

Excerpt from the CATT Manual of Procedures (Chapter 14, Clinical Center Staff Responsibilities and Certification Requirements)

#### 14.1. RESPONSIBILITIES OF THE CATT FUNDUS PHOTOGRAPHERS

The fundus photographer is responsible for:

- Completing the requirements to certify the digital imaging system (Chapter 8, Section 8.2),
- Obtaining the fundus photographs and fluorescein angiograms,
- Downloading images to CDs for submission to the FPRC, and
- Maintaining the digital imaging system certification during the course of the study.

##### 14.1.1. CERTIFICATION OF PHOTOGRAPHERS

Photographers must demonstrate their ability to consistently obtain good quality stereo photographs and stereo angiograms so that the Photograph Reading Center can determine patient eligibility with confidence and determine the status of the neovascular AMD lesion at baseline and during follow-up. The photographer must also demonstrate the ability to download digital images and submit the images to the Fundus Photograph Reading Center to confirm that the digital imaging system conforms to study specifications and that the images submitted can be accessed at the FPRC. The photographers are required to demonstrate their general understanding of the CATT study procedures on the knowledge assessment forms as well as to demonstrate their proficiency in performing the CATT photography protocol.

If a Clinical Center is certified for film photography rather than digital or if the Clinical Center's digital system does not meet the study criteria (See Chapter 8, Procedures for Fundus Photography), the requirements for the photographer certification are the same as for digital certification, except film will be submitted.

##### 14.1.2. Digital Angiography and Film Color Photography

If the Clinical Center's digital imaging system meets the criteria for fluorescein angiography but does not meet the standards for color digital images, a Clinical Center can be certified to submit color film images and digital fluorescein angiograms. The photographer will need to submit photographs for certification in the format for which his/her Clinical Center is certified. **A Clinical Center cannot be certified to submit color digital images and film fluorescein angiograms.**

Upon successful completion of all certification requirements, a certification number for each photographer and digital imaging system will be issued by the Coordinating Center.

##### 14.1.3. Specific Requirements for Photographer Certification for CATT

Photographers must be certified by the Fundus Photograph Reading Center for study procedures prior to photographing and submitting photographs of study patients. Only study certified photographers are permitted to take photographs for initial study visits.

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To be certified a study photographer is required to:

- Submit acceptable quality stereo color photographs and stereo fluorescein angiograms acquired on a CATT certified imaging system (Section 14.13.3);
- Read specific chapters of CATT Manual of Procedures;
- Complete the online CATT Study General Knowledge Assessment
- Complete the online CATT Photographer Knowledge Assessment;

### **14.1.3.1. Submission of Photographs for Certification**

Photographers may submit images for certification purposes only after the imaging system is certified by the CATT FPRC. Each photographer is required to submit color photographs and fluorescein angiograms of four patients with AMD taken according to the CATT protocol (see Chapter 8, Procedures for Fundus Photography). These four patients would have had an angiogram performed for management of their condition, not just for photographer certification purposes. The color photographs and angiogram of an individual patient must be taken on the same day. The four patients must be photographed within a 4-week period.

The photographs and angiograms must be labeled and submitted to the FPRC according to the procedures detailed in Chapter 8, Procedures for Fundus Photography. The patient's name must not appear on the photographs or angiograms. The materials for certification must include a completed Photograph Inventory Form for each patient. A Photographer Certification Submission of Images for Review Form should be completed also, listing the four sets of submitted images.

A senior photograph reader reviews the color photographs and angiograms and makes one of the following judgments:

- The photographs are acceptable and photographer certification is granted;
- The quality of the photographs is marginally acceptable or inconsistent and improvement is necessary. In this case, the senior reader contacts the photographer and discusses the deficiencies. Another two sets of photographs must be submitted and evaluated as acceptable before certification can be granted.

### **14.1.3.2. Read Specific Chapters CATT Manual of Procedures**

To be familiar with the study design and procedures, photographers are required to read the following chapters of the CATT Manual of Procedures: Chapters 1 through 5, 8, 12 through 14 (Certification Requirements for CATT Photographers) and 17.

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### 14.1.3.3. Waiver for Photographer Certification for Digital Images

Digital Fluorescein Angiography: If a photographer is certified by the University of Wisconsin-Madison Fundus Photograph Reading Center (UW FPRC) for another study that is using the UW FPRC Digital Fluorescein Angiography protocol, the photographer may be granted a waiver for the submission of fluorescein angiography. A photographer qualifies for a waiver if 75% of his/her angiograms taken within the last 365 days were graded as Fair and no more than 10% of the photographs were graded as Poor. Documentation of the certification and the quality of the images will be required from the UW FPRC.

Digital Color Images: A waiver based on documentation from the UW FPRC reduces the number of sets of digital color photographs to be submitted from four to two. This is necessary to document the quality of the digital color images that are not required by the UW FPRC. The waiver does not change the requirement to complete the knowledge assessment forms. A waiver will be granted once the prior certification is confirmed and the color digital images submitted are evaluated as acceptable.

Provisional Status with Waiver Granted: When a waiver is granted for digital images, provisional status will be established. The first five digital angiograms submitted will be reviewed for quality and completeness. If the quality is acceptable, full certification will be granted. This will ensure that the photographer is currently obtaining acceptable quality images for CATT.

### 14.1.3.4. Waiver for Photographer Certification for Film Images

If a photographer is certified by the University of Wisconsin-Madison Fundus Photograph Reading Center (UW FPRC) for another study that is using the UW FPRC Fluorescein Angiography protocol, the photographer may be granted a waiver. The waiver reduces the number of sets photographs (angiogram and colors photos) to be submitted from four to one. A photographer qualifies for a waiver if 75% of his/her angiograms taken within the last 365 days were graded as Fair and no more than 10% of the photographs were graded as Poor. Documentation of the certification and the quality of the images will be required from the UW FPRC. The waiver does not change the requirement to complete the knowledge assessment forms. A waiver will be granted once the prior certification is confirmed and the color photographs and angiogram are submitted to the CATT FPRC and are evaluated as acceptable.

Provisional Status with Waiver Granted: When a waiver is granted for film images, provisional status will be established. The first five sets of photographs submitted will be reviewed for quality and completeness. If the quality is acceptable, full certification will be granted. This will ensure that the photographer is currently obtaining acceptable quality images for CATT.