

SCHEIE IMAGE READING CENTER

STAFFING AND GENERAL PROCEDURES

Staff

Staffing may change as a study progresses. The staffing of SIRC includes the following roles:

- Principal Investigator (ophthalmologist)
- Director
- Co-Director
- Fundus Photograph Readers
- Administrative Coordinator
- Data Coordinator

The Principal Investigator leads the general scientific affairs of the Reading Center and photograph interpretation responsibilities in particular. The Director has primary responsibility for the day-to-day activities of the Reading Center, while the Co-Director oversees the Grading System and supervision of the readers.

Staff Responsibilities

The Principal Investigator is responsible for the overall performance of the Reading Center. Specific responsibilities in this role include:

- Reviews baseline photographs to confirm eligibility of all patients enrolled in the study;
- Collaborates with the Director and Co-Director to maintain and refine the grading program;
- Establishes standards of treatment performance that can be documented photographically;
- Serves as the clinical director of the Reading Center;
- Assists with Reading Center procedural changes involving the interpretation of photographs;
- Organizes research efforts for publications involving Reading Center data and methods;
- Serves as a voting member on various study committees;

The Director is responsible for the day-to-day operations of the Reading Center. Specific responsibilities in this role include:

- Reviews all baseline photographs to ensure compliance with the photographic and angiographic eligibility criteria and treatment protocols;

- Organizes and supervises daily operations;
- Recruits and trains Reading Center personnel;
- Serves as a photograph reader as needed;
- Serves as a voting member on various study committees;
- Establishes and oversees the Quality Assurance (QA) procedures;
- Assists in training ophthalmologists and clinic coordinators at Study Group Training Meetings;
- Develops a Reading Center Handbook of Procedures;
- Designs appropriate data collection forms;
- Updates Reading Center related chapters in the *Manual of Procedures*;
- Serves as liaison with Coordinating Center regarding Reading Center database issues, photograph interpretation, data queries, and other data collection issues;
- Coordinates the Data Checking Program of Reading Center database;
- Prepares presentations for Study meetings and scientific forums;
- Assists in preparation of general study publications;
- Participates in research efforts for publication of Reading Center methods;
- Administers certification procedures for ophthalmologists to identify eligible patients and perform protocol treatments;
- Supervises certification procedures for study photographers;
- Communicates with clinical centers on issues of patient eligibility and clinic performance;
- Administers Reading Center budget and reviews monthly budget reports;
- Coordinates resolution of photographic data queries from the Coordinating Center;
- Prepares grant continuation and renewals for review and approval by the Reading Center Principal Investigator.

The Co-Director is primarily responsible for the STUDY Grading System. Specific responsibilities include:

- Designs and executes the reader training program to ensure that adequately trained reading staff are available throughout the term of the study;
- Participates in the recruiting and hiring of readers;
- Supervises the readers;
- Performs lead role in refining study grading scheme;

- Serves as Senior Reader on baseline photographs and treatment photographs as needed;
- Serves as second reader on all gradings as needed;
- Collaborates with the Reading Center Principal Investigator and Director regarding clinical interpretation of photographs;
- Assists with communication with clinical centers regarding patient eligibility, advancing stages of the disease process, treatment adequacy, complications and criteria for retreatment as appropriate;
- Administers photographer certification procedures;
- Assists with study publications;
- Assists with presentations at Study Group meetings and scientific forums;
- Participates in the training of ophthalmologists and clinic coordinators at Study training meetings;
- Participates in the Data Checking and Materials Checking programs;
- Participates in the preparation of the Reading Center Handbook of Procedures;
- Serves as liaison with Coordinating Center as needed.

The Fundus Photograph Readers are responsible for the evaluation and interpretation of study photographs according to the Grading Scheme of a specific study. The general responsibilities of the readers include:

- Identify inclusion and exclusion criteria on initial visit photographs of patients randomized in the study;
- Evaluate initial visit photographs for detailed description of the characteristics of the disease process under investigation;
- Evaluate same-day treatment photographs for adherence to the treatment protocol when appropriate;
- Evaluate follow-up visit photographs compared to initial visit photographs for changes in the characteristics of the disease;
- Evaluate quality of photographs read;
- Evaluate photographs for eligibility prior to randomization at the request of clinical centers;
- Resolve photograph reading data queries as identified by the Coordinating Center;
- Participate in Quality Assurance Reading procedures;
- Participate in data checking procedures of the Reading Center database;
- Participate in Study training meetings;

- Participate in Study Group meetings, and attend Ophthalmologist workshops at those meetings;
- Assist with administrative tasks as needed.

The Administrative Coordinator assists the Principal Investigator, Director and Co-Director with the administrative matters of the Reading Center such as routine correspondence, budget tracking, ordering of supplies, word processing and graphics, and travel arrangements. Additional responsibilities include:

- Interacts with clinical centers regarding photographic materials issues;
- Serves as liaison between the Reading Center data coordinator and the clinical centers;
- Maintains an inventory and obtains duplicate slides for internal use, presentations, and publications;
- Prepares templates of all Reading Center forms and maintains record of all revisions;
- Coordinates the implementation of the Quality Assurance Reading system;
- Participates in the study training meetings;
- Assists with training of clinic coordinators;
- Supervises the Reading Center data coordinator;
- Prioritizes workload of the Reading Center data coordinator;
- Serves as liaison with Coordinating Center as appropriate;
- Participates in development of Reading Center Handbook of Procedures;
- Participates in Study Group meetings;
- Maintains budget and monthly reporting of expenditures;
- Assists with preparation of annual budget for grant continuation.

The Data Coordinator is responsible for inventory, tracking and storage of all photographic materials received at the Reading Center. Specific tasks are:

- Confirms receipt of all photographic materials received at the Reading Center;
- Checks all materials for completeness and consistency of labeling;
- Notifies clinical centers and resolves any discrepancies of identifying information;
- Establishes Reading Center patient files as patients are enrolled (either files of slides/angiogram or electronic folders for digital files);
- Prepares materials for the grading process;
- Performs data entry of all inventory and grading forms;

- Responds to data queries as appropriate;
- Files and retrieves all study photographs from study files;
- Prepares materials for data checking and materials checking programs;
- Prepares photographs for QA cycles;
- Scans study photographs into computer–assisted grading data base;
- Assists with word processing and graphics as needed;
- Assists all Reading Center staff members as necessary to meet the needs of the Study;
- Attends Study Group meetings.

PHOTOGRAPHIC MATERIAL HANDLING AND CONTROLS

Procedures (as detailed in the Reading Center Handbook of Procedures) are in place to ensure efficient and accurate handling of all materials received at the Reading Center. A summary of these procedures follows.

Receipt and Processing of Photographic Materials

Photographs of study patients are coded, labeled and presented in slide and negative pages at the clinical centers according to the procedures established by the study protocol. The Clinic Coordinators ship the photographs along with the Photograph Inventory Forms and Reading Center Transmittal Logs to the Reading Center.

The Reading Center Data Coordinator receives all materials, checks the forms and labeling of photographs for completeness, and confirms that all information on the materials matches the information on the accompanying forms. Any inconsistencies or discrepancies are resolved before photographs are graded.

The Data Coordinator makes the photographs and appropriate grading forms available to the Readers. The Readers read the photographs, complete the grading forms and initial and date each form according to the study Grading Scheme.

The Reader returns the photographs and completed grading forms to the Data Coordinator to be checked for completeness of the grading. The Data Coordinator returns any forms with ambiguous, incomplete, illegible or missing information to the Readers for resolution.

The Data Coordinator enters the grading data into the study database and initials and dates the forms indicating completion of the data entry process. The Data Coordinator files the photographs separately from the grading forms within the patient file. Patient files are organized by Clinical Center in patient ID order.

Grading Procedures

Grading procedures vary for different studies according to the study question and outcome measures. A senior reader (Director or Co-Director) may serve as a single reader. Otherwise, any two readers grade the photographs independently. Differences are openly adjudicated, and the adjudicated record is data entered. If necessary, the Director or Principal Investigator may be asked to resolve discrepancies or a difficult presentation. The Readers also assess the focus/clarity and stereoscopic quality of all photographs based on their confidence to complete the grading of the photographs.

QUALITY ASSURANCE ACTIVITIES

The purpose of the Quality Assurance (QA) activities of the Reading Center is to ensure the integrity and completeness of the data collected from the evaluation of the photographs and angiograms. These activities include the following:

- Masking Readers to Treatment Assignment
- Regrading of photographs for reproducibility
- Automatic edit queries and consistency checks of grading data
- Confirming accuracy of data entry
- Confirming completeness of inventory of photographic materials and their labels.
- Compliance with HIPPA.

Masking Readers to Treatment Assignment

Upon receipt of the initial visit photographic materials, the Reading Center Data Coordinator confirms that the treatment assignment has not been inadvertently indicated on any of the photographic materials received.

Regrading of Photographs for Reproducibility

The purpose of the Quality Assurance (QA) system is to measure reproducibility of the grading scheme, reproducibility of the Readers, and to monitor for grader drift. The procedures involve the regrading of a predetermined set of photographs by each grader at specified times. The results of the QA system identify agreement between Readers as well as the reproducibility of each grader.

The QA set of photographs consists of both eyes of 25 patients selected randomly by the Coordinating Center from the first 200 patients enrolled. The quality assurance set of photographs is graded every 3 months. The set of QA photographs of 25 patients are graded together so that the gradings represent the reader's interpretation at a given period of time. All Readers are given the same set of photographs within a specified period of time in order to evaluate inter as well as intra Reader variability throughout the study. The original gradings and subsequent gradings of these QA photographs are secured from access by the Readers. Details of the QA Procedures are included in the Reading Center Handbook.

The Reading Center Directors and Principal Investigator review results of the QA gradings for discussion with the Readers of any needed corrective actions. The results of the QA gradings are reported to the Executive Committee, and to the Data Safety and Monitoring Committee or any appropriate study committee. In addition to the regrading of the QA set of photographs, grading issues are identified on a regular basis and discussed with the Readers.

Automatic Edit Queries And Consistency Checks Of Grading Data And Corrections

Consistency checks are performed at the time of data entry of Reading Center grading forms. These checks include validation of patient ID numbers, name codes, and visit codes.

Edit messages are generated to identify inconsistencies within the grading system. These edit messages, generated by the Coordinating Center may result in a confirmation of original grading or the need to correct the original grading. The Reading Center Data Coordinator retrieves the appropriate photographs and grading form from the Reading Center files and presents them along with the edit message to the reader. The reader reviews photographs and decides on the appropriate response. If the reader decides that a change to the grading is appropriate, she/he indicates the change in red on the grading form and initials and dates the change. The grader indicates the corrected data on the edit message and returns the photographs, grading form, and edit message to the Reading Center Data Coordinator. The Data Coordinator attaches the edit message to the grading form, and then makes the correction to the database.

The Coordinating Center must be informed when errors are identified in the grading data at the Reading Center. The reader makes the corrections to the grading form in red and initials and dates the grading form. The source and reason for the error, as well as the original data and corrected data, are indicated on a Data Correction Form. As with an edit message, the Data Coordinator attaches the Correction Form to the grading form and makes corrections to the database.

Confirming Accuracy of Data Entry

The accuracy of the data entry system used for the Reading Center gradings is assessed on a monthly basis. A 5% random sample of all Reading Center grading forms is identified for a specified period of time, usually the previous month. The records identified as the sample are printed and checked against the grading forms in the Reading Center files. Discrepancies are noted and corrections made to the data records as appropriate. A report of the frequency and types of errors is provided to the Reading Center Principal Investigator, Coordinating Principal Investigator, and the Coordinating Center Project Director. Details of these procedures are in the Reading Center Handbook of Procedures.

Confirming Completeness of Inventory of Photographic Materials and Their Labels

The accuracy of the inventory of the photographic materials received from the participating clinical centers is assessed on a monthly basis. A 5% random sample of materials received for a specified period of time, based on the data entry of the Photograph Inventory Forms, is assessed. The data records identified as the sample are printed and checked against the Photograph Inventory Forms. In addition, the photographs identified as present on the Photograph Inventory Forms are checked against the photographs in the patient files. At the same time the labels on the photographs are checked for accuracy. Discrepancies are noted and corrections made to the data records as appropriate. Discrepancies that may indicate a recurrent problem are investigated. A report of the frequency and types of errors is provided to the Reading Center Principal Investigator, Coordinating Principal Investigator, and the Coordinating Center Project Director. Details of these procedures are in the Reading Center Handbook of Procedures.

READING CENTER HANDBOOK OF PROCEDURES

The Reading Center Directors, Principal Investigator and staff are responsible for developing a Handbook of Procedures as a reference document for the Reading Center staff and for others interested in Reading Center operations. The descriptions of procedures included in the Handbook are more detailed than those presented in the relevant chapters of the Study Manual of Procedures and give step by step instructions for each task required to carry out the responsibilities of the Reading Center. This document is constantly updated as procedures are changed.