



LOMA LINDA UNIVERSITY
HEALTH



QUALITY

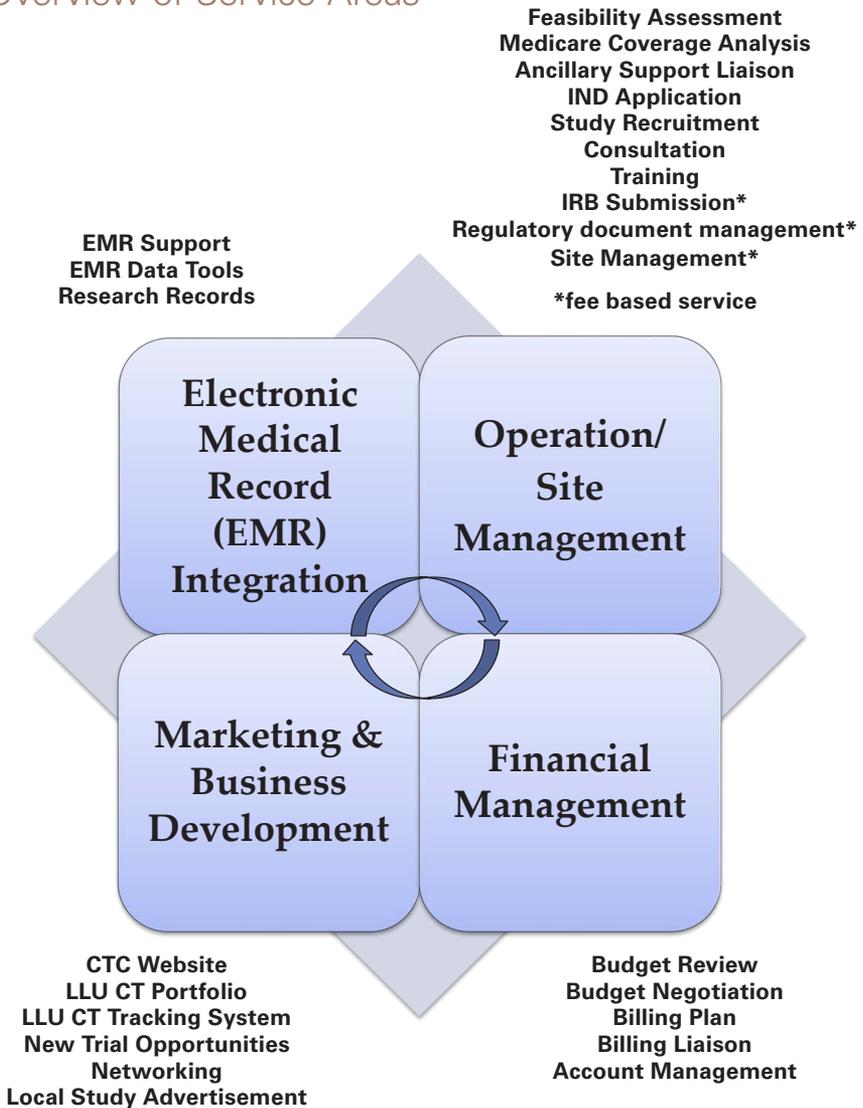
The mission of the Clinical Trial Center (CTC) is to facilitate the timely execution of quality clinical trials with information, resources and expertise in order to foster and promote the clinical trial enterprise within the institution. The CTC provides centralized support for Loma Linda University (LLU) clinical investigators and departments involving the management of privately and federally-sponsored clinical trials.

The Loma Linda University Clinical Trial Center provides the following services:

- ✦ Feasibility analysis
- ✦ Budget development and negotiation
- ✦ Medicare coverage analysis
- ✦ Ancillary support and billing facilitation
- ✦ Financial management
- ✦ Regulatory management
- ✦ Study advertisement and recruitment
- ✦ Coordinate administrative needs among LLU research stakeholders
- ✦ Marketing and liaison services with external sponsors

Operating as a centralized logistics office with the highest level of efficiency and customer service, the CTC promotes clinical trial quality and development through consultation, training and the pursuit of new trial opportunities. The CTC ultimately seeks to ensure that stakeholders have the information that they need to facilitate the compliant execution of clinical trials.

Overview of Service Areas



Site Background Information

The Loma Linda University Health has nearly 770,000 patient visits annually. Loma Linda University Health is comprised of the following entities:

- ♦ Loma Linda University Medical Center
 - ~ 371 beds
 - ~ Houses the only Level 1 Trauma Center in a four-county area (two million residents)
- ♦ Loma Linda University Children's Hospital
 - ~ 343 beds
 - ~ 84 NICU beds (one of the largest in the country)
- ♦ Loma Linda University Medical Center East Campus
 - ~ Urgent Care (over 30,000 visits annually)
- ♦ Loma Linda University Behavioral Medicine Center
 - ~ 89 beds
 - ~ Serving adults, seniors, adolescents and children (only facility in San Bernardino and Riverside Counties serving children 4-13 years old)
- ♦ Loma Linda University Heart & Surgical Hospital
 - ~ 28 inpatient beds, 4 ICU beds, 20 PACU beds
 - ~ Ambulatory infusion center
- ♦ Loma Linda University Medical Center – Murrieta
 - ~ 112 beds
 - ~ Full service acute care hospital bringing high quality care to the region
- ♦ Loma Linda University Beaumont-Banning
 - ~ Primary Care, Outpatient Rehabilitation, Pharmacy, Surgery Center, Laboratory Services, Urgent Care





Research Areas

Anesthesiology
Behavioral Medicine
Cancer - Adult & Pediatrics
Cardiology
Cardiothoracic Surgery
Critical Care
Dentistry
Dermatology
Emergency Medicine
Gastroenterology
General Surgery
Maternal/Fetal
Medicine
Neonatology
Neurology
Neurosurgery
Nutrition & Lifestyle Medicine

Obstetrics & Gynecology
Ophthalmology
Orthopaedics
Pediatrics
Perinatal Medicine
Physical Medicine/
Pain Management
Physical Therapy
Plastic & Reconstructive Surgery
Pre Hospital Care
Proton Treatment
Pulmonary Medicine
Radiation Medicine
Rheumatology/Immunology
Transplant Medicine
Trauma Services
Urology

On-Site Information

IDS Pharmacy Loma Linda University Medical Center

Office

*Investigational Drug Services, Loma Linda University Medical Center
Department of Pharmacy*

- ♦ *Study drug management inpatient and outpatient (as requested).*

Desiree Wallace, PharmD, Rph
IDS Pharmacist
dwallace@llu.edu
909-558-4000 ext. 83773

Mayra L. Gonzalez, CPhT
IDS Pharmacy Technician
mlgonzalez@llu.edu
909-558-4000 ext. 85486

Shipping

Investigational Drug Service
LLUMC Dept of Pharmacy
11223 Campus Street, Dock B
Loma Linda, California 92354

Local IRB

Loma Linda University
Research Protection Programs
24887 Taylor Street, Suite 202
Loma Linda, CA 92354
909-558-4531
Fax 909-558-0131

- ♦ 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
- ♦ Fully executed contract required prior to receiving IRB approval

Original Medical Records/ Source Documentations/ CRF's

- ♦ Electronic medical records utilized: 21 CFR Electronic Medical Record
- ♦ 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+ weeks prior to visit
- ♦ Designated monitoring space provided
- ♦ Phone, fax and copies available in research office
- ♦ Internet access available; a signed data access request form is required.

Local Laboratory

Loma Linda University
Medical Center
11234 Anderson Street
Loma Linda, CA 92354
909-558-4400

Contracts and Budget Information

Budget Requirements

- ♦ Institutional overhead
- ♦ Study startup and closeout fees

Loma Linda University
Clinical Trial Center
11374 Mountain View Ave.
Dover Building, Suite C
Loma Linda, CA 92354
909-558-5830
clinicaltrials@llu.edu

Contracts

- ♦ Contract reviews run concurrently with IRB review
- ♦ 8-12 weeks to obtain fully executed contract

Contracts are handled through
Industry Relations (909) 558-4831

Email: rair@llu.edu

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

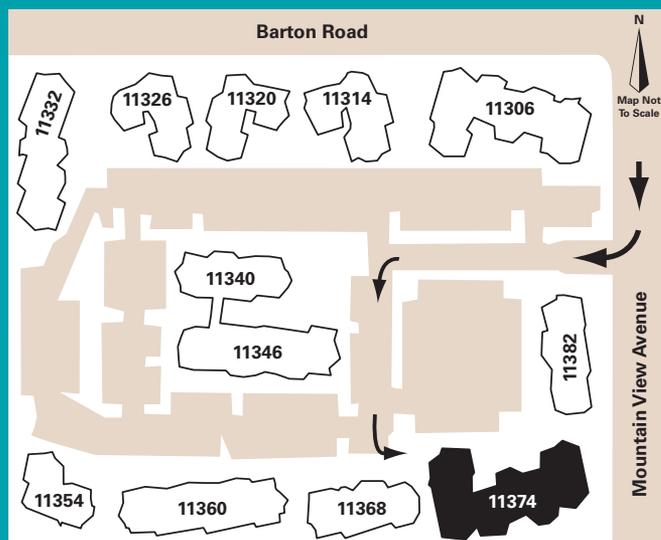
Research Consulting Group

Study Design &
Biostatistic Analysis
24871 Taylor Street
Loma Linda, CA 92354
909-558-4988
Fax 909-558-0268
ngrove@llu.edu
www.llu.edu/public-health/
research-consulting-group/

Research Education and Training

- ♦ Biohazardous Materials
- ♦ Hazardous Waste Shipping
- ♦ Good Clinical Practice (GCP)
- ♦ IATA Training and Certification
- ♦ NIH Training
- ♦ CITI Training
- ♦ Monthly Coordinator Networking with CEUs available

*A Logistics Center for
Transforming Lives Through Clinical Research*



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HEALTH

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