# University of Wisconsin-Madison Fundus Photograph Reading Center (UW-FPRC)

# Modified 7-Standard Field Color Fundus Photography Procedure

(adapted from the Early Treatment Diabetic Retinopathy Study (ETDRS) and the Age-Related Eye Disease Study (AREDS), Manuals of Operations<sup>1, 2</sup>)

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Attachment B: Study Forms and Labels for Photographs (See Appendix 2)

## **1.0 Photographer Certification**

Photographers taking photographs for studies read by the UW-FRPC must be certified for the relevant procedure(s), *before submitting actual patient photographs*. Clinical sites are strongly encouraged to have a minimum of two, but no more than three, certified photographers. Photographers are encouraged to contact the Reading Center's photographic consultants, Michael Neider (608-263-9858) or Hugh Wabers (608-263-0740) with any photography related questions. Pointers on photographic technique may be found in Attachment A.

Certification consists of (1) review of study synopsis and photography procedures and (2) demonstrated ability to perform the photographic procedure by submission of photographs of acceptable quality. The second requirement may be waived if the photographer has prior certification at the UW-FPRC using a similar procedure. Photographs must have been taken within the past year.

Photographers who are not eligible for certification on the basis of previous certification in another study should submit photographs of two patients taken using this procedure. The photographs may be taken of patients in whom photography is being carried out for clinical purposes or in normal volunteers. The slides should be mounted as shown in Section 7. Preprinted labels may be unavailable for labeling certification photographs, please hand label the color slides indicating the field and the eye photographed and the right side (RS) or left side (LS) of the stereo pair. The slide pages should be labeled with a page identification label indicating the patient initials or patient identifier, photographer's name, date of photography and that the photographs are certification sets. A signed UW-FPRC certification request form is also required. (See Attachment B: Study Forms and Labels)

Photographers who meet certification criteria will receive written confirmation of certification. Photographers who do not meet these criteria will receive feedback from the UW-FPRC photographic consultants, and will be required to submit additional sets of photographs. After three unsuccessful attempts for certification, no additional photographic submissions will be accepted until a plan for improving photographic quality has been developed in collaboration with the sponsor and principal investigator.

#### 2.0 Uncertified Photographers

On rare occasions when a certified photographer is not available, an uncertified photographer, familiar with the procedure, may take study photographs. The name of the uncertified photographer should be entered on the photo page labels.

# 3.0 Camera and Equipment

The Zeiss FF4 series and the Topcon TRC-50EX (used at the 35° setting) or similar model are suitable cameras for the study. Cameras other than these may be substituted upon approval of the UW-FPRC. Approval may be obtained by submitting two sets of photographs taken according to this procedure, together with a letter requesting camera substitution, to the Fundus Photograph Reading Center, 610 N. Walnut Street, Room 438, Madison, WI 53705, Attention: Michael Neider. Photographer certification photographs may also be used for camera approval.

# 4.0 Film and Processing

The recommended films are Kodachrome 25 or 64 Daylight film, processed by any authorized Kodalux Laboratory, or Professional Ektachrome 100 Daylight film, or its equivalent, preferably processed by a certified "Q-Lab" to ensure consistent quality. It is important that the processor correctly number the slide mounts to make slide sorting more accurate and easier.

## 5.0 Obtaining Both Good Image Quality and Adequate Stereoscopic Effect

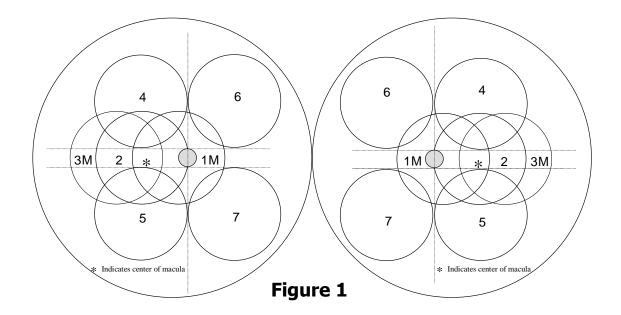
When obtaining stereo pairs, care should be taken that at least one member of the pair is of good technical quality with crisp focus. In many cases, it will be possible to obtain good quality in both members of the pair, but if this is not the case, the aim should be to obtain good quality in one member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

**Dilation of the pupil to at least 6mm is important to permit good quality stereo photography.** *If the pupils cannot be dilated to at least 4mm for the screening visit, the subject should not be entered into the study.* The cornea should be undisturbed by prior examination with diagnostic contact lens.

For more suggestions regarding photographic technique, see Attachment A.

## 6.0 Modified 7-standard Fields and Fundus Reflex Photographs [Figure 1]

The modified 7-standard fields for color photography specified by this procedure differs from the ETDRS 7-standard field protocol in the position of two fields: Field 1M and Field 3M are both modified to include the center of the macula, in Field 1M near the edge of the field and in Field 3M midway between the edge and center of the field.



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 1M** - Disc: Center the temporal edge of the optic disc at the intersection of the cross hairs in the ocular.

**Field 2** - Macula: Center the macula near the intersection of the cross hairs in the ocular. To keep the central gray artifact created by some cameras from obscuring the center of the macula, the intersection of the cross hairs should be placed about 1/8 - 1/4 DD above the center of the macula. A suitable position can often be obtained by rotating the camera temporally from the Field 1M position, without vertical adjustment.

**Field 3M** - Temporal to Macula: Position the intersection of the cross hairs in the ocular 1.0-1.5DD temporal to the center of the macula. If Field 2 was centered above the center of the macula, as suggested above, Field 3M may be centered 1.0-1.5 DD temporal to Field 2, a position easily achieved by rotating the camera without making any vertical adjustment or movement of the fixation device.

**Field 4** - Superior Temporal: The lower edge of the field is tangent to a horizontal line passing through the upper edge of the optic disc and the nasal edge of the field is tangent to a vertical line passing through the center of the disc.

It is convenient to take Field 6 immediately after Field 4 by rotating the camera nasally.

**Field 6** - Superior Nasal: The lower edge of the field is tangent to a horizontal line passing through the upper edge of optic disc and the temporal edge of the field is tangent to a vertical line passing through the center of the disc.

**Field 5** - Inferior Temporal: The upper edge of the field is tangent to a horizontal line passing through the lower edge of the optic disc and the nasal edge of the field is tangent to a vertical line passing through the center of the disc.

**Field 7** - Inferior Nasal: The upper edge of the field is tangent to a horizontal line passing through the lower edge of the optic disc and the temporal edge of the field is tangent to a vertical line passing through the center of the disc.

**Field 8** - An optional field outside the modified 7-standard fields should be taken to document new vessels and/or pre-retinal or vitreous hemorrhage when these features are not well documented in the standard fields. The label should reflect the area photographed.

If two or more photographs outside the modified 7-standard fields are needed to document new vessels, they should be labeled "Field 8a," "Field 8b," and so on sequentially. *If one or more Field 8's are taken at screening, their location should be noted and these fields should be taken at each follow-up visit.* 

At all visits, a stereoscopic fundus reflex photograph should be taken to document media opacities. The photographer is asked to use his/her discretion to achieve a limbal diameter of approximately 13mm on the finished slide. The best stereo effect is obtained by moving the camera laterally about 3mm between exposures. The lateral shift can be obtained by moving the joystick, sliding the camera, or using the Allen stereo separator. A fixation target should be positioned to direct the subject's gaze in the primary (straight ahead) position, so that the optic nerve *does not appear* directly behind the lens.

# 7.0 Mounting and Labeling Photographs [Figure 2]

The transparencies returned from the processing lab are mounted in standard 2X2 inch mounts. The mounted transparencies are labeled with individual labels (see Attachment B).

Photographs of each eye should be mounted in an individual plastic sheet.<sup>†</sup> The plastic sheets should be constructed so that the pockets open at the side rather than at the top; that is, the *open* side of the left pocket should face the *open* side of the right pocket. A sheet identification label is completed and attached to the front of each plastic sheet (see Attachment B).

<sup>&</sup>lt;sup>†</sup> The Reading Center recommends Bardes 20-pocket pages, product #62022C available from Bardes Products, Inc., 5245 West Clinton Avenue, Milwaukee, WI 53223-9839, phone 800-223-1357. X:\NIDDK\niddk-dr\_studies1\FIND\private\_created\_data\FIND\_V5\Documents\MOOP\Eye\_Study\App 1 Modified7StdF 1.01 20Feb2002.doc Appendix 1 -- 6 of 10

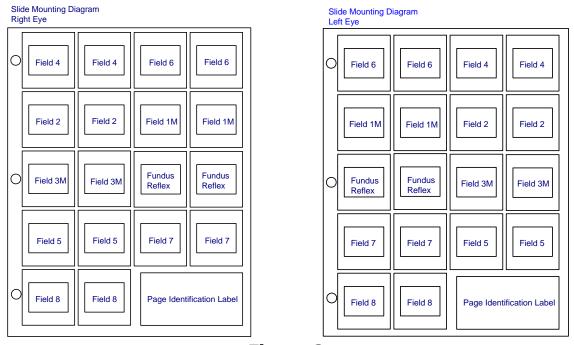


Figure 2

Photographs submitted in frosted plastic pages or thin "archival" plastics may be returned to the site for remounting.

It is suggested, but not required, that duplicates of the photographs be retained at the clinical center for patient management.

# 8.0 Transmission of Photographs to the UW-FPRC

The original transparencies should be processed, assembled and labeled as described above within 10 working days (sooner if possible) after being taken. Sets should be sent together with the completed Transmittal Log (see Attachment B) to the UW-FRPC.

#### 9.0 Retakes

Photos should be evaluated for quality by the *principal investigator and/or photographer* before submission to the UW-FPRC. If quality is not adequate for assessment of key features of the study eye, such as extent of macular edema, and if no irremedial cause of inadequate quality is present (such as lens opacities or a pupil that will not dilate adequately), the photos should be retaken before submission to the UW-FPRC. When photos are considered ungradeable because of poor quality, the UW-FPRC may issue a Retake Request Form (See Attachment B).

#### **10.0 Evaluation of Photographic Quality**

Photographs of each eye are reviewed and assigned a grade for overall quality. The grades include three indicating that a set can be evaluated with no problem (excellent, good, fair), two signifying that a set can be assessed although quality interferes somewhat (borderline-explained, borderline-unexplained), and two indicating that a set cannot be completely

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evaluated (inadequate-explained, inadequate-unexplained). The "explained" variant of borderline or ungradeable is selected if the UW-FPRC grader sees media opacities in the fundus reflex (anterior segment) photograph explaining the reduced quality, or if the photographer records that the patient had difficulty cooperating.

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.

#### 11.0 References

- 1. Early Treatment Diabetic Retinopathy Study Research Group, Manual of Operations. Chapter 13. Baltimore: ETDRS Coordinating Center, University of Maryland. Available from: National Technical Information Service, 52285 Port Royal Road, Springfield, VA 22161; Accession No. PB85 223006/AS Chapter 13.
- Age Related Eye Diseases Research Group, Manual of Operations. Chapter 8. Potomac, MD: AREDS Coordinating Center, EMMES Corporation, 11325 Seven Locks Road, Suite 214, Potomac, MD 20854.

#### Attachment A

#### Pointers on Photographic Technique Prepared by the UW-FPRC

#### **Field Definition**

When the modified seven standard stereo fields are taken, the following sequence is recommended: disc (Field 1M), macula (Field 2), temporal to macula (Field 3M), superior temporal (Field 4), superior nasal (Field 6), inferior temporal (Field 5), inferior nasal (Field 7). Stereo Fields 1M, 2 and 3M may be taken on the same horizontal plane.

The following technique may be used for attaining proper definition of Field 4: (1) move the camera from the center of the disc upwards until the upper edge of the disc meets the bottom of the photographic field, (2) take note of some landmark at the intersection of the cross hairs (e.g., a small vessel or microaneurysms), (3) swing the camera temporally until this landmark is at the nasal border of the photographic field (at this point, the lower edge of the field will fall on the same plane as the upper edge of the disc) -- this is the proper position for Field 4. To locate Field 6, rotate the camera nasally until the landmark is at the temporal edge of the field. A similar approach can be used to obtain Fields 5 and 7.

#### **Focus/Clarity**

# Constant attention must be paid to keeping the cross hairs in the camera ocular in focus, otherwise the photos will be out of focus.

Proper camera-to-eye distance should be maintained to avoid haziness and artifacts.

If it is not possible to get the entire photographic field in crisp focus, the photographer should concentrate on getting the center of the field in focus, sacrificing a bit on the periphery if necessary. This is especially important in Fields 1M and 2.

When the photographer moves to Field 2, having just taken Field 1M, **he/she should refocus on retinal vessels near the center of the field.** *Failure to do so results in photographs that show the foveal area to be slightly out of focus while the periphery is in focus.* 

A common problem is focusing too deep. Photographs which include the disc (Fields 1M and often Field 2) sometimes show clear focus on the bottom of the cup, while the retina is slightly out of focus. It appears that some photographers use the lamina cribrosa (at the bottom of the cup), the disc margin, or the granular pattern of the pigment epithelium for focusing. Instead, it is desirable to focus on fine retinal vessels. Since the depth of focus is greater posterior to the plane of absolute focus than anterior to it, it makes sense to err on the side of focusing slightly up into the vitreous rather than too deep. This should keep both the anterior surface of the retina and the pigment epithelial background in focus. Such a strategy is of special importance when macular edema is present.

#### Stereoscopic Effect

The technique described by Allen<sup>1</sup> is used for taking stereo fundus photographs. An Allen stereo separator or manual lateral movement of the camera may be used to obtain the X:\NIDDK\niddk-dr\_studies1\FIND\private\_created\_data\FIND\_V5\Documents\MOOP\Eye\_Study\App 1 Modified7StdF 1.01 20Feb2002.doc Appendix 1 -- 9 of 10

required, non-simultaneous stereo pairs. If the manual method is used, the camera should not be rotated; instead, it should be moved from left to right with the joystick (or by sliding the camera base on its table, if preferred). It is customary to take the left member of the pair first, but this is optional. The first member of the pair is taken as far to one side of the pupil as possible, while maintaining good illumination and a clear image. If the separator is used, it is then flipped to the other side and the second photograph is taken if its quality is good. If the quality is not good, refocusing with spherical or astigmatic correction and/or slight vertical movement of the camera (to avoid lens opacity) may be needed. Such vertical movement will not impair the stereoscopic effect. **Somewhat less than optimal focus and clarity is acceptable, if necessary, in the second member of the pair in order to maintain the stereoscopic effect.** The same principles apply when the manual technique is used. If the stereo separator is used, it should be set between 2.25 and 2.75mm. About 2mm is the minimum separation between members of the stereo pair to be aimed for when moving the joystick or sliding the camera.

#### Photographers should monitor their own work

A 4X or 5X magnification stereoscopic viewer for examining stereo fundus photographs is required, so that the photographer can critically examine his/her work and make appropriate corrections in technique. Examples of good stereoscopic photos can be found at the UW-FPRC website, <u>http://eyephoto.ophth.wisc.edu.</u>

## **Questions or Comments**

For questions or comments concerning this photography procedure, please contact the UW-FPRC photographic consultants, Michael Neider (608/263-9858; <u>neider@rc.ophth.wisc.edu</u>) or Hugh Wabers (608/263-0740; <u>wabers@rc.ophth.wisc.edu</u>).

#### Reference

1. Allen L. Ocular fundus photography. Am J Ophthalmol 1964;57:13-28.