CHAPTER 7

MANAGING PARTICIPANTS AND MAXIMIZING COMPLIANCE

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Managing participants to minimize dropouts and maximize dietary compliance (adherence) is an art as well as a science (1). This chapter addresses specific areas that impinge on initiating and executing a study protocol involving human participants. The concepts discussed are based on years of experience from a wide variety of studies conducted by the authors. This experience is seldom described in the research literature. The topics that are discussed include study initiation, implementation and orientation (staff and participants), study management, maintenance of morale, and close-out and discharge.

PARTICIPANT SELECTION

Participant selection is one of the most critical factors related to managing study participants with the intent of maximizing dietary adherence and minimizing dropouts. (Also see Chapter 6, "Recruitment and Screening of Study Participants.") Because a comprehensive participant selection protocol frequently requires more than one screening visit, the willingness and ability of a potential participant to comply with this process is itself a good indicator of subsequent compliance in the study. Potential study participants need to be well informed with respect to what is involved and expected of them so that they understand their commitments and can make an informed judgment about whether these commitments can be met. Likewise, the investigator needs to make an independent assessment of the likelihood that a potential participant can in fact complete the study in accordance with the protocol.

The ultimate decision whether a potential participant will be included in a particular study depends on the judgment of both the participant and investigator. A comprehensive evaluation of the potential participant can minimize the management demands necessary during the actual study period.

STUDY INITIATION

The initiation stage or run-in period of a new protocol may well be the most critical period of the investigation. A smooth start to a study can maximize efficiency and create a positive framework within which both staff and participants can operate. Alternatively, unnecessary ambiguity, confusion, or the burden of unnecessary data collection early

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in a study can undermine working relationships among participants and staff, the consequences of which may resurface throughout the study period.

Investigators

A number of responsibilities must be borne by the person taking primary responsibility for actually supervising the study. If these duties are divided among individuals, a detailed plan should be in place for delineating specific responsibilities well ahead of study implementation. This will help to ensure that all necessary groundwork is accomplished in a timely manner and that staff and participants know the person who can resolve specific issues and provide clarification or direction.

For many areas, failure to plan well can create small discrepancies that may be difficult to reconcile as the study progresses. Alternatively, some areas, such as diet, are of such a pervasive, repetitive, and immediate nature that all staff should be prepared to field basic questions and be aware of when to defer them.

Institutional Review Board (IRB)

The management schedule must allow enough time to make alterations in accordance with institutional review board (IRB) requests and obtain final approval from the IRB before the study is scheduled to begin. This can add several months to the time line. The consent forms should be as detailed as possible and include the expectations of both the investigators and participants as well as any restrictions placed on the participants. (See Chapter 5, ''Ethical Considerations in Dietary Studies.'')

Written Materials, Scheduling, and Flow Sheets

Prior to the initiation of a protocol, a staff meeting should be held to review the protocol (which should be a written document) and its implementation in detail. It is important for the principal investigator and all staff involved in the study to attend. At this meeting the responsibilities of each staff member should be defined and discussed thoroughly, as should the day-by-day study procedures and tests. Additionally, all written procedures, instructions, and educational materials should be reviewed in their final form.

The complexity of the study and the number of staff people involved will dictate the level of complexity of procedures, instructions, and flow sheets provided to the staff and participants. The advantage of providing separate written procedures to both the staff and participants is that the staff material can be more detailed and customized without risk of confusion. A disadvantage to this approach is the increased risk of ambiguity. Slight wording differences may eventually cause confusion.

However, unless the study is relatively short in duration and has a simple schedule, having separate materials for staff and participants is preferable. Useful differences in the instructions and schedules provided the staff and participants are as follows.

Participant materials should be more specific with respect to their roles and responsibilities in language that is appropriate to their educational level. Clearly indicated and highlighted should be such issues as the day the participant is scheduled to come into the research center fasting or days that the participant is responsible for urine collections. Wording should be set at about a high school level. The format of materials designed for the participants is frequently dictated by the characteristics of the specific group. For example, schedules designed for elderly participants should have relatively large print and be printed on heavy paper that is easy to grip. Instructions for studies involving groups whose primary language is not English should be provided in their native tongue. Translating materials properly requires translating into the common vernacular of the participant's language. There should also be a subsequent ''back translation'' into English to assure the investigators that the translation conveys the message and associated nuances accurately.

Staff materials should stress days that necessitate reminder calls to the participants about fasting or specific containers to be used for multiple blood samples or urine collections. Any material provided to the participants should be available and on file for the staff, even if the staff material is an expanded version of the participants' information.

The Study Diet

All staff in contact with the participants must understand all the procedures involved in the dietary aspect of the study because questions will arise. The participants will assume that anyone associated with the study will be able to address their queries. Although it is perfectly acceptable to refer answers or decisions to the appropriate staff member, the more quickly an issue is resolved, the happier the participant will be. A detailed discussion of developing, producing, and delivering research diets is provided in Chapters 10–13.

Staff Protocol Meeting

Before the study begins, staff should meet to review all written materials in their final form, clarify any ambiguities that are perceived, and consider potential problems and strategies for solving them (see Study Management). At this time all staff members should thoroughly review their subject area with the rest of the staff. As before, these meetings should involve as many staff as possible so that a consistent approach is maintained throughout the study period. Optimally, a pilot test of the protocol should be made. Any investment in time and labor will most likely be offset by the avoidance of problems once the full protocol is initiated.

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STUDY IMPLEMENTATION

Because a large number of staff frequently are involved in bringing a study to completion it is important for clear policies and procedures to be communicated orally and in writing. A convenient technique for this is a formal orientation to the study. The orientation provides an opportunity for both reflection on the written material and discussion about implementation protocols so that the procedures are fine-tuned prior to the start of the study. As with most projects, a clear and unambiguous initiation phase to the study protocol can ''set the stage'' for the entire study.

Orientation for Staff

A well-thought-out, comprehensive orientation is crucial to ensure that staff adhere to the study protocol and that study operations proceed smoothly. In addition to providing uniform training and information, the orientation process defines rules, expectations, and standards of performance. Critical during the staff orientation is a review of the overall study. This review would include a brief description of reasons the study is being conducted, its specific objectives, the characteristics of the participants, data collection activities, time frames, and other procedures.

Also important to clarify are such issues as job responsibilities, administrative organization, and channels of communication. Clearly written descriptions of tasks to be performed and standards of acceptable performance should be presented. Staff orientation procedures are summarized in Table 7–1.

Additional orientation meetings may be scheduled after this general orientation for specific groups of staff. For example, staff involved in food preparation should receive an in-depth orientation on issues pertaining to the study diet. Special emphasis would be placed on diet specifications; specific foods and menu cycle; food preparation and service; rules regarding food substitutions, if any; quality control procedures; and a review of food handling and sanitation standards.

In addition to orientation meetings, regular staff meetings provide a forum for timely resolution of problems. Information on study progress can be shared and staff contributions toward accomplishing study goals can be recognized. Meetings also allow for an ongoing assessment of quality control and efficiency of operations on a regular basis. It is important to keep in mind that inconsistent answers from different staff members will lead participants to conclude that the study is not well managed. This leads to a sense of insecurity and loss of respect for the investigators with attendant consequences for adherence and retention.

Orientation for Participants

It is important from the outset that participants have a clear understanding of their roles and responsibilities, as well as the benefits they will realize as a result of their participation in the study. Participants should be aware of the nature and extent of the changes and constraints in lifestyle that will result from study participation. Orientation topics that are specifically important to the participants are discussed here.

Study Overview

The study overview comprises a description of study objectives, conduct of the study, testing procedures, data collection, and frequency of data collection.

Study Diet

If possible, a copy of the study menus should be provided prior to the study so that participants are aware of the foods they will be served. Policies regarding the number of meals per day to be eaten at the facility, missed meals, study food items not eaten, and nonstudy food eaten require extensive discussion and should be provided in oral and written form. Rules regarding the frequency and number of off-site meals

TABLE 7-1

Staff Orientation

Area	Major Points
Study overview	Purpose of the study Specific objectives Characteristics of participants Details of data to be collected Time lines Procedures
Organizational structure	General descriptions of job responsibilities Administrative organization Channels of communication
Job description	Clearly written descriptions of tasks Standards of acceptable performance

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(eg, total number permitted) and procedures for obtaining food in emergency situations also require discussion.

Problems and uncertainties related to dietary infractions are major concerns in well-controlled diet studies. Thus, areas in which the participant has flexibility or ''freedom in food choice'' need particular emphasis. Providing a discretionary snack that meets study specifications or a list of allowable snacks can be helpful in reducing the likelihood of eating nonstudy foods or discarding food provided. Staff should provide a specific list of any ''free foods,'' such as diet soft drinks, tea or coffee, mineral water, tap water, condiments, and hard candy, that participants may consume. It is important to be specific and absolutely clear in instructions to avoid confusion for the participants. Levels of knowledge vary greatly, and nothing is obvious. If there are limits to the use of free foods, staff should be even more specific, eg, ''You can have two 12-ounce diet, caffeine-free colas a day, and one 12-ounce mineral water per day.''

Staff should include a ''packing list'' of food items on the bag or cooler as part of quality control procedures for packed meals. This checklist reduces errors of omission for the staff when putting together several take-out meals, and the list identifies for the participants the food items and when they are to be consumed.

Staff should give clear, written directions for safe storage and reheating of foods. Again, staff should not take anything for granted; participants' levels of knowledge on food safety and sanitation vary widely. Instructions must list a phone number and contact person to call for questions or emergency situations. Include a preweighed paper towel in a resealable plastic bag for collecting spills and instruct subjects to collect any spilled food and secure it in the plastic bag so that it can be weighed. Also, participants should learn that they are to return any food or beverage not eaten and report any illness immediately.

Some research units have meals delivered by a staff member or by courier directly to participants. However, most units require participants to come to the facility to pick up their food. A contact person is essential in order to answer questions and solve problems such as, ''My son ate my lunch,'' ''I dropped the cheese and the dog ate it,'' ''I spilled the apple juice on the meatloaf,'' or ''My car broke down, and I can't come today to pick up my food.'' A staff member or courier can be sent to deliver the replacement food.

Data Collection Policies and Schedules

An atmosphere that fosters a trusting relationship between the staff and participants is important in supporting the data collection process. Such a relationship can contribute to smooth study operations and promote participant compliance and accurate self-reporting of deviations from the study protocol. The nature of the data to be collected (ie, what, how, and when) must be clearly described. It is helpful in this regard to distribute a data collection calendar listing such information.

Participants also need to understand the importance of reporting lifestyle changes (ie, exercise patterns) to appropriate staff. They need to know which behaviors should not be undertaken during the study (ie, smoking, alcohol). Finally, policies regarding special circumstances and criteria for termination from the study should be reiterated. At this point the study coordinator should meet with each participant to ensure that the orientation material has been read and understood and the informed consent signed. A checklist can be used to ensure that all essential information has been discussed during the orientation.

Study Management

Managing a study can be challenging. It can frequently become a balancing act between maintaining the integrity of the study and trying to keep all parties happy. Once a study begins, only rarely does management entail sitting back and hearing how well things are going. Anticipating potential trouble areas and planning strategies to deal with them can be a valuable and efficient use of time.

Managing Conflicts or Problems

Clear lines of responsibility need be established for the management of participants to ensure that problems get handled quickly, efficiently, and without confusion of the participant or manipulation of the staff. The following are general guidelines. The specifics are determined by the number of staff involved and the predetermined role of each. Problems or conflicts raised by a participant to the staff or investigator should be directed to the appropriate staff person. Immediate action should be taken to avoid any ''domino effect'' with the other participants.

Flexibility within the constraints of the protocol is very helpful. All encounters should be documented and the resolution reported to all staff coming in contact with the participant. The decision should be communicated to the participant by a mutually agreed-upon staff member. A respect for delineated roles is critical to this system.

Participants' Requests for Changes or Modifications

Participants are likely to have difficulties complying with even the best-thought-out and most detailed protocols. The first step in resolving problems without compromising adherence to the protocol is for the staff person first contacted to refer the issue to the colleague responsible for that aspect of the study. For example, a participant may ask the nurse taking his blood pressure whether milk from an evening meal can be shifted to midmorning because he really misses a traditional morning milk and tea break. This issue should be brought to the dietitian, who would determine whether this request could be accommodated within the confines of the protocol. Another participant may request that the principal investigator change the days she comes in for blood

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sampling. This issue should be referred to the person responsible for scheduling, even though the requested change may not breach the study protocol and the principal investigator would like to personally accommodate the participant and foster a positive relationship. In the vast majority of such cases the request can be accommodated with no problem, but, occasionally, the schedule change cannot be made because it would overburden the workload of either the phlebotomist or laboratory for a given day. Sometimes, however, the participant has first requested the change from the appropriate person, been turned down, and then decided to try an alternative means of achieving his or her goals.

Getting first a ''yes'' from the principal investigator and then a ''no'' when the conflict is discovered can lead to an awkward situation for all involved. A situation of this sort can undermine working relationships among staff and the participant as well as among staff members. The only way to avoid this is for all staff to respect the predetermined roles of their colleagues and to always defer questions or requests to the appropriate person (2).

Resolution of Minor Conflicts

When studies are carefully planned, they typically proceed smoothly and minor changes as requested by participants can be accommodated. However, regardless of how well thought out and meticulously executed a protocol is, questions, misunderstandings, and special requests will occur. If clear lines of responsibility are defined and adhered to, a satisfactory resolution can be reached without the participant dropping out of the study. However, if an issue is raised and the outcome is unsatisfactory to the participant or staff, the principal investigator will have to resolve it. Under most circumstances the ultimate decision will be acceptable to all parties involved, especially when the rules are clearly detailed at the beginning of the study.

Examples of minor conflicts are given here. A participant was under the impression that when he had blood draws scheduled for 2 consecutive days he could choose the more convenient day. A week prior to the dates he committed himself to another activity for 1 of the 2 days. The situation was communicated to the staff 2 days prior to the first scheduled blood draw during a review of the schedule with the participant. An explanation concerning the necessity of obtaining 2 *consecutive* blood samples and shifting the inconvenient date forward or backward solved the problem.

In another case, a participant's work schedule was changed without warning in midstudy. Although the dietary department could accommodate different meal pickup and/or consumption times, the participant for this study could not come in for the collection of fasting blood samples in the morning. She did not want to drop out of the study and did not understand why, if she were willing to fast all day, the fasting sample could not be taken in the evening, especially because she knew that staff would be available to collect the sample at that time. At this point it was necessary for staff to clarify that although the now agitated participant did not perceive a problem in compliance, the effects of circadian rhythms precluded the proposed change. The manager suggested that the fasting blood samples be collected on a nonwork day if the laboratories involved could accommodate this schedule change.

Mediating Issues Among Participants

Situations arise where one participant perceives that another participant is making inappropriate comments or breaching the protocol and feels compelled to inform a staff person. For example, Participant A continually complained about the packaging of the food prepared for take-out. Participant B did not perceive a problem and did not like to hear the continual complaining. Participant B requested some intervention but did not want to be identified as the person bringing the issue to the attention of the investigator.

Another example might be the witnessing of Participant C hiding a disliked food in a napkin and disposing of it. Similarly, Participant C might boast that he never eats a certain food and there is no way the investigators can find out.

It is important to address such issues when they occur; failure or perceived failure to do so undermines the morale of the other participants. If a staff member is present and mingling with the participants at a mealtime, he or she will frequently overhear conversations and be able to resolve conflicts readily. Possibly asking, in the presence of others, how things are going or how the new food wrap is working out can adequately redress the problem. Issues pertaining to bragging about nonconsumption of food are far more difficult to verify and address. A casual private interview with the purported offending participant could rectify the situation by allowing him or her to bring up a specific problem or by providing the extra attention the participant sought.

Investigators must keep in mind, especially for long-term diet studies, that participants surrender a tremendous amount of control over everyday life during diet studies. This lack of control can manifest itself in many ways. For example, participants might revert to surprisingly childlike behavior such as blatantly testing limits. Awareness of this possible hidden resentment when investigators deal with staff-participant or participant-participant problems can help focus the issue. Planning can help to resolve such issues in a manner that saves face for the participant and fosters strict adherence to the protocol.

Areas of Flexibility

It is important to remain as flexible as possible, especially when the study is relatively long and restrictive. However, to advertise this policy up front is probably not advisable. Handling specific issues with participants on a case-by-case basis in a confidential manner is probably the wisest approach. Even the appearance of willingness to accommodate a small schedule or food change may make the difference

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between a participant completing a study or not. In some situations if a request cannot be accommodated, an alternative can be proposed that creates good will with the participant and conveys the willingness of the staff to treat the participant as an individual and not just a number.

Although inconvenient, it is not unreasonable for participants to request small changes in their diets to accommodate personal preferences, especially if participants will consume the diet for a long period of time. In an ideal situation, sample menus are available in advance. This enables the participant to note a food or food combination he or she feels is totally unacceptable, and the issue can be resolved in advance. For example, Participant X does not normally eat broccoli but felt that, if it meant participation in the study, she could. After the first week, however, Participant X felt she could no longer consume broccoli and wanted to switch to string beans. In some studies, such a switch would not present a problem with respect to the study protocol. Should the change be made? If possible, yes, without question. However, although this solution appears relatively straightforward, the following ramifications occur:

- Participant Y now has seen the switch made for Participant X and also wants ''one small change.''
- Participant Z heard that Participant X was able to switch a food, and he requested to switch an orange for orange juice because he hates to peel oranges. In this case, the substitution could not be made because the fiber content of the diet was being controlled. An apple might be an acceptable substitute.

In another scenario, carrot sticks were incorporated into the menu. Because of her denture problems, carrots were difficult for one of the participants to chew. Incorporating grated carrots into a salad solved what could have potentially turned into an embarrassing situation. The ultimate resolution would be dictated by the specific protocol. Incorporating a limited number of food choices into the menus from the outset is an alternative approach that may serve to avoid a large number of requests for changes as a study progresses.

Voluntary Premature Terminations (Dropouts)

What can be done to keep participants from deciding to stop participating in a protocol before the study ends? A thorough screening process as discussed in Chapter 6, ''Recruitment and Screening of Study Participants,'' will probably contribute the most to minimizing the dropout rate by avoiding enrollment of participants who will find the protocol too difficult to comply with. However, unavoidable situations do occur, especially during studies of relatively long duration.

If a participant indicates that he or she has decided to terminate participation in a study, all efforts should be made to meet with the participant immediately. Without any attempt or appearance of an attempt to coerce the participant, the reason for termination should be discussed. At this point it will most likely become clear whether there is a way to avoid losing the participant midstudy or whether the situation is unresolvable. Keeping in mind that it is legally and ethically within the rights of a participant at any time and for any reason to terminate participation in the study, the meeting should end on a positive note. An offer should likewise be made to follow up with any data that would normally be provided to the remaining participants once the protocol is completed. Queries by other participants about why the person terminated should be addressed with as few details as possible. This protects the departing participant's privacy unless he or she gives specific instructions for this information to be divulged. Experience indicates that in most cases, the other participants are aware of the situation, sometimes before the staff know anything about it.

Involuntary Premature Termination

It may become necessary to terminate a participant who wishes to remain in the study. Clear criteria for involuntary termination should be incorporated into the consent form. (See Chapter 5, ''Ethical Considerations in Dietary Studies.'') Whenever possible, a warning should first be given both verbally and in writing that failure to adhere to the policies and procedures will result in involuntary termination if the protocol allows for such an action. This is not always possible, as in the case of unexplained absence.

In one example of noncompliance, a participant continually returns uneaten food although it was clearly stated at the onset that a criterion of the study was total food consumption. The investigator should confront the participant and provide the participant with a written summary of the discussion. Possible solutions might include spreading food consumption out over the entire day. The issue and a summary of the meeting should also be discussed at a staff meeting to make all the staff aware of the situation and determine whether there is an underlying problem that can be addressed. If after a specified period of time the participant continues to breach the protocol, the investigator should inform the participant that his participation in the study is being terminated. This information should be communicated immediately to all staff involved. Once the decision is made, it should be final. Similar to instances of voluntary termination, queries by other participants as to why the person terminated should be addressed with as few details as possible.

Handling Emergency Situations

It is difficult to predict why, when, and how emergency situations will arise. With regard to the staff, it is important not to configure a management plan in which one person is ''indispensable,'' regardless of how tempting or efficient this is. With regard to the participants, it is important to keep in mind that when an emergency does arise the overall aim is to avoid having a situation that causes a participant to drop out. Dropouts are disappointing to the investigators, lower

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the morale of the remaining participants, and obviously have adverse consequences for the study. It is therefore helpful to have a variety of strategies in place to cope with various situations, to anticipate as many permutations of calamities as possible, and, most importantly, to be creative. Some planning suggestions are to create:

- Extra cycle of frozen and nonperishable foods stored by the participant.
- Rules for making substitutions for perishable items.
- Written instructions concerning substitutions.
- Emergency meal delivery systems.

Maintaining Morale Among Participants

The participants' morale will wax and wane for reasons unrelated and related to the protocol. Factors pertaining to this area are outside the scope of this discussion. However, certain situations frequently occur within the context of experimental protocols that have been found to affect the morale of participants as a group and, occasionally, as individuals. Most of these issues have already been dealt with in other sections of this chapter.

Briefly, careful attention must be paid to the characteristics of potential participants during the screening process, with emphasis on the ability of the participant to follow directions and comply with requests. The tendency of a potential participant to complain about routine requests is important to note. Although these minor complaints can be handled by staff on a one-to-one basis, discussion with fellow participants can serve to lower the morale of the entire group. It can be unsettling to all the participants if the investigators keep changing the study schedules or protocols. Optimally, studies will be designed to have a run-in period; very large studies can allow a few participants to ''pilot'' the materials and diet prior to the start of the full-scale study. Unfortunately, these optimal situations may not always be possible.

Morale-building Strategies

Factors that have a positive effect on morale, no matter how small, can result in big improvements in the quality of the data. Conversely, factors that have a negative effect on morale can undermine protocol adherence, increase the risk of participant dropout, and compromise the study's results. Ongoing communication with participants is necessary to remain aware of situations that potentially threaten morale.

Special incentives can be a valuable asset in building morale and supporting adherence to protocol. These can include gifts (tokens, gift certificates, flowers, or magazines) or special events. In the latter case, a little creativity can turn routine meal service into a festive occasion such as a ''special evening out,'' for which participants bring a guest to dinner. The meal might be served by staff in special attire and include entertainment and changes in decor. Other suggestions to boost morale and promote enthusiasm and commitment of participants include:

- Partial payment of the honorarium at each period of data collection.
- A get-acquainted event during the early stages of the study, followed by periodic social events or holiday celebrations that include family and friends.
- Availability of a participant suggestion box with timely, prompt responses to individual complaints and concerns.
- Special attention to the atmosphere and environment. The provision of a pleasant environment builds morale, particularly if the facility provides a ''home away from home'' atmosphere. The availability of magazines, newspaper, TVs, VCRs, and other amenities are important fringe benefits for the participant.
- A common channel for disseminating information, answering questions, and responding to comments. Regular newsletters and communiques can be valuable in providing information about study progress and can build a sense of cohesion through human interest features.

Study Close-out, Discharge, and Follow-up

An exit interview should be conducted with each participant at the end of the study. The purpose of the interview is to allow participants an opportunity to freely discuss feelings about the study and the degree to which they actually adhered to the protocol. Dietary infractions, including their nature and frequency, should be discussed in detail and documented in terms of when they occurred. Alternatively, information on dietary infractions can be obtained by an anonymous questionnaire.

Providing individual results can enhance participants' motivation to participate in the exit interview. Additionally, an individual or group follow-up session at the end of the study (eg, topics selected by participants) helps to show the investigators' commitment to addressing diet-related concerns and questions of participants in a broader context than the study per se. An offer to provide individualized nutrition counseling or diet plans (ie, for weight loss or cholesterol reduction) at the end of the study is also helpful. An example of an exit interview for an inpatient feeding study aimed at lowering blood cholesterol is given in Exhibit 7–1. The questions can be modified to be appropriate for studies using other types of diets.

Assessing and Fostering Dietary Compliance

One of the primary questions of conducting feeding studies is whether the participant really ate only and all the food and

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EXHIBIT 7-1

Sample Exit Interview for an Inpatient Feeding Study

Name _____ Date _____

During the diet study, there may have been things that you were hesitant to report or record. This is natural. Now that the study is over, it is important that we know about these things to have accurate information in assessing the effectiveness of the study. Please answer the following questions as honestly as possible.

1. What motivated you to join this study?
2. Do you feel you still want to follow a cholesterol-lowering diet? Why or why not?
3. When specifically were the most difficult times to follow the study diet and why?
4. What could we have done to help you during these ''difficult times''?
5. Please tell us what you liked about the study. What did you dislike?
6. Please tell us how we could have improved the study.
7. Personally, what do you feel you gained from the study?
8. Did you eat any nonstudy food or drink nonstudy beverages or alcohol during the study period that you did not report or record? If so please try to remember what you consumed, how much, and how often. Please record below.

Food Eaten	Average Portion	Number of Times Eaten		
		Daily	Weekly	Monthly

9. What caused you to consume nonstudy items if you did so?
10. How could we have helped you prevent this?
11. Did you eat all the food we provided during the study? If you did not eat all the study foods, please record below.

Food Not Eaten	Average Portion Not Eaten	Number of Times Not Eaten		
		Daily	Weekly	Monthly

12. If you did not eat all of the food provided, why do you think this happened?
13. What could we have done to help you prevent this?
14. Did you notice any changes in your physical health or feeling of well-being during the study period, compared to before the study began? If so, what changes did you notice? Please be specific.
15. Are there any other comments you would like to make?

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TABLE 7-2

Screening Information Used in Planning for Maximal Compliance

Factor	Interview Information	Participant Management Planning
Personal health	Participant has poor dentition or arthritis in his or her hands.	Cut up or shred food items. Substitute soft foods for hard-to-chew items. Send food home in easy-to-open containers.
Psychosocial	Participant is out of work and needs to be at job interviews sporadically. This also can apply to students with variable schedules (ie, medical students with unpredictable ward rotation requirements).	Give participant clear instructions about when data are to be collected and when his or her presence at the research facility is required. Do not enroll participant until daily routines are predictable.
Diet/Nutrition	Participant will be required to drink a large amount of milk at each meal. Participant admits to not liking milk but is not sure why.	Have participant try a certain specified amount of milk at home and report on the results. Acceptance into the study is contingent on these results.
	The study prohibits consumption of caffeine-containing foods.	If participant is sensitive, try going without caffeine for a specified period of time to be ''weaned'' from caffeine prior to study.

drink that was provided. The verification of this information is difficult; however, there are some techniques, both objective and subjective, of assessing adherence that can be used in the research setting. Additionally, methods can be built into each study that can directly optimize a participant's performance.

Objective Methods

A detailed discussion of the objective techniques used for assessing dietary adherence is included in Chapter 24, ''Biological Sample Collection and Markers of Dietary Compliance.'' To date, no one single biochemical marker, urine test, or serum level of a nutrient can predict with 100% accuracy whether an individual ate only the food and drink provided. The measurements that do exist all have limitations and are only useful within a narrow context or as a measure of group adherence. For this reason, although less precise, subjective measures of assessing dietary adherence have been found to be helpful.

Subjective Methods

Selecting appropriate participants is the cornerstone of a well-controlled study. This selection should be done in a team approach, with input from all the staff involved with study implementation. Techniques for screening research participants are discussed in Chapter 6, ''Recruitment and Screening of Study Participants''; however, careful investigation on this point cannot be stressed enough. Screening the study participants carefully with respect to personal and psychosocial health, dietary habits, and nutritional status helps in the initial assessment of participant selection. These findings should be factored into a study orientation and education program tailored specifically to the population chosen. Table 7–2 shows how screening can be conducted within this framework and provides ideas for individualizing a research protocol to accommodate participants' circumstances.

Compliance checks that can be standardized for each study are outlined here.

Meal- and Food-Related Methods

Checklists

Participants should be provided with a copy of their menu plan as a quality control check. When the participant receives his or her tray, the food can be checked against the menu. This method of checking for all food provided is also imperative for take-out meals when the participant is free living. Dietary employees use it to verify that the take-out meal bags were packed with all necessary food items. For hungry participants who arrive home without the dinner entree, study adherence may not seem to be of primary importance, particularly if they have to travel quite a distance to the research center. Experience suggests that the participants do compare their food to the list and readily point out inconsistencies.

Meal checklists can also be used for the participant to check off and initial all food consumed. Checklists can be collected at each visit for outpatients or after each meal for residents. Additional questions can be added to these meal lists, such as whether anything was eaten in addition to the menu items, or which free foods were consumed. This is important both for assessing compliance and for total nutrient intake records. An example of a meal checklist is provided in Chapter 18, ''Documentation, Record Keeping, and Recipes.'' Computer-generated checklists are described in Chapter 3, ''Computer Applications in Controlled Diet Studies.''

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Tray Checks

A tray-check procedure should be part of every research unit's meal delivery routine. The participant's meal tray should be checked for completeness prior to serving and for uneaten foods after the tray is returned after the meal. If the food is not completely consumed, the participant should be called back to finish the food. If for some reason the participant cannot finish the food, the food should be weighed and recorded, consumed at the next meal, or replaced. This deviation should always be noted in the participant's record, along with the reason for not finishing the food. This is a way of not only assessing compliance but also of determining whether the foods are acceptable or if the study design is realistic. For example, a participant in an inpatient study returned her food to the dish room and retired to her living quarters. The diet technician who was checking the lunch tray noticed that she did not consume all of her sandwich. The participant was called back to finish it and responded that she was very uncomfortable because she had undergone an experimental procedure early that morning that didn't end until 10:00 a.m. She had eaten a late breakfast and then was expected to consume the full lunch tray at 12:00 p.m. She felt she could not finish the sandwich.

This example describes a problem distinct from the participant's not consuming all of her study diet. It is a flag to the study coordinators to reassess the meals that are provided on testing days. It needs to be determined whether the participant must consume all of the food on those days. If so, the food should be rearranged in a different way, such as spreading out the breakfast items over lunch, dinner, and snack to make the participant more comfortable. Additionally, a participant should be encouraged to voice his or her discomfort rather than being placed in a position of compromising his or her performance on the research study.

Food Containers Returned

For outpatient studies, sending food home in returnable containers can be a method of documenting food consumed. However, just as counting pills is no guarantee that the participant took the medication, neither is returning food containers an indication that the individual ate the food. The message conveyed through this effort is the interest that the investigators take in encouraging compliance, which is then communicated to participants by having them complete this exercise. An added benefit to returning food containers is that they can be reused or recycled, cutting down on the research budget and waste.

Regular Interviews

It is important to meet with participants to review the diet and ascertain whether there are problems with any of the food items. Making food substitutions or modifications can be beneficial. Discussing or graphically illustrating what may look like compliance problems, such as unexpected weight fluctuations when they take out meals or go away for the weekend, helps to inform participants that the study personnel are aware of these inconsistencies. Participants also should be questioned directly about whether they ate anything other than their experimental diet. Elderly participants may need these interviews to remind them of study guidelines if they are not residing at the research unit. Likewise, young participants may need to have ''pep talks'' if they are anticipating a problem socializing with their friends.

Role-playing exercises in which the participant is placed in a position of being tempted by a friend not to adhere to the diet can help participants withstand events such as sit-down dinners, weddings, and cocktail parties.

''Gut Feeling''

Research study personnel can often sense when a participant is being evasive or uncomfortable about participation in a study. If a participant feels he or she cannot forthrightly speak with the investigator or cannot discuss issues about the study that create discomfort, he or she may give other signals that he or she cannot comply with this research study. For example, if something on the diet is unpleasant or the study procedures result in feelings of discomfort, the participant may simply avoid eating the food and rationalize the nonadherence. If a participant's complaints about a study protocol are numerous enough, the individual generally finds a way to withdraw. This is one of the reasons that direct communication at regular intervals is important. It is difficult to assess whether a participant really is complying with the protocol without any direct two-way communication.

Involvement of Family and ''Significant Others''

Long-term studies requiring resident living and separation from family members can frequently impose undue stress on both the participant and the family. On the other hand, eating a controlled research diet while living with people eating an uncontrolled diet can present many temptations and opportunities for food sharing or extra food consumption. It is suggested that, at the time of screening, this burden be outlined thoroughly to the potential participant, so that he or she can discuss the study diet and routine at length with family before participating in the study. Food sharing should not be tolerated, nor should the food be prepared (rewarmed or heated) in a different way than the instructions describe. Inviting the participant's housemates to the research center and to review the particulars of the study diet involves them in the study and is a good way of providing extra support to the participant.

For example, a woman was participating in a closely controlled calcium balance study. Because of the length of this study, she participated as a nonresident. She continued to live at home with her husband and came into the research center daily for meal pick-ups. While she was in the middle of the study, her husband called the study dietitian to ask what kind of cake he could serve her on her birthday, which was going to be celebrated with some friends coming over for a surprise dinner. When told that she could not eat any

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EXHIBIT 7-2

Example of an Interim Questionnaire for Free-Living Participants in a Well-Controlled Diet Study

Name _____ Date _____

Please answer the following questions about meals and snacks. The information that you provide will be used to improve diets for future studies.

1. What is your favorite meal(s)?
2. What meal(s) do you like least?
3. How do you handle less favored meals?
4. If you are adding foods from the ''What to Choose When I'm Definitely Going to Have a Snack List,'' please list types and amounts of foods added.
5. What are the types and amounts of foods deleted per week? List them here and indicate rationale.
6. How often do you take a free day or use free meals?
7. What kinds and amounts of foods do you substitute for unused jams?
8. Do you have additional ideas for meals or snacks?
9. Do you have additional comments, suggestions, or criticisms?

cake, he decided it would be an unfair temptation to present her with one and asked for alternatives. The dietitian suggested that he make a dinner for the invited guests that resembled the study meal she would eat that night (chicken, rice, and green beans). There was some food allowable as a dessert within the diet study guidelines (jelly beans and soft drinks). This family support was an extra bonus for maximizing dietary compliance for this woman.

Team Approach

Other areas within the study may require the participants to collect data for which they may exhibit noncompliant behavior. Examples include not completing a 24-hour urine or stool collection, not keeping appointments, or forgetting to fast for blood draws. This could be reason to suspect that the participant is not adhering to the protocol at all. Keeping an active communication with the nursing department or the clinical labs that process the participant's specimens is important. If a participant keeps forgetting appointments, often has discrepant pill counts, or overtly does not complete a task required on a protocol, this undesirable conduct must be discussed immediately as a team.

Knowing of such behavior early on in the protocol may necessitate participant dismissal but can save precious resources. This team approach also is important in lending support and credibility when a participant is being counseled to withdraw from the study (see Involuntary Premature Termination).

Evaluation of the Research Study

An effective method of eliciting participant feedback and gauging protocol adherence is to employ interim and exit questionnaires. These tools are designed to assess participants' perceived compliance and to register suggestions or complaints. Additionally, staff perceptions can be compared to participants' perceptions.

In response to interim questionnaires, some suggestions may be appropriate for immediate implementation whereas others, which would substantially alter the study, may be implemented in subsequent studies. Comments from interim questionnaires can be used to develop a menu cycle composed of favorite meals from a number of studies and to provide for specific food substitutions where appropriate.

Interim questionnaires may identify specific participants who need counseling or specific topics that need to be discussed or clarified. Comments in response to interim questionnaires can be summarized in a newsletter and distributed to all study participants. For example, it can be valuable for a participant to see that his least favorite meal is someone else's favorite meal. An example of an interim questionnaire used in a diet study aimed at lowering blood cholesterol is given in Exhibit 7–2. This questionnaire can be modified to be appropriate for other types of diet studies.

Participants may find it easier to be frank when answering questions on exit questionnaires as compared to interim questionnaires, and candid answers should be encouraged. Explaining that information from exit questionnaires is used to improve future studies also encourages honest responses. An example, which can be modified for other types of diet studies, is given in Exhibit 7–3.

Conclusion

Managing participants to maximize dietary adherence and minimize dropouts is crucial to the success of a study and is accomplished through careful planning. Participant selection

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EXHIBIT 7-3

Example of an Exit Questionnaire for Free-Living Participants in a Diet Study

Name _____ Date _____

During the diet study there may have been infractions or misunderstandings that you were hesitant to report or record. This is natural. However, it is important that we know about these occurrences to accurately assess the effectiveness of the study diets and to make appropriate changes for future studies. Please provide frank answers to the questions that follow.

1. What initially motivated you to participate in the diet study?
2. How do you feel about following a low-fat, low-cholesterol diet in the future?
3. Describe new food choices or nutrition strategies you have acquired as a result of study involvement.
4. When was it most difficult to follow the study diet? Why?
5. What could have been done to help you through the rough times?
6. Describe the strengths of this study.
7. Describe what you did not like and how we could have improved the study.
8. List the points that you feel would be important to tell your successors.
9. What have you gained from study involvement?
10. Describe your compliance with entrees, breakfast, and snack foods. Overall, on a scale of 0 to 10, rate how well you followed the study guidelines. (A score of 0 indicates least compliant and a score of 10 indicates most compliant.)
11. Describe any nonstudy foods, beverages, or alcohol consumed during the study period that you did not report or record. Please indicate type of food, amount, and frequency eaten.
12. If you did consume nonstudy foods, what may have caused you to choose nonstudy items?
13. How could we have anticipated the need or desire to include additional foods?
14. Describe the amount of study foods, including entrees, breakfast or snack items and beverages not consumed. Indicate percent of portions not eaten and the frequency with which this occurred.
15. If you did not consume all study foods or beverages, what caused this to happen?
16. What could we have done to prevent this?
17. Describe changes in your physical health or feeling of well being during the first 6 weeks of the study, compared to before enrollment.
18. Describe changes in your physical health or well-being during the low-fat intervention phases, the last 24 weeks of the study, compared to before enrollment.
19. List any medications (prescription or over-the-counter medications) taken that were not listed on your daily reports. Indicate dosage and frequency used.
20. Describe any illnesses or accidents subsequent to starting the diet study.
21. Would you participate in this study (or one like it) again?

procedures are critical for recruiting individuals who are likely to adhere to the study protocol. The process of participant management occurs throughout the study and even before the study actually begins. The principal investigator has the primary and ultimate responsibility for managing study participants. Management of the study staff is also important to the ability to successfully manage study participants. Staff must be trained to follow the protocol and study procedures. Effective means of communication among staff, including regular meetings, are essential.

Providing information to participants, including a clear understanding of their responsibilities, is a key component of participant management. Clearly written study materials that include instructions and procedures assist this process.

Managing and resolving problems and conflicts require good understanding of the study purpose and protocol, knowledge of human behavior, and common sense. Flexibility appropriately applied provides the means for managing difficult situations. Planning for commonly occurring contingencies prior to the start of the study is usually helpful. Assessing dietary adherence is useful for the interpretation of study results as well as for planning for the next study. Strategies should be developed to boost morale for both the participants and the study staff. Finally, maintaining good

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relations with study participants at the end of the study is important and requires careful planning, including procedures for study close-out, for providing information about their individual results, and for conducting an exit interview whereby the participant evaluates the experience of being a participant. Thus, throughout the entire study, careful planning is key to managing participants.

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