



**Diabetes Interventions
Reaching Educating
Communities Together**

Management Plan

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1. OVERVIEW

Mission

The mission of this multi-year project is to improve the health-related quality of life of an African-American community by reducing the burden of diabetes and its complications through a comprehensive community-based intervention program (Centers for Disease Control and Prevention [CDC], 1994b). Project DIRECT is also intended to develop, carry out and evaluate strategies that will be incorporated into state-based diabetes control programs nationwide (CDC, 1994a). The target population is the African-American community in Southeast Raleigh, NC (CDC, 1995).

Aims

The Centers for Disease Control and Prevention Goals outlined overall goals or aims for Project DIRECT (CDC, 1994a). They are described below for the three major areas of intervention: Diabetes Care, Health Promotion, and Outreach. These three components of the Project are discussed in more detail later. The aims were further developed by the entities of the Project. The long-term Project goals can be found in Appendix A. From that list, goals are selected for each year and specific objectives are developed.

Diabetes Care. The goals are to increase access to care, improve the quality of care provided to people with diabetes and to improve self-care practices related to diabetes management. This involves modifying office practices and systems so they are more effective in meeting the health care needs of people with diabetes. This process must be sensitive to the existing health care delivery system and to the demands on providers and office staff.

Health Promotion. The goal is to reduce risk factors related to diabetes, especially by increasing physical activity and decreasing fat intake. This involves promoting lifestyle, environmental, and policy changes.

Outreach. The goal is to increase the awareness of the burden of and risk for diabetes among the general public and community policy makers in the targeted community.

Significance

Project DIRECT is intended to provide critical information to benefit diabetes prevention, treatment, and control programs across the country (CDC, 1994b). This project is the first study with a comprehensive approach to improve the health-related quality of life of a community by reducing the burden of diabetes and its complications. The major aspects of DIRECT were developed from the experience of other community-based trials, especially the cardiovascular disease studies.

“Community” is defined in both structural and functional terms. Structurally, a community is an area with geographic and often political boundaries that demarcate the area as a county, parish, metropolitan area, city, township, neighborhood, or block. Functionally, a community is a place where community members share a sense of identity and belonging, values and norms, communication, and helping patterns (CDC, 1994b). For Project DIRECT, the target community is Southeast Raleigh, NC. Interventions and evaluations focus on the people living in Southeast Raleigh and the places where they get services.

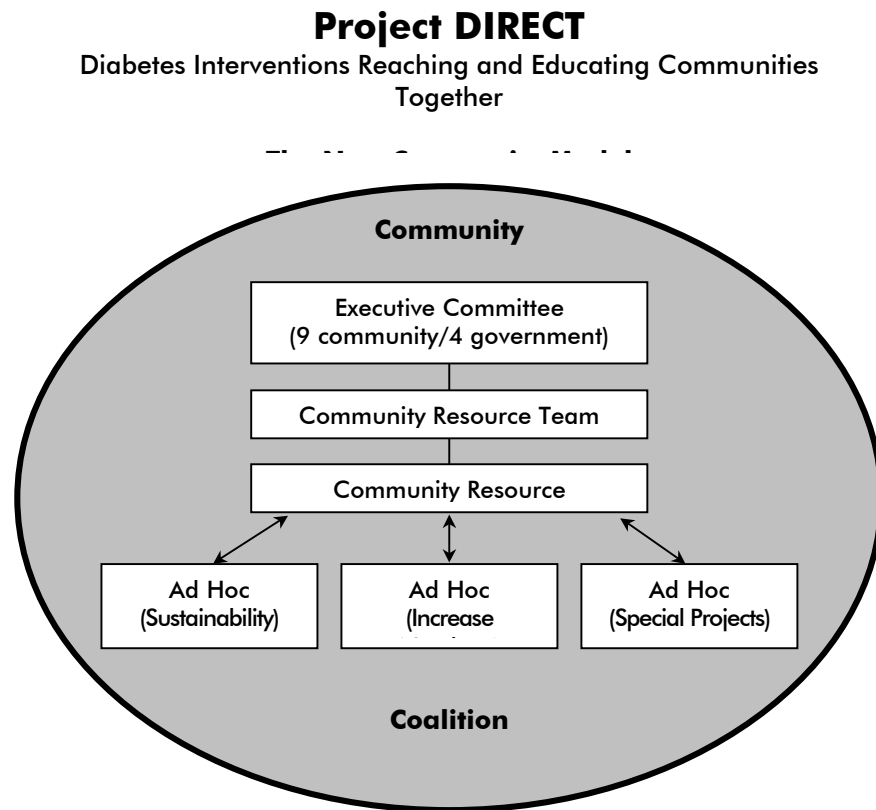
An important distinction between Project DIRECT and previous cardiovascular disease studies is that DIRECT includes all three levels of prevention: primary, secondary, and tertiary. Previous community-based approaches have frequently omitted or minimized interventions aimed at tertiary prevention. Project DIRECT involves three complementary parts: diabetes care, health promotion, and educational outreach.

Project DIRECT has a high level of community participation. Figure 1 illustrates the interrelationships of the Coalition and the work areas. The project reflects the importance of community participation in planning operations. Community residents have first-hand knowledge about the problems they experience, as well as expertise in designing solutions for those problems. There are a number of groups and individuals involved in Project DIRECT. Their roles and responsibilities are outlined in Appendix B.

Project DIRECT should demonstrate and document the effectiveness of a model diabetes program for state and local health departments (CDC, 1994a). It is an opportunity to:

- provide guidance on interventions that have been tested and validated at the community level;
- establish a model for diabetes prevention with emphasis on community and systems approaches;
- respond better to diabetes in African-American communities with culturally appropriate interventions; coordinate existing community resources in the delivery and evaluation of interventions.

Figure 1. This model was presented to and approved by the Administrative/Scientific Team, Project DIRECT Coalition and the Executive Committee during YR06.



2. ORGANIZATION

Coalition

Coalitions are generally composed of individuals representing organizations and the community groups (McLeroy et al, 1994). The members work on behalf of their organizations as well as the coalition itself. They are issue oriented and focused on specific goals. Formal working relationships are developed, but coalitions are also rather fluid, allowing movement into and out of the coalition over time (Appendix H).

The Project DIRECT Coalition supports the Project in its mission of reducing the burden of diabetes within the African-American community of Raleigh, and especially of Southeast Raleigh. The DIRECT Coalition involves key individuals and organizations in facilitating the work of the Project. The Coalition includes representation from community leaders, business and industry, media, public health agencies, professional organizations, health care providers, religious leaders, fraternities and sororities, and historically African-American colleges and universities. Individuals in the Coalition provide input in planning and implementing the project and serve as members of the Executive Committee Community Resource Team, Coalition Committees and ad hoc committees. The ad hoc committees provide advice and assistance in planning and implementing the interventions of Project DIRECT. The program manager provides staff support to the Coalition and its committees.

Community Organizations

Project DIRECT collaborates with community organizations, agencies, and institutions to implement this project (Table 1).

Table 1. Institutions collaborating with Project DIRECT.

Businesses/ Government	Faith Organizations	Colleges/ Universities	Community Organizations	Health- Related Organizations
City of Raleigh, Parks and Recreation Triangle Association of Black Media WCLY Radio News & Observer Triangle Tribune Carolinian Newspaper Radio One	Raleigh Interdenominational Ministerial Alliance General Baptist State Convention of NC, Inc.	Bowman Gray School of Medicine NC Central University Shaw University St. Augustine's College Meredith College NC State University	YWCA, Hargett Street Strengthening the Black Family, Inc. Cooperative Extension Agency Community Recreation Centers (i.e. Roberts's Parks, Worthdale, etc.)	Diverse Home Health Services, Inc. Inner City Mental Health Rex Senior Center Wake Carolina Wake Health Services, Inc. NC Affiliate, American Diabetes Association Old North State Medical Society La Scruggs Medical Local providers serving target population

New Community Model

During the development phase and early years of Project DIRECT, the need was identified to include community members in the development of the interventions that would be conducted in each of the three areas of interest: diabetes care, health promotion, and outreach. Workgroups consisting of community volunteers and members of the coalition were established in each area and worked to meet these needs. DIRECT has transitioned from a developing program to one with established programs and protocols. The emphasis has changed from one of program development to implementation and evaluation of programming. The New Community Model (Figure 1) was developed in an effort to transition coalition and workgroup members into a larger “community resource team” and away from the more structured role they had held previously. Individuals involved in this team would be encouraged to participate and serve as community advocates for activities and serve as a resource for the project when specific needs are identified.

Community Leaders

Community leaders and representatives are an important part of the Project. They have been recruited with formal recruitment techniques and one-to-one contacts. The individuals recruited and participating represent a number of organizations and professions in the community. They include health educators, nurses, physicians, community leaders and development workers, pastors, university faculty members, state employees, and day care owners. These individuals serve on the Executive Committee, Community Resource Team, Coalition Committees and ad hoc committees.

Public Health Agencies

Project DIRECT is supported primarily by funds from the Division of Diabetes Translation, CDC in Atlanta. There is a cooperative agreement with the NC Department of Health, and Human Services Division of Public Health (NC DHHS). Wake County Human Services (WCHS) has a contract with the NC DHHS for community program management, planning and development of interventions and coalition support (NC DHHS, 1994). This is done through the consolidated contract process. Appendix B summarizes the roles and responsibilities of the public agencies involved.

Ten staff members are located within the NC DHHS and at WCHS. These individuals have the main responsibility for meeting the Project's objectives. This is primarily accomplished with the Community Resource Team, Scientific Team, and the Executive Committee. Other Coalition entities and members also facilitate progress toward the Project's objectives. Staff operations are described in the section on Staff Team and are outlined in Appendix B.

Executive Committee

Project DIRECT is built on relationships and partnerships among many organizations, agencies, and individuals. The collaborative effort is reflected in the Executive Committee.

Composition

Of the 13 Committee members, nine are community representatives. There are two representatives from the DHHS Division of Public Health, and two from WCHS.

Roles and Responsibilities

The Executive Committee is responsible for the policy management of Project DIRECT. The members set project goals and assist with interviewing and selecting the Project Director/Principal Investigator (PI) and other Project Staff. The Committee gives input on the Coalition, sets policies, and provides guidance on the interventions and evaluation for the Project. The policy on external activity, for example, addresses the way the Project considers proposals of external organizations or researchers wanting to conduct studies with Project DIRECT. That policy is given in Appendices C and E.

The Executive Committee promotes community leadership by reviewing and approving action plans, reviewing the objectives and accomplishments throughout the year, and assisting the Project in identifying opportunities for visibility. Appendix B outlines the roles of the Committee.

The key roles of the Executive Committee are as follows:

1. The chair provides leadership to the Executive Committee. The project director/PI provides staff support to the Committee.
2. The vice-chair of the Executive Committee serves as chair of the Coalition. The program manager provides staff support to the Coalition.
3. Operating expenses for the Executive Committee and are provided through the contract with WCHS.

Election and terms of office for the Executive Committee are described in the Bylaws (Appendix I).

Executive Committee Meetings

Meetings of the Executive Committee are regularly scheduled each month. Additional meetings are called by the chair as needed. These meetings are led by the chair or vice-chair. Notices of meetings are mailed to members prior to each meeting. This is generally done a

Coalition Committees

week before the meeting. The staff members, in consultation with the chair, develop agendas and minutes. Minutes are submitted for approval at the meeting. Meetings are usually held at the Project's community office in Southeast Raleigh.

Ad hoc committee members are selected from the Project DIRECT Community Resource Team. Ad hoc committees shall address membership and special projects (i.e. media/special events) and shall have at least five members. The following responsibilities will be addressed by the Coalition Committees and staffed by the Project DIRECT program manager or his/her designee:

- Develop a plan for recruitment and retention of members for the Community Resource Team.
- Develop an information database for membership and keep accurate record of the membership.
- Review the bylaws annually, review proposed amendments to bylaws, and report proposed amendments to the Coalition and Executive Committee for final approval.
- Facilitate a Nominating Committee for an annual election.
- Plan and implement the annual Coalition election process.
- The committee members shall conduct ad hoc committee meetings when the need arises and shall establish a meeting time.

Scientific Team

The Scientific Team is composed of the evaluation coordinator, project director, program manager, co-principal investigators, representatives from the DHHS Division Public Health and WCHS, and community representatives from the Executive Committee. The Scientific Team shall establish a meeting schedule agreeable to the team membership.

The Scientific Team will:

- Develop an overall evaluation plan for Project DIRECT.
- Design a formative evaluation of community organization activities.
- Develop indicators for evaluating interventions.
- Review abstracts, publications, and products that will be disseminated.

While overall coordination of the project's evaluation activities is the responsibility of the evaluation coordinator, portions of the evaluation work will be assigned to outside parties. This particularly includes programming and data entry. The Scientific Team will solicit technical assistance from others in evaluation research as the need arises.

Impact Evaluation

The evaluation contractor, once selected by the CDC, will perform the provider survey and the population-based surveys (baseline and follow-up). The contractor will keep the project team informed of its activities through the Evaluation Coordinator and the Evaluation Team. The Team will facilitate the work of the contractor, particularly in providing community contacts and sharing relevant evaluation results. Likewise, the contractor will make available the results of the surveys it conducts. This may facilitate project decision making and planning.

Formative Evaluation

This is an ongoing process throughout the life of the project. It will document the planning and implementation of all project activities, particularly those at the community level. Formative evaluation includes the following processes:

- Evaluation of community participation and the decision-making process; collaboration with project staff; how decisions and activities are implemented and their effects on the project.
- Evaluation of the work of project staff, which documents the division of tasks, how decisions are made and implemented, staff collaboration with community representatives, and fulfillment of job responsibilities.
- Achievement of short-term objectives and progress toward the fulfillment of long-term objectives.
- The development of a project monitoring system which will provide feedback on key aspects of project operation, problems encountered and changes made to the original implementation plan resulting from ongoing evaluation results.

The formative evaluation was used to track the process of objective completion (Appendix G). The heavy arrows represent the processes that must occur in measuring community changes. All decision making and group processes directly influence every stage of this model. In essence, it is the success of this decision making process which the formative evaluation will measure. Co-principal investigators for Community Organization and Diabetes Care, NC DHHS have developed contracts to support Project

DIRECT in the intervention planning and community organization areas. There was a contract with the Bowman-Gray School of Medicine for work on diabetes care and one with North Carolina Central University for research on community organization. Those individuals reported to the project director/PI.

For intervention planning, the contract involved the Health Services Research Center at Bowman Gray. Expertise focused on diabetes care intervention planning in primary care settings. Activities included training and development for the Project DIRECT staff and Executive Committee on successful strategies for working with physician practices; consultation with the Diabetes Care Advisory Ad-Hoc Committee on assessing the current status of diabetes care in Wake County; development of tracking forms, documents and procedures to assess diabetes care; and strategies to gain support for improving physician care for persons with diabetes in Wake County.

During the first year, the community organization contract involved the Center for Human Services Research at Bowman Gray. Expertise focused on guided community change, Community organization and health promotion interventions. When that investigator relocated abroad, a new contract was developed with North Carolina Central University, Department of Health Education. This new contract and co-PI for Community Organization will bring expertise in community organization and in developing health promotion interventions. This contact will provide consultation on community systems analyses, the design of community interventions, and the evaluation design for the community organization activities.

3. PROCEDURES

Communication

Effective communication is essential in this complex Project (Appendix H). However, the very nature of its complexity creates challenges in communications. The Project has a number of mechanisms to facilitate the sharing of information among the various entities.

Meetings

There are a number of opportunities for sharing and hearing updates of activities and concerns. The **Executive Committee** meets monthly and includes representatives from the Evaluation Team, the community, and the lead agencies. Agenda items each month include updates from the evaluation coordinator, the coalition chair, program manager, project coordinators, and project director.

Similarly, the **Evaluation Team** meets monthly and includes representation from NC DHHS, WCHS, Executive Committee, and project consultants (community and staff members), Project management, contractors, and other individuals representing collaborating groups. Plans for evaluating interventions are discussed at these meetings.

Information Coordination consists of the project coordinators, program manager, evaluation coordinator and director of the Diabetes Control and Prevention Unit. These meetings keep partners abreast of project progress, providing a forum to share ideas and input and creating consensus towards the goals.

The **Staff Team** includes the Project staff from NC DHHS and WCHS. The project director/PI and program manager meet weekly. The Wake County director of Community Health Promotion meets with the program manager once a week. The director of the Diabetes Prevention and Control Unit, project director/PI and program manager meet once a month with the CDC project officer via telephone. They discuss Project progress and barriers to progress; develop action plans and goals and

Documents and Materials

identify resources for achieving those goals; determine communication channels; and plan training for staff, Executive Committee, and Coalition members. Roles and responsibilities for staffing the Executive Committee and Coalition are defined and coordinated by the project director.

There are different procedures for developing internal documents that will be used by Project participants and for external materials that go to the general public. Internal documents are discussed below under Documents and Plans. External materials will be addressed in a separate document.

Documents and Plans

To facilitate the process of developing formal documents and plans, relatively small ad hoc groups will develop drafts. A larger audience representing the relevant entities will then review the drafts. The Annual Application and the Annual Report to the CDC are exceptions, for they require greater involvement of the various entities. Those documents are described separately below.

Project Documents

If the document affects the overall Project, the chair of the Executive Committee will appoint ad hoc writing groups. Documents and plans include policies and procedures. Examples include this Management Plan and the Policy on External Activities (Appendices C and F).

A small writing group of five or six people should initially draft a document or plan. This group should include at least two community members representing the Coalition, two staff members, and a member of the Executive Committee. Any groups directly affected by the plan or document should be included in this group. The writing group revises the document or plan, using the comments of a review group, as discussed below. They might choose to have the document reviewed by others as well, either before or after the review group sees it. Additional reviews and comments bring different perspectives and generally serve to strengthen a document. Staff members have the primary responsibility for making the recommended changes.

The members of the review group differ from those of the writing group. The review group should include representation from the

community as well as the staff. The chair of the Group or Team can designate these individuals. The group should also include representatives from NC DHHS and from WCHS.

After review and revisions, the Executive Committee reviews and approves the document.

Scientific Team Documents

If the document is specific to one of these entities, then the chair of that Group or Team will appoint the writing group. The size of the group may be smaller; three or four people may be sufficient. The writing group should include the staff coordinator, as well as the community members. Revisions should be made as needed. The document or plan would then go to the whole Group or Team for review and approval. As above, the writing group may choose to have additional reviewers, either formally or informally.

Review Process for Abstracts, Presentations, Manuscripts, and Monographs

This document provides necessary details to the general policy on review of abstracts and manuscripts, which appears in Appendix C, Policy Statement Governing External Activities Related to Project DIRECT, adopted by the Executive Committee in June 1995.

The document as outlined in Appendix D will supercede the draft of a similar document dated 3/24/98. This document addresses only the review process for Project DIRECT, and not that of other institutions, including CDC.

Annual Application to the CDC

This is a commitment by each entity to accomplish certain objectives in the coming year. Therefore, all the relevant entities need to be involved in determining their action plans for the coming year. This process should be started in February, to allow for planning and coordination of activities of the various entities by June. Examples of the needed coordination include that of the contractors, the evaluation coordinator, Scientific Team and Project staff with the Executive Committee. Since these groups generally meet once a month, preliminary discussions should begin several months before the application is due. Task teams are needed for writing and reviewing the group's portions of the

annual application. This shortens the turnaround time. The director/PI is responsible for the coordination and timely submission of the annual application.

The CDC provides guidance on the development of the application each year. From that guidance, the director/PI and staff team will draft an outline and timeline with proposed responsibilities. The staff team will provide the outline and time line to the Executive Committee, Scientific Team, evaluation coordinator, co-PIs for Community Organization and Diabetes Care, and Coalition Committees. The staff members will also work with contractors and potential contractors as needed.

For each entity, the development process should involve identifying the following:

- Accomplishments and progress on current goals and objectives, including any reasons why objectives were not met.
- The concerns and interests of the community, using qualitative and quantitative information (the needs).
- Appropriate interventions to meet those concerns and interests (the plans).
- Resources needed to help implement proposed interventions.
- Community organizations or other contractors with the capacity to implement specific interventions.
- The Project's relationship and interactions with those community organizations.
- The capacity of the Project to evaluate proposed interventions or identify additional resources for those activities.
- Any other factors potentially affecting the implementation or evaluation of the proposed interventions.

Executive Committee

The Scientific Team and public health agencies are represented on the Executive Committee, as are other community members. While the Executive Committee has final review and approval of the application, most members are involved in the early stages of application development, due to their other Project roles.

Co-PI's for Community Organization and Diabetes Care

These individuals are responsible for drafting their progress updates for the past year and their plans for the coming year. They generally do this with the other relevant entities; that is, those with whom they have worked during the past year and those with whom they will work in the year ahead.

Annual Progress Report to the CDC

This annual report is due by September 30, 90 days after the end of the project year. It is in addition to the Annual Application. It presents the accomplishments of the preceding year and explains where and why objectives were met or not. The director/PI is responsible for the coordination and timely submission of the Annual Progress Report. Consequently, the director/PI will provide a draft outline and timeline to the Project entities, as with the Annual Application.

Since the Annual Progress Report describes the work of many entities, all the entities represented should have writing and review groups for their sections. The State Office maintains a central file of project activities. It includes progress on objectives, which comes from reports of interventions and their evaluations. It also includes meetings and major activities of the Scientific Team, the Executive Committee, and other entities. The central files are described in the section on Operational Plan. The staff team and co-PIs can provide the first drafts from the materials and reports submitted during the year. The rest of the writing and review process can proceed as outlined in the section on Documents and Plans. Staff members for each entity are responsible for incorporating the recommendation of the groups. This process should be started in early June, as soon as the project year is finished.

Contracting

Project DIRECT provides an opportunity to use a contracting mechanism to solicit, evaluate, and award competitive subcontracts with appropriate local institutions such as university prevention and research centers, historically African-American colleges and universities, local health departments, and community-based organizations, including civic groups, churches, and community centers, that have demonstrated the experience, capacity, and relationships

needed with the target community to enable them to successfully provide interventions in the targeted community (CDC, 1994a).

The director/PI is responsible for monitoring the progress of contracts executed through NC DHHS. The program manager is responsible for monitoring the progress of subcontracts executed through WCHS. Monitoring includes tracking deliverables, identifying reasons for changes in the planned delivery time or content, and assuring receipt of deliverables before approving payment. The NC DHHS contract with WCHS is executed through the consolidated contract process.

There is a process for awarding competitive subcontracts from WCHS to community-based organizations and institutions for selected Project DIRECT interventions. This process is consistent with contracting procedures established by WCHS and selection considerations outlined by the Project DIRECT Interim Executive Committee.

The steps for awarding competitive subcontracts include the following:

- Develop a Statement of Work describing services needed.
- Develop criteria for selection of a contractor.
- Identify appropriate subcontractors based on location, experience with the designated service, and performance record.
- Interview potential contractors to determine their ability to perform the activities identified in the Statement of Work.
- Rank potential contractors.
- Endorsement of the Statement of Work by the Executive Committee.
- Execute the contract through the contract management system.

The director/PI and the program manager work together to develop and review all contracts and subcontracts. Copies of all executed contracts and subcontracts should be filed with the State Office central files.

Training and Technical Assistance

Project DIRECT recognizes and relies upon the expertise and experience of community leaders. These individuals have knowledge of and personal experience within the community. Input from these leaders is vital for developing community capacity for diabetes control. Members of the Community Resource Team, ad-hoc committees, and the Scientific Team also provide technical assistance and input on health and human service issues. Project staff members provide technical assistance on health and programming issues.

For community members and the staff team, there are opportunities for training and technical assistance in planning, implementing, and evaluating Project activities. This may include training on diabetes and implementing a community-based program. It may be obtained at local, state, or national conferences and workshops. Other types of training may include screening protocols, such as completing intake and registration forms. Volunteers regularly provide consultation and technical assistance, both formally and informally. Consultation and technical assistance are also provided through contracts with community organizations and agencies. Technical assistance includes orientation for the Community Resource Team members as described below.

Training should be practical. That is, it should be applicable to the issues and usable by the participants. It should also be interactive, current and accurate, acceptable to the audience/participants, and appropriate for the target group.

The program manager and chair of the Coalition provide a structured briefing and orientation process. Briefing notebooks are available for each member. The orientation includes discussion about community participation in planning and implementing project interventions. Roles of the program manager, project coordinators, and Community Resource Team member are described Appendix B. Specific attention is given to identifying and recruiting community members, planning and organizing the Community Resource Team, developing a timeline for activities, and discussions about organizing and

maintaining ad-hoc committees.

Wake County Human Services is responsible for coordinating at least one training workshop for the Executive Committee and Coalition members annually. A co-PI for Community Outreach provides consultation and technical assistance in community organization and development. Another co-PI for Diabetes Care provides technical assistance and consultation in diabetes care and intervention planning.

Operational Plan for Staff Team

The staff team is composed of the eight staff members in NC DHHS and seven staff members in WCHS. Some of their functions are given in Appendix B (Roles and Responsibilities) as well as elsewhere in this document.

Organization

In the Division of Public Health (DPH) of NC DHHS, Project DIRECT is administratively positioned in the Health Promotion Disease Prevention Section. The project director/principal investigator for Project DIRECT reports to the director of the Diabetes Prevention and Control Unit. The director/PI is responsible for the overall administration of the project and for the research components. The social research assistant, office assistant and program assistant report to the director of the Diabetes Prevention and Control Unit.

In WCHS, Project DIRECT is positioned within the Community Health Promotion Section of Community Initiative and Health Services. The program manager reports to the director for Community Health Promotion. The program manager is responsible for the day-to-day operation and management of the Project's intervention activities. The staff members who report to the program manager include the three coordinators, one clerical assistant and any temporary staff for project support.

The intent of having a staff team is to coordinate intervention and evaluation activities. This includes discussing the feasibility and limitations of certain interventions. The team also assesses progress toward the objectives, and determines ways to facilitate progress. Another function is to document the development of interventions and the short-term evaluations.

Most of the staff team meetings include the director, program manager, coordinators, and social research assistant (evaluation coordinator). At other times, the clerical support staff also participates. The latter example might include discussions of the central files and tracking system and assessing overall progress (Appendix F).

Project Records

The State Office keeps a central file of Project information for tracking and accountability. It includes the following:

- Progress on objectives
- Reports of Project activities and events, and the related materials
- Contracts and subcontracts, as well as the Cooperative Agreement
- Documents and plans
- Educational or promotional materials developed
- Relevant official correspondence

The Project DIRECT local office keeps the following information:

- Agendas, minutes and/or reports of regular meetings (Executive Committee, Scientific Team, Coalition Committees)
- Reports of ad hoc meetings
- Intervention data

There are checklists for the following staff team members: project director/PI, program manager, and evaluation specialist. The checklists serve as reminders to the individuals of what should go into the files, and are used for reviewing the files for currency and completeness. These people are responsible for providing the materials monthly to the central files. The office assistant for the State Office maintains the central files, in coordination with the director/PI and the evaluation coordinator.

These central files are one part of the tracking system. Other activities include formative evaluation of management and intervention development, feedback from participants and community members, and short-term outcome evaluation. These are discussed in the section on the Evaluation Team. Details depend on the specific intervention. Copies of all evaluation forms, materials, and reports are kept in the central files.

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APPENDICES

APPENDIX A

Long-Term Goals

The Centers for Disease Control and Prevention developed overall aims or goals for each of the three intervention areas (CDC, 1994a). Those goals were provided in the Overview section of this document. The CDC also provided more detailed goals for the three areas (CDC, 1994b). Those objectives were further developed by the entities of the Project (DAHP, 1994). From this list, objectives are developed for each year of the Project, along with action plans.

- I. The long-term goals of the **Diabetes Care** component are as follows:
 - a. To decrease the mean hemoglobin A1c among persons with diagnosed diabetes in the targeted community.
 - b. To increase the percentage of persons with diagnosed diabetes that has received an eye examination in the past 12 months in the targeted community.
 - c. To increase the prevalence of foot exams among persons with diagnosed diabetes during regular quarterly health care examinations in the targeted community.
 - d. To decrease the incidence of foot lesions among persons with diagnosed diabetes in the targeted community.
 - e. To decrease the prevalence of cigarette smoking among persons with diagnosed diabetes in the targeted community.
 - f. To decrease the prevalence of uncontrolled hypertension among persons with diagnosed diabetes in the targeted community.
 - g. To decrease the average total cholesterol level in the targeted community, thereby increasing the percentage of persons with diabetes who have lipid levels within the acceptable range, i.e., total cholesterol and triglycerides below 200 mg/dl, LDL below 130 mg/dl, and HDL above 35 mg/dl.

- h. To increase physical activity and good nutrition, including proper alcohol use, among persons with diabetes in the targeted community.

II. The long-term goals of the **Health Promotion** component are as follows:

- a. To increase the percentage of persons in the targeted community participating in regular physical activity (three to four times per week for 30 minutes or more per day).
- b. To reduce the percentage of total calories from fat intake among persons in the targeted community.
- c. To increase the knowledge and practice of accepted nutritional guidelines, including alcohol.

III. The long-term goals of the **Outreach** component are as follows:

- a. To decrease the prevalence of undiagnosed diabetes among the general population in the targeted community at high risk for developing diabetes.
- b. To increase the proportion of persons with diagnosed diabetes in the targeted community who receive recommended diabetes care.
- c. To increase the awareness of the burden of and risks for diabetes among the general public and community policy makers in the targeted community.

APPENDIX B Roles and Responsibilities, Project DIRECT

NC Department of Health and Human Services

Provide administrative home for project and funds	Project Director/Principal Investigator
Manage cooperative agreement with CDC	Project Director/Principal Investigator
Coordinate and submit annual application for funding	Project Director/Principal Investigator
Coordinate and submit annual progress reports and financial status reports	Project Director/Principal Investigator
Provide overall project management and leadership	Project Director/Principal Investigator
Plan and implement project evaluation activities	Evaluation Coordinator
Provide staff to the Scientific Team	Evaluation Coordinator
Coordinate development and dissemination of research findings	Project Director/Principal Investigator
Manage NC DHHS contracts	Project Director/Principal Investigator
Provide staff to the Coalition's Executive Committee	Project Director/Principal Investigator
Appoint two members to the Coalition's Executive Committee	Division Director
Manage the Project DIRECT staff team	Project Director/Principal Investigator

Wake County Human Services

Provide administrative home for community-based project	Director for Community Health Promotion
Provide staff to the Coalition	Program Manager
Manage subcontracts for community intervention development and implementation	Program Manager
Manage community relations activities	Program Manager
Appoint two members to the Coalition's Executive Committee	Director of Community Health Promotion
Participate on the Project DIRECT staff team	All Project DIRECT staff
Manage day-to-day intervention activities	Program Manager
Provide staff to the ad-hoc Coalition committees	Coordinators

Centers for Disease Control, Division of Diabetes Translation

Assist in the design of interventions and evaluation protocols used in conducting and evaluating the project	CDC Project Officer
Provide technical assistance in the design of demonstration protocols	CDC Project Officer
As needed, provide other programmatic consultation and guidance in support of the project	CDC Project Officer
Coordinate with NC DHHS in sharing and distributing information, data, and successful strategies and intervention to states and other appropriate agencies	CDC Project Officer
Provide Project DIRECT Intervention Plan guidelines	CDC Project Officer

Executive Committee

<p>Provide a forum for Project DIRECT partners to conduct strategic planning</p> <p>Review and approve plans and recommendations of the Coalition’s Community Resource Team and ad-hoc committees</p> <p>Endorse plans for expenditure of funds, especially contracts; participate in the selection of Project DIRECT staff</p> <p>Coordinate communication among the project entities and other organizations/individuals</p> <p>Serve as focal point for the handling of community concerns</p>	Executive Committee Chair and Project Director
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Coalition

Provide a forum to inform the community about diabetes as a major health problem impacting African Americans	Coalition Chair
Provide a forum for the community to participate in planning and implementing Project DIRECT and to share information about the project	Coalition Chair
Provide a forum to broaden community stakeholders in diabetes control	Coalition Chair
Establish and maintain an Executive Committee for coordination and decision making for Project DIRECT	Coalition Chair

Project DIRECT Management Plan

Establish and maintain a Community Resource Team	Program Manager and Coalition Chair
Establish and maintain ad-hoc committees to support administrative and communication functions of the Coalition	Program Manager and Coalition Chair

**Co-PI's for
Diabetes Care
and
Community
Organizations**

Advise and consult with the Coalition, Executive Committee, and Project DIRECT staff on the development and evaluation of strategic and action plans for project interventions	Co-PI's and Project Director/PI
Participate in the development of appropriate publications	Co-PI's and Project Director/PI

**Scientific
Team**

Develop a strategic plan to evaluate Project DIRECT	Scientific Team and Coordinator
Develop annual action plans for carrying out the strategies	Scientific Team and Coordinator
Recommend to the Executive Committee methods of completing action plans such as subcontracts, memoranda of understanding, etc.	Scientific Team and Coordinator
Coordinate evaluation activities with CDC and the evaluation coordinator	Scientific Team and Coordinator

APPENDIX C

Policy Statement Governing External Activities Related to Project DIRECT

Executive Committee (June, 1995)

Project DIRECT (Diabetes Interventions Reaching and Educating Communities Together) is a community-based research and demonstration project intending to reduce the burden of diabetes and its associated risk factors among African-American adults living in Raleigh, NC, primarily in the Southeastern part of the city. Given the interplay of individual attitudes and behaviors, community norms, provider practices, and the health care system in diabetes management, Project DIRECT proposes a comprehensive, multi-level intervention approach to meet its goals and objectives. Considerable time, resources, and study by the community advisory board, Wake County Department of Health, NC Department of Environment, Health and Natural Resources, and the Centers for Disease Control and Prevention (CDC) have been invested in framing the project to insure that all components are scientifically sound, culturally appropriate, ethical, and sensitive to the diabetes-related needs and priorities of the community. We are committed to maintaining the integrity of the project and protecting the community's trust by establishing the following guidelines related to Project DIRECT:

1. All research, intervention, and/or policy proposals must be consistent with established goals and objectives of the Project.
2. All proposals for ancillary or secondary research, interventions, or policies must be reviewed and approved by a two-thirds vote of the Executive Committee with concurrence of CDC. The foremost consideration in reviewing such proposals is that they not divert time, energy, or resources from the primary goals and objectives of the Project and that they in no way jeopardize the successful implementation and evaluation of the Project.

3. Funding provided for Project DIRECT will not be diverted to “external” research, i.e., research proposals developed by individuals, organizations, and institutions outside of the Project’s infrastructure unless the proposal is solicited by the Executive Committee with concurrence from CDC.
4. Student participation in the Project is encouraged provided that their efforts support an existing activity and a memorandum of understanding between the university and responsible faculty is approved and on record with the Executive Committee documenting the students’ roles and accountability.
5. No scientific reports or peer-reviewed publications related to the Project shall be prepared or published without preauthorization of and review by the Executive Committee or its designee and CDC.
6. Project DIRECT may accept donations of educational and other resources that support the Project’s primary objectives subject to state law, but Project DIRECT does not endorse or promote any commercial products or services.

APPENDIX D

Project DIRECT Review Process for Abstracts, Presentations, Manuscripts, Monographs

Revised 9/18/00

Effective Date

The policy was approved by the Executive Committee on September 18, 2000 and became effective on this date.

Purpose

This document will provide necessary detail to the general policy on review of abstracts and manuscripts, which appears in Appendix B, Policy Statement Governing External Activities Related to Project DIRECT, of the *Project Direct Management Plan*, adopted by the Executive Committee in June 1995:

No scientific reports or peer-reviewed publications related to the project shall be prepared or published without preauthorization of and review by the Executive Committee or its designee and CDC.

This document will supercede the draft of a similar document, which was prepared in draft form on 3/24/98. This document addresses only the review process for Project DIRECT, and not that of other institutions, including CDC.

Review Process

1. Prior to development of an abstract or manuscript, a description of the title, proposed authors and general content of the product will be submitted to the principal investigator (PI). The principal investigator will provide copies to the Administrative and Scientific Team and CDC project officer. It is understood that this is not a binding proposal and that some elements of this preliminary plan may change.
2. A general goal is that staff and community members are encouraged to be authors. Guidelines for types of contributions that will be considered necessary for authorship are based on

the criteria of the International Committee of Medical Journal Editors (JAMA.1997; 277: 927-934).

3. Timeline for review:
 - For abstracts: allow two weeks
 - For manuscripts (articles, peer reviewed/juried publications): allow three weeks
 - For monographs (books): allow four weeks
4. Products for review should be submitted to the principal investigator (PI). The PI will forward copies of the document to:
 - The Administrative and Scientific Team
 - CDC project officer
 - The program manager
5. Reviewers may designate another person to review the product for them. The PI or his/her designee will assemble all the comments of the reviewers and forward them to the author.
6. The author agrees to make appropriate changes or communicate with the PI if they feel a change is not warranted. If the PI and author disagree on changes recommended then a consensus would be reached.
7. If an abstract is selected for presentation, the content of the presentation should be submitted in hard copy for review.
8. A new protocol will be necessary to handle publications and abstracts that are developed after the Project is over.
9. CDC requests for presentations on “short notice” will be handled by the PI following the above procedure to the extent possible.

Approved by the Executive Committee on 9/18/00.

APPENDIX D2

Project DIRECT Review Process Tracking Sheet

Date submitted to Scientific Team: _____

Person coordinating review process (PI or designee): _____

Date Mailed or Delivered	Sent to: (List Name & Title)	Date Returned:
_____	<input type="checkbox"/> _____, CDC Project Officer	_____
_____	<input type="checkbox"/> _____, Project Manager	_____
_____	<input type="checkbox"/> _____,	_____
_____	<input type="checkbox"/> _____,	_____
_____	<input type="checkbox"/> _____,	_____
_____	<input type="checkbox"/> _____,	_____
_____	<input type="checkbox"/> _____,	_____
_____	<input type="checkbox"/> _____,	_____
_____	<input type="checkbox"/> _____,	_____

Notes from discussion with author:

Date review process complete: _____

Approved by DIRECT: Yes No

Approved by the Executive Committee on 9/18/00.

APPENDIX E

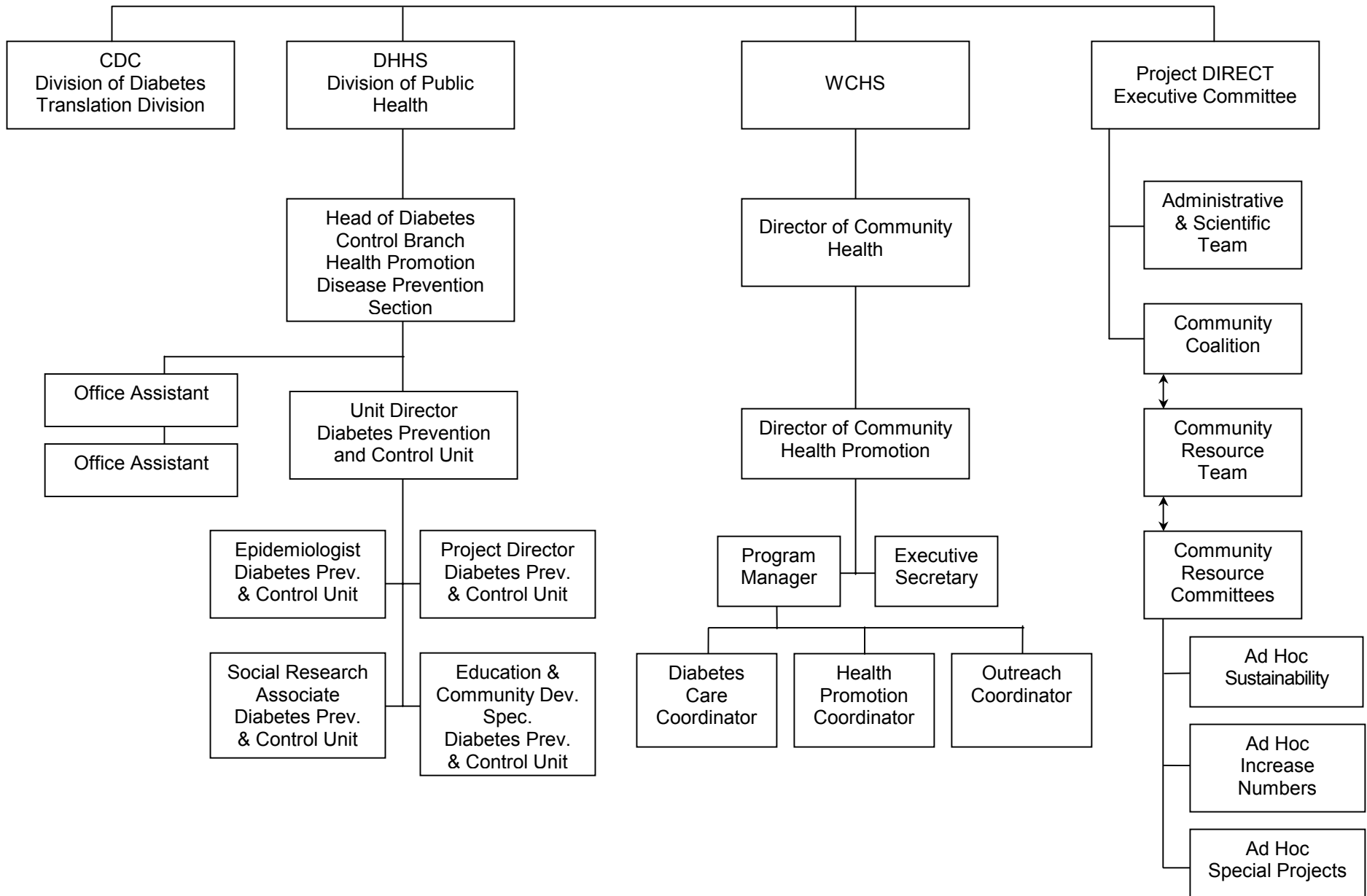
Policy Statement Governing Requests to Recruit Subjects for Other Studies

Project DIRECT does not assist other projects or investigators with recruitment of research subjects. DIRECT is a community-based project. Assisting with recruitment or advertising for other studies could imply endorsement. Project personnel cannot review all the protocol of other investigators and cannot ensure that other protocols are being followed. DIRECT would not be knowledgeable about the risks and benefits to potential participants in other projects.

APPENDIX F

Organizational Chart

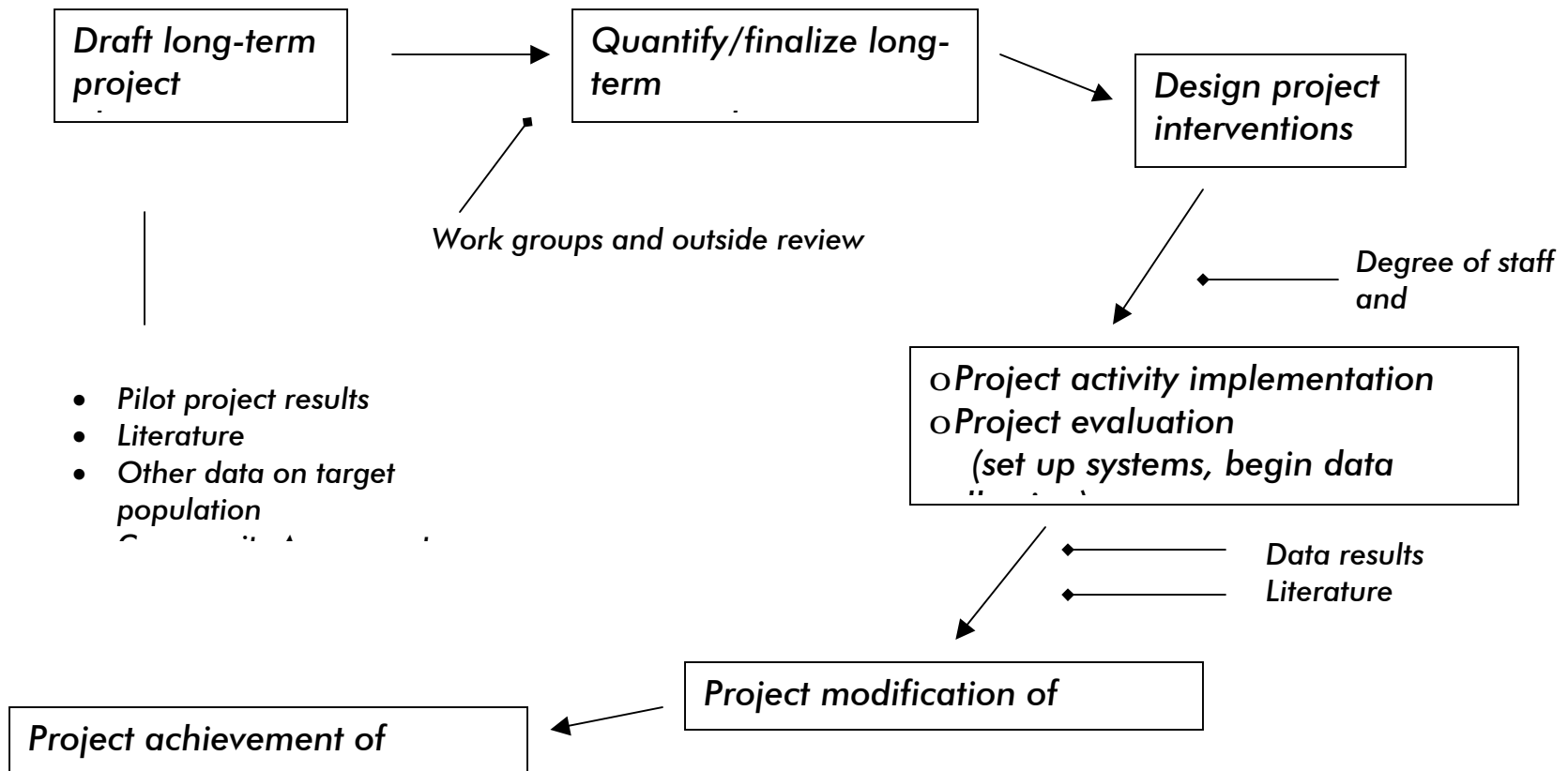
**Project DIRECT
Diabetes Prevention and Control Unit
Organization Chart
2001**



APPENDIX G

Model of Project DIRECT Achievement of Objectives

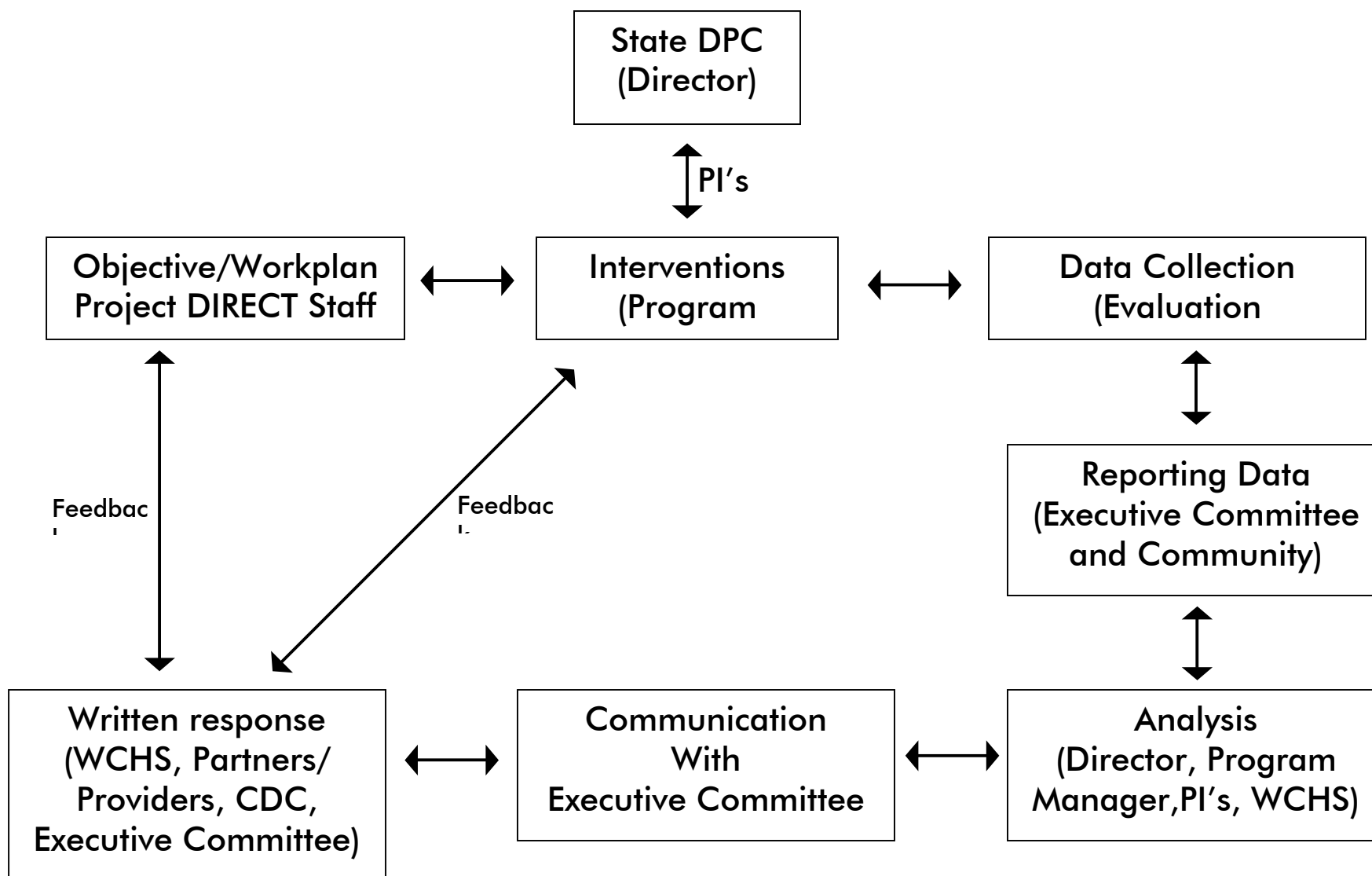
Model of Project DIRECT Achievement of Objectives



APPENDIX H

Project DIRECT Communication Process

Project DIRECT Communication Process



APPENDIX I
Project DIRECT Coalition
Diabetes Intervention Reaching and Educating Communities
Together

BYLAWS

Article I. NAME

The name of this organization is the Project DIRECT Coalition (Diabetes Interventions Reaching and Educating Communities Together), hereinafter referred to as the Coalition.

Article II. PURPOSE OF THE ORGANIZATION

Section 1. Purpose Statement

The purpose of the Coalition is to support Project DIRECT and improve the health-related quality of life for African Americans in Southeast Raleigh by reducing the burden of diabetes and its complications.

Section 2. Goals

The goals of the Coalition are to:

- a. Provide input on community needs for design and implementation of a comprehensive community-based diabetes project.
- b. Participate in development, evaluation, and promotion of diabetes interventions.
- c. Recruit community volunteers to promote Project DIRECT activities.
- d. Build and maintain a broad base of support in the community for Project DIRECT.
- e. Work with Project DIRECT staff to implement Project DIRECT activities.
- f. Increase awareness about diabetes as a major health problem in Southeast Raleigh.

Section 3. Principles of Community Participation

Project DIRECT implementation is based on a high level of community participation. Principles of community participation include community volunteers who:

- a. Are a critical link in planning, implementing and governing activities for Project DIRECT.
- b. Have a high volunteer commitment to Project DIRECT.
- c. Have first-hand knowledge of community norms and practices in Southeast Raleigh.
- d. Are vital to program planning for community-based programs.

Article III. PROJECT DIRECT COALITION

The Project DIRECT Coalition shall be composed of the Executive Committee, Community Resource Team (which includes ad hoc committees), Scientific Team, Administrative Team (state and local staff), Consultants, Co-PI (s), Centers for Disease Control and Prevention (CDC) Project Officer, and Project DIRECT staff.

Section 1. Coalition Officers

- a. The Officers of the Project DIRECT Coalition shall be chair, vice-chair, and secretary.
- b. **Chair.** The chair of the Coalition shall preside over Coalition meetings. The chair shall perform duties as parliamentary procedures allow. The chair of the Coalition shall serve as vice-chair of the Executive Committee.
- c. **Vice-Chair.** The vice-chair shall preside over Coalition meetings in the absence of the chair. The vice-chair shall perform duties as assigned by the chair.
- d. The **Secretary** shall record, review and sign minutes from the Coalition meetings. These minutes will be prepared by the Project DIRECT program manager and/or designee.

Section 2. Executive Committee

- a. The Executive Committee is the governing body for Project DIRECT. It shall be responsible for policy level decisions involving Project DIRECT.
- b. The Executive Committee consists of thirteen (13) members: two (2) from the Division of Public Health, Department of Health and Human Services; two (2) from Wake County Human Services; nine (9) from the community.
- c. There shall be a chair and vice-chair for the Executive Committee. The chair and vice-chair shall be elected by the Coalition.

- d. The length of term of membership on the Executive Committee is one year. Members may serve consecutive terms.
- e. The representatives of the Division of Public Health, Department of Health and Human Services and Wake County Human Services are appointed by the respective agencies. The community representatives will be elected by the Executive Committee. However, if circumstances prevent a community member from serving his or her one-year term, the Executive Committee can replace the community member by appointment.
- f. Each Executive Committee member has one (1) vote. An Executive Committee member may designate someone else to cast votes in a meeting when the member is absent. The membership present shall constitute a quorum. A minimum of five (5) community representatives must be included in this quorum.
- g. Executive Committee members absent without justification for three (3) consecutive meetings will have their membership reviewed by the chair of the Executive Committee. The chair will make a recommendation to the full Executive Committee for approval. The member in question will be notified in writing about the actions of the Executive Committee.
- h. The Executive Committee shall meet quarterly or at additional times at the discretion of the chair.

Section 3. Coalition Committees

- a. The ad hoc committee members are selected from the Project DIRECT Community Resource Team.
- b. The ad hoc committees shall address membership and special projects (i.e. media/special events) and shall have at least five (5) members.
- c. The following responsibilities will be addressed by the Coalition Committees and staffed by the Project DIRECT program manager or his/her designee:
 - Develop a plan for recruitment and retention of members for the Community Resource Team.
 - Develop information database for membership and keep accurate record of the membership.
 - Review the bylaws annually, review proposed amendments to bylaws and report proposed amendments to the Coalition and Executive Committee for final approval.

- Facilitate a Nominating Committee for annual election.
 - Plan and implement the annual Coalition election process.
- d. Ad hoc committee meetings shall be determined by the committee members when the need arises and shall establish a meeting time.

Section 4. Scientific Team

- a. The Scientific Team is composed of the evaluation coordinator, project director, program manager, co-principal investigators, representatives from the division of Public Health, Department of Health and Human Services, Wake County Human Services, and community representatives from the Executive Committee.
- b. The Scientific Team will:
- develop an overall evaluation plan for Project DIRECT.
 - design a formative evaluation of the community organization activities.
 - develop indicators for evaluating interventions.
- c. The Scientific Team shall establish a meeting schedule to be determined by the team membership.

Article IV. MEMBERSHIP (Article IV is addressed with the make up of the approved and adopted Community Model.)

Section 1. Membership in the Project DIRECT Coalition can be individual or organizational.

Organizational Members. Organizational members will be recruited based on their ability to represent the public health community, health care providers, volunteer agencies, professional organizations, educational institutions, businesses and civic organizations.

Individual Members. Individual members may include individuals with expertise to support and/or contribute to the work of the Coalition. Individual members may have expertise in a specific technical area, knowledge of the community or target group, or a special interest in supporting a diabetes project.

Section 2. Membership is open to individuals and organizations that agree to be governed by the Coalition bylaws.

Section 3. In order to be a member, individuals are asked to sign a Letter of Commitment. Those who have signed the Letter of Commitment are eligible to vote in the annual election.

Section 4. Membership in the Coalition's Community Resource Team is always open.

Article V. MEETINGS

Section 1. The Project DIRECT Coalition will meet annually. The annual meeting is dedicated for the election process of the Coalition and Executive Committee officers.

- a. The annual meeting will be held the last quarter (April, May, June) of the Project DIRECT fiscal year. Communication will be widely disseminated in the community to announce the election at least 30 days prior to the annual meeting. This communication will contain the following:
 - Date, time and location of the annual meeting.
 - List of current officers.
 - List of Coalition offices to be filled during the annual meeting.
- b. The Nominating Committee will organize and coordinate the annual meeting.
- c. The following Coalition positions will be filled each election:
 - Chair, Executive Committee
 - Chair, Coalition (also serves as vice-chair of the Executive Committee)
 - Vice-Chair, Coalition
 - Secretary
- d. Nominations for Coalition officers will be accepted during the annual meeting. Nominations may be made for an individual who is not present if the individual provides written confirmation of intent to accept office in advance of the annual meeting.
- e. A majority count, by show of hands, will determine the winner for each office.
- f. A complete slate of officers elected at the annual meeting will be disseminated to all Coalition members and publicized in the community.

Section 2. The Executive Committee or the Coalition Chair, as needed, may call special meetings of the Coalition.

Section 3. Notices of all meetings of the Coalition, Executive Committee and ad hoc committees shall be distributed through the Project DIRECT calendar, media, or direct mail.

Article VI. AMENDMENTS

Section 1. The Executive Committee shall review these bylaws at least annually. Amendments shall be made in writing to the Executive Committee for final approval.

Section 2. Notices of approved changes in bylaws will be mailed to all Coalition members within thirty days of the approved change/amendment.