sent to the participant prior to the initial posttreatment followup assessment. Such specialized let-

Sample Participant Schedule Files
Baseline Assessment

PID	Scheduled date	Scheduled time	Completed date
0700001	10/12/98	1:30 pm	10/12/98
0700002	10/13/98	10:00 am	10/13/98
0700003	10/16/98	9:30 am	10/16/98
0700004	10/17/98	9:30 am	10/18/98
0700005	10/18/98	2:00 pm	10/18/98

First Followup Assessment

PID	Scheduled date	Scheduled time	Completed date
0700001	12/12/98	1:30 pm	00/00/00
0700002	12/13/98	10:00 am	00/00/00
0700003	12/16/98	9:30 am	00/00/00
0700004	12/17/98	9:30 am	00/00/00
0700005	12/18/98	2:00 pm	00/00/00

Second Followup Assessment

PID	Scheduled date	Scheduled time	Completed date
0700001	12/12/98	1:30 pm	00/00/00
0700002	12/13/98	10:00 am	00/00/00
0700003	12/16/98	9:30 am	00/00/00
0700004	12/17/98	9:30 am	00/00/00
0700005	12/18/98	2:00 pm	00/00/00

Third Followup Assessment

PID	Scheduled date	Scheduled time	Completed date
0700001	12/12/98	1:30 pm	00/00/00
0700002	12/13/98	10:00 am	00/00/00
0700003	12/16/98	9:30 am	00/00/00
0700004	12/17/98	9:30 am	00/00/00
0700005	12/18/98	2:00 pm	00/00/00

Sample Treatment Attendance File

PID	Code
0700001	1
	1
0700002	3
	1
0700003	1
	1
0700004	2
	3
0700005	2
	1

ters can acknowledge participants' dropping out of treatment and inform them that it is nonetheless important to the study that they participate in the posttreatment assessments.

Clearly, a participant's attendance during treatment is just the type of information that could bias the research staff who conduct the posttreatment assessments. However, using the data base tool described in this chapter eliminates the concern that "blind" research interviewers would have access to information about the treatment history of participants. A common feature of data base programs (password lock) can restrict access to these files so the information can be hidden from inappropriate exposure to research assistants. In the Project MATCH protocol, part of the function of Project Coordinators was to monitor treatment participation and to initiate specialized letters to treatment dropouts at the appropriate time. Research interviewers could thus maintain their ignorance of a participant's treatment experience.

It is equally important to construct similar schedule files for the collaterals. In Project MATCH, contact with the collateral source did not occur as frequently as contact with the participant. This made it all the more important to project the contact schedule so that the relationship with the collateral could be maintained with timely reminders.

Reminder Letters and Telephone Calls

One method of enhancing participant compliance is the use of letter reminders. In terms of the electronic data base, two things are suggested. The first is to create in the data base a letter schedule file. Only a few fields are required, because dates on which the reminder letters should be sent can be cued from the scheduled dates in the participant (or collateral) schedule file. Client ID (collateral ID), date letter sent, and status code should be sufficient.

Second, in some data bases, the text of the letters can be entered as a file. Some data bases also have a mail merge feature that allows staff to take mailing addresses from the participant (or collateral) demographic file, put these together with a form letter, and print the mailing envelopes as well. In other data bases, it is possible to

Sample Participant Reminder for Telephone Calls File

PID	3 month		6 month		9 month		12 month		15 month	
700001	12/4/92	1	2/8/93	1	4/9/93	1	6/8/93	1	8/9/93	1
700002	12/6/92	1	2/10/93	2	4/10/93	1	6/10/93	1	8/11/93	1
700003	12/11/92	1	2/10/93	1	4/11/93	1	6/12/93	2	8/14/93	1
700004	12/15/92	1	2/15/93	1	4/16/93	1	6/17/93	1	8/18/93	1
700005	12/25/92	1	3/1/93	0	5/9/93	1	7/8/93	1	9/9/93	1

retrieve relevant information for each participant, such as name, address, and pertinent dates, but that information must be exported to a text processor in order to merge with the form letters.

A telephone call schedule file should also be created in the data base. As with the letter schedule file, only a few fields are needed. Participant ID, telephone number(s), date and time of contact, and a status code should be sufficient. Create a similar file for the collateral.

Compensation and Incentives

In treatment research, it is useful to offer participants some type of compensation for the time they spend involved in research assessments. Under current federal efforts to increase the participation of women and minority populations, it is also becoming common for research projects to offer compensation as a means of reducing barriers for these groups. For example, transportation fees and childcare arrangements might be offered to participants on a case-by-case basis.

Sample Participant Compensation File

PID	To date	Current	Childcare	Travel	Total
0700001	0	75	0	2.5	77.5
0700002	100	25	0	0	125.0
0700003	125	50	0	2.5	177.5
0700004	175	10	0	0	185.0
0700005	185	50	0	0	235.0

In addition, monetary incentives are sometimes offered to noncompliant clients to tip the balance in favor of participation. A common practice in such cases is to offer recalcitrant clients the sum total of compensation that would have been paid to them had they cooperated up to the assessment in question.

From a management perspective, having the ability to track cash outlays on a microlevel helps in monitoring project budget expenditures. It also helps ensure that participants are compensated in a timely fashion and with the correct amounts. Further, it is important to be aware of potential problems associated with preserving confidentiality when checks are used. The best solution is to have cash in hand, which can be paid immediately to participants upon completion of the appropriate session.

In a trial with rolling recruitment, where client assessments are staggered on a week-to-week basis, a participant compensation file also allows the research staff to plan for upcoming assessments by

identifying the correct amount that each participant is due at that point in the trial.

Choosing a Computer Data Base

After taking all of the foregoing into consideration, the next step is the selection of a data base program. Because of the desire to limit access to the scientific data, a participant monitoring data base will probably be constructed to operate independently. This principle also holds when the parent data already exist in a data base.

The most elemental choice to make is between programs that use either a "flat file" or a "relational file" organizational structure. Without being too technical, flat files string all fields onto one record. The result is a very long record for each participant and a large degree of duplication. The total file would soon become very large and unwieldy, even for virtual space. Further, whenever one piece of information changes, no matter how small the item, the change would be made anywhere the field appeared, perhaps a dozen places. Even minor changes could require significant time, and the risk of transcription errors would likewise increase. Data bases with flat file structures are generally to be avoided.

A relational structure allows data to be maintained in small, distinct files analogous to folders. Data that have logical similarity are grouped together. In relational data bases, each piece of information need be stored in only one place. The relational structure allows changes to be made with greater ease, since only the folder containing the change need be accessed and updated. New information is added to existing folders or new folders can be created in the data base.

A data base is like a file cabinet. Information organized by topic resides in folders, and the data base is analogous to a file cabinet drawer. When the drawer is opened, there is access to the topic folders the drawer contains. A relational data base is the best tool for creating this type of data base.

The Relational Data Base

The following describes some of the generic features that make a relational data base an effective tool for monitoring participant compliance.

Folders

The data in a folder are usually presented as rows and columns. The columns are called fields (or variables), and the rows are called records. Each record in the folder contains the same set of fields, and each field contains the same type of information. Records can be the collection of information about one participant. In order to allow records containing data about one participant across folders,

there must be a unique identifier for each participant, and this identifier must be a field in each record.

Primary Key Field

In a relational data base, the information in multiple folders is linked by assigning a unique identifier called a primary key field. The participant identification number is a good example of a primary key field. By specifying the PID as the primary key, data from all of the folders in the data base can be retrieved under a case organization. The primary key field facilitates using the information contained in the data base in a very flexible manner.

Query

A query is a question that is asked about the data in a given data base. The query function allows answers to come from records in any number of folders in the data base. In essence, the query is the means whereby pieces of data in separate folders are related to one another. The query function is common to all relational data bases. Different terms might be used, but in order to effectively use the relational structure of the data base, there must be a function that allows the user to identify and bring together information from different folders.

When a query is defined, users describe the set of records that they want. The records might be drawn from several folders. As an example, suppose that it is Friday and the staff would like to contact all participants who are due for followup assessments between Monday and Wednesday of the upcoming week. The task is to query the data base for a listing of participants whose assessments are due in that period. The needed information is identified as participant name, due date and time, date of last assessment, telephone number, best time to call, and any notations that previous interviewers might have entered into the data base. Staff also need the name, address, and telephone number of the collateral so that this information can be checked with the participant to ensure that it remains current and that no changes have occurred that would prohibit contacting the collateral.

The query function allows the user to select each of these fields. The date and time schedule fields are located in one folder, while the participant's name, telephone, best time, and notes are located in another folder. The fields for the collateral information reside in a third folder. The query function allows the user to bring all these fields together and display the fields participant by participant. Keep in mind that the query function of any relational data base is quite flexible, and the appearance of the display can be customized to a project's particular needs.

One feature to look for in a relational data base is the capacity to transmit changes made to data in the query as updates to the

source folders. For example, if staff contact the participant to confirm an assessment appointment and find that the participant no longer is on speaking terms with the collateral, the staff member can solicit a new collateral source and update the data base form. Clearly, this is a time-saving feature. Then, when it is time to conduct the next collateral assessment, the collateral is current.

There are many examples of questions that can be translated into queries. For instance, a researcher may ask: Which participants are due in March, which participants are overdue, or which participant interviews were completed in March. Reports can easily be generated for each of these requests. These queries are useful in performing the day-to-day functions of a research project, such as scheduling or contacting participants, assigning participants to staff members, and printing the data necessary for participant tracking.

When generating queries, it is important to clearly formulate questions and to know what types of information are available before attempting to translate these questions. As noted by Brunner et al. (1992), common obstacles in query formulation are "poor knowledge of the data base's constituent structure" and lack of skill in translating a general question into a correct query.

Reports produced from queries benefit the long-term planning and maintenance of the research project. For example, reports can focus on the projected workload or the distribution of the workload among staff members. Information that details characteristics of the study that are not necessary for its day-to-day or long-term maintenance can also be generated. For instance, demographic information (i.e., all participants born before 1930) may be reported.

Forms

Data base programs allow users to display data in different layouts. A form is a layout for entering, changing, and viewing records in a folder. This common feature of a data base allows the user to create a display that is best suited to the task in hand. It is often desirable, for example, to have the option of displaying data in a spreadsheet format so that information is visible and easy to access. However, forms allow users to do things not available in the default spreadsheet, such as include lists of values to choose from, display error messages for incorrectly entered data, fill in data, display check-off boxes, and show the results of calculations.

Reports

The report function of a data base is the means for printing information selected from records in a customized layout. Like a form, a report allows the user to manipulate records in a number of different ways without altering organizational structure of the

folders. Generally, reports allow users to display data from fields, the results of calculations, graphs, pictures, or even other forms or reports.

Passwords

The password feature makes it easy to protect participant confidentiality. Research staff often have a password assigned that allows access to a specific level of information in the data base. In addition, fields can be created so that all information entered in the field is invisible unless the field is specifically activated.

Note Fields

Note fields are special fields within folders that also allow users to hide confidential (Social Security Numbers) or sensitive (AIDS test results) information from the view of casual onlookers who are not permitted access. It also hides specific information in a folder from those who have access to other, less sensitive information in that folder.

Mail Merge

A data base should also permit users to retrieve information for the purpose of printing letters or postcards. By merging text from the data base file into a previously written document, letters or postcards can be generated easily and quickly. Letters can be written for a variety of compliance enhancement tasks, such as confirming assessment appointments, contacting participants who fail to attend scheduled appointments, and contacting participants who cannot be reached by telephone. Personalized participant letters can be tailored to specific functions. The use of personalized correspondence has been demonstrated to be more effective than standardized correspondence in stimulating compliance to an assessment schedule (Curry et al. 1993).

Updating

The use of the form function should simplify the task of updating the data in folders. That leaves the scheduling and execution of timely updates to consider, and these are administrative matters. However, sometimes a research project will have multiple recruitment sites and maintain a separate data base for each site. In this case, consideration must be given to whether the data base allows concatenation of two or more data bases to form a master data base.

Other Features

It is helpful if the data base allows deleted fields to remain in the folder unless the folder is reorganized to remove them. Fields that have been deleted sometimes later prove useful, and having a way to reinstate the field is often of great benefit.

It is important to select a data base that allows fields to be continually modified without reentering data. For example, an address field of 25 characters might be created, but after entering several records, it is discovered that some participant addresses are longer than 25 characters. The data base program should make it simple to alter the field without having to reenter data. Similarly, the data base should allow for alteration in field type from numeric to character.

Project MATCH—A Case Study

The Role of a Coordinating Center in Facilitating Research Compliance in a Multisite Clinical Trial

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A large number of coordinating center activities can influence participant adherence to the protocol. Because a coordinating center does not directly interact with research participants, the impact of its activities on participant compliance is often overlooked. It is clear, however, that external monitoring of recruitment and followup rates, preparation of protocols, and training and supervision of staff can play an important role in increasing participant compliance. This chapter draws on Project MATCH as an example of how a coordinating center can facilitate research compliance in a multisite clinical trial.

Role of the Center

A multisite clinical trial involves diverse sites often widely dispersed geographically. Accurate and timely communication about procedures, problems, and staff concerns is essential (Fuller et al. 1994). Coordinating centers are typical components of multisite efforts and, in addition to managing data and staff training, are also responsible for facilitating communication. Research sites in Project MATCH, as in similar cooperative studies, relied upon the coordinating center to provide technical and logistical support to maintain the integrity of the common research protocol. This entailed developing, implementing, and supporting trialwide procedures for tracking the enrollment and followup of study clients, monitoring and ensuring the quality and completeness of the data, and organizing the data base to conduct statistical analyses. Another function was to ensure that treatments were delivered in accordance with the study protocol. However, for purposes of this monograph, only the data gathering functions are discussed.

Although investigators have often emphasized participant behavior in understanding compliance, there is increasing recognition that treatment providers and research staff may play an important role in determining compliance levels. Even external agencies, such as funding organizations, outcome monitoring committees, and coordinating centers that are responsible for defining the clinical trial, may influence compliance levels (Spilker 1991*b*).

Project MATCH experienced several examples of poor compliance that were related to the research context as well as to the participant. These factors were frequently mitigated by coordinating center activities. For example, monitoring by the coordinating center can alert clinical sites when followup rates fall below norms. Similarly, the degree of training and supervision of research assistants by the coordinating center can influence staff adherence to the protocol, which, in turn, is likely to affect the quality of the data generated by participants.

Organizational Structure

An overview of the organizational structure of the Project MATCH trial is presented to provide a context for the remaining sections, which focus on specific MATCH Coordinating Center activities that directly and indirectly promoted compliance to the research protocol. Because the accuracy of research reports may be influenced by participants' perceptions regarding data confidentiality, Project MATCH established two coordinating centers. The research center was responsible for coordinating the data generation activities of the trial; the treatment coordinating center was responsible for the administration of the three study treatments. The separation of these functions minimized the possibility that research assistants might inadvertently bias their interviews as a result of preconceived notions regarding the status of particular participants or the effectiveness of specific therapies. The separation also enhanced the candor of participants, who could be confident that their responses would not be shared with treatment staff.

The activities of a research coordinating center vary not only by the stage of the trial but by the organizational structure of the trial as well (Meinert 1986). In some multisite trials, the coordinating center has the primary responsibility for protocol development and implementation. In other studies, direction and management are the function of the study chairperson, and various coordinating duties are localized in one or more of the collaborating sites. Project MATCH was unusual in that a Steering Committee, composed of the participating Investigators, an NIAAA staff person, and a statistician, supervised the study in close collaboration with the coordinating center (Fuller et al. 1994).

Selected Reasons for Poor Participant Compliance and Examples of Coordinating Center Activities to Enhance Compliance

Factor	*Reason*	*CC activities to enhance compliance (examples)*
Participant-related	• Severity of disease	• Oversee randomization procedure and monitor participant eligibility criteria for study
	• Mental illness (e.g.. suicidal intent or psychotic behavior)	• Same as above
	• Confidentiality risks	• Utilize staff certification procedures, conduct site visits, monitor data coding and storage procedures
	• Lack of belief in the value of the study or treatment	• Disseminate project description for participant handouts and pamphlets
	• Personal cost (e.g., time and inconvenience) in attending sessions	• Monitor facility settings through onsite visits, observe participant-staff relations and time spent in waiting area, etc., and give recommendations based on other sites visited
	• Forgetfulness	• Create sample form letters and reminder protocols
	• Incomplete understanding of how to be compliant with the protocol	• Disseminate participant information describing obligations and timeline, utilize staff certification and training, conduct onsite visits, query incomplete or incorrect data forms (questionnaires)
	• Anger or dissatisfaction with research staff	• Implement trialwide staff hiring protocol, certification procedures, and training; conduct onsite visits
Investigator/ research staff-related	• Long delay from screening, referral, or scheduling to appointment	• Monitor through trialwide participant tracking data base, report information to Steering Committee, make recommendations based on site visits
	• Long time kept in waiting room	• Make recommendations based on site visits/ successes of other sites
	• Failure of staff to keep appointments or to schedule appointments (especially with difficult participants)	• Monitor low followup rates using trialwide participant tracking data base, report information to Steering Committee, monitor staff morale, schedule conference calls to discuss problematic issues
	• Poor staff-participant relations	• See above
External agency-related	• Long duration of study or followup period	• Foster healthy competition between sites, report followup rates at Steering Committee meetings, monitor staff morale, schedule conference calls to problemsolve around difficult participants
	• Protocol requirements are extensive, demanding, or confusing	• Develop standardized data collection forms, query incomplete or incorrect interviews and questionnaires, problemsolve using conference calls between site staff
	• Unpleasant or invasive medical testing (e.g., blood/ urine samples)	• Monitor rates of biological testing through participant tracking data base, report rates to Steering Committee, schedule conference calls to discuss problematic participants

Source: Adapted from Spilker 1991b.

Project MATCH Coordinating Center Activities by Stage of Trial

Stage	*MATCH Coordinating Center Activities*
Protocol development stage	• Developed and pilot-tested data collection forms • Developed research protocol manual (MATCHBook) • Developed trialwide hiring, training, certifying, and monitoring procedures for research staff • Conducted two training sessions for research staff • Developed data entry programs for interviews and questionnaires
Participant recruitment (and treatment) stage	• Developed and conducted centralized treatment randomization program • Developed participant tracking data base and monitored recruitment of participants by reporting to funding agency and Steering Committee • Implemented data management procedures, including data transmission procedures, from sites to the coordinating center • Completed first round of site visits • Conducted across-site and within-site reliability study
Followup stage	• Monitored followup rates using participant tracking data base and reported on a regular basis to funding agency and Steering Committee • Conducted second round of site visits • Monitored research assistants through certification of new staff

Protocol Development Stage

By definition, a multisite trial employs a common protocol at more than one site. It is the role of the coordinating center to organize and implement procedures that will ensure uniformity or standardization among sites (Spilker 1984). The common implementation of a single protocol allows the coordinating center the opportunity to correct noncompliance by focusing on site differences when problems occur. For the MATCH trial, nonadherence to the protocol was often the cause of problems associated with data accuracy, data timeliness, and number of completed assessments. A major function of the coordinating center is to observe and correct these problems by data-cleaning efforts and data analysis, monitoring research staff at each site, and overseeing randomization procedures and participant selection.

Data Collection Forms and Research Protocol

After the initial design phase of a trial, it is the role of the research coordinating center to translate the selected interviews, questionnaires, and items into standardized data collection forms and to begin pilot testing before the main phase of the study begins. Carefully designed forms are necessary for checking the outline and practicality of the protocol, for quickly and accurately processing the data, and for checking the protocol compliance of both participant and research staff (Spilker and Schoenfelder 1991).

An extensive and complicated battery can be a reason for poor participant compliance in a trial. In the case of Project MATCH, the comprehensive protocol—spanning three baseline and six followup sessions—was indeed a challenge to simplify and standardize for use. In addition, a number of interviews and questionnaires were created expressly for Project MATCH or were used for the first time in a large-scale clinical trial. Pilot testing, using both staff and test participants, was essential for correcting the problems associated with the new assessments in order to prepare them for use in the main phase.

Guidelines for developing data collection forms to enhance compliance using lessons from MATCH appear on page 98. It should be noted that established or copyrighted assessments may be modified to fit the needs of a study for trialwide standardization purposes. It is necessary first, however, to obtain permission from the authors or companies involved. All those contacted by MATCH were willing to accept the changes.

MATCHBook, the protocol manual for the MATCH trial, was developed by the coordinating center to include specific study aims, rationale for study design, inclusion/exclusion criteria, randomization procedures, baseline diagnostic procedures, followup operations, all data collection forms, research-assistant training material, quality assurance instruction, data coding, transmission and management procedures, biological testing protocols, informed consent procedures, study information for participants, and participant confidentiality instruction. The protocol manual was essential in ensuring research consistency, which in turn influences participant compliance.

This juncture may be the best place to note that the time schedule for a trial in the design and development stages frequently proves to be unrealistic. Ambitious time schedules tend to exert pressure on investigators to begin data collection before the necessary forms and instruction manuals have been fully developed and tested. Doing so can lead to a chronic crisis atmosphere in the research coordinating center that spills over to the individual sites as staff struggle to develop better forms while trying to maintain existing procedures (Meinert 1986). Through the efforts of the MATCH Coordinating Center and site staff, exceptional data collection forms were designed; nevertheless, the demands on staff were great during early phases of the trial.

Staff Hiring Policy

Because the staffing configuration at each individual site directly influences staffing needs at the coordinating center, it is extremely valuable to develop trialwide policies for hiring research personnel prior to the beginning of the study. It is not adequate to simply specify the number of FTEs needed for each site; one site investi-

Guidelines for Developing and Pilot-Testing Data Collection Forms

Activity	*Guidelines*
Developing data collection forms, general	• Employ uniform style and coding options (0=no, 1=yes) on all interviews and questionnaires. Avoid change of response direction from question to question. Modify existing or copyrighted assessments to meet trial standards, if needed (obtain approval from authors or company). • Link forms only by participant ID number, avoiding client names or initials for trials of a confidential nature. • Develop data entry programs that follow the data collection forms as closely as possible to minimize entry errors. • Include a date and page number on every form so that when changes are made, staff at each site can be certain of using the most current form. • Avoid changing the forms once the main phase of the trial has begun. • Copy the forms onto colored paper, using a different color for each baseline or followup session. This practice can minimize using the wrong set of assessments for different data-gathering periods and is less tedious for staff and participants.
Developing interview forms	• For diagnostic assessments, list the diagnostic criteria on the interview form to minimize error by research staff. For vague diagnostic criteria (e.g., often or repeatedly), define for purposes of the research and list on the form (e.g., often=15 days out of the month; repeatedly=2 or more times). • Questions should be sufficiently detailed on the form so that the interviewer does not have to refer to the protocol manual to accurately code the answers.
Developing participant self-report forms	• Conduct a readability analysis to determine reading grade level on self-report questionnaires. Use a grade level that corresponds to the participant population. Use simple language and avoid slang words and phrases. • Avoid "skip" patterns by using forced responses for each question. If the battery is very time consuming, however, skip patterns on self-report questionnaires may keep the participant from becoming frustrated during the data collection process. • Include units of measurements that will be needed by the respondent to accurately answer the questions (e.g., 1 standard drink=1 bottle or can of beer, 1 glass of wine, or 1 mixed drink of gin, vodka, rum).
Pilot-testing data collection forms	• When forms are sent to each site, staff may conduct practice runs with each other to test for ease of administration, clarity, and time to complete. Suggestions for changes are then returned to the coordinating center so that alterations can be made. • Modified forms can then be tried with "real" test participants. This activity should be done in a formal manner, with each site completing a specified number of participants. If possible, practice sessions should be audiotaped and mailed with the completed forms to the coordinating center for final modifications. It is useful to administer the entire battery to examine overlap among instruments and to time the session. • It is also useful to data-enter the pilot-tested information to check for data entry problems and for logical inconsistencies within the assessments.

Project MATCH Hiring Protocol

Research Staff Qualifications

Project Coordinator
- 100-percent effort
- Master's or Ph.D. level with psychiatric clinical experience
- Responsible for supervising site, recruiting subjects, conducting diagnostic evaluations, and training staff
- Responsible for reporting to and working with the coordinating center

Senior research assistant
- 100-percent effort
- BS or Master's in behavioral science with clinical research experience and data management skills
- Responsible for conducting all assessments, taking blood and urine samples, checking errors on data forms, conducting followup sessions, and overall data management for the site
- Responsible for assisting in the training of new staff

Junior research assistant
- 100-percent effort
- BS degree with clinical research experience and data entry skills
- Responsible for participant screening and interviewing and for data entry, verification, and cleaning

gator may hire a single research assistant for one FTE while another may hire four research assistants at 25 percent time each for that same full-time equivalent! This pattern quadruples the amount of coordinating center responsibility for that site with regard to certifying and monitoring research staff.

Additionally, investigators in university settings often hire students as research personnel, making staff turnover another problem. These issues, as well as the education and experience levels of staff, should be determined as early as possible in the design phase of the trial so that the coordinating center is able to function effectively as a monitoring body.

Training and Certifying Research Staff

A trialwide research staff training procedure and certification process is necessary to ensure that new staff understand the goals of the research, are thoroughly familiar with the study procedures, are meticulous about data quality, and are skilled in the appropriate interviewing techniques. Onsite Principal Investigators, or Project Coordinators are responsible for the bulk of the training, under the supervision of the coordinating center personnel. The role of the coordinating center is to evaluate the performance, accuracy, and interrater reliability of research staff and to monitor procedures that will prevent interviewers from straying

from the study protocol. Certification requires consistent, adequate performance in major areas (i.e., adherence to interview format, probing skills, remaining in a research role, and following the instrument's coding scheme and decision rules).

The training and certification procedures used in Project MATCH were the most uniform methods of ensuring the accuracy of the data collected. In addition, two centralized training sessions were conducted prior to the beginning of the trial. These intensive sessions were conducted over 3 or 4 days and were taught by MATCH Coordinating Center staff and by the primary authors of the MATCH assessments. Finally, the coordinating center conducted a cross-site and within-site reliability study to evaluate the consistency of interview administration across participating sites. The most feasible approach for evaluating reliability in MATCH was the Test-Retest method. Please refer to Del Boca et al. (1994) for a discussion of reliability enhancement and estimation in multisite trials.

Table 6.5.—Project MATCH Training and Certification Protocol

Research Staff	*Site Procedure*	*Coordinating Center Procedure*
New research staff hired	• Notify the coordinating center of name and interviewer ID code.	• Send necessary training tapes and coding exercises to the site.
New research staff training and certification	• Apprentice new staff with most appropriate staff member. • Read and study protocol. • Observe participant sessions with staff member, code assessments, and discuss coding differences upon completion of session. • Practice the appropriate interviews with staff members. • Complete tape-coding exercise and return coded forms to coordinating center. • Complete interviewer-observer exercise by videotaping one session with a practice participant. The new staff member interviews the participant while the experienced trainer observes. Both code the assessments and send the tape and documents to the coordinating center. • Feedback is given to the new research staff member by the observer and is recorded. This is sent to the coordinating center.	• Review tape-coding exercise and provide written feedback to new research staff member. • Review videotape of interview • Review feedback of observer. • Send written feedback to Project Coordinator and staff member along with certification decision. • If certified, request random audiotapes of participant sessions. • If not certified, request another exercise.

Recruitment and Followup Stages

Monitoring participant recruitment, randomization into treatment condition, and followup rates is the most important role of the coordinating center and is the surest method of enhancing compliance across sites. Participant retention is high when staff-client relations are good and the facilities are pleasant and comfortable. Data accuracy and timeliness of completion are more likely when the protocol is followed and when staff members fulfill their responsibilities. Monitoring, both onsite and offsite, allows for poor performance in these areas to be identified and corrected.

Several factors determine which sites will need the most attention; not all sites will need to be monitored in the same way. During the beginning phases of the trial, enrollment rate is an important factor to be considered. If a site is recruiting at a slower rate than others, why is this occurring? When a site enrolls at a high rate, for example, it is important to monitor assessments at that site to determine if participants are meeting the inclusion criteria. Another reason for monitoring is staff size and turnover. A larger site with new research staff will need to be monitored more often than smaller, more stable sites. Sites that are well managed with motivated staff need less monitoring than others (Spilker 1991*a*).

Treatment Randomization Program

In comparative or matching research involving two or more treatments, the equivalence of the research groups is crucial. The presence of bias across treatment groups is a major threat to study validity (Stout et al. 1994). A centralized randomization procedure, based at the coordinating center, can minimize the bias that may occur with onsite randomization.

In Project MATCH, an urn randomization program, based on a probabilistic balancing procedure, was developed using a relational data base. A Randomization Form (appendix E) was completed onsite for each participant; it included values for all balancing variables as well as certification that the participant met eligibility criteria. The form was then faxed to the coordinating center, which entered the information into the randomization program. Once the participant was randomized to one of three treatments, the treatment assignment was faxed back to the site. This procedure not only ensured a balanced randomization procedure across the trial, but it also allowed the coordinating center to monitor potentially ineligible participant randomization.

There is, however, always the possibility that a participant who is randomly assigned to treatment will be found at a later date to have been ineligible for the trial from the start. Although instances of inappropriate enrollment are rare, a participant deletion procedure should be put into place. For Project MATCH, a Client

Deletion Form (appendix E) was completed by site staff to request derandomization. The form had to be approved by the local Principal Investigator and faxed to the MATCH Coordinating Center. Coordinating center staff removed the participant from the data base if the participant derandomization was approved.

Participant Tracking Data Base

A trialwide participant tracking data base is necessary for monitoring the recruitment process, participant accrual, compliance with treatment, and participation in followup evaluations. A relational data base was created by the Project MATCH Coordinating Center as a means of monitoring trial progress. Although individual sites were inclined to develop their own methods of following participants, the trialwide data base was an invaluable tool for monitoring participant compliance within the study.

Prior to the quarterly Project MATCH Steering Committee meetings, participant tracking reports were sent to the coordinating center. Compliance was reviewed during the meetings when trial progress was reported by the coordinating center. This practice fostered a healthy competition among sites, as they were compared to each other on a number of outcomes. Results from the participant tracking data base included enrollment rates; followup rates, including mean days overdue and percentage completed in person versus over the telephone; collateral rates; and biological testing rates.

Offsite Monitoring

In a large, multisite trial, especially one in which sites are dispersed around the country, onsite monitoring visits are expensive and time consuming. It is necessary to track the trial through data checks and telephone conversations with staff at individual sites as well as conference calls of combined staff at all sites. In Project MATCH, all assessments were audiotaped, providing an offsite means of monitoring diagnostic accuracy, eligibility, and protocol drift. The following are specific examples of offsite monitoring of protocol-related activities.

Completed Intake Sessions (Enrollment)

Site A enrolled participants at a lower rate compared to the other sites. Telephone conversations with staff indicated that there was little involvement of the Principal Investigator, and no regular staff meetings were held. Suggestions were made to the Investigator, who initiated weekly staffings with local reporting of problems and suggestions. Additionally, the coordinating center reported the low rates at the next Steering Committee. Enrollment at this site slowly improved over the next several months.

Completed Followup Sessions

Four sites consistently followed up participants at a lower rate than the other five. A conference call among Project Coordinators was initiated to discuss strategies for locating and completing

sessions with difficult participants. Staff at the more successful sites were able to give suggestions for locating and following participants. The conference calls were scheduled on a regular basis. The followup rates for the four sites gradually improved and even surpassed the more successful sites in some followup areas.

Eligibility Criteria

Site B requested derandomization or withdrawal of participants after enrollment. Derandomization, an appeals process, was reserved for those participants who had been randomized through false means (e.g., lying to the research staff). The coordinating center requested the site's baseline assessment tapes and discovered that many participants were enrolled prior to meeting the average length of hospital stay required for the study protocol, a violation of eligibility criteria. Site B staff were forced to request withdrawal if the participant left the hospital earlier than expected. No other derandomization requests were made once this matter was corrected.

Diagnostic Criteria

Site C recruited participants at a very rapid pace. The coordinating center staff requested the site's baseline assessment tapes and found that the diagnostic inclusion criteria were not met in all cases (i.e., minimum numbers of symptoms required for study eligibility). The coordinating center requested assessment tapes for questionable participants (i.e., those with few symptoms) and monitored the research interviewers. With the assistance of the Investigator at that site, this problem was immediately corrected.

Data Accuracy

Site D was invariably late in sending participant tracking data prior to Steering Committee meetings. In order to meet the reporting deadlines, coordinating center staff hand-calculated rates for this site on numerous occasions. After discussions with the staff and Investigator did not improve the situation, this site was excluded from the next Steering Committee report. Although every attempt was made to avoid embarrassing the Investigator at the meeting, the coordinating center was left with no options. The problem was immediately resolved.

Onsite Monitoring

Although offsite monitoring is a convenient, relatively inexpensive, and necessary technique, excessive reliance on distant observations may lead to a false sense of security with regard to a trial's progress. Although there are times when policing the trial is necessary, this role is unpleasant, stressful, and occasionally ineffective. One opportunity for coordinating center staff to strengthen relations with site staff occurs during an onsite visit.

Whenever possible, the coordinating center staff should act as part of the team to promote interest in the trial and encourage good staff morale. Site visits provide an occasion to spend time with

staff members and Investigators in order to understand how the team administers the protocol at each location. Site visits also provide an opportunity to observe the facility and to understand what administrative issues may affect good or poor compliance.

Furthermore, a trip to the trial sites enables coordinating center staff to obtain firsthand knowledge of the similarities and differences among them. Without the knowledge provided by external observers, discrepancies or procedural differences might influence participant compliance in unpredictable ways. The goal of onsite monitoring is to gather careful descriptive information, check on the reliability of the data-gathering procedures, and become familiar enough with the workings and context of each site to make possible the most accurate interpretation of the findings, especially where site differences occur.

For Project MATCH, two members of the coordinating center as well as one member of the funding agency visited each of the nine sites on two different occasions, with several specific aims.

- To check the reliability (i.e., consistency) of research personnel both within and among centers in terms of their adherence to the established protocol

- To meet personally with trial staff at each site in order to communicate a uniform set of expectations concerning the purpose of the research and to evaluate staff roles and responsibilities according to specifications in the study protocol

- To obtain firsthand descriptions, including photographs, of each site in terms of physical setting, institutional context, and other possible sources of influence on the quality of the data collected

- To identify practical and methodological problems and provide consultation early in the process of data collection

- To review procedures for screening, recruitment, random assignment, interviewing, questionnaire completion, followup, data entry, and project monitoring

Some specific procedural and facility differences found at Site G can serve as an example of how a site visit may be used to understand the problems associated with one aspect of compliance, the number of completed baseline sessions. Although Site G was housed in an impressive facility with competent and committed staff, the enrollment rate was one of the lowest in the trial. The differences discovered during the site visit fell into three catego-

ries: (1) marketing the trial, (2) enrollment procedures, and (3) project visibility within the housing facility. The coordinating center members were able to make recommendations to Site G aimed at increasing their enrollment rate.

Marketing

Site G differed from others in the frequency of advertising for participants as well as in the advertisement itself. Suggestions were made to increase the regularity with which the ad appeared in the paper as well as to modify the ad to appear more like other MATCH advertisements (e.g., "Free treatment" rather than "No charges") to emphasize the benefits of MATCH treatment.

Other marketing approaches, based on successful strategies used by other sites, were suggested by the coordinating center to increase the pool of potential participants. These included publicizing the project through a press release in the local newspaper, holding interviews with representatives from the print and broadcast media, and preparing public service announcements. These efforts provide an effective and inexpensive method of disseminating information about projects to the public as well as to the treatment community. During the site visit, samples of press releases and newspaper articles that worked to enhance recruitment at other sites were distributed to the staff at Site G.

Other strategies for increasing the visibility of MATCH within the local community were also presented.

- Revisiting area hotlines that include the MATCH number
- Conducting a workshop or inservice presentation for emergency room staff
- Investigating court mandates regarding DUI and DWI offenses with a view toward presenting MATCH treatment as a means of fulfilling court requirements for alcohol-related education and treatment
- Contacting local attorneys for MATCH referrals
- Placing a notice regarding Project MATCH in local church bulletins
- Presenting Project MATCH to Al Anon members or to other appropriate self-help groups
- Posting fliers at unemployment offices and local health clinics
- Presenting workshops at local health and mental health clinics

Enrollment Procedures

Site G also differed from the other sites in terms of initial contact with potential participants, attention to participant needs, length of time to complete all baseline enrollment assessments, and staff involvement. Collectively, these procedural differences may have a large impact on participant recruitment.

Initial contact.—Unlike the other sites, the newspaper advertisement for Project MATCH at Site G listed the telephone number of the facility in which MATCH was housed rather than a dedicated MATCH line. A clinic secretary answered the calls from the advertisement and scheduled appointments for participants to meet in person with a staff member who administered the initial screening questionnaire. Other sites administered the screening assessment immediately by telephone and scheduled a diagnostic appointment with the participant to minimize the number of inperson visits a participant would have to make. Additionally, it was noted that at Site G, calls could not be taken during the evening or on weekends, and there was no answering machine to record names and numbers for contact at a later time.

Recommendations were made to list a dedicated Project MATCH number in the ad and to purchase an answering machine to take calls when the line was busy and for coverage on evenings and weekends. It was also suggested that Site G personnel staff the MATCH telephone line for several days just after ads appear and that they screen potential participants over the telephone. Staff members were then able to schedule participants for the diagnostic appointment or refer them to the non-MATCH screening staff for other appropriate research projects or treatment. Telephone screening allows the staff to enter participants into the study in a timely manner and to screen a larger number of participants during a shorter period of time. This protocol worked very well in the other sites.

Attention to participant needs.—Mattson et al. (1985) described two major factors that affect willingness to participate in treatment studies—the ease of transportation to and from the clinic and the amount of time spent in the waiting room. Also, decreased participant compliance was noted with scheduling problems, lack of adequate communication, and blood draws. It was observed during the visit to Site G that potential participants had to invest a considerable amount of time in the project before they were enrolled in treatment. If they appeared eligible, participants were asked to provide blood and urine specimens following the screening, which was an alteration to the protocol (i.e., too early). They received little information about the initiation of therapy during the screening process. All in all, prior to enrollment, nothing pleasant happened to the participant.

The coordinating center staff recommended the following: Once screened and deemed appropriate for MATCH, the participant should be escorted to the MATCH offices and introduced to the Project Coordinator or research assistants, depending on who is available. The participant should be offered a cup of coffee or other beverage and shown the general location of the MATCH offices where assessment and treatment occurs. The diagnostic session should be scheduled, or even completed, if possible, at that time. Blood and urine specimens should be collected only after the diagnostic session is completed and participant eligibility is fully determined.

Duration of the intake assessment process.—Length of time to complete assessments is both a recruitment and client care issue. Site G participant-tracking data for 41 cases indicated that the length of time between completion of the initial screening questionnaire and the second screening session was approximately 6 days, while the average time between the initial screening and the first therapy session was 30 days! Other sites, in contrast, averaged 1 day between the two screening sessions with only 10 days between the initial screening and first therapy session. The coordinating center staff recommended that the Site G Project Coordinator talk to other Project Coordinators about attention to participant needs and about speeding up the enrollment assessment process.

Staff involvement.—Informal discussion during the site visit suggested that staff were generally unaware of the site's enrollment problem. At the other sites, Principal Investigators and Project Coordinators devoted considerable time to this issue during staff meetings and regularly brainstormed ideas for increasing participant intakes. The coordinating center recommendation was that the Site G Investigator and Project Coordinator spend more time with staff in an attempt to implement some of the recommendations suggested during the site visit and to generate additional ideas for enhancing accrual.

Project Visibility

Compared to the other trial sites, Project MATCH at Site G was relatively invisible within its institutional context. During the onsite visit, coordinating center staff found no "Project MATCH" signs within the building to assist in way-finding and no signs to distinguish this research project from other treatments or projects within the institution. If participants seemed appropriate for MATCH after the screening, they were seated in the building lobby where a secretary arranged yet another appointment for the diagnostic evaluation. No attempt was made to introduce the participant to the staff or to make the participant feel comfortable about the next step in the process. Very little was done to foster an identification with, or an attachment to, the project.

It was recommended that efforts be made to increase awareness of Project MATCH within the facility, beginning with a workshop to present the study. Project MATCH signs were another recommendation. Although these suggestions seem small and inconsequential, they have enhanced participants' willingness to participate at other sites in the trial.

The suggestions made to Site G were based on observations made by the coordinating center from previous visits to other sites. It was also recommended that the Investigator develop a written strategy for tackling the problem of low enrollment at the site and submit it to the Steering Committee by a certain date. A second site visit was also scheduled.

Data Entry and Data Management Procedures

Rigorous quality assurance procedures for the collection of data are integral to enhancing compliance. Through careful screening and monitoring, data entry and management procedures can affect all areas of compliance.

In Project MATCH, the data entry task was carried out by each individual site, while the coordinating center was responsible for overseeing the data entry and ensuring high, trialwide data quality standards. The coordinating center created each data entry program, complete with warning messages when out-of-range data were being entered. The MATCH policy also required double-entry verification for each case. These steps were implemented for premium data accuracy.

Data Timeliness

The coordinating center issued a timeline to each site requesting that a certain percentage of cases be entered, verified, and mailed to the coordinating center by a given due date. That percentage was determined both by a site's particular recruitment goal and the needs of investigators to review the data during the course of the trial. Upon receipt of a data shipment, the coordinating center reviewed the number of complete cases received. Sites were requested to send extensive documentation with each mailing that would detail missing cases, variables, and any anomalies.

The coordinating center reviewed the documentation in comparison with the data received. Any discrepancies between documentation and data or undocumented missing data was queried by the coordinating center for explanation by the sites in a weekly mailing. In many cases, missing data were simply a result of data entry error or misplacement of forms. When necessary, participants were queried by research staff to clarify their answers, or the audiotapes of interviews were reviewed to complete an assessment.

This careful scrutiny of missing data significantly increased the number of completed sessions, thereby enhancing compliance.

Another benefit of due dates is increased timeliness of data. That is, research staff working to fulfill a due date would hasten to complete followup visits with participants. The extent to which the sites met the deadlines was later reported to the Steering Committee, thereby providing an incentive to staff to collect and enter as much data as possible for the due date.

Data Accuracy

Perhaps the bulk of the activities by the data management staff at the coordinating center was devoted to data accuracy. They expended a considerable amount of energy conducting checks of out-of-range data, values that appeared to be outliers, and incongruent responses, as well as validating data by cross-checking different information sources. On a weekly basis, the coordinating center would circulate queries to each site concerning such anomalous responses and would request that an explanation be provided by a certain date. Not only did this system increase data cleanliness, but it enhanced compliance in another way. Namely, the types of incongruences the coordinating center probed demonstrated to the staff the types of problems they should look for and, consequently, taught them how to better gather information from the participants. Because they knew the coordinating center would query inconsistencies, they began to ask the questions of the participants themselves.

Careful review also assisted in identifying participants who did not meet the diagnostic criteria, that is, they were technically ineligible. Thus, Project MATCH analysts were able to identify and remove the very small number of such participants from the data base.

Data Coordination

Not surprisingly, the task of coordinating such a nationwide data management effort requires remarkable coordination among sites. Among the strategies found to be very helpful was identifying a person at each site to be a contact person regarding data quality. Whenever one site uncovered a problem with a data entry program, coding a form, or collecting an interview or had a helpful hint to offer, the information was distributed to all data quality persons. At the outset, it became clear that mistakes are commonly duplicated and that sharing information is critical to avoid this problem. It was also apparent that data quality personnel at the sites often found innovative ways of dealing with problems that should be shared with others. In retrospect, a monthly data quality conference call might have been very helpful for just these reasons.

The conference call could have also served another purpose. That is, a good relationship among data quality personnel at the sites is very important but sometimes difficult to maintain. To achieve the best possible results, it is important that the staff at each site feel that they are team members working in conjunction with the coordinating center toward the goal of data accuracy. It was clear in this study that the coordinating center encountered more data quality problems with sites who viewed the coordinating center as adversarial, where they felt that procedures were dictated to them. Maintaining a balance between implementing project procedures and facilitating a good team feeling is challenging. Allowing adequate input from site personnel is an important step; a monthly conference call would be one method of achieving that goal.

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Appendix A — A Participant's Guide to Alcoholism Research

You have agreed to become a participant in a research project that is investigating some aspect of problem drinking or treatment for this problem. You play a very important part in learning about HOW people drink, WHY people drink, WHAT helps people overcome their drinking problem, and WHAT can go wrong or get in the way. This *Guide* is to help you understand your role as a research participant and to answer some questions that you may have about what happens in a research project.

Question What is the difference between *treatment* and *research?*

Answer Treatment is given to an individual who has a problem with alcohol or other drugs. Treatment is generally provided in medical settings under the supervision of a physician. This means that the person receiving treatment must have a medical diagnosis of substance abuse or dependence. Research is not aimed at changing behavior or restoring health through the actions of the therapist. Research monitors change during or after treatment so that the quality or helpfulness of the treatment itself can be evaluated. Research assists professionals to improve the treatment they provide.

Question Why do people volunteer for research?

Answer The most common reasons people give for participating are—

- *To receive a new treatment*: The treatments being tested are new, or innovative, and show evidence of effectiveness. In addition, they are not available elsewhere in the community and are generally free of charge.
- *For additional medical monitoring*: Research is closely monitored to protect the health and welfare of the individual participants. This additional monitoring is to guard against problems arising from the treatment itself.
- *You want to help advance the treatment of alcoholism:* Your

participation helps advance our knowledge about treating alcoholism that can only be discovered in studies such as this.

Question How will it help me to be a part of a research project?

Answer Exceptional care is taken in developing a treatment that is to be tested in clinical research. You can be assured that you will be given excellent care.

Question What are the potential dangers of being a research subject?

Answer It is impossible to eliminate every risk in testing a new treatment. However, unnecessary risks are avoided, and many safeguards are built into the research to minimize the harm that might occur if you have an unfavorable response to the treatment. A careful review process to protect the health of human subjects is conducted before a study is approved.

Question What if I don't like the treatment I receive?

Answer Your personal reaction or opinion about the treatment you are given is important information for the professionals conducting the study. It is important to remember that some treatments take a while before they are effective. We ask that you give it a fair chance to work before you decide it isn't helpful.

Question What if I decide I don't want to continue to participate in the research project?

Answer You have a right to drop out of the study. Before making a decision to participate, we ask potential volunteers to carefully consider the commitment because it is worse for the quality of the research for a person to start and not finish than to not start at all. If you want to quit, we ask that you discuss this with the research director before you make your final decision.

Question How will my privacy be protected?

Answer Your privacy is protected by law. The information you share cannot be revealed without your consent.

Question How can I find out about the results of this research?

Answer The results of the study will not be published until all of the participants have finished. A summary of the main findings is usually provided to interested participants.

Appendix B — Routine Forms and Letters

Intake Form

PID _____ H# _____ hours _____

Name _____ Listed to _____

Address _____ Apt# _____ B# _____

City _____ St _____ Zip _____

Telephone _____ ext _____ hours _____

Name of collateral _____

Permanent address (if different from above) _____

_____

Date of birth _____ Target date _____

Social Security # _____ Schedule date/time _____

Method of interview: Site _____ Home _____ Telephone _____ Other _____

Confirmation letter sent _____ Telephone to confirm _____

Locators:

Name _____ Name _____

Address _____ Address _____

City _____ St __ Zip _____ City _____ St __ Zip _____

Telephone# _____ hours _____ Telephone# _____ hours

Relationship _____ Relationship _____

Group Affiliations: (Community centers, religious organizations)

Hobbies/activities:

Support groups: (AA, Parents Without Partners, etc.)

Students:

ID# (include school name) _____

Source of income—scholarship, work study _____

Activities/major _____

Roommates _____

Personal comments: (Events or changes that may affect the participant's life and possible commitment to the study)

Timetable for Followup Procedures

Schedule followup appointment

- Limit time availability to two choices—one in the morning and one in the afternoon of a different day
- Note any unique needs to enhance successful completion (babysitting, transportation, time constraints)
- Remind of commitment
- Appointment card
- Thank-you!!

Three months later:

Confirmation letter mailed

- 2 weeks prior to scheduled appointment
- Address correction requested, do not forward (ACRDNF)
- Returned; moved with a forwarding address
  - Reissue confirmation letter
- Returned; moved, left no address
  - Customized strategies; identify problem

Telephone confirmation

- 3 days prior to scheduled interview
- Telephone number disconnected; new listing
  - Call new number, confirm appointment, confirm address
- Telephone number disconnected; no new listing
  - customized strategies; determine problem

Conduct interview

- Client cancels appointment
  - Reschedule appointment
  - Determine reason for canceling
  - Verify demographic information
- Client is late
  - Determine reason/problem
  - Reiterate the importance of being prompt

Confirm demographic data

- Address
- Telephone numbers
- Locators
- Collateral
- Anticipated changes in lifestyle, etc.

Schedule followup appointment

Routine Notification and Reminder Letter

(Date)

(Client Name)
(Address)
(City/State/Zip)

Dear (Client's Name):

You recently applied for possible treatment in our alcohol treatment research project. It appears from the telephone screen that you are eligible to participate. Since we have not yet had an opportunity to follow up with the inperson interview that will allow us to make a final decision regarding your involvement in the project, I am writing to invite you to complete the interviewing process.

If you are still interested in participating in the project, and if your circumstances have not changed dramatically (your drinking or drug use, for example), please call (Phone Number) and inform (Name of staff person) of your decision. You will be able to schedule an interview at that time. If I don't hear from you within 10 days of receiving this letter, I will assume that you are not interested in the project and will close your file.

Sincerely,

(Name of Project Coordinator)
(Title)

Interim Contact Letters (Prior to Initial Followup Appointment)

(Date)

Dear (Client's Name),

Welcome to the followup phase of this research study. As has been explained, we will be contacting you every 3 months to conduct followup interviews. You, of course, will be compensated for your participation.

We appreciate your time and commitment to this project. We have scheduled your first followup interview for (date, time, location). I look forward to meeting with you in (room) of (building). If you have any questions or need to reschedule, feel free to call me. If you call long distance, we accept collect calls at (telephone number).

Sincerely,

(Name)
(Title)
(Telephone number)

(Date)

To: (Client's Name)

I would like to remind you of your upcoming (indicate which followup) month followup interview to be scheduled around (due date).

(This is not your actual appointment date; only a *tentative* target date.)

The interview will last approximately 1½ to 2 hours, and you will be reimbursed (amount of money being paid for this interview) for your help.

Blood will be drawn and, as usual, a breathalizer reading will be taken.

I will call you during the next week to set up this appointment. However, you can call me or any of the research assistants, day or evening, at (office phone number) to schedule this appointment at your convenience.

Remember, if you have any concerns or need other assistance, call (name and telephone number of Project Coordinator or other assigned staff person).

Thank you for your time and attention.

(Name)
(Title)

Anniversary Letter for Reminding of Interview (2 Weeks Prior to Interview)

(Date)

Dear (Client's Name),

We are coming up on the 1-year anniversary of our meeting through our research study. Your continuing commitment and time are appreciated.

Our next scheduled appointment is (day, date, time, location). Again, you will be compensated for completing the interview. If you have any questions or need to reschedule, please feel free to call me. If you are calling long distance, we accept collect calls at (telephone number).

I look forward to meeting with you.

Sincerely,

(Name)
(Title)
(Telephone number)

Notification That Laboratory Work Is Not Within Normal Range

(Date)

Dear (Client's Name),

We recently received your bloodwork results from our laboratory. As is indicated in the enclosed copy of these results, some of your levels are not within the normal range.

We suggest that you discuss this information with your doctor. Please feel free to call us if you have any questions. If you are calling long distance, we accept collect calls at (telephone number).

Sincerely,

(Name)
(Title)
(Telephone number)
Enc.

Reluctant to Attend, Remind of Commitment To Study

(Date)

Dear (Client's Name),

As a volunteer in our study on alcohol abuse treatment effectiveness, you received treatment at (location of treatment center).

We appreciate your contribution to the study and wish to emphasize that your continued participation in this study is important to its success. Remember that compensation for these confidential interview is ($ amount) and is still available to you.

We can schedule an appointment for (day, date, time, location) for this interview. Please contact me at (telephone number) to confirm this appointment or make other arrangements. As you know, we do accept collect calls. I look forward to hearing from you.

Sincerely,

(Name)
(Title)
(Telephone number)

No Show for Scheduled Appointment

(Date)

Dear (Client's Name),

We had an appointment scheduled for the (date and time) for the followup interview for our research study. Since you were unavailable for this meeting, we have scheduled a tentative appointment for (day, date, time, location)

Your continued participation is valuable and important to the success of the study. Please call me at (telephone number) to confirm this appointment or make other arrangements. If you are calling long distance, we do accept collect calls. Thank you for your cooperation.

Sincerely,

(Name)
(Title)
(Telephone number)

Thank You Letters

(Date)

TO: (Client's Name)

Thank you again for your participation in our research study. You have completed our treatment, and this check is to reimburse you for your time and travel for the followup visit.

The information you share with us will help us understand what happens to people after they receive alcohol treatment. We know that individuals respond differently to treatment, so please don't think that we have any expectations about what *YOU* will do. Your honesty and openness about your situation is what we need to draw accurate conclusions about the study. Your name and what you tell us will be treated with complete confidentiality.

If you have any questions or concerns at any time during the next year, I am available to you. We will be contacting you again in three months to schedule your next followup visit.

Sincerely,

(Name of Project Coordinator) (Title) Enc.

(Date)

To: (Name of Client)
Re: 39-month followup interview

Thank you again for your participation in our research study. This check is to reimburse you for your time and travel for the interview you just completed.

We expect this to be your last followup interview. We feel proud to have been a part of an effort that involved so many professionals from around the country and such a large and dedicated group of participants, like yourself. Your willingness to share the details of your life for the last 4 years will be a great help to understanding treatment for alcohol problems.

As you may know, the results of this study will not be known until some time in 1999. If you have requested information, it will be sent to you when it becomes available.

If you have a question or we can be of some assistance to you, feel free to call. We will be glad to help in any way we can.

Sincerely,

(Name of Project Coordinator) (Title) Enc.

Appendix C — Letters to Address Compliance Problems

No Treatment

(Date)

Dear (Client's Name):

It has come to my attention that you never began the therapy to which you were assigned. I understand that there could be several reasons for this. You may be too busy to continue at this time, and perhaps you intend to begin when your schedule is easier. Perhaps you have decided you don't need treatment or that you need a different type of treatment program other than what is offered in our study. However, as you may recall, the therapy phase of the research project is available for only ninety (90) days from the last assessment session.

Please remember that we still consider you a part of the research project even if you receive no treatment at this time. We are interested in what you do for the next 15 months. Many people recover without any professional help. We have no set expectations about what will be helpful for different people. You will help us by telling us what is happening in your life—the good and the bad.

If you have any questions or need assistance, please call me at (telephone number). I'll help any way that I can.

Sincerely,

(Name)
(Title)

Dropped Out of Therapy

(Date)

Dear (Client's Name):

I has come to my attention that you are no longer active in the therapy to which you were assigned. I understand that there could be several reasons for this change in your status. You may be too busy to continue at this time, and perhaps you intend to continue. However, the therapy phase of the research project is available for only ninety (90) days from the first therapy session.

Your inactivity may also mean you are dissatisfied with therapy or question whether it can help you. We encourage all clients to give the therapy a chance to work by completing the 12 weeks as we originally agreed. If you are not willing to do this, we understand and will wait to contact you until your first research followup appointment at the end of the 90-day therapy period.

Please remember that we are interested in *all* outcomes of therapy. We have no set expectations about what will be helpful for different people. You help us by telling us what is happening in your life—the good and the bad.

If you have any questions or need assistance, please call me at (telephone number). I'll help any way that I can.

Sincerely,

(Name)
(Title)

Unable To Contact for Final Evaluation

(Date)

Dear (Client's Name):

I am writing to you because I understand that the staff have been unable to contact you to schedule your final evaluation with the research project. I hope that this is just a case of missed communication and that we can complete the interview at your earliest convenience.

I know that a lot can happen to a person in the course of 15 months. If something has come up in your life that makes it difficult for you to follow through with this interview, please let us know. We greatly appreciate your loyalty to the project so far and want to do whatever we can to make it possible for you to complete.

If you need some special arrangements like transportation or a home visit, please call (name of office staff) or myself at (telephone number), and we will make the arrangements.

Sincerely,

(Name)
(Title)

Thank You for Scheduling Followup Interview (Participant Reinduction)

(Date)

Dear (Client's Name):

I want to thank you for agreeing to schedule a followup interview with the research team. We are very pleased with your recent decision to come in. Your continued participation in this study is important to its success. We will reimburse you (dollar amount) for your time and travel. This amount is more than the usual reimbursement rate.

For future followup visits, if scheduling at our office is difficult for you, we have some flexibility in how we conduct the followup evaluations. We want to make this as convenient as possible for you, so let us know what your needs are. If you missed one of the scheduled followup appointments, we will attempt to recapture that time missed.

Please feel free to call me at (telephone number) if you have any questions or need some assistance. Part of our commitment to you is to offer support during the 12-month period of the followup. Again, thank you for your willingness to remain a part of the project.

Sincerely,

(Name)
(Title)

Deter Dropout

(Date)

Dear (Client's Name):

I am writing to talk to you about our concern about your potential for dropping out of our research study. We understand that during the course of the study some clients will change their minds about being involved with the research project. They may be dissatisfied with the services they received, or their circumstances may have changed, making it difficult to continue. While we understand the reasons why this change may occur, and we respect the individual's right to leave the study prematurely, we want you to know what impact this decision has on the overall quality of the research.

If you recall, at the intake assessment we talked with you about the importance of the long-term followup. In order to say with confidence what treatments have been helpful or not helpful for what kinds of people, we need to have a high percentage of clients complete the full 15 months. Dropouts in a particular client group limit our ability to draw conclusions about the treatment results for the client group. In other words, your decision to stay or not stay with the study may affect other people like yourself seeking treatment in the future.

Our dilemma is to balance out the client's right to choose with our need to keep people in the project. We have several options available to us. If you do not want to come to our office, we can send a research assistant to your home, or we can do the interview over the telephone. If there is some part of the interview that you object to, we can omit it. Remember, we want to make this as convenient as possible for you.

Please help us do the job we've been asked to do. If you are ready to schedule your 3-month interview or willing to consider another option, call (name) at (telephone number). We will continue to attempt to reach you. Thank you for your cooperation.

Sincerely,

(Name)
(Title)

Decision to Drop Out

(Date)

Dear (Client's Name):

I am writing to you about your decision to drop out of our research project. I understand that this is your right, and you have been very clear about the reason why you made this decision: you feel you were not helped by the treatment. Given that fact, I am writing to ask you to reconsider your decision. If you will hear me out, I will tell you why this is so important to us and what we are willing to do to make it worth your while.

If you recall, at the intake assessment we talked about the importance of the long-term followup. In order to say with confidence what treatments are helpful or NOT helpful for what kinds of people, we need to have a high percentage of clients complete the full 15 months of followup. Dropouts in a particular client group limit our ability to draw conclusions about the treatment results for the client group. In other words, your decision to not stay with the project may affect other people like yourself seeking treatment in the future.

The fact that you have not completed your (name the missing followups) followups does not mean you can't help us. If you are willing to talk with one of our research assistants, we can get the information needed for us to count you IN the project. We have several options. We can do a telephone interview and send self-reports to your home. We can do a telephone interview only. Or we can schedule the 15-month interview and see you in person, which will take approximately three hours of your time, including lab and self-reports. I can reimburse you (amount) for that interview.

Please help us to do our job so we can meet the goals of this nationwide, federally sponsored treatment research study. I will give you a week to consider this. If I don't hear from you by (date), I will do a followup telephone call. I hope you will give some careful thought to this matter and allow us to interview you.

Sincerely,

(Name)
(Title)

Accept Dropout With Respectful Acceptance of Decision to Drop Out

(Date)

Dear (Client's Name):

You recently spoke with one of our research assistants regarding the additional 2 years of followup interviews. You said you had no interest in continuing with these interviews.

We regret your decision; however, we understand that it is not uncommon for people's attitudes to change over time about their involvement in a study like ours. You had your own reasons for declining at that time, and we will respect your decision. We will not be sending you reminder letters or calling you to confirm your decision.

However, if your circumstances change and you wish to reinvolve yourself, I hope that you will call us at (telephone number) to let us know that you would like to continue in the study.

Thank you for your past involvement and best wishes from all of the project staff.

Sincerely,

(Name)
(Title)

39-Month Contact

(Date)

Dear (Client's Name):

It's been 39 months since you enrolled in our research study. Your final interview is soon due. You gave us permission to invite you to complete this interview.

It would be a tremendous help to us as a site, and to the project as a whole, if you would agree to this interview. It will cover the period of time since your last followup interview. Depending on how much information you are willing to provide, this could take as little as 1 hour, or as much as 2½ hours. We will compensate you accordingly for your time and effort.

I hope you will consider this request. If you have questions, please discuss them withus. If you want more information, or are prepared to schedule this interview, call us at (telephone number). If we don't hear from you, we will assume that it is okay to call you as a followup to this letter.

If I can be of any assistance, please call me at (telephone number). I am looking forward to meeting with you.

Sincerely,

(Name)

(Title)

Reconsider 39-Month Interview

(Date)

Dear (Client's Name):

Some time ago, you said you were not interested in participating in our research study. At that time, it was unclear to us whether or not that was a permanent decision, so I am writing you to invite you for the FINAL (39-month) interview. Like yourself, a number of the original (number) (city) participants dropped out of the research followup at some time. This is not unusual given the amount of time the project has run. What is extraordinary is that almost all of them have become reinvolved. Nearly (percent) of our participants completed the original 15-month project. The vast majority of those people have continued in some fashion with the long-term followup interviews.

If you are willing to consider a final interview, please call any of us at the project office (telephone number) for more information. You will be reimbursed $50 for a telephone interview and $150 for an in-person interview. If you are ready to schedule, the interview will cover the last 2 years.

I hope you will consider this request.

Sincerely,

(Name)
(Title)

Appendix D — Letters to Collaterals

Dear (Name):

A research interviewer from a study being conducted through the ABC Alcohol Study Center, will be contacting you soon to conduct a telephone interview. A participant in this study has granted us permission to contact you in reference to his/her progress.

We appreciate your participation in this research project and look forward to talking with you soon. If you have any questions or need to change an interview date, please call me collect at (telephone number).

Sincerely,

(Name, Title)

Followup Interview With Collateral

Dear (Name):

(Participant name) has been involved in a treatment research project with us, and you may remember on (date) of last year and on (date) of this year we conducted telephone interviews with you. These interviews were conducted with (participant's) full permission. At the beginning of his/her involvement with us, he/she gave us your name as a trusted person who could answer these questions for us. We appreciate your past cooperation with these interviews because they are a very important part of our research. They help to validate the information we receive from (participant).

It is now time to conduct another telephone interview with you. You may recall that these interviews take only about 10 minutes to complete. Please call when it is convenient for you or I will try to reach you again soon.

Thank you for returning my call on (date) and for your past involvement with our research project. I look forward to your continued participation.

Sincerely,

(Name, Title)

Ask for Collateral Help in Locating Participant

Dear (Name of contact):

I am writing to you because we have been unable to reach (participant's name) to schedule him/her for a followup interview. As we have spoken to you in the past, you are aware of how very important it is to the integrity of our treatment research that we meet with (participant's name) to get some information from him/her. We would like to do a followup interview with him/her that will take about an hour. We will meet with him/her at a location that is convenient for him/her, and we will pay him/her (amount of money paid for this visit) for his/her time and travel.

When I last spoke to you, we talked briefly about the possibility of your helping us make contact with (participant's name). If you can persuade him/her to come in to do the interview, we will send you (amount of money) as well [optional offer]. This information is valuable to our research, and we appreciate the efforts you have made on our behalf.

Please call us at (telephone number) if you have any questions or concerns. Thank you again for your help.

Sincerely,

(Name, Title)

Ask for Collateral Help in Locating Participant—For Cash

Dear (Name):

I am writing to thank you for your cooperation in doing the telephone interview with me last (date). Unfortunately, (participant's name) has not called us yet to schedule his/her interview. I wrote him/her a letter offering him/her (amount) to complete this interview and to explain to him/her why we chose to contact you for help.

If you can persuade (participant's name) to come in to do the interview, we will send you (amount) as well. This may seem very odd to you, but the information is valuable to our research, and we appreciate the efforts you have made on our behalf.

Please call me at (telephone number) if you have any questions or concerns. Thanks again for your help.

Sincerely,

(Name, Title)

Appendix E — Coordinating Center Forms

Randomization Form

Client ID: _____ CRU: _____ Code: _____ Date: _____

Meets inclusion/exclusion criteria:	Y N
Signed informed consent:	Y N
Age:	_____
Sex:	M F
Marital status: Married and living with spouse at least 1 year?	Y N
Ethnicity:	W B H O
Education: Number of years completed	_____
Employment status: Employed full-time in same job continuously for past 6 months?	Y N
Treatment history—alcohol problems:	
Number of previous treatments, beyond detox, excluding current inpatient stay	_____
Alcohol diagnosis (SCID): Symptom count (1–9)	_____
Treatment history—psychiatric problems:	
(ASI: Psychiatric status)	_____
Number of inpatient treatments:	_____
Number of outpatient treatment:	_____
CPI score:	_____

_____ Telephone: _____
(Person requesting treatment assignment)

Treatment assignment confirmation: Mail:_____ FAX:_____

_____ Date: _____
(CC person making treatment assignment)

Treatment: _____

Assignment communicated to CRU:

Telephone _____ Date: _____

Hard copy _____ Date: _____

Client Deletion Form

Date: _____

CRU: _____ Code: _____

The following client who was enrolled in the project has been found to have been ineligible to participate in the project *at the time he/she was randomly assigned to treatment*:

Client ID: _____

Reason for exclusion:

- ☐ Less than 18 years of age
- ☐ Legal or probation/parole status
- ☐ Reading ability (less than grade 6)
- ☐ Failed to meet criteria for alcohol abuse or dependence
- ☐ Involved in concurrent therapy
- ☐ Alcohol was not principle drug of abuse
- ☐ Not treatable within an outpatient setting
- ☐ Involved in intensive therapy within 3 months of enrollment
- ☐ Dirty urine inconsistent for Form 90-1
- ☐ Other

Please provide a description of the circumstances that resulted in this client's inappropriate enrollment in, and subsequent deletion from, the trial.

_____

_____

_____

_____

_____

_____

_____

_____

Project MATCH Accrual

April 20, 1993
108 Weeks of Recruitment
Total Accrual = 1728

Outpatient Study

(Outpatient accrual = 954 Males = 688, Females = 266)

Site	Treatment 1	Treatment 2	Treatment 3	Total	% of goal to date
Site 1	72	75	79	226	100%
Site 2	67	61	72	200	100%
Site 3	61	74	66	201	100%
Site 4	51	72	57	180	103%
Site 5	50	53	44	147	90%
Total	301	335	318	954	99%

Aftercare Study

(Aftercare accrual = 774 Males = 619, Females = 155)

Site	Treatment 1	Treatment 2	Treatment 3	Total	% of goal to date
Site 6	53	57	55	165	82%
Site 7	69	61	61	191	95%
Site 8	55	52	61	168	84%
Site 9	62	47	57	166	83%
Site 10	27	30	27	84	84%
Total	266	247	261	774	86%

Project MATCH Followup Completion Dates, Outpatient Sites, 2/6/94

	3 Month	6 Month	9 Month	12 Month	15 Month
Site 1					
Eligible	226	225	219	190	164
Complete	220	216	206	172	143
Completed after due date	121	131	122	85	78
Mean days overdue	31	29	27	27	29
Site 2					
Eligible	200	200	184	139	108
Complete	194	187	164	121	93
Completed after due date	177	173	156	114	88
Mean days overdue	31	32	25	23	25
Site 3					
Eligible	200	199	195	165	138
Complete	193	187	179	153	122
Completed after due date	163	167	168	136	115
Mean days overdue	31	30	31	30	26
Site 4					
Eligible	180	180	179	164	148
Complete	178	177	172	156	141
Completed after due date	149	131	128	104	114
Mean days overdue	15	16	16	12	15
Site 5					
Eligible	147	147	145	124	108
Complete	144	143	138	116	100
Completed after due date	107	117	118	93	86
Mean days overdue	26	20	24	23	21
Outpatient Combined					
Eligible	953	951	922	782	666
Complete	929	910	859	718	599
Completed after due date	717	719	692	532	481
Mean days overdue	27	26	25	23	23
by phone	1%	1%	1%	—	1%

Project MATCH Collateral Rates 8/25/93

	Site 1	Site 2	Site 3	Site 4	Site 5	Total
Number randomized	165	191	168	166	84	774
Intake collateral rate	86%	70%	92%	92%	96%	86%
n complete/	142	134	154	152	81	663
n eligible	165	191	168	166	84	774
3-month collateral rate	72%	52%	85%	88%	77%	74%
n complete/	117	98	141	146	62	564
n eligible	162	189	166	166	81	764
9-month collateral rate	75%	47%	78%	78%	77%	69%
n complete/	86	65	88	103	30	372
n eligible	115	139	113	132	39	538
15-month collateral rate	69%	53%	80%	73%	68%	68%
n complete/	49	41	51	59	13	213
n eligible	71	78	64	81	19	313