3.1

Lens Photography Introduction

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3.1

Photography - General

EYE STUDY PHOTOGRAPHY PROTOCOL

3.1.1 INTRODUCTION

The Study of Osteoporotic Fractures (SOF) is an investigation with an ophthalmic component designed to contribute to a better understanding of the relation between hip fractures and treatable eye conditions that are frequent among older women. As part of the ophthalmic component, photographs of the retina and lens 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. Several lens photographs will be taken using a Topcon SL-7E Photo Slit Lamp Camera and a Marcher Retro-Illumination Cataract Camera. The Topcon SL-7E slit lamp camera (modified) will be used to take a slit lamp (cross-sectional) photographs through the nucleus of the lens. The Marcher Retro-Illumination camera will take photographs of each lens to document cortical lens opacities.

3.1.2 PHOTOGRAPHY PROTOCOLS

Lens photography protocols are modified from protocols used in the Age-Related Eye Disease Study (AREDS) Manual of Operations, Chapter 8. The fundus (retinal) photography protocol is a modified version of the protocols used in the Atherosclerosis Risk in Communities Study (ARIC) - Retinal Photography Protocol

3.1.3 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, 5.3, 5.3). 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, <u>THE RIGHT EYE IS ALWAYS PHOTOGRAPHED FIRST</u>.

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 and lenses, that the bright lights are not harmful, and that any afterimage (often associated with color changes) will fade within a half hour or so.

3.1.4 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 front (the lens) and of the inside of the back (the retina) of both 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 the 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.

3.1.5 EXAMINATION PROTOCOL

All subjects will have 16 photographs taken of both eyes, and an additional 2 ID photos containing information about the subject. If the eye is considered too difficult to photograph with adequate photographic quality, with any camera(s) an explanatory note should be entered in the photography film log and in the (Camera) Photos Form. Conditions falling into this category are (based upon the photographer or technician's judgement): eye missing, inability to dilate at least 4 mm, inability to fixate adequately for proper photographic field definition, and opacities of the media preventing a reasonably clear view of the retinal vasculature.

3.1.6 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 assigned each of the four sites the following numbers:

Baltimore - 1	Pittsburgh - 3
Minnesota - 2	Portland - 4

The next four digits are the subjects number. The ID number of an individual consists of the site number followed by the individuals 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 Minnesota.

3.1.7 SUBJECT EXCLUSION

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 the **Canon photos are the most important to the study**, and during the use of this camera with difficult subjects ***it is better to have the nerve closer to the center of the picture than off too close to the edge***. Additionally, the optic nerve can be displaced up or down by about one disc diameter and ***still provide useful information***. Even if no photos can be taken with any particular camera(s), the photographer should still try to obtain photos with the other camera(s). If, in the photographer's judgement, no acceptable photograph can be taken, the subject will be excused from photography by one, two. or all three cameras.

The photographer should attempt all 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 lowered to the appropriate height. Care should be taken when lowering the camera table to avoid pressing against the subjects legs. If, in the photographer's estimation, the subject can not be comfortably positioned, no photography will be performed.

3.2

Supplies

3.2.1 SUPPLIES

Supplies can be divided into two categories: one-time purchases, and those bought on a repeat basis. One-time purchases include the cameras and ancillary equipment, adjustable table(s), two stools, and a camera cleaning kit containing a brush and air bulb for dust and lint removal.

Slide film for **fundus photography**: **Kodak EPP-135-36**, (35 mm, Professional Ektachrome 100 speed 36 exposure film)

Slide film for **lens photography**: **Kodak EPD-135-36**, (35 mm, Professional Ektachrome, 200 speed, 36 exposure film)

A list of supplies that need to be reordered on a repeat basis follows:

- Photographic lens tissue
- Lens cleaning fluid (100% alcohol)
- Kleenex tissues
- Spare view and slit lamps
- Fuses for electrical circuits
- Film roll processing labels (1" x 2")
- SR44, 1.5-volt silver oxide batteries for Mitutoyo potentiometer on Marcher camera
- Varta 2CR5, lithium 6-volt batteries for 35 mm Canon camera body
- AA penlight batteries for Olympus motor winder
- MS76, 1.5-volt silver oxide batteries for Olympus OM-4 camera body
- SR44 , 1.5 volt silver oxide batteries for Olympus Recordata Back 4 data back
- Contact lens holder and saline solution
- Paper tape
- Sharpie markers (black, fine point)

3.2.2 INVENTORY

An inventory of supplies for each of 4 study centers (assuming an average of 1,500 subjects per center) follows:

- **Kodak EPP-135-36** (from UCLA)	250 rolls
- **Kodak EPD-135-36** (from UCLA)	500 rolls
- Lens tissue	1 package (500 sheets/package)
- Lens fluid (100% alcohol)	1 bottle (8 oz)
- Facial tissues	5 boxes (200 tissues/box)
- Spare lamps	View and split (1 each)
- Spare assorted fuses (see Ch 5)	Boxes (6/box)
- Film roll labels	530 (minimum)
- SR44, 1.5-volt silver oxide batteries	2 batteries
- Varta 2CR5, lithium 6-volt batteries	2 batteries
- AA penlight batteries	1 battery
- MS76, 1.5-volt silver oxide batteries	8 batteries
- SR44 , 1.5 volt silver oxide batteries	2 batteries
- Sharpie markers (black, fine point)	1 box (1 dozen/box)

3.3

Equipment Set-up

3.3.1 EQUIPMENT SET-UP

The camera dust covers and lens caps should be removed at the beginning of the day and the lenses inspected and cleaned as necessary. **Dust is the greatest enemy**, producing the majority of artifacts on the photographs. ***When the cameras are not in use, the lens caps should be in place and the special dust covers must remain on the cameras.*** The 35 mm cameras and camera backs should be checked for sufficient battery power, and the film counters should be checked to be certain that all cameras are loaded with adequate film before beginning photography.

3.4

Retinal Photography and the Care and Maintenance of the Canon CR-45UAF Camera

3.4.1 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.

3.4.2 THE CANON CR-45UAF CAMERA

A Canon non-mydriatic, auto-focus fundus camera with 35 mm camera back will be used for this segment of the photography. 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 CR45-UAF camera. A copy of the Canon Non-Mydriatic Retinal Camera Operation Manual (5.1) accompanies this protocol.

3.4.3 CARE AND MAINTENANCE OF THE CANON CR-45UAF 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 field center.

3.4.3.1 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 tissued using a circular, polishing motion 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. pg 42).*** The body of the camera should be kept clean 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 infra-red 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.**

3.4.3.2 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 casters 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 or current.

3.4.3.3 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 are 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 field 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 Michael Cornish, 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 field center staff who have been trained to do this.***

3.4.4 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 Michael Cornish, 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, 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 Michael Cornish, UCLA Senior Photographer at all times (to page call 1-800-BEEP231, pager ID # 90885) - 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 in Itasca, Illinois or Lake Success, New York. Our contacts there are Tom Penkala, Canon USA, 100 Park Blvd., Itasca, IL 60143-2693, telephone number: 708-250-6230 or Ron Kaiser, Canon USA, 1 Canon Plaza, Lake Success, NY 11042-1113, telephone number: 516-328-4645. In addition, you can also contact James News, a technician , at 714-753-4279, 15955 Alton Parkway, Irvine, CA 92618.

3.5

Pre-photography Procedure (Retinal)

3.5.1 PRE-PHOTOGRAPHY PROCEDURE

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 subject 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 Canon Photos Form and in the Photography Film Log.**

The 35 mm camera body should be attached to the main unit and loaded with EPP-135-36 film. ***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 (Ch 5.1 pg 30) 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 K:	**ON**	(blink detector on)
SPLIT:	**IN**	(split focus detector in)
NO:	**H 030001**	(SOF Eye Study subject ID)*
DATE:	**MM-DD-YY 12:00**	(correct date and time)

* 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 (Retinal)

3.6.1 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.

3.6.2 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 (Ch 2,9 pg 30)**.

3.6.3 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 to 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 ID number, examiners ID number and date are all entered on the Canon Photos Form 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.

3.6.4 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 eye lids 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 forward or back until the pupil appears perfectly round. At this point, proper external alignment has been. A pupil larger than the central 4 mm circle on the monitor is required for adequate fundus photography. If the eye does not dilate to at least 4 mm, the photographer should nevertheless attempt to view the retina. If any retinal detail is visible, photographs should be taken. If no retinal detail is visible on the television monitor, then no fundus photos are taken and the opposite eye is examined for photography.

3.6.5 PHOTOGRAPHY THROUGH SMALL PUPILS

The photographer will experience more difficulty attempting photography through small (less than 4 mm) pupils because all of the camera light doesn't enter through the smaller pupil. This usually results in uneven illumination (seen as dark shadows) on the monitor. In this situation, the photographer must make careful camera adjustments to position the shadows ***as far away from the optic nerve and macula as possible.***

A small percentage of participants' eyes do not dilate to the minimum 4 mm required for adequate photography. Certain medications may prevent any dilation and the pupil size observed on the monitor

may be 1-2 mm, inadequate for the photographer to appreciate any retinal landmarks on the viewing monitor.
If no landmarks are visible, the photographer should adjust the camera slightly to position the corneal reflection dots **slightly above or below their optimum position**. This technique allows a portion of the illumination light (which falls on the iris when the pupil is small) to enter the eye. If any retinal landmarks become visible with this technique, ***pictures should be taken***. However, if no retinal landmarks are visible, which is often the case when dilation is less than 1.5 mm, ***no fundus photo is taken***. of the particular eye.

3.6.6 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.***

3.6.7 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 can be 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 Doesnt 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 effect viewing; ***they do not*** effect final photo quality (Ch 5.1, pg 3, part# 5).

3.6.8 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 eye being photographed. **To facilitate consistent positioning of the optic disc, 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 2 disk 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.

3.6.9 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.

3.6.10 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 (Ch 5.1, pg 8).

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.

3.6.11 SEQUENCE OF RETINAL PHOTOS

Two retinal exposures will be made for 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

3.6.12 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 with at "+" (a 1/3 f-stop increase in exposure). The external photo will always be exposed at "N."

3.6.13 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.

3.6.14 SEQUENCING MODIFICATIONS FOLLOWING RETAKES

The photographer must be careful to try to avoid retakes. However, when these are absoloutely necesscary **in order to obtain a gradeable photo,** retakes are permitted.

3.6.14.1 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 subjects 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 Ch 5 pg 30).

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

If this particular subject happens to be the last (6 th) subject on the roll in order to complete the photographic sequence, a new roll of film will have to 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. When this occurs, thr Photography Film Log must be marked "incomplete" in the space directly beneath "Film Roll # _____." These deviations must also be noted in the Canon CR-45 UAF Fundus Photos form in the "Comments on Canon Photographs:" section.**

3.7

Lens Photography and the Modifications, Care, and Maintenance of the Topcon SL-7E Slit Lamp and Marcher Retro-Illumination Cameras

3.7.1 INTRODUCTION TO LENS PHOTOGRAPHY

As the other part of the ophthalmic photography component, ten lens photos of each subject will be taken through pharmacologically dilated pupils. These photographs will be taken on 35 mm slide film using a Topcon SL-7E Photo Slit Lamp Camera and a Marcher Cataract Camera. Both cameras have been modified and preset. **Lens photographs will be taken directly following the fundus photos while the subjects eyes are still dilated.**

Consistent high quality photographs should be obtained for every participant in the study. The presence or absence of cataracts will be determined based on the grading of the photographs. No part of the lens images should be lost because of interference from lids or lashes. Help should be summoned, if needed, to hold eyelids or eye lashes.

3.7.2 THE TOPCON SL-7E SLIT LAMP AND MARCHER RETRO-ILLUMINATION CAMERAS

A Topcon SL-7E Slit Lamp and Marcher Retro-Illumination camera both with 35 mm camera backs will be used for this segment of the photography. The cameras are mounted on motorized instrument tables to allow optimum alignment. Both photographer and subjects have pneumatically adjustable stools, the latter with a back rest and floor lock mechanism.

3.7.3. LENS CAMERA MODIFICATIONS

The Marcher Retro-Illumination and Topcon Slit Lamp cameras have been modified and pre set in order to increase the reproducibility of lens photographs among clinical centers and among participants at each center. The Topcon camera modifications provide a slit beam of standard dimensions and orientation, and, by controlling fixation, produce comparable slit lamp photographs for right and left eyes. The Marcher camera modification provides a mechanism for focusing the photographs at standardized depths within the lens.

3.7.3.1 Topcon SL-7E Slit Lamp Camera

a) The slit width and height are fixed at 0.3 and 9.0 mm, respectively. The binocular assembly, with the magnification changer, is fixed perpendicular to the cross-slide base. The slit beam is locked at an angle of 45 degrees (Fig 3-1, pg 3-14) to the assembly, and remains always at the photographer's left. The magnification changer is fixed at 16X magnification and the fill-in illuminator is disconnected.

b) Fixation for each eye is controlled by a separate light emitting diode (LED). The two LEDs are suspended from a ring mounted around the camera's objective lens (Fig 3-2, pg 3-14). The LEDs, 1 mm in diameter and of approximately equal brightness, fall on an imaginary horizontal line bisecting the front objective lens. The LED for fixation of the right eye is positioned directly between the two viewing lenses. The LED for the left eye is mounted approximately 11 mm to the right of the first LED, so that the left eye is turned inward by twice angle alpha, the angle between the optical and visual axes of an average emmetropic eye. This rotation is necessary so that the path of the slit beam through the lens is symmetrical in the two eyes, although it comes from the temporal side of the right eye and from the nasal side of the left eye, as shown in Fig 3-3, pg 3-14 (a scaled diagram based on Gullstrand's schematic eye, with a diameter of 24.3 mm and a nodal point 17 mm from the posterior focal point). The LED viewed by the participant's left eye is in the optical pathway of the observers left eye, but this has little effect on stereo viewing and no effect on the photograph, which is taken through the right side of the biomicroscope. Test slit lamp photographs using these fixation targets have confirmed that the sections of lens illuminated in right and left eyes are similar.

c) A small switch box, mounted near the magnification lens changer assembly, allows the photographer to switch on the appropriate fixation LED for the eye being photographed. **The switch is**

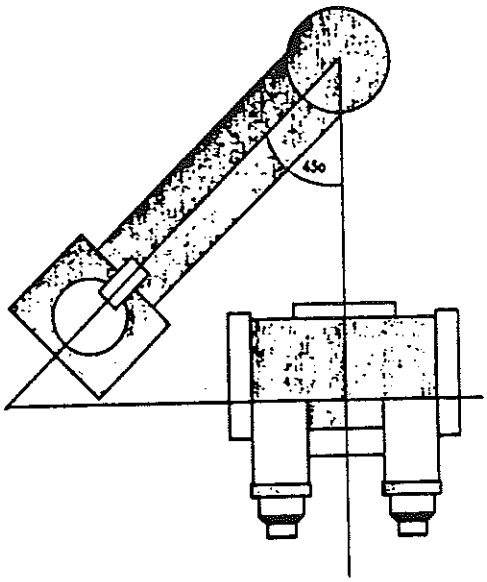

Fig 3.1 Slit lamp camera beam locked at a standard 45 degree angle

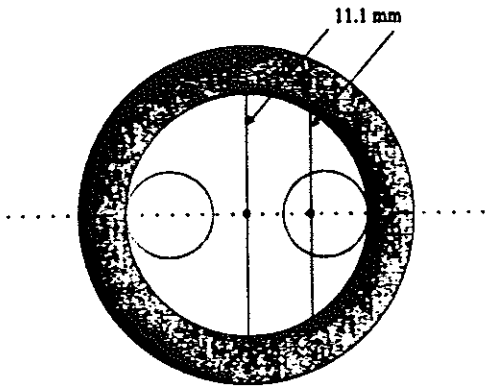

Fig 3.2 Slit lamp camera fixation targets suspended from a ring mounted around the objective lenses

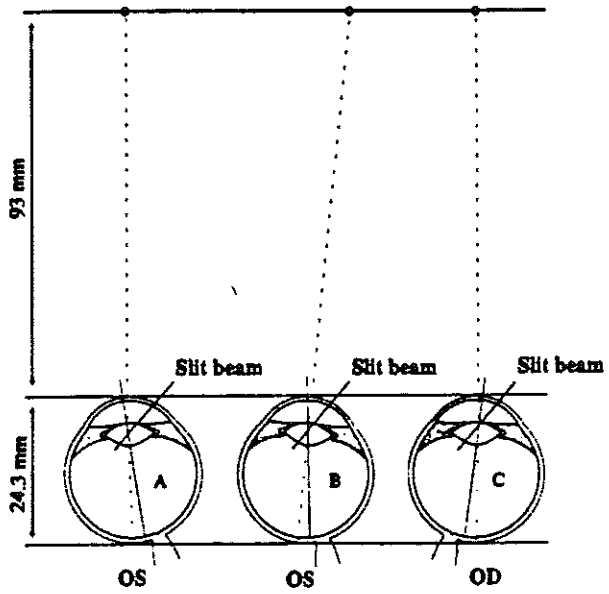

Fig 3.3 Schematic diagram based upon Gulstrand's showing the paths of the slit lamp beam and the fixation of the eye upon the target (dashed lines). Diagrams B and C show correct fixation resulting in symmetrical sections of the lenses of the left and right eyes. Diagram A shows incorrect fixation of a left lens resulting in a nonstandard section of the lens.

pointed to the participant's right for photography of the right eye and to the participant's left for photography of the left eye.

3.7.3.2 Marcher Retro-Illumination Camera

A linear potentiometer (an electronic ruler) capable of measuring anterior - posterior movement to an accuracy of .01 mm is attached to the wheel cover on the right hand side of the camera platform. The measuring arm rides over the cross-slide base axle and is positioned so that the operator experiences no restriction in camera movement. A digital display unit is mounted on top of the Marcher camera body. The initial (anterior) photographs are focused on the edge of the pupillary margin with the digital display set at zero. As the camera is moved forward, to focus deeper into the lens, the distance traveled is displayed in the window of the potentiometer. The second (and additional if needed) photographs are taken between 3 and 5 mm posterior to the first, favoring the middle of this range if no posterior subcapsular lens opacities are observed, but focusing on such opacities if they are seen.

3.7.4 CARE AND MAINTENANCE: TOPCON SL-7E AND MARCHER RETRO-ILLUMINATION CAMERA

3.7.4.1 Topcon SL-7E Slit Lamp Camera

a) **Daily:** The mirror involved in the delivery of the slit beam should be kept free of dust, dirt, and finger prints. It is preferable to remove loose dirt with dry compressed air or an air bulb instead of wiping since this is a front surface mirror. If it must be wiped, ***use only a soft wet cloth and apply the least amount of pressure necessary to clean the surface.*** A spare mirror is provided with the microscope in the event the original mirror is damaged. The headrest and chin assembly should be kept clean with isopropyl alcohol (need for this can be minimized by the use of paper chin rest pads).

The camera back should be inspected each time film is changed to remove any loose film particles, dust or dirt. Care should be taken not to touch or damage the shutter when blowing the dirt from the camera back. Camera cables and shutter release connections should be kept tight and inspected for damage. The mounting screw between the motor drive and the camera body needs periodic tightening. A daily check of the integrity of the LED lamps should be made. The lamps were selected because of their long life and should last for the duration of the study. Should one burn out, contact Michael Cornish at UCLA, and if necesscary, he will arrange for Michael Neider to replace the entire LED ring. If the defective ring needs to be shipped to Michael Neider for repair, his address is the following:

Michael Neider
University of Wisconsin-Madison Medical School
Department of Ophthalmology and Visual Sciences
610 Walnut street, Room 460 WARF
Madison, WI 53705-2397

The microscope is equipped with a dust cover which should be used whenever the microscope is not in use to keep dust and dirt collection to a minimum.

b) **Weekly:** The camera tabletop should be cleaned weekly with a conventional kitchen cleaner. The plastic pad under the joystick should be kept very clean to prevent sticking. This can be done with an alcohol pad followed by a tissue sprayed with a ***little*** WD-40 (or a similar light lubricant). This creates a very slick surface and allows the microscope to travel freely.

c) **Every Two Years:** The flash lamp should be changed every two years to insure consistent maximum illumination. A spare flash lamp should be available to each site should a premature lamp failure occur. Image quality needs to be monitored throughout the life of the study. The flash lamp may discolor over time gradually producing darker images, requiring it to be changed more frequently than at the routine two year interval.

d) **As Needed:** The front objective lens should be inspected frequently and, when necessary, cleaned before photography. Past experience shows us that this cleaning is required about every three months. When cleaning is necessary, this is done by removing the small set screw that holds the fixation light ring to the front of the lens barrel. ***This ring must be carefully repositioned*** after the objective lens is cleaned to insure that the LEDs remain in the same horizontal plane. Orientation marks have been placed on the ring, fixation lamp control box and microscope body to aid with the alignment.

The tracks for the microscope should be inspected and cleaned to remove loose dirt and dust that accumulates on them. This can be done by removing the protective covers and wiping a damp cloth across the teeth on the camera platform. The wheels should also be kept clean with a ***light film*** of WD-40 spray. Spare viewing and flash lamps should be stocked in each clinic for easy replacement as they burn out.

The optical surfaces involved in the slit production need to be kept clean. The viewing lamp housing and condensing lens system (with the flash lamp attached) can be removed, cleaned and reassembled without effecting the slit width or height.

3.7.4.2 Marcher Retro-Illumination Camera

a) **Daily:** The observation ocular should be kept clean to provide the clearest view possible. The 35 mm Olympus camera body and data-back should be inspected and cleaned internally each time the film is changed. This is done in the same manner as for the Topcon camera body.

A daily check of the fixation lamps should be made. These lamps have been selected because of their long life and are expected to last the duration of the study. Should one fail, a replacement assembly must be obtained from International Ophthalmic Industries Corporation, the sole importer and service site for the Marcher camera in the United States. Please contact Michael Cornish at UCLA if one of the fixation lamps fail.

b) **Weekly:** The camera table should be wiped with a damp cloth to keep it clean and free of dust and the plastic pad under the joystick should also be cleaned and treated with WD-40 spray to keep it operating smoothly. Any cleaning of the camera tracks which involves removal of the wheel cover requires disconnection of the potentiometer. The power cable is easily removed from the potentiometer. The wheel cover, with potentiometer attached, can be removed and set aside. ***A routine inspection for loose or frayed cables or connections should be made.The Marcher camera is particularly prone to loose wires and special attention must be paid to assure that electrical connections are tight.***

c) **Monthly:** The metal edges of the linear potentiometer rail should be wiped with WD-40 to keep the potentiometer moving freely. Otherwise, as the tracks become dry the camera becomes difficult to move.

d) **As Needed:** Routine flash and view lamp replacements should be made as these lamps deteriorate and burn out. As these lamps continue to be used the number of lumens produced is decreased, and, the each lamp takes an increased time interval to reach its flash point. The life expectancy of the Marcher flash lamp is approximately 2000 flashes and should be replaced at that time.

Image quality needs to be monitored throughout the life of the study and the flash lamp will be changed at a reduced interval if the images become unacceptably dark.

The 35 mm camera body and data - back require separate batteries for their operation. Neither the camera nor the data - back will operate when these batteries expire. The camera contains a battery check function that can be used to test the battery. This check that should be performed whenever the camera shutter fails to operate, or at least once a month. Similarly, the batteries in the data - back need to be checked monthly and replaced as needed.

Motor drive batteries should be replaced as they wear down, unless rechargeable batteries such as nickel cadmium are used. ***Nickel cadmium batteries require special care and should should never be allowed to drain completely***. They should be recharged periodically when the voltage drops off. ***A set of alkaline batteries should be kept as spares in case the nickel cadmium batteries can-not be recharged in time for a photo session.*** The potentiometer is powered by a battery which should last one year. ***The potentiometer should be turned off after each participant is photographed to prolong battery life***. The liquid crystal display on the face of the potentiometer will not light if the battery is weak. A weak battery will also cause the display on the black box to fail. If the wrong mode is selected, i.e. inches rather than millimeters, the black box display will brighten and freeze to show all 8's.

3.8

Subject Photography (Lens)

SOF-ES Addendum
to Manual of Procedures

Section: Photography Section 3.8.3.1
Extra Marcher Retro-illumination Photos

Page: 3-20

Changes: **1.) Extra or duplicate Marcher camera photogaphs**

All extra Marcher photographs should be anterior NOT posterior OR note on the log sheet that it's a posterior shot.

2.) Order in which Marcher photographs are taken

The order in which Marcher camera photographs are taken is three (3) of the right eye -- anterior, posterior, anterior -- then three (3) of the left eye -- anterior, posterior, anterior.

3.8.1 TOPCON SL-7E SLIT LAMP AND MARCHER RETRO-ILLUMINATION PHOTOGRAPHY

If an eye is aphakic (has no lens), or pseudophakic (has had cataract surgery , and now has an implanted lens), no Topcon of Marcher photographs are taken.

The Photography Film Log for each camera should be carefully maintained. In addition, the Topco SL-7E Slit Lamp Lens Photos, and Marcher Retro-Illumination Photos forms (see FORMS) should also be maintained for each specific camera. **Redundant information both in the Photography Film Log and in the appropriate Camera Lens Photos forms** should include the film roll number, photography date, photographer's ID number, participant's ID number, eye photographed and any comments to be passed on to the Reading Center to explain problems encountered. ***A routine must be established so that the right eye is always photographed first.*** **As the Topcon camera has no data imprinting ability, you must photograph an ID frame; which consists of the date, subject ID, and eye photographed**. After this, you will take two seperate exposures of each lens with the Topcon slit lamp camera to assure proper beam placement and focus on the sulcus.

3.8.2 TOPCON SL-7E SLIT LAMP PHOTOGRAPHY

Concentration on alignment and focus is essential. When aligning the slit beam be sure that the beam is centered from 12:00 to 6:00 in order to illuminate all of the lens visible through the dilated pupil. Remember that the goal for slit lamp photographs is to ***illuminate the lens sulcus*** from 12:00 to 6:00. That means that the slit beam will strike the ***anterior lens surface*** a few millimeters to the left of center.

a) Film, Illumination and Magnification

The following film ***must be used***:

- EPD-135-36 film

Precise aperture and flash settings will be set during initial camera installation at each clinical center to provide consistently uniform exposures. Thereafter they must not be changed. The following parameters are specified, are preset on the camera, and ***must not be changed by the photographer***:

- Slit angle 45 degrees
- Beam width 0.3 mm
- Beam height 9 mm
- Flash intensity 5 (maximum)
- Magnification 16X

b) Initial Preparation

The photograph is taken through a maximally-dilated pupil or a pupil that is 6 mm in diameter if possible. If a subject has droopy eyelids that would interfere with any of the camera images (for example, the lids prevent visualization of dilated pupil), then the upper lids should be taped with paper tape. The flash intensity is preset to position 5 and EPD-135-36 film loaded into the camera.

The right eye is photographed first.The photographer positions the ocular with the focusing hairs in the right ocular and adjusts it to the sharpest focus possible. The chin rest is adjusted so that the lateral canthus is in line with the black mark on the headrest support. An ID frame is taken with this camera as unlike the other two cameras there is no data imprinting capability. **This ID frame should include the participant's name and ID number, the date, and eye (right or left).** ***This is essential because, unlike the Canon photographs, there is no data imprinting capability. Also, no clear landmarks exist to differentiate the right eye from the left eye.*** If no ID

frames are taken to separate them, it is impossible to sort the photographs and incorrect identifiers may be assigned. At the same time redundant entries must be made in the Topcon SL-7E Lens Photos form and in the Photography Film Log.

c) Participant Fixation

The participant is asked to fixate on the red target light with the fellow eye occluded to avoid diplopia and confusion. ***The photographer must be certain that the correct fixation light is illuminated.*** The fixation light switch is set to the participant's right for photography of the right eye and to the participant's left for photography of the left eye. When the fixation lights are correctly plugged in, the center fixation light is illuminated for the right eye.

d) Slit Beam Placement and Focus

The slit beam should completely fill the pupil vertically bisecting the central lens from 12:00 to 6:00. In the proper position, the slit beam falls on the anterior lens surface 1-2 mm to the left of center. Focus should be on the sulcus of the lens, if visible, so that the presence and extent of a central optically-clear zone (the sulcus) can be graded. For the right eye, the red fixation target reflection will appear near the center of the sulcus. For the left eye, this reflection may appear up to 3 "fixation dot widths" further left of the anterior edge of the sulcus. The red fixation target reflection should appear out of focus (because it is reflected from the anterior corneal surface). The photographer should imagine that the clearly-focused sulcus, if extended superiorly and inferiorly, would contact the iris at 12:00 and 6:00, respectively. If the sulcus is not clearly visible (as is the case with more advanced nuclear sclerosis), then the photographer must use his/her best judgement to estimate the proper position so that the degree of lens opalescence can be accurately graded.

The reflection of the mirror from the anterior lens surface (appearing at or near the posterior lens surface) should fall directly behind the lens, where it may help delineate posterior subcapsular opacities and will aid in estimating lens color.

Two high quality slit lamp photographs are taken of each lens to document nuclear sclerosis. ***The focus should be carefully adjusted for each photograph*** so that at least one photograph will allow for accurate grading of the degree of lens opalescence.

<u>The procedure is now repeated for the left eye.</u>

Both the Photography Film Log, and the Topcon SL-7E Slit Lamp Photos Form should be completely filled.

3.8.3. MARCHER RETRO-ILLUMINATION PHOTOGRAPHY

a) Film and Illumination

The following film ***must be used***:

- EPD-135-36

Precise aperture and flash settings will be set during initial camera installation at each clinical center to provide consistently uniform exposures. Thereafter they must not be changed. The following parameters are specified, preset in the camera, and ***must not be changed by the photographer***:

- View lamp intensity is preset and fixed.

b) Initial Preparation

The pupil is dilated to 6 mm.

The right eye is always photographed first. The participants ID numbers and date are entered into the 35 mm databack, while synchronously this information along with the eye photographed, photographers ID number etc. is entered in the Photography Film Log and in the Marcher Retro-Illumination Lens Photos form..

The participant is seated comfortably behind the camera with chin firmly on the chin rest and forehead snugly against the headrest. The chin rest is adjusted so that the participant's lateral canthus is in line with the black mark on the headrest support. The photographer adjusts the ocular to focus the cross hairs to the sharpest image possible

c) Participant Fixation

A hand-held occluder is adjusted in front of the participant's left eye and ***the right eye is photographed first.*** The photographer selects the appropriate fixation light and instructs the participant to **fixate on the flashing red light**. At this point it is helpful to keep the viewing lamp outside the pupil to enable the participant to locate the target. Once fixation is confirmed, the camera can be centered on the pupil.

d) Focus

In order to permit the linear potentiometer to work, it is very important that the subject remain as motionless as possible during this part of the photographic procedure. The camera is focused on the iris at the pupillary margin, at 12:00 and 6:00, and the first photograph is taken with the potentiometer at zero. The circular illumination lamp should be centered in the pupil to maximize entry of light into the eye so as to produce the brightest retro-illumination. When the participant is fixating on the correct target, the entire iris edge will not be in sharp focus because the plane of the iris is not parallel to the film plane. One anterior photograph of the lens is taken. The photographer pushes the button to initialize the potentiometer, advances the camera to scan the 3-5 mm range for opacities, and then takes one more picture, ***focusing on posterior subcapsular opacities, if present, or using the potentiometer to focus about 4 mm posterior to the plane of the anterior photograph.*** The potentiometer reading is recorded on the Photography Film Log and in the Marcher Retro-Illuminations Lens Photos form. Two lens photographs should be taken per eye with the Marcher camera.

This procedure is repeated with the left eye, being certain to use the appropriate (green) fixation light.

3.8.3.1 Extra Marcher Retro-Illumination Photos

The photographer **must now retake two photos.** These are taken in order to maintain the correct sequence and will be best used to duplicate those photos that might have been marginal in the photographers judgement. **All of this information such as eye re-photographed, and anterior or posterior focus, MUST BE NOTED IN THE PHOTOGRAPHY FILM LOG AND IN THE MARCHER RETRO-ILLUMINATION LENS PHOTOS FORM**

3.9

Reversal of Dilation and Subject Referral

3.9.1 REVERSAL OF DILATION OF PUPILS

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.

3.9.2 SUBJECTS TO BE REFERRED TO AN OPHTHALMOLOGIST WITHIN 8 HOURS

1. Subjects with eye pain and redness that is not relieved with blinking or with artificial tears
2. Subjects that see new halos around lights
3. Subjects that become nauseated and vomit
4. Subjects that complain of itchy, red, and swollen eyelids
5. Subjects that have eye pressures greater than 35 mmHg

3.9.3 SUBJECTS TO BE REFERRED TO AN EYE DOCTOR WITHIN ONE WEEK

1. Any subject with eye pressures between 24 mmHg and 35 mmHg.

3.10

Film: Handling, Shipping, and Logs and Records

3.10.1 FILM CONCERNS

The most consistent exposure will be obtained using a ***professional grade*** slide film that will be distributed from 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 UCLA Reading Center ***within a week after the last exposure is taken.***

3.10.2 FILM TRACKING AND NUMBERING

Before any film is loaded into a camera it must be marked for identification Use a fine point Sharpie and write on the cassette label. **Never write on or obscure the dx code if present (the pattern of silver and black rectangles below the exit lip) as this provides the camera with information about the film.** The marking system will consist of the date the film was loaded into the camera and following alpha-numeric code as shown below:

Date loaded
Center number - camera used - roll number.

for example:

Feb 05 97
1-T-023

shows that roll number 23 was loaded into a Topcon in Baltimore, on 02-05-97.

A roll marked:

Jun 17 98
4-M-206

shows that roll number 206 was loaded into a Marcher in Portland, on 06-17-98.

Additionally, once film is exposed and unloaded, a numbered film roll label is attached to each exposed roll.

3.10.3 PHOTOGRAPHY FILM LOG

The photographer will keep a manual film log on the SOF Photography Film Log kept 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.
Each roll of film will be assigned a unique roll number **and will contain photographs of both eyes of 6 subjects.** 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 the Reading Center, which can take this information into account when

providing feedback.

3.10.4 FILM SEQUENCING

We will be taking 6 photos per subject with each of the three cameras used. Therefore, all three cameras will use film at the same rate. **This means that all three cameras will be ready to have the film unloaded after every 6 subjects photographed.**

3.10.5 FILM PROCESSING

After checking that all three rolls have have been correctly identified, it is important to ship these at the same time, together with the Photography Film Log and a COPY of the Canon Photos, Topcon SL-7E Slit Lamp Photos, and Marcher Retro-Illumination Photos forms.

The film will be removed from the camera after each roll is fully exposed. Film will be sent to UCLA via U.P.S. or Federal Express weekly ***via overnight delivery*, never on a Friday or the day before a holiday**. Partially exposed rolls of film in the Canon camera may be removed after rewinding the film automatically by depressing the Manual Rewind Button on the 35 mm camera body (Ch 5.1, pg 30). With the Topcon camera, partially exposed rolls are removed by depressing the rewind button on the 35 mm camera body and manually winding the film back onto the cassette (Ch 5.2. pg 33). For the Marcher camera, the Olympus OM-4 35 mm camera manual film advance crank must be partially cocked to access the "r" button. Depress this "r" button and then manually rewind the film back onto the cassette (see the Olympus OM-4 instruction manual). ***The photographer must attach a numbered film roll label to each exposed roll of film before sending it to UCLA.*** The film roll label appears as follows:

SOF Eye Study
Film Roll # _____
Center # _____
Date: _____
Camera_____
ID #'s ____;____
____;____
____;____

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 Canon, Topcon and Marcher forms accompany each roll of film.

The undeveloped rolls of film will be sent to UCLA where we will have the film processed within two days so that the results can be reviewed by the Michael Cornish, UCLA Senior Photographer 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.

3.10.6 FILM SHIPPING

Packages of exposed film and the relevant Photography Film and specific camera forms are sent promptly to UCLA . Film rolls should be reinserted back into their plastic containers for shipping.

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

3.10.7 SHIPPING COURIERS

When using couriers such as Federal Express or UPS, please use the Reading Center's complete street address. The following shippng label example contains the correct address to be used for all photograph shipments sent to the the Reading Center.

Dr. Anne Coleman
UCLA Reading Center
100 Stein Plaza, JSEI 2-118
Los Angeles, CA 90095-7004

3.11

Photograpic Standards and Photographer Certification

3.11.1 PHOTOGRAPHIC STANDARDS

Photographic quality will be continuously monitored throughout the study. **All photographs will be reviewed by the UCLA Senior Photographer Michael Cornish 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. All of the photographs will be reviewed by Michael Cornish, and feedback will be provided to the local photographer in cases that warrant critique

3.11.2 PHOTOGRAPHER CERTIFICATION

Each examiner taking photographs will need to become certified before taking photographs for the study. The initial group of photographers received didactic and hands-on training during the September 28 to October 2, 1996 training session in Los Angeles, California. Following the training session, photographers return to their respective centers and begin practicing retinal photographs. An additional training session will concentrate on the Topcon and Marcher cameras. A photographer is fully certified after submitting satisfactory quality photographs of a total of 10 eyes taken on all three cameras 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 SOF Eye Study protocol, and the Canon Non-Mydriatic Retinal Camera,Topcon SL 7E Camera and Marcher Retro Illumination Camera Operation Manuals. The trainee photographer will practice on volunteers and, when ready, prepare and submit photographs of 10 eyes for consideration for provisional certification.

3.11.2.1 Certification for SOF-ES photography

All photographers in the study must first receive provisional certification before they can take photographs of the SOF participants. To become provisionally certified, photographers must submit photographs of ten eyes of non-study participants taken using all three cameras to the Reading Center 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 using all three cameras of SOF 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 backup photographer participate and take photographs with all 3 cameras on at least one subject once a week.
All photographs are assessed for quality at the Reading Center and feedback is given to the photographers as needed to help with resolution of any problems.

Based upon assessment of photographic characteristics, the Reading Center grader assigns overall quality grades to the Topcon slit lamp and Marcher photographs. Specific criteria for the evaluation of fundus photographic quality are presented in the grading protocol.

3.11.3 READING CENTER - PHOTOGRAPHER COMMUNICATION

As film is received at the UCLA Reading Center, it will be developed and the photographs will be graded for quality. Initially, on a bi-weekly basis, and then quarterly, the grading staff will review the quality of each photographer's work with the UCLA Reading Center photographic protocol monitor, a photographer with extensive experience in study photography. The monitor will then call the photographer 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 transparancies or Polaroid photos will be returned to the photographer as necesscary. This contact will also allow the photographer an opportunity to ask questions or make comments. The monitor will represent the viewpoints of photographers to the study as a whole.
When substantial problems are observed (particularly if a photographer has reverted from full to provisional certification), the photographic protocol monitor will phone the photographer more frequently. If the problems cannot be adequately addressed by telephone, the monitor may arrange to conduct a special photographic site visit for the purpose of observing the photographer at work and demonstrating the desired technique.

Occasionally, the UCLA Reading Center will issue a newsletter for study photographers, regarding issues of particular interest to them and discussing methods for obtaining the most optimum results.

3.12 EXAMINATION PROTOCOL

All subjects will have three different, bracketed, 45-degree photographs taken of each eye. If the eye is considered too difficult to photograph with adequate photographic quality, an explanatory note should be entered in the photography log. Conditions falling into this category are (based upon the technician's judgement): eye missing, inability to dilate at least 4 mm, inability to fixate adequately for proper photographic field definition, and opacities of the media preventing a reasonably clear view of the retinal vasculature.

3.13

Subject Exclusion

3.13 SUBJECT EXCLUSION

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 (as may be the case where both eyes are blind or when the subject is deaf and communication with them is impossible). In these cases, the photographer should get the best field definition possible remembering that it is better to have the nerve closer to the center of the picture than off too close to the edge. Additionally, the optic nerve can be displaced up or down by about one DD (disc diameter) and still provide useful information. If, in the photographer's judgement, no acceptable photograph can be taken, the subject will be excused from photography.

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 lowered to the appropriate height. Care should be taken when lowering the camera table to avoid pressing against the subjects legs. If, in the photographer's estimation, the subject can not be comfortably positioned, no photography will be performed.

3.14

Pre-Examination Procedure

3.14 PRE-EXAMINATION PROCEDURE

Before attempting photography, the photographer should become very familiar with the camera through a training session and by learning the terminology on pages 3, 4 and 24 of the camera's operation manual (Appendix A). The following protocol uses terminology from the operation manual and it is recommended that the entire manual (Appendix A) be reviewed by each photographer.

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 chief photographer at each field center.

3.14.1 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 (also see Exhibit 1-8).

> *We will be taking a photograph of the inside of the back (the retina) of both your eyes so we can study the blood vessels and look for any unusual changes. 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 before a special camera with your chin in a chin rest. We darken the room so we can align and focus the camera on your retina. During the aligning process, you will only be aware of some small red lights and a blinking green light visible in the camera lens. We will ask you to follow the blinking green as we move it. Just before we take the picture, we will ask you to blink your eyes and then open them real wide. The camera will flash a bright flash from within the camera lens as the picture is taken.*
>
> *Just after the 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 one picture (not an x-ray) of a small portion of your eyes and that this picture 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.*

3.14.2 Preparing the Camera

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.

SOF EYE STUDY - Sample Script

(suitable for use as written material for deaf or interested subjects).

We will be taking a photograph of the inside of the back (the retina) of both your eyes so we can study the blood vessels and look for any unusual changes. 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 before a special camera with your chin in a chin rest. We darken the room so we can align and focus the camera on your retina. During the aligning process, you will only be aware of some small red lights and a blinking green light visible in the camera lens. We will ask you to follow the blinking green as we move it. Just before we take the picture, we will ask you to blink your eyes and then open them real wide. The camera will flash a bright flash from within the camera lens as the picture is taken.

Just after the 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 one picture (not an x-ray) of a small portion of your eyes and that this picture 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.

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 a six-digit subject 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.**

The 35 mm camera body should be attached to the main unit and loaded with a fresh roll of Professional Ektachrome 100 EPN color slide film (36 exposures). **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 (Appendix A, page 30) needs to be depressed.

To load the camera, 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 K:	**OFF**	(blink detector off)
SPLIT:	**IN**	(split focus detector in)
NO:	**H 000001**	(5-digit SOF Eye Study subject ID)*
DATE:	**MM-DD-YY 12:00**	(correct date and time)

* 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.

The photographer will keep a manual film log on the SOF Photography Log Form (Exhibit 1-6) kept in the camera room. This log file will include: film roll number, date, photographer ID number, subject name or subject ID number, eye photographed, and a comments section. Each roll of film will be assigned a unique roll number and will contain photographs of 13 eyes, or 6 subjects. 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.

* Please note any special circumstances such as excessive blinking, patient wearing contact lenses, or concern about retinal pathology.

SOF EYE STUDY -- Photography Log Form

FILM ROLL NO. _____

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

1. M = Marcher, T = Topcon, C = Canon

SOF EYE STUDY -- Photography Log Form

FILM ROLL NO. _____

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

1. M = Marcher, T = Topcon, C = Canon

3.15

Subject Photography

3.15 SUBJECT PHOTOGRAPHY

3.15.1 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.

3.15.2 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 he/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. 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 enters the last five digits of the subject ID 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. After the number is entered, the photographer pushes the "DSP" button (explained above) to display the current camera values on the monitor and checks the accuracy of subject ID entry. It may be helpful to have the subject to rest her arms on the table if that makes her more comfortable.

3.15.3 Pupil Size and Alignment

The camera stage holding knob is unlocked, the alignment switch is turned on and the stage is moved to center the eye to be photographed horizontally and the height adjustment ring is used to position the eye vertically. The pupil should appear on the TV screen coincident with the central circle on the monitor. Look for evidence of eye lids 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 forward or back until the pupil appears perfectly round. At this point, proper external alignment has been achieved. A pupil larger than the central 4 mm circle on the monitor is required for adequate photography. If the eye does not dilate to at least 4 mm, the photographer should attempt to view the retina. If any retinal detail is visible, a photograph should be taken. If no retinal detail is visible on the television monitor, than no photo is taken and the opposite eye is examined for photography.

3.15.4 Photography Through Small Pupils

The photographer will experience more difficulty attempting photography through small (less than 4 mm) pupils because all of the camera light doesn't enter through the smaller pupil. This usually results in uneven illumination (seen as dark shadows) on the monitor. In this situation, the photographer must make careful camera adjustments to position the shadows as far away from the optic nerve and macula as possible.

A small percentage of participants' eyes do not dilate to the minimum 4 mm required for adequate photography. Certain medications may prevent any dilation and the pupil size observed on the monitor may be 1-2 mm, inadequate for the photographer to appreciate any retinal landmarks on the viewing monitor.

If no landmarks are visible, the photographer should adjust the camera slightly to position the corneal reflection dots **slightly above or below their optimum position.** This technique allows a portion of the illumination light (which falls on the iris when the pupil is small) to enter the eye. If any retinal landmarks become visible with this technique, a picture should be taken. However, if no retinal landmarks are visible, which is often the case when dilation is less than 1.5 mm, no picture is taken and the fellow eye is examined for dilation instead.

3.15.5 Additional Exposure

One additional exposure will be done for all subjects. 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. Then a photograph of the right eye will be obtained. Thus each eye will have two photographs, one at "N" and one with a 1/3 f-stop increase in exposure .

3.15.6 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, fixation is on the target; and lids and lashes are held wide open.**

3.15.7 Focus with High Myopia or Hyperopia (more than 8 diopters of plus or minus 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 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 can be 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.

Standard TV monitor functions can be adjusted for the photographer's viewing comfort (including contrast and brightness) by opening the access door below the TV monitor. These are standard controls similar to those found on a home TV set and only effect viewing; they **do not** effect final photo quality.

3.15.8 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 eye being photographed. To facilitate consistent positioning of the optic disc, 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 2DD from the nasal edge of the camera frame and should be centered on an imaginary horizontal line bisecting the camera monitor.

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 (Appendix A, page 18) on the monitor. Remember to disable the blink mechanism. If the blink mechanism is left on, it will turn off the auto-focus.

3.15.9 Focusing Manually When The Auto-Focus Mechanism Doesn't Lock

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.
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, he/she 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.

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.

3.15.10 Retake Policy

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

3.16

Logs and Records

3.16 LOGS AND RECORDS

3.16.1 PHOTOGRAPHY LOG FORM

A daily Photography Log Form (see Exhibit 1-6) will be maintained for each roll of film to provide an accurate listing of each subject photographed. The complete log for each film roll will contain the film roll number, date, photographer ID number, subject name or subject ID number, eye photographed, and a comments section. 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 the Reading Center, staff there can take this information into account when providing feedback.

SOF EYE STUDY -- Photography Log Form

FILM ROLL NO. _____

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

1. M = Marcher, T = Topcon, C = Canon

3.17

Film Handling

3.17 FILM HANDLING

3.17.1 Film Processing

The film will be removed from the camera after automatically rewinding as each roll is fully exposed. Film will be sent to UCLA via U.P.S. or Federal Express weekly. Partially exposed rolls of film may be removed after rewinding the film automatically by depressing the Manual Rewind Button (Appendix A, page 30). **The photographer will attach a numbered film roll label to each exposed roll of film before sending it to UCLA.** The film roll label appears as follows:

SOF Eye Study
Film Roll # _____
Center # _____
Date:

The film roll number must correspond with the sequential number appearing on the corresponding Photography Film Log page. It is critical that a Xeroxed copy of the appropriate pages from the Photography Film Log accompany each roll of film.

The undeveloped rolls of film will be sent to UCLA where we will have the film processed within two days so that the results can be reviewed with the Senior Photographer 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.

3.17.2 Film Shipping

Packages of exposed film and the relevant Photography Log Forms and Retinal Photography Shipping List (Exhibit 1-1) are sent weekly to the UCLA Reading Center. Film rolls should be reinserted back into their plastic containers for shipping.
The standard Federal Express or UPS envelopes, reinforced with a manila folder around the film is acceptable.

3.17.3 Shipping Couriers

When using couriers such as Federal Express or UPS, please use the Reading Center's complete street address. The following shippng label example contains the correct address to be used for all photograph shipments sent to the the Reading Center.

Dr. Anne Coleman
UCLA Reading Center
100 Stein Plaza, JSEI 2-118
Los Angeles, CA 90095-7004

SOF EYE STUDY - Retinal Photography Shipping List

ID Number:		Retinal Photo Date:	
Clinical Center:	Portland		
Shipping Batch:	ARFR3		
No. of Rolls of Film:		No. of Retinal Photographs:	
Date Shipped:		Person Shipping:	

* * * * * * * * * * * * * * * * * **Reading Center Use Only** * * * * * * * * * * * * * *

Date Received:		Person Receiving:	
Comments:			

3.18

Quality Control

3.18 QUALITY CONTROL

Photographic quality will be continuously monitored throughout the study. Initially **all photographs** will be reviewed by the UCLA Senior Photographer 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. A small percentage of the photographs will be reviewed by the UCLA Senior Photographer, and feedback will be provided to the local photographer in cases that warrant critique.

3.19

Photographer Certification

3.19 PHOTOGRAPHER CERTIFICATION

Each examiner taking fundus photographs will need to become certified before taking photographs for the study. The initial group of photographers received didactic and hands-on training during the September 28 to October 2, 1996 training session in Los Angeles, California. Following the training session, photographers return to their respective centers and begin practicing retinal photographs. A photographer is fully certified after submitting satisfactory quality photographs 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 SOF Eye Study protocol, and the Canon Non-Mydriatic Retinal Camera Operation Manual (Appendix A) . The trainee photographer will practice on volunteers and, when ready, prepare and submit photographs of 10 eyes for consideration for provisional certification.

3.20

Reading Center - Photographer Communication

3.20 READING CENTER - PHOTOGRAPHER COMMUNICATION

As film is received at the UCLA Reading Center, it will be developed and the photographs will be graded for quality. Quarterly, the grading staff will review the quality of each photographer's work with the UCLA Reading Center photographic protocol monitor, a photographer with extensive experience in study photography. The monitor will then call the photographer by telephone to discuss any significant problems observed. This contact will also allow the photographer an opportunity to ask questions or make comments. The monitor will represent the viewpoints of photographers to the study as a whole.

When substantial problems are observed (particularly if a photographer has reverted from full to provisional certification), the photographic protocol monitor will phone the photographer more frequently. If the problems cannot be adequately addressed by telephone, the monitor may arrange to conduct a special photographic site visit for the purpose of observing the photographer at work and demonstrating the desired technique.

Occasionally, the UCLA Reading Center will issue a newsletter for study photographers, regarding issues of particular interest to them and discussing methods for obtaining the most optimum results.

3.21 REVERSAL OF DILATION OF PUPILS

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.

3.22 SUBJECTS TO BE REFERRED TO AN OPHTHALMOLOGIST WITHIN 8 HOURS

1. Subjects with eye pain and redness that is not relieved with blinking or with artificial tears
2. Subjects that see halos around lights
3. Subjects that become nauseated and vomit
4. Subjects that complain of itchy, red, and swollen eyelids
5. Subjects that have eye pressures greater than 35 mmHg

All of the above subjects should see an opthalmologist or her eye doctor within 8 hours.

3.23 SUBJECTS TO BE REFERRED TO AN EYE DOCTOR WITHIN ONE WEEK

1. Any subject with eye pressures between 24 mmHg and 35 mmHg.