

# SCHEIE IMAGE READING CENTER STANDARD PROCEDURES FOR PHOTOGRAPHY

## 1. INTRODUCTION

Good quality stereoscopic photographic images are required to describe pathology present and to determine whether an eye meets the eligibility criteria for a specific trial. A general photographic protocol has been developed to ensure consistently high photographic quality and standardization of camera equipment, image acquisition, and film processing.

Photographers must be certified before photographing study patients. Clinical Centers are strongly urged to have at least 2 photographers certified.

Until high-resolution color images are available at the majority of the clinical centers, color photographs will be obtained on film.

Fluorescein angiography may be acquired as digital images or on film. The required angiography sequence is the same, whether the angiography is digital or film based. It is not acceptable for a clinical center to obtain images on film and then digitize them with the use of a scanner. However, the images obtained on film may be scanned at the Photograph Reading Center for grading purposes. Digital images must be obtained with an acceptable SIRC-certified digital imaging system.

Although not accepted as a standard, DICOM (Digital Imaging and Communications in Medicine) format will be supported by the Photograph Reading Center if a digital imaging system does not support exportation of files in BMP or TIFF file formats.

All color photographs and fluorescein angiograms are submitted to the Photograph Reading Center for evaluation.

## 2. TECHNIQUES FOR GOOD QUALITY IMAGES

### 2.1. Dilation

Adequate dilation of the pupil is important to permit good quality stereo photography. Sufficient time should be allowed for dilation to *at least 6 mm*, repeating drops if necessary, to achieve and maintain a pupil of at least 6 mm during photography. If repeated instillation of drops and the passage of at least 45 minutes after the last drops fail to produce dilation of 6 mm, the photographs can be taken through a smaller pupil. If the pupil cannot be dilated to at least 4 mm, adequate stereoscopic effect may not be possible. The cornea should be undisturbed by prior examination with a diagnostic contact lens<sup>1</sup> (Saine & Tyler, 2002).

## 2.2. Stereopsis

If it is not possible to obtain good quality (sharp focus) in both frames of the stereo pair, the photographer should attempt to obtain good quality in one frame and some stereo separation and accept poorer quality in the other frame<sup>1</sup>. This may be the case if the eye has any media opacity.

***Sequence of Stereo Pairs on Film-based Angiography:*** The frames of each pair must be taken in the correct order for viewing directly on the film. The film should not have to be cut in order to view a pair in stereo. To achieve this, the angiogram should be taken in "reverse stereo", taking the right frame of the stereo pair first, followed by the left frame, thereafter, alternating right frame, left frame.

***Sequence of Stereo Pairs for Digital Angiography:*** The frames of each pair should be taken in the order they will be viewed on the screen. Although the digital images can be viewed in any order chosen, it is more convenient (for both the photographer and the photograph reader) to take the left frame of the stereo pair first, followed by the right frame and thereafter alternating left frame, right frame.

## 2.3. Fluorescein injection

Five ml of 10% sodium fluorescein should be injected into the antecubital region with a 21 or 23 gauge butterfly infusion set with a push no longer than 6 seconds in duration. In some patients, the use of 1 ml of 25% fluorescein followed by a saline flush may provide better resolution of the para- and perifoveal capillary net.

## 3. FILM BASED PHOTOGRAPHY

**Cameras:** The Zeiss 30° or Topcon 35° fundus cameras with 2.5x to 3x magnification should be used for both color photographs and fluorescein angiograms on film. Other cameras may be acceptable pending specific certification by the Photograph Reading Center.

A cone should not be used in the camera, as some information in the area of eligibility may not be visible when a true Field 2 is not taken.

To avoid photographic artifacts, frequent inspection and cleaning of the front surface of the objective lens is essential to remove dust and debris.

### 3.1. Required Fields

The color stereoscopic fundus photographs of the disc (DRS Field 1) and the macula (DRS Field 2) of each eye are required at all study visits unless otherwise noted in a trial specific manual of procedures.

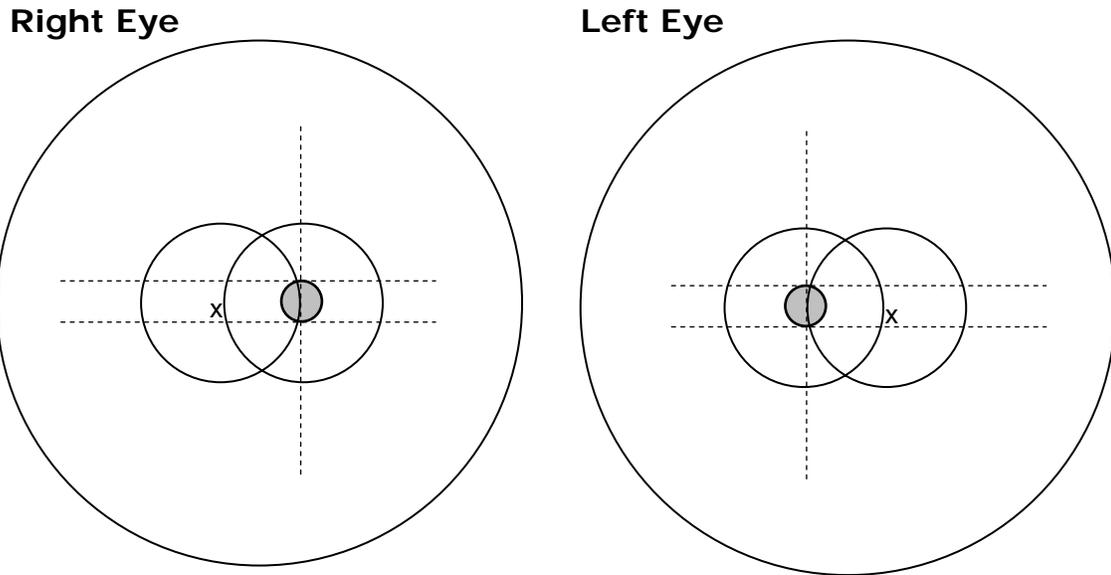
The two standard Fields of the fundus are defined and illustrated below for each eye. This description assumes that there are two cross hairs in the camera ocular, one vertical and the other horizontal.

**Field 1 – Disc**

*Center of optic disc at intersection of hairs in ocular.*

**Field 2 - Macula**

*Center of macula at intersection of cross hairs in ocular.*



**3.2. Film-Based Color Photography**

**3.2.1. Film and Film Processing**

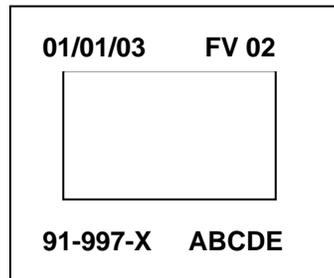
- The recommended films for color photography are Kodak Professional 100 daylight films or their equivalent. Ektachrome EPN, EPP, or E100S, preferably processed by a certified “Q-Lab” to ensure consistent quality, are preferred. Kodak Kodachrome 25 or 64 Daylight film, processed by any authorized Kodalux Laboratory is also acceptable.
- The processed film from Initial Visit photographs must be received at the Photograph Reading Center within 15 working days.
- Since there may be a slight difference in the color balance of different films, the Photograph Reading Center investigators recommend that whenever possible the same film type be used for all photographs for a patient.

**3.2.2. Labeling and Presentation of Color Photographs**

Color photographs from all visits must be labeled with the date of the photographs, the visit type and visit number at the top of each slide mount, and the patient identification number and name code at the bottom of the slide mount. Patient-specific labels will be provided by the

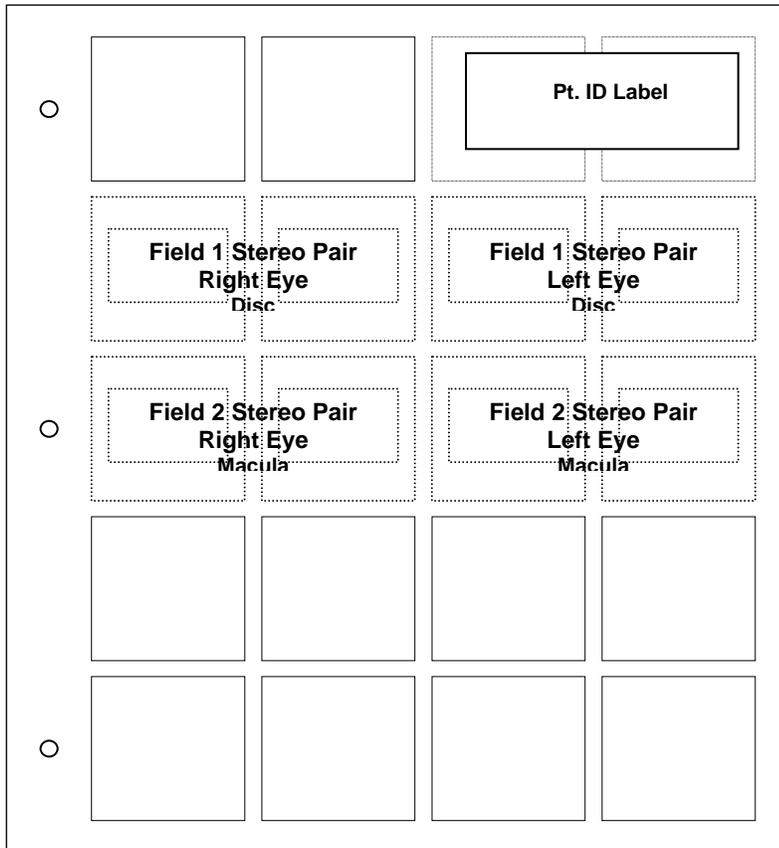
Coordinating Center following randomization. If at any time these labels are not available, information should be printed on the slide mount as shown here.

**Slide Mount Label Format**



A complete set of color photographs will contain 4 stereo pairs, one pair of each disc and one pair of each macula. The slides are placed in the slide sheets in the following order:

**Slide Placement Diagram**



The slides are to be placed into a side-loading transparent slide sheet to allow for grading without removal from the slide sheet. Side-loading pockets on the slide sheets decrease the chance of slides slipping out of the slide pages because the slide mounts touch at the adjacent openings. The slide sheet should be oriented with the 3-hole punch on the left and the pockets opening from the front. Empty pockets in the slide sheet should not be cut off. One slide sheet should not contain photographs of more than one patient, or photographs for more than one visit. To facilitate grading and filing of the photographs, a whole slide sheet should be submitted for each visit.

The patient ID label is placed in the upper right hand corner of the slide sheet to facilitate identification of the patient and visit.

**3.3. Film-Based Fluorescein Angiography**

### 3.3.1. Camera Equipment

- Delori or Spectratech filters should be used for excitation and barrier filtration: SE-40 Excitation, SB-50 Barrier. These filters should be changed every 24 months, or when inspection at a site visit or any other time proves them defective.
- A Spectratech 540 nanometer filter is used for the black and white red-free stereo pairs taken prior to fluorescein injection. The Kodak gelatin filter is not acceptable.

### 3.3.2. Film and Film Processing

- Kodak T-Max or Ilford 400 speed films are recommended for angiography. The film may be processed by clinic staff or at a local processing laboratory. Fluorescein angiograms should be taken on Kodak Tri-X or Tmax film.
- Since the original angiogram negatives are submitted for reading, it is recommended that a high contrast developer be used to maximize capillary detail. Kodak D-11, diluted 1:1, should be used at approximately 70° for eight minutes or Kodak HC-110, dilution A, at 75° for six minutes. The exact processing time and temperature can be adjusted at the Clinical Center to compensate for differences in cameras and flash settings and to provide negative density acceptable to the Photograph Reading Center.

### 3.3.3. Angiography Sequence

Stereo pairs should be shot in reverse order (right side first) for correct viewing on an uncut strip of film.

There are two angiography sequences that may be required for the Study. One sequence has the early phase of the "study eye" as used in the Macular Photocoagulation Study (MPS). The other sequence has the early phase that includes stereo pairs of both eyes as used in Complications of AMD Prevention Trial (CAPT). The latter sequence would be used when a trial protocol requires that both eyes meet eligibility criteria and requires information from the early phase of the angiogram for both eyes.

#### **Early Phase of Study Eye:**

The following sequence of frames should be followed for fluorescein angiography with the early phase of the study eye:

- Prior to the fluorescein dye injection, black and white red free stereo photographs of the macula (Field 2) of both eyes are taken.
- Study Eye: Stereo pairs of the macula are taken during the transit phase and at 30, 40, 60 and 90 seconds and 2, 3, 5 and 10 minutes and stereo photographs of the disc taken at anytime after 2 minutes.

- Non-Study Eye: Stereo pairs of the macula are taken after 2 minutes and at 5 and 10 minutes, and stereo pairs of the discs taken anytime after 2 minutes.

Note: A second roll of film may be required to obtain all of the required frames on film.

### **Early Phase of Both Eyes**

The following sequence of frames should be followed for fluorescein angiography with the early phase of both eyes:

- Prior to fluorescein dye injection, black and white red-free stereo photographs should be taken of the macula of each eye are taken.
- Begin with the right eye by taking 3 stereo pairs of the macula at 20-35 seconds.
- Move the left eye to take stereo pairs of the macula between 45-50 seconds and again at 60 seconds.
- Return to the right eye for stereo pairs of the macula between 70-75 seconds, and again at 90 seconds.
- Return to the left eye for stereo pairs of the macula between 100-110 seconds and again at 120 seconds.
- Return to the right eye for stereo pairs of the macula between 130-140 seconds and again at 3 minutes.
- Return to the left eye to take a stereo pair of the macula at 3 ½ - 4 minutes. Change film.
- Begin the second roll of film by taking stereo pairs of both the macula and disc of the left eye between 5-5½ minutes.
- Return to the right eye for stereo pairs of both the macula and disc at 5 ½ -6 minutes.
- Remain in the right eye to take a stereo pair of the macula at 10 minutes.
- Return to the left eye to take a stereo pair of the macula at 10 ½ minutes.

#### **3.3.4. Lesions that Extend Beyond Field 2**

When a neovascular lesion extends beyond Field 2, the photographer should attempt to obtain at least one stereo pair centered on the lesion to show its full extent. This stereo pair can be taken at any time during the angiogram that is most convenient for the photographer.

#### **3.3.5. Labeling, Presentation, and Duplication of Film-Based Angiograms**

A label that contains the date of the photographs, the visit type and visit number, the patient identification number, and name code is placed in the upper right-hand corner of the negative sleeve. When more than one roll of film has been used and two negative sleeves are

required, the first negative page should be labeled 1 of 2, and the second 2 of 2. As with the color photographs, patient-specific labels will be provided by the Coordinating Center. If at any time these labels are not available, information should be printed on a label as shown below.

The roll of fluorescein negative images should be cut into 6 frames per strip and placed in negative sleeves starting with the second row so that placement of the Study label in the upper right hand corner does not cover any of the images on the film. If the protocol has been followed, i.e. the right side of the stereo pair taken first, followed by the left side, thereafter alternating right side, left side, there will be three stereo pairs per strip of six images. When cutting the film into strips, the photographer should take care not to separate the members of a stereo pair, i.e., not to leave one member of the pair at the end of one strip and the second member of the pair at the beginning of the next strip.

Blank frames should not be removed from the film. A second negative sleeve may be necessary to keep the pairs together. All frames of the roll of film should be submitted. If all the frames of the second roll of film are not used, include a few blank frames in the last strip of film to indicate the rest of the roll is blank. This is particularly important when the last frames were not taken at 10 minutes.

Do not staple the negative sleeves together.

**To comply with HIPAA regulations, the patient's name should always be removed from the film.**

A positive transparency or other form of duplicate angiogram should be prepared prior to submitting the negatives to the Photograph Reading Center. Negatives will not be returned to the Study Clinical Centers. If a copy is needed by a Clinical Center after submission to the Photograph Reading Center, a copy will be made by the Photograph Reading Center with the cost, including shipping, billed to the Study Clinical Center. Timeliness of these requests cannot be guaranteed. It is hoped that the number of requests for copies of angiograms will be minimal due to adequate planning.

# Presentation Of Fluorescein Film In Negative Sleeve

## First Page of Angiogram

<b>Study Patient ID Label</b> <i>Page 1 of 2</i> <b>Date of Angiogram</b> <b>Visit</b> ##/##/##                      XX   XX <b>ID #</b> <b>Name Code</b> XX-XXX-X                      ABCDE					
End Injection	Begin Injection Time "0":	Macula LE Red-Free L	Macula LE Red-Free R	Macula RE Red-Free L	Macula RE Red-Free R
Macula Study Eye Early Phase L	Macula Study Eye Early Phase R	Macula Study Eye Early Phase L	Macula Study Eye Early Phase R	Macula Study Eye Early Phase L	Macula Study Eye Early Phase R
Macula Study Eye 60 sec L	Macula Study Eye 60 sec R	Macula Study Eye 40 sec L	Macula Study Eye 40 sec R	Macula Study Eye 30 sec L	Macula Study Eye 30 sec R
Macula Fellow Eye 2 min L	Macula Fellow Eye 2 min R	Macula Study Eye 2 min L	Macula Study Eye 2 min R	Macula Study Eye 90 sec L	Macula Study Eye 90 sec R
Macula Study Eye 5 min L	Macula Study Eye 5 min R	Disc Study Eye 3 min L	Disc Study Eye 3 min R	Macula Study Eye 3 min L	Macula Study Eye 3 min R



### **3.3.6. Modifications To Film Based Imaging Requirements**

Acceptable results can be obtained with different development techniques and different films. Therefore, the following provisions are made for exceptions and revisions to this protocol.

If a Study certified photographer at a Clinical Center believes that there is just cause for deviation from protocol, he/she may apply to the Photograph Reading Center for a variance. The application should include a letter of explanation, and several sample photographs produced by the proposed method. If the Photograph Reading Center agrees that the standards of the Study Trial are upheld, the variance will be granted.

If the Photograph Reading Center staff identifies methods that they consider superior to those in use, those methods will be presented to participating Study Photographers for implementation.

## **4. DIGITAL IMAGING**

**Set-Up:** Prior to the black and white red-free stereo pair, the photographer is required to take 2 frames of the target at a constant distance from the objective before each Study patient is photographed. When the angiogram is received at the Photograph Reading Center, a computer software program automatically analyzes the target parameters from the image to calibrate the Scheie Digital Image Analyzer (SEDIA) for the proper measurement scale. A warning will be issued if the certified fundus camera parameters set at the time of certification at any time don't match the parameters during the study. The Study photographer will be notified to recalibrate the camera. This target calibrating process will insure consistent camera parameters and consistent fundus measurements throughout a specific trial.

Digital images are acquired at the maximal resolution allowed by the camera.

## **5. Fluorescein Angiography**

- Delori or Spectratech filters should be used for excitation and barrier filtration: SE-40 Excitation, SB-50 Barrier. These filters should be changed every 24 months, or when inspection at a site visit or any other time proves them to be defective.
- A black and white red-free stereo pair of the study eye is taken prior to fluorescein injection using a Spectratech 540 nanometer filter. The Kodak gelatin filter is not acceptable.
- Images should be stored on the computer at the maximum resolution of the camera and optical system in the loss-less " Bitmap or Tagged Image File Format (TIFF)" format.

- To avoid photographic artifacts, frequent inspection and cleaning of the front surface of the objective lens is essential to remove dust and debris.

## **5.1. Required Fields**

### **5.1.1. Angiography Sequence**

There are two angiography sequences that may be required for the Study. One sequence has the early phase of the “study eye” as used in the Macular Photocoagulation Study (MPS) (MPS, 1991). The other sequence has the early phase that includes stereo pairs of both eyes as used in Complications of AMD Prevention Trial (CAPT). The latter sequence would be used when a trial protocol requires that both eyes meet eligibility criteria and requires information from the early phase of the angiogram for both eyes.

#### **Early Phase of Study Eye:**

The following sequence of frames should be followed for fluorescein angiography with the early phase of the study eye:

- Prior to the fluorescein dye injection, black and white red free stereo photographs of the macula (Field 2) of both eyes are taken.
- Study Eye: Stereo pairs of the macula are taken during the transit phase and at 30, 40, 60 and 90 seconds and 2, 3, 5 and 10 minutes and stereo photographs of the disc taken at anytime after 2 minutes
- Non-Study Eye: Stereo pairs of the macula are taken after 2 minutes and at 5 and 10 minutes, and stereo pairs of the discs taken anytime after 2 minutes

Note: A second roll of film may be required to obtain all of the required frames on film.

#### **Early Phase of Both Eyes**

The following sequence of frames should be followed for fluorescein angiography when the early phase is required of both eyes:

- Prior to fluorescein dye injection, black and white red-free stereo photographs should be taken of the macula of each eye are taken.
- Begin with the right eye by taking 3 stereo pairs of the macula at 20-35 seconds.
- Move the left eye to take stereo pairs of the macula between 45-50 seconds and again at 60 seconds.
- Return to the right eye for stereo pairs of the macula between 70-75 seconds, and again at 90 seconds.

- Return to the left eye for stereo pairs of the macula between 100-110 seconds and again at 120 seconds.
- Return to the right eye for stereo pairs of the macula between 130-140 seconds and again at 3 minutes.
- Return to the left eye to take a stereo pair of the macula at 3 ½ -4 minutes. Change film.
- Begin the second roll of film by taking stereo pairs of both the macula and disc of the left eye between 5-5½ minutes.
- Return to the right eye for stereo pairs of both the macula and disc at 5 ½ -6 minutes.
- Remain in the right eye to take a stereo pair of the macula at 10 minutes.
- Return to the left eye to take a stereo pair of the macula at 10 ½ minutes.

### **5.1.2. Lesions that Extend Beyond Field 2**

When a neovascular lesion extends beyond Field 2, the photographer should attempt to obtain at least one stereo pair centered on the lesion to show its full extent. This stereo pair can be taken at any time during the angiogram that is most convenient for the photographer.

## **5.2. Archiving, CD Preparation, CD Labeling**

The image file to be submitted for a trial is not to be compressed or altered in any way. In order to submit the images to the Photograph Reading Center, the image files must be copied to a CD-R disk for study purposes only. At the time of imaging, the patient has not yet enrolled in the trial; therefore, the study identification number and name code are not available. The images are identified by the patient name from the images files at the clinical center. The patient name should not appear on any images or file identifiers submitted to the Photograph Reading Center.

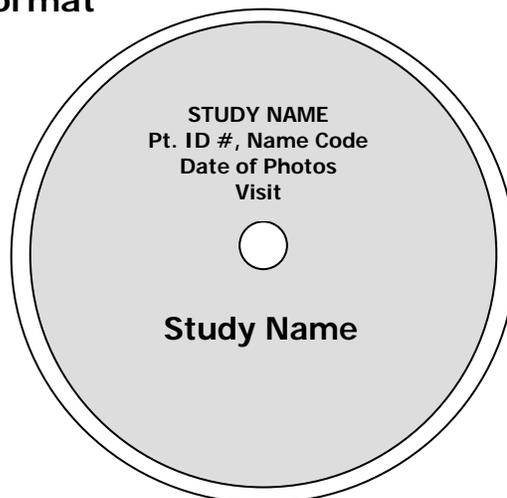
## **5.3. Transfer of Digital Images to CD-R Disk at the Clinical Center**

Custom developed software (Submission module) will be distributed for use at the Clinical Centers for management of digital photographs. The graphical user interface allows the photographer to locate on the local computer and bring the previously stored digital images within the application environment on the screen. The incorporated conversion capabilities will recognize automatically the manufacturer of the digital fundus camera from the file format and it will convert it to a uniform, secure, lossless, storage image format. The photographer enters in the fields provided; the patient ID and name code and selects the appropriate eye, photographer, and fundus camera type. Filtering capabilities will prompt the photographer for missing, or incomplete entries.

The submission module will also check for the image resolution, bit depth and other certified image parameters and it will warn if mismatch is encountered. Because angiography is performed prior to enrollment in the Study, digital image files may contain confidential patient information. The file name of each image from the image set will be replaced with the new name containing the patient ID, the order number of the picture in the set, the date when the photograph was acquired and the eye photographed. For the Topcon ImageNet™ generated image files the software will locate the patient name, if any, in the file header and will automatically delete it for masking, security, and confidentiality purposes. After the patient information is entered and verified the images are visually inspected. The image and data information is compiled in a single file and recorded on write once CD-R media. A paper form (Inventory form) will be generated from the software with the patient study and image information. The CD-R disk together with the form will be delivered via mail to the Photograph Reading Center.

Disk labels will be provided by the Coordinating Center that contains the patient identification number and name code with blanks to insert the date of the angiogram and the study visit identifier. The CD-R disk is placed in a protective sleeve and a CD mailer to protect the CD from damage in transit. The Clinical Center Coordinator submits the CD-R disk along with the other photographs and materials for the trial visit to the Photograph Reading Center according to the procedures detailed below.

### **CD Label Format**



## **6. SUBMISSION OF MATERIALS TO PHOTOGRAPH READING CENTER**

All photographs, CD's, and other materials submitted to the Photograph Reading Center must be clearly labeled with the appropriate study identification information and accompanied by the appropriate Photograph Inventory Form. Clinic Coordinators will be notified of any missing or discrepant information. Incorrect labeling of photographic materials may

require that the materials be returned to a clinical center for corrections. Photographic materials are not considered as "received" by the Photograph Reading Center until all information regarding the materials is complete and they are correctly labeled. Photographs are not read until all discrepancies are resolved.

All materials should be shipped in a timely matter. Initial visit photographs are considered late when received more than 15 working days after randomization. Follow-up visit photographs are considered late when received more than 20 working days after date of visit. Initial visit photographs and fluorescein angiogram must be obtained within 28 days prior to randomization. Follow-up visit photographs should be obtained the day of the visit, but must be taken within 28 days of the visual acuity.

### **6.1. Photograph Inventory Forms**

A Photograph Inventory Form is to accompany each set of photographs/angiograms submitted to the Photograph Reading Center. A set of photographs consists of both the required color photographs and the angiogram, whether it is film-based or digital. The Photograph Reading Center Data Coordinator confirms the patient information with patient information from the Coordinating Center data to ensure that the photographs are correctly identified for each patient visit. The Photograph Inventory Form provides a means to log and track photographs received, and provides information about the timeliness of the submission of materials. The Data Coordinator at the Photograph Reading Center documents on the form the date materials are received, if there are inconsistencies to be resolved, and the date the photographs are considered complete. The Photograph Inventory Forms are filed according to patient identification number in loose-leaf binders at the Photograph Reading Center.

### **6.2. Transmittal Log**

The Reading Center Transmittal Log is used to document materials included in a shipment to the Photograph Reading Center. A separate line is used for each set of photographs submitted. One Transmittal Log is submitted per shipment. A copy is retained at the Clinical Center to identify any missing or partial shipments and to document that the materials have been sent. The Photograph Reading Center Data Coordinator confirms that the appropriate materials for patient visits listed are included in the shipment. The Clinical Center is notified whenever any materials are missing, incomplete, or enclosed but not indicated on the log. The Photograph Reading Center Transmittal Logs are filed in chronological order by receipt date by clinic in loose-leaf binders at the Photograph Reading Center. No data entry is performed for the Photograph Reading Center Transmittal Log.

### **6.3. Incomplete Sets of Photographs**

A complete set of photographs consists of color photographs and a fluorescein angiogram. An incomplete set of photographs could occur when all required photographs are not taken or when photographs that were taken were subsequently lost, damaged, or misplaced. When not all of the required photographs are available for submission to the Photograph Reading Center, an explanation of the missing photographs should be included in the "comments" section of the Photograph Inventory Form. This procedure is followed for film-based as well as for digital color photographs (film or digital). Incomplete angiograms are identified at the Photograph Reading Center at time of receipt or during the grading process. An explanation of an incomplete angiogram is not required on the Photograph Inventory Form.

### **6.4. Study Visits with No Photographs**

When no color photographs are taken at a study visit or all of the color photographs for a visit are lost, destroyed, or misplaced, an explanation of the missing photographs should be included in the "comments" section of the Photograph Inventory Form. This procedure is followed for film-based as well as for digital color photographs and when there is no angiogram to submit (film or digital).

### **6.5. Missed Study Visits**

When a patient misses a study visit (time window has closed), a Photograph Inventory Form is submitted to the Photograph Reading Center indicating that the visit was missed and that no photographs are being submitted.

## **7. Shipping Materials to Photograph Reading Center**

All shipments should be sent in a large envelope so that the slide pages, negative sleeves, CDs, and forms are not folded or bent. Each shipment should include:

- Photograph Reading Center Transmittal Log- listing each patient visit
- Photograph Inventory Forms- one for each patient visit
- Slides properly labeled and appropriately presented on the slide page
- Film-based angiograms appropriately labeled and presented in the negative sleeve
- Digital angiograms recorded to an appropriately labeled write-once CD placed in a protective sleeve and mailer
- Double-checked to be sure the patient's name does not appear on any of the materials submitted to the Photograph Reading Center.

All materials must be shipped in a timely manner. Initial Visit photographs are considered late when received more than 15 working days after randomization and more than 20 working days after the date taken for a follow-up visit.

Copies of all photographs and forms should be retained at the Clinical Center in the patient study files.

All materials should be shipped to:  
Data Coordinator (Trial Specific)  
Scheie Image Reading Center  
3535 Market Street, Suite 700  
Philadelphia, PA 19104-3309

## **8. READING CENTER NOTICES**

Whenever there is missing, discrepant, or incomplete information on the photographs, angiograms, Photograph Inventory Form, or Reading Center Transmittal Log, and Reading Center Notice will be issued. This notice will be sent via FAX to the Clinical Center Coordinator identifying the problem, with instructions as to the resolution of the problem.

There may be circumstances when the photographs will be returned to the Clinical Center Coordinator. A Reading Center Notice will be sent via facsimile to the Clinical Center Coordinator as notification that the photographs are being returned, the reason, and instructions for resolving the problems. A copy of this notice will be included with the photographs.

Materials are not recorded as complete until all problems are resolved. Photographs are not read until they are complete; therefore, it is important that all Reading Center Notices are responded to in a timely manner.

## **9. MONITORING PHOTOGRAPHIC QUALITY**

The quality of the focus/clarity and stereopsis of color photographs and angiograms is evaluated upon receipt at the Photograph Reading Center to monitor for problems or deviations from the photography protocol, missing photographs, and to provide timely feedback to photographers. Periodic reports will be issued to the clinical centers summarizing image quality and identifying deficiencies that need attention.

## **10. REQUIRED PHOTOGRAPHS BY VISIT**

Unless otherwise stated for a specific trial, the required photographs at each study visit consist of stereo pairs of the disc and macula of each eye

and a stereo fluorescein angiogram with the early phase on the study eye.

### **References**

1. Saine PJ, Tyler ME. Ophthalmic Photography: Retinal Photography, Angiography, and Electronic Imaging, (2<sup>nd</sup> ed). Boston: Butterworth-Heinemann, 2002.