TABLE OF CONTENTS

CHAPTER 15	DIETARY ASSESSMENT AND INTERVENTION METHODS	PAGE
	15.1 24-Hour Dietary Recalls	15-1
	15.1.1 Introduction 15.1.2 Clinic Setting for Face-to-Face Recall 15.1.3 Use of Models	15-1 15-2 15-2
	15.1.3.1 NASCO Models 15.1.3.2 Two-Dimensional Food Model Training	15-2 15-3
	15.1.4 Defaults 15.1.5 Forms 15.1.6 How to Handle Sick Days/Insufficient Intake 15.1.7 Evening Snack 15.1.8 Specific Instructions on Procedure	15-4 15-4 15-5 15-6 15-6
	15.1.8.1 Partial Script for Face-to-Face Recall	15-6
	15.1.8.1.1 Greeting 15.1.8.1.2 Introduction 15.1.8.1.3 Now Start Recall	15-6 15-7 15-7
	15.1.8.2 Telephone Recall 15.1.8.3 Special Considerations for Follow-up Interviews	15-8 15-8
	15.2 Intervention Methods	15-9
	15.2.1 Introduction 15.2.2 Group Sessions 15.2.3 Individual Sessions 15.2.4 The Personalized Contact Method and Case Management	15-9 15-10 15-11
	15.2.4.1 Introduction 15.2.4.2 Motivational Interviewing	15-11 15-12
	15.2.5 Case Management Plan and Schedule	15-14
	15.2.5.1 Case Management 15.2.5.2 Follow-up Sessions II and III 15.2.5.3 Other Contacts 15.2.5.4 Additional Intervention Tools	15-14 15-15 15-15 15-15
	15.2.6 Documenting Intervention Progress	15-16

TABLE OF CONTENTS (Continued)

CHAPTER 15	DIETARY ASSESS	MENT AND INTERVENTION METHODS (Continued)	PAGE
	15.3 Training	and Certification for	
		Nutritionists	15-16
	15.3.1 L	ocal Training and Certification for	15 17
	15 2 2 т	Other Data Collection Nutritionists ocal Certification Procedures	15-17 15-18
	13.3.2 1	ocal certification Procedures	13-16
	15.4 Quality	Control Control	15-18
	15.4.1 N	utrition Data Collection	
		Re-Certification	15-19
	15.4.2 E	xternal Quality Assessment of NCC	
		Coding of 24-Hour Dietary Recalls	15-20
		15.4.2.1 Introduction	15-20
		15.4.2.2 Selection of Participants	15-20
		15.4.2.3 Preparation of 24-Hour	13 20
		Recall Forms	15-21
		15.4.2.4 Identification of Copied	
		Recall Forms	15-21
		15.4.2.5 Shipment of Copied Recall	
		Forms to the NCC	15-22
		15.4.2.6 Notification of the	
		Coordinating Center	15-22
	15.4.3 O	uality Control Checklist for	
	231110 4	Site Visits	15-23
	Exhibit 15-1	NASCO Food Models	
		Mock 24-Hour Recall Instruction	
		Documentation Checklist	
	Exhibit 15-4	24-Hour Dietary Recall - Disposition Form	
	Exhibit 15-5	Stages of Change Wheel	
	Exhibit 15-6	Overview of Motivational Interviewing	
	Exhibit 15-7	Theory of Motivational Interviewing	
	Exhibit 15-8	Tips on Motivational Interviewing	
	Exhibit 15-9	Key Components of Motivational Interviewing	
	Exhibit 15-10	FRAMES Model	
	Exhibit 15-11	Readiness to Change Ruler	
	Exhibit 15-12	Adherence Ruler	
	Exhibit 15-13	Recertification Checklist	
	Exhibit 15-14	Quality Control Checklist for Site Visits	

CHAPTER 15

DIETARY ASSESSMENT AND INTERVENTION METHODS

15.1 24-Hour Dietary Recalls

15.1.1 <u>Introduction</u>

The 24-hour recall method will be used to collect dietary endpoint data in DISC. At baseline and each endpoint data collection visit (12 and 36 months, and Year 05, Year 07, Year 09, and the FV01 final visit), a 24-hour recall interview will be conducted with two subsequent recalls collected by telephone (preferably within one week, and no more than two weeks, of the clinic visit). A total of three days, including two weekdays and one weekend day, will be averaged to comprise the mean nutrient intake to be used in DISC dietary assessment.

Convenient times of day for the participant and parent to conduct the telephone recalls should be discussed at the first visit. Local clinics are encouraged to develop a form for scheduling the calls, noting the preferred time of day and correct phone number for the participant. The child should be the primary respondent, but the parent can clarify, elaborate or otherwise enhance the documentation process to help assure accuracy and to make the recall codable.

The day of the telephone recall should be selected randomly by the nutritionist among the various days available. All three interviews must be completed in a timely fashion so as to be representative of the time period closest to the blood draw. To accomplish this objective, nutritionists should try to complete the two phone calls during the first week. The second week should be used as a backup in case the interviews cannot be completed due to insufficient intake or inability to contact the participant. It is expected that all three recalls will be completed within two weeks of the initial baseline data collection.

The three baseline recalls must be completed before the participant is randomized.

15.1.2 Clinic Setting for Face-to-Face Recall

During the clinic visit the participant is asked to see the nutritionist for a private dietary data collection session. The DISC participant will first be asked to complete the 24-hour recall independently without a parent present. The nutritionist should reassure the participant that he/she is fully capable of performing this task and that there are no right or wrong answers. The nutritionist should help encourage the participant to be candid by assuring him of the confidentiality of the data. An instructional session regarding use of food models will precede the interview. Parents or guardians who accompany the participant to the clinic and/or are at home during the telephone recalls, will only be asked to clarify information provided by the participant, i.e., to give brand names, recipe ingredients or preparation details, exact portion sizes and/or other descriptive information. The nutritionist should do whatever possible to make the recall a positive, favorable and interesting experience. No dietary intervention or nutrition education should occur during the endpoint data assessment.

15.1.3 Use of Models

15.1.3.1 NASCO Models

During the baseline and subsequent clinic recalls, the set of NASCO food models ordered by each clinic in this study should be used to help teach the participant how to recall serving sizes. The specific models are listed in Exhibit 15-1. The NASCO food models will be used only during an instructional period prior to collecting the first face-to-face 24-hour recall. They will be used to help participants visualize

actual food portions and compare them to two dimensional models, as exemplified in Exhibit 15-2. Since the two-dimensional paper models in the participant "Food Record Guide" will be used for all subsequent recalls, they will be used in the baseline clinic recall as well. NASCO models are used to help the participant understand the nature of the recall process and how to accurately assess portion size. nutritionist should use the NASCO models during a "mock" interview where the procedure is explained. Then the paper models should be introduced as the standard for future data collection. The NASCO models are used to help the participant make the transition to the two-dimensional The DISC "Food Record Guide" contains the two dimensional models. visuals that will be utilized during the actual face-to-face and telephone recalls. Each participant will be given a Food Record Guide to take home for use during future telephone recalls. They should be encouraged to store these Guidebooks in a safe place since they will be used throughout the years of the trial.

15.1.3.2 <u>Two-Dimensional Food Model Training</u>

Use the following NASCO model to demonstrate use of each type of paper model:

If you ate/drank this, use this model to describe the amount:

- 1. 3-D glasses paper glasses.
- 2. Pizza, apple pie wedges and thickness indicator.
- 3. Cookie circles and thickness indicator
- 4. Cheese slice grid and thickness indicator
- 5. Applesauce mound.
- 6. Pork chop meat models and thickness indicator.
- 7. Chicken chicken pieces and thickness indicator.

15.1.4 Defaults

When performing 24-hour recalls on DISC participants, nutritionists may not always be able to get specific information on the food, preparation method or the quantity consumed. For example, a participant may know that he/she ate cheese but not know the type; a participant may know he/she ate chicken but not know how it was prepared; or, a participant may know he/she ate a cupcake, but not know how big it was. If a parent/guardian cannot clarify the information provided by the participant, the nutritionist will document as much information as possible for NCC coders to select the most appropriate default code.

As part of the analysis of DISC dietary data, distributions of default codes will be investigated to ascertain if there are differences between intervention and control group participants that could potentially affect study results. To facilitate this, the nutritionist will put a check mark in the column on the dietary intake form labelled "Type/Kind Default" if sufficient information on a food or preparation method is not obtained to select a specific NCC code. Specific NCC codes do not include standard NCC default codes such as milk, percent fat unknown. If this were the appropriate code, a check mark would be placed in the type/kind default column. Similarly, if sufficient information is not obtained on the quantity of food consumed, the nutritionist will put a check mark in the column on the form labelled "Quantity Default." Checking default columns can be done by the nutritionist during or after the recall. The nutritionist who reviews the recall for completeness before sending it to the NCC should also check to make sure default columns are checked as appropriate.

15.1.5 Forms

The DISC 24-hour dietary recall forms should be used to collect all dietary recall data. Header questions noting the date, day of the week,

etc., should be completed; and participant numbers should be inscribed before the recall begins. It should be noted that the question about interviewer's opinion of information applies to overall information contributed by the participant and parent. Questions regarding salt use, vitamin/mineral intake and other information requested should be documented. Record the type of food, the amount and descriptive information as indicated on the form. Use NCC code book guidelines for required documentation. Provide as much detail as possible.

These forms should be edited and initialed for codability by both the NCC-certified nutritionist completing the interview and by one other NCC-trained/certified nutritionist prior to sending it to the DISC Nutrition Coding Center for analysis. All three 24-hour recall forms should be sent together for coding to the Nutrition Coding Center (NCC).

15.1.6 How to Handle Sick Days/Insufficient Intake

Nutritionists are likely to encounter problems with some participants who have insufficient intake due to illness on the day of the recall. In such cases the nutritionists should call on another day, weekday or weekend day as needed, to get three complete days' records. There are several strategies to facilitate this process.

- At the first face-to-face recall, while instructing the participant about the upcoming telephone recalls, indicate to the participant that he/she should inform the nutritionist immediately of illness the prior day. In such cases the nutritionist can simply call back on another day.
- 2. At the time of the telephone recall, begin with an open-ended question such as, "How was yesterday?" rather than leading the response with a question about whether or not the participant was sick. If the participant or parent says yesterday was

highly unusual due to illness, the interview can be terminated there. The nutritionist should then call on another day.

3. If the participant does not volunteer information about illness but after the interview the nutritionist suspects it was a sick day, she should confirm that suspicion with the parent and try to collect another day's intake.

The dietary endpoint data in DISC will be based upon means of three days' intake. Nutritionists are encouraged to be prompt in initiating telephone recalls as soon as possible following baseline visit to allow for a cushion of time in case of sick days or missed calls.

15.1.7 Evening Snack

The baseline face-to-face dietary recall will not include dietary intakes on the eve of a fasting blood sample. However, at subsequent data collection visits this may occur. If the participant was fasting the night before the face-to-face recall because of the need to collect a fasting blood sample, the nutritionist should probe for the previous night's snack to add to the fasting day's intake.

15.1.8 Specific Instructions on Procedure

15.1.8.1 Partial Script for Face-to-Face Recall

This is an example of the dialogue to be used in a DISC 24-hour recall interview. These guidelines are specific to DISC to be combined with the "Introduction to Interviewing" presented by NCC.

15.1.8.1.1 Greeting

Make the participant comfortable; using first names can reduce tension. Example: "Hi, Susie. I'm so glad to have a chance to talk with you. How are things going so far?"

15.1.8.1.2 Introduction

"What we will be doing now is talking about what you had to eat and drink yesterday, starting from the time you woke up until bedtime. There are no wrong answers, so you can't make a mistake. Just try to remember as best you can.

This dietary recall is very important, <u>participant's name</u>. We're one of six centers in the U.S. trying to get a clearer idea of what people in your age group are eating. Up to now, there is very little information available on what people your age eat so we are very interested in hearing exactly what you had. This may also help us to understand how different foods affect your health.

To help you tell me how much you ate, we will be using food models. These plastic models will be used during a practice interview along with these paper models. Then I will ask you to tell me everything you ate and drank yesterday with you using the paper models to tell me the amount you had of each food and drink. After today I am going to do this type of interview with you over the phone. Twice within the next two weeks, I will be calling you again to ask what you ate during that day. At home you will have only the paper models to use, so we will try to refer to them frequently today so that you will feel comfortable using them."

15.1.8.1.3 Now Start Recall

"Yesterday was day . . . " (use NCC probing techniques: See NCC Documentation Checklist, Exhibit 15-3).

At the conclusion of the recall, review the foods eaten and determine if anything was missed. Use the probe sheets in the participant's "Food Record Guide." Probe the parent for additional clarification on brand names, serving size, recipe ingredients and preparation techniques.

15.1.8.2 Telephone Recall

Explain to both the parent and the participant that we will be calling two times within the next two weeks to get this type of information. We will call to talk with participant's name, but we need your mother to be available afterwards to clarify the data reported. Keep the paper models handy, near the phone. Verify home phone number. Ask for the most convenient times to call on both weekdays and weekends. Record this information on the Recall Disposition Form (See Exhibit 15-4). Explain that you cannot tell the exact day of the call, but that it should be at a time that is least intrusive to the family. A total of three 24-hour recalls will be collected in all, two weekdays and one weekend day, including today's recall. Please have your "Food Record Guide" handy so you can refer to the two-dimensional food models to describe your serving sizes. End the interview with "Thank you. Do you have any questions?"

15.1.8.3 Special Considerations for Follow-Up Interviews

The NCC-certified DISC nutritionists assigned to 24-hour recall data collection should be blinded as to the group assignment of each participant. While this is not a problem during baseline interviews since they precede randomization, follow-up recalls may pose some concerns.

Nutritionists should try to maintain objectivity with each interview by probing for brand names of foods, specific ingredients used in preparation, etc. During follow-up interviews at 12 and 36 months, Year 05, Year 07, Year 09 and final visits, the objective is to preserve the blinded nature of the interview whenever possible. Despite these attempts to maintain blindedness, it is likely that intervention children may rely on DISC terminology, i.e., "DISC-Speak" in describing their intake. Having spent many months in learning the DISC diet and

methodology, participants cannot be expected to disregard these terms when recalling their food intake.

If a participant volunteers that he/she ate "GO!" cookies or "GO!" pizza, recognizing the preferred fat used in these foods, but cannot recall the brand name, the nutritionist should reflect this in her documentation. If she were to simply use the "unknown" default code, there is a risk of misclassifying the participant's intake. Likewise, if the participant reports eating "WHOA!" cake, this too should be appropriately noted.

The Chief Nutritionist should review these techniques with each nutritionist prior to follow-up data collection. The somewhat subtle differences in nutrient composition between foods underscores the need to be as specific as possible in documentation and in accurately representing the participant's intake.

15.2 <u>Intervention Methods</u>

15.2.1 Introduction

Intervention in DISC will be provided through group sessions and individual family sessions. An intense intervention phase of about 12 months duration will be followed by long-term intervention and then a period of maintenance. The intense phase of intervention will include 15 group sessions and five individual family sessions. Initially, intervention sessions will be held weekly. After the first six sessions, participants will meet biweekly. Long-term intervention and maintenance will consist of regular sessions, at least two group and two individual sessions per year in DISC I, at least two face-to-face sessions per year in DISC II until about Year 06, and at least three face to face sessions using the "personalized contact" method after Year 05 (see section 15.2.4 for details). Other intervention contacts will

be arranged as needed. At least once per month families will be contacted by phone or mail.

15.2.2 Group Sessions

Most of the DISC intervention will take place during group sessions led by nutritionists and behaviorists. Groups will be made up of approximately ten families. Group sessions will be 100 minutes in First, children and parents will meet jointly for a brief duration. five minute overview and then separately for a 35 minute session. These separate groups will emphasize food information and skills, motivation for behavior change, support for behavior change and food preparation. They will then have a meal as a family with DISC diet appropriate foods (25 minutes). The joint family group will then discuss family support for change and past and future goals (40 minutes). DISC intervention will take a food group approach to diet modification. The majority of group sessions will target a particular food group. Within that food group desirable ("GO") foods will be identified and encouraged and undesirable ("WHOA") foods will be identified and discouraged. There will be additional group sessions on shopping and label reading, fast foods and recipe modification. The content of children's group sessions will parallel the content of adults' group sessions.

A number of behavior change techniques will be used in group sessions. Information will be provided verbally and in writing. Activities including demonstrations, games and food tasting will be used to reinforce didactic material and encourage dietary change. Goal setting and problem solving will be utilized to produce compliance with DISC dietary goals.

15.2.3 <u>Individual Sessions</u>

Individual family sessions will be held in conjunction with group sessions during intervention. These family sessions will usually occur either before or after the group session. They will be designed to discuss and resolve individual family issues and other problems that are not being dealt with effectively in group sessions. They will also be used to make up missed material when a participant is absent from a group session. The individual session will be with a nutritionist or behaviorist depending on the specific needs of the participant.

15.2.4 The Personalized Contact Method and Case Management

15.2.4.1 Introduction

The goal of intervention after Year 05 is to personalize dietary guidance among older adolescents and to maximize adherence according to each individual's current status. This represents a decisive shift away from family and parentally oriented methods to self-directed participant intervention and self-rewards. This process begins with reassessment of both usual dietary intake and readiness to change. Together, the interventionist and participant will establish new goals for achieving dietary adherence and target solutions to relevant problem behaviors.

During DISC I-II, maintenance of adequate fat intake at around 28% of total calories was encouraged to prevent growth failure. After Year 05, DISC dietary intervention will be more aggressive. Participants who are currently adhering to the goal and are not at nutritional risk will be offered the opportunity to reduce total fat and thereby meet or further reduce the goal for saturated fat intake. The overall study goal will remain the same, but the individual goals will be based on current level of adherence and participants' expressed willingness to intensify adherence. Ongoing dietary assessment using NDS will ensure nutrient adequacy as well as dietary adherence to the reduced fat goals.

To summarize, the DISC intervention strategy after Year 05 will:

- Shift the focus from group to individual interaction, using group activities as reinforcement.
- Initiate a case management approach that enlists participants as partners in establishing and monitoring new goals.
- Renew efforts to use motivational interviewing strategies.

Group efforts that were a successful feature of DISC I and DISC II will continue to be offered periodically. After Year 05, DISC will be geared to meet the needs of older adolescents who are more independent and have developed their own sets of priorities, separate and sometimes conflicting with those of their parents and families. Knowledge of the diet will no longer be the limiting factor, rather, promoting the willingness of the adolescent to apply the appropriate eating behavior across a wide range of social settlings will be the challenge.

15.2.4.2 Motivational Interviewing

DISC Interventionists will counsel each participant individually and address his/her willingness to change eating patterns that deviate from the recommended DISC diet. The "Stages of Change" model (see Exhibit 15-5) developed by Prochaska¹ for adults will be adapted to this younger age group. The stages include:

Stages of Change

- 1. Pre-contemplation
- 2. Contemplation
- 3. Preparation
- 4. Action
- 5. Maintenance
- 6. Relapse

Each participant's current stage of change will be assessed and further intervention will be initiated as warranted. For some participants, who are engaged in the action or maintenance stage, this will mean only continued support and encouragement. For others, who may have

relapsed or never internalized responsibility for adhering to the diet without parental support, a more intensive effort will be needed. DISC interventionists will assess the participant's current stage of change and seek ways to progress with each individual toward the goal of initiating action and maintenance of these changes.

The Motivational Interviewing method described by Miller and Rollnick² will be applied to this process of assessing current stage of change and eliciting participant-initiated goals and objectives for the immediate future (see Exhibits 15-6, 15-7, 15-8, and 15-9). The five fundamental principles are as follows:

Motivational Interviewing

- 1. Express empathy
- 2. Develop discrepancy
- 3. Avoid argumentation
- 4. Roll with resistance
- 5. Support self-efficacy

These principles support the interviewing method to be used in DISC after Year 05. In addition, the following elements described by Miller and Sanchez³, known as the FRAMES model will be incorporated as a personalized counseling tool (see Exhibit 15-10). FRAMES will provide the steps used by interventionists in eliciting a self-directed action plan from the participant.

The letters of this acronym represent the following:

Feedback: Providing results to the participant on

personal progress.

Responsibility: Establishing that it is the participant's

choice to change.

Advice: Providing a prescription to assist in

making a change.

Menu: Providing options for the participant to

choose.

Empathy: Providing a supportive, caring environ-

ment in which the participant can make

the changes.

Self-Efficacy: Reassuring the participant that he/she is capable of making the changes.

15.2.5 <u>Case Management Plan and Schedule</u>

A minimum of three individualized, face to face contacts will be initiated with each participant each year. Centralized tracking of these contacts regarding their content, goals and objectives will be facilitated by the Coordinating Center. At least one dietary assessment using NDS will be performed each year to monitor nutrient adequacy and trouble shoot potential deficiencies.

15.2.5.1 Case Management Session I

The goal of Session I is to establish each participants' current level of dietary adherence and Stage of Change in order to develop a personalized set of goals and an Action Plan. Prior to this session, the results of the Confidence Rating Form will be reviewed and used to better target interventions. Also, the most recent NDS analysis will be reviewed.

Session I should take an average of 40 minutes. At least one interventionist will meet with the participant. Whenever possible, both a nutritionist and a behaviorist will work together. These sessions will be conducted at any mutually convenient location, i.e., at the clinic, home, school, or other appropriate setting. Participant and interventionist will first meet alone and then, when appropriate and logistically feasible, meet with the family and participant together.

Contents of Session I will include:

- A. Review of Confidence Rating
- B. Review of most recent NDS
- C. Participant Self-Assessments:
 - 1. Readiness to change score (see Exhibit 15-11)
 - 2. Adherence score (see Exhibit 15-12)

- D. Action Plan
- E. Next Visit

15.2.5.2 Follow-up Sessions II and III

A minimum of two follow-up sessions are planned with each participant. The following elements will be included in these sessions:

- A. Review of the overall progress as previously negotiated in the Action Plan.
- B. Reassessment of current Stage of Change.
- C. Reassessment of dietary adherence score.
- D. Development or revision of Action Plan and scheduling follow-up sessions accordingly.
- E. Mutually agreement on next steps and expectations.
- F. Addressing parent-relevant concerns or goals as appropriate.

Sessions II and III should also take 30-40 minutes and include at least one interventionist.

15.2.5.3 Other Contacts

Follow-up phone calls, mailings or additional visits will be planned as needed based on the participants' progress, individual goals and personal preference. Some adolescents will require more frequent contacts for motivation and moral support. Others will prefer a less intrusive schedule, but will cooperate if their need to be independent is respected. Each interventionist will consider these alternatives with each participant.

15.2.5.4 Additional Intervention Tools

Follow-up lipid measures will be offered for interested participants on an interim basis. These will be analyzed and paid for locally. Interventionists should be prepared to cope with potentially negative lipid results despite outstanding adherence. The opposite

outcome, i.e., poor adherence and favorable lipid level, should be addressed as well. These contradictory findings should not alter the goal of adherence to the diet.

The DISC Newsletter will be mailed twice a year for purposes of ongoing motivation and encouragement. Personalized input to highlight individual accomplishments by DISC participants will be emphasized.

Incentives are highly encouraged and will be determined at the local level.

15.2.6 <u>Documenting Intervention Progress</u>

The use of Case Management Forms 58 and 85 with time windows and an accompanying Tracking Form 93 will facilitate consistency of documentation across all clinical centers and participants. In addition, documentation of all contacts will be encouraged. For example, the following information will be recorded on individual visits:

Individual Visit Checklist:

- A. In person (preferred)
- B. On phone (when in-person visit is not possible)
- C. Other contact
- D. Refused contact
- E. No visit required

15.3 Training and Certification for Chief Nutritionists

Each DISC Clinical Center is to have at least one nutritionist who has been trained and certified by the Nutrition Coordinating Center (NCC) in Minneapolis. This person will serve as the Master Nutrition Trainer or Chief Nutritionist. Training will include:

 Orientation to the NCC data base (specifically tape 20 will be used in DISC).

- 2. Training on interviewing and documentation methodology.
- Viewing training videos and practicing the 24-hour recall procedures and use of forms.
- 4. Training in the use of food models (NASCO and the DISC Food Record Guidebook).
- 5. Training in use of the Nutrient Data System (NDS).

15.3.1 <u>Local Training and Certification for Other Data Collection</u> Nutritionists

Other DISC nutritionists, who will perform dietary assessment for outcome measures of nutrient adequacy and adherence, may be trained either locally or by NCC, in the application of NCC coding rules, nutrient database and data collection procedures. They will also be trained locally by the Chief Nutritionist in DISC-specific dietary assessment methodology including the telephone 24-hour recall, use of the Food Record Guidebook and other study-related matters. All DISC nutritionists whether trained locally by the Chief Nutritionist or centrally at the NCC will be certified by the NCC and will be assigned code numbers for use in data collection.

In some DISC clinics the baseline 24-hour recalls will be collected by unblinded nutritionists prior to randomization. In subsequent 24-hour recalls, however, trained, certified nutritionists who are blinded to treatment group assignment will conduct the interviews in person and over the phone to minimize bias. Supervision, training and quality control procedures for these individuals is the responsibility of the local Chief Nutritionist. Upon completion of certification and assignment of certification numbers, the Chief Nutritionist should send the name, certification number and date of certification to the Coordinating Center.

15.3.2 Local Certification Procedures

The Chief Nutritionist at each Clinical Center is responsible locally for coordinating the training, and certification process for new staff. Dietary data collection must be performed by nutritionists (R.D.'s, R.D.-eligible or graduate level nutritionists) who have been trained and certified using the DISC criteria. All nutritionists who collect 24-hour recall data for analysis by NCC must be certified by NCC and receive an official NCC code number.

The following procedures are required for certification:

- Send ten edited, documented recalls (duplicate DISC-related recalls are acceptable) to Mary Stevens at NCC and indicate these are for purposes of certification (also notify the DISC Coordinating Center of such).
- 2. If training has occurred via teaching the NCC-codebook, then eight of the recalls submitted must also be coded.
- 3. If training was supplemented with NDS experience on at least three recalls, then the Chief Nutritionist may waive the coding requirement and so indicate to NGC.

As part of the local clinic certification process to meet study standards, nutritionists will also successfully complete at least three face-to-face and three telephone recalls with study-eligible individuals. These recalls should be supervised by the Chief Nutritionist who will review documentation based on NCC-standards and assure that interviewing technique is appropriate for DISC.

15.4 Quality Control

Any problems or discrepancies with 24-hour recalls noted during coding at the NCC will be reported back to the local DISC nutritionist who collected the data. Periodically, nutritionists will be asked to tape record the 24-hour recalls. These tapes will be reviewed by the

local Chief Nutritionist to evaluate interviewing skills and documentation procedures.

15.4.1 <u>Nutrition Data Collection Re-Certification</u>

There are two options for re-certification of locally trained nutritionists depending upon the frequency and regularity of data collection by the nutritionist. Re-certification will be required for all previously certified nutritionists who will be collecting dietary recall data at 12 and 36 months, Year 05, Year 07, Year 09 and final visits. Re-certification is also required for those who have not collected dietary data in the past nine months. Chief Nutritionists should complete the re-certification process for all nutritionists before the annual visit windows are opened.

The steps for local re-certification of nutritionists collecting end-point data include:

- Review use of the DISC Food Record Guidebook, use of NASCO food models and documentation checklist.
- Review previously collected data; BV00 recalls, 12 month recalls, quality control recalls (preferably the nutritionist reviews her own previously collected data).
- Review process and instructions for setting up follow-up telephone recalls.
- 4. Complete at least 2 in-person and 2 telephone recalls (but not DISC participants). Tape record at least 1 in-person recall for review by the Chief Nutritionist.
- 5. Chief Nutritionist should complete the Re-certification Checklist on the nutritionist being re-certified.
- 6. Send completed Re-certification Checklist and list of certified R.D.'s to the Coordinating Center. (see Exhibit 15.13).

No re-certification will be required for Chief Nutritionists (Master Nutrition Trainers).

15.4.2 External Quality Assessment of NCC Coding of 24-Hour Dietary Recalls

15.4.2.1 Introduction

The DISC Nutrition Coordinating Center (NCC) has its own established internal quality assurance procedures that it carries out on a regular basis. However, it has been deemed appropriate by the DISC Quality Assurance Committee to carry out a blinded, external surveillance of the NCC by having the DISC Clinical Centers submit to the NCC hand-copied duplicates of 24-hour recall forms previously submitted to and coded by the NCC. A sampling fraction of 10% of the children having the BV, the 12 and 36 month, and the Year 05, Year 07, Year 09, and final follow-up visits will be used for this external surveillance program. Instructions for carrying out this surveillance are given in the following sections.

15.4.2.2 <u>Selection of Participants</u>

The following ID numbers of participants randomized into the Feasibility Study have been selected randomly by the Coordinating Center for inclusion of their three Baseline Visit (BV) 24-hour recalls in this program:

1-0008	2-0033	3-0024	4-0024	5-0058	6-0220
1-0114	2-0063	3-0090	4-0133	5-0061	6-0235
		3-0136		5-0170	
				5-0196	

For the Full-Scale Trial, the three BV dietary recalls of every tenth participant to have a BV will be selected for this quality assessment program. If it is not possible to obtain three 24-hour recalls on the selected participants, then the next participant for whom three 24-hour recalls are obtained at BV will be selected for this program. For the

12 and 36 month, and Year 05, Year 07, Year 09, and final visits, for both the participants enrolled initially in the Feasibility Trial and those enrolled in the Full-Scale Trial, every tenth participant appearing for the particular follow-up visit will be selected to have the three 24-hour dietary recalls included in this quality assessment program. If three recalls are not obtained on the selected participant, then the next participant for whom three recalls are obtained at the particular follow-up visit will be included in this program.

15.4.2.3 Preparation of 24-Hour Recall Forms

For those participants selected for this program, the three 24-hour recalls will be <u>hand-copied</u> (NOT photocopied) from the original dietary recall forms. If different types of pens or colors of ink are used on the original forms, or if two or more different persons - say, one or more interviewers and an editor - have written on the form, the copy should reflect as closely as possible the different types of pens, colors of ink and handwritings.

15.4.2.4 <u>Identification of Copied Recall Forms</u>

The Coordinating Center has generated and distributed a random set of participant ID numbers - one number out of every block of ten - that the Clinic should set aside for use in the external surveillance of the NCC and the Central Lipoprotein Laboratory (CLL), and should not assign to any DISC participant. Each hand-copied set of three 24-hour dietary recall forms should be given one of the randomly generated ID numbers from this list. If possible, a number that is within or close to the range of ID numbers of the other, original recall forms included in the same shipment to the NCC should be used. For 12 and 36 month visit recalls of Feasibility Study (Cohort 1) participants, pseudo ID numbers should be selected by the Clinical Center from those Feasibility Study

numbers never assigned to DISC participants. Care should be taken to use each of the pseudo ID numbers only once for a given DISC visit (although the same pseudo ID number may be used for a set of dietary recalls for NCC and a CLL specimen for the same visit). A pseudo name code must also be assigned to each pseudo ID number; it is suggested that these name codes be developed from real first and last names (randomly selected from a telephone directory) rather than using random sets of letters that might be a tip-off to the NCC that this is a repeat submission.

15.4.2.5 Shipment of Copied Recall Forms to the NCC

Copied recall forms should be sent to the NCC at least a month after the original forms have been sent. The copied forms should, if at all possible, be sent along with original forms for other participants.

15.4.2.6 Notification of the Coordinating Center

Each time a set of recall forms is hand-copied for submission to the NCC, the ID number and name code of the participant from whom the dietary recalls were obtained, plus the pseudo ID number and pseudo name code used for the hand-copied forms, should be recorded on Form 62, the Nutrition Coordinating Center External Surveillance Form. The visit number and the dates of shipment of the original and hand-copied forms should also be recorded on this form. This form should be mailed immediately to the DISC Coordinating Center. Photocopies of the six 24-hour recall forms - three original and three hand-copied - should be sent along with the Form 62 to the Coordinating Center. This will allow the Coordinating Center to assess accuracy of copying of the recall forms at the Clinics.

15.4.3 Quality Control Checklist for Site Visits

Site visits may be conducted periodically. The Quality Control Checklist for Site Visits (see Exhibit 15-14) is to be completed by the qualified visiting nutritionist.

In the absence of centrally organized site visits, monitoring quality control among the nutrition data collectors becomes the responsibility of the local center, specifically the Chief Nutritionist. This continuing process is vital to maintaining study accuracy.

Each nutritionist should be reviewed at least annually to verify that standardized procedures are being followed. The Chief Nutritionist should monitor quality control as well as maintain certification and recertification criteria for each nutritionist at her center.

Completed Quality Control Checklists should be returned to the Coordinating Center.

EXHIBIT 15-1 NASCO Food Models

Catalog Item Number	Description	Size
W7379HR	pizza wedge with pepperoni and sausage	5 1/2" sector
W7375HR	2 crust apple pie	4" sector
W6634HR	American cheese slice	1 oz.
W7144HR	Weiner, raw, beef	1 1/2 oz.
W7410HR	Bologna, large round slice	1 oz.
W5771HR	Hamburger, fried	2 oz.
W7412HR	Pork chop, fried	2.3 oz.
W5817HR	Chicken leg, fried	3 oz.
W5819HR	Chicken breast, fried	3 oz.
W6121HR	Chicken wing, fried	3 oz.
W6656HR	Chicken, sliced	2 oz.
WA526OHR	Cookie, chocolate chip	2" dia.
W5644HR	Corn, whole kernel, canned	1/2 cup
W6718HR	Chocolate ice cream	8 scoop
W6629HR	Corn flakes	3/4 cup
W7402HR	Applesauce, canned	1/2 cup

EXHIBIT 15-2

Mock 24-Hour Recall Instruction

1.	2D wedges and thickness indicator		
	<u>Nasco</u>	<u>2D</u>	
	Pizza wedge Apple pie		
2.	Rectangles and thickness indicator		
	Nasco	<u>2D</u>	
	American cheese slice Weiner		
3.	Circles and thickness indicator		
	<u>Nasco</u>	<u>2D</u>	
	Bologna Cookies Hamburger pattie		These will be noted once the 2D models are complete and
4.	Cups, mounds, bowls <u>Nasco</u>	<u>2D</u>	code names/ numbers are assigned
	Corn Applesauce Corn flakes Ice cream		
5.	Meat models and thickness indicator		
	Nasco	<u>2D</u>	
	Chicken, sliced Chicken, wing Chicken, breast Chicken, leg Pork chop		

DOCUMENTATION CHECKLIST

Record portion sizes in the following standard measurements:

Weight in grams or ounces
Volume in fluid ounces, cups, tablespoons or teaspoons
Fraction of the whole (e.g., 1/8 of 9" pie)
Comparison to approved food model
Dimensions for the following shapes:

Shape	Measurement Needed	Example
Sphere	Diameter	Orange
Cylinder or disk	Diameter x thickness	Meat patty
Rectangle or cube	Length x height x width	Lasagne
Wedge	Length x height x width of arc	Pie

Food Crown	Did You Specific	Did You Probe for Additions
Food Group	Did You Specify:	and Amounts of:
Beverages Coffee, Tea	Brewed, instant, decaf, herbal, cereal type (e.g., Postum)	Sweetener, whitener, cream (type)
Cocoa	Mix (brand; regular, sugar-free or low-cal) Milk (% fat)	Marshmallows Whipped topping (dairy or non-dairy)
Beer	Regular, light or low alcohol	
Liquor, Mixed Drinks, Liqueur	Name of mixed drink, liqueur Proportion of ice	Mix (juice, other non-alcoholic beverage) Cherry, olive, etc.
Wine	Dinner or dessert	
Carbonated Beverages	Cola or non-cola, caffeine-free, diet, sodium-free Proportion of ice	
Dairy/Non-Dairy Products		
Milk, Cream, Toppings	% fat, dairy or non-dairy (brand) If non-dairy: powder, liquid or aerosol	Sweetener, cocoa mixes, etc.
Cheese	Natural or processed Kind (Cheddar, Swiss, etc.) If low fat: brand or % fat Low sodium	
Yogurt	% fat, plain or flavored	Fruit, nuts, etc.
ice Cream, ice Milk	Flavor Rich or average fat	Topping
Milk Shakes, Maits	Homemade or restaurant Flavor Ice cream or ice milk	
Egg. Egg Substitute	Method of preparation Brand of substitute Milk (% fat) if scrambled Fat in preparation (kind) Salt in preparation	Cheese, vegetables, meat, etc.

EXHIBIT 15-3 (Continued)

510		Did You Probe for Additions
Food Group	Did You Specify:	and Amounts of:
Desserts, Baked Goods		
Puddings, Custards	Kind Mix or scratch Low-cal or regular Milk (% fat) With or without egg	Topping
Cookies	Kind, brand Mix. scratch or commercial Ingredient fat	•
Cakes	Kind Mix. scratch or commercial Layer, sneet or cupcake Number of layers Ingredient tat Additional oil, egg Pudding in mix	Frosting, filling, topping
Pies	Kind (filling) Mix, scratch or commercial Single or double crust Ingredient fat for filling and crust	Topping
Gelatin Desserts	Low-cal or regular	Topping, other additions (fruit, etc.)
Fats	Bened and the same of the	
Oil, Shortening	Brand and/or type of fat	
Salad Dressing	Brand, type Ingredient oil, if homemade Creamy or clear Low-cal or low sodium	
Margarine, Butter	Brand and major oil Form (stick, tub, diet, whipped, spread, squeeze) Salt free	
Fruits/Fruit Juices	Fresh, canned or dried Cooked or uncooked Sweetened or unsweetened With or without peel	Fat (kind)
Grain Products		
Bread, Rolls	Kind (white, whole wheat, rye, etc.)	Butter, marganne, other spread
French Toast	Egg or egg substitute Fat in preparation Kind of bread	Butter, marganne, syrup, etc.
Sweet Rolls, Doughnuts	Yeast or cake-type Mix. scratch or commercial Ingredient fat	Frosting, glaze. nuts, preserves
Pancakes. Waffles Biscuits. Muffins	Kind (whole wheat, buckwheat, bran, etc.) Mix. scratch or commercial Ingredient fat	Butter, margarine, syrup, etc.
Cereal, Granola	Kind, brand Ingredient fat for homemade granola	Milk (% fat) Sweetener, fat, fruit, etc.

EXHIBIT 15-3 (Continued)

Food Group	Dld You Specity:	Did You Probe for Additions
	Did fou Specify:	and Amounts of:
Grain Products (Cont.) Pasta, Rice	Kind (spaghetti, brown rice, egg noodles, etc.) Salt in preparation	Fat (kind), sauce, cheese, etc.
Crackers	Kind, brand	Spread
Tortilla	Corn or flour Fat used if fried	Fillings
Gravies, Sauces	Mix or scratch Milk (% fat) or water Fat (kind) Salt in preparation	
Meat. Poultry, Fish Meat	Kind, cut Trimmed or untnmmed. % fat of hamburger or type of ground beef (e.g., ground chuck) Fat in preparation (kind) Salt in preparation Cooked or raw weight	Sauce. gravy, etc.
Meatioaf, Meatbails	With or without bone Kind, % fat or type of meat (e.g., ground round)	Sauce, gravy, etc.
Poultry	Light or dark meat (or name of part) Prepared with or without skin Skin eaten or not Breaded or battered and fried Fat in preparation (kind) Salt in preparation Cooked or raw weight With or without bone	Sauce, gravy, etc.
Fish . Cold Cuts.	Kind Breaded or battered and fried Fat in preparation (kind) Salt in preparation Cooked or raw weight Fresh or canned If canned, water or oil pack, drained, undrained or rinsed, low sodium	Sauce. etc.
Luncheon Meats	Kind, % fat, brand	
Mixed Dishes	Mix. scratch or commercial Fat in preparation (kind) Salt in preparation Meat. kind and % fat Sauce or gravy Milk or cneese (% fat or kind) Pasta or vegetables	Topping (e.g. croutons. crackers, cneese. etc.)
Pizza	Thick or thin crust	Topping
Restaurant Meals	Price range, name of restaurant	
Seasonings/ Condiments	Salt or seasonings (e.g. celery salt, garric salt. MSG) added in prep or at table	Pickle, relish, catsup, mustard, steak sauce, etc.

Food Group	Did You Specify:		Did You Probe for Additions and Amounts of:
Snacks/Candy	Kind. brand		and Amounts of.
Soups	Kind; homemade or commercial (Ready to serve, Milk (% fat) or cream added Chunky or regular Low sodium		Croutons, crackers, cheese, etc.
Vegetables	Cooked or raw Fresh, frozen or canned Low sodium Salt in preparation		Fat (kind), cheese sauce, nuts, dip, etc.
Salads	Kind (major vegetables)		Dressing, kind and/or brand Croutons, seeds, etc.
Baked Potato	Skin eaten or not		Butter, sour cream, etc.
French Fries	Frozen, scratch Fat in preparation (kind)		Catsup
Miscellaneous Medications containing nutrients such as sodium and/or caffeine	Type (e.g. analgesics, antacids, decongestants Brand	5)	
Dietary Supplements	Kind, brand, amount of ear nutnent (I.U., mg, gm, m on the Dietary Supplemental Information Form Number of tablets	ica)	
	APPROVED ABBREVIATION	ONS	· · · ·
Use these and other sta Dietary Intake Records.	indard abbreviations when o	documer	nting food intake on
approx - approximate avg - average brd - breaded c̄ - with cnd - canned choc - chocolate chpd - chopped comm - commercial ckd - cooked crax - cracker cp - cup	fl oz – fluid ounce gm – gram gr – ground hyd – hydrogenated Ig – large mayo – mayonnaise med – medium misc – miscellaneous pkg – package pc – piece poly – polyunsaturated	si - siid sm - s swt - s tb - tal ts - tea TVP - prot unkn -	mail sweetened blespoon aspoon textured vegetable ein - unknown vegetable
diam – diameter fg – few grains	prep - preparation S - without		without

Nutrition Coordinating Center 2829 University Avenue SE Minneapolis, MN 55414

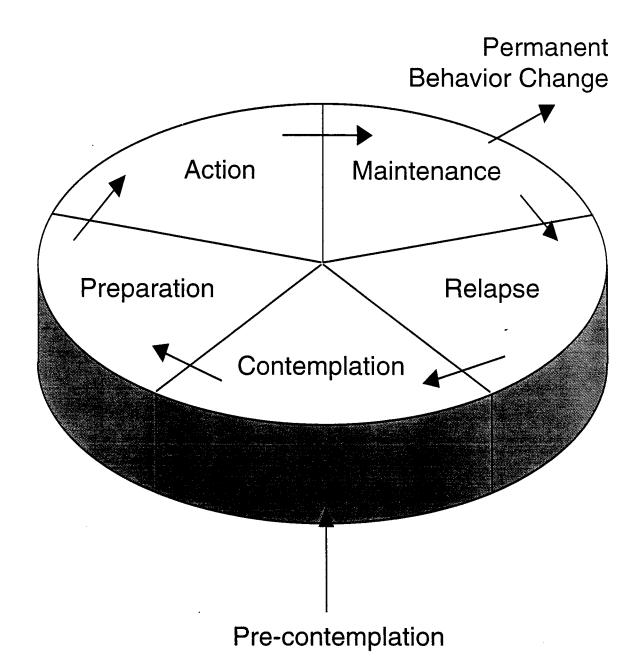
EXHIBIT 15-4

24-Hour Dietary Recall - Disposition Form

		Preferred	Date Contracts	Dates	0bta	ined*
<u>Name</u>	Phone	Times	First Recall was	1	2	3

^{*}Each participant should provide recall information for two week days and one weekend day. All three recalls should be completed within two weeks of the first recall day.

EXHIBIT 15-5



Kaiser Permanente Center for Health Research, Portland Oregon Adapted from: Prochaska & DiClemente Six Stages of Change

What is motivational interviewing?

A directive, participant-centered helping style for enhancing a teen's intrinsic motivation and commitment for health behavior change.

Primary goal:

To help a teen explore and resolve ambivalence about behavior change; and assist them to move through the stages of change toward successful sustained change.

Basic Assumptions:

The responsibility and capability for change lies within the participant.

Health care professionals can significantly influence a participant's motivation to change.

Highlights:

- 1. The practioner creates a positive environment based on "accurate empathy," warmth, genuineness, acceptance, and respect.
- The practioner does not assume an authoritarian role. One avoids the attitude - "I'm the expert and I'm going to tell you how to run your life."
- 3. Responsibility for change is left with the teen. The general message: "It is your choice if, when, and how to change, and nobody can make that decision for you."
- 4. A variety of participant-tailored strategies are used to build motivation. The direction pursued by the practioner is based on the teens "readiness to change."
- 5. Change efforts are not started until the teen has made a decision and commitment to change.
- 6. The teen, rather than the practioner, is the one who presents reasons for change.
- 7. The practioner facilitates the release of the "natural change" potential in the participant.
- 8. Motivational Interviewing combines elements of directive and nondirective approaches: The interviewing session is participant-centered, yet the practioner maintains a strong sense of purpose and direction.

EXHIBIT 15-7

A theoretical understanding of motivational interviewing includes the following:

- 1. Motivation is a fluctuating state.
- 2. Confrontation yields poorer compliance results.
- 3. Participant resistance is strongly influenced by the "helping style" of the practioner.
- 4. Health care professionals can significantly influence participants' motivation to change.
- 5. People often have within themselves the resources needed to change, but lack a firm decision, or commitment.
- 6. Brief interventions can lead to long-term change.
- 7. People normally pass through several stages in the process of changing (See Stages-of-Change Wheel).
- 8. Ambivalence is a normal stage in the process of changing.
- 9. Helping participants resolve their ambivalence and reach a firm decision is the key to change.
- 10. Effective behavior change intervention are tailored to the participant's "readiness" to change.
- 11. Common elements of effective brief interventions (Miller and Sanchez, 1994) represented by the acronym FRAMES (See FRAMES Model):

FEEDBACK - providing participants with personal feedback regarding their individual status

RESPONSIBILITY - emphasizing the teen's freedom of choice and personal responsibility for change

ADVICE - a clear recommendation on the need for change, conveyed in a supportive and concerned manner rather than authoritatively

MENU - providing a variety of options for change

EMPATHY - a style of helping based on reflective listening, warmth, genuineness, and respect

SELF-EFFICACY - reinforcing the teen's expectations that he or she can change

DISC MOTIVATIONAL INTERVIEWING

PURPOSE:	To increase the probability that participants will adhere to the DISC diet.
1. Establish R	apport:
How's it going	? What's new in your life?
2. Obtain Heig	ght and Weight Measurements
3. Opening St	atement:
"We have	_ minutes to meet. This is what I thought we might do:
- Give you s	the DISC diet is going for you some information about your last diet recall and cholesterol values what, if anything, you might want to change in your eating centive
How does this	sound? Is there anything else you're wanting to do?"
	rent Eating Behavior (an important step for establishing a ''baseline, '' ing progress, and to get the teen talking):
the DISC	erence Ruler": "This ruler will help me understand where you're at right now with C diet. Over the past month, are you following the DISC Diet - NEVER, Y, SOMETIMES (about 1/2 the time), MOST OF THE TIME, or ALWAYS."
- Explore par	ticipant's current eating behavior and progress by asking open-ended questions:
* "Tell me	more about"
	more about 'sometimes.' At what times do you follow the DISC diet, and at mes don't you?"
	e the easy times to follow the DISC diet?" o you follow the DISC diet?")
* "What are	e the hard times to follow the DISC diet?"

Kaiser Permanente Center for Health Research Portland, Oregon, 1995

("When don't you follow the DISC diet?")
* "How are you feeling about the DISC diet?"
* "The last time we met, you were working on How is that going?"
- Affirm, Compliment, and Reinforce positive eating behaviors:
* "That's great you're following the DISC diet about half the time"
5. Give Feedback:
- Show participant feedback graphs and forms.
- Give participant feedback in a neutral, non-dramatic, factual way.
- Compare participant's results with normative data or other interpretive information.
* Your total cholesterol level is This is how your cholesterol has changed over the years. Most teenagers your age have a cholesterol level of Cholesterol levels above increase your risk of"
- After giving feedback, ask about the participant's over-all response:
* "What do you make of all this information?"
* "Is this information surprising to you?"
6. Assess Readiness to Change:
Show "readiness to change" ruler. "How interested are you in making new changes in your diet to eat foods lower in SAT fat and cholesterol?" Or, "How interested are you in moving from 'rarely' to 'sometimes' follow the DISC diet?"
7. Tailor Intervention Approach to Readiness to Change: ask stage-specific open-ended questions to help participant explore and give voice to concerns, ambivalence, reasons for change, and ideas and strategies for change.

STAGE 1 (Not ready or ambivalent 1-4)-

GOAL: To build motivation and help tip the participant's decisional balance in favor of change.

Possible Open-ended questions:

- * "What are some of the good reasons for not making a change in your eating habits?"
- * "What do you like about eating food high in SAT fat and cholesterol?" "Any dislikes?"
- * "Are there any important reasons why you might want to make a change in your eating habits?"

 Or, "What are some of the less good things (disadvantages) for not making a change in your eating habits?"
- * "Ideally, how would you like to be eating?"
- * "What do you think might happen if you kept eating like this the rest of your life?"
- *** If a teen is not ready to make a further change, or could care less about DISC and low-fat eating -- that's OK. Not pushing them at this point may leave the door open for change and adherence in the future when they are ready. For the not-interested teen, find out what he/she is interested in. Sometimes, current interests can be tied to eating. For example, the teen who is heavily involved in a sport might be willing to take a closer look at eating behaviors if he/she thought it might affect performance. Be creative in opening the door to talk about the DISC diet, but back off if you encounter resistance.

Stage 2 (Ready - "seriously considering" 4-7) -

GOAL: To strengthen commitment to change by eliciting from the participant viable goals and strategies for change.

Possible Open-ended Questions:

- * "What are your reasons for wanting to eat foods lower in SAT fat and cholesterol?"
- * "What has helped you eat foods low in SAT fat and cholesterol in the past?"
- * "What do you think needs to change?"
- * "What are your ideas for making a change in your eating?"

*	"What	do	you	think	is	the	first	step?'
---	-------	----	-----	-------	----	-----	-------	--------

STAGE 3 (Action/Maintenance 7-12) -

Goal: To help the participant take additional steps to change and prevent backward slips.

Possible open-ended questions:

- * "What do you like about low-fat eating?"
- * "What are you doing that is working?"
- * "How would you change what you are now doing?"
- * "Anything else you see as a challenge?"
- 8. Provide Advice and/or Information (if appropriate)
- 9. Negotiate a Plan (if appropriate) use "action plan worksheet"
- 10. Summarize Encounter
- 11. Affirm, Compliment, and Reinforce support participant's self-efficacy
- 12. Provide Incentive
- 13. Report Back to Parent if Present

EXHIBIT 15-8 (Continued)

DISC MOTIVATIONAL INTERVIEWING [Phone Script]

PURPOSE: 10 increase the probability that participants will adhere to the DISC diet
1. Establish Rapport:
"Hello, this is calling from DISC. Do you have a few minutes to talk?"
[IF NO "When is a better time to call you back?"] [IF YES"I'm calling to see how things are going for you." "What's new in your life?"]
2. Opening Statement:
"There are several things I wanted to check in with you about:
 Hear how the DISC diet is going for you; and hear about your progress on the goal you set from last time ***Give you some information about your last diet recall and cholesterol values (include this piece for the teens you only have phone contact with it) Talk about what, if anything, you might want to change in your eating Find another time in the future for us either to talk by phone or meet in person
This should take aboutminutes. How does this sound? Is there anything else you're wanting to talk about?
3. <u>Assess Current Eating Behavior</u> (an important step for establishing a "baseline," reviewing progress, and to get the teen talking):
- "I have a question that will help me understand where you're at right now with the DISC diet. Over the past month - on a scale of 1-5 are you following the DISC never or always (1 = never; 5 = always)?"
- Explore participant's current eating behavior and progress by asking open-ended questions:
* "Tell me more about"
* "Tell me more about #3. At what times do you follow the DISC diet, and at what times don't you.?"
* "What are the easy times to follow the DISC diet?"

Kaiser Permanente Center for Health Research Portland, Oregon, 1995

("When do you follow the DISC diet?")
* "What are the hard times to follow the DISC diet?" ("When don't you follow the DISC diet?")
* "How are you feeling about the DISC diet?"
Affirm, compliment, and reinforce positive eating behaviors:
* "That's great you're following the DISC diet about 1/2 the time"
Review goal from previous encounter - "The last time we talked, you set a goal (s). How has it been going?"
Affirm, compliment, and reinforce positive eating behaviors:
If achieved goal - "Great!" "What did you learn?" What could you do differently next time?"]
4. ***Give Feedback (Include this piece for the teens you only have phone contact with):
Provide feedback to the participant in a neutral, non-dramatic, factual way.
Compare participant's results with normative data or other interpretive information.
* Your total cholesterol level is This is how your cholesterol has changed over the years. Most teenagers your age have a cholesterol level of Cholesterol levels above increase your risk of"
- After completing feedback, ask for the participant's over-all response:
* "What do you make of all this information?"
* "Is this information surprising to you?"
5. Assess Readiness to Change:
- "I have another question to ask - On a scale of 1-5, how interested are you in making new changes in your diet to eat foods lower in SAT fat and cholesterol?" (1 = not al all interested;

5 = very interested)

6. <u>Tailor Intervention Approach to Readiness to Change</u>: ask stage-specific open-ended questions to help participant explore and give voice to concerns, ambivalence, reasons for change, and ideas and strategies for change.

STAGE 1 (Not ready or ambivalent 1-2)-

GOAL: To build motivation and help tip the participant's decisional balance in favor of change.

Possible Open-ended Questions:

- * "What are some of the good things (important reasons) for not making a change in your eating habits?"
- * "What do you like about eating food high in SAT fat and cholesterol?" "Any dislikes?"
- * "Are there any important reasons why you might want to make a change in your eating habits?"

 Or, "What are some of the less good things (disadvantages) for not making a change in your eating habits?"
- * "Ideally, how would you like to be eating?"
- * "What do you think might happen if you kept eating like this the rest of your life?"
- *** If a teen is not ready to make a further change, or could care less about DISC and low-fat eating -- that's OK. Not pushing them at this point may leave the door open for change and adherence in the future when they are ready. For the not-interested teen, find out what he/she is interested in. Sometimes, current interests can be tied to eating. For example, the teen who is heavily involved in a sport might be willing to take a closer look at eating behaviors if he/she thought it might affect performance. Be creative in opening the door to talk about the DISC diet, but back off if resistance is elicited.

Stage 2 (Ready - "seriously considering" 3,4, and 5) -

GOAL: To strengthen commitment to change by eliciting from the participant viable goals and strategies for change.

Possible Open-ended Questions:

- * "What are your reasons for wanting to eat foods lower in SAT fat and cholesterol?"
- * "What has helped you eat foods low in SAT fat and cholesterol in the past?"
- * "What do you think needs to change?"

EXHIBIT 15-8 (Continued)

- * "What are your ideas for making a change in your eating?"
- * "What do you think is the first step?"

STAGE 3 (Action/Maintenance - for the teen who is diligently following the DISC diet) -

Goal: To help the participant take additional steps to change and prevent backward slips.

Possible Open-ended Questions:

- * "What do you like about low-fat eating?"
- * "What are you doing that is working?"
- * "How would you change what you are now doing?"
- * "Anything else you see as a challenge?"
- 7. Provide Advice and/or Information (if appropriate)
- 8. Negotiate a Plan (if appropriate) use "action plan worksheet"; send copy in mail to teen.
- 9. Summarize Encounter
- 10. Affirm, Compliment, and Reinforce support participant's self-efficacy
- 11. Arrange a future time to talk by phone or meet in person.

ひしつし Individual Visit Algorithm

ESTABLISH RAPPORT

-How's it going? **OBTAIN HEIGHT & WEIGHT MEASUREMENTS OPENING STATEMENT** minutes to meet. This is what I thought we might do: -Hear how the DISC diet is going for you -Give you some information about your last diet recall and cholesterol values -Talk about what, if anything, you might want to change in your eating Provide Incentive "How does this sound? is there anything else you're wanting to do?" ASSESS CURRENT EATING BEHAVIOR -Show Adherence Ruler -Ask open-end questions to explore current eating behavior and progress "Tell me more about "Tell me more about "sometimes". At what times do you follow the DISC diet, and at what times don't you "How are feeling about the DISC diet?" _. How is that going?" "The last time we met, you were working on __ Affirm, Compliment, and Reinforce **GIVE FEEDBACK** -Show participant feedback graphs and forms -Compare participant results with normative data or other interpretative information -After giving feedback, ask about the participant's over-all response: **What do you make of all this information?" ASSESS READINESS TO CHANGE -Show "readiness to change" ruler **How interested are you in making new changes in your diet to eat food lower in sat fat and cholesterol?" ASK STAGE SPECIFIC OPEN-ENDED QUESTIONS Stage III - 8-12 Stage II - 4-7 Stage I — 1-4 Action/Maintenance Not ready or ambivalen Ready - "seriously considering" GOAL: To help the participant take GOAL: To strengthen commitment to additional steps to change and change by eliciting from the prevent backward slips. participant viable goals and strategies for change. "What do you like about low-fat What do you think about eating food

GOAL: To build motivation and help tip the participant's decisional balance in favor of change.

- high in sat fat and cholesteroi? Any
- "What are some of the good reasons for not making a change in your eating habits?
- *Are there any reasons why you might want to make a change in your eating habits?"
- "Ideally, how would you like to be eating?"
- "What do you think might happen if you kept eating like this the rest of your life?"
- What are your reasons for wanting to eat foods lower in sat fat and cholesterol?'
- What has helped you eat foods low in sat fat and choiesterol in the past?"
- "What do you think needs to change?
- "What are your ideas for making a change in your eating?"
- eating?
- "-What are you doing that is working?
- "How would you change what you are now doing?"
- "Anything else you see as a challenge?"

	PROVIDE INFORMATION	OR ADVICE (If appropriate)	
<u></u>			
	NEGOTIATE A P	AN (If appropriate)	
	SUMMARIZE	ENCOUNTER	
	AFFIRM, COMPLIME	NT, AND REINFORCE	
L			
	PROVIDE	INCENTIVE	
	REPORT BACK TO	PARENT IF PRESENT	

DISC KEY COMPONENTS

EXHIBIT 15-9

- Try to understand the participant. Be warm, empathic, interested, and non-judgemental.
- 2. Assess the participant's readiness to change. Tailor your intervention approach to the patient's readiness to change.
- 3. Help the participant explore and resolve ambivalence about behavior change and reach a firm decision to change.
- 4. Acknowledge that the choice and responsibility to change is the participant's.
- 5. Offer objective feedback and professional advice where appropriate, while acknowledging that it is their decision if, when, and how to change.
- 6. Help the participant see options for support in making changes.
- 7. Avoid confrontation and raising the participant's resistance. Meet resistance with "reflection."
- 8. Emphasize your confidence in the participant's ability to change.

DISC FRAMES MODEL

EXHIBIT 15-10

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Г	ee	dŀ	12	ck	٠.

This step gives the participant information on their eating status and how it might relate to their personal health.

Your total cholesterol is ______. This is how your cholesterol has changed over the years. Most teenagers your age have a cholesterol level of ______. Cholesterol levels above ______ increase your risk of _____.

Responsibility:

It is the participant's choice to change.

"This is a very personal choice, and the decision is yours about what you want to do regarding your eating."

 ${
m A}$ dvice:

This is a "prescription" from the interventionist to recommend a change or particular course of action.

"I don't know how you feel, but fast food eating (skipping breakfast, poor snack choices, etc.) is what I see as most important for you to change."

Menu:

Offer a variety of strategies and options so that the participant can choose one that meets his or her needs, depending on stage of change.

"These are the things we normally talk to DISC participants about changing. Which of these are you interested in changing, or is there something else?"

Empathy:

Convey a supportive, non-judgmental, and caring manner in all messages you give. This "style" of interaction avoids arguments and resistance and is critical to the success of brief intervention.

"All of us in DISC really care about your health and want to support you in any changes you are ready to make."

Self Efficacy: change.

Support the participant's ability to successfully make a desired Your belief in the participants ability to change can be a significant factor in the outcome.

"I'm confident you can do it, once you decide the time is right."

Kaiser Permanente Center for Health Research, Portland, Oregon Adapted from: Miller & Rollnick, *Motivational Interviewing*, 1991

Doing it		lo it
Thinking about it in next week		t in Already starting to do it
Not interested in changing what I eat	$\frac{\text{Made in U.S.A.}}{1}$	Thinking about it in next month

DISC ADHERENCE RULER

EXHIBIT 15-12

ALWAYS		
A		 MOST OF THE TIME
SOMETIMES		ΞLY
NEVER	$\frac{1}{2} \frac{3}{3}$ Made in U.S.A.	RAR

EXHIBIT 15-13

DISC NUTRITIONIST

Recertification Checklist

	DISC Center:		
	Nutritionist being Recertified:		
	Chief Nutritionist Performing Review:		
	Date of Review:		
	Date of Certification (if never recertified) or Date of Last Recertification:	· · · · · ·	
		YES	<u>NO</u>
1.	Has this nutritionist completed at least one DISC recall within the past 9 months?	1	2
	If <u>YES</u> , skip to Part B.		
PART	A (Re-Certification for Nutritionists who have not completed a recall within the past 9 months):		
2.	Has this nutritionist performed dietary data collection in the past 9 months?	1	2
3.	Were two in-person and two telephone recalls completed on DISC-age children? (not participation)	1	2
4.	Was use of food models reviewed?	1	2
5.	Were previously collected recalls reviewed and considered acceptable?	1	2
PART	B (Continued Certification)		
6.	Was this a taped or in-person review?		Taped In-person
		YES	NO
7.	Was the participant adequately instructed on use of NASCO food models?	1	2
8.	Was the DISC Food Record Guide used appropriately?	1	2
9.	Were header questions asked appropriately?	1	2
10.	Was the interview thorough with all foods, meals and snacks discussed?	1	2
11.	Was probing technique appropriate without "leading" responses?	1	2

Nutrition 4/92 Page 1 of 2

		YES	<u>NO</u>
12.	Was snack from previous day discussed (if this visit included a fasting blood draw)?	1	2
13.	Was editing thorough and appropriate with all missing data completed appropriately?	1	2
14.	Was the nutritionist pleasant, encouraging and patient?	1	2
15.	Overall, was this interview conducted according to protocol. (If responses to any of the above are "NO," repeat on another day).	1	2
16.	Signature of Chief Nutritionist:	· · · · · ·	
17.	Date:		

EXHIBIT 15-14

DISC DIETARY ASSESSMENT

Quality Control Checklist for Site Visits

Nutritionist site visitor should be NCC-certified and should observe 24 hour recall administration if at all possible. In addition site visitor should discuss overall quality control issues with Intervention Director or Chief Nutritionist at center. In the absence of an annual site visit, the Chief Nutritionist is responsible for completing these quality control measures on each data collector on an annual basis.

1.	DISC Center:		·-	
2.	Nutritionist Site Visitor or Center Chief Nutritionist:			
3.	Individual Observed:			
	24 HOUR RECALL ADMINISTRATION FOR END POINT DATA	ANALYS	SES (NO	CC)
DATA	COLLECTION	YES	<u>NO</u>	COMMENTS
4.	Are recalls collected within time windows?	1	2	
5.	Are two week days and one week-end day included?	1	2	
6.	Are atypical days excluded?	1	2	
ISSU	ES PERTAINING TO INTERVIEWER			
7.	Is interviewer blinded to group identities?	1	2	
8.	Is interviewer a registered dietitian or RD-eligible?	1	2	
9.	Is interviewer NCC or DISC certified?	1	2	
ACTU!	AL ADMINISTRATION OF RECALL			
10.	Interviewer directs questions to participant and only seeks parental input as needed?	1	2	
11.	Interviewer uses NASCO food models and teaches/ reviews use of Food Record Guidebooks?	1	2	
12.	Uses NCC 24 hour recall form and correctly completes all header information?	1	2	
13.	Uses open ended questioning style, does not lead participant's responses?	1	2	
14.	Reviews all information, elicits additional information from parent as needed and edits as needed prior to participant's departure?	1	2	

Diet Asses 4/92 Page 1 of 3

		YES	NO	COMMENTS
ACTU.	AL ADMINISTRATION OF RECALL	<u> </u>	<u>o</u>	<u> </u>
15.	Gives instructions regarding subsequent telephone recalls within two weeks?	1	2	
16.	Appropriately uses "unknown" default for documentation purposes?	1	2	
	IC OPERATION/CHIEF NUTRITIONIST ESSING DATA/QUALITY CONTROL	<u>YES</u>	<u>NO</u>	COMMENTS
17.	NCC-Certified nutritionist reviews/edits all 24 hour recall forms prior to shipping to NCC?	1	2	
18.	Duplicate recalls are submitted on every tenth participant?	1	2	
19.	NCC data analyses are reviewed and compared with raw data to detect possible discrepancies?	1	2	
20.	Chief nutritionist periodically observes interview process or tape records interviews?	1	2	
21.	Chief nutritionist has trained the following individuals:			
	Name Date DISC Certified			
22.	Each center, by protocol, needs at least one NCC-certified nutritionist.			
	Name(s) of individual(s): NCC Cert	ification	No.	

DIETARY ASSESSMENT FORMS		<u>YES</u>	<u>NO</u>	COMMENTS
23.	Are Diet Acceptability Forms (18, 49, 52) collected at appropriate intervals?	1	2	
24.	Copies of all dietary assessment forms are kept in the clinic?	1	2	
<u>USE</u>	OF NDS FOR MONITORING INTERVENTION PROGRESS			
25.	Current version of NDS is in operation at the local center?	1	2	
26.	Staff trained to perform NDS analyses?	1	2	
27.	Identify all staff performing NDS analyses:			
				
				· · · · · · · · · · · · · · · · · · ·
28.	NDS analyses are performed for all intervention	YES	<u>NO</u>	COMMENTS
20.	participants as scheduled in protocol?	1	2	
29.	NDS analyses are obtained from three telephone recalls or child's written records for three days?	1	2	
30.	NDS analyses are utilized as part of case conference procedures?	1	2	
31.	NDS analyses are routinely shipped to the Coordinating Center?	1	2	
<u>ove</u>	RALL ASSESSMENT			
32.	Overall assessment of dietary assessment?			
	Excellent Good Fair Poor		•	
33.	Comments:			
		·		
34.	Signature of Site Visitor:		<u>. </u>	
25	- Date:			