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6. ENROLLMENT OF PARTICIPANTS

6.1 Recruitment: Goals and Strategy

The target cohort for DPP is approximately 50% minorities (African Americans, Hispanic Americans, Native Americans, and Asian and Pacific Island Americans) and at least 50% women. In addition, approximately 20% of the target cohort is older Americans, of age 65 years and older.

The Recruitment Coordinator, with approval of the Program Coordinator and the Principal Investigator, will develop a clinic specific recruitment strategy. All centers will be represented at an initial 4-5 day series of training sessions before recruitment is initiated. Additional training sessions will be held during the three years of participant recruitment. In addition to education about sophisticated technical and interpersonal skills necessary for recruitment, the goal of these sessions is for the Recruitment Coordinators to form a dynamic system of support for problem solving and development of DPP-specific recruitment techniques.

6.1.1 Publicity and Participant Contacts

Centrally prepared publicity and recruitment procedures and tools that address the target cohort in a culturally sensitive manner include print and radio public service announcements, participant contact brochures, flyers, fact sheets, and posters. Publicity and recruitment efforts are primarily the responsibility of the local Recruitment Coordinators. Where appropriate, clinics are urged to form Advisory Boards and hold community meetings to support and assist in formulating the message and methods for publicity and participant recruitment. A variety of methods will be used to contact community members including, for example, work-site mailings and publicity, hospital record reviews, mass mailings, and PSAs.

A national press conference and kickoff for recruitment will support the credibility of local initiatives. Statements of support will be sought from national interest groups such as the ADA and organizations that represent minority interests. These will provide a framework for clinic recruitment staff to contact the local affiliates of these organizations for similar endorsements.

6.2 Informed Consent and Staged Screening

6.2.1 Informed Consent Policy

The DPP informed consent process is staged, in order to maximize potential volunteer's understanding of information required for an informed decision regarding participation, including their personal risks and benefits, and to promote efficiency.

This process is designed to meet the ethical obligations to the participant and improve retention by fostering a progressively increasing understanding of the DPP by the participant as well as the development of a positive relationship between the volunteer and clinic staff. It is an interactive and conversational process, the ultimate goal being maximum understanding of DPP and its impact upon the volunteer's life. This understanding includes what the responsibility of the participant is to the DPP and the responsibility of the investigators to the participant. It is anticipated that one result of this process is maximized retention of participants in DPP. This informed consent process is integrated with the screening and enrollment process.

Each stage in the Informed Consent process includes both verbal and written descriptions of relevant information, and discussion including opportunities for questions to be addressed. Each stage allows the participant to make a decision whether to proceed to the next screening step. Early steps include a description of the Informed Consent and Screening Process and the ultimate goal of the process. The participant views a video presentation during which DPP investigators are present to answer any questions. After the presentation and discussion of this information the participant is asked to sign the consent form relevant to that stage. Prior to presentation of the final two consent forms, a "volunteer understanding questionnaire" is answered by the participant in order to assure that the participant understands DPP.

6.2.2 Staged Screening Policy

The staged screening process is intended to accomplish the following:

- Identify potentially eligible volunteers for the DPP;

- Verify eligibility of potential participants;
- Accomplish the objectives of the informed consent process;
- Refer persons diagnosed with NIDDM during screening to clinical care;
- Complete baseline procedures;
- Randomize volunteers into the DPP.

Overview

The staged screening process is a series of five steps that will identify high risk volunteers with impaired glucose tolerance (IGT) who are potentially eligible for the DPP. Each sequential step will identify a subset of high-risk individuals who meet increasingly restrictive eligibility criteria. During the final steps, participants will be tested for remaining eligibility criteria, complete a run-in period to explore their ability to participate, and sign a final informed consent for randomization. The intent is to allow participating centers some flexibility in approach while maintaining a standard set of baseline procedure entry criteria. This flexibility includes the possibility to combine certain steps, as noted below. Those that cannot be combined are: Steps 2 and 3 because of the delay until the central laboratory OGTT values are available, and Steps 3 and 4 because of the mandatory 3-week Run-in interval. Complete definitions and procedures can be found in the Manual of Operations.

6.2.3 Screening and Informed Consent Procedures

A recruitment strategy based upon local needs and resources is established by each clinical center. Section 6.1 describes goals, strategy, and publicity that usually provides the first information about the study to potential participants.

Initial Contact (Step 1)

Interested persons contact the clinical center by phone or in person, and are given basic information about the study. If they appear eligible based on a brief medical history, they are invited to have a screening glucose level drawn after informed consent is obtained.

Clinical centers have the option of conducting the screening glucose step in several ways: a capillary test without regard to meals (random glucose), a fasting capillary or plasma test, or both in sequence, depending on logistics at the center. The results of tests are evaluated using appropriate criteria to determine if they are in the target range. Persons with results in the target range are given more information about the DPP and those who give informed consent will continue through the screening process and are scheduled for an oral glucose tolerance test (OGTT).

Oral Glucose Tolerance Test - OGTT (Step 2)

Fasting laboratory tests and a two-hour 75 gram OGTT is performed to diagnose IGT utilizing the criteria developed by the American Diabetes Association (ADA Study Group, 1997). This criteria has been modified to include a fasting plasma glucose between 95-125 mg/dL in addition to a two hour value of 140-199 mg/dL in order to identify participants who are at higher risk for progression to NIDDM. A video presentation provides additional information about the study.

OGTT samples are centrally analyzed by the DPP Central Biochemistry Laboratory (CBL) for eligibility criteria. Fasting glucose readings will be analyzed locally and compared to appropriate criteria to determine if the glucose tolerance test should be continued. Centers have the option of stopping the OGTT when the fasting sample does not meet the criteria, or completing the test to screen for non-eligible disorders of glucose tolerance (i.e., diabetes, non-eligible IGT). Participants are informed of their results within ranges: normal (not eligible), elevated (not eligible and either: IGT but fasting level below criteria; or requiring further workup for possible diabetes), and eligible. Specific glucose values are furnished only to those who are ineligible in order to maintain the masking of outcomes. Persons with IGT who do not meet DPP criteria will be notified and are eligible for rescreening in 6 months.

Those who meet OGTT eligibility criteria are invited to continue the screening process. The participant's family is encouraged to participate in the decision by attending (at least) the next step. Additional screening and baseline bloods may be drawn at this visit, or may be drawn at the next visit, at clinic discretion.

Initiate Run-in (Step 3 - Start)

Prior to the run-in, the participant receives additional information about DPP, including further reviews of the research interventions, randomization, masking, test procedures, risks and benefits, and informed consent is obtained. The 3 week run-in period is designed to allow participants to make an informed decision about participation in the study, based on completing tasks similar to those required of participants (taking placebo pills on the correct schedule, completing diet and activity diaries and keeping appointments). It will also allow staff to determine a participant's suitability for the DPP. During this time, additional information about the DPP is provided and a volunteer understanding questionnaire is administered to confirm understanding. Additional eligibility screening and baseline tests, including a history and physical examination, are completed during this time.

Run-in Follow-up (Step 3 - End)

At this visit performance of the run-in period is evaluated. Eligibility requires satisfactory completion of the placebo pill taking, and other assigned tasks. If participants do not successfully complete the run-in, but the investigator and staff at the center feel that a second run-in period would prove useful, the run-in may be repeated.

Following successful completion of the run-in phase, all eligibility criteria are reviewed and baseline procedures are completed. Participants will be scheduled for carotid ultrasound evaluation before or at the randomization visit (Step 4, prior to actual randomization).

Randomization Visit (Step 4)

Final informed consent will be reviewed in detail. If the participant is eligible and signs the informed consent, baseline laboratory samples are collected and the participant is randomly assigned to a treatment group at this visit and begins meetings with appropriate DPP staff.