



LOMA LINDA UNIVERSITY

Eye Institute

# Research Division

# Research

As an institution, Loma Linda University Health Systems takes research very seriously. Our world-renowned scientists are always striving to advance the understanding of human health to fulfill our mission **"To Make Man Whole."**

Here, at Loma Linda University Eye Institute (LLUEI), we play a pivotal role in caring for the health of our patients' eyes, and we contribute a substantial amount of effort in research to fulfill that mission.

Our purpose is to develop and apply knowledge that will improve the quality of life of patients suffering from ocular diseases through patient-centered and community driven research. We hope to pursue this innovative path by dedicating ourselves to our community, to excellence, and toward providing exceptional patient care.

Loma Linda University Eye Institute, Clinical Research, pursues research and expands knowledge in the following fields:

- Retina
- Glaucoma
- Cornea
- Cataracts
- Neuro-Ophthalmology
- Uveitis
- Pediatrics
- Occuloplastics
- Investigator Initiated Studies



## Physicians

Michael E. Rauser, MD

*Chairman, Ophthalmology*

*Retina, Cataract Surgery*

Joseph T. Fan, MD

*Director of Research, Ophthalmology*

*Retina/ Vitreous & Cataract Surgery*

John C. Affeldt, MD

*Cornea*

Jennifer A. Dunbar, MD

*Pediatric Ophthalmology*

Fatema Q. Esmail, MD

*Pediatric Ophthalmology*

Howard V. Gimbel, MD

*Cataract & Refractive Surgery*

Lynn L. Huang, MD, MPH

*Retina*

Jennifer I. Hui, MD

*Oculoplastics*

David K. Isaacs, MD

*Orbital-Facial Plastic & Reconstructive  
Surgery*

Leila M. Khazaeni, MD

*Pediatric Ophthalmology*

William H. Kiernan, OD

*Optometry*

Priscilla K. Luke, MD

*Comprehensive Ophthalmology*

Enoch H. Nam, MD

*Cornea, External Eye Disease*

*& Refractive Surgery*

Rosalynn H. Nguyen-Strongin, OD

*Optometry*

Samantha E. Perea, MD

*Glaucoma & Cataract Surgery*

Mukesh B. Suthar, MD

*Surgical Retina*

Donald G. Tohm, MD

*Comprehensive & Cataract Surgery*

Terry D. Wood, MD

*Neuro Ophthalmology*

## Local IRB

Loma Linda University  
Research Protection Programs  
24887 Taylor Street, Suite 202  
Loma Linda, CA 92350  
909-558-4531  
Fax 909-558-0131  
researchaffairs@llu.edu

- IRB meets twice a month January through October, and once a month in November and December
- Budget must be approved before submission to IRB
- Submission deadline 10 days prior to meeting
- Approval documentation 1-3 weeks after meeting
- A fully executed contract is required prior to receiving IRB approval

## Clinical Trial Center

Loma Linda University Health Care  
Clinical Trial Center  
Coleman Pavilion, Suite 11113  
11175 Campus Street  
Loma Linda, CA 92350  
909-651-5002  
Fax 909-558-2196  
clinicaltrials@llu.edu

- Perform comprehensive feasibility analysis in partnership with Principal Investigators
- Perform budget, contract and financial management for industry sponsored studies and assist with budget development and review for non-industry sponsored clinical studies
- Perform Medicare Coverage analysis and facilitates compliant research billing
- Provide regulatory management and clinical coordinator support as a contracted service
- Serve as a liaison for enterprise electronic medical records and research application support
- Coordinate study advertising and subject recruitment and promote clinical research collaboration

## Contracts & Budget Information

### Budget Requirements

- Institutional overhead
- Study startup and closeout fees

### Contracts

- Contract review runs concurrently with IRB review
- 6-8 weeks to obtain fully executed contract

## Institution Signatory

*Associate Vice President for Research Affairs*

## Payee Information

Loma Linda University  
Adventist Health Sciences  
Center  
11175 Campus Street, CSP  
11006  
Loma Linda, CA 92354  
Tax ID: 95-3804495

## **Department Study Drug Maintenance**

- Main door to storage locked-access by research staff only
- Refrigerator for investigational product only, with temperature monitored daily
- Freezer for investigational product: -20° C and -70° C
- Locked storage cabinets for investigational products
- Room temperature monitored daily

## **Department Laboratory**

- Freezer: -10 to -20° C
- Fridge: 2 to 6° C
- Dry ice available
- Interdepartmental processing includes non-refrigerated centrifuge, and special arrangements available for special processing
- Certified staff for shipment of biologicals, dry Ice, and blood borne pathogens

## **Local Laboratory**

Loma Linda University Medical Center

11234 Anderson Street

Loma Linda, CA 92354

909-558-4400

## **Study Drug Compounding Capabilities**

Compounding capabilities are available for sterile products that can be processed with an outpatient prescription for our site.

## **Exam Rooms**

- 15 exam rooms, including one designated for research

## **Original Medical Records/Source Documentations/CRF's**

- Electronic medical records utilized
- Protected EMR work queue provided for monitoring
- Experience with hard copy and electronic CRF's

## **Monitoring Visits**

- Monitoring visit to be scheduled with coordinator 2-4 weeks prior to visit in order to order temporary access to e-files in EPIC.
- Designated monitoring space provided
- Phone, fax and copies available in research office
- Internet access available

## **Emergency Measures**

- Crash cart in the same building
- Defibrillator in the clinic
- Oxygen available
- CPR certified staff
- ER located across the street at the main hospital

## Available Equipment for Research

- Konan Specular Microscope Noncon Robo Model: SP-9000
- Topcon 50DX Fundus Camera (x 2)
- Zeiss FF450 Plus Fundus Camera
- Haag Streit BX900 Slit-Lamp Camera
- Heidelberg HRT Spectralis OCT w/ Autofluorescence, Fluorescein Angiography, and Indocyanine Green capabilities.
- Ellex V4 Ultrasound with Posterior B-scan, UBM (40 MHz high resolution, Anterior Segment Ultrasound), Immersion A-scan, and Diagnostic A-scan.
- Retcam Fundus Camera
- IOL Master V5
- Pentacam Anterior and Posterior Corneal Topography
- Nidek OPD Anterior Corneal Topography
- Nidek Endothelial Cell Count
- Zeiss Humphrey Visual Field (x 3)
- Pneumotonometer (x 2)
- Ultra Select LW Scientific Centrifuge Model: U8S-1

## Ophthalmology Clinic

### Director

Wendy Lee

*Ophthalmology Clinic Director*

wlee@llu.edu

909-558-2522

Fax 909-558-2180

### Research Staff

Gisela Santiago

*Research Coordinator*

909-558-2170

gsantiago@llu.edu

L. Marvyn Cerdenio, BS

*Research Coordinator*

909-558-2168

lcerdenio@llu.edu

### Contact Information

Faculty Medical Offices

11370 Anderson Street, Suite 1800

Loma Linda, CA 92354

909-558-2170 or 909-558-2168

Fax 909-558-2478



## Current Certifications

<b><u>Study Staff</u></b>	<b><u>Certification Type</u></b>	<b><u>Center</u></b>
John C. Affeldt, MD	GCP	Dompé
L. Marvyn Cerdenio	Visual Acuity GCP	JCHR CITI
Raquel Hernandez	Visual Acuity & Refraction Fundus Photos, OCT	JCHR Wisconsin Reading Center Duke Reading Center
William H. Kiernan, OD	Visual Acuity & Refraction	JCHR
Jesse Knabb	Fundus Photos, OCT, FA Fundus Autofluorescence	Wisconsin Reading Center Duke Reading Center
Daisy Martinez	OCT	Duke Reading Center
Michael E. Rauser, MD	GCP	CITI
Gisela Santiago	Visual Acuity GCP	JCHR CITI
Armand Assissini	Fundus Photos, OCT Fundus Autofluorescence	Wisconsin Reading Center Duke Reading Center

## **Awards and Recognitions**

### **Diabetic Retinopathy Clinical Research Network**

#### **Quality Award**

In recognition of being one of the top sites for 2010 demonstrating outstanding performance in the DRCR Network.



### **Diabetic Retinopathy Clinical Research Network**

#### **Site of the Month Award**

In recognition of outstanding performance for the month of February in the DRCR Network

February 2010



#### **AREDS2**

#### **Certificate of Appreciation**

#### **Presented to Gisela Santiago**

In recognition of Most Improved Data Audit Error Rate

April 2010 to September 2011





LOMA LINDA UNIVERSITY

Eye Institute

**Many Strengths.  
One Mission.**

[www.LLUEyes.com](http://www.LLUEyes.com)