

## **DIABETIC RETINOPATHY CLINICAL RESEARCH NETWORK (DRCR.net)**

<http://www.drcr.net>

### **Description of Project**

- The *DRCR.net* is a cooperative agreement for the development of a collaborative network dedicated to facilitating multi-center clinical research of diabetic retinopathy, diabetic macular edema, and associated conditions.
- The *DRCR.net* supports the identification, design, and implementation of multi-center clinical research initiatives focused on diabetes-induced retinal disorders. Principal emphasis is placed on clinical trials, but epidemiologic, outcomes, and other research may be supported as well.
- Network participation is open to all qualified investigators whose sites have the requisite equipment needed to conduct a study protocol. In soliciting site participants, involvement of community-based as well as academic-oriented partners within the United States has been encouraged.

### **Accomplishments**

- Development of needed infrastructure, organization and interaction between the central units.
  - Procedures established at each central unit;
  - Multi-functional website developed to support multiple network functions;
  - Committees established for network oversight and protocol development.
- Define and disseminate network goals to the ophthalmic community.
  - Multiple efforts made to inform and involve the ophthalmic community (including public website (<http://www.drcr.net/>), announcements in ophthalmic journals, announcements at meetings, and an informational meeting)
  - As of 4/13/04:
    - 121 clinical sites have applied for participation in the network
    - 66% of the sites are community-based; 44% are institution based
    - Sites include 353 clinical investigators and 703 additional personnel
    - 38 states are represented
- Initiate the first DRCR.net protocol - **A Pilot Study of Laser Photocoagulation for Diabetic Macular Edema**
  - As of 4/13/04, 163 patients have been randomized into this study by 69 clinical sites.
- Developed the second DRCR.net protocol - **A Randomized Trial Comparing Intravitreal Triamcinolone Acetonide and Laser Photocoagulation for Diabetic Macular Edema**
  - Established collaboration with industry.
  - Initiation expected in June 2004.

### **Technological milestones:**

- Development of fully functional website to support all aspects of protocol conduct;

- Electronic ETDRS visual acuity testing at all participating sites;
- Tablet PC data entry for all case report forms at all sites;
- Wireless integration of tablet PCs at desiring sites.

**Future directions**

Protocols under development involve the following:

- Vitrectomy for diabetic macular edema;
- Effect of cataract surgery in diabetic retinopathy and role of corticosteroids;
- OCT reproducibility and diurnal variation of retinal thickening;
- Management of subclinical diabetic macular edema detected by OCT;
- Pharmacological treatment of mild clinical diabetic macular edema.

**Materials to be made available to researchers**

The data collected in network studies will be placed in the public domain after the conclusion of each protocol and the publication of the primary results. The Coordinating Center will prepare datasets (with patient identifiers removed) for this purpose.

If samples (such as blood) are collected in DRRC.net protocols, the network will develop procedures for sharing them with the scientific community. In addition, the network will entertain proposals from the scientific community to collaborate in the collection of samples from network patients as ancillary studies.

**Participants**

Sponsor: National Eye Institute

Participating Institutions

*Office of the Network Chair*  
 Joslin Diabetes Center

*Coordinating Center*  
 Jaeb Center for Health Research

*Fundus Photograph Reading Center*  
 University of Wisconsin

DRRC.net has over 120 clinical centers located throughout the U.S.

Steering Committee Members

<u>Name</u>	<u>Affiliation</u>
Lloyd P. Aiello, M.D., Ph.D.	Joslin Diabetes Center
Roy W. Beck, M.D., Ph.D.	Jaeb Center for Health Research
Matthew D. Davis, M.D.	Fundus Photograph Reading Center

Donald F. Everett, M.A.  
Frederick Ferris, M.D.  
Malcolm Anderson, Jr., P.A.C.  
Dave Browning, M.D.  
Don S. Fong, M.D., MPH  
Thomas W. Gardner, M.D.  
Julia A. Haller, M.D.  
Michael Ip, M.D.  
Ingrid Scott, M.D., M.P.H.  
Kimberly E. McLeod, M.P.H.

NEI, NIH  
NEI, NIH  
Duke University  
Charlotte Eye, Ear, Nose and Throat  
Southern California Permanente Medical Group  
Pennsylvania State University College of Medicine  
Johns Hopkins Hospital  
University of Wisconsin  
Bascom Palmer Eye Institute  
Jaeb Center for Health Research