CHAPTER 2

RECRUITMENT OF PARTICIPANTS, INFORMED CONSENT, SAMPLE LETTERS AND BROCHURES

2.1 Goals

Each local Clinical Center is required to recruit and randomize 20 participants for the feasibility study and 80 participants for the full-scale study. Both girls and boys should be equally represented at each center and, as far as possible, a number of non-white children should be recruited.

2.2 Overview of All Centers

The potential respondent universe for the DISC is non-institutionalized males between the ages of 8 years, 10 months and 10 years, 10 months, or a female between the ages of 7 years, 10 months and 9 years, 10 months, as of the day of Screening Visit 1 (SV1) with a window of two weeks on either side of the day of SV1 for satisfying the age eligibility criteria, in six Clinical Centers in Newark, NJ, Baltimore, MD, New Orleans, LA, Chicago, IL, Iowa City, IA, and Portland, OR. These Clinical Centers will identify eligible children by means of a prescreening assessment and two screening visits. Four of the Centers (Newark, Baltimore, New Orleans and Iowa City) will perform the prescreening primarily in elementary schools. One of the Centers (Chicago) will perform the prescreening in the offices of pediatricians in a large pediatric research group. The sixth Center (Portland) will be screening children identified through parents with elevated total cholesterol in the Portland area.

Specific recruitment strategies employed by the six Clinical Centers for recruiting schools and proposed approaches for recruiting children are discussed in the following sections.

2.3 Specific Strategies for Clinical Centers

2.3.1 Johns Hopkins University

The following recruitment strategy will be employed by the Johns Hopkins DISC Clinical Center. There are 92 elementary schools in the Baltimore County school districts, with a total enrollment of approximately 16,359 pupils (8,438 boys, 7,921 girls) in the third, fourth, and fifth grades. Using a computer printout from the schools, the pages were numbered sequentially and each school assigned a number. Using a random number table, ten schools were chosen for the purposes of cholesterol screening for the feasibility study. Additional schools will be randomly chosen as needed for the purposes of the full-scale study.

Based on data from September 1986, an estimate of breakdown of the schools for September 1987 is 73.7% white and 26.3% black. Two of the schools have greater than 50% black enrollment. We estimate that there are 1,133 eligible children for the purpose of cholesterol screening for the feasibility study.

2.3.2 Northwestern University

Children potentially eligible for DISC will be identified via pre-screening in offices of pediatricians in the Pediatric Practice Research Group (PPRG).

In two practices, desktop fingerstick screening for nonfasting total cholesterol will be done on children in the eligible age range who present for routine care (school physical or minor complaint) during the period June 18-October 15, 1987. One practice will use a Seralyzer machine, the other a Clay-Adams machine. After obtaining parental consent, fingerstick blood will be drawn and spun; serum will be frozen for weekly total cholesterol (TC) determinations. The results of these, along with a log of all patients seen, will be provided to the PPRG office on a weekly basis. TC results will

be mailed to the parents in accordance with DISC procedures. Children with prescreen TCs at the 75th percentile or more of the reference distribution will be recalled in September and October for lipid screening in the DISC laboratory.

In other practices, some potentially eligible children identified by other types of lipid determination will be referred to the PPRG for DISC screening. This is likely to occur in one of two ways: two PPRG pediatricians routinely obtain fasting TC, HDL/Cholesterol, and triglyceride measures on their patients; others receive the results of blood tests done for other reasons (e.g., postoperative). For nonfasting values, the same cutoff for DISC screening will be used as for the practices prescreening for DISC as described above. For fasting values, the threshold for DISC screening will be the 80th percentile.

2.3.3 University of Iowa

Children who are potentially eligible for DISC feasibility trial will be identified via pre-screening in the schools of Clinton and Muscatine, Iowa. These school districts are predominantly white. Recruitment will begin by sending home a letter and brochure from each classroom along with a consent form for pre-screening. The consent forms are to be returned to each classroom teacher. These permission slips will be gathered, and those students not returning consent forms will have a mailing sent to their homes of the identical material previously taken home by the children with a return self-stamped, self-addressed envelope to our study center. On the day prior to screening, a reminder will be sent to each classroom teacher involved identifying the children to be examined.

In Muscatine, Iowa the pre-screening has been completed as part of the ongoing Muscatine Study. Venous bloods have been drawn from the children

and the analyses carried out in the Lipid Research Center laboratory for total cholesterol and triglycerides. Heights and weights of these children have also been obtained. In Clinton, beginning in the fall of 1987, the children will be sampled utilizing the Kodak DT-60 Analyzer for total cholesterol.

By these techniques the Center anticipates contacting approximately 1,000 students, with approximately a 70% participation rate for the pre-screening. It appears that eight to ten schools will need to be contacted to supply the required number of students to appropriate age.

2.3.4 Louisiana State University

The DISC recruitment strategy incorporates the procedures used in other school-based screenings conducted over the past 15 years, particularly the Bogalusa Heart Study.

A total of 76 schools are available in the Archdiocese of New Orleans. Schools are contacted initially by a letter, after receiving approval from Howard Jenkins, superintendent of schools. Seventeen schools on the west bank of the Mississippi River were eliminated due to their lack of proximity to the clinical site. Of the remaining 59 schools, 33 have been classified as predominantly white student body and 26 predominantly black. Of these schools, 41 are located in Orleans parish (county) and 18 in Jefferson parish. Five predominantly white schools are contacted for each predominantly black school to assure the appropriate racial balance, i.e., 10-15% black. One week later, a telephone contact is made to set-up a session with the principal to explain the rationale and scope of the study and recruit the school to participate. After permission is granted, the school is requested to furnish the center with census information on 3rd, 4th and 5th grades

and the school calendar for 1987-1988. For the feasibility study, this phase began in April 1987.

Early in the fall, the schools will be recontacted. A parent meeting will be scheduled in conjunction with the fall meeting of the parent-teacher organization to explain the program and answer any questions or concerns. A similar meeting will be held with each school faculty to enlist their support. Similarly, a presentation is planned at a system-wide meeting of principals. Approximately three to four weeks prior to screening, an initial consent letter will be distributed via the classroom teacher. The next week a follow-up letter will be sent to parents of children who did not return consent. The day prior to screening, a reminder will be sent to the classroom teachers involved, identifying the children to be examined. The center anticipates contacting 1,000 students with approximately 65-90% consenting to screening. It appears that 8-10 schools will be needed to supply the required number of appropriate aged students.

2.3.5 New Jersey Medical School

The DISC center at the New Jersey Medical School in Newark will center its recruitment plans around screening at school sites. While a total population of over 30,000 children in the 8-10 age group were identified in the original grant application, it is planned to concentrate recruitment for the feasibility study in two school systems, union township and Montclair, with over 2,000 children in the DISC age range. After return of consent forms by parents, screening through fingerstick samples will take place at the schools, with cholesterol determinations on the Eastman Kodak DT60, if possible, at the screening site. In addition, letters will be sent to pediatricians participating in health maintenance organizations soliciting referrals for

screening in the clinic, and volunteers for such screening will be sought through press releases and other media coverage. Participants in other studies, such as the Trials of Hypertension Prevention, will be informed of the availability of free screening, as will private patients in the preventive cardiology program and those contacted during recruitment for the Trials of Hypertension Prevention. These same strategies will be extended and utilized for the full-scale trial.

2.3.6 Kaiser Permanente Center for Health Research

(To be written)

2.4 Informed Consent

Obtaining informed consent is an important part of the screening and recruitment procedure. The process will begin with parental permissions for the children to participate in the prescreening assessment. Immediately after the prescreening assessment, an introductory letter and information sheet will be sent to the parents of prospective participants, which will include those children identified in the prescreening process as having elevated total cholesterol. A second consent form will be sent to the child's parents/guardians prior to Screening Visit 1 (SV1) for permission to carry out SV1, Screening Visit 2, and Baseline Visit (BV) measurements and interviews on the child. A third consent form will be presented by an interviewer during the BV and will be signed by both the child and his/her parents/guardians. This form contains an explanation of the randomized trial, information about the intervention and its possible risks, the intervention and examination schedule, steps taken to insure confidentiality and safety, information about later withdrawal from participation, and an offer to answer any questions about study procedures.

Any modifications required by Institutional Review Boards of the local Clinical Centers may be made by the Principal Investigator of the clinic involved as long as the guidelines established by the Steering Committee are maintained. All final consent forms are reviewed by the Steering Committee.

Copies of consent forms used by the DISC Clinical Centers are given in Exhibits 2-1 (prescreen consent), 2-2 (screening visit consent), and 2-3 (randomized trial consent).

2.5 Informational Letters and Brochures

Sample copies of informational letters and brochures for potential DISC participants, their families, and their personal physicians are given in Exhibits 2-4 through 2-10.

(Exhibits 2-1 to 2-10 are in preparation.)