

Chapter 9

CERTIFICATION OF STAFF AND CLINICS

9.1 INTRODUCTION

This chapter describes the AREDS activities which require certification and the procedures for obtaining certification.

9.1.1 Activities Requiring Certification

Exhibit 9-1 shows AREDS activities for which training and certification are required and the personnel categories eligible to conduct each activity.

There are three levels of certification for refraction and visual acuity measurement: (1) preliminary, (2) provisional, and (3) full. Personnel must receive preliminary certification to be eligible for provisional certification, and provisional certification to be eligible for full certification. The AREDS Training and Certification Committee (Appendix A) designates and authorizes AREDS certifiers to issue provisional and full certification.

Examiners must be at least provisionally certified before they are authorized to examine AREDS participants.

Two levels of certification are required to use the AREDS Interactive Data Entry System, and to perform photography and all other measurements: (1) provisional certification and (2) full certification. Personnel must receive provisional certification to be eligible for full certification.

A certification number is issued by the Coordinating Center when provisional certification has been achieved in an activity. This number must be recorded on AREDS worksheets and data forms and is used to document that a procedure was performed by certified personnel. The number identifies the user so that the AREDS Interactive Data Entry System may be accessed. A summary of a person's certification status in each activity (Exhibit 9-2) will be mailed to the person before the study begins and will be updated periodically thereafter.

9.1.2 Obtaining and Maintaining Certification

The Clinic Coordinator should notify the Coordinating Center when a staff member of the Clinical Center wishes to begin the certification process. The remainder of this section applies to activities other than photography (Section 9.6 for certification of photographers).

Preliminary certification is valid for the duration of AREDS. Provisional certification in all study procedures is valid for 1 year or until the next Site Visit if the Site Visit occurs more than 12 months after achievement of provisional certification. Full certification is automatically renewed for one year each January 1, based on evidence that the certified activity has been performed by the staff member at least three times during the past calendar year. Persons for whom the Coordinating Center lacks evidence that the minimum frequency requirement has been satisfied will be notified by the Protocol Monitor that their certification has lapsed.

Staff persons for whom the Coordinating Center lacks evidence that they have completed the required minimum number of procedures, and who wish to maintain full certification in an activity, will need to provide evidence on the Certification Maintenance Worksheet that they have performed the required minimum number of procedures before the year is up in order to maintain full certification. Persons who have already completed the required minimum number of procedures, as evidenced by Coordinating Center information, will need only to so indicate on the AREDS Certification Maintenance Worksheet.

To satisfy the maintenance requirement for AREDS examinations, the examinations need not be performed on AREDS participants. However, if they are performed on non-AREDS participants, the examiner must complete and keep on file the appropriate portion of an AREDS worksheet and identify the non-AREDS participant on the Certification Maintenance Worksheet.

To maintain certification, Clinical Center personnel must comply with the foregoing requirements and with the requirements that are specified for each task in Sections 9.1 through 9.5. Persons who allow their certification to lapse, and subsequently wish to regain full certification, will need to be observed by an AREDS certifier satisfactorily performing those activities.

9.2 CERTIFICATION FOR REFRACTION AND VISUAL ACUITY

Certification is awarded separately for refraction and visual acuity.

9.2.1 Preliminary Certification

After reading relevant materials in the Manual of Operations, persons seeking preliminary certification must attend the central training session held before the study begins or participate in a review and training session with a fully certified examiner at the Clinical Center, which includes witnessing an actual refraction and visual acuity testing on two eyes. This exercise may be performed on the fully certified examiner or another individual. Upon satisfactory completion of this session, the technician receives preliminary certification. Preliminary certification is required to insure adequate training and familiarity with the study prior to applying for provisional certification.

9.2.2 Provisional Certification

A candidate for certification who has been certified previously in the Early Treatment Diabetic Retinopathy Study, or in similar trials for refraction and visual acuity testing, may qualify

for provisional certification after completion of: (1) a brief telephone discussion of the protocol with the Protocol Monitor and (2) demonstration of satisfactory technique to a fully certified examiner. If such certification has not been achieved previously, a simulated refraction and visual acuity testing procedure will be conducted by telephone. Satisfactory performance resulting in provisional certification permits the technician to examine AREDS participants.

Ophthalmologists and optometrists may be certified, through a modified procedure, to perform visual acuity examinations. Two completed AREDS Visual Acuity Worksheets (Appendix C) should be submitted to the Protocol Monitor at the Coordinating Center, who will submit the worksheets to a member of the Training and Certification Committee. The candidate will be provisionally certified following a review by telephone of the details of visual testing with the committee member. Full certification will take place at a subsequent site visit.

9.2.3 Full Certification

Examiners achieving provisional certification will be issued full certification by an AREDS certifier after satisfactorily completing a performance test observed by the certifier. This test consists of examining at least two eyes of one or two participants.

9.2.4 Decertification

Decertification may be necessary for a provisionally or fully certified technician who performs in a substandard manner. Substandard performance may be determined on the basis of (a) review of forms submitted, (b) observation of performance during site visits, or (c) recommendation of the Clinic Director at the technician's Clinical Center. Decertification must be implemented by a member of the Training and Certification Committee. The member of that committee must follow these procedures:

- (1) Prepare a letter of decertification containing:
 - (a) Name of technician.
 - (b) Date that decertification is effective.
 - (c) Clear statement of reasons for decertification.
 - (d) Specific tests for which decertification is applicable. (For example, a fully certified technician may be decertified in refraction but maintain certification for visual acuity testing.)
 - (e) Recommendations for retraining and resubmission of forms for renewing the provisional certification.
- (2) Send the letter to the Clinic Director and Clinic Monitor.

- (3) Contact the Clinic Director and Clinic Monitor by telephone to review the letter of decertification before sending the letter to the Coordinating Center.
- (4) Send a copy of the letter to the Coordinating Center.

9.3 CERTIFICATION FOR OTHER MEASUREMENTS

9.3.1 Height, Weight, IOP, Blood Pressure, Food Frequency Questionnaire, Interview Techniques

Clinical personnel applying for certification to measure height and weight, IOP, and blood pressure, and to administer the Food Frequency Questionnaire will be asked to read the relevant information in the Manual of Operations and to participate in a 15-minute presentation by an AREDS certifier on the topic of certification, either in person or on the telephone. Following the presentation, the applicant will be considered provisionally certified. Examiners who have achieved provisional certification will be issued full certification by an AREDS certifier once they have satisfactorily completed a performance test observed by the certifier and involving the examination of at least two persons.

9.3.2 Blood Specimens

Hematocrit testing must be performed by certified facilities. Clinical Centers participating in the additional blood specimens studies will be certified according to the procedures outlined in Chapter 18.

9.4 CERTIFICATION FOR USING AREDS INTERACTIVE DATA ENTRY SYSTEM

The AREDS Interactive Data Entry System may be used only by personnel authorized by the Coordinating Center. There are three levels of authorized users: System Administrators, Full-Rights Users, and Limited-Rights Users. Initially, the Coordinating Center assigns each Clinical Center and the Reading Center two user names and passwords--one for a System Administrator and one for a Full-Rights User that allows access to the AREDS Interactive Data Entry System's training version.

The Clinic Coordinator is the designated System Administrator at the Clinical Center and is responsible for maintaining the system, creating users and granting full or limited rights once the individual has attained full certification from the Coordinating Center, maintaining certification numbers, and passwords, deleting users, and transferring participant data to another AREDS clinic. Entering the System Administrator's user name and password allows access to only the system administration functions.

Entering the name and password of Full-Rights User allows complete access to data entry and communications functions, but not to system administration functions.

Users who have been assigned limited rights may view data and generate and print existing reports but may not make changes in the database, initiate communications, or create backup data files. Exhibit 9-3 summarizes the rights granted to each user.

9.4.1 Provisional Certification of System Administrator, Full-Rights and Limited-Rights User

Clinic Coordinators who attend the Phase I orientation and training session at the Coordinating Center before the study begins will be considered provisionally certified as System Administrators and Full-Rights Users. Other AREDS personnel attending this session also will be granted provisional certification as Full or Limited-Rights Users. Training and assigning user rights for these individuals will proceed as deemed appropriate by the System Administrator.

To achieve provisional certification as a System Administrator (Clinic Coordinators only) or Full or Limited-Rights User after the study begins, candidates must read the AREDS Data Management Handbook and demonstrate to a fully certified System Administrator or the Database Administrator at the Coordinating Center a working knowledge of the Interactive Data System. The Database Administrator at the Coordinating Center should be notified that the individual has completed the above requirements and is prepared to attain full certification.

9.4.2 Full Certification of System Administrator and Full-Rights User

During Phase I, all AREDS personnel who have attained provisional certification for using the AREDS Interactive Data Entry System will be granted full certification following successful transmission to the Coordinating Center of the data entered and processed for the training practicum in the Phase I Data Management Handbook. When all clinics have transmitted training practicum data for at least two staff members, preferably the Clinic Coordinator and the Assistant Coordinator, all subsequent data from a training session will be copied to a diskette and mailed to the Coordinating Center. The data will be reviewed for accuracy and appropriateness by the Database Administrator and the candidate will be notified if any further demonstrations are required or if full certification is granted.

During Phase II, all AREDS personnel who have attained provisional certification for using the AREDS Interactive Data Entry System will be granted full certification following successful completion of the training session in the Training option of the AREDS Data System. Training data existing in this option can be modified or new data can be added to it as suggested in Appendix B of the Phase II Data Management Handbook. When the candidate for full certification is well practiced in Phase II training, the existing data are copied to a diskette and sent to the Database Administrator of the Coordinating Center. The data will be reviewed for accuracy and appropriateness by the Database Administrator and the candidate will be notified if any further demonstrations are required or if full certification is granted.

During Phase I and II the System Administrator will be granted full certification following an interview with the Database Administrator at the Coordinating Center in which knowledge of the responsibilities of the System Administrator are satisfactorily demonstrated.

9.4.3 Provisional and Full Certification of Limited-Rights User

Limited-Rights Users may be provisionally or fully certified by a fully certified System Administrator. Following a satisfactory demonstration of the individual's ability to correctly access the system and generate and print reports, the fully certified System Administrator can grant full certification for limited rights by notifying the Database Administrator at the Coordinating Center.

9.5 CERTIFICATION FOR RANDOMIZATION

Only Clinic Coordinators, Assistant Clinic Coordinators, and participating ophthalmologists may apply for randomization certification. Prior to applying the candidate must have received full certification as a Full-Rights User of the AREDS Interactive Data Entry System (Section 9.4). To achieve provisional certification for randomization, the candidate must have a thorough knowledge of the AREDS eligibility criteria and procedures for randomization, database backup, and handling anomalies that could occur during the randomization process. Verification of familiarity with these procedures and subsequent granting of provisional certification must be obtained by calling the Database Administrator at the Coordinating Center for an interview. To obtain full certification, a candidate must randomize three participants using the training version of the data system and mail a diskette and supporting forms to the Database Administrator at the Coordinating Center. The data will be reviewed for accuracy, and the candidate will be notified by the Database Administrator if any further testing is required or if full certification has been granted.

9.6 CERTIFICATION OF PHOTOGRAPHERS

The AREDS Photograph Reading Center conducts a program to certify photographers and monitor the quality of their work. Certification status is established separately for fundus and lens photographs (the latter category includes both slit lamp and Neitz retro-illuminated photographs).

During Phase II photographers must be at least provisionally certified before taking official photographs of AREDS participants. Photographers who became certified on the basis of photographs taken during Phase I are automatically certified for photography in Phase II. If a photographer received provisional certification during Phase I through nomination by the Clinical Center Clinic Director but took no photographs during that period, provisional certification must be renewed for Phase II by submitting the sample photographs of non-study participants specified below.

Photographers joining the study are required to submit fundus photographs and/or lens photographs of four eyes of non-study participants, and will be provisionally certified for that type of photography if all of these are of at least fair quality. The eyes selected for fundus certification should allow reasonably clear visualization of retinal features. The eyes selected for lens certification should have lens opacities ranging from mild to extensive, with at least one eye having posterior subcapsular opacities and one having moderate to severe nuclear cataract.

Once photographers are provisionally certified, their work will be monitored in detail at the Reading Center. Photographers whose photographs of the fundus and/or lens are consistently of

good quality (overall grade of fair or better for at least 75% of a series of 20 or more eyes) will be "fully certified." At that stage, both the Reading Center and the photographer can abbreviate their evaluation of photographic quality for that type, although the photographer should continue to monitor his/her work. The Reading Center notifies the photographer and the Coordinating Center Protocol Monitor of changes in photographer certification.

If photographic quality for a fully certified photographer falls below this criterion, certification will revert to provisional. Such photographers will be monitored closely and appropriate suggestions will be made for improvement (see Section 8.4). If a photographer has problems that cannot be resolved in a reasonable period of time, a special site visit by a consulting AREDS photographer may be made to determine the nature of the problems and to identify possible solutions. If this proves to be ineffective, certification for AREDS photography will be revoked.

9.7 EXAMINATION BY NON-CERTIFIED PERSONNEL

When an AREDS participant is scheduled for a study visit but, unexpectedly, no certified personnel are available to perform a task, then personnel familiar with the proper performance of the activity, but not certified, are permitted to perform the task. For example, fellows may perform the retinal examination if the Clinic Director or a Co-Investigator is unexpectedly absent. Other tasks that may be performed by uncertified personnel in an emergency are lens/fundus photography, refraction, visual acuity, IOP measurement, height and weight, blood pressure, Baseline Interview, and Food Frequency Questionnaires administration. Under no circumstances should procedures relating to blood drawing/processing for the Central Laboratory, or use of the distributed data entry system be performed by uncertified personnel.

If an uncertified person performs a task, a certification number consisting of the clinic number, e.g., 51, 52, etc followed by 99 should be entered on all relevant forms and worksheets. The use of uncertified personnel is closely monitored by the Coordinating Center to assure that it occurs only rarely.

**Exhibit 9-1. AREDS ACTIVITIES FOR WHICH TRAINING AND CERTIFICATION
ARE REQUIRED AND PERSONNEL CATEGORIES ELIGIBLE
FOR CERTIFICATION**

CC = Clinic Coordinator. **ACC** = Assistant Clinic Coordinator. **T** = Technician.
O = Ophthalmologist. **P** = Photographer.

| Activity | Personnel category |
|-------------------------------------|---------------------------|
| Refraction | CC, ACC, T, P, O |
| Visual acuity measurement | CC, ACC, T, P, O |
| Height and weight | CC, ACC, T, P, O |
| IOP | CC, ACC, T, P, O |
| Blood pressure measurement | CC, ACC, T, P, O |
| Blood specimens | CC, ACC, T, P, O |
| Food frequency questionnaire | CC, ACC, T, P, O |
| Interviewing techniques | CC, ACC, T, P, O |
| AREDS Interactive Data Entry System | CC, ACC, T, P, O |
| Randomization | CC, ACC, O |
| Photography | P |

Exhibit 9-2. AGE-RELATED EYE DISEASE STUDY CERTIFICATION SUMMARY

PERSON CERTIFIED

CERTIFICATION NUMBER

AREDS CLINIC

| CERTIFICATION | DATE CERTIFIED | CERTIFIER |
|---------------|----------------|-----------|
|---------------|----------------|-----------|

REFRACTION:

| | | |
|-------------|-------|-------|
| PRELIMINARY | _____ | _____ |
| PROVISIONAL | _____ | _____ |
| FULL | _____ | _____ |

VISUAL ACUITY MEASUREMENT:

| | | |
|-------------|-------|-------|
| PRELIMINARY | _____ | _____ |
| PROVISIONAL | _____ | _____ |
| FULL | _____ | _____ |

HEIGHT AND WEIGHT:

| | | |
|-------------|-------|-------|
| PROVISIONAL | _____ | _____ |
| FULL | _____ | _____ |

IOP:

| | | |
|-------------|-------|-------|
| PROVISIONAL | _____ | _____ |
| FULL | _____ | _____ |

BLOOD PRESSURE MEASUREMENT:

| | | |
|-------------|-------|-------|
| PROVISIONAL | _____ | _____ |
| FULL | _____ | _____ |

BLOOD SPECIMENS:

| | | |
|-------------|-------|-------|
| PROVISIONAL | _____ | _____ |
| FULL | _____ | _____ |

**Exhibit 9-2. (Continued) AGE-RELATED EYE DISEASE STUDY
CERTIFICATION SUMMARY**

CERTIFICATION NUMBER

| CERTIFICATION | DATE CERTIFIED | CERTIFIER |
|---------------|----------------|-----------|
|---------------|----------------|-----------|

FOOD FREQUENCY QUESTIONNAIRE:

PROVISIONAL _____

FULL _____

INTERVIEW TECHNIQUES:

PROVISIONAL _____

FULL _____

SYSTEM ADMINISTRATOR FUNCTIONS:

INTERACTIVE DATA ENTRY:

PROVISIONAL _____

FULL _____

RANDOMIZATION:

PROVISIONAL _____

FULL _____

PHOTOGRAPHY:

PROVISIONAL _____

FULL _____

Coordinating Center Protocol Monitor

Date

Exhibit 9-3. AREDS USERS' RIGHTS

| | <u>System Administrator</u> | <u>Full-Rights User</u> | <u>Limited-Rights User</u> |
|---|---------------------------------|-------------------------|----------------------------|
| Add and delete users | √ | | |
| Assign certification numbers | √ | | |
| Grant user rights | √ | | |
| Transfer participant data to/from AREDS facility | √ | | |
| Randomize participants | | √ | |
| Add, modify, delete data | | √ | |
| Initiate communications | | √ | |
| Backup data files | | √ | |
| Force out-of-range values | | √ | |
| Generate new reports | | √ | √ |
| View data | | √ | √ |
| View edit/error reports and other existing reports | | √ | √ |
| Generate and print: | | | |
| Activity Calendar | | √ | √ |
| Participant Information | | √ | √ |
| Participant Appointment Schedule | | √ | √ |
| Access WordPerfect | | √ | √ |