

## **Fundus Photograph Reading Center**

# 9-Standard Field Color Fundus Photography (9-Std-D)

Effective Date: 06 Jul 2012

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#### 1. 9-Std-D Overview

This document details the Fundus Photograph Reading Center (FPRC) procedure for photographer certification, provides instruction to image the 9 Standard Fields (9-Std-D), and offers pointers on imaging technique.

Digital systems must be certified for each study separately. See the *Digital System Certification* document for further details.

Further clarification regarding any information included in this document may be obtained by contacting the FPRC Imaging staff at (608) 410-0619 or by sending an email to Imaging\_administrators@rc.ophth.wisc.edu.

## 2. Photographer Certification

#### 2.1. Overview

Photographer certification is specific to each study, and photographers taking digital images for studies evaluated by the FPRC must be certified for the relevant procedure(s) before submitting actual subject images. The certification images may be taken on subjects being photographed for clinical purposes or of volunteers. Once a photographer is certified for a specific study, he/she is certified for the duration of that study, provided he/she meets the quality standards set by the FPRC. See section 7 *Evaluation of Image Quality*.

## 2.2. Certification Requirements

Certification consists of:

- Review of the study synopsis/protocol and imaging procedure(s)
- The ability to perform the imaging procedure(s), demonstrated by the submission of images of acceptable quality

### 2.2.1. Images Required if Previously Certified

The second certification requirement listed above will be waived if all of the following criteria are met:

- The photographer has prior certification at the FPRC using an identical procedure.
- The photographer has been actively taking images during the past 12 months.
- The images are judged to be of good quality by the FPRC.

If a photographer feels that these criteria have been met, or has been certified by the FPRC for a similar procedure, submit a certification request (see section 2.3 Submission for Certification) without sending images.

#### 2.2.2. Images Required if Not Previously Certified

Submit a certification request (see section 2.3 Submission for Certification) and send color images of four eyes (two right eyes and two left eyes) taken using this procedure (9-Std-D).

#### 2.3. Submission for Certification

Photographers are encouraged to send complete submissions for each procedure for which he/she is requesting certification (i.e., if four eyes are required for a certification submission, send all four eyes together).

Photographers who meet certification criteria will receive confirmation of certification. Those who do not meet these criteria will receive feedback from the FPRC imaging consultants and may be required to submit additional sets of images. A plan for improving image quality may be necessary after three complete unsuccessful certification submissions.

## 2.4. Uncertified Photographers

#### 2.4.1. Baseline/Screening Visits

Only FPRC-certified photographers are allowed to take baseline (screening visit) photos, unless an exception to this rule is granted (on a case-by-case basis) by the study sponsor. The baseline images for a subject are critical since all follow-up measurements are compared to this point to determine the study outcome.

The sponsor may suspend subject enrollment if the site does not have a certified photographer available to take the baseline images.

## 2.4.2. Follow up Visits

On rare occasions during **follow-up** visits ONLY, when a certified photographer is not available, an uncertified photographer familiar with the procedure(s) may take the images. The uncertified photographer should review the imaging procedure(s) before performing photography to be certain they understand the procedure and follow the study requirements. Include a comment with the submission or any official documentation indicating that the images were taken by an uncertified photographer and the reason why.

## 3. Fundus Cameras

Retinal cameras suitable for this procedure will have 50° or 60° magnification settings. Contact the FPRC if you have questions about the camera you intend to use.

## 4. 9-Standard Fields and Fundus Reflex Images

The nine standard photographic fields of the fundus are defined below for both right and left eyes (see figures following this section). These fields are designed for documentation of the

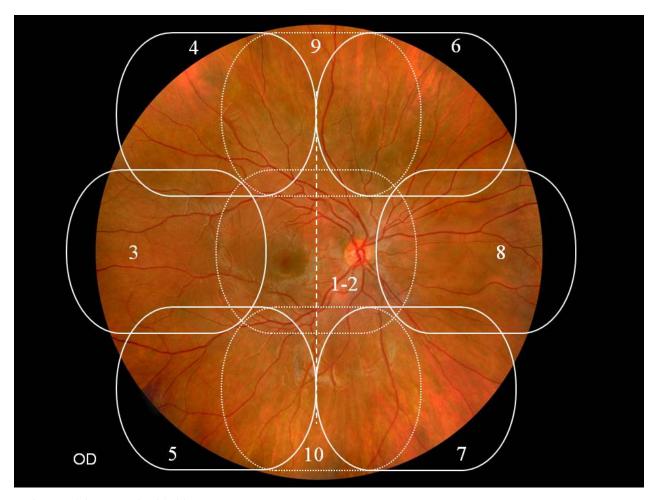
retina which may be involved in CMV retinitis (i.e., most of the post-equatorial fundus). All fields are taken as single photos except *Field 1-2 which is photographed as a stereo pair*.

The following descriptions of the standard fields assume that there are two cross hairs in the camera ocular, one vertical and the other horizontal, intersecting in the center of the ocular.

- **Field 1-2** (F1-2) Optic Disc/Macula Center the camera midway between temporal margin of the optic disc and the center of the macula. This is the only field taken as a stereo pair. A stereoscopic view is obtained by taking one picture through the left portion of the pupil, moving the joystick laterally, and then taking a second picture through the right portion of the pupil. This field must include both the optic disc head and macula.
- **Field 3** (F-3) Temporal to macula Rotate or pivot the camera temporally from F1-2 along the same horizontal meridian (i.e., straight temporally). The nasal edge of F3 should be located one disc diameter (DD) temporal to the center of the macula; typically just beyond the temporal margin of the hyperpigmented area (thus the center of the macula will not appear in F3). There will be an overlap of about three disc diameters between F3 and F1-2.
- **Field 8** (F-8) Nasal to the optic disc Rotate or pivot the camera nasal to F1-2 along the same horizontal meridian (i.e., straight nasally). The temporal edge of F8 should be located adjacent to the nasal margin of the disc (thus the disc will not appear in F8). There will be an overlap of about three disc diameters between F8 and F1-2.
- **Field 9** (F-9) Superior Move the camera directly superior to F1-2. The inferior edge of F9 should overlap the superior edge of F1-2 by 1 to 1½ disc diameters (be careful to retain at least 1 DD overlap). Selecting a retinal landmark (such as a vessel crossing) located one disc diameter below the center of the superior edge of F1-2 prior to shifting the camera will facilitate placement of F9.
- **Field 4** (F-4) Superior temporal From F9, Rotate or pivot the camera temporally along the same horizontal meridian. The nasal edge of F4 should be located at the center of F9, resulting in an overlap of about five disc diameters between F4 and F9. (The inferior edge of F4 will overlap the superior margin of F3 by 1 to  $1\frac{1}{2}$  disc diameter, although F4 is not as far temporal as F3). Selecting a retinal landmark located at or near the center of F9 prior to shifting the camera will facilitate placement of F4.
- **Field 6** (F-6) Superior nasal From F9, Rotate or pivot the camera nasally along the same horizontal meridian. The temporal edge of F6 should be located at the center of F9, resulting in an overlap of about five disc diameters between F6 and F9. (The inferior edge of F6 will overlap the superior margin of F8 by 1 to 1½ disc diameter, although F6 is not as far nasal as F8). Selecting a retinal landmark at or near the center of F9 prior to shifting the camera will facilitate placement of F6.
- **Field 10** (F-10) Inferior Rotate or pivot the camera directly inferior to F1-2. The superior edge of F10 should overlap the inferior edge of F1-2 by 1 to 1½ disc diameters. (Be careful to retain at least 1 DD overlap). Selecting a retinal landmark located one disc diameter above the center of the inferior edge of F1-2 prior to shifting the camera will facilitate placement of F10.
- **Field 5** (F-5) Inferior temporal From F10, rotate or pivot the camera temporally along the same horizontal meridian. The nasal edge of F5 should be located at the center of F10, resulting in an overlap of about five disc diameters between F5 and F10. (The superior edge of F5 will

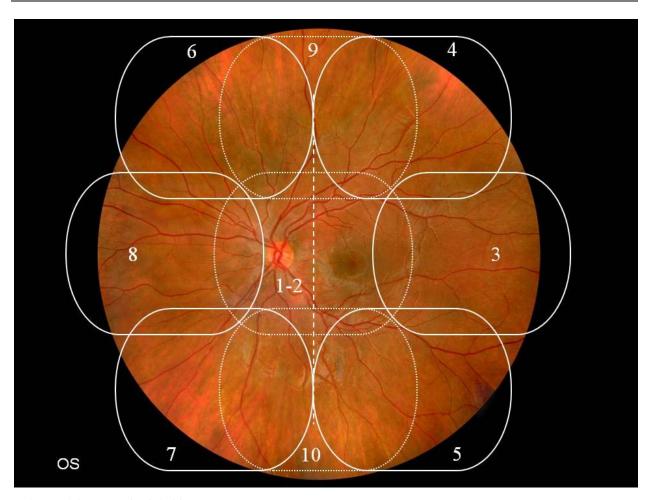
overlap the inferior margin of F3 by 1 to 1½ disc diameter, although F5 is not as far temporal as F3). Selecting a retinal landmark located at or near the center of F10 prior to shifting the camera will facilitate placement of F5.

**Field 7** (F-7) Inferior nasal - From F10, rotate or pivot the camera nasally along the same horizontal meridian. The temporal edge of F7 should be located at the center of F10, resulting in an overlap of about five disc diameters between F7 and F10. (The superior edge of F7 will overlap the inferior margin of F8 by 1 to  $1\frac{1}{2}$  disc diameter, although F7 is not as far nasal as F8). Selecting a retinal landmark located at or near the center of F10.



Right eye of the 9-standard fields

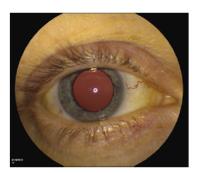
Image courtesy of Richard Hackel



Left eye of the 9-standard fields

Images courtesy of Richard Hackel

At all visits, a single fundus reflex photo (an external eye view) should be taken of each eye to document media opacities. If no opacities are present, focus on the pupillary margin of the iris; if opacities are present, focus on the lens opacities. The magnification of these images should match that of the image in the figure below. A fixation target should be positioned to direct the subject's gaze in the primary (straight ahead) position, so the optic disc *does not appear* directly behind the lens.



Fundus Reflex

## 5. Minimum Protocol When Patients Cannot Adequately Cooperate

Although photographers are strongly encouraged to obtain all photographs specified by the 9-Std-D procedure at each visit, there may be instances during follow-up in which patients are not able to tolerate the complete procedure. In such cases the following abbreviated procedure (which allows omission of up to four fields if CMV lesions are not present in them and a different sequence than indicated) should be substituted:

- (1) Take a stereoscopic pair of Field 1-2.
- (2) Move nasally to Field 8, focus, and take a photograph.
- (3) Move temporally to Field 3, focus, and take a photograph.
- (4) Move superiorly to Field 9, focus, and take a photograph.
- (5) Move nasally to Field 6 from Field 9, and if any CMV lesions are visible, take photograph (otherwise omit).
- (6) Move temporally to Field 4 from Field 9, and if any CMV lesions are visible take a photograph (otherwise omit).
- (7) Move inferiorly to Field 10, focus, and take a photograph.
- (8) Move nasally to Field 7 from Field 10, and if any CMV lesions are visible, take a photograph (otherwise omit).
- (9) Move temporally to Field 5 from Field 10, and if any CMV lesions are visible, take a photograph (otherwise omit).
- (10) Take the red reflex photograph.

If the patient is unable to cooperate sufficiently even to carry out the abbreviated procedure described above, the photographer should make every effort to obtain the stereoscopic photograph of Field 1-2. If opacities of the ocular media are so great that no red retinal reflex is observed, the photographer should obtain only the "red reflex" photograph to document the opacities.

## 6. Format for Study Images Submitted to the FPRC

Images should be saved and sent at full resolution, using no compression or lossless compression (PNG). For additional information on specific image-handling procedures, see the *Digital System Certification* document.

## 7. Evaluation of Image Quality

## 7.1. At the Study Site

The color images should be evaluated for quality by the principal investigator and/or photographer (unless prohibited by study protocol) before submission to the FPRC. If quality is not adequate for assessment of key features of the study eye (e.g., extent of macular edema), and if no irremediable cause of inadequate quality is present (e.g., lens

opacities or a pupil that will not dilate adequately), the images should be retaken before submission to the FPRC.

#### 7.2. At the FPRC

Color images of each eye are reviewed and assigned a grade for overall quality. Feedback will be provided to the photographers as needed to help with resolution of any problems. Special attention will be given to photographers having difficulty meeting study photo quality standards. If a certified photographer consistently fails to meet study standards, certification may be suspended.

## 8. Pointers on Imaging Technique

#### 8.1. General

If the patient has Opportunistic Ocular Infection (OOI) take photos of that eye first.

## **8.2.** Patient Cooperation

Photography of the photophobic subject can be challenging for the photographer and uncomfortable for the subject. Minimizing the number of flashes and the length of time the eye is exposed to a bright viewing lamp are two things that can help make the photography procedure more comfortable. Additionally, keeping the view lamp as low as possible (maybe even dimming the room lights) can make the photography procedure more tolerable. Patients should be asked to blink frequently to help keep the cornea clear.

If the subject has great difficulty tolerating the screening visit photography procedure and the photographer thinks this will lead to a problem at follow-up visits, the situation should be discussed with the principal investigator and/or coordinator. Consideration should be given to not enrolling the subject in the study.

## 8.3. Photo Sequence

When the 9-std fields are taken, the following sequence is recommended: disc and macula (Field 1-2), temporal to macula (Field 3), nasal to optic nerve (Field 8), superior to macula (Field 9), superior temporal (Field 4), superior nasal (Field 6),inferior to macula (Field 10), inferior temporal (Field 5), inferior nasal (Field 7). Fields 1-2, 3 and 8 should be taken on the same horizontal plane. Field 1-2 is taken as a stereo pair.

All of the peripheral fields specified above are obtained through a combination of shifting the camera and directing the gaze of the subject in the appropriate direction. For example, the following sequence of actions works well to locate Field 9 (superior). Starting from Field 1-2 (centered midway between the temporal margin of the disc and the center of the macula), first tilt the camera up to the limit of its travel (this maneuver achieves about half of the vertical elevation required for Field 9). Then move the fixation target up carefully, being sure not to drift nasally or temporally, until the location described in the protocol is reached.

Because of the extent of the periphery photographed, it is not always possible to move the fixation target to the ideal location. It may collide with the nose in some instances, or with the camera lens barrel in others. It may be necessary to instruct the patient to look further to the side than the fixation target for proper alignment of the field. In the case of F4 (superior temporal), the lens barrel may contact the subject's nose, which necessarily restricts the temporal placement of that field.

Sometimes it is not possible to obtain even illumination across the entire photographic field, especially in the periphery. This problem is more likely to occur in patients who do not dilate well. If it is not possible to equalize the illumination across the field, it is preferable to restrict the darker area to the more anterior portion of the field.

## 8.4. Focus/Clarity

Remember that the best image quality is obtained if corneas are not disturbed by prior examination with a diagnostic contact lens.

In a properly aligned digital system, the cross hairs and the retina are in focus at the same time. In these instances, constant attention must be paid to keeping the cross hairs in the camera ocular in focus when focusing on the retinal vessels. However, some digital systems are not par focal with the eyepiece; in these cases, it is important to confirm that the image on the monitor is as sharp as possible. Proper camera-to-eye distance should be maintained to avoid haziness and artifacts.

It will probably be necessary to refocus the camera from field to field, concentrating upon the sharpness of retinal landmarks near the center of each field. This is especially important for the peripheral fields since it is not always possible to get all of the retinal features in crisp focus across the entire field. Only if the sole pathology observed in the field is located near the edge should the picture be focused there rather than on retinal detail near the center.

Since changing the focus has an appreciable effect on the area of retina included in the photographic field (changing the boundary by as much as one disc diameter), it is advisable to focus the camera at least approximately after moving to the desired position of each field and before finalizing its location.

## 8.5. Stereoscopic Effect

Dilation of the pupil to at least 6mm is important to support quality stereo photography. If the pupils cannot be dilated to at least 4mm for the screening visit, the stereo effect will be minimal or nonexistent.

The technique described by Allen<sup>1</sup> is used for taking non-simultaneous stereo fundus images. The camera **should not be rotated or pivoted**; instead it should be moved laterally from left to right with the joystick (or by sliding the camera base on its table, if preferred).

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<sup>&</sup>lt;sup>1</sup> Allen L. Ocular fundus photography. Am J Ophthalmol 1964; 57:13-28.

Obtain about 2mm as the minimum separation between members of the stereo pair when moving the joystick or sliding the camera.

Stereo pairs should be taken shooting the left member of the pair first, followed by the right member of the pair. When obtaining stereo pairs, care should be taken that at least one member of the pair is of good technical quality with crisp focus. In many cases, it will be possible to obtain good quality in both members of the pair, but if this is not the case, the aim should be to obtain good quality in one member and some stereo separation between the members, accepting somewhat poorer quality in the second member of the pair, if necessary.

## 8.6. Exposure, Gain and Flash

It is important that photographers adjust flash, gain, and gamma to obtain optimal exposure, as well as avoiding severe over- or under-exposure. Over-exposure is more damaging than under-exposure often resulting in total loss of image detail. Photographers should become familiar with using the camera and software controls available to ensure optimal exposure and good color balance. The most commonly occurring color balance problem is an over-saturation of the red channel. The FPRC Imaging staff is available to assist in recommending acceptable settings.

Most digital systems have a wide variety of image enhancement tools to adjust image contrast, brightness or sharpness after image capture. Enhancement tools should not be used at the clinical site to adjust image quality. Pay careful attention to obtaining optimum exposure and image sharpness so enhancements are not necessary. For more information on color balance for retinal images, read the Color Balance Paper on the FPRC website by clicking on the hyperlink <a href="Color Balance of Film Vs. Digital Retinal Images">Color Balance of Film Vs. Digital Retinal Images</a> or by going to the digital system certification section of the website (http://eyephoto.ophth.wisc.edu/DSES.html).

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