May 10, 1995

TABLE OF CONTENTS

TABLE OF CONTENTS (CONTINUED)

CHAPTER 7

DATA COLLECTION AND PRIORITIES

7.1 Lipid and Lipoprotein Measurements

Inasmuch as an assessment of the effect of dietary treatment on blood lipids, lipoproteins and apolipoproteins will be a measure of the efficacy of dietary treatment, the following measurements will be made in DISC I and DISC II study subjects: total cholesterol (TC), triglycerides (TG), HDL cholesterol (HDL-C), LDL-C (calculated from a modified Friedewald equation in which VLDL is estimated as TG/X, where X = 6.5 for children and 6.3 for adults, derived from the Lipid Research Clinics (LRC) Prevalence Study data), apolipoprotein A-1 (apo A-I) and LDL apolipoprotein B (apo B). These measurements will be performed in a Central Lipoprotein Laboratory at Johns Hopkins University which is standardized for TC, TG and HDL-C measurements according to criteria of the CDC-NHLBI Lipid Standardization Program. The measurements will be made in serum that will be collected at the Clinical Centers, separated into aliquots of appropriate size, and sent on dry ice to the Central Lipoprotein Laboratory. In DISC I, serum cholesterol ester linoleate:oleate ratio will be determined at the Central Micronutrient Laboratory at the Centers for Disease Control in Atlanta. This dietary adherence measure will be done initially at SV2 in the feasibility study (FS), with a decision to be made later whether to extend this measure to later follow-up visits in the FS as well as to the full-scale trial (FST).

Blood samples will be collected as follows. Initially the children will be evaluated for TC, and those whose TC exceeds the 75th percentile of the reference distribution will be invited to participate in the screening visits. The prescreening cholesterol measurements will be made locally at all six Clinical Centers. Four Centers will analyze

fingerstick samples with the Kodak DT-60 device and two Centers will use other methods. These cholesterol values will be used only to identify likely candidates for the study and the values will not be used to establish pretreatment baseline cholesterol levels. Following the prescreening assessment, participants will be brought into the clinic for Screening Visit 1 (SV1) and Screening Visit 2 (SV2). At both screening visits, a blood sample will be obtained after a 12-hour fast for the measurement of TC, TG and HDL-C. Aliquots of serum from SV1 and SV2 will be stored frozen at the Central Lipoprotein Laboratory for determination of apo A-I and apo B on only those children who are randomized into the trial. Follow-up fasting blood specimens will be collected at 6 months (FS only), 12, 36, and 37 months, Year 5, Year 7, Year 9, as well as at the final visit (FV01) and a final visit repeat (FV02) for shipment to the Central Lipoprotein Laboratory for the measurement of TC, TG, HDL-C, apo A-I, apo B and a calculation of estimated LDL-C concentration. The 36-month LDL-C result will be averaged with the 37-month result and the final visit and final visit repeat results will be averaged to provide more stable primary efficacy outcome measures.

The parents/guardians of DISC I children randomized into the intervention group will give a blood sample at the first intervention session for the measurement of TC, TG, HDL-C, apo A-I, and apo B, and calculation of LDL-C. The same determinations will be made on parents/guardians in both the intervention and control groups at the 36-month DISC I follow-up visit. (In the FS blood samples were taken on all parents/guardians who attended the BV, but the serum was put into long-term storage for analysis at the time of the 36-month visit.)

Each time a venous blood sample is taken from a child or parent/guardian for Central Lipoprotein Laboratory determinations in DISC I

before the 36-month visit, a drop of the blood sample will be analyzed for total cholesterol using the DT-60 at the DISC Clinical Center and this value will be given to the participant. (In the FS, however, this was not done for the BV blood sample from parents/ guardians.) Additionally, intervention group participants--children and their parents/guardians alike--will be given the opportunity to have their total cholesterol measured periodically during intervention sessions using the DT-60 analyzer. Laboratory MN36 lipid determinations on children will also be returned to participants before the beginning of DISC II follow-up visits.

The decision to make lipid and lipoprotein measurements on serum rather than plasma took several considerations into account. First, the LRC data were obtained from fasting plasma samples and give some idea of prevailing lipid and lipoprotein concentration in the U.S. population. It is recognized, however, that the LRC data are not actually from a random subset of the U.S. population. On the other hand, the much larger data set that is being collected from the ongoing National Health and Nutrition Examination Surveys (NHANES) are being conducted in frozen serum samples and, beginning with the upcoming NHANES III survey, will include measures of apo A-I and apo B. Furthermore, beginning with NHANES II conducted in the 1970's, Hispanic HANES, which was conducted in the mid-1980's, and continuing into NHANES III, which will begin in 1987 and be completed in the early 1990's, all of the lipid and lipoprotein analyses will have been performed with CDC standardized methods for TC, TG and HDL-C. Therefore, it is felt that the adoption of similar procedures will allow the data collected in the DISC to be more readily compared with national population-based data. Second, the use of frozen serum is expected to minimize technical difficulties that

might develop in the event that the analyses are delayed due to laboratory or other logistical problems during the course of the study.

Training sessions will be held in which clinic personnel are taught how to collect, process, store and ship study samples to the Central Lipoprotein Laboratory. The use of a common sample handling protocol in all of the Clinical Centers as well as the performance of lipoprotein analyses in a single laboratory will minimize various sources of analytical variability. Provision will be made for repeating the training sessions annually, if necessary, for the benefit of new personnel who may join the study and as a refresher course for continuing personnel.

7.2 Clinical Assessment

7.2.1 Medical History

Medical and social history information will be obtained by standardized questionnaires on several occasions. At SV1, a questionnaire administered by DISC clinic staff will cover historical factors which might result in exclusion from DISC. Early ascertainment of these factors will reduce needless phlebotomy and other assessments on children not eligible for DISC for reasons established by medical history. This questionnaire will cover the following areas.

1. Medical conditions which may affect growth and/or cholesterol level (if present, the child will be referred for treatment):
    a. Nephrotic Syndrome.
    b. Liver Disease.
    c. Diabetes Mellitus.
    d. Inflammatory bowel disease (Crohn's or ulcerative colitis).
    e. Renal failure.

2. Medications which may affect lipids, growth, or other outcome measures:
   a. Thiazide diuretics.
   b. Retinoids.
   c. Steroids.
   d. Lipid-lowering medications.
   e. Ritalin.
   f. Phenobarbital.
   g. Dilantin.
   h. Therapeutic iron.
   i. Thyroid medication.
3. Factors likely to increase adherence to the study diet in controls (compared to intervention children):
   a. Parent on physician-prescribed fat-modified diet.
   b. Parental history of myocardial infarction before age 45.
4. Behavior or other problems in child or family likely to reduce adherence to the diet:
   a. Truancy.
   b. Left back in school two grades or more.
   c. Alcoholic parent.
   d. Use of vitamin or mineral supplements.
   e. Meals provided by more than three adults on a regular basis (two or more days/week) and/or adults providing meals unwilling or unable to learn diet modification or unable to provide school lunch from home.
   f. In special education class.
   g. History of anorexia nervosa and/or bulimia.
   h. History of intentional rapid weight loss (seven pounds or more in two weeks).

i. Weight of parents/guardians over 175% ideal weight for height (FS only).

j. Parents and/or child non-English speaking.

5. Other

a. Plans to move more than 50 miles from area within three years.

b. Greater than Tanner Stage 1.

A more extensive self-administered questionnaire will be sent to the parents/guardians prior to SV2 to collect data for DISC enrollment. The SV2 parent history will include the following:

1. Identity, place of residence, education and occupation of parents/guardians.
2. Race.
3. Household composition: number and ages of all individuals living in household.
4. Place and type of residence.
5. Family income.
6. Additional medical history on child: hospitalizations, operations, days school missed.
7. Family medical history: angina, MI, coronary bypass surgery or angioplasty, high cholesterol, hypertension, diabetes.

Parents will be asked to update their child's medical history at annual follow-up visits. Beginning in Year 06, when participants will be 15 and 16 years of age, the medical history will be completed by either the participant or a parent. Also beginning around Year 06, parents will no longer be asked to supply information about girls' menstrual cycle, contraceptive use, and pregnancy.

In addition, a child history questionnaire will be administered to the child at SV2 and at annual follow-up visits to ascertain

information only he/she may have. This form will ask about the following:

1. Alcohol/drug use.
2. Cigarette use.
3. Use of contraceptives (not SV2).
4. Use of steroids (not SV2).
5. Pregnancy (not SV2).

7.2.2 Physical Examination

A physical examination on DISC children will be performed at SV2 and at annual follow-up visits. The purpose of the initial physical examination before randomization (SV2) is to establish that each child meets the medical eligibility criteria for inclusion in DISC and serves as a baseline medical evaluation for each participant. This examination should reveal a generally healthy prepubescent child (Tanner Stage 1).

Follow-up physical examinations on DISC study children are intended to assess their general physical health, growth and maturation during the course of this study. Special attention will be given to their nutritional status. The purpose of these examinations is to monitor the safety of the dietary intervention and to provide information on study end points.

These examinations will be brief but complete, lasting approximately 10-15 minutes. During this study children will present with acute illnesses, such as otitis media, pharyngitis, asthma, bronchitis, and pre-existing chronic problems such as scoliosis, inguinal hernia, or a significant heart murmur. Beginning at the 36 month annual follow-up visit a screening question for practices associated with eating disorders will be administered. The question, together with changes in body mass, will be used to identify possible

cases of anorexia or bulimia in DISC participants. These conditions may require evaluation, treatment and/or follow-up and should be referred to the child's usual health care provider.

The physical examination of DISC children will be performed by either a pediatric nurse practitioner, a child health associate, or a pediatrician. Whenever possible, the examiner will remain the same for each child throughout the study and, if possible, he/she will be the same gender as the study child.

The examination will briefly cover the child's general appearance, head, ears, nose, mouth, teeth, eyes, neck, chest, lungs, heart, abdomen, genitalia, musculo-skeletal system, nutritional status and note the presence of active infections.

7.2.3 Tanner Staging

An assessment of pubertal development will be made on each DISC child at SV2 and at each annual follow-up visit until the child has reached Tanner stage 5. One purpose of the initial (SV2) evaluation is to establish that the child is prepubescent. Evidence of beginning sexual maturation is an exclusion criterion from this study.

Female pubertal development will be assessed by evaluating breast and pubic hair development. Male pubertal development will be assessed by evaluating genitalia and pubic hair development and measuring testicular volume. These observations will provide data on the initiation and progression of pubertal development in the DISC population.

The assessment of pubertal development on DISC children will be performed by either a pediatric nurse practitioner, a child health associate, or a pediatrician. Whenever possible, the examiner will

remain the same for each child throughout the study and, if possible, he/she will be the same gender as the study child.

7.2.4 Menstrual History in Girls

As part of the physical exam, questions about menarche will be asked at all clinic visits until girls have started to menstruate. Beginning at the 36 month clinic visit, girls who have reached menarche will complete menses calendars for six weeks before and six weeks after each clinic visit that includes a blood draw.

7.2.5 Anthropometry

Height and weight will be obtained on the child participants, wearing hospital gowns, at SV2 and at each annual follow-up visit. Triceps, subscapular and suprailiac skinfolds and arm, waist, hip (bitrochanter), and maximum below waist circumferences will be measured on children at SV2 and at 12 months, 36 months, and at the final follow-up visit.

Weight will be measured using a Health-o-Meter electronic scale and skinfolds will be measured using Tanner-Whitehouse (Holtain) skinfold calipers. Each of these measurements can be made twice by the same observer. A third measurement will be made if the second measure differs from the first measure (by the same measurer) by more than 0.2 kg for weight, 1 mm for each of the three skinfolds, 0.5 cm for arm circumferences, or 1.0 cm for the waist and hip circumferences.

Height will be measured using a special-order stadiometer. For height, measurements will be performed once each by two observers. The second height measurer will be blinded to the results of the first measurement. A third measurement will be made if the second measure differs from the first by more than 0.5 cm. The mean of the two closest height measurements will be used for data analysis purposes. See the

DISC Manual of Operations Chapter 10 for detailed anthropometric measurement procedures.

For eligibility purposes, single measurements of height and weight will also be taken at SV1 and weight at SV2 with the child in street clothes.

For adults, height and weight will be measured during the baseline period and at the 36-month follow-up visit. Each measurement will be made once.

Each center will designate a primary and back-up anthropometrist. Central training will be followed by weekly practice measurements performed by the anthropometrists at their respective centers, with documentation to be forwarded to the trainer for evaluation. Certification of anthropometrists will be done annually. Quality control of anthropometry will be based on duplicate measurements of 10% of the participants measured in each examination cycle.

7.2.6 Blood Pressure and Pulse Measurements

Systolic and diastolic (fourth and fifth phase) blood pressures will be measured in children at SV2, BV, 12, 36 months and at the final DISC II visit. Prior to taking blood pressure measurements, the right arm circumference will be measured in order to select the appropriate blood pressure cuff size. Two blood pressure measurements will be taken at 60 second intervals, with the child in a sitting position, using a Baum random zero mercury sphygmomanometer. In general, both measurements will be made by the same person. The mean of the two measurements will be used as the child's blood pressure for that exam. For a 10% sample of the children, a second blood pressure measurer will take an additional set of blood pressure readings for quality

assessment purposes. A 30-second pulse rate will be measured once, between the two blood pressure readings.

7.2.7 Nonlipid Laboratory Tests

7.2.7.1 Introduction and Tests To Be Performed

A number of nonlipid laboratory tests will be done at SV2, at 12 and 36 months, and at the DISC II final visit. At these visits, 35-40 ml of blood will be drawn; hemoglobin and hematocrit determinations will be done locally, while other determinations will be done centrally. (In the FS, additionally, a urine sample was obtained for dipstick protein analysis, and a complete blood count and cell indices were determined locally.) Serum and red cell hemolysate will be frozen and sent to the Central Lipoprotein Laboratory at Johns Hopkins University. A portion of the serum will be used by that Laboratory for lipoprotein and apolipoprotein determinations; another portion will be sent to the Central Non-Lipid Laboratory at Johns Hopkins University for determinations of serum T4 and components of a standard chemistry panel. The remaining portion of serum and the red cell hemolysate will be sent to the Central Micronutrient Laboratory at the Centers for Disease Control in Atlanta for determinations of serum retinol, tocopherol, five carotenoids (alpha-carotene, beta-carotene, cryptoxanthin, lutein, and lycopene), ferritin, zinc, copper, and red cell folate.

Tests to be performed can be grouped according to three major objectives:

1. Assessment of presence of specific exclusion criteria: serum albumin, SGPT (or alanine amino transferase), fasting serum glucose, and serum T4 (thyroxine).
2. Assessment of the primary and secondary nutrition safety outcome measures: hemoglobin, hematocrit, serum ferritin,

zinc, copper, retinol, tocopherol, and carotenoids, red cell folate, and albumin.

3. Assessment of changes over time in additional components of a standard chemistry panel, including serum urea nitrogen, creatinine, total and direct bilirubin, calcium, phosphorus, uric acid, total protein, SGOT (or aspartate amino transferase), and alkaline phosphatase.

All tests in the second group plus albumin will be done at SV2 and at 12 and 36 months and at the final visit. Additionally, SGPT, glucose, and the tests in the third group will be done at SV2 and 36 months. T4 is mainly an exclusionary test and done only at baseline. The likelihood of new hypothyroidism is considered too low to warrant reassessment during follow-up. Non-lipid laboratory tests will not be done on parents/guardians.

Beginning in DISC I at the 12 and 36 month visits and continuing in DISC II at the Year 5, 7, 9 and final visits, a number of hormone determinations will be performed on serum samples for both male and female children. At SV2 and at the 12 month visit, 2.5 ml of serum will be collected for hormone analyses from participants who have not completed these visits prior to the initiation of the hormone study. At the 36 and 37 month visits, 2.5 ml of serum will be collected from all participants. At the Year 5, Year 7, Year 9, and the final visits, 5 ml of serum will be collected from all participants for hormone analyses. See Chapter 9A for the rationale and details of tests to be performed.

Beginning in DISC II at Year 7, a one-time sample of 5 ml of whole blood will be drawn from participants at an annual or final visit for DNA analyses (DNA Ancillary Study). See Chapter 13, Exhibit 13.2 for the rationale and tests to be performed.

7.2.7.2 Rationale

The measurements of SGPT and albumin serve several purposes. Hypoalbuminemia can be an indicator of protein-calorie malnutrition, and SGPT and albumin can serve as screening measures for infection and/or liver disease. Finally, the albumin level may be correlated with and affect the serum zinc level, which will also be measured.

Serum glucose will be used to exclude those with diabetes. Thyroxine will be measured and in the few cases of values below a lower cutpoint, thyroid stimulating hormone will be determined to rule out hypothyroidism. Because hypothyroidism is so infrequent, it is extremely unlikely that a child with hypothyroidism will be randomized in DISC if the T4 is normal.

The second group of tests listed in the preceding section is being done to obtain objective assessments of the nutritional status of participants. Iron and zinc status will be assessed because these are the nutrients for which dietary data indicate the greatest likelihood of borderline deficiency in cholesterol-lowering diets. Iron status will be evaluated by the hemoglobin and hematocrit indices and serum ferritin. These are considered sufficient to establish safety and identify long-term changes in iron status. Although longitudinal tracking of ferritin levels in children this age is not established, the test can be accurately and precisely done and is considered the best measure of long-term changes in iron stores. Ferritin was therefore chosen as the primary nutrition safety outcome measure and blood will be drawn for ferritin assay on each child after ascertaining that the child is not acutely infected at the time of the clinic visit. Hemoglobin and hematocrit are included as confirmatory measures of iron status.

There are no tests currently accepted as adequate to assess zinc status. Even though nutrient analyses of the DISC dietary intervention consistently find zinc to be the nutrient most likely to be deficient relative to the RDA, zinc was not chosen as the primary nutrition safety outcome measure in DISC because of the lack of specificity of hypozincemia. However, because of the potential zinc deficiency in the diet, it was felt important to evaluate zinc status as well as possible. Group differences in serum zinc levels could be meaningful. DISC staff will standardize the interval from eating to phlebotomy, assess the possibility of infection, measure serum albumin and alkaline phosphatase, and also measure serum copper in order to reduce the effect of artifacts in serum zinc measurements and to maximize specificity of the assay.

Serum retinol and red cell folate will be determined as possible measures of a positive effect of the new dietary pattern, since it encourages an increase in vegetable consumption. In addition, because 28% fat, while not extremely low, does represent a decrease from the average child's diet in the United States, it is felt desirable to assess the status of fat-soluble vitamins. Measurement of retinol and tocopherol serves this purpose.

7.3 Psychosocial Assessment

7.3.1 Introduction

Psychosocial assessment in DISC is designed to implement the two primary DISC goals. These are to demonstrate that the DISC diet is safe for children in the 8 to 18 year age group, and that it is effective in lowering LDL-C in children at risk. Accordingly, the goals of psychosocial assessment in DISC are the following:

1. To demonstrate the safety of the DISC intervention and control group diets regarding the cognitive, behavioral, attitudinal, and social functioning of children in the intervention group.
2. To identify cognitive, behavioral, attitudinal, and social factors which predict compliance with the prescribed diet in the DISC intervention group.

The first task of psychological monitoring in DISC is to test the hypothesis that dietary intervention is safe, i.e., that children are not harmed by being identified and placed on a reduced fat cholesterol diet. Four major types of indicators will be used in DISC to provide information about participants' developmental progress: indicators of cognitive development, behavior problems, attitudes and emotions, and family environment. Each type of indicator will be important for assessing potential dietary or screening effects of the DISC program. No single area is sufficient in and of itself.

The general types of psychosocial safety monitoring indicators in DISC II will remain essentially unchanged in order to provide for continuous psychosocial safety monitoring from recruitment at ages 9 and 10 to age 18. However, some changes in emphasis and in the methods used for psychosocial safety monitoring are appropriate for adolescent participants. Concerns have been raised about increases in morbidity resulting from suicide, violence, and accidents in an adult population enrolled in cholesterol reducing clinical trials. Therefore, increased emphasis will be given to monitoring for behavior and related adjustment problems in adolescent DISC II participants.

Other changes in DISC methodology will be necessary due to the increased literacy and independence of DISC participants after age 15. Standardized psychological scales for children used during DISC I will be changed to age appropriate versions for young adults. Self-reported

adolescent behavior problems will be gathered in addition to parental reports of adolescent behavior problems. Alternative methods of psychosocial data collection by mail or phone may be developed in order to minimize possible missing data at the final data collection visit.

7.3.1.1 Cognitive Development

The Woodcock-Johnson Math and Reading Clusters[1] are standardized math and reading achievement tests suitable for use from age 3 to 65 years. Math and reading achievement subtests will be used in the DISC I and continued in the DISC II battery because of the key role these subjects play in over-all academic performance before high school graduation. Reading subtests to be used are letter-word identification, word attack, and passage comprehension. Math subtests chosen for administration are calculation and applied problems. Normative data were collected from a sample of 4700 nationwide, with subjects stratified by gender, race, occupational status, geographical region, and type of community.

7.3.1.2 Behavior Problems

Problems reported by parents constitute another meaningful source of information about children's progress. In younger DISC I participants, these natural observers will be able to judge how their child is doing at mastering basic social-developmental challenges involved in becoming more independent, expressing feelings in appropriate ways, interacting with others, and taking part in his or her social group. Because parents are with the child over prolonged periods, their reports provide information not captured in a brief test. A variety of problem behavior rating scales have been developed for teacher and parent use; the best of these is the Achenbach Child Behavior Checklist (CBCL).[2] CBCL subscale scores indicate the degree to

which a child is manifesting high levels of internalizing problem behaviors (acting withdrawn, avoidant, depressed) or externalizing problem behaviors (acting aggressive and openly angry). The CBCL also can be used to measure the child's level of social competence, i.e., how well he or she does at making friends and being part of a social group.

To monitor behavior problems in older DISC II participants, the Youth Self-Report[3] will be used in addition to the parental report. This is a standardized instrument which parallels the Achenbach Child Behavior Checklist used for parents. It is a self-report measure for ages 11 to 18 yielding scores for total behavior problems, internalizing and externalizing problems, as well as individual subscale scores.

7.3.1.3 Self-Reported Attitudes and Emotions

Children often have difficulty putting threatening feelings into words, however they can report their inner emotional states if the questions are phrased carefully in a non-threatening context. Children's self-reports provide unique and important information about fears and worries, and are invaluable aids to detecting conditions such as depression or anxiety. Because DISC screening and intervention could engender fear or self-doubt, reliable and interpretable measures of these emotions will be included in the DISC safety assessments.

To monitor depression, the Kovacs Child Depression Inventory[5] (DISC I) and the Beck Depression Inventory[6] (DISC II) will be used. These are well-known 21 and 27 item scales for assessing depression in children and adolescents that are well correlated with other depression scales and clinical ratings of depression. Measurement of depression in adolescents is particularly important because of concerns raised about suicide. The Children's Depression Inventory used in DISC I is a

downward extension of the Beck Depression Inventory for adolescents and adults.

To monitor anxiety, the Spielberger Trait Anxiety Inventory[7] (Children's version in DISC I and adult version in DISC II) will be administered. These are one page trait anxiety inventories which are widely used and well standardized instruments.

7.3.1.4 Family Environment

To monitor the effect of intervention and the diet on the family environment, the Family Environment Scale[8] (Moos) will be administered in DISC I and II. The instrument has been used in studies of stress and depression in community samples, and in measures of chronically ill children. Subscales include: cohesion, expressiveness, conflict, independence, achievement orientation, intellectual-cultural orientation, moral-religious orientation, organization, and control. Second order factors of support, conflict, and control have also been identified.

7.3.2 Summary of the DISC Psychosocial Assessment Battery

Safety of the DISC diet for children will be monitored in four areas of general concern: cognitive development, behavioral adjustment, self-reported emotions and attitudes, and family environment. In each area, we have reviewed the most widely used measures and have selected the instrument with the best track record for reproducibility and utility for developmental monitoring. Selection of specific instruments was based on suitability in terms of age and literacy requirements. Attention was also given to the length of forms, methods of administration, and cost to the project.

7.3.2.1 Monitoring Psychosocial Safety of the Diet

1. Woodcock-Johnson Math and Reading Clusters[1] (25 minutes). Administered to child by trained technician at baseline and 12-month, 36-month and final follow-up visits. Measures child's mastery of math and reading skills. (DISC I and II)

2. Achenbach Child Behavior Checklist (CBCL)[2] (20 minutes). This will be administered to at least one and preferably both parents at SV2 and 12 months, 36 months, and the final visit. Parents can complete this paper and pencil questionnaire at home or while waiting at the clinic. The CBCL includes indices of internalizing behavior (withdrawal, avoidance, shyness), externalizing behavior (anger, aggression, non-compliance) that might occur in response to DISC labeling and diet, as well as social competence (ability to interact with others and make friends) which might also be affected. (DISC I and DISC II)

3. Youth Self-Report[3] (Achenbach, 1988). Parallels the CBCL used in DISC I and II for ages 11 to 18. (DISC II) Final visit only.

4. Kovacs Child Depression Inventory[5] (CDI) (10 minutes). The technician administers this to the child at baseline and 12 and 36 months. The CDI picks up feelings of low self-worth, hopelessness, or indicators of depression that could occur in response to being placed on an unusual diet. (DISC I)

5. Beck Depression Inventory[6] (Beck and Steer, 1987). Adult form of the CDI used in DISC I. Administered at the final visit. (DISC II).

6. Spielberger Trait Anxiety Inventory[7] (STAI-C2 Children's version) (10 minutes). The child will complete this at baseline and 12 and 36 months. The STAI-(C2) provides a reliable indicator of the child's usual or trait level of fear or anxiety. (DISC I)
7. Spielberger Trait Anxiety Inventory[7] (Spielberger, Gorsuch, and Lushene, 1970). Adult form of the STAI administered at the final visit. (DISC II)
8. Moos Family Environment Scale (FES)[8] (25 minutes). One or both parents will complete this paper and pencil questionnaire while waiting at the clinic at baseline, 12 months, 36 months, and the final visit. The FES measures aspects of family structure, interaction, and climate that could be affected by participation in DISC. (DISC I and II)

7.3.2.2 Predicting Compliance to Diet

In addition to monitoring safety, the psychological assessment will assist in identifying behavioral and social factors that influence the degree to which families adhere to the recommended diet. For example, children with higher scores on the CBCL, CDI, or STAI could do less well when asked to comply with the DISC diet. An important outcome of DISC will be to suggest normative guidelines for identifying children and families in which diet interventions are likely to succeed. Three other important predictor variables qualify as compliance measures: the degree to which parents appear to have been successful in managing the child's behavior in the past, the number and severity of stressful life events experienced by the family at baseline, and the family's basic socioeconomic resources. Instruments to assess these variables will be administered in DISC I on a take-home basis at the beginning of

intervention, and will only be completed by families in the intervention group. Socioeconomic status will be obtained from both intervention and control group families prior to randomization.

The following instruments will be used in DISC I to predict compliance to diet:

1. Eyberg Child Behavior Inventory[9] (10 minutes). Administered at the first intervention session (intervention group only). Measures degree of influence parents have been able to establish over the child's behavior, as reflected in behavioral compliance problems and signs of immaturity.
2. Sarason Life Experiences Scale[10] (20 minutes). Administered separately to both parents at the first intervention session (intervention group only). Parent reports stressful events occurring in recent months. This could be important for predicting noncompliance or tendency to drop out of the intervention.
3. DISC Household Information Form (10 minutes). Sent home prior to SV2 for completion by a parent (both intervention and control groups). Gathers information on socioeconomic status in the form of occupation, education, and income of both parents; household composition; and ethnic group affiliation. Demographic information will also be important for describing the sample of DISC participants and comparing findings to data from other studies. Table 7-1 summarizes the forms used for monitoring dietary safety and predicting dietary compliance.

7.3.3 Validation of Psychosocial Instruments

Previously published instruments chosen for DISC have already demonstrated construct validity. For most of these instruments age,

gender, and race specific norms are available. Data from the DISC population of high-LDL children will be compared to published norms to determine whether results are consistent with those from prior investigations.

7.3.4 Time Required to Complete Psychosocial Assessment

Table 7-2 shows the estimated time requirements for parent and child to complete the psychosocial questionnaires at each visit. In DISC I, children and their parents will be asked to spend approximately 45 minutes completing study psychosocial questions at the baseline, 12 and 36 month visits. In DISC II, questionnaires will take about 65 minutes for children and 45 minutes for parents to complete at the final data collection visit.

7.4 Dietary Assessment

7.4.1 Objectives

Measurement of dietary adherence in DISC will provide the basis for evaluating the efficacy, safety and feasibility of dietary intervention after 36 months (DISC I) and at age 18 (DISC II). The overall objectives of dietary assessment in this study are:

1. To ensure that the intake of dietary fat at baseline provides a margin for change.
2. To estimate usual individual intake for establishing baseline dietary patterns and to monitor longitudinal changes in dietary intake throughout the study.
3. To periodically assess current individual intake for monitoring nutritional adequacy in the intervention group.
4. To periodically assess individual and group adherence to dietary intervention objectives in the intervention group.

7.4.2 Methods

The proposed methodologies to meet these objectives include the following for both intervention and usual care group participants (Table 7-3):

1. Dietary Eligibility Questionnaire (modified from Connor and Connor) completed at first screening visit: (DISC I)
   a. To determine eligibility based on current food selection patterns that will ensure adequate margin for change.
   b. To assess capability and willingness to participate in the study.
   c. To identify baseline eating patterns.
2. Multiple (3) 24-Hour Random Recalls completed by children at baseline, 12 months, 36 months, Year 5, Year 7, Year 9 and the final visit. One face-to-face and two telephone recalls will be administered within two weeks and will include one weekend day per record: (DISC I and II)
   a. To establish baseline and follow-up visit individual and group dietary intakes for end point data analyses.
   b. To assess weekday versus weekend eating patterns.
   c. To assess dietary adequacy of intakes at baseline and follow-up visits.
   d. To assess levels of participant/parental cooperation and adherence.
   e. To provide preliminary evidence to the feasibility study of participant adherence to the diet.

Proposed methodologies to meet dietary assessment goals which will be used in the intervention group only include the following (Table 7-2):

1. Diet Patterns Questionnaire completed by parent/caretaker at baseline: (DISC I)
   a. To assess child's behaviors that influence food intake such as meal and snacking patterns and eating outside the home.
   b. To assess parent's/caretaker's behaviors that influence child's food intake such as food purchasing and preparation methods.
2. Three Day Food Records or Recalls completed by children at regular intervals throughout intervention: (DISC I and II)
   a. To assess baseline eating patterns in individuals in intervention group.
   b. To measure dietary adherence to recommended eating pattern during follow-up.
   c. To assess dietary adequacy and nutrient intake during follow-up.
3. GO/WHOA Checklists between intervention visits: (DISC I and II)
   a. To provide opportunity for self-assessment of dietary adherence.
   b. To provide opportunity for self-assessment of dietary change over time.
4. DISC Intervention Goals completed by parent/caretaker and child during intervention visits: (DISC I and II)
   a. To allow participants to specify in writing at each intervention session a behavioral goal.
   b. To allow self-monitoring of achievement of goals.
5. Monthly Contact Form completed by clinic personnel listing nature of monthly contacts with intervention group parents and children. Returned to Coordinating Center monthly until July 1, 1993. (DISC I)

6. Growth Monitoring Form completed by clinic interventionists and recording intervention children's height and weight measured every three months beginning at 15 months and ending July 1, 1993. (DISC I)
7. Participant Tracking Form completed by clinic personnel every six months beginning July 1, 1993 until the final visit. Records monthly participant contacts and mid-year results of height and weight measures for intervention group participants. (DISC II)
8. Saturated Fat Monitoring Book developed by DISC as a specialized tool that will assist participants to identify and control sources of saturated fat in their diet. It was designed to act as an aid to self-monitoring and will be used on a case by case basis during individual visits with older intervention group participants. (DISC II)
9. Diet Acceptability Questionnaire (DAQ) administered to parents and children every 6 months in DISC I and to children yearly in DISC II to evaluate both general reactions and specific problems in carrying out the DISC diet.
10. Case Management Conference and Case Management Summary Form A case management conference will be held every six months in DISC I and yearly in DISC II. During the conference, clinic staff will focus on individual intervention participants and their families. Their purpose will be to exchange information, evaluate the adherence of each participant, and facilitate better adherence to the recommended diet. A Case Management Form will be completed for each participant at his/her conference and will record the information reviewed and decisions made. (DISC I and II)
11. Knowledge Test is a 20 question multiple-choice test of participant knowledge of the saturated fat content of various foods. It was

designed by DISC nutritionists as a tool to be used on a case by case basis during individual intervention sessions to assess participant knowledge of recommended food choices. (DISC II)

12. Confidence Rating Form I adapted from a section of the Barr Taylor Diet Self-Efficacy Scale (DSES)[11] developed at Leland Stanford Jr. University. This form asks participants to rate their confidence that they can control their eating habits. It will be administered to intervention and control group participants at the final visit. (DISC II)

13. Confidence Rating Form II adapted from a section of the Barr Taylor Diet Self-Efficacy Scale (DSES)[11] developed at Leland Stanford Jr. University. This form will be administered to intervention group participants only beginning at IY06 and asks participants to rate their confidence that they can stick to a low-fat eating pattern. (DISC II)

14. The DISC Cookbook is a collection of recommended and tested recipes provided by DISC intervention group participants. The Cookbook will be distributed at all DISC clinics at intervention sessions. Children will receive credit for their contributions. (DISC II)

15. The DISC Dictionary is a dictionary of recommended foods, advice on preparation, serving and portion sizes, and nutritional content by food group. (DISC I and II)

16. The Food Record Guide is supplied to intervention group participants to use as an aid in measuring and reporting food intakes on food records and recalls. The goals are to improve accuracy of the records and recalls. (DISC I and II)

7.4.3 Rationale

Only children whose dietary fat intake at the first screening visit is sufficient to allow a margin for intervention will be eligible to participate in DISC. The Diet Eligibility Questionnaire will assess usual fat intake and will be designed so that it can be easily administered and scored at clinical centers.

Dietary data used to assess efficacy and safety of the intervention in the feasibility and full-scale trials will be derived from three 24-hour recalls collected from the intervention and control groups at baseline, 12 and 36 months, Year 5, Year 7, Year 9 and at the final visit, plus one 24-hour recall at 6 months for the feasibility group only. Multiple recalls will be used because of the large intra-individual variation in daily dietary intake. The first of the three recalls will be performed in-person and the second two will be performed over the telephone. The in-person recall will provide the opportunity for familiarizing participants with the method and instructing them on using two dimensional food models. The telephone recalls will provide the opportunity for collecting dietary data on random days. Therefore, participants will not be able to vary their intakes on particular days because they know they will be asked what they ate. Also, telephone recalls will decrease the number of clinic visits participants have to make and possibly reduce contamination of controls.

Ongoing evaluation of adherence and nutritional adequacy in the intervention group will be performed using 3-day food records or recalls. Food records or recalls will be completed at regular intervals throughout intervention, using the method that nutritionists and children feel most comfortable with.

In addition to providing a means for monitoring adherence and safety, 3-day food records will be used by dietitians at clinical centers as a teaching tool. Nutrient intake will be evaluated by dietitians using a micro-computer

based nutrient analysis system (NDS). This will provide rapid feedback of information to participants and maximize usefulness of the data. The DISC GO/WHOA Checklist, Diet Patterns Questionnaire, and Intervention Goals, the Saturated Fat Monitoring Book, The Knowledge Test, the DISC Cookbook, the Dictionary, and the Food Record Guide are intervention tools that are intended to enhance adherence to the DISC diet.

7.4.4 Nutritional Coding and Analyses

The 3-day food records and 24-hour recalls will be coded using the Nutrition Coordinating Center (NCC) data base. Over 60 nutrients are included and together provide detailed information regarding dietary intake. DISC dietary recommendations are primarily focused on fatty acids and cholesterol. Meeting adequacy requirements for other nutrients focuses on percent of calories from protein, vitamins A and C, iron, zinc, and calcium relative to the usual care group and RDA recommendations.

Assessment of dietary adherence will be based upon the variables that best reflect the change from a high fat intake at baseline to a lower fat intake following intervention. The assessment of adherence to dietary recommendations in DISC will include the following factors in terms of both grams and percent of total calories: total fat, saturated fatty acids (SFA), polyunsaturated fatty acids (PFA), monounsaturated fatty acids, and cholesterol. Dietary adherence will also be assessed by means of the Keys Score, defined as

$$1.35[2(\%\text{SFA kcal})-(\%\text{PFA kcal})] + 1.5(\text{mg cholesterol}/1000\ \text{kcal})^{1/2}.$$

The intervention group means will be compared as well as the percent of the DISC goals achieved and the percent of participants who achieve them. The Keys Score, although limited to fat and cholesterol criteria only, will also be calculated to reflect a change in these variables. Since the Keys

Score predicts the potential serum cholesterol lowering effect of reduced fat intake, the lower the Keys Score the better the response.

It is helpful to study multiple nutrients and dietary factors to provide a general picture of the initial compliance with dietary intervention. Among these factors the Keys Score serves as a valuable measure of dietary adherence since it incorporates the weighted effects of three factors known to influence blood cholesterol simultaneously. The Keys Score is not intended to predict cholesterol response in this case, but only to serve as one of the measures of dietary adherence.

7.5 Physical Activity Assessment

7.5.1 Objectives

The primary objectives for assessing physical activity in DISC are:

1. To estimate baseline level of activity in study participants and monitor change over time.
2. To rank participants according to activity level (e.g., high, medium, low) so that potential confounding of the association between diet and blood lipids or hormone levels and blood lipids by physical activity can be evaluated and, if appropriate, adjusted for in analyses.
3. To identify intervention group participants who are either very active or very sedentary to help explain possible differences in lipoprotein response.

7.5.2 Methods

There are currently no satisfactory standards for adequately measuring physical activity in children. Various assessment tools have been used in previous studies and these have been reviewed for applicability to DISC. The DISC Physical Activity Questionnaire was adapted for children from physical activity recall items developed for adults at Stanford University.[12] Physical

activity will be assessed using the interviewer-administered DISC questionnaire completed by the parent with input from the child in DISC I and by the child with help from the parent in DISC II. The questionnaire will be administered at baseline, 12 and 36 months, Year 5, Year 7, Year 9 and at the final visit.

7.6 Makeup of a Clinic Visit and Time Table

Children in both the control and intervention groups will be seen at two screening visits, a baseline visit, at 6 months (feasibility study only) and then annually following randomization. Data to be collected at clinic visits will include history, dietary assessment, physical examination including anthropometric data, serum lipid and lipoprotein levels, other laboratory tests for exclusion and monitoring, and psychometric tests. The administration schedule is outlined in Tables 7-4 and 7-5. Table 7-6 summarizes the schedule of administration of selected intervention forms for intervention group children and their parents.

7.7 Priorities for Data Collection

Priorities for data collection for all in-clinic visits will be the same as for non-clinic visits (See Chapter 20 in the DISC Manual of Operations "Procedures for Non-Clinic Data Collection Visits in DISC"). The measurement of height and weight and obtaining blood for lipids are the highest priority items. The priority ranking for annual visit data collection is as follows:

HIGHEST PRIORITY:

1. Height
2. Weight
3. Blood draw (when required for visit)

SECONDARY PRIORITY:

4. Menses data (when required for visit)
5. Medical history and tobacco use

6. 24-hour dietary recalls (when required for visit)
7. Physical activity assessment (when required for visit)
8. Maturation assessment
9. Complete anthropometry (when required for visit)
10. Blood pressure (when required for visit)
11. Psychosocial assessments (when required for visit)

Data should be obtained on the highest priority items, and as much of the data as possible on the secondary priority items. If the participant refuses to provide the information or to allow examination, data collection should proceed on to the next item.

7.8 References

1. Woodcock RW, Johnson MB. Woodcock-Johnson Psycho-educational Battery. Teaching Resources Corp., Hingham, MA, 1977.
2. Achenbach TM, Edelbrock CS. Manual for the Child Behavior Checklist and Revised Child Behavior Profile. Burlington, VT.: Dept. of Psychiatry, Univ. of Vermont, 1983.
3. Achenbach TM. Manual for the Youth Self-Report and Profile. University Associates in Psychiatry. Burlington, 1988.
4. Helzer JE, Robins LN. The Diagnostic Interview Schedule: Its development, evolution and use. Soc. Psychiatry Psychiatr Epidemiol 23, 6-16, 1988.
5. Kovacs M. Rating scales to assess depression in school-aged children. Acta Paedopsychiatrica 45:305-15, 1981.
6. Beck AT, Steer RA. Manual for the Beck Depression Inventory. San Antonio: The Psychological Corp. 1987.
7. Spielberger CD, Gorsuch RI, Lushene RE. Manual for the State-Trait Anxiety Inventory. Consulting Psychologists Press, Palo Alto, CA, 1970.

8. Moos RH, Moos BS. Family Environment Scale (Form R) Manual. Consulting Psychologists Press, Palo Alto, CA, 1984.

9. Eyberg SDM, Robinson EA. Conduct problem behavior: Standardization of a behavioral rating scale with adolescents. J Clin Child Psych 12:347-54, 1983.

10. Sarason I, Johnson J, Siegel J. Assessing the impact of life changes. J Consult Clin Psych 46:932-46, 1978.

11. Taylor CB, Houston-Miller N, DeBusk R et al. in The Active Partnership Workbook, American Heart Association, 1994.

12. Sallis JF et al. Physical activity assessment methodology in the Fire-City Project. Amer. J. Epid. 121:91-106, 1985.

Table 7-1

A. Psychosocial Assessment Instruments Used To Monitor Dietary Safety. (Control and Intervention Groups in DISC I and II)

Variable and Measure	Time for Admin.	Visit SV2	BL	IV1*	12 Mo.	36 Mo.	Final
1. Cognitive Development							
. Woodcock-Johnson Math/Reading	25 min.		C		C	C	C
2. Behavior Problems							
. CBCL	20 min.	P		P	P	P	P
. Youth Self Report	20 min.						C
3. Self-Reported Emotions and Attitudes							
. Child Depression Inventory	10 min.		C		C	C	
. Beck Depression Inventory	10 min.						C
. Trait Anxiety Inventory (child version)	10 min.		C		C	C	
. Trait Anxiety Inventory (adult version)	10 min.						C
4. Family Environment Scale	25 min.		P		P	P	P

B. Psychosocial Assessment Instruments Used to Predict Dietary Compliance (Intervention Group Only in DISC I).

Variable and Measure	Time for Admin.	Visit SV2	BL	IV1*	12 Mo.	36 Mo.	Final
1. Compliance with Instructions							
Child Behavior Inventory	10 min.			P			
2. Recent Stressful Events							
Life Experience Scale	20 min.			P			
3. Social and Economic Resources							
Demographics--Education, Occupation, Income, Household Composition, Race	10 min.	P					

P = Parent
C = Child
* First intervention visit

Table 7-2

Total Amount of Time Required to Administer DISC Psychosocial Assessment Instruments to Parent and Child at Baseline (BL), 12 Months, 36 Months, and Final Visits.

	Visit					
Participant	SV2	BL	IV1*	12 Mo.	36 Mo.	Final
Parent	30 min.	25 min.	30 min.	45 min.	45 min.	45 min.
Child		45 min.		45 min.	45 min.	65 min.

*First intervention visit.

Table 7-3

DIETARY ASSESSMENT METHODS AND TOOLS FOR DISC

Method	Objective	Target Variables	Frequency of Administration
I. Intervention and Usual Care Groups:			
Dietary Eligibility Questionnaire	▪ Quick estimate of usual individual intake for eligibility ▪ Assess willingness to cooperate with dietary intervention	▪ Intake of high fat foods	Screening Visit 1 (DISC I)
3 X 24 Hour Recalls (1 at clinic, 2 telephone)	▪ Assess mean intake of individuals ▪ Assess nutritional adequacy ▪ Assess adherence ▪ Assess changes in dietary intake	▪ Macro- and micro-nutrients and calories	Baseline, 12 months, 36 months, Year 5, Year 7, Year 9 and Final Visit (DISC I and II)
II. Intervention Group Only:			
3 Day Food Record	▪ Assess current mean intake of individuals ▪ Measure dietary adherence ▪ Assess changes over time	▪ Macro- and micro-nutrients and calories ▪ Food groups	Regular intervals throughout intervention (DISC I and II)
GO/WHOA Checklist	▪ Assess habitual meal and snacking pattern ▪ Scoring of weekly meal pattern for self monitoring	▪ Use of high fat and/or undesirable foods	Between intervention sessions (DISC I and II)
Diet Patterns Questionnaire	▪ Assess family resources ▪ Assess child's & parents/caretakers behaviors that influence food intake	▪ Food preferences, purchasing and preparation, eating out	Parents at baseline (DISC I)
DISC Intervention Goals	▪ Assess weekly achievement of specified diet intervention goals	▪ Food selection, purchasing, preparation and modeling behavior	Parents and children at intervention visits (DISC I and II)

Table 7-3 (Continued)

DIETARY ASSESSMENT METHODS AND TOOLS FOR DISC

Method	Objective	Target Variables	Frequency of Administration
Monthly Contact Form	▪ Assess nature of monthly contact	▪ Attendance and participation in intervention sessions	Monthly by clinic personnel (DISC I)
Participant Tracking Form	▪ Assess nature of contacts within 6 mon. tracking period	▪ Attendance at intervention sessions, mail and phone contacts	Every 6 mons. by clinic personnel (DISC II)
Growth Monitoring Form	▪ Monitor height and weight between data collection visits	▪ Child Growth	Every 3 months from 15 months to 7/31/93 (DISC I)
Case Management Form	▪ Record results of case conference	▪ Adherence to diet; monitor height, weight, adequacy of dietary intake	Every 6 months (DISC I); every year (DISC II)
Diet Acceptability Questionnaires	▪ Evaluate general reactions to diet and specific problems	▪ Diet acceptability	Parents and children every 6 mons (DISC I) and children yearly (DISC II)
Confidence Rating Form I	▪ Evaluate feelings of control over eating habits	▪ Diet Self-Efficacy	One time at the final visit (DISC II)
Confidence Rating Form II	▪ Evaluate ability to stick to a low-fat eating pattern	▪ Diet Self-Efficacy	Annually after IY06 (DISC II)
Saturated Fat Monitoring Book	▪ Reduction of saturated fat intake through self-monitoring	▪ Dietary intake of saturated fat	Throughout intervention on an individual basis (DISC II)

Table 7-3 (Continued)

DIETARY ASSESSMENT METHODS AND TOOLS FOR DISC

Method	Objective	Target Variables	Frequency of Administration
Knowledge Test	▪ Improved dietary choices of foods low in saturated fat	▪ Knowledge of the DISC recommended diet	Throughout intervention on an individual basis (DISC II)
DISC Cookbook	▪ Cooking practice; better use of low fat recipes at home	▪ Preparation of low fat recipes	Throughout intervention (DISC II)
DISC Dictionary	▪ Description of recommended foods, servings, and preparation by food group	▪ Knowledge of DISC diet and preparation by food group	Throughout intervention (DISC I and II)
DISC Food Record Guide	▪ Teach accurate estimation of food types and portions	▪ Reporting of intakes on food records and recalls	Throughout intervention (DISC I and II)

Table 7-4
Schedule of Information to be Collected in DISC I

Item	SV1	SV2	BV	Months after Randomization 6	12	24	36	48
Consent form								
Screening	A							
Baseline			A					
Demographic information	A							
Medical history								
Eligibility assessments	C	C,A						
Family history		A						
Illness, medications	C,A				C		C	C
Physical examination								
Height, weight		C	A	C	C	C	C,A	C
Blood pressure		C	C		C		C,A	C
Skinfold thickness								
Triceps		C			C		C	
Subscapular, suprailiac		C			C		C	
Arm, waist, hip circumference		C			C		C	
Tanner staging		C		C	C	C	C	C
General physical exam		C			C		C	
Menses calendars							C	
Dietary assessment								
Dietary Eligibility Questionnaire	C			C				
3 24-hour dietary recalls			C	C*	C		C	
Physical activity assessment			C		C		C	
Psychosocial assessment								
Woodcock-Johnson			C		C		C	
Achenbach CBCL		A			A		A	
Child Depression Inventory			C		C		C	
State-Trait Anxiety Inventory			C		C		C	
Family Environment Scale			A		A		A	
Biochemical determination								
TC, TG, HDL-C, LDL-C, apo A-I, apo B	C	C	A**	C**	C		C#,A	C
Albumin		C			C		C	
SGPT, glucose, chemistry panel		C					C	
Urinary protein		C**						
T4		C						
Hemoglobin, hematocrit, ferritin, zinc, copper, retinol, tocopherol, carotenoids, folate		C			C		C	
Linoleate:oleate ratio		C		C				
Hormone assays†					C		C	

C = Child
A = Adult

*A single 24-hour dietary recall at 6 months, feasibility group only
**Feasibility study only
#Two determinations one month apart
†Estrone, steroids, bioavailable fractions, and SHBG

Table 7-5

SUMMARY OF DISC II CLINIC VISIT CONTENT
(Children Only)
August 1993 - January 2001

Months After Randomization/ Visit Number	36* MN36	48 MN48	60 YR05	72 YR06	84 YR07	96 YR08	108 YR09	Final# FV01	Final Repeat FV02
MEDICAL HIST.: Illness, Hospit., Meds, Pregnancy	X	X	X	X	X	X	X	X	X
PHYSICAL EXAM:									
Height, Weight	X	X	X	X	X	X	X	X	
Blood Pressure	X							X	
Skinfolds	X							X	
Circumferences	X							X	
Tanner Stage**	X	X	X	X	X	X	X	X	
Menses Calendars	X		X		X		X	X	X
Gen. Physical	X							X	
DIETARY ASSESS.:									
3 - 24hr.recalls	X		X		X		X	X	
PHYSICAL ACTIV. ASSESSMENT	X		X		X		X	X	
PSYCHOL.BATTERY	X							X	
BIOCHEMICAL TESTS:									
Lipids, Apos	X		X		X		X	X	X
Chemistry Panel&	X								
CDC Assays***	X							X	
Hormone Assays†	X		X		X		X	X	X
DNA ANALYSES@									

*DISC I only
#Randomization anniversary after 18th brithday
**Until Tanner stage 5 only
&Serum albumin, SGPT, fasting serum glucose, serum urea nitrogen, creatinine, total and direct bilirubin, calcium, phosphorus, uric acid, total protein, SGOT, and alkaline phosphatase.
***Ferritin, Zinc, Copper, Retinol, Tocopherol, Carotinoids, Red Cell Folate
†Estrone, steroids, bioavailable fractions, and SHGB
@DNA polymorphisms in the APOA-I promoter, the APOE, and APOA-IV genes. One-time collection after YR06.

Table 7-6

SCHEDULE FOR THE ADMINISTRATION OF DISC I AND II
Intervention Forms

VISIT	FORM						
	Diet Eligibility:	Diet Patterns:	Diet Acceptability (DAQ)				Case Management Summary
	Form 21	Form 24	Form 17: Baseline	Form 18: Interim	Form 52: Annual	Form 49: Annual	Form 58
SV1	C						
BL		A	C				
5 weeks				C		A	
12 weeks				C		A	
6 months*				C		A	
12 months*					C	A	
24 months					C	A	
36 months*					C	A	
42 months							C
48 months*					C	A	
54 months							C
60 months*					C		
66 months							C
72 months*					C		
78 months							C
84 months*					C		
90 months							C
96 months*					C		
102 months							C
108 months*					C		
Final*					C		C

C = child A = adult
* studywide data collection visits/± one month window

DIETARY INTERVENTION STUDY IN CHILDREN

DISC Form ___
Rev. 0 10/26/87

DEMOGRAPHIC PROBING EXERCISES FOR FORM 07

This form should be completed by all personnel who administer the Parent/Guardian Information Form (07). It is required for the general interviewing certification and should be answered, self-scored, and returned to the Coordinating Center with the total score written clearly on the first page under the cover sheet. Have a Form 07 to refer to while completing these exercises.

1. The child's female guardian has answered question 8C by saying that she is both "separated" and "living as married." When probed she says that both are in fact true. What should be your criterion for correcting the response?

2. A female guardian has answered education question 8D by marking answer 03 and writing that she finished the 9th grade and part of the 10th. What should you check on with the guardian?

3. Another respondent to question 8D has marked two answers: 05 and 06. How should you probe?

EXHIBIT 7-1 (Continued)

4. On occupation 8F, the guardian has answered that she is (1) an educator, that she (2) teaches children, that the (3) business or industry is the public school system, and (4) other category of the (5) local government. In the spaces below supply more detailed information that would have to be probed for in order to supply adequate detail for coding:

   (1) _____

   (2) _____

   (3) _____

   (4) _____

   (5) _____

5. On question 8F, the child's mother says that she last worked in 1980 part-time (5 hr. a week) as a pipe-fitter in the People's Republic of China. She has made satisfactory answers to all of the occupational questions. Is the occupational information gathered valid?

   a) No, because she worked in a foreign country.

   b) Yes, because even as little as five hours a week is considered employment.

   c) Yes, because she gave her most recent occupation.

   d) None of the above.

6. On question 11F, the child's male guardian says that he is employed as (1) an assistant manager, and that he (2) sells home improvement supplies in a (3) paint and wallpaper store that is a (5) private business. (4) is left blank. What else do you need to know?

   _____

   _____

   _____

EXHIBIT 7-1 (Continued)

7. Another male guardian answers occupation question 11F in the following way: His occupation is (1) tile setter, and (2) he lays ceramic and other tiles in kitchens, baths, and on patios. His business is described as (3) a subcontractor to builders of houses and commerical buildings. The business is (4) "other" "building trades" and (5) is scored (a) private business. When questioned Mr. X adds that he works for his father, and that they are partners in the business. What needs to be clarified?

_____

_____

_____

_____

8. The child's mother answers question 8F and says that she is a (1) secretary, her activities include (2) typing, filing, and compiling statistics for her employer. She works in a (3) law office in the (4) "other" business, left unspecified. It is a (5) private business. Write out a set of details to be added through probing in order to make this a codable occupation.

(1) _____

(2) _____

(3) _____

(4) _____

(5) _____

DIETARY INTERVENTION STUDY IN CHILDREN

ANSWER KEY

DEMOGRAPHIC PROBING EXERCISES FOR FORM 07

Answers are listed with the number of points allowed for each part to the right. Points should be given as whole numbers. You can receive partial credit if part of the question is right. Mark each question and then total the points. Write the total number of points on Page 1 under the cover sheet and see that the form is sent to the Coordinating Center.

	Answer	Possible Points
1.	Your criterion should be her current relationship with the other adults in the household. If she is living with someone, "living as married" is her marital status.	1
2.	Check to be sure that she did not finish the 10th grade. If not, the correct response is 02.	1
3.	Ask her if she has had both "other formal training" after high school and some college as well	1
	If both are true, the correct response is the highest level completed or 06.	
4.	(1) Secondary (level - not elementary or college)	1
	School teacher (not administrator or aide)	1
	(2) Teaches 12th grade (specific grade)	1
	Biology (subject)	1
	Disciplines, directs, grades students and runs Science Club (more details)	1
	(3) County public school system (kind of industry)	1
	(4) Other - public schools (industry type)	1
	(5) Local government (class of worker)	1
5.	The correct answer is d) None of the above. The occupational information will not be used because she was employed more than five years ago.	1

ANSWER KEY

Answer	Possible Points
6. Getting the answer to subpart (4) on question 11F or 8F is critical since a salesman (principle activity is selling) is coded differently if he/she is in retail business vs. manufacturing or wholesale business. Since the parent has described his employer's activity as "a store," the coder could infer that this is a retail activity; however, the question should be asked directly.	1
7. If the interviewer had just scanned the answers to these questions and not asked the parent to review them once more, the information provided might look satisfactory. However, the parent's random comment should alert the interviewer to the fact that he has misunderstood the meaning of subpart 5 of question 11F (or 8F). By answering a., he has indicated that he is an employee of the business. However, a "partner" is really a part owner unless the business is incorporated. If the business has been incorporated, all workers are employees according to Census definitions. The interviewer should go over 5e and f and help the parent to decide which describes his situation.	1
8. Almost all parts of this response need to have detail added:	
(1) The job title should be more specific since there are many different types of secretarial occupations.	1
(2) If the parent cannot decide on a specific job title, probing for a primary or range of activities may help. Does she prepare legal documents or briefs with special training? (legal secretary) Does she compile information and statistics (statistical clerk), or take notes in the clerical department of a large firm (stenographer). Does she work primarily in the typing pool (typist) rather than at numerous activities in a small office?	1
(3) You must also probe to see if the employer's business was a private law practive or a legal department of some other private activity such as a college, hospital, or insurance company.	1
(4) Check the "other" response and ask them to specify.	1
(5) Also review this response to make sure the parent understood the meaning of "private" and that there was no ownership involved.	

EXHIBIT 7-2

INDUSTRIAL CLASSIFICATION SYSTEM

Equivalent alphabetic codes follow some codes. Either code may be utilized, depending upon the processing method. Numbers in parentheses following the industry categories are the SIC definitions. "N.e.c." means "not elsewhere classified."

Industry Code	AGRICULTURE, FORESTRY, AND FISHERIES
017 (A)	Agricultural production (01)
018	Agricultural services, except horticultural (07 except 0713 and 073)
019	Horticultural services (073)
027	Forestry (08)
028	Fisheries (09)
	MINING
047	Metal mining (10)
048	Coal mining (11, 12)
049	Crude petroleum and natural gas extractions (13)
057	Nonmetallic mining and quarrying, except fuel (14)
	CONSTRUCTION
067	General building contractors (15)
068	General contractors, except building (16)
069 (B)	Special trade contractors (17)
077	Not specified construction
	MANUFACTURING
	Durable goods
	Lumber and wood products, except furniture
107	Logging (241)
108	Sawmills, planing mills, and mill work (242, 243)
109	Miscellaneous wood products (244, 249)
118	Furniture and fixtures (25)
	Stone, clay, and glass products
119	Glass and glass products (321-323)
127	Cement, concrete, gypsum, and plaster products (324, 327)
128	Structural clay products (325)
137	Pottery and related products (326)
138	Miscellaneous nonmetallic mineral and stone products (328, 329)
	Metal industries
139	Blast furnaces, steel works, rolling and finishing mills (3312, 3313)
147	Other primary iron and steel industries (3315 3317, 332, 3391, part 3399)
148	Primary aluminum industries (3334, part 334, 3352, 3361, part 3392, part 3399)
149	Other primary nonferrous industries (3331-3333, 3339, part 334, 3351, 3356, 3357, 3362, 3369, part 3392, part 3399)
157	Cutlery, hand tools, and other hardware (342)
158	Fabricated structural metal products (344)
159	Screw machine products (345)
167	Metal stamping (346)

Industry Code	MANUFACTURING—Continued
168	Miscellaneous fabricated metal products (341, 343, 347, 348, 349)
169	Not specified metal industries
	Machinery, except electrical
177	Engines and turbines (351)
178	Farm machinery and equipment (352)
179	Construction and material handling machines (353)
187	Metalworking machinery (354)
188	Office and accounting machines (357 except 3573)
189	Electronic computing equipment (3573)
197	Machinery, except electrical, n.e.c. (355, 356, 358, 359)
198	Not specified machinery
	Electrical machinery, equipment, and supplies
199	Household appliances (363)
207	Radio, T.V., and communication equipment (365, 366)
208	Electrical machinery, equipment, and supplies, n.e.c. (361, 362, 364, 367, 369)
209	Not specified electrical machinery, equipment, and supplies
	Transportation equipment
219	Motor vehicles and motor vehicle equipment (371)
227	Aircraft and parts (372)
228	Ship and boat building and repairing (373)
229	Railroad locomotives and equipment (374)
237	Mobile dwellings and campers (3791)
238	Cycles and miscellaneous transportation equipment (375, 3799)
	Professional and photographic equipment, and watches
239	Scientific and controlling instruments (381, 382)
247	Optical and health services supplies (383, 384, 385)
248	Photographic equipment and supplies (386)
249	Watches, clocks, and clockwork-operated devices (387)
257	Not specified professional equipment
258	Ordnance (19)
259	Miscellaneous manufacturing industries (39)
	Nondurable goods
	Food and kindred products
268	Meat products (201)
269	Dairy products (202)
278	Canning and preserving fruits, vegetables, and sea foods (203)
279	Grain mill products (204, 0713)
287	Bakery products (205)
288	Confectionery and related products (207)

EXHIBIT 7-2 (Continued)

Industry Code	MANUFACTURING—Continued
289	Beverage industries (208)
297	Miscellaneous food preparation and kindred products (206, 209)
298	Not specified food industries
299	Tobacco manufactures (21)
	Textile mill products
307	Knitting mills (225)
308	Dyeing and finishing textiles, except wool and knit goods (226)
309	Floor coverings, except hard surface (227)
317	Yarn, thread, and fabric mills (221-224, 228)
318	Miscellaneous textile mill products (229)
	Apparel and other fabricated textile products
319 (C)	Apparel and accessories (231-238)
327	Miscellaneous fabricated textile products (239)
	Paper and allied products
328	Pulp, paper, and paperboard mills (261-263, 266)
329	Miscellaneous paper and pulp products (264)
337	Paperboard containers and boxes (265)
	Printing, publishing, and allied industries
338	Newspaper publishing and printing (271)
339	Printing, publishing, and allied industries, except newspapers (272-279)
	Chemicals and allied products
347	Industrial chemicals (281)
348	Plastics, synthetics and resins, except fibers (282, except 2823 and 2824)
349	Synthetic fibers (2823, 2824)
357	Drugs and medicines (283)
358	Soaps and cosmetics (284)
359	Paints, varnishes, and related products (285)
367	Agricultural chemicals (287)
368	Miscellaneous chemicals (286, 289)
369	Not specified chemicals and allied products
	Petroleum and coal products
377	Petroleum refining (291)
378	Miscellaneous petroleum and coal products (295, 299)
	Rubber and miscellaneous plastic products
379	Rubber products (301-303, 306)
387	Miscellaneous plastic products (307)
	Leather and leather products
388	Tanned, curried, and finished leather (311)
389	Footwear, except rubber (313, 314)
397	Leather products, except footwear (312, 315-317, 319)
398	Not specified manufacturing industries

Industry Code	TRANSPORTATION, COMMUNICATIONS, AND OTHER PUBLIC UTILITIES
	TRANSPORTATION, COMMUNICATIONS, AND OTHER PUBLIC UTILITIES
	Transportation
407 (D)	Railroads and railway express service (40)
408	Street railways and bus lines (411, 413-415, 417)
409	Taxicab service (412)
417	Trucking service (421, 423)
418	Warehousing and storage (422)
419	Water transportation (44)
427	Air transportation (45)
428	Pipe lines, except natural gas (46)
429	Services incidental to transportation (47)
	Communications
447	Radio broadcasting and television (483)
448	Telephone (wire and radio) (481)
449	Telegraph and miscellaneous communication services (482, 489)
	Utilities and sanitary services
467	Electric light and power (491)
468	Electric gas utilities (493)
469	Gas and steam supply systems (492, 496)
477	Water supply (494)
478	Sanitary services (495)
479	Other and not specified utilities (497)
	WHOLESALE AND RETAIL TRADE
	Wholesale trade
507	Motor vehicles and equipment (501)
508	Drugs, chemicals, and allied products (502)
509	Dry goods and apparel (503)
527	Food and related products (504)
528	Farm products—raw materials (505)
529	Electrical goods (506)
537	Hardware, plumbing, and heating supplies (507)
538	Not specified electrical and hardware products
539	Machinery equipment and supplies (508)
557	Metals and minerals, n.e.c. (5091)
558	Petroleum products (5092)
559	Scrap and waste materials (5093)
567	Alcoholic beverages (5095)
568	Paper and its products (5096)
569	Lumber and construction materials (5098)
587	Wholesalers, n.e.c. (5094, 5097, 5099)
588	Not specified wholesale trade
	Retail trade
607	Lumber and building material retailing (521-524)
608	Hardware and farm equipment stores (525)
609 (E)	Department and mail order establishments (531, 532)
617	Limited price variety stores (533)
618	Vending machine operators (534)
619	Direct selling establishments (535)
627	Miscellaneous general merchandise stores (539)
628 (F)	Grocery stores (541)
629	Dairy products stores (545)
637	Retail bakeries (546)
638	Food stores, n.e.c. (542-544, 549)
639	Motor vehicle dealers (551, 552)
647	Tire, battery, and accessory dealers (553)
648	Gasoline service stations (554)
649	Miscellaneous vehicle dealers (559)
657	Apparel and accessories stores, except shoe stores (56 except 566)
658	Shoe stores (566)
667	Furniture and home furnishings stores (571)
668	Household appliances, TV, and radio stores (572, 573)
669 (G)	Eating and drinking places (58)
677	Drug stores (591)

Code	WHOLESALE AND RETAIL TRADE- Continued
	Retail trade Continued
678	Liquor stores (592)
679	Farm and garden supply stores (596)
687	Jewelry stores (597)
688	Fuel and ice dealers (598)
689	Retail florists (5992)
697	Miscellaneous retail stores (593-595, 599 exc. 5992)
698	Not specified retail trade
	FINANCE, INSURANCE, AND REAL ESTATE
707	Banking (60)
708	Credit agencies (61)
709	Security, commodity brokerage, and investment companies (62, 67)
717	Insurance (63, 64)
718	Real estate, incl. real estate-insurance-law offices (65, 66)
	BUSINESS AND REPAIR SERVICES
727	Advertising (731)
728	Services to dwellings and other buildings (734)
729	Commercial research, development, and testing labs (7391, 7397)
737	Employment and temporary help agencies (736, 7398)
738	Business management and consulting services (part 7392)
739	Computer programing services (part 7392)
747	Detective and protective services (7393)
748	Business services, n.e.c. (732, 733, 735, 7394, 7395, 7396, 7399)
749	Automobile services, except repair (751, 752, 754)
757	Automobile repair and related services (753)
758	Electrical repair shops (762, 7694)
759	Miscellaneous repair services (763, 764, 769, except 7694)
	PERSONAL SERVICES
769 (H)	Private households (88)
777	Hotels and motels (701)
778	Lodging places, except hotels and motels (702, 703, 704)
779	Laundering, cleaning, and other garment services (721, 727)
787	Beauty shops (723)
788	Barber shops (724)
789	Shoe repair shops (725)
797	Dressmaking shops (part 729)
798	Miscellaneous personal services (722, 726, part 729)
	ENTERTAINMENT AND RECREATION SERVICES
807	Theaters and motion pictures (78, 792)
808	Bowling alleys, billiard and pool parlors (793)
809	Miscellaneous entertainment and recreation services (791, 794)

Code	PROFESSIONAL AND RELATED SERVICES
828	Offices of physicians (801, 803)
829	Offices of dentists (802)
837	Offices of chiropractors (804)
838 (J)	Hospitals (806)
839	Convalescent institutions (8092)
847	Offices of health practitioners, n.e.c. (part 8099)
848	Health services, n.e.c. (807, part 8099)
849	Legal services (81)
857 (K)	Elementary and secondary schools (821)
858	Colleges and universities (822)
859	Libraries (823)
867	Educational services, n.e.c. (824, 829)
868	Not specified educational services
869	Museums, art galleries, and zoos (84)
877	Religious organizations (866)
878	Welfare services (part 867)
879	Residential welfare facilities (part 867)
887	Nonprofit membership organizations (861-865, 869)
888	Engineering and architectural services (891)
889	Accounting, auditing, and bookkeeping services (893)
897	Miscellaneous professional and related services (892, 899)
	PUBLIC ADMINISTRATION
907	Postal service (part 9190)
917 (L)	Federal public administration (part 9190, 9490)
927	State public administration (9290)
937 (M)	Local public administration (9390)
999	**INDUSTRY NOT REPORTED**[1]
	ALLOCATION CATEGORIES[2]
029	Agriculture, forestry, and fisheries—allocated
058	Mining—allocated
078	Construction—allocated
267	Manufacturing, durable goods—allocated
399	Manufacturing, nondurable goods—allocated
499	Transportation, communications, and other public utilities—allocated
599	Wholesale trade—allocated
699	Retail trade—allocated
719	Finance, insurance, and real estate—allocated
767	Business and repair services—allocated
799	Personal services—allocated
817	Entertainment and recreation services—allocated
899	Professional and related services—allocated
947	Public administration—allocated

[1]This code is used to identify not reported industries in surveys where the not reported cases are not allocated.

[2]Those returns from the Population Census which do not have an industry entry are allocated among the major industry groups during computer processing. These cases are labeled with the code for the "allocation" category to which they are assigned. (See text, page VI).

EXHIBIT 7-3

OCCUPATIONAL CLASSIFICATION SYSTEM

Equivalent alphabetic codes follow some codes. Either code may be utilized, depending on the processing method. "N.e.c." means "not elsewhere classified."

Occupation Code	PROFESSIONAL, TECHNICAL, AND KINDRED WORKERS
001	Accountants
002	Architects
	Computer specialists
003	Computer programmers
004	Computer systems analysts
005	Computer specialists, n.e.c.
	Engineers
006	Aeronautical and astronautical engineers
010	Chemical engineers
011	Civil engineers
012	Electrical and electronic engineers
013	Industrial engineers
014	Mechanical engineers
015	Metallurgical and materials engineers
020	Mining engineers
021	Petroleum engineers
022	Sales engineers
023	Engineers, n.e.c.
024	Farm management advisors
025	Foresters and conservationists
026	Home management advisors
	Lawyers and judges
030	Judges
031	Lawyers
	Librarians, archivists, and curators
032	Librarians
033	Archivists and curators
	Mathematical specialists
034	Actuaries
035	Mathematicians
036	Statisticians
	Life and physical scientists
042	Agricultural scientists
043	Atmospheric and space scientists
044	Biological scientists
045	Chemists
051	Geologists
052	Marine scientists
053	Physicists and astronomers
054	Life and physical scientists, n.e.c.
055	Operations and systems researchers and analysts
056	Personnel and labor relations workers
	Physicians, dentists, and related practitioners
061	Chiropractors
062	Dentists
063	Optometrists
064	Pharmacists
065	Physicians, medical and osteopathic
071	Podiatrists
072	Veterinarians
073	Health practitioners, n.e.c.

Occupation Code	PROFESSIONAL, TECHNICAL, AND KINDRED WORKERS—Continued
	Nurses, dietitians, and therapists
074	Dietitians
075	Registered nurses
076	Therapists
	Health technologists and technicians
080	Clinical laboratory technologists and technicians
081	Dental hygienists
082	Health record technologists and technicians
083	Radiologic technologists and technicians
084	Therapy assistants
085	Health technologists and technicians, n.e.c.
	Religious workers
086	Clergymen
090	Religious workers, n.e.c.
	Social scientists
091	Economists
092	Political scientists
093	Psychologists
094	Sociologists
095	Urban and regional planners
096	Social scientists, n.e.c.
	Social and recreation workers
100	Social workers
101	Recreation workers
	Teachers, college and university
102	Agriculture teachers
103	Atmospheric, earth, marine, and space teachers
104	Biology teachers
105	Chemistry teachers
110	Physics teachers
111	Engineering teachers
112	Mathematics teachers
113	Health specialties teachers
114	Psychology teachers
115	Business and commerce teachers
116	Economics teachers
120	History teachers
121	Sociology teachers
122	Social science teachers, n.e.c.
123	Art, drama, and music teachers
124	Coaches and physical education teachers
125	Education teachers
126	English teachers
130	Foreign language teachers
131	Home economics teachers
132	Law teachers
133	Theology teachers
134	Trade, industrial, and technical teachers
135	Miscellaneous teachers, college and university
140	Teachers, college and university, subject not specified

X

Code	WORKERS- Continued
	Teachers, except college and university
141	Adult education teachers
142 (N)	Elementary school teachers
143	Prekindergarten and kindergarten teachers
144	Secondary school teachers
145	Teachers, except college and university, n.e.c.
	Engineering and science technicians
150	Agriculture and biological technicians, except health
151	Chemical technicians
152	Draftsmen
153	Electrical and electronic engineering technicians
154	Industrial engineering technicians
155	Mechanical engineering technicians
156	Mathematical technicians
161	Surveyors
162	Engineering and science technicians, n.e.c.
	Technicians, except health, and engineering and science
163	Airplane pilots
164	Air traffic controllers
165	Embalmers
170	Flight engineers
171	Radio operators
172	Tool programmers, numerical control
173	Technicians, n.e.c.
174	Vocational and educational counselors
	Writers, artists, and entertainers
175	Actors
180	Athletes and kindred workers
181	Authors
182	Dancers
183	Designers
184	Editors and reporters
185	Musicians and composers
190	Painters and sculptors
191	Photographers
192	Public relations men and publicity writers
193	Radio and television announcers
194	Writers, artists, and entertainers, n.e.c.
195	Research workers, not specified

MANAGERS AND ADMINISTRATORS, EXCEPT FARM

201	Assessors, controllers, and treasurers; local public administration
202	Bank officers and financial managers
203	Buyers and shippers, farm products
205	Buyers, wholesale and retail trade
210	Credit men
211	Funeral directors
212	Health administrators
213	Construction inspectors, public administration
215	Inspectors, except construction, public administration
216	Managers and superintendents, building
220	Office managers, n.e.c.
221	Officers, pilots, and pursers; ship
222	Officials and administrators; public administration, n.e.c.
223	Officials of lodges, societies, and unions
224	Postmasters and mail superintendents
225	Purchasing agents and buyers, n.e.c.
226	Railroad conductors

Code	FARM - Continued
230	Restaurant, cafeteria, and bar managers
231	Sales managers and department heads, retail trade
233	Sales managers, except retail trade
235	School administrators, college
240	School administrators, elementary and secondary
245	Managers and administrators, n.e.c.

SALES WORKERS

260	Advertising agents and salesmen
261	Auctioneers
262	Demonstrators
264	Hucksters and peddlers
265	Insurance agents, brokers, and underwriters
266	Newsboys
270	Real estate agents and brokers
271	Stock and bond salesmen
280	Salesmen and sales clerks, n.e.c.[1]

CLERICAL AND KINDRED WORKERS

301	Bank tellers
303	Billing clerks
305 (P)	Bookkeepers
310	Cashiers
311	Clerical assistants, social welfare
312	Clerical supervisors, n.e.c.
313	Collectors, bill and account
314	Counter clerks, except food
315	Dispatchers and starters, vehicle
320	Enumerators and interviewers
321	Estimators and investigators, n.e.c.
323	Expediters and production controllers
325	File clerks
326	Insurance adjusters, examiners, and investigators
330	Library attendants and assistants
331	Mail carriers, post office
332	Mail handlers, except post office
333	Messengers and office boys
334	Meter readers, utilities
	Office machine operators
341	Bookkeeping and billing machine operators
342	Calculating machine operators
343	Computer and peripheral equipment operators
344	Duplicating machine operators

[1] Category "280 Salesmen and sales clerks, n.e.c." was subdivided in the Census into 5 occupation groups dependent on industry. The industry codes are shown in parentheses.

Occ. Code	
281	Sales representatives, manufacturing industries (Ind. 107-399)
282	Sales representatives, wholesale trade (Ind. 017-058, 507-599)
283	Sales clerks, retail trade (Ind. 608-699 except 618, 639, 649, 667, 668, 688)
284	Salesmen, retail trade (Ind. 607, 618, 639, 649, 667, 668, 688)
285	Salesmen of services and construction (Ind. 067-078, 407-499, 707-947)

EXHIBIT 7-3 (Continued)

Occupation Code	CLERICAL AND KINDRED WORKERS--Continued
	Office machine operators--Continued
345	Key punch operators
350	Tabulating machine operators
355	Office machine operators, n.e.c.
360	Payroll and timekeeping clerks
361	Postal clerks
362	Proofreaders
363	Real estate appraisers
364	Receptionists
	Secretaries
370	Secretaries, legal
371	Secretaries, medical
372 (Q)	Secretaries, n.e.c.
374	Shipping and receiving clerks
375	Statistical clerks
376	Stenographers
381	Stock clerks and storekeepers
382	Teacher aides, exc. school monitors
383	Telegraph messengers
384	Telegraph operators
385	Telephone operators
390	Ticket, station, and express agents
391	Typists
392	Weighers
394	Miscellaneous clerical workers
395	Not specified clerical workers

CRAFTSMEN AND KINDRED WORKERS

401	Automobile accessories installers
402	Bakers
403	Blacksmiths
404	Boilermakers
405	Bookbinders
410	Brickmasons and stonemasons
411	Brickmasons and stonemasons, apprentices
412	Bulldozer operators
413	Cabinetmakers
415 (R)	Carpenters
416	Carpenter apprentices
420	Carpet installers
421	Cement and concrete finishers
422	Compositors and typesetters
423	Printing trades apprentices, exc. pressmen
424	Cranemen, derrickmen, and hoistmen
425	Decorators and window dressers
426	Dental laboratory technicians
430	Electricians
431	Electrician apprentices
433	Electric power linemen and cablemen
434	Electrotypers and stereotypers
435	Engravers, exc. photoengravers
436	Excavating, grading, and road machine operators; exc. bulldozer
440	Floor layers, exc. tile setters
441	Foremen, n.e.c.
442	Forgemen and hammermen
443	Furniture and wood finishers
444	Furriers
445	Glaziers
446	Heat treaters, annealers, and temperers
450	Inspectors, scalers, and graders; log and lumber
452	Inspectors, n.e.c.

Occupation Code	CRAFTSMEN AND KINDRED WORKERS--Continued
453	Jewelers and watchmakers
454	Job and die setters, metal
455	Locomotive engineers
456	Locomotive firemen
461	Machinists
462	Machinist apprentices
	Mechanics and repairmen
470	Air conditioning, heating, and refrigeration
471	Aircraft
472	Automobile body repairmen
473 (S)	Automobile mechanics
474	Automobile mechanic apprentices
475	Data processing machine repairmen
480	Farm implement
481	Heavy equipment mechanics, incl. diesel
482	Household appliance and accessory installers mechanics
483	Loom fixers
484	Office machine
485	Radio and television
486	Railroad and car shop
491	Mechanic, exc. auto, apprentices
492	Miscellaneous mechanics and repairmen
495	Not specified mechanics and repairmen
501	Millers; grain, flour, and feed
502	Millwrights
503	Molders, metal
504	Molder apprentices
505	Motion picture projectionists
506	Opticians, and lens grinders and polishers
510	Painters, construction and maintenance
511	Painter apprentices
512	Paperhangers
514	Pattern and model makers, exc. paper
515	Photoengravers and lithographers
516	Piano and organ tuners and repairmen
520	Plasterers
521	Plasterer apprentices
522	Plumbers and pipe fitters
523	Plumber and pipe fitter apprentices
525	Power station operators
530	Pressmen and plate printers, printing
531	Pressman apprentices
533	Rollers and finishers, metal
534	Roofers and slaters
535	Sheetmetal workers and tinsmiths
536	Sheetmetal apprentices
540	Shipfitters
542	Shoe repairmen
543	Sign painters and letterers
545	Stationary engineers
546	Stone cutters and stone carvers
550	Structural metal craftsmen
551	Tailors
552	Telephone installers and repairmen
554	Telephone linemen and splicers
560	Tile setters
561	Tool and die makers
562	Tool and die maker apprentices
563	Upholsterers
571	Specified craft apprentices, n.e.c.
572	Not specified apprentices

EXHIBIT 7-3 (Continued)

Code — Continued

575 Craftsmen and kindred workers, n.e.c.
580 Former members of the Armed Forces

OPERATIVES, EXCEPT TRANSPORT

601 Asbestos and insulation workers
602 (T) Assemblers
603 Blasters and powdermen
604 Bottling and canning operatives
605 Chainmen, rodmen, and axmen; surveying
610 Checkers, examiners, and inspectors; manufacturing
611 Clothing ironers and pressers
612 Cutting operatives, n.e.c.
613 Dressmakers and seamstresses, except factory
614 Drillers, earth
615 Dry wall installers and lathers
620 Dyers
621 Filers, polishers, sanders, and buffers
622 Furnacemen, smeltermen, and pourers
623 Garage workers and gas station attendants
624 Graders and sorters, manufacturing
625 Produce graders and packers, except factory and farm
626 Heaters, metal
630 Laundry and dry cleaning operatives, n.e.c.
631 Meat cutters and butchers, exc. manufacturing
633 Meat cutters and butchers, manufacturing
634 Meat wrappers, retail trade
635 Metal platers
636 Milliners
640 Mine operatives, n.e.c.
641 Mixing operatives
642 Oilers and greasers, exc. auto
643 Packers and wrappers, except meat and produce
644 Painters, manufactured articles
645 Photographic process workers
Precision machine operatives
650 Drill press operatives
651 Grinding machine operatives
652 Lathe and milling machine operatives
653 Precision machine operatives, n.e.c.
656 Punch and stamping press operatives
660 Riveters and fasteners
661 Sailors and deckhands
662 Sawyers
663 Sewers and stitchers
664 Shoemaking machine operatives
665 Solderers
666 Stationary firemen
Textile operatives
670 Carding, lapping, and combing operatives
671 Knitters, loopers, and toppers
672 Spinners, twisters, and winders
673 Weavers
674 Textile operatives, n.e.c.
680 Welders and flame cutters
681 Winding operatives, n.e.c.
690 Machine operatives, miscellaneous specified
692 Machine operatives, not specified
694 Miscellaneous operatives
695 Not specified operatives

Code

701 Boatmen and canalmen
703 Bus drivers
704 Conductors and motormen, urban rail transit
705 Deliverymen and routemen
706 Fork lift and tow motor operatives
710 Motormen; mine, factory, logging camp, etc.
711 Parking attendants
712 Railroad brakemen
713 Railroad switchmen
714 Taxicab drivers and chauffeurs
715 (U) Truck drivers

LABORERS, EXCEPT FARM

740 Animal caretakers, exc. farm
750 Carpenters' helpers
751 (V) Construction laborers, exc. carpenters' helpers
752 Fishermen and oystermen
753 Freight and material handlers
754 Garbage collectors
755 Gardeners and groundskeepers, exc. farm
760 Longshoremen and stevedores
761 Lumbermen, raftsmen, and woodchoppers
762 Stock handlers
763 Teamsters
764 Vehicle washers and equipment cleaners
770 Warehousemen, n.e.c.
780 Miscellaneous laborers
785 Not specified laborers

FARMERS AND FARM MANAGERS

801 (W) Farmers (owners and tenants)
802 Farm managers

FARM LABORERS AND FARM FOREMEN

821 Farm foremen
822 Farm laborers, wage workers
823 Farm laborers, unpaid family workers
824 Farm service laborers, self-employed

SERVICE WORKERS, EXC. PRIVATE HOUSEHOLD

Cleaning service workers
901 Chambermaids and maids, except private household
902 Cleaners and charwomen
903 (X) Janitors and sextons

Food service workers
910 Bartenders
911 Busboys
912 Cooks, except private household
913 Dishwashers
914 Food counter and fountain workers
915 (Y) Waiters
916 Food service workers, n.e.c., except private household

EXHIBIT 7-3 (Continued)

Occupation Code	SERVICE WORKERS, EXC. PRIVATE HOUSEHOLD—Continued
	Health service workers
921	Dental assistants
922	Health aides, exc. nursing
923	Health trainees
924	Lay midwives
925	Nursing aides, orderlies, and attendants
926	Practical nurses
	Personal service workers
931	Airline stewardesses
932	Attendants, recreation and amusement
933	Attendants, personal service, n.e.c.
934	Baggage porters and bellhops
935	Barbers
940	Boarding and lodging house keepers
941	Bootblacks
942	Child care workers, exc. private household
943	Elevator operators
944	Hairdressers and cosmetologists
945	Personal service apprentices
950	Housekeepers, exc. private household
952	School monitors
953	Ushers, recreation and amusement
954	Welfare service aides
	Protective service workers
960	Crossing guards and bridge tenders
961	Firemen, fire protection
962	Guards and watchmen
963	Marshals and constables
964	Policemen and detectives
965	Sheriffs and bailiffs

Occupation Code	PRIVATE HOUSEHOLD WORKERS
980	Child care workers, private household
981	Cooks, private household
982	Housekeepers, private household
983	Laundresses, private household
984 (Z)	Maids and servants, private household
995	OCCUPATION NOT REPORTED[2]
	ALLOCATION CATEGORIES[3]
196	Professional, technical, and kindred workers—allocated
246	Managers and administrators, except farm—allocated
296	Sales workers—allocated
396	Clerical and kindred workers—allocated
586	Craftsmen and kindred workers—allocated
696	Operatives, except transport—allocated
726	Transport equipment operatives—allocated
796	Laborers, except farm—allocated
806	Farmers and farm managers—allocated
846	Farm laborers and farm foremen—allocated
976	Service workers, exc. private household—allocated
986	Private household workers—allocated

[2]This code is used to identify not reported occupations in surveys where the not reported cases are not allocated.

[3]Those returns from the Population Census which do not have an occupation entry are allocated among the major occupation groups during computer processing. These cases are labeled with the code for the "allocation" category to which they are assigned. (See text, page VI).