

Chapter 13

CLINICAL CENTER PROCEDURES

13.1 STAFFING AND ORGANIZATION

Each AREDS Clinical Center is staffed, at a minimum, by

- ! Clinic Director (an ophthalmologist)
- ! Clinic Coordinator
- ! Ophthalmic technician
- ! Photographer.

There may be additional ophthalmologists, designated as co-investigators, additional technicians, and an Assistant Clinic Coordinator who simultaneously functions as an ophthalmic technician. The Clinic Director designates one staff member to serve as Clinic Monitor (Section 13.5).

13.2 FUNCTIONS OF THE CLINIC DIRECTOR

The responsibilities of the Clinic Director, who is an ophthalmologist and the Principal Investigator named on the Clinical Center contract with NEI, are to:

- a. Direct the activities of AREDS personnel in the clinic
- b. Ensure adherence by clinic personnel to the procedures described in and required by the AREDS Manual of Operations
- c. Spend adequate time in the clinic to observe study procedures and to hold regular discussions with staff to review all aspects of the study and resolve any problems that may arise
- d. Represent the clinic at meetings of the Executive Committee and Technical Group
- e. Perform ophthalmologic exams, introduce the study to potential participants, and ensure that the recruitment goal for the clinic is obtained.
- f. Ensure security of sealed envelopes containing the treatment code for each bottle number.

13.3 FUNCTIONS OF THE CLINIC COORDINATOR

The Clinic Coordinator is responsible for supervising day-to-day operations in the clinic and serves as primary contact for the participants in the study and for the Coordinating Center. The duties of the Clinic Coordinator are to:

- a. Ensure that potential AREDS participants receive appropriate written information about the study (e.g., leaflet, booklet), including the Informed Consent statements
- b. Ensure that potential AREDS participants have the opportunity to ask questions about AREDS
- c. Register participants in AREDS
- d. Schedule participant appointments
- e. Prepare for participant visits, ensuring that the equipment needed for examinations is in place and functioning and that clinic personnel are prepared to meet their responsibilities when a participant appears for an appointment
- f. Attend to a participant's comfort at the clinic and minimize a participant's waiting time
- g. Maintain good rapport with each participant
- h. Notify the Coordinating Center of changes or impending changes in the clinic personnel, address, or telephone number(s) of the clinic
- i. Maintain a calendar of participant visits, meetings, and scheduled telephone calls or visits from the Protocol Monitor, etc.
- j. Maintain a file of correspondence with the Coordinating Center
- k. Obtain necessary information about deceased participants (e.g., death certificates) and hospitalizations (e.g., discharge summaries)
- l. Maintain an inventory of supplies needed
- m. Update the AREDS Manual of Operations and Clinical Center Data Management Handbook
- n. Check completed data forms for accuracy and completeness
- o. Prepare required photographs for submission to the Reading Center
- p. Ensure transmission of data to the Coordinating Center

- q. Respond to edit statements (queries) from the Coordinating Center.

Each Clinic Coordinator will be given a copy of the AREDS Clinical Center Data Management Handbook for using the AREDS Interactive Data Entry System.

13.4 FUNCTIONS OF THE OPHTHALMIC TECHNICIAN

The ophthalmic technician performs examinations on all AREDS participants assigned to him or her by the Clinic Director. Ophthalmic technicians must be certified to perform the AREDS procedures (Chapter 9). In some clinics, the Clinic Coordinator also fulfills the functions of the ophthalmic technician.

13.5 FUNCTIONS OF THE CLINIC MONITOR

The Clinic Monitor at each Clinical Center is appointed by the Clinic Director of that center. The Clinic Monitor may be the Clinic Director, another ophthalmologist at the clinic who is certified to treat and examine AREDS participants, the Clinic Coordinator, or another staff member who is thoroughly familiar with the activities and equipment of the clinic and with the AREDS Manual of Operations.

The Clinic Monitor has the following responsibilities:

- a. Monitor clinic activities for conformance to the requirements of the AREDS Manual of Operations. The activities to be monitored include:
 - ! Ensure local IRB approval is obtained and a copy of the 596 form and IRB-approved informed consent statements are mailed to the Coordinating Center and Project Office
 - ! Ensure that personnel performing AREDS procedures are properly trained and certified
 - ! Ensure that equipment used to perform AREDS procedures is calibrated properly (e.g., illumination for visual acuity test)
 - ! Ensure that participants are not unnecessarily inconvenienced or irritated
 - ! Ensure that all data forms are complete and transmitted to the Coordinating Center
 - ! Maintain awareness of data editing problems identified by the Coordinating Center
 - ! Maintain an up-to-date Manual of Operations and Data Management Handbook and inform the local IRB of important changes

- ! Participate in regularly scheduled telephone calls (Protocol Review Calls) with the Protocol Monitor (Section 12.5.2)
 - ! Meet with the Protocol Monitor during Protocol Review Visits at the Clinical Center (Section 12.5.3).
- b. Report irregularities or problems that can affect the quality of the data collected to the Clinic Director and the Protocol Monitor (Section 12.4).

13.6 RECRUITMENT

As described in Section 12.2, each Clinical Center will develop a written plan for meeting the recruitment goals and requirements of AREDS. Specifically, each funded Clinical Center is required to enroll 100 participants from AMD Category 1, 100 from Category 2, and 260 from Categories 3 and 4. The goal is to enroll 130 participants each in Categories 3 and 4. Recruitment techniques may include:

- ! Use of AREDS Participant Leaflet
- ! Use of AREDS Physician Leaflet
- ! Advertisements in community publications
- ! Letter to referring ophthalmologists
- ! Presentations at local ophthalmologic society meetings

13.7 ELIGIBILITY SCREENING

If a participant appears to be eligible, the following steps should be taken:

1. The plan of the study, as outlined in the Participant Information Booklet (Appendix B) should be reviewed with the participant, and any questions by the participant should be answered.
2. The participant should be asked to sign the Initial Informed Consent statement (Appendix B) for the run-in period.
3. If the participant signs the consent form, the Qualifying Visit information should be entered into the AREDS Interactive Data Entry System and a registration number will be assigned by the computer, and the participant should be asked to complete the Food Frequency Questionnaire while at the clinic.
4. Based on the participant schedule generated by the AREDS Interactive Data Entry System, the participant should be informed that if he or she appears to be eligible following a review of the photographs by the Reading Center, he or she will be asked to return to the clinic within the next 4 months for final eligibility evaluation (an ideal date is between 1 and 3 months). The participant should be given a 1-month supply of the Trial Medication, instructions for using the Trial Medication, a postcard

to mail to the clinic when the participant stops taking the Trial Medication, and an AREDS medication bag (Chapter 6).

5. If, following the Reading Center evaluation, the participant appears eligible, he or she will be asked to return to the clinic for the Randomization Visit. He or she should be asked to place all the medications currently being taken and the bottles of Trial Medication in the AREDS medication bag and to bring the bag to the clinic.

If the participant is not eligible based on the evaluation of the photographs by the Reading Center, he or she should be telephoned or brought to the clinic and the reasons for ineligibility should be discussed. The Trial Medication bottles should be retrieved from the participant.

6. Participants who return to the clinic for the Randomization Visit and who satisfy the eligibility criteria should be asked to sign the Randomization Informed Consent statement (Appendix B). If the participant signs the consent statement he or she will be randomized by entering the information into the AREDS Interactive Data Entry System. A bottle number and sequence number will be assigned by the computer. The participant should be given a sufficient supply of the AREDS medication identified with the assigned bottle number. A followup appointment to return to the clinic in 6 months should be scheduled using the participant schedule generated by the AREDS Interactive Data Entry System.

Once a participant has been assigned a registration number, the number remains associated with the participant throughout the study and will not be reassigned.

13.8 SCHEDULING PARTICIPANT APPOINTMENTS

After a participant has been randomized, the AREDS Interactive Data Entry System will generate a schedule for followup visits for the duration of Phase II of the study. The Participant Schedule specifies the target appointment dates and the maximum and minimum dates (time windows) for each scheduled visit. When scheduling appointments during Phase II, the various time windows must be kept in mind. Efforts should be made to avoid missed visits and to keep scheduled visits as close to the target date as possible. This is the responsibility of the Clinic Coordinator.

13.9 CHECKING COMPLETED FORMS

Before transmitting data to the Coordinating Center, the Clinic Coordinator should carefully check all data for completeness and consistency. Some checking will be made automatically as data are entered. Further edits will be made by the Coordinating Center following transmission. When necessary, error reports will be generated by the Coordinating Center and transmitted to the Clinical Center for resolution.

13.10 TRANSFERRING PARTICIPANTS

When an AREDS participant moves from one AREDS clinic area to another, the two Clinic Coordinators should cooperate with the participant in arranging a transfer between the two clinics. When the transfer has been arranged, the Coordinating Center should be notified, and the participant's AREDS computer records will be transferred from the first clinic to the second (AREDS Clinical Center Data Management Handbook). After the computer records have been transferred, the new clinic will be responsible for continued followup.

If an AREDS participant is moving to an area that is not near a Clinical Center, staff should encourage the participant to return to one of the AREDS Clinical Centers for scheduled visits every 6 months. Maintaining participant contact is important, and every effort should be made to obtain followup data on participants who are no longer under the care of their original clinic.

13.11 PREPARING FOR THE PARTICIPANT VISIT

Before a participant appears for a visit, the Clinic Coordinator should:

- ! Call the participant to remind him or her of the appointment and to bring back all of the bottles of study tablets and other medications or supplements being taken.
- ! Retrieve the participant's file.
- ! Record the participant's name code and registration number on all forms and worksheets to be completed during the visit
- ! If a Nonannual or first Annual visit, generate the Change in Visual Acuity Worksheet
- ! Be prepared to welcome the participant and inform him or her of what is going to happen
- ! Ensure that all equipment is in place and functioning
- ! Check that clinic personnel are prepared to complete their responsibilities.

13.12 THE ROLE OF CLINICAL FELLOWS AND AREDS OPHTHALMOLOGISTS IN THE RECRUITMENT AND FOLLOWUP OF AREDS PARTICIPANTS

During the screening phase of AREDS, clinical fellows may perform examinations to assess a potential participant's eligibility. Once the study visits begin, it becomes more critical that the AREDS ophthalmologist sees the participants. If the study ophthalmologist is personally motivated to take the time to see the participant, talk to the participant, and answer any questions concerning

the study, the participant is more likely to understand that he or she is a partner in the long-term study. Although AREDS ophthalmologists may change during the course of the study, it is certain that the fellows will only be in the clinic for a relatively short period of time during the followup period.