



▶ CLINICAL TRIAL CENTER:  
LENDING A HELPING HAND  
TO LLU RESEARCH .....1



▶ FIRST CLINICAL TRIALS  
WORKSHOP A SUCCESS ..2



▶ DEPARTMENT OF THE  
MONTH: HIGHLIGHTING  
OPHTHALMOLOGY.....3

# LLU *clinical trials*

*The Clinical Trial Center's mission is "to facilitate the timely execution of quality clinical trials with information, resources, and expertise in order to foster and promote the clinical trial enterprise within the institution."*

## The Clinical Trial Center: Supporting LLU Research

Since its official rollout in January, the Clinical Trial Center has commenced its groundbreaking endeavor to establish high-quality support for Loma Linda University staff involved in the conduct of clinical trials.

Milestones so far this year include the first Clinical Trials & Good Clinical Practice (GCP) Workshop as well as the development and rollout of the Clinical Trial Center website.

The Clinical Trial Center currently offers a number of services, including:

- Feasibility Analysis
- Budget Development & Negotiation
- Contract Review & Negotiation
- Medicare Coverage Analysis
- Consultation
- Training
- New Trial Opportunities

To find out more about the services provided by the Clinical Trial Center, visit [www.llu.edu/clinical-trials](http://www.llu.edu/clinical-trials).



Linda Wu,  
Director, CTC



Lila Dalton,  
Associate Director, CTC



Amy Casey,  
Assistant Director  
of Clinical Trial  
Contracts, CTC



Sarah Roper  
Project Specialist, CTC



## TRIAL TRIVIA

Did you know you can complete your Clinical Trial Center submissions online?

Whether it's a CDA, New Clinical Trial, Amendment, or Study Closure, you can get the ball rolling by visiting "For Researchers" at [www.llu.edu/clinical-trials](http://www.llu.edu/clinical-trials).

# First “Clinical Trials & Good Clinical Practice Workshop” A Success



education



On March 24th and 25th, fifty-six LLU research professionals attended the first Clinical Trials and Good Clinical Practice Workshop on-site at Loma Linda University. Attendees included principal investigators, clinical research coordinators, and a variety of other research support staff. The workshop was organized by the Clinical Trial Center in partnership with LLUMC Staff Development and LLUAHSC Research Affairs.

Seventeen clinical trial experts imparted their knowledge on a broad variety of topics, ranging from Dr. Deming’s exploration of Study Protocols to Desiree Wallace’s look at Study Drug Management. Dr. Zuccarelli, Associate Vice President of Research Affairs, provided a number

of case studies demonstrating the importance of Conflict of Interest Disclosures at Loma Linda University.

Kristy Burroughs and Cindy Kronbeck educated and entertained the audience with their role-play version of Informed Consent, and Linda Wu provided a sneak-peak at the Clinical Trial Center website as she guided participants through the Clinical Trial Life Cycle.

Round-table discussions and Expert Panel sessions afforded attendees the opportunity to ask questions and delve into conversations on hot-topic issues. In addition, clickers, games, giveaways, and group activities helped to keep everyone engaged with the topics at hand.

The workshop also provided a networking environment in which participants spent time connecting with fellow colleagues within LLU’s research community.

A special thanks to the speakers and panel experts for their valuable contributions at this event: Donna Bennett, Dr. Arlin Blood, Kristy Burroughs, Amy Casey, Dr. Douglas Deming, Sharon Fabbri, Linda Halstead, JR Krausz, Cindy Kronbeck, Dharmaseeli Moses, Janice Quick-Wolfe, Patti Radovich, Tami Terry, Candy Turner, Desiree Wallace, Linda Wu, Dr. Anthony Zuccarelli.

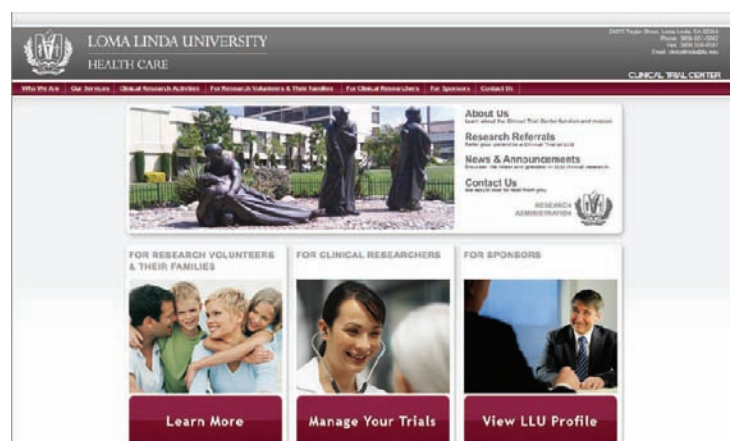
The new Clinical Trial Center website ([www.llu.edu/clinical-trials](http://www.llu.edu/clinical-trials)) was introduced on April 26.

Website users will find the following resources for their convenience:

- Information about the Clinical Trial Center’s services
- LLU research activities and news
- Resources for research participants and their families
- Trial management tools, including online submissions for LLU researchers and staff
- LLU profile information for sponsors

In order to best serve users, the Clinical Trial Center welcomes any questions or comments about the website.

## CTC Website Rolls Out





*Pictured L to R:*  
 Gisela Santiago (Research Coordinator),  
 Cara Davidson (Research Coordinator),  
 Jesse Knabb (Ophthalmic Photographer),  
 Dr. Kiernan (Optometrist),  
 Kara Rollins (Research Coordinator),  
 Blen Eshete (Assistant)

## Department Of The Month

# *ophthalmology*

Research is booming at Loma Linda University's Ophthalmology department. With nine principal investigators taking the lead on a variety of successful projects, the department is abounding with the fruits of their labor.

In addition to their principal investigators, the Ophthalmology team also includes dedicated support staff. The department currently employs three research coordinators (two full-time and one part-time). Additional support is provided by twelve residents, two retina fellows, two retinal photographers, an optometrist, a part-time assistant for resident projects, and a fluctuating number of students. Volunteer and student positions usually range between one and eight, depending upon availability.

In February, the Jaeb Center for Health Research honored the Ophthalmology team with their Site of the Month award, offering their congratulations for "excellent work in recruiting." The announcement was published in Jaeb's monthly newsletter.

The results of one of Ophthalmology's Jaeb-sponsored

clinical trials were released by the National Eye Institute on Tuesday, April 27. The study established that ranibizumab injections in combination with laser therapy act as a more effective treatment than laser treatment alone for retina swelling associated with diabetes. Details about the study outcome can be viewed at <http://www.nei.nih.gov/news/pressreleases/042710.asp>.

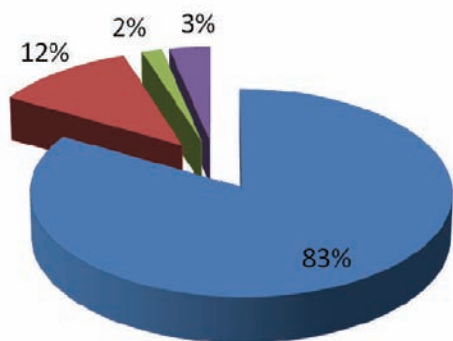
The team is now working on fifteen sponsored projects as well as thirteen investigator-initiated trials. The majority of their studies focus on the retina, and most of their subjects are seen for conditions such as Diabetic Retinopathy and Age-Related Macular Degeneration (AMD). While they are seeing a great deal of success in retina-related studies, they would like to increase their number of cornea and glaucoma trials.

Ophthalmology has received support from various sponsors, including Regeneron Pharmaceuticals; Genentech, Inc.; Pfizer; and the JAEB Center for Health Research (funded by the NIH, NEI, and DHHS).



*Pictured L to R:*  
 Dr. Bowes,  
 Dr. Affeldt,  
 Dr. Tokuhara,  
 Dr. Suthar,  
 Dr. Rauser,  
 Dr. Fan,  
 Dr. Narvaez,  
 Dr. Dunbar

# 2009 Clinical Trial Submissions At A Glance

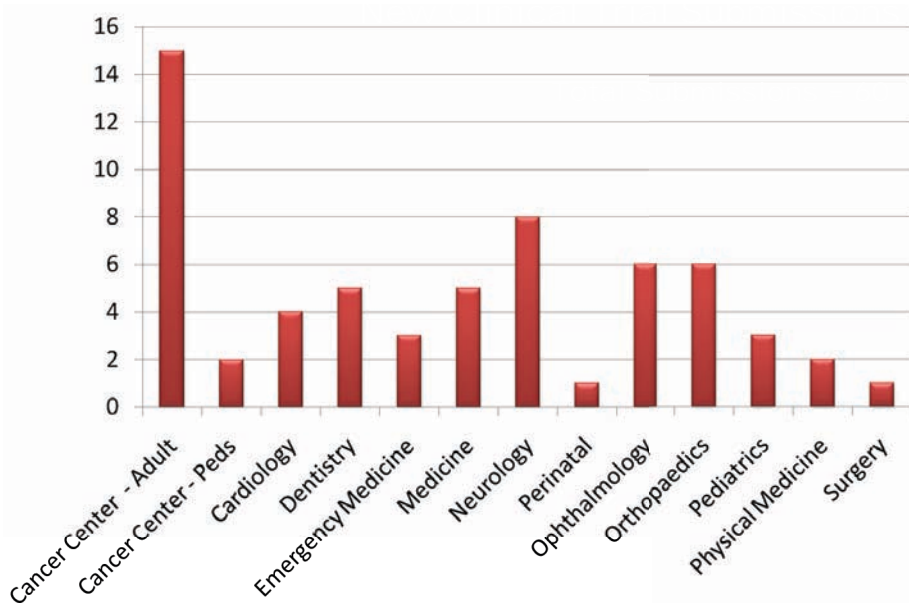


■ Contract

■ Cooperative Agreement

■ Grant

■ Investigator Initiated Trial/Intramural



## *policy particulars*

### R1: Investigational Drugs

The Pharmacy  
Loma Linda  
Children's Hospital

Physician  
Nuclear

- All
- D

invest

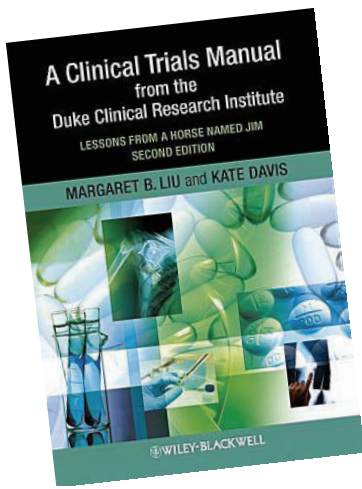
Complete  
including  
consent.

Physician(s)/Designee  
area with copy of ap

Physician(s)/Designee  
information on each drug to  
administration (including the  
monitoring of the patient receive







If you are looking for a cutting-edge guide to clinical trials, the newly-released Second Edition of “A Clinical Trials Manual from the Duke Clinical Research Institute: Lessons From A Horse Named Jim” is highly recommendable.

Authors Margaret B. Liu and Kate Davis have integrated their international and domestic experiences from the past ten

# Researcher's Resources

*Your toolbox is only useful if you fill it with the right things. Here are some ideas...*

years into this all-inclusive edition. Their expertise holds significant value and utility for investigators, coordinators, students, and other research support staff.

A variety of key clinical trials components are explored, including thorough information about the conduct of medical device and biologics trials, the IRB's role and responsibilities, and recent developments regarding subject privacy.

**“This concise handbook provides a practical ‘nuts and bolts’ approach to the process of conducting clinical trials.”**

The first half of the manual lays a framework of background information and reviews rules and regulations. The second half hones in on practical application.

According to Robert Harrington, Professor of Medicine and Director at Duke Clinical Research Institute: “Those who study this manual will be well aware of how to ensure patient safety along with fiscal responsibility, trial efficacy, and research integrity.”

## CENTER WATCH MONTHLY



“CenterWatch Monthly” provides comprehensive information about the business aspect of clinical trials. Highlights typically include grant opportunities, industry reports, and a review of the month.

<http://store.centerwatch.com/>



LOMA LINDA UNIVERSITY  
HEALTH CARE

Clinical Trial Center

909.651.5002

[www.llu.edu/clinical-trials](http://www.llu.edu/clinical-trials)