Organization of the Scheie Image Reading Center (SIRC)

The responsibilities of SIRC are organized according to the phase of the clinical trial. The phases are categorized as initial design and protocol development, final preparation for trial initiation, patient recruitment, patient treatment and follow-up, patient closeout, and final termination of the trials.

1. Initial Design Phase and Protocol Development

During the initial design phase of a clinical trial, SIRC plays a major role in the following activities:

- Initial testing and refining of the grading system during the pilot study;
- Developing standard photographs illustrating eligibility and treatment criteria;
- Developing standard photographs for identifying pathology to be used by Reading Center personnel;
- Drafting appropriate chapters of the *Manual of Procedures*;
- Drafting the photographic data collection forms;
- Initial testing and refining of the photographic data collection forms and procedures during the pilot study;
- Initial testing and refining of the photographic data processing procedures during the pilot study;
- Participating in the development of procedures for training and certifying staff at the clinical centers;
- Preparing other materials to be used by clinical center staff, such as photograph logs and other auxiliary forms;
- Developing quality assurance procedures for all aspects of the Reading Center.

2. Final Preparation for the Initiation of the Trial

Prior to initiating a study, a number of activities are performed by SIRC staff to begin the trial with a fully developed protocol and well-trained staff for all aspects of a clinical trial. These activities include:

- Finalizing the protocol details regarding photographic eligibility, identification of exudation at follow-up visits, evaluation of treatment and related issues;

- Fine tuning the data collection activities at the Reading Center in conjunction with the activities of the other study resource centers;
- Training Clinic Coordinators and Principal Investigators of the clinical centers;
- Certifying photographers and imaging systems at the clinical centers;
- Certifying ophthalmologists at the clinical centers;
- Collaborating with the other study resource centers to refine the editing of photograph grading forms;
- Collaborating with the other study resource centers to finalize the quality control program for photograph grading;
- Collaborating with the other study resource centers to prepare standard images for presentations to enhance recruitment.

3. Patient Recruitment and Treatment and Follow-up Phase

Activities during this phase can generally be categorized as administrative, data collection and processing, photograph reading, quality assurance, and planning for future phases. SIRC responsibilities are summarized for each category.

Study Administration

- Participating in the affairs of each of the standing committees as appropriate;
- Providing the necessary logistical support for all study meetings;
- Establishing communications between SIRC and various study centers and committees;
- Assisting the staff at each clinical center to interpret and follow the protocol and procedures relating to SIRC as documented in the *Manual of Procedures*.

Material Collection and Processing

- Maintaining an inventory, tracking, and storage system of all materials received at SIRC;
- Confirming that all photographic materials received from the clinical centers are identified and labeled consistently and accurately;

- Conveying the photographic data collected at SIRC to the study data collection center on a regular schedule;
- Notifying the Clinical Centers of late or delinquent photographs;
- Informing the study coordinating center of clinical centers that fail to conform to the photography protocols.

Photograph Reading

- Performing grading of all study photographs according the established Grading System in order to:
  - ► Document that patients selected for the Study at the various clinical centers meet the angiographic and photographic eligibility criteria specified;
  - ► Document that treatment performed at the clinical centers on Study eyes assigned to treatment is carried out according to the treatment protocol when discernable on photography;
  - ► Interpret the follow-up photographs and/or fluorescein angiograms for the status of fundus features being studied;
- Determining photographic eligibility of patients prior to randomization at the request of a clinic when included in the study design.

Data Analysis and Reporting

- Preparing reports concerning the status of receipt of initial visit and follow-up photographs, adherence to the eligibility and treatment protocols, quality of photographs collected, and clinic response to queries;
- Assisting with the development of analytic methods of the photographic data in conjunction with other study resource centers;
- Assisting with the preparation of photographic interpretation to be reported in all study publications;
- Participating in the drafting of all study publications;
- Reporting to appropriate audiences Reading Center methodological innovations developed during the course of the study.

Quality Assurance

- Participating in the execution of an initial training sessions for clinic personnel to review study design, data collection methods,

and procedures for interfacing with the Reading Center and other study resource centers;

- Certifying participating ophthalmologists and photographers as competent in the protocol procedures;
- Masking of initial visit photographs as to the randomization assignment until photographic eligibility has been determined;
- Performing Quality Assurance procedures of the Grading System;
- Performing Quality Assurance procedures of the grading data records;
- Performing Quality Assurance procedures of the inventory of materials received;
- Monitoring the quality of the photographs at all study visits;
- Preparing monthly reports summarizing status of photographs received versus the visits completed at each center;
- Assisting in the preparation of all reports on adherence to protocol in the clinical centers as it pertains to the Reading Center;
- Maintaining documentation of all procedures and operations at the Reading Center;
- Maintaining the photographic files in a secure manner to assure their integrity;
- Backing up the Reading Center data files to assure that data are not lost;
- Reporting periodically on the quality of the data accumulated at the Reading Center;
- Cooperating with any individual or group assigned to review operations at the Reading Center;

Planning for Future Phases

- Developing procedures for closing out patient follow-up at the appropriate time;
- Planning for permanent, accessible storage of study images.

4. Patient Closeout Phase

As with earlier phases of the study, during the Patient Closeout phase the primary responsibilities of the SIRC staff are concerned with coordination, developing and refining closeout procedures, and data

processing and analysis. Specific responsibilities during this period are:

- Assist with familiarizing clinic staff with closeout procedures regarding photography;
- Assist with monitoring adherence to established procedures for patient closeout;
- Assist with developing plans for final editing of photographic data and storage;
- Completing plans for final analysis of photographic data and preparation of publications;
- Developing plans for final disposition of the photographic files;
- Participating in paper writing activities.

5. Termination Phase

During the last phase of CAPT for which funding is available, the Reading Center may be only minimally funded. The following activities are those anticipated for the Reading Center during this period:

- Responding to any final photographic data queries from other study resource centers as required for final data analysis;
- Participating in the completion of manuscripts for publication which may require access to the photographs for illustrations;
- Placing of image files and other materials in the selected archives.