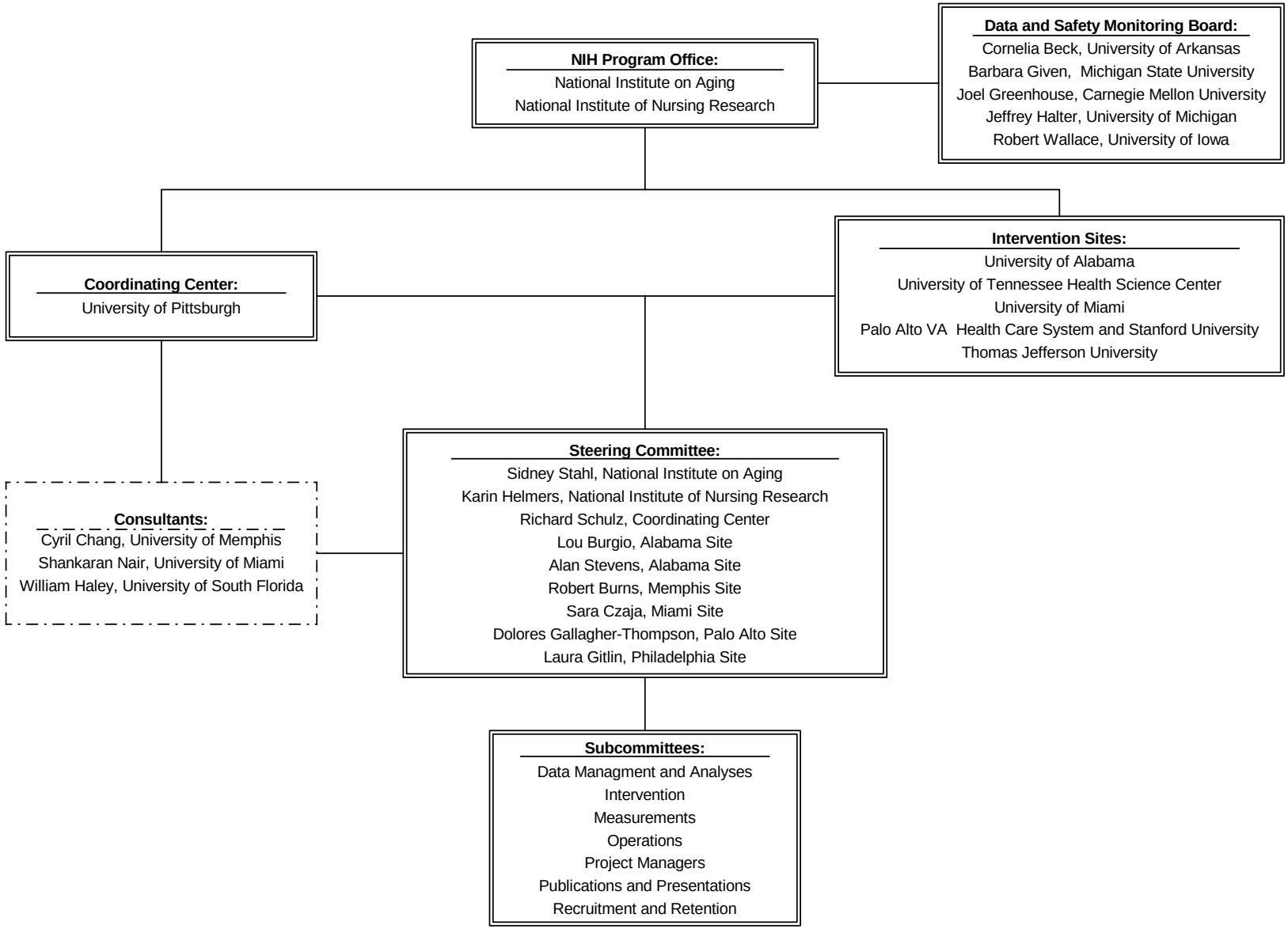
SECTION 2

STUDY ORGANIZATION

REACH II Project Organizational Chart



REACH II ORGANIZATIONAL COMPONENTS

Overview

The REACH Project consists of five Intervention Sites, a Coordinating Center, NIH Program Administrators from the National Institute on Aging (NIA) and National Institute of Nursing Research (NINR), a Steering Committee, a group of Subcommittees, a Data Safety and Monitoring Board, and Consultants. The following outlines the organizational components of the REACH II Project and describes how the various components are organized to meet the study goals.

Intervention Sites

The Interventions Sites are responsible for carrying out a single multi-component intervention among family caregivers of persons with Alzheimer's Disease and related disorders. Each site's Principal Investigator has formed a multidisciplinary team and is responsible for recruiting an adequate number of subjects in order to address the primary hypotheses about the impact of the proposed psychosocial intervention. The Sites must be willing to follow shared aspects of design, measures and analysis as approved by the Steering Committee.

Coordinating Center

The Coordinating Center interacts with the Sites, the Steering Committee, the NIH Program Administrators, and the Data and Safety Monitoring Board on a variety of topics ranging from seeking and compiling information, to providing technical assistance, to conducting data analyses. In consultation with other organizational components, the Coordinating Center has primary responsibility for:

- Instrument development and testing activities (e.g., compiling the listing of proposed measures; reviewing the literature and assessing the advantages and disadvantages of different measures for study variables; conducting psychometric analyses on the data set; and making recommendations at the end of the study about the most parsimonious set of measures to be archived). Its staff may author articles on measurement and statistical issues, alone or in conjunction with others involved in this cooperative agreement.

- Tracking recruitment and retention across the different Sites, and advising the Sites on strategies for enhancing recruitment/retention, especially in minority or ethnic populations.

- Standardizing data collection and management and analysis of the data set. The Coordinating Center will work with projects to ensure that protocols and definitions are consistent across projects through training sessions. It will provide key assistance in designing the data collection system (e.g., centralized and/or distributive) for the shared data and will also be responsible for developing and monitoring quality control.

- Printing and distributing all final data collection forms as well as collecting, editing, storing, and analyzing all data generated by the Sites.

- In addition, the Coordinating Center performs a variety of functions, such as, developing and maintaining a core Manual of Procedures; maintaining a directory of investigators and co-investigators; arranging all conference calls and meetings, e.g., for the Steering Committee and Data and Safety Monitoring Board; and facilitating information exchange among the Sites and NIH, and between the NIH and the general research community. The latter role includes compiling specific reports and developing and implementing common formats across Sites for all reports,

protocols and descriptions (e.g., progress reports, instrument protocols, manuals of operation). The Coordinating Center will also devise plans for the dissemination of information resulting from these studies, including the preparation of slides for presentation of study objectives, methods, and findings.

NIH Program Administrators

The NIH Program Administrators have substantial scientific/programmatic involvement during this study, through technical assistance, advice and coordination above and beyond normal program stewardship for grants. The NIH Program Administrators:

- Participate in the development of the protocol for common measures
- Monitor performance issues relating to Steering Committee assignments necessary for the development of the common protocol, recruitment, follow-up, quality control, adherence to protocol and attainment of study objectives.
- Provide technical assistance in the formulation or consideration of refinements and adjustments of study objectives, designs and protocols.
- Assist in analysis and reporting of intervention study results

The NIH Program Administrators may provide advice on staffing, statistical requirements, and will cooperate with awardees in considering protocol adjustments. In instances where there has been significant involvement in study design and analysis by the NIH Program Administrators, and in accordance with the Publication Guidelines developed by the Steering Committee and with NIH policies regarding staff co-authorship of publications resulting from extramural awards, he/she may cooperate with awardees as co-authors in preparing manuscripts that report results from these studies.

Steering Committee

The Steering Committee serves as the main decision-making body for the shared aspects of the study. The REACH Steering Committee consists of the Principal Investigator from each Site and the Coordinating Center, as well as the NIA and NINR Program Administrators. The Steering Committee will meet every six months as needed. The chairperson must be someone other than an NIH staff member and will be selected by the Steering Committee.

Subcommittees

To develop and coordinate the shared aspects of the REACH project, subcommittees have been organized. These subcommittees are intended to address both substantive and procedural issues. The subcommittees are open to any REACH project personnel. A Chair is elected for each subcommittee.

The following REACH II subcommittees have been established:

- Data Management and Analysis – the principal functions of the Data Management and Analysis Workgroup are to address issues related to design, data collection, data management, and data analysis. Through this process, the workgroup will seek to maximize the quality control and utilization of data across sites.
- Intervention – the Intervention Workgroup will address issues related to design and implementation of the intervention.

- Measurement – The primary goals of the Measurement Workgroup are to identify areas of measurement for the battery, evaluate measurement options for the identified areas, attempt to achieve consensus on the selection of specific measures to be implemented, and make recommendations regarding the selection of measures to the Reach Steering Committee.

- Recruitment and Retention – the primary goals of the Recruitment and Retention Workgroup are to define the care recipient and caregiver, identify the inclusion and exclusion criteria to be used at each site for care recipients and caregivers, and to develop recruitment and retention strategies to be used study wide and at individual sites.

- Operations – the Operations Committee consists of the NIH program officers, the Coordinating Center Principal Investigator, and the Steering Committee Chair. The Committee meets every six weeks via conference call, two weeks prior to the Steering Committee call, to discuss both substantive and procedural issues related to the research project.

- Project Managers – the project managers will meet monthly via conference call to discuss issues related to implementation of the study protocol.

A Publications and Presentations Committee has also been established (refer to the procedures outlined later in this section).

Data and Safety Monitoring Board

An independent Data and Safety Monitoring Board has been appointed by the National Institutes of Health to assure subject safety and human subject protection policies, recommend protocol modification, recommend recruitment initiation, and monitor all aspects of the study. The board consists of experts in relevant clinical, social and behavioral, statistical, and bioethical fields and will convene once per year. Interim conference calls and review of protocols and other correspondence may be necessary between meetings. At the initial meeting, the board will review the protocol (e.g., interventions, data collection, sample size determination, monitoring plan) and recommend changes. At subsequent meetings and calls the board will review the progress of the study (e.g., recruitment by race/ethnicity at each site, protocol deviations, intervention adherence, adverse events, site visit summaries, data quality, attrition, descriptive characteristics of the population at baseline by intervention group, and efficacy of the intervention) and make recommendations concerning its continuation. The chairperson of the Steering Committee, the Principal Investigator from the Coordinating Center, and the NIH Program Administrators will participate as non-voting members during each board meeting. Board members will be reimbursed for necessary travel and receive a $500 honorarium for attendance at meetings.

Consultants

The use of Consultants will be based upon available resources and applications of the following protocol:

- Preference for use of consultants will be made to cross-site issues

- Consultants will be available only to provide technical assistance/advice

- Consultants cannot function as Co-Investigators or staff assigned to current projects.

The major differences between the Consultants and the Data and Safety Monitoring Board are that members of the former group participate only as needed, and are reimbursed as consultants for necessary travel and time, at the daily government rate.

REACH II WEBSITE

The REACH II website (**www.edc.gsph.pitt.edu/reach2/**) serves as a hub of communication for the REACH II project. The site has been designed with features to promote the accurate and efficient operation of the study and serves as a central location for retrieving and disseminating information. News bulletins, operations memos, calendars, personnel directories, manuals of operations, and frequently asked questions are example features that are made accessible by the Coordinating Center. Additionally, reports including data integrity and compliance reports will periodically be posted and made available for individual site review. A shared documents section provides a restricted area for adding and retrieving shared manuscripts, operations memos, training documentation, and various other reports. The website features are categorized into two areas, public and private, based on the level of security required for access.

REACH II PUBLICATIONS AND PRESENTATIONS COMMITTEE

Objectives

To assure and expedite orderly and timely presentations to the scientific community of all pertinent data resulting from REACH II;

To have scientifically accurate presentations and papers from REACH II investigators;

To assure that all investigators, particularly those of junior rank, have the opportunity to participate and be recognized in the study-wide presentations of REACH II papers;

To assure that press releases, interviews, presentations, and publications of REACH II materials are accurate and objective, and do not compromise the scientific integrity of this collaborative study;

To establish procedures that allow the REACH II Steering Committee to exercise review responsibility in a timely fashion for REACH II publications and presentations;

To maintain a complete up-to-date list of REACH II presentations and publications, and to distribute such lists to all REACH II investigators on a regular basis; and

To assure that membership in writing committees for REACH II papers will serve as an opportunity to participate in formulating plans for analysis and the writing of manuscripts by active participation in the preparation of the respective paper

Administrative Structure

The REACH II Steering Committee will appoint a Publications and Presentations Subcommittee. Each site, the Coordinating Center, and NIH will have one representative.

The Chair of the Publications and Presentations Subcommittee will report to the REACH II Steering Committee, on behalf of the membership of the Publications and Presentations Subcommittee, on all matters relating to the publications or presentations of REACH II material.

This subcommittee will serve an executive function to the REACH II Steering Committee which has the final authority for approval or disapproval of all recommendations of the subcommittee on REACH II publications, presentations, and the composition of the respective writing committees.

The Publications and Presentations Subcommittee, with approval of the REACH II Steering Committee, shall set priorities for REACH II related publications.

Authorship Guidelines

The originating author is defined as the individual who has primary responsibility for organizing the writing group, directing the analysis, and drafting the abstract and manuscript. Originating authors can be individuals from sites, the Coordinating Center, or the NIH. For major outcome manuscripts, the Steering Committee may designate an originating author as well as the writing group. Originating authors will have the responsibility of assuring the timely completion of manuscripts they have agreed to write. If there is no progress on an agreed upon manuscript for a three month period, than a new originating author and writing group may be assigned.

General guidelines for authorship are: active participation in the production of the manuscript, substantive contribution to the conceptual basis of the paper, and ongoing responsiveness to responsibilities negotiated initially with the originating author. The originating author will determine order of authorship based on level of participating in the preparation of the manuscript. In the rare

case where there is need for resolution of conflicts, the NIH project officers will work with all authors involved in a paper to resolve any conflicts.

Procedures
These procedures will govern all publications and presentations ("papers") reflecting the work of REACH II.

1. Abstracts. Abstracts to be submitted to professional meetings should be sent, along with the REACH II P & P Proposal Form, to the Coordinating Center at least three weeks prior to the submission deadline. The initiating author must give relevant sites the opportunity to be part of the writing/presentation group. The abstract should include a brief summary of the presentation, proposed participants, and the target meeting. The Coordinating Center will review abstracts for accuracy and the appropriate application of statistical methods and provide feedback to the author within three working days of receipt of the abstract. Accurate abstracts will be forwarded to the P& P Committee for review within four days of receipt; abstracts that require revision will be returned to the author for appropriate changes and will be forwarded to the P & P Committee once those changes have been made. P & P Committee members will have one week to respond. Responses should be sent to the Coordinating Center, and will be forwarded to the chairperson of the P&P for further action. The chairperson will communicate the decision of the P& P Committee to the applicant within one working day of receiving these materials.

Papers can be identified by individual originating authors or collectively by the Steering Committee (e.g. major outcomes papers):

2. Investigator initiated manuscripts. Any eligible investigator interested in writing a paper representing multi-site data should submit a proposal to the Coordinating Center in the form of an abstract and the REACH II P & P Proposal Form. The abstract will include a title, background statement, proposed hypotheses, and target journal/book. The investigator may also wish to propose members of the writing group. This abstract will be submitted to the Steering Committee for the identification of additional individuals interested in becoming a member of the writing group for that paper. Members of the Steering Committee will have one week to identify individuals who wish to contribute to the production of a paper. The Coordinating Center will review the abstract for accuracy and the appropriate application of statistical methods and provide feedback to the author within one week of receipt of the abstract. Accurate abstracts will be forwarded, along with the identified writing group, to the P & P for review within four days of receipt; abstracts that require revision will be returned to the author for appropriate changes and will be forwarded to the P & P Committee, along with the identified writing group, once those changes have been made. P & P Committee members will have one week to respond. Responses should be sent to the Coordinating Center, and will be forwarded to the chairperson of the P&P for further action. The chairperson will communicate the decision of the P& P Committee to the applicant within one working day of receiving these materials.

   For approved papers, a time frame for the completion of the paper will be established in consultation with the originating author. Progress on approved manuscripts will be monitored by the P & P through the Coordinating Center, and will be reported to the Steering Committee on a quarterly basis. Completed papers will be reviewed by the Coordinating Center and two individuals assigned by the P & P Committee Chair within three weeks of submission. The purpose of the review will be to assess the appropriateness of analytic methods used, the validity of conclusions reported, and to monitor the consistency of findings reported across manuscripts.

3. Major outcome papers. Topics for major papers will be identified by the Steering Committee. The P & P Committee will be responsible for coordinating and monitoring these manuscripts.

Individuals at each site will identify paper preferences. An individual may select two preferences from each of the major paper categories (nondata conceptual/review papers, baseline papers, outcome papers). The list of preferred papers from each site will be compiled and sent as one packet to the Coordinating Center.

The Coordinating Center will generate a master list of the major paper topics and individual preferences. The P & P Committee will review the master list and define writing groups. The Committee will take into account REACH II publications already in progress.

The writing groups will identify an originating author and make this recommendation to the P & P Committee. The P & P Committee will submit their recommendations regarding originating author/ writing group for each paper to the Steering Committee. The Steering Committee will vote on these recommendations taking into account factors such as the distribution of papers across sites and the ability of individuals to follow through on assigned papers.

Once an originating author and writing group has been designated, the originating author, in collaboration with the writing group, will be responsible for developing a detailed, one page description and hypotheses for the assigned manuscript.

The P & P Committee will monitor the progress of all papers. If there is a problem, the P & P Committee will report this to the Steering Committee. The Steering Committee will make the final decision regarding whether an originating author needs to be replaced.

The originating author, in collaboration with the writing group, will be responsible for designating order of authorship. Only if problems arise will this issue go to the Steering Committee for resolution.

Individuals who wish to be active in additional writing groups may do so as long as they have completed (up to the point of submission) the papers that they originally committed to.

During the process of paper writing, individuals should be open to the possibility that authors will be joining and leaving writing groups. In addition, a paper may unfold into several papers and additional writing groups/originating authors will need to be identified. The goal is to establish a sense of openness and flexibility.

As papers are being developed, the originating author/working group may notice that they are moving away from the original focus of the paper and into other territory. In these instances, the originating author must alert the P & P Committee Chair early in the writing process so that the new paper developments can be cross referenced with other REACH II papers. This will ensure that any conflicts are resolved before the final draft is completed.

Responsibilities of the Coordinating Center

The Coordinating Center will:

1. Carry out all data analyses involving data collected and stored at the Coordinating Center. This will be done in order of priority determined by the Steering Committee.

2. Review all manuscripts and abstracts for accuracy and the appropriate application of statistical methods, and provide timely feedback to authors; disagreements between authors and the Coordinating Center will be referred to the P & P Committee for resolution; the P& P Committee may solicit consultation from appropriate experts to resolve such conflicts.

3. Keep an up-to-date list of manuscripts and abstracts developed as part of REACH II and report to the Steering Committee on the status and progress of all approved manuscripts and abstracts on a quarterly basis.

4. Archive the data, within one year of the completion of the study, for use by investigators outside of REACH II.

Acknowledgments

All papers will indicate support from the NIH as part of the REACH II project. The P& P Committee will develop appropriate citation language and text citing each of the participating sites.

REACH II Publications & Presentations Proposal Form

This form should be completed and attached to all proposals submitted to the REACH Publications & Presentations (P&P) Committee.

Today's Date: _____ **Requested Approval Date:** _____

Originating Author:_____ **Site:** _____

1. Complete the following items if the proposal is a <u>Journal Publication, Book Chapter, or Book</u>.

Check one: **Journal Publication**_____ **Book Chapter**_____ **Book** _____

Title: _____

_____

Targeted Journal(s): _____

_____

Initial Draft Deadline: _____

Final Draft Deadline: _____

2. Complete the following items if the proposal is an <u>Abstract for Presentation</u>.

Title: _____

_____

Submission Date: _____

Meeting/Location/Date of Presentation (if known):_____

_____

Data Required to Complete Request

Data Set(s) (check all that apply)	Core Time Points (circle all that apply)	
Standard Baseline and Follow-up Core Battery		
___Screening	Baseline	6-Month
___Mini-Mental State Exam	Baseline	6-Month
___Screening	Baseline	6-Month
___Personal Appearance	Baseline	6-Month
___Sociodemographic (CG & CR)	Baseline	6-Month
___ADL/IADL	Baseline	6-Month
___Vigilance	Baseline	6-Month
___Revised Memory and Behavior Problems	Baseline	6-Month
___Burden Interview	Baseline	6-Month
___Formal Care and Services	Baseline	6-Month
___Positive Aspects of Caregiving	Baseline	6-Month
___Desire to Institutionalize	Baseline	6-Month
___Caregiver Health and Health Behaviors	Baseline	6-Month
___CES-D	Baseline	6-Month
___Social Support	Baseline	6-Month
___Religiosity	Baseline	6-Month
___Social Activities	Baseline	6-Month
___Quality of Care	Baseline	6-Month
___Risk Appraisal	Baseline	6-Month
___Medications (CG & CR)	Baseline	6-Month
___Project Evaluation		6-Month
Placement Battery		
___Sociodemographic (CG & CR)		6-Month
___Revised Memory and Behavior Problems		6-Month
___Placement Burden Interview		6-Month
___Formal Care and Services		6-Month
___Caregiver Health and Health Behaviors		6-Month
___CES-D		6-Month
___Social Support		6-Month
___Religiosity		6-Month
___Social Activities		6-Month
___Placement		6-Month
___Placement Risk Appraisal		6-Month
___Medications (CG)		6-Month
___Project Evaluation		6-Month
Bereavement Battery		
___Sociodemographic (CG & CR)		6-Month
___Formal Care and Services		6-Month
___Caregiver Health and Health Behaviors		6-Month
___CES-D		6-Month
___Social Support		6-Month
___Religiosity		6-Month
___Social Activities		6-Month
___Bereavement		6-Month
___Bereavement Risk Appraisal		6-Month
___Medications (CG)		6-Month
___Project Evaluation		6-Month
Discontinued Battery		
___Discontinued		6-Month
Caregiver Delivery		
___Caregiver Implementation		
___Caregiver Delivery Assessment		

Resources for Enhancing Alzheimer's Caregiver Health II

Site Visit Guide

Site Visitor' Name: _____

Date of Site Visit: _____

REACH II Site: _____

NOTE: Prior to site visit, examine data for interview differences

OPENING REMARKS AND INTRODUCTIONS

Introduction of REACH II Site Visit Team.

Introduction of REACH II Site Personnel.

Name	Position	Percent Support	Percent Effort

Have there been changes in personnel since the last site visit? If so, what changes have been made?

General comments.

TOUR OF FACILITIES

Examine the location/security of the data entry computer.

Examine the location/security of the participant records.

ADMINISTRATIVE REVIEW

How are subjects identified?

What changes have been made to the recruitment strategies?

Has any type of promotion been done for recruitment? If so, please describe.

Who is the contact person for potential study participants and how is this person contacted?

How many sites exist where potential study participants can be screened (list the sites)?

How many Re-screens have you had in the last three months?

How far in advance are subjects contacted to schedule follow-up visits?

Does the same interviewer perform all of the interviews (baseline and follow-up) for a given participant?

How many people have dropped out of the study?

Why have these people dropped out of the study?

What is done to keep participants involved in the study?

How are interviewers notified of changes in the Q by Q's?

General comments.

REVIEW OF FILING SYSTEM AND CERTIFICATION

Are all of the interviewers certified? (List certified and non-certified interviewers)

Are all of the data entry personnel certified? (List certified and non-certified data entry personnel)

Is the data manager certified?

Does the interviewer administering the core battery also administer the MMSE? If not, is the person administering the MMSE certified?

Review filing system for correspondence and memos.

Examine the filing system for data collection forms and consent forms.

Examine forms to make sure that they are the most recent versions.

Examine the historical events file.

Examine Q by Q's to make sure that they are the most recent versions.

General comments.

REVIEW OF INTERVIEWING PROCEDURES

Have an interview performed on a member of the site visit team or have the site visitor monitor an interview of a REACH participant.

Identify all currently active interviewers date of certification

Preparedness

Did the interview have all of the necessary materials on hand and readily available during the interview?

Was the interviewer able to answer any questions asked by the respondent regarding the study, site location, funding agency, etc.?

Did the interviewer appear well practiced and confident?

Did the interview appear to flow well?

Professionalism

Did the interviewer speak clearly?

Was the interviewer polite?

Did it appear that sufficient rapport was established between interviewer and respondent?

Were eye contact and personal space norms maintained?

Did the interviewer handle interruptions and/or other unexpected occurrences professionally?

At any time, did it appear that the interview introduced bias into the responses?

Compliance with Instructions
Did the interviewer read the question in the correct order?

Were the questions read exactly as printed?

Were the response options read (or not read) when appropriate?

Were response cards used when required?

Were optional response cards used appropriately?

Were the skip patterns followed correctly?

Were the appropriate probes used?

DATA AUDITS

Examine specific charts and data collection forms. Compare these data to the data in the REACH II database.

Review forms for corrections (no erasures, lines through incorrect data, initials, dates, reasons)

Review Core Quality questionnaires for Principal Investigator's initials.

Review site-specific quality control procedures.

Review the site-specific data management system.

Review computer booting and PoP starting procedures

Review back-up procedures and log.

Review scanning diskettes for viruses.

Examine REACH computer for non-REACH software.

General comments.

REVIEW OF INTERVENTION

Review Problem Tracking forms.

Review Delivery Assessment forms.

Review Intervention Progress forms.

Review personalized prescriptions.

Review documentation of case debriefing in supervision session.

Attend actual or mock intervention or observe video or tape of intervention.

General comments.

SITE VISIT SUMMARY