

Incidence of Macular Degeneration in Older Women

**Clinical Examination
Manual of Procedures**

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1.1 OVERVIEW

Age-related macular degeneration is the number one cause of irreversible blindness in the United States and is more prevalent in older, Caucasian women. Although there have been several studies on the incidence of ARM, none of these studies has been able to provide accurate estimates on the incidence of late ARM and/or the progression of ARM in the oldest old, those individuals over 80 years of age, because of the limited sample sizes in these studies in this age group. The population in the Study of Osteoporotic Fractures (SOF) is an appropriate cohort in which to evaluate the incidence of late ARM and progression of ARM, because the mean age of the women at the re-examination will be 84.4 years of age and the sample is mainly Caucasian. The proposed research study aims to determine the incidence of late ARM, the rate of progression of ARM, and the association of specific risk factors such as diabetes mellitus and prior cataract surgery with late ARM and the progression of ARM in elderly women. In addition, it aims to determine the impact of late ARM on vision-targeted health-related quality of life and to determine whether or not an association exists between the progression of ARM and the risk of falling and hip/non-spine fractures. In 1997 to 1998 (Visit 6), 5,482 women had an eye examination that consisted of a medical and ocular history, nine questions from the National Eye Institute Visual Function Questionnaire (NEI-VFQ), and measurements of visual acuity, contrast sensitivity, peripheral vision and imaging of their lenses and fundi of both eyes through dilated pupils. Approximately 4.5% of these women have photographically validated late ARM, 41.5% have early ARM, and 54% have no ARM or hard drusen only. In the proposed re-examination, we will update their medical and ocular history and ask them the nine questions from the NEI-VFQ. In addition, visual acuity and contrast sensitivity will be re-measured. Fundus photographs of both eyes through dilated pupils will be obtained. These photographs and the relevant photographs from 1997 to 1998 will be graded for ARM with the Wisconsin Age-Related Maculopathy Grading System (WARMGS) *in a masked fashion so that the readers do not know which film is from which visit. The University of Wisconsin will also grade the fundus photographs on 30% of the eyes with ARM and 10% of the total sample.* This will allow the identification of women in SOF who have had progression of their ARM and developed late ARM since 1997 and 1998.

The Incidence of Macular Degeneration in Older Women Study will consist of an interview and a detailed examination. During the interview we will ask participants if they have any chronic eye diseases. We will also ask them about previous eye surgeries for the treatment of glaucoma, macular degeneration or cataracts, use of systemic or topical medications, and five questions about their visual functioning.

The eye examination will consist of measurements of visual acuity using Bailey-Lovie targets with habitual correction, contrast sensitivity testing, autorefraction, and measurement of intraocular pressure. After dilation, photographs of the fundi will be taken. All of these data will be used to determine the incidence of macular degeneration in older women.

All film from fundus photography will be forwarded weekly to the Senior Photographer, Colleen Gillis, who will have the film developed and will monitor data quality. The UCLA Reading Center will establish a photographic archive for SOF, from which the incidence of AMD will be assessed.

1.2 ORGANIZATION

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PROCEDURES FOR OCULAR EXAMINATIONS

2.1 INTRODUCTION

The purpose of the eye examination of subjects in SOF-AMD is to determine whether there is evidence of age-related macular disease. During the examination, the examiner will perform visual acuity testing, contrast sensitivity testing, intraocular pressure measurement, and photography after dilation. Photographs of the fundus or back of the eye will be taken using a Canon Non-mydratic camera.

In a large study such as this, there is great opportunity for potential errors to become manifest. This is particularly true when more than one examiner participates in the study. As you are all well aware from previous examinations in the Study of Osteoporotic Fractures and Falls, a patient examination performed as part of a study must be conducted in a different fashion and different frame of mind than a clinical office examination.

A study patient must be examined according to a set procedure that cannot vary from patient to patient or with time. The technique of examination and criteria for filling out the examination forms must be identical for all examiners participating in the study. The protocol must be strictly adhered to and extreme care must be taken in examining the patient. It is recommended that the protocol be reviewed periodically to keep these points fresh in your memory. The protocol is necessarily long in order to maintain consistency and reduce the examiner variability, and to provide a reference guide as you begin to collect data back at your home institutions.

When filling out the forms, please use blue or black ink, and specifically do not use either pencil or red ink. In most instances, data recording involves writing the appropriate code for each item being assessed in the proper box. When errors in the recording are made, do not write over the initial entry, but cross it out and write the new entry above or the side. If an entry becomes too confusing for the coder to understand, make a comment to the side describing the correct entry.

2.1.1 Introduction for Participants

Participants should be told to wear the eyeglasses they usually wear for driving or watching TV (distance activities). If they wear contact lenses and their distance glasses have not been recently changed, they should wear their contact lenses. Participants who have had recent eye surgery should be encouraged to participate in SOF-AMD at least 30 days after their surgery. **Please remind all participants to bring their glasses.**

2.1.2 Backup Examiners

Backup examiners should do the complete exam on at least one subject a week so that he/she maintains his/her skills.

2.2 PATIENT IDENTIFICATION

The examinee's SOF record number, date of birth, date of examination and place of examination will be filled in when the patient is first registered for the eye examination. Make sure that the visit is marked as a home visit or a clinic visit on the Visit 8 Checklist (Page 0 of the clinic visit forms).

In all exams, the right eye will be evaluated first. Prior to beginning the exam, the examiner will determine the status of both eyes by asking the following questions, which are included in depth on the vision interview, ocular history and medication forms (p.2-5):

Vision Interview

1. At present time, would say your eyesight (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor, or are you completely blind?
2. How much of the time do you worry about your eyesight?
3. Are you currently using eye drops in your eye for any reason?
4. Have you ever used eye drops prescribed by a doctor to lower the pressure in your eyes?
5. Have you ever been hit in the eye with a fist or an object?

The next questions are about how much difficulty, if any, you have doing certain activities while wearing your glasses or contact lenses, if you use them for this activity.

6. How much difficulty do you have reading ordinary print in newspapers? Would you say you have:
7. How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say:
8. Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs, in dim light or at night?
9. How much difficulty do you have driving during the daytime in familiar places?
10. Are you limited in how long you can work or do other daily activities such as housework, child care, school, or community activities because of your vision?
11. Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along?
12. Because of your eyesight, how much difficulty do you have finding something on a crowded shelf?

Ocular History

1. Has a doctor ever told you that you had any of the following?
 - a. Cataracts?
 - a1. Cataract extraction (surgery)?
 - a2. Combined cataract/glaucoma surgery?
 - a3. If YES to b or c, during cataract surgery was a new lens placed in your eye?
 - a4. Yag capsulotomy or treatment for 2nd cataract in the same eye?
 - b. Glaucoma?
 - c. Macular degeneration?
 - d. Uveitis (inflammation of the eye)?
 - e. Stroke or hemorrhage of the eyes?
 - f. Diabetes in the eyes?
 - g. Blind eye?
1. Have you ever had eye surgery or laser treatment other than cataract surgery?
 - a. Laser surgery for diabetes?
 - b. Laser surgery for macular degeneration?
 - c. Glaucoma surgery, including laser surgery for glaucoma?
 - d. Retina surgery?
 - e. Corneal graft or transplant?
 - f. Refractive surgery (a procedure that allows you to either not wear glasses, or to wear less powerful ones)?
 - g. Enucleation (removal of eye)?
 - h. Other eye surgery?

Please be sure to return to the Vision Checklist (Page 1 of the forms) and mark your rating of the ocular history and any comments you feel are relevant.

2.2.1 Letter Literary Test May Be Ignored

2.3 BAILEY-LOVIE VISUAL ACUITY TESTING

- a) Illumination: It is important that all of the vision tests be performed in areas of UNIFORM illumination, e.g., no abrupt changes in illumination or shadows when moving a few feet or changing orientation. Diffuse natural light, fluorescent light or a combination of the two is best. The chart luminance test should result in a luminance reading of 50-70 ft-Lamberts (10.4 to 11.0) on the Sekonic Zoom Meter for each of the two tests performed in the office (Home visit uses the VisTech Red-Light-Green-Light meter that is part of the VisTech Kit). The light meter should be used to standardize chart luminance. If natural light levels vary considerably during the day or from day to day you should check luminance levels for each participant. If the luminance levels are stable you may check it once each morning before the first participant. The spatial relation of the targets to the subject should be positioned in such a way as to **minimize glare** on target surfaces. Determine the optimal positioning through trial and error under a range of naturally varying light conditions.
- b) Distance: The test is administered with the participant seated at 10 feet from the target. This distance should be marked on the floor with tape. Measure from the target to the middle of the chair.
- c) Glasses: Acuity is tested with habitual correction for distance vision.

Before testing vision, ask the subject if she normally wears glasses, or contact lenses, or both for distance vision. (probes: "Do you wear glasses to see things far away, like when you go to a movie theater or when you drive a car?") If she answers that she has glasses for distance but sees better without them, distance tests should be performed with glasses on. When scheduling participants for visits, remind them to bring or wear the glasses that they use most often for distance vision. If she wears glasses please identify if she wears distance only or bifocals or no line bifocals (trifocals, progressives, or any multifocal eyeglasses will be marked as "bifocals," or "no line bifocals" on the form [p. 17]).

2.3.1 Visual Acuity (Bailey-Lovie Visual Acuity Charts)

Introduction:

The Bailey-Lovie visual acuity letter charts incorporate the following features:

- a) geometric progression of letter size;
- b) near equal legibility of all letters in the chart;
- c) each row has the same number of letters (5);
- d) between row spacing is equal to the height of the letters in the smaller row;
- e) letter spacing is equal to one letter width.

These features ensure that the visual acuity task is essentially the same for all letter sizes so that the angular size of the letters is the only parameter, which determines the visual acuity score. This combined with letter size progression on a uniform logarithmic scale, allows for acuity testing at optional non-standard distances determined by the progression of letter sizes. We are assessing acuity at the optional distance of 10 feet. The size of the chart is reduced to produce standard scores at this critical viewing distance. (See Bailey IL, Lovie JE. New design principles for visual acuity letter charts. *Am J Optom Physiol Optics* 53(11): 740-745, 1976.)

2.3.2 Equipment

- a) Bailey-Lovie Letter Charts
- b) Occluder
- c) The Sekonic Zoom meter will be used to test illumination in the office (Home Visits will not require checking the lighting for the visual acuity chart because it is a lighted Goodlight box).

Please use the instructions for the Sekonic Zoom meter:

- d) A Pointer

2.3.3 Measurement Procedures

- a) The target should be placed at approximately the eye level of seated subjects. Seat subject on straight-backed chair, 10 feet from the midline of the body to the target. Use a pointer to indicate rows on the chart.
- b) If the participant wears glasses (bifocals or regular glasses) for distance viewing, such as driving, walking or at a theater, test with her glasses on. If she only wears glasses (bifocals or regular) when she reads, test distance vision at 10 feet without glasses. Test contact lens wearers with lenses in. If a participant says that she wears glasses but sees better without them, test **WITH THEM** (her "normal" state).
- c) Ask the subject to hold the occluder so that her left eye's vision is blocked and only the right eye can be tested. Then ask the subject to start reading the letters on the chart starting with the row with the double bar, proceeding down the chart toward the smaller letters. Say:

"I would you to read aloud the letters on this chart." (Read from left to right)

"Don't squint and don't lean forward. Start at the row with the double bar and read down as far as you can and then say 'That's all'."

"Now, can you easily read the row with the double bar?"

If she says yes or reads the row without error then say:

"OK (begin/continue)."

If she says no or reads it with one or more errors, then say:

"How about the top row? Can you read that one?"

If she says no or reads it with error, then test at 5 feet (low vision distance) using the same procedure. Be sure to record that you are testing at 5 feet.

- d) As the subject reads, keep a running tally of the total number of letters missed by drawing a line through the letters read incorrectly.
- e) When it is apparent that the subject is struggling (e.g. misses 2 letters on a row or goes very slowly) then point to the next row and say:

"I want you to try reading the next row even if you just have to guess"?

If she misses 3 letters on any row, stop. If she says "That's all," in the middle of a row, have her guess at the rest of the row (unless she has already missed 3 letters). Draw a line through the first row not attempted.

- f) **REMEMBER TO RECORD THE NUMBER OF LETTERS READ CORRECTLY.** The number next to each line on the score sheet is the number of all the letters from the top row to that row. So, if a subject attempted to read up to the line marked 40, she read a total of 40 letters. Compute the number of letters she read correctly by subtracting the number of letters crossed off from the number on the last line read e.g. 40 - 5 crossed off = 35 correct.
- g) If the subject reads 50 letters correctly at 10 feet, record the actual number of letters that can be read on the form.

For your information: with the Bailey-Lovie chart, the logarithm of minutes of arc (Log MAR) is computed according to the formula $\text{Log MAR} = 1.1 - [(55n).02]$, where n = total letters missed. Snellen fraction equivalents can be obtained from the Log MAR scale along the side of the chart. They can also be obtained directly from the number of errors and the testing distance. You can tell the participants their acuity score in a form they will understand by locating it along the side of the chart.

Rationale for using a non-standard testing distance; Acuity is usually measured at 16 inches for near and 20 feet for distance. However, for this study we are interested in acuity at viewing distances representative of all situations, or mid-distances. Acuity at near may not be representative of acuity at 10 feet, especially in the elderly. Elderly with glasses may be out of focus at near distances. Very restricted pupils could affect acuity differently at different distances, as could light scatter due to cataracts. Reduced focusing flexibility in the elderly could also cause focus error across different distances. These problems are not likely to contribute to any significant differences in the result at 10 feet versus 20 feet. So we could test at 20 feet, but a larger room would be required. So we chose 10 feet.

- (h) If a subject cannot see the chart at 10 feet, you may move the test distance to 5 feet. Please record this on page 17.
- (i) For subjects that cannot see the chart at 5 feet, you need to test their vision with your fingers. Finger counting is tested by holding two or three fingers two feet from the patient and should be recorded as 96. Hand motions is tested by moving a hand back and forth in front of the patient with the other eye occluded. This should be recorded as 97. Light perception is tested by carefully occluding the fellow eye and directing the

light of the penlight at the examinee's eye from about one-foot distance. This should be recorded as 98. No light perception should be recorded as 99 on page 17 in the location where it says number of letters read correctly.

- (j) The subject now holds the occluder so that the vision from the right eye is blocked. Steps c-i are repeated for the left eye. Please note that on form 17, you indicate your findings for the left eye first.

3.1 Contrast Sensitivity

2.40 Before testing confront sensitivity, please note whether subject wear glasses, contact lenses, bifocals, or has implants.

2.4.1 Equipment

VISTECH VCTS 6500 wall chart and the Sekonic L508 Zoom light meter. Mark the right and left hand sides of chart with a large R and L, clearly visible to the participant.

2.4.2 Description

Vision is generally measured by acuity tests that determine the smallest detail that can be seen, such as black letters on a white background. However, our everyday visual world contains objects that have varying levels of contrast (the level of black and white parts of an object and background) and a range of sizes. Those objects must often be seen under visually degraded conditions such as nighttime, fog, or rain. Contrast sensitivity measurements are needed to determine an observer's ability to see a wide range of everyday objects under normal and visually degraded conditions. Because any object can be decomposed into a combination of simple patterns, called sine waves, contrast sensitivity to sine waves provides a generalized measure of visual sensitivity to everyday objects.

The VISTECH contrast sensitivity test system, Model 6500, uses highly controlled photographic and printing techniques to present a series of sine wave gratings at calibrated levels of contrast. In a manner similar to reading the typical acuity chart, the observer simply reports whether or not a grating is visible; and if visible, at what orientation of all grating sizes. At the 10 foot distance, this spatial frequencies tested can be made higher or lower by simply changing viewing distance.

2.4.3 Illumination

The VCTS is designed so that it can accurately measure contrast sensitivity under normal room illumination corresponding to a chart luminance of 50-70 ft-Lamberts. For consistent measurement of contrast sensitivity, luminance must be kept constant from one area of the chart to another, and from one test to the next.

2.4.4 Light Meter Instructions

1. Please use the instructions with the Sekonic Zoom Meter.

2. If your test area has significant natural light, evaluate chart illumination under a variety of naturally varying conditions to determine if additional artificial light will sometimes be needed, especially at different times of day.

Administration

- a. Place chart system in an area where it receives uniform lighting. Shadows or glare on the chart can affect contrast sensitivity measurement. To minimize glare, the chart should not be facing a window or have a window directly behind it. Measure chart luminance to insure lighting conditions are within desirable limits (see Light Meter Instructions). HAVE A POINTER HANDY.
- b. The subject should be seated 10 feet from the chart, with the middle of the chart around eye level. TEST WITH GLASSES ON IF SHE WEARS GLASSES FOR DISTANCE. Mark the appropriate circle on page 6 of the forms packet to describe the subject's glasses.
- c. Tell the subject: "This test measures your contrast sensitivity, or how well you are able to see differences in shades of dark and light. Your ability to see these bars relates to how well you see everyday objects."

Pointing to the upper left hand patch (A1) state, "Can you see the light and dark bars on this patch?" (If "no", point to C1 and ask again. If unable to see the bars on c1, then follow instructions for low vision.) Then point up and down the first column (1). "Each row contains a different size bar pattern."

"The bars will be slanted slightly to the left, slanted slightly to the right, and straight up. Some patches are blank." Use large motions to demonstrate this with your pointer.

"Your task is to read across each row, starting at row A. Patch 1 and call out whether the patch is pointing to the left, right, straight up and down or blank. Some of the patches are very low in contrast and you may not see any bars in these patches. If this is the case, simply answer 'blank'. However, if you do see something in a patch, but you are not sure which direction the bars are pointing, you are allowed to guess."

- d. Scoring: Record the subject's response for each patch in the appropriate place on the scoring sheet by drawing a line through those called out incorrectly. Circle the patch number just before the first incorrect one on each line. This is the score for that line.

Point at each circle. Ask about every circle don't stop. Cross out the first one missed then circle the one just before that. Continue testing on the next row until one circle is missed, then cross that one out and circle the one before that was read correctly. Repeat for every row on the chart. Score each row before going on to the next.

Next, transpose the scores for both eyes from the worksheet to page 9 of the vision forms.

- e. **Low Vision:** If the subject cannot see the bars in patch C1, mark the box for low vision on the scoring sheet and test at 5 feet.

For low vision, a quantitative measure of the subject's visual capability in terms of contrast sensitivity is accurately obtained. The low vision subjects may be moved to 5 feet from the chart. The spatial frequencies change in direct proportion to distance. (for example, at a 5ft. viewing distance, the spatial frequencies become .75, 1.5, 3, 6, and 9 cycles per degree).

2.5 PROCEDURE FOR OBJECTIVE REFRACTION USING THE HUMPHREY AUTOREFRACTOR

Overview:

The Humphrey Automatic Refractor 570 is an automatic instrument that provides a fast, accurate objective refraction in seconds. The Automatic Refractor is easy to use. The operator takes only a few simple steps to align the patient, and then the instrument's auto-tracking mechanism takes over. A single push of the MODE button initiates the refraction cycle and prints the patient's prescription.

2.5.1 Objective Refraction

An objective refraction is a measurement of refractive error that requires no response from the patient. The equipment makes an objective measurement.

An objective refraction may be performed using the READ sequence. READ permits the taking of final acuities and the measurement of a single eye.

- a) Set up the refractor.
 1. If this is the first refraction of the day, remove the dust cover and the lens cover. Turn the refractor on.
 2. If this is not the first refraction of the day, press CLEAR before beginning to refract a new patient.
 3. For every patient, clean the chin and forehead rest areas with an alcohol swab. Remove the top chin paper to expose a fresh one.

- b) Position the subject.
 1. Make sure the subject is seated comfortably with his or her chin and forehead resting firmly in the subject support system. (The subject's glasses should be off for the refraction.)
 2. Use the chin rest knob to raise or lower the chin rest until the subject's eyes are lined up with the silver marker on the forehead rest.

- c) Align the Refractor.
 1. Since you are using READ, press Right Eye (R. EYE), to indicate that the right eye is to be tested first.
 2. Ask the patient to look at the acuity chart while you look at the subject's eye through the viewing window.

3. Use the control ball to position the blinking green alignment light in the middle of the pupil and let go. The Refractor will then make an automatic vertex adjustment for the patient. You should observe that the instrument has positioned the green light between the two yellow lights.
4. Perform an Objective Refraction by pressing READ.
5. Once you have the refraction, then measure visual acuity and enter on the form for the refraction. Participants can only miss one letter in a given row to get credit for that row.
6. When the Refractor has completed its measurement cycle, press PRINT. The print out will show the visual acuity measurements that you arrived at with the patient. Be sure that you are on the row "best" read.
7. Record the refraction on the form for "Autorefractor" (page 10).

To initiate the refraction for the left eye select the left eye, (L. EYE).

Repeat the same procedures, b and c, for the left eye.

Print the information, add the participant's study number and the date, keep the printout with the vision forms, but do not send the print out to the data system.

SCRIPT for AUTOREFRACTOR

"Mrs. _____, I would like you to remove your eyeglasses and place your chin in the chin rest. You will be reading letters from left to right. The machine will try to make your vision sharper in place of your eyeglasses."

If the patient was successful at the 20/30 line, move down to the 20/25 and then to the 20/20 line. Record the results for the right eye.

"Now, we will repeat the test for your left eye."

2.6 PROCEDURE FOR MEASUREMENT OF INTRAOCULAR PRESSURES USING THE MENTOR TONOPEN XL

Overview:

The Mentor Tonopen XL unit is a precision electronic tonometer, which measures intraocular eye pressures (IOP). The Tonopen is easy to use and can measure IOP reliably with minimal training. It is easily portable and versatile. The accuracy of the Tonopen is equal to that of other electronic applanation tonometers. It is highly correlated with Goldmann applanation tonometry and other measurements of intraocular pressure.

Intraocular pressure is measured in both eyes using the Tonopen before the pupils are dilated.

2.6.1 Calibration check

- a) The Tonopen is internally calibrated, thus the instrument calibration should be checked only before the first use each day, after changing batteries, or after depressing the RESET button.
- b) If the previous calibration was good, the LCD (the small window on the Tonopen that displays messages) will briefly display “----” followed by “=====“ and a beep.
- c) If the previous calibration was bad, then a long beep sounds, followed by “CAL” and a short beep. The display will then change to “----” and another short beep will sound.
- d) Hold the Tonometer vertically with the probe tip pointing straight down.
- e) Press and release the activation switch twice in rapid succession. Two beeps will sound and “CAL” will appear on the LCD.
- f) Wait until a beep sounds and “UP” appears.
- g) Quickly turn the Tonopen XL unit so that the probe tip is pointing straight up.
- h) Wait a few seconds. A second beep will sound indicating the end of the calibration check.
- i) Read the output on the LCD. If it says “Good” it was successful, if it says “bAd” it was not and you need to repeat the process.

2.6.2 Patient Preparation

- a) Instill one drop of the Ophthalmic (topical anesthetic) into the lower fornix of the eye to be examined. Avoid contact with lashes or lid margins.
- b) Position the patient in front of a fixation target (any item at eye level at least 3 ft away that the patient can look at with the eye not being tested) to minimize eye movement.

- c) Place a fresh latex Ocufilm cover over the tonometer tip for each patient. It is not necessary to change it between testing the eyes of the same patient, unless a patient has had eye surgery within the past month.

2.6.3 Patient Examination

- a) In order to measure the eye pressure of the right eye, you need to instruct the patient to look at the fixation target with the left eye.
- b) Hold the Tonopen XL as you would a pencil.
- c) Position yourself to facilitate viewing of the probe tip and patient's cornea (the very front of the eye). Central corneal contact is recommended.
- d) Before making contact with the cornea, activate the Tonopen XL unit by depressing the activation switch momentarily, then release.
- e) The LCD will change to "—" and a beep will sound when the Tonopen XL is ready to take a measurement.
- f) Once activated, touch the tip to the cornea lightly and briefly, then withdraw. Repeat several times. The corneal surface needs to be momentarily contacted; indentation is not required and may lead to inaccurate readings.
- g) A click will sound and a digital IOP measurement will be displayed each time a valid reading is obtained.
- h) After four (4) quick valid readings are obtained by the tonopen, a final beep will sound and the averaged measurement will appear on the LCD along with the single bar denoting the amount of statistical error (reliability). 5% or less reliability is required for accurate measurement to be recorded.
- i) If there was 5% or less statistical error, then only two additional average eye pressures should be obtained so that on form page 8, there will be a total of 3 average eye pressure measurements with a statistical error of 5% or less.

If there was greater than 5% statistical error, then take a fourth reading. Record each of the average eye pressures (a total of 4) and its statistical error (a total of 4).

- j) To take another measurement, reactivate the Tonopen XL unit by pressing the activation switch as described previously. Record the information on page 11.

- k) Now, measure the eye pressure for the left eye and record the information on page 11.
- l) Replace the OcuFilm tono-tip cover before using the Tonopen XL on another patient and before storage.
- m) Do not clean the Tonopen tip. See the instructions for cleaning the Tonopen in the Tonopen Appendix.
- n) If the eye pressure is equal to or greater than 30 mmHg, the subject should not be dilated. The subject should have one non-dilated Canon Fundus photograph per eye. If the pressure is equal to or greater than 35 mmHg, the subject should be referred to an eye doctor within 8 hours.
- o) If the eye pressure is between 24 and 30 mmHg, the subject can be dilated if there are no other exclusions. The subject should be referred to an eye doctor within one week.
- p) If the eye pressure is equal to or greater than 30 but less than 35 mmHg, the subject should be referred to an eye doctor within 48 hours.

2.7 PUPIL DILATION

Angle depth should be estimated with penlight. The penlight is held several inches from the temporal limbus of the cornea with its light beam traversing horizontally across the anterior chamber of the eye. In patients with wide open angles, the light will be seen from the temporal limbus to the nasal limbus. If the chamber is shallow, a shadow will be cast onto the nasal iris due to the bowing forward of the lens-iris diaphragm in patients with shallow anterior chamber (van Herick W, Shaffer RN: Estimation of width of angle of anterior chamber; Incidence and significance of the narrow angle. AM J Ophthalmol 68:624-629, 1969).

Whether or not the subject is to be dilated, record the pupil size of both pupils on the Eye Photo form, page 9 of the packet, prior to dilation. If it is okay for the subject to be dilated, dilate both eyes with one drop of 1% tropicamide. Make sure the subject closes their eyes after you instill the drop and practices nasolacrimal occlusion. While the eyes are dilating, the patient may go back to the central waiting area or continue to the next station in the SOF exam. After a period of 15 minutes, the examinee will be brought back by the examiner for the remainder of the examination.

Persons not to dilate:

1. Subject's eye doctor told patient to not be dilated
2. Subject is allergic to dilating drops
3. Subject refuses dilation
4. Anterior chamber appears to be narrow by penlight exam
5. Subjects with eye pressures of 30 mmHg or more.

For patients, who cannot or are not dilated, darken the room where the Canon fundus camera is located, or patch both eyes for 10 minutes. One non-dilated canon fundus photograph should then be taken of the eye with the worse visual acuity (fewest letters read on the Bailey Lovie chart). Repeat this procedure for the other eye

Adequate dilation of the pupil is important to permit good quality photography. Sufficient time should be allowed for dilation to at least 5mm, if necessary, to achieve and maintain a pupil of at least this size during photography. You may use a millimeter ruler held up near the patient's eye to determine the size of the pupil. Remember to check pupil dilation with a bright light. If the pupil is not 5mm in diameter after 15-20 minutes, another set of drops may be instilled. If after another 30 minutes the pupil is not 5mm, the subjects should still be prepared for the next part of the exam. Record the pupil measurement in mm on page 9 of the forms packet for each eye again after dilation.

Proper placement of eye drops in a patient's eye. Note that the patient should be looking up and away from the bottle tip, that the tip does NOT touch the patient's eyelid or eye, and that the lower lid is gently held down to form a "pocket" for the drop.

FUNDUS PHOTOGRAPHY

CHAPTER 3

3.1 Introduction

Photographs of the retina of each eye will be taken through pharmacologically-dilated pupils. The retinal photographs will be taken with a Canon CR-45UAF 45-degree auto-focus fundus camera or a Canon CR-6 45-degree auto-focus fundus camera.

Photography Protocols

The fundus (retinal) photography protocol is a modified version of the protocols used in the Atherosclerosis Risk in Communities Study (ARIC)- Retinal Photography Protocol.

Photographic Guidelines

Before attempting photography, the photographer should become very familiar with the camera through a training session and by learning the terminology in the camera's operations manuals (5.1). The following protocol uses terminology from the operation manual and it is recommended that the entire manual (Chapter 5) be reviewed by each photographer.

IN OPHTHALMIC PHOTOGRAPHY, IN ALL CASES WHERE BOTH EYES ARE PHOTOGRAPHED, THE RIGHT EYE IS ALWAYS PHOTOGRAPHED FIRST.

The examiner (photographer) should describe the photographic procedures to the participant prior to taking photographs. Participants are often anxious about this part of the examination, being frightened that the bright lights may cause a problem or that x-rays are used. The examiner should stress how important photography is for evaluating the retina, that the bright lights are not harmful, and that any afterimage (often associated with color changes) will fade within a half hour or so.

Subject Explanation and Informed Consent

Photography begins with a complete explanation of the procedure by the photographer. A Polaroid print may be useful to show what the optic nerve and retina looks like. It is important to reassure the subject that no retinal damage is caused by this procedure. The camera flash is bright and the subject should know when to expect a flash. The pictures will include the macula (area of central vision) and it is normal to experience a blue or red tint to vision immediately following the flash. This disappears within

five to seven minutes. Dilation drops will be used for this examination *and the eyes will not be touched*. A sample script of a typical retinal photography explanation (suitable for use as written material for deaf or interested subjects) follows.

We will be taking photographs of the inside of the back (the retina) of both of your eyes so we can study whether there is any evidence of eye problems. We will not be touching your eyes, but will be giving you eye drops before we take the pictures. You will be asked to sit in a room in front of a special camera with your chin in a chin rest. We darken the room so we can align and focus the camera. During the aligning process, you will only be aware of some small red or green lights, which may be visible in the camera, lens. We will ask you to follow the lights. Just before we take the picture, we will ask you to blink your eyes and then open them real wide. When we photograph the retina, the camera will flash a bright flash from within the camera lens.

Sometimes, just after this picture is taken, you may see a blue or red circular spot. This will disappear within 5-7 minutes and causes no permanent damage to the eye. Please remember that we are only taking pictures (not x-rays) of a small portion of your eyes and a picture of your whole outside eye and that these pictures will not substitute as an eye examination. You will certainly be notified should we notice anything requiring immediate attention. Please continue to see your eye doctor on a regular basis for your complete eye examinations.

EXAMINATION PROTOCOL

SUBJECT ID NUMBERING

It is crucial to the study that all photographers become thoroughly familiar with the subject ID numbering system that will be used to identify all of the photos taken.

All subjects are assigned an ID number that is consistent with the numbering system used in the SOF study. This consists of a five-digit sequence. The first **non-zero digit** indicates the site. We have:

Baltimore = 1 Minneapolis = 2 Pittsburgh = 3 Portland = 4

The next four digits are the subject's number. The ID number of an individual consists of the site number followed by the individual's number. Individual subjects are numbered from 0001 to approximately 1500 (depending on enrollment per site).

For example, ID number 040010 identifies subject number 10 from Portland, whereas ID number 21245 identifies subject number 1245 from Minneapolis.

PHOTOGRAPHY WITH POOR FIXATION

The photographer will attempt photography on subjects with poor visual acuity who may be unable to direct their gaze so that their nerve is properly positioned in the field alignment circle on the Canon camera monitor (as may be the case where both eyes are blind or when the subject is deaf and communication with her is impossible). In these cases, the photographer should get the best field definition possible under the circumstances. Remember that during the use of the Canon camera with difficult subjects, it is better to position the macula closer to the center when viewing the retina on the visual monitor and taking a picture.

The photographer should attempt photography on those subjects who are physically disabled, to the point that they can be comfortably positioned at the camera. To facilitate this, the subject may remain in a wheel chair positioned before the motorized camera table, which can be lowered to the appropriate height. Care should be taken when lowering the camera table to avoid pressing against the subject's legs. If, in the photographer's estimation, the subject cannot be comfortable positioned, no photography will be performed.

3.2 SUPPLIES

The following supplies will be provided to you by the UCLA Coordinating Center:

- Film
- Proparacaine 0.5% eye drops
- Tropicamide 1.0% eye drops
- Rev. Eyes 0.5 eye drops
- 100% Cotton
- Lens cleaning fluid (100% alcohol)
- Kleenex tissues
- Alcohol wipes
- Spare view bulbs
- Fuses for electrical circuits
- Film roll processing labels (1" by 2")
- Varta 2CR5, lithium 6-volt batteries for 35 mm Canon camera body
- Contact lens holder and saline solution
- Paper tape
- Sharpie markers (black, fine point)
- Disposable pen lights
- Mydriatic glasses

3.3 EQUIPMENT SET UP

The camera dust cover and lens cap should be removed at the beginning of the day and the lens inspected and cleaned as necessary. **Dust is the greatest enemy**, producing the majority of artifacts on the photographs. **When the camera is not in use, the lens cap should be in place and the special dust cover must remain on the camera.** The 35 mm camera and the camera back should be checked for sufficient battery power, and the film counter should be checked to be certain that the camera is loaded with adequate film before beginning photography. Please do not allow smoking in the rooms near the camera.

3.4 RETINAL PHOTOGRAPHY AND THE CARE AND MAINTENANCE OF THE CANON CR-45 OR CR-6 CAMERA

Introduction to Retinal Photography

As part of the ophthalmic photography component, one external (fundus reference) photo of each eye and two retinal photos of each eye will be taken through pharmacologically dilated pupils.

The Canon CR-45 UAF or CR-6 Camera

A Canon non-mydratic, auto-focus fundus camera with a 35 mm camera back will be used for the photography section of the eye exam. The camera is mounted on a motorized instrument table to allow optimum alignment. Both photographer and subjects have pneumatically adjustable stools, the latter with a back rest and floor lock mechanism. Aside from the template for right and left optic nerve placement that has been superimposed on the viewing screen, there are no other modifications made to the Canon CR-45UAF or the CR-6 camera. A copy of the Canon Non-Mydratic Retinal Camera Operation Manual (5.1) accompanies this protocol.

Care and Maintenance of the Canon CR-45UAF or CR-6 Camera.

The retinal camera should remain covered when not in use. ***High humidity or temperatures must be avoided.*** Dusty conditions mean that the camera will need frequent cleaning. The objective lens should be checked and cleaned with the air bulb if necessary ***before each subject is photographed.*** A more extensive cleaning is required to remove grease, smudges or stubborn spots from the lens. This cleaning

requires removal of the lens "boot" and external alignment lamp ring and should be referred to the primary photographer at each clinical center.

Lens and Camera Body Care

Before each photograph, the camera lens must be inspected and, if dirty, cleaned with the brush and air bulb to remove debris. Should more extensive cleaning of the lens be required, the lens can be fogged with your breath or moistened with absolute alcohol and then wipe gently using a circular, polishing motion with the 100% cotton until no dirt or oily film is visible on the lens when it is viewed from the front *with the alignment lens removed and the view lamp on and turned up to its maximum intensity (5.1)*. The body of the camera should be kept cleaned and free of dirt with a soft cloth and water or a common spray cleaner. The headrest may be cleaned with alcohol. The inside of the 35 mm camera back should be inspected for dirt and film fragments *each time the film is changed*. The air bulb or a puff of air is used to clean inside the camera back. The infrared mirror relay lens assembly is cleaned as necessary to remove dirt or dust when seen on the display monitor. While these specks do not affect final photo quality, they are distracting and should be removed. *Never touch, brush, or puff air onto the mirror that is located at the front of the 35 mm body.*

Instrument Table and Stools

The instrument table and stools can be kept clean by wiping with a common spray cleaner and a soft cloth. A drop of WD 40 may be used occasionally on the caster on the table and stools. The electric motor on the table requires no lubrication. The motor is protected by fuses that may need replacing should they be damaged by excessive current.

Flash and View Lamp Concerns

It is anticipated that the flash, and view lamps will fail at some point. Remember to keep all oil from your fingers off these lamps during replacement. The view lamp should last approximately one to two years and is easily replaced as needed. The flash lamp has a life of at least 5,000 flashes, enough to complete the study. Since the view lamps are relatively inexpensive bulbs, one spare should be ordered from Canon and kept at the clinical center. The flash lamp is expensive and can be ordered by overnight delivery, if needed, from Canon.

As the flash lamp ages, the light output can gradually diminish, producing progressively darker photographs. This can temporarily be over-ridden by an adjustment of the transformer output, although ultimately the lamp should be replaced. The decision to replace the lamp, due to dark photos will be made with the UCLA Senior Photographer following routine review of processed photographs. *The flash lamp requires careful handling during installation (the burned out lamp may be hot and the new lamp must be properly aligned). Thus, replacement should be attempted only by clinical center staff who have been trained to do this.*

Camera Malfunctions and Errors

Since the camera requires virtually no other maintenance, any malfunction will need to be investigated first by the examiners at each center and, when necessary, via telephone with the UCLA Senior Photographer. Trouble-shooting can be performed via telephone to diagnose any malfunction. Some camera malfunctions or photographer errors are not evident during photography and will only be discovered after examination of the processed films at UCLA. This includes camera flash synchronization, transformer power settings, and problems with a dirty objective lens or film loading problems. For this reason, prompt shipping of the film is important. A telephone link should be available between the photographers and the UCLA Senior Photographer at all times should a malfunction be discovered during the photography or following processing, or should the photographers have a problem or question needing immediate attention.

Service information can also be obtained directly from Canon USA and our contact person there is Gary Rackler, Technical Support Specialist, Canon Medical Systems, (972) 409-8872 or email at grackler@cusa.canon.com.

3.5 PRE-PHOTOGRAPHY PROCEDURE (RETINAL)

The video display is activated when the power switch on the side of the main unit is turned on. If no photography or switch operations are performed for 10 minutes, a power saving mode is activated, turning the lamps and display off to prevent unnecessary wear. During this power saving mode a "ready" lamp blinks on the monitor. Pressing any button below the arrows under the monitor, the joystick trigger, or the alignment button will reactivate the system.

Notice that three vertical arrows blink on the monitor when the main unit is switched on. This indicates the system is charging up. **Do not take photographs until the blinking stops, indicating a fully-charged flash. Pictures taken before the flash is fully charged will be severely underexposed.** The current date and subject ID number are displayed in the upper left-hand corner of the monitor. The camera contains an internal clock and the date will automatically change each day. The photographer must manually change the date if this clock should fail or if the camera is left unplugged for a long period of time. The date and time display is changed through Menu 3. The date format will read Month-Day-Year. The "Time Set" screen is used to adjust the current date and correct time. The camera is capable of recording up to a five-digit ID number, accessed through Menu 3, which *must be reset for each subject photographed*. Once properly entered into the camera, the number will appear below the date on the monitor. *This number must be checked and adjusted before each subject is photographed because this information is recorded on each slide and will become a permanent part of the data slides and will become the primary identifier for each picture. At the same time that each photo is taken an entry must be made in the Eye Photo Form (p. 12) and in the Photography Film Log.*

The 35 mm camera body should be attached to the main unit and loaded with the film provided to you from the Central Coordinating Center. The photographer needs to check that film is loaded in the camera at the beginning of each photography session. The frame counter on the top of the camera will indicate the number of exposures taken. After 36 pictures are taken, the camera automatically rewinds the film. If the film needs to be removed before 36 exposures have been taken, a manual rewind button on the 35 mm camera back (5.1) needs to be depressed. To load the film, open the camera by sliding the camera latch down while pressing in on the cover lock button. Insert the new film cartridge in the left side and thread the film across the shutter to the right side, making sure that the film leader is aligned with the orange index mark. Be careful not to poke the shutter blades with a finger because damage to the blades can easily occur. Take up any slack in the film by sliding excess film back into the cartridge. Close the back; the camera automatically threads the film and advances the film and counter to the number one exposure position. A blinking "check film back" warning on the monitor or blinking film marks on the camera back LCD display indicates the film is not loaded properly. In this case, reload the film. When the film is properly loaded, the camera back "reads" the film speed and automatically adjusts the flash output. At this point the photographer must press the "DSP" (display) button below the monitor to confirm that the following settings are correct:

Back:	RE 100 45	(35 mm EOS body, 100 ASA, 45 degree field)
AF:	ON	(autofocus on)
AE:	ON	(autoexposure on)
BLIN:	ON	(blink detector on)
K:		
SPLIT:	IN	(split focus detector in)
NO:	H 030001	(SOF Eye Study Subject ID #)*
DATE:	MM-DD-YY	(correct date and time
	12:00	

* The "H" before the subject ID number stands for "HOLD" (i.e. the camera holds the same number until it is changed for another participant).

3.6 SUBJECT PHOTOGRAPHY

Candidates for Retinal Photography

Canon photos can be taken regardless of whether or not an eye is aphakic (has no lens), or pseudophakic (has had cataract surgery and now has an implanted lens), or, that has not been dilated.

Pupil Dilation

All subjects will have both eyes maximally dilated (unless medically contraindicated) before photography is performed. The pupils should be larger than 4 mm in diameter and not reactive to a bright light. Please see Pupil Dilation (2.6).

Subject Positioning and ID Entry

The subject and photographer are seated on the appropriate sides of the retinal camera. The subject is positioned so that she is comfortable with chin and forehead in the headrest after identification information has been entered. Chin height should be adjusted so that the eyes are approximately level with the height adjustment mark on the face rest pole. It may be helpful to have the subject rest her arms on the table if that makes her more comfortable. The room is darkened to the level where a newspaper can barely be read (equal to about 5 lux) and the camera room door is closed. The only light in the room should come from the display monitor. If a red lamp is used to aid the examiner during administration of the questionnaire, it must be turned off when photography is performed. **While the subject begins to dilate, the photographer checks to make sure that the five digits of the subject ID number have been entered into the camera via the number pad on the control panel, so that this can be imprinted at the edge of the photographic frame along with the date when the photograph is taken.** At the same time, make sure that the subject's ID number, examiner's ID number and date are all entered on the Eye Photo Form (page 12) and in the Photography Film Log. Once the subject ID number has been entered into the camera, the photographer pushes the "DSP" button (explained above) to display the current camera values on the monitor and checks the accuracy of subject ID number entry.

Pupil Size and Alignment

The alignment switch is turned on and the stage is moved to center the **right eye (the right eye is always photographed first)** to be photographed horizontally and the height adjustment ring is used to position the eye vertically. The pupil should appear on the monitor coincident with the central circle on the monitor. Look for evidence of eyelids that do not open all the way. If you see this, ask the patients to open their eyes wider, or consider holding the eye open. The camera joystick is moved forwards or backwards until the pupil appears perfectly round. At this point, proper external alignment has been achieved. A pupil larger than the central 5 mm circle on the monitor is required for adequate fundus photography. If the eye does not dilate to at least 5 mm, the photographer should never -the- less attempt to view the retina. If the eye doesn't dilate to at least 5 mm, the photographer should never- the- less attempt to view the retina and photograph all the required fields to the best of ones ability.

Internal Eye Alignment

Once proper external pupil alignment is achieved, the alignment switch is pressed to provide a view of the fundus, split focusing lines, corneal reflection dots, and the fixation light. If no split lines are seen, the height or left/right adjustment is improper, the "SPLT" (split lines) setting is set to "OUT" (Menu 1), or

the diopter compensating slider is pulled out. The split lines may fade in and out if the pupil is too small, the alignment of the camera is not centered on the pupil, or if the eyelashes or lids eclipse the light. If no corneal reflection dots are seen, the forward/backward adjustment is improper. *The best photographs are obtained when the eye is well dilated, fixated on the target, and lids and lashes are held wide open.*

Focus with High Myopia (Near-sightedness, over -12.00 diopters of correction) or, Hyperopia (Far-sightedness, over $+15.00$ diopters of correction).

The diopter compensation slide should be set to the "0" position for most eyes. This is the only setting in which the auto-focus mechanism works and allows photography of eyes with refractions between -12 and $+15$ diopters. In the event that the eye photographed falls outside this range and auto-focus cannot be achieved, as in the case of aphakia (where a subject has had the lens removed) or high myopia, the diopter compensation slider must be adjusted for the clearest focus to the "+" or "-" position and the focusing knob is then turned manually to provide the sharpest image on the monitor. This is facilitated by obtaining a brighter retinal image on the monitor by increasing the view light intensity. The normal setting for the view light intensity adjustment is approximately 4. Remember that the camera is now in manual focus rather than auto focus. For instructions on manually focusing the Canon camera, see section 3.6.9 "Focusing Manually When the Auto-Focus Mechanism Doesn't Lock" below. Standard monitor functions can be adjusted for the photographer's viewing comfort (including contrast and brightness) by opening the access door below the monitor. These are standard controls similar to those found on any TV monitor and only affect viewing; they do not affect final photo quality (5.1).

Alignment, Focus and Proper Fixation

While viewing the fundus image on the screen, the photographer adjusts the internal fixation light while instructing the patient to look at the blinking green light visible in the camera lens. The subject should view the target with the eye being photographed. **To facilitate consistent positioning of the macula, the camera monitor will have a transparent overlay added indicating the proper optic nerve position for right and left eyes.** In the absence of this overlay, the optic nerve should be positioned two disc diameters from the nasal edge of the camera frame and should be centered on an imaginary horizontal line bisecting the camera monitor. When the auto-focus mechanism focuses the camera on the retina, a motor adjusts the focus knob until the auto-focus "locks" and a clear image is identified. This "lock" is confirmed in two ways. Two vertically stacked equal signs appear in the lower left-hand corner of the screen. Also, two rectangular boxes appear, stacked one on top of the other, in the center of the monitor.

Focusing Manually When the Auto-Focus Mechanism Doesn't Lock

If the operator notices that the auto-focus mechanism can't "lock" (obvious when the motor keeps running for several seconds and then shuts off) or if the mechanism "locks" without stacking the vertical boxes, the photographer should manually focus the camera by turning the focus knob until the two

rectangular boxes in the middle of the monitor appear stacked. This method of assisting the auto-focus mechanism will help assure the most accurate focus possible.

Camera Positioning

Once the fixation is confirmed, the photographer must **constantly** adjust and position the camera to maintain the correct position of the corneal reflection dots. **It is important that these dots be properly positioned at the 3:00 and 9:00 positions before the picture is taken.** This will ensure the correct distance from the eye and will allow a sharp image to be produced on the film. Focus is done automatically, but should be confirmed by the photographer by assessing image sharpness and by checking the auto-focus confirmation indicator on the monitor (5.1).

The photographer will instruct the subject to blink once or twice just before the picture is taken. This blinking will insure a moist (and subsequently clearer) cornea and will safeguard against unwanted blinks at the moment of exposure. Once alignment is satisfactory, the shutter release, located in the tip of the joystick, is depressed and the exposure is made.

Sequence of Retinal Photos

Two retinal exposures will be made for each eye of all subjects. Following the first N (normal) exposure, another increased exposure will be made. The photographer will press the "RE-N" button under the main screen until a "+" appears in place of the "N" thus indicating a 1/3 f-stop *increase* in exposure.

External Whole Eye Photo

Following the retinal photos, each eye will also have an external whole eye (fundus reference) photo taken.

The camera is pulled back toward the operator, and the compensating lens slider is moved to display an "a". The photographer *focuses the camera manually on the iris*, sets the exposure to "N", frames the orbit with the lens at the center, and takes the photo.

Then three similar photographs of the other eye will be obtained. Thus each eye will have two retinal photographs and one external photograph. One of the retinal photos will be at "N" and one at "+" (a 1/3 f=stop increase in exposure). The external photo will always be exposed at "N".

Retake Policy

Should the photographer suspect that an inadequate photograph was taken (due to a possible shadow, excessive movement or misalignment, or should the subject comment that they did not see the flash), a second picture at that exposure (N or +) should be taken.

Retakes When the Subject is Not Last on the Film Roll

When retakes are present on a roll of film, and the subject is the first through the fifth, the photographer must unload the roll from the camera following the end of the particular subject's sequence of photos, even though the roll is not used completely. To unload film, when the roll is not used completely, the photographer must depress and hold down the manual rewind button for over two seconds. The camera then rewinds the film automatically (see 5). When this occurs, the Photography Film Log must be marked "Incomplete/Retakes" in the space directly beneath "Film Roll #_____." These deviations must also be noted in the Eye Photo Form (p.12) in the "Comments on Photos" section.

Retakes When the Subject is Last (6th) on the Film Roll

If this particular subject happens to be the last (6th) subject on the roll in order to complete the photographic sequence, a new roll of film will be loaded into the camera. The photographer must unload the new roll following the last photo of the subject that is taken, even though there will be unused film remaining. The Photography Film Log should indicate the eye and the number or retakes. When this occurs, the Photography Film Log must be marked "Incomplete/Retakes" in the space directly beneath "Film Roll #_____." These deviations must also be noted in the Eye Photo Form (p.12) in the "Comments on Canon Photographs" section.

3.7 REVERSAL OF DILATION AND SUBJECT REFERRAL

One drop of daprizolamide is to be instilled into each eye after the photography session is completed. Since the dilation may take an hour to be reversed, the subject should be offered the use of temporary sunshields or sunglasses. They should be instructed not to drive for several hours.

Subjects to be referred to an Ophthalmologist Within 8 Hours

- Subjects with eye pain and redness that is not relieved with blinking or with artificial tears.
- Subjects that see new halos around lights.
- Subjects that become nauseated and vomit.
- Subjects that complain of itchy, red, and swollen eyelids.
- Subjects that have eye pressures equal to or greater than 35 mm Hg.

Subjects to referred to an Ophthalmologist within 48 hours

Subjects that have eye pressures equal to or greater than 30mm Hg and less than or equal to 34 mm Hg.

Subjects to be referred to an Ophthalmologist within One Week

Any subject with eye pressures between 24 mm Hg and 30 mm Hg.

3.8 FILM: HANDLING, SHIPPING, AND LOGS AND RECORDS

Film Concerns

The most consistent exposure will be obtained using a professional grade slide film that will be distributed from the supplier for UCLA. All professional grade films must be stored at a temperature of 55 degrees Fahrenheit or lower. A conventional refrigerator is the perfect storage container for the Professional Ektachrome. Please remove the film from refrigeration at least 1 hour (but no more than 24 hours) to allow it to warm to room temperature before use. This warming is necessary to prevent condensation inside the camera or film tearing, which can occur when the film is cold. You may also freeze this film if refrigerator space is at a premium. In this case, please be sure to remove any rolls at least 3 hours before use to allow ample time for the film to reach room temperature. Any film warming to room temperature must be left in its plastic storage container to prevent condensation. Do not refrigerate the film after exposure. Film should be sent to the Colleen Gillis at Advanced Vision once a week on a Monday, Tuesday, or Wednesday.

Film Tracking and Numbering

Once film is exposed and unloaded, a numbered film roll label is attached to the exposed roll. The number on the film roll must correspond with the roll number listed on the Photography Film Log Form. The marking system on the label will consist of the date the film was loaded into the camera and the following alphanumeric code as show below:

Date loaded
Center number- roll number.

For example:

Feb 05 00
1-023

Shows that roll number 23 was loaded in Baltimore on 02-05-00.

A roll marked:

Jun 17 00
4-206

Shows that roll number 206 was loaded in Portland, on 06-17-00.

Photography Film Log

The photographer will keep a manual film log in the camera room. This log will include: film roll number, date, photographer ID number, subject ID number, eye photographed, and a comments section. Please note any special circumstances, such as excessive blinking, patient wearing contact lenses, or concern about retinal pathology.

The film rolls will be numbered consecutively beginning at each site with roll number one and advancing to the next numerical digit as a new roll of film is used. Once a roll is completely exposed, it is removed from the camera and identified with a film roll number label for identification during processing and mounting. The photographer is encouraged to comment on anything unusual such as strange artifacts, small pupil size, pathology or other problems. This information will be helpful in identifying specific photographs and in understanding any artifacts that may appear on the processed slides. Since comments from the log accompany the photographs to Colleen Gillis at Advanced Vision, this information can be taken into consideration when providing feedback to the Clinical Sites.

Film Sequencing

We will be taking 6 photos per subject. Therefore the camera will need a new roll of film after every six subjects are photographed.

Film Processing

After checking that the roll of film has been correctly identified, it is important to ship it together with the Photography Film Log.

Even if a roll of film is not completely exposed, it should be sent to Ms. Gillis after two weeks from loading it in the camera.

The film will be removed from the camera after each roll is fully exposed. Film will be sent to Colleen Gillis at Advanced Vision via Federal Express weekly VIA 2ND DAY DELIVERY on Mondays, Tuesdays or Wednesdays, BUT NEVER on Thursdays or Fridays or the day before a holiday. The photographer must attach a numbered film roll label to each exposed roll of film before sending it to UCLA.

The film roll number must correspond with the sequential number appearing on the corresponding Photography Log page and also with the numbers written on the film cassette. It is critical that a Xeroxed copy of the appropriate pages from the Photography Film Log and copy of the corresponding Eye Photo form (page 12) accompany each roll of film.

The undeveloped rolls of film will be sent to Colleen Gillis where we will have the film processed within two days so that the results can be reviewed by the UCLA Senior Photographer, Ms. Gillis as soon as possible for possible camera malfunctions. Also, the opportunity for photographers to critique their work is critical to the maintenance of satisfactory photographic quality.

Film Shipping

Packages of exposed film and the relevant Photography Film Log and Eye Photo Forms (p. 12) are sent weekly to Colleen Gillis. Film rolls should be reinserted back into their plastic containers for shipping.

The standard Federal Express envelope, reinforced with a manila folder around the film is acceptable.

Shipping Couriers

When using couriers, such as Federal Express it is important to use Colleen Gillis's complete street address. The following shipping label example contains the correct address to be used for all photographic shipments sent to Colleen Gillis.

Ms. Colleen Gillis (SOF-AMD) Advanced Vision 2100 W. State Road 434, Suite 1020 Longwood, FL 32799 Phone: 407-389-0800
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3.9 PHOTOGRAPHIC STANDARDS AND PHOTOGRAPHER CERTIFICATION

Photographic quality will be continuously monitored throughout the study. All photographs will be reviewed by the UCLA Senior Photographer, Colleen Gillis, and feedback will be provided to the photographers in cases that warrant critique. A telephone call or faxed letter will be used detailing problems and suggesting improvements. Once the study is well underway and the photographers

sufficiently trained, data on quality will be generated from the photograph readers' evaluations of all photographs.

Photographer Certification

Each examiner taking photographs will need to become certified before taking photographs for the study. Training will be provided initially in a group setting where the photographers will receive didactic and hands-on training. Following the training session, photographers will return to their respective centers and begin practicing retinal photographs. A photographer is fully certified after submitting satisfactory quality photographs of a total of 10 eyes to the Reading Center for evaluation. These photographs must show proper field definition, exposure, alignment and focus.

As additional personnel need training to become certified, a certified photographer at that center will provide complete instructions, copies of the protocol, and the Canon Non-Mydriatic Retinal Camera Operation Manual. The trainee photographer will practice on volunteers and, when ready, prepare and submit photographs of 10 eyes for consideration for provisional certification.

Certification for Incidence of Macular Degeneration in Older Women Photography

All photographers in the study must first receive provisional certification before they can take photographs of the study participants. To become provisionally certified, photographers must submit photographs of ten eyes of non-study participants to the Colleen Gillis and will be provisionally certified if all of these are of at least fair quality. Photographers whose photographs are consistently of good quality (overall grade of good or fair in at least 75% of a series of 10 eyes of study participants) will become fully certified. If photographic quality for a fully-certified photographer falls below this criterion, certification will revert to provisional and special attention will be paid to Reading Center-photographer interaction aimed at improving quality. In order to retain familiarity with equipment, technique and protocol, it is crucial that the back-up photographer participates and takes photographs on at least one subject once a week.

All photographs are assessed for quality by Colleen Gillis and feed back given to the photographers as needed to help with resolution of any problems.

Specific criteria for the evaluation of fundus photographic quality are presented in the grading protocol.

Reading Center-Photographer Communication

As film is received by Colleen Gillis, it will be developed and the photographs will be graded for quality. Ms. Gillis will call the photographers by telephone to discuss any significant problems observed. Depending on the nature and/or extent of the problem(s), either gif files will be transmitted, or, duplicate developed transparencies or Polaroid photos will be returned to the photographer as necessary. This contact will also allow the photographer an opportunity to ask questions or make comments.

When substantial problems are observed (particularly if a photographer has reverted from full to provisional certification), the Ms. Gillis will arrange to conduct a special photographic site visit for the purpose of observing the photographer at work and demonstrating the desired technique.

Chapter 4 HOME EXAMINATION

The home examination consists of three parts: Ocular History, Visual Acuity and Contrast Sensitivity.

4.1 Patient Identification & History

The examinee's SOF record number, date of birth, date of examination and place of examination will be filled in when the patient is first registered for the eye examination. Under the place of examination; 1 = "clinic" refers to examining rooms, 2 = "local" refers to any exam done by the SOF staff outside the "clinic", e.g., in the examinee's home, nursing home, hospital, etc. Please make same change that was made to earlier paragraph regarding the location on the SOF forms of this info, even if they are not vision forms.

In all exams, the right eye will be evaluated first. Prior to beginning the exam, the examiner will determine the status of both eyes by asking the following questions:

Vision Interview

1. At present time, would say your eyesight (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor, or are you completely blind?
2. How much of the time do you worry about your eyesight?
3. Are you currently using eye drops in your eye for any reason?
4. Have you ever used eye drops prescribed by a doctor to lower the pressure in your eyes?
5. Have you ever been hit in the eye with a fist or an object?

The next questions are about how much difficulty, if any, you have doing certain activities while wearing your glasses or contact lenses, if you use them for this activity.

6. How much difficulty do you have reading ordinary print in newspapers? Would you say you have:
7. How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say:
8. Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs, in dim light or at night?
9. How much difficulty do you have driving during the daytime in familiar places?
10. Are you limited in how long you can work or do other daily activities such as housework, child care, school, or community activities because of your vision?
11. Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along?
12. Because of your eyesight, how much difficulty do you have finding something on a crowded shelf?

Ocular History

1. Has a doctor ever told you that you had any of the following?
 - a. Cataracts?
 - a1. Cataract extraction (surgery)?
 - a2. Combined cataract/glaucoma surgery?
 - a3. If YES to b or c, during cataract surgery was a new lens placed in your eye?
 - a4. Yag capsulotomy or treatment for 2nd cataract in the same eye?
 - b. Glaucoma?
 - c. Macular degeneration?
 - d. Uveitis (inflammation of the eye)?
 - e. Stroke or hemorrhage of the eyes?
 - f. Diabetes in the eyes?
 - g. Blind eye?
2. Have you ever had eye surgery or laser treatment other than cataract surgery?
 - a. Laser surgery for diabetes?
 - b. Laser surgery for macular degeneration?
 - c. Glaucoma surgery, including laser surgery for glaucoma?
 - d. Retina surgery?
 - e. Corneal graft or transplant?
 - f. Refractive surgery (a procedure that allows you to either not wear glasses, or to wear less powerful ones)?
 - g. Enucleation (removal of eye)?
 - h. Other eye surgery?

Please be sure to return to the Vision Checklist (Page 1 of the forms) and mark your rating of the ocular history and any comments you feel are relevant.

4.2 Visual Acuity Testing Using A Portable Eyetest Case (Good-Lite Box)

- a) Illumination: The portable eye test case is illuminated, so abrupt changes in illumination should not be a problem.
- b) Distance: The test is administered with the participant seated at 10 feet from the eyetest case. Measure from the eyetest case to the middle of the chair using a metal tape measure.
- c) Glasses: Acuity is tested with habitual correction for distance vision.

Before testing vision, ask the subject if she normally wears glasses, or contact lenses, or both for distance vision. (probes: “Do you wear glasses to see things far away, like when you go to a movie theater or when you drive a car?”) If she answers that she has glasses for distance but sees better without them, distance tests should be performed with glasses on. When scheduling participants for visits, remind them to bring or wear the glasses that they use most often for distance vision. If she wears glasses please identify if she wears distance only or bifocals or no line bifocals (trifocals, progressives, or any multifocal eyeglasses will be marked as “bifocals,” or “no line bifocals” on the form [p. 17]).

Equipment

- a) Pointer
- b) Occluder
- c) Illuminated eye chart- Good Lite Box, with “SLOAN” chart for 10 feet.

20/100	KHOR
20/80	CKZDV
20/60	OZNRHVC
20/50	RKCSZHVD
20/40	SDKH ORCV
20/30	HOCZR KDSVN
20/25	NZCOS KDVRH
20/20	DCSKO VRNHZ
20/15	ZSVDK HNORC

The Sloan Chart for ten feet will show the above configuration of letters.

Measurement Procedures

- a) The portable eye test case should be placed at approximately the eye level of seated subjects. Seat subject on straight-backed chair, 10 feet from the midline of the body to the chart. Use a pointer to indicate rows on the chart.
- b) If the participant wears glasses (bifocals or regular glasses) for distance viewing, such as driving, walking or at a theater, test with her glasses on. If she only wears glasses (bifocals or regular) when she reads, test distance vision at 10 feet without glasses. Test contact lens wearers with lenses in. If a participant says that she wears glasses but sees better without them, test WITH THEM (her “normal” state).

- c) Ask the subject to hold the occluder so that her left eye's vision is blocked and only the right eye can be tested. Then ask the subject to start reading the letters on the chart starting with the 20/50 line and proceed down the chart toward the smaller letters. Say:

"I'd like you to read aloud the letters on this chart." (Read from left to right)

"Don't squint and don't lean forward. Start here and read down as far as you can and then say 'That's all'.

"Now, can you easily read this row?"(point)

If she says yes or reads the row without error then say:

"OK continue."

If she says no or reads it with three or more errors, then say:

"How about the top row? Can you read that one?"

If she says no or reads it with three or more errors, then test at 5 feet (low vision distance) using the same procedure. Be sure to record that you are testing at 5 feet, on form p. 17.

- d) As the subject reads, mark the letters by drawing a line over those read correctly and drawing a line through the incorrect ones.
- e) When it is apparent that the subject is struggling (e.g. misses 3 letters on a row or goes very slowly) stop.

Note the errors on that row. If she misses three of the letters on a row, use the previous row as the Snellen Acuity score if the participant missed two or less letters in that row. If she says "That's all," in the middle of a row, have her guess at the rest of the row and then stop. Draw a line through the first row not attempted.

Be watchful for participants who inadvertently "peek" out from under the eye paddle. They may have their best eye covered and unintentionally will move the paddle over a bit in order to see better. Move the eye paddle into the proper position on the participant's face yourself, if needed. You may even need to hold it in place for some patients.

If the participant is trying to read too quickly, be sure to slow her down. Ask her to take her time and read each letter carefully.

Encourage the patient to tilt her head or move it left or right, if needed, in order to read the letters. This may be necessary for some patients who have central vision loss. Please notate on the form that the participant used eccentric fixation or head tilt. (You may notice these participants because they may miss the same letter positions in each row, for example; the last one or two letters in each row, the center one or two letters in each row, or the first one or two letters in each row. However, they can often read the other letters in the row quite easily). **Do Not** allow her to lean forward.

- f) REMEMBER TO RECORD THE NUMBER OF LETTERS READ CORRECTLY AND THE CHART DISTANCE.
- g) For subjects that cannot see the chart at 5 feet, you need to test their vision with your fingers. Finger counting is tested by holding two or three fingers two feet from the patient and should be recorded as 97. Hand motions is tested by moving a hand back and forth in front of the patient with the other eye occluded. This is recorded as 98. Light perception is tested by carefully occluding the fellow eye and directing the light of the penlight at the examinee's eye from about one-foot distance. This is recorded as 99. No light perception is recorded as 00 on page 17.
- h) The subject now holds the occluder so that the vision from the right eye is blocked. Steps c-g are repeated for the left eye.

4.3 Contrast Sensitivity

Equipment

VISTECH VCTS 6500 wall chart and light meter. Mark the right and left hand sides of chart with a large R and L, clearly visible to the participant.

Description

Vision is generally measured by acuity tests that determine the smallest detail that can be seen, such as black letters on a white background. However, our everyday visual world contains objects that have varying levels of contrast (the level of black and white parts of an object and background) and a range of sizes. Those objects must often be seen under visually degraded conditions such as nighttime, fog, or rain. Contrast sensitivity measurements are needed to determine an observer's ability to see a wide range of everyday objects under normal and visually degraded conditions. Because any object can be decomposed into a combination of simple patterns, called sine waves, contrast sensitivity to sine waves provides a generalized measure of visual sensitivity to everyday objects.

The VISTECH contrast sensitivity test system, Model 6500, uses highly controlled photographic and printing techniques to present a series of sine wave gratings at calibrated levels of contrast. In a manner similar to reading the typical acuity chart, the observer simply reports whether or not a grating is visible; and if visible, at what orientation of all grating sizes. At the 10-foot distance, the spatial frequencies tested can be made higher or lower by simply changing viewing distance.

Illumination

The VCTS is designed so that it can accurately measure contrast sensitivity under normal room illumination corresponding to a chart luminance of 50-70 ft-Lamberts. For consistent measurement of contrast sensitivity, luminance must be kept constant from one area of the chart to another, and from one test to the next.

Light Meter Instructions

1. With the silver side facing up, hold the light meter two inches from and perpendicular to the upper right corner of the chart. Be sure you are not casting a shadow on the chart as you measure luminance.
2. Press the square on the silver side of the meter to measure the light level. If the illumination is appropriate the green light will be illuminated to indicate "Proper Level". If either red light is illuminated for "Too Bright" or "Too Dark", make the appropriate adjustments and re-evaluate the light.
3. Repeat the measurement holding the meter two inches from the lower left corner of the chart.
4. If your test area has significant natural light, evaluate chart illumination under a variety of conditions to determine if additional artificial light will be needed.

Administration

- a. Place chart system in an area where it receives uniform lighting. Shadows or glare on the chart can affect contrast sensitivity measurement. **To minimize glare, the chart should not be facing a window or have a window directly behind it.** Measure chart luminance to insure lighting conditions are within desirable limits (see Light Meter Instructions). **HAVE A POINTER HANDY.**

b. The subject should be seated 10 feet from the chart, with the middle of the chart around eye level. IF SHE WEARS GLASSES FOR DISTANCE, TEST WITH GLASSES ON.

c. Tell the subject: "This test measures your contrast sensitivity, or how well you are able to see differences in shades of dark and light. (We test this by seeing how well you are able to see the fuzzy bars on this chart at different levels of contrast between dark and light. Your ability to see these bars relates to how well you see everyday objects.)"

Continue, pointing to the upper left hand patch (A1). "Each of the circular patches on the chart contain bars that vary in contrast. Can you see the light and dark bars on this patch?" (If "no", point to C1 and ask again. If unable to see the bars on c1, then follow instructions for low vision.) Then point up and down the first column (1). "Each row contains a different size bar pattern. The patches on the far left of each row are high contrast sample patches which show the size bars you will be looking for to the right of that sample patch on the same row."

"The four patches on the bottom of the chart show the three ways the bars may be oriented and a blank. The bars will be slanted slightly up to the left, slanted slightly up to the right, and straight up. Some patches are blank."

"Your task is to read across each row, starting at row A. Patch 1. You will then call out weather the patch is pointing to the left, right, straight up and down or blank. I will record your responses. (Some of the patches are very low in contrast and you may not see any bars in these patches). If this is the case, simply answer 'blank'. However, if you do see something in a patch but you are not sure which direction the bars are pointing, you are allowed to guess."

d. Scoring: Record the subject's response for each patch in the appropriate place on the scoring sheet by drawing an X through those called out incorrectly. Circle the patch number just before the first incorrect one on each line. This is the score for that line. Point at each circle. Ask about every circle don't stop. Cross out the first one missed then circle the one just before that. Continue testing on the next row until one circle is missed, then cross that one out and circle the one before that was read correctly. Repeat for every row on the chart. Score each row before going on to the next. This score should be entered on page 9.

e. Low Vision: If the subject cannot see the bars in patch C1, mark the box for low vision on the scoring sheet and test at 5 feet.

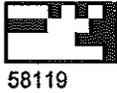
For low vision, a quantitative measure of the subject's visual capability in terms of contrast sensitivity is accurately obtained. Low vision subjects can be tested by simply moving them closer to the chart. The spatial frequencies change in direct proportion to distance. (for example, at a 5ft. viewing distance, the spatial frequencies become .75, 1.5, 3, 6, and 9 cycles per degree).

SOF-AMD—Photography Log Form
Page 1 of 2. FILM ROLL NO. _____

	Date	Tech ID No.	Subject ID No.	Eye	Comments
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					

SOF-AMD—Photography Log Form
Page 2 of 2. FILM ROLL NO. _____

	Date	Tech ID No.	Subject ID No.	Eye	Comments
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
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32					
33					
34					
35					
36					



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Vision Measures

Office Use Only									
SOF ID#					Acrostic			Staff ID#	

1 Did the participant complete ANY of the vision measurements listed below (besides the Visual Acuity exam)?

Yes No →

STOP. Complete only this page of the Vision Forms Packet and submit to data system. DO NOT SEND REST OF VISION FORMS.

Vision Checklist

(Complete the vision measures in the following order and indicate which measures were completed by filling in the circle):

Vision Interview

Ocular History →

Examiner rating of ocular history:

Excellent Satisfactory Unsatisfactory

Comments: _____

Functional Vision

Visual Acuity (Form is in the Clinic Interview Packet)

Contrast Sensitivity

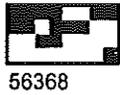
Auto Refraction

Intraocular Pressure

Dilation

Eye Photographs





Vision Interview

Office Use Only					Acrostic			Staff ID#				
SOF ID#												

1 At present time, would you say your eyesight (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor, or are you completely blind?
 Excellent Good Fair Poor Very Poor Completely blind

2 How much of the time do you worry about your eyesight?
 None of the time A little of the time Some of the time All of the time

3 Are you currently using eye drops in your eye for any reason?
 RIGHT EYE: Yes No Don't Know LEFT EYE: Yes No Don't Know

Are these eye drops used to lower the pressure in your eye?
 RIGHT EYE: Yes No Don't Know

Are these eye drops used to lower the pressure in your eye?
 LEFT EYE: Yes No Don't Know

4 Have you EVER used eye drops prescribed by a doctor to lower the pressure in your eyes?
 RIGHT EYE: Yes No Don't Know LEFT EYE: Yes No Don't Know

5 Have you ever been hit in the eye with a fist or an object?
 RIGHT EYE: Yes → No Don't Know LEFT EYE: Yes → No Don't Know

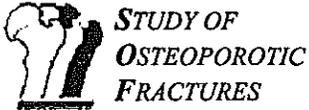
Month/year hit: /

Make sure that the eye drops were recorded on the Medication Inventory Form (Page 5 of the Clinic Interview Forms).

If completely blind, stop vision interview and proceed to Ocular History.

The next questions are about how much difficulty, if any, you have doing certain activities while wearing your glasses or contact lenses, if you use them for this activity.

6 How much difficulty do you have reading ordinary print in newspapers? Would you say you have:
 No difficulty at all Extreme difficulty
 A little difficulty Stopped doing this because of your eyesight
 Moderate difficulty Stopped doing this for other reasons or not interested in doing this



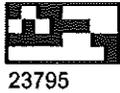


Vision Interview

Office Use Only					Acrostic					Staff ID#		
SOF ID#												

- 7) How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools?
Would you say:
- No difficulty at all
 - A little difficulty
 - Moderate difficulty
 - Extreme difficulty
 - Stopped doing this because of your eyesight
 - Stopped doing this for other reasons or not interested in doing this
- 8) Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night?
- No difficulty at all
 - A little difficulty
 - Moderate difficulty
 - Extreme difficulty
 - Stopped doing this because of your eyesight
 - Stopped doing this for other reasons or not interested in doing this
- 9) How much difficulty do you have driving during the daytime in familiar places?
- Not currently driving
 - No difficulty at all
 - A little difficulty
 - Moderate difficulty
 - Extreme difficulty
 - Stopped doing this because of your eyesight
 - Stopped doing this for other reasons or not interested in doing this
- 10) Are you limited in how long you can work or do other daily activities such as housework, child care, school, or community activities because of your vision?
- All of the time
 - Most of the time
 - Some of the time
 - A little of the time
 - None of the time
- 11) Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along?
- No difficulty at all
 - A little difficulty
 - Moderate difficulty
 - Extreme difficulty
 - Stopped doing this because of your eyesight
 - Stopped doing this for other reasons or not interested in doing this
- 12) Because of your eyesight, how much difficulty do you have finding something on a crowded shelf?
- No difficulty at all
 - A little difficulty
 - Moderate difficulty
 - Extreme difficulty
 - Stopped doing this because of your eyesight
 - Stopped doing this for other reasons or not interested in doing this





Ocular History

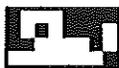
Office Use Only					Acrostic			Staff ID#		
SOF ID#										

1 Has a doctor ever told you that you had any of the following?

	<u>RIGHT EYE</u>	<u>LEFT EYE</u>
a. Cataracts?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year first told: [] [] / [] []	Month/year first told: [] [] / [] []
a.1. Cataract extraction (surgery)?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year done: [] [] / [] []	Month/year done: [] [] / [] []
a.2. Combined cataract/glaucoma surgery?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year done: [] [] / [] []	Month/year done: [] [] / [] []
a.3. If YES to a.1. or a.2, during cataract surgery was a new lens placed in your eye?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know
a.4. Yag capsulotomy or treatment for 2nd cataract in the same eye?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year done: [] [] / [] []	Month/year done: [] [] / [] []
b. Glaucoma?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year first told: [] [] / [] []	Month/year first told: [] [] / [] []
c. Macular degeneration?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year first told: [] [] / [] []	Month/year first told: [] [] / [] []
d. Uveitis (inflammation of the eye)?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year first told: [] [] / [] []	Month/year first told: [] [] / [] []
e. Stroke or hemorrhage of the eyes?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year first told: [] [] / [] []	Month/year first told: [] [] / [] []
f. Diabetes in the eyes?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year first told: [] [] / [] []	Month/year first told: [] [] / [] []
g. Blind eye?	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know	<input type="radio"/> Yes → <input type="radio"/> No <input type="radio"/> Don't Know
	Month/year first told: [] [] / [] []	Month/year first told: [] [] / [] []

Reason for loss of sight: _____





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Ocular History

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SOF ID#

Acrostic

Staff ID#

2 Have you ever had eye surgery or laser treatment other than cataract surgery?

Yes No

SKIP TO VISUAL ACUIITY

RIGHT EYE

LEFT EYE

a. Laser surgery for diabetes?

Yes No Don't Know

Yes No Don't Know

Number of surgeries: Date of most recent /

Number of surgeries: Date of most recent /

b. Laser surgery for macular degeneration?

Yes No Don't Know

Yes No Don't Know

Number of surgeries: Date of most recent /

Number of surgeries: Date of most recent /

c. Glaucoma surgery, including laser surgery for glaucoma?

Yes No Don't Know

Yes No Don't Know

Number of surgeries: Date of most recent /

Number of surgeries: Date of most recent /

d. Retina surgery?

Yes No Don't Know

Yes No Don't Know

Number of surgeries: Date of most recent /

Number of surgeries: Date of most recent /

e. Corneal graft or transplant?

Yes No Don't Know

Yes No Don't Know

Number of surgeries: Date of most recent /

Number of surgeries: Date of most recent /

f. Refractive surgery (a procedure that allows you to either not wear glasses, or to wear less powerful ones)?

Yes No Don't Know

Yes No Don't Know

Number of surgeries: Date of most recent /

Number of surgeries: Date of most recent /

g. Enucleation (removal of eye)?

Yes No Don't Know

Yes No Don't Know

Number of surgeries: Date of most recent /

Number of surgeries: Date of most recent /

h. Other eye surgery?

Yes No Don't Know

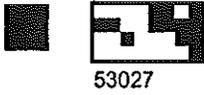
Yes No Don't Know

Number of surgeries: Date of most recent /

Number of surgeries: Date of most recent /

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Contrast Sensitivity

Office Use Only									
SOF ID#				Acrostic			Staff ID#		

1 Glasses/Contact Lenses/Lens implants (Check all that apply):

- Does not wear glasses
- Does not wear contact lenses
- Wears glasses most of the time
- Wears contact lenses most of the time
- Different glasses for distance and near
- Left eye lens implant
- Right eye lens implant
- Wears glasses for reading over contact lenses
- Wears glasses for reading/near viewing only
- Always wears multifocals
- Wears glasses for distance only
- Wears one contact lens for near and one for distance

R is near/L is distance
 L is near/R is distance

2 Was the Contrast Sensitivity test administered?

Yes No →

- Participant fatigued Did not understand
 Unable to see chart Refused

HOME VISIT ONLY: Illumination (Use Vistech Meter)

- Top right corner OK (green light) Bottom left corner OK (green light)

3 RIGHT EYE

Which distance was used?

- 10 feet 5 feet
 Participant unable to read chart at 5 feet

Number of circles correctly identified:

Row A	<input type="text"/>		Row D	<input type="text"/>
Row B	<input type="text"/>		Row E	<input type="text"/>
Row C	<input type="text"/>			

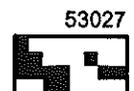
4 LEFT EYE

Which distance was used?

- 10 feet 5 feet
 Participant unable to read chart at 5 feet

Number of circles correctly identified:

Row A	<input type="text"/>		Row D	<input type="text"/>
Row B	<input type="text"/>		Row E	<input type="text"/>
Row C	<input type="text"/>			





Humphrey Autorefractor

Office Use Only											
SOF ID#				Acrostic				Staff ID#			

1 Was visual acuity measured in BOTH eyes by the Humphrey Autorefractor?

<input type="radio"/> Yes	<input type="radio"/> Right Eye Not Tested	→	Record information for the eye that was tested
<input type="radio"/> No →	<input type="radio"/> Left Eye Not Tested	→	
	<input type="radio"/> Neither Eye Tested	→	

2 Visual acuity with "best correction" as determined by the Humphrey Autorefractor (with glasses removed):

RIGHT EYE

20/

LEFT EYE

20/

3 "Best correction" results from the Humphrey Autorefractor:

RIGHT EYE

+ . sphere
 - . sphere

+ . cylinder x axis

LEFT EYE

+ . sphere
 - . sphere

+ . cylinder x axis





Intraocular Pressure

Office Use Only				Acrostic				Staff ID#			
SOF ID#											

Be sure to instill a drop of ophthetic (anesthetic) into each eye before you check intraocular pressures.

- ① Has the participant had eye surgery within the past two weeks? Yes No
- ② Is the participant allergic to any eye drops? Yes No
- ③ Has the participant's doctor ever told her to not be dilated? Yes No

If the answer is "YES" to 1, 2, OR 3, DO NOT check Intraocular Pressure. GO TO Eye Photo, after answering Question 4.

- ④ Was intraocular pressure measured in BOTH eyes?
 - Yes
 - No →

<input type="radio"/> Right Eye Not Measured	→	Record information for the eye that was tested
<input type="radio"/> Left Eye Not Measured	→	
<input type="radio"/> Neither Eye Measured	→	

- ⑤ Time intraocular measurement taken: : A.M. P.M.

⑥ Intraocular measurements:

		a. 1st	b. 2nd	c. 3rd	d. 4th
RIGHT EYE	Avg. IOP	<input type="text"/> mmHg	<input type="text"/> mmHg	<input type="text"/> mmHg	<input type="text"/> mmHg
	% of error	<input type="text"/> %	<input type="text"/> %	<input type="text"/> %	<input type="text"/> %
LEFT EYE	Avg. IOP	<input type="text"/> mmHg	<input type="text"/> mmHg	<input type="text"/> mmHg	<input type="text"/> mmHg
	% of error	<input type="text"/> %	<input type="text"/> %	<input type="text"/> %	<input type="text"/> %

- ⑦ Was there an anterior chamber intraocular lens present?
 - RIGHT EYE No Yes → Do Not Dilate
 - LEFT EYE No Yes → Do Not Dilate
- ⑧ Were the angles shallow on penlight exam?
 - RIGHT EYE No Yes → Do Not Dilate
 - LEFT EYE No Yes → Do Not Dilate
- ⑨ Was the eye pressure equal to, or greater than 30mmHg?
 - RIGHT EYE No Yes → Do Not Dilate
 - LEFT EYE No Yes → Do Not Dilate

Comments: _____



Eye Photo

Office Use Only				Acrostic			Staff ID#		
SOF ID#									

IF INTRAOCULAR PRESSURE WAS NOT CHECKED, DO NOT DILATE. TAKE THE PHOTOS WITHOUT DILATING THE EYES.

IF THE ANSWER TO QUESTION 7, 8, OR 9 ON THE INTRAOCULAR PRESSURE FORM WAS ANSWERED YES, DO NOT DILATE. TAKE EYE PHOTOS WITHOUT DILATING THE EYES. OTHERWISE, DILATE AND THEN TAKE EYE PHOTOS.

- ① Record the diameter of the pupils in mm PRIOR to dilating to help determine if the participant is dilated. If the participant did not have one or both eyes dilated due to criteria above, record diameter after 10 minutes in a dark room or after patched for 10 minutes.

RIGHT EYE Before dilation: . mm After dilation: . mm
 dilating drops not used

LEFT EYE Before dilation: . mm After dilation: . mm
 dilating drops not used

- ② Were photos of RIGHT EYE taken? Yes No
- ③ Were photos of LEFT EYE taken? Yes No

Canon Fundus Photos Film Roll # Film Type

Check as completed:	<u>RIGHT EYE</u>	<u>LEFT EYE</u>
a. (N) Photo #1	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
b. (+) Photo #2	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
c. External #3	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
d. Retakes?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No

Comments on photos: _____



Functional Vision

Office Use Only					Acrostic			Staff ID#		
SOF ID#										

LETTER LITERACY TEST

① Number of letters read correctly: letters

② Were 10 or more letters read correctly?

Yes →

No →

BAILEY-LOVIE DISTANCE VISUAL ACUITY

③ Does the participant usually wear glasses and/or contact lenses for distance tasks?

Yes No Both

Is the participant wearing glasses and/or contact lenses for the Bailey-Lovie test?

Yes No

What is the participant wearing - glasses or contact lenses?

Glasses →

What type of glasses?

Distance Bifocal No-line bifocal

Both →

Contact lenses →

What type of contact lenses?

Distance Bifocal Monovision (one eye corrected for near, one for distance)

④ Was the Bailey-Lovie test administered?

Yes No

Why not? Check the main reason test was not administered.

Participant fatigued Unable to see chart Did not understand Refused

⑤ LEFT EYE

Which distance was used?

10 feet 5 feet

Participant unable to read chart at 5 feet

Which chart was used?

Chart 1 Chart 2 Home visit light box

Number of letters read correctly: letters

⑥ RIGHT EYE

Which distance was used?

10 feet 5 feet

Participant unable to read chart at 5 feet

Which chart was used?

Chart 1 Chart 2 Home visit light box

Number of letters read correctly: letters

(If unable to see any letters at 5 feet use code for light perception -- 99, 98, 97, 96 only)



Contrast Sensitivity Worksheet



STUDY OF
OSTEOPOROTIC
FRACTURES

SOF ID#

Acrostic

Staff ID#

Test each eye separately, starting with the right eye. Point at each circle. Ask about every circle, don't stop. Cross out the first one missed then circle the one just before that. Continue testing on the next row until one circle is missed, then cross that one out and circle the one before that was read correctly. Repeat for every row on the chart. Record the row totals below and transfer to the Contrast Sensitivity Form.

RIGHT									
ROW A	U1	U2	R3	R4	L5	L6	L7	R8	B9
ROW B	U1	L2	R3	U4	U5	L6	R7	U8	B9
ROW C	U1	R2	L3	L4	R5	R6	U7	L8	B9
ROW D	U1	U2	R3	U4	L5	L6	U7	R8	B9
ROW E	U1	L2	U3	L4	R5	U6	R7	U8	B9

Number of circles read correctly with **RIGHT EYE**:

A circles B circles C circles D circles E circles

LEFT									
ROW A	U1	U2	R3	R4	L5	L6	L7	R8	B9
ROW B	U1	L2	R3	U4	U5	L6	R7	U8	B9
ROW C	U1	R2	L3	L4	R5	R6	U7	L8	B9
ROW D	U1	U2	R3	U4	L5	L6	U7	R8	B9
ROW E	U1	L2	U3	L4	R5	U6	R7	U8	B9

Number of circles read correctly with **LEFT EYE**:

A circles B circles C circles D circles E circles