

Clinical Trial Center



LOMA LINDA UNIVERSITY
HEALTH



QUALITY

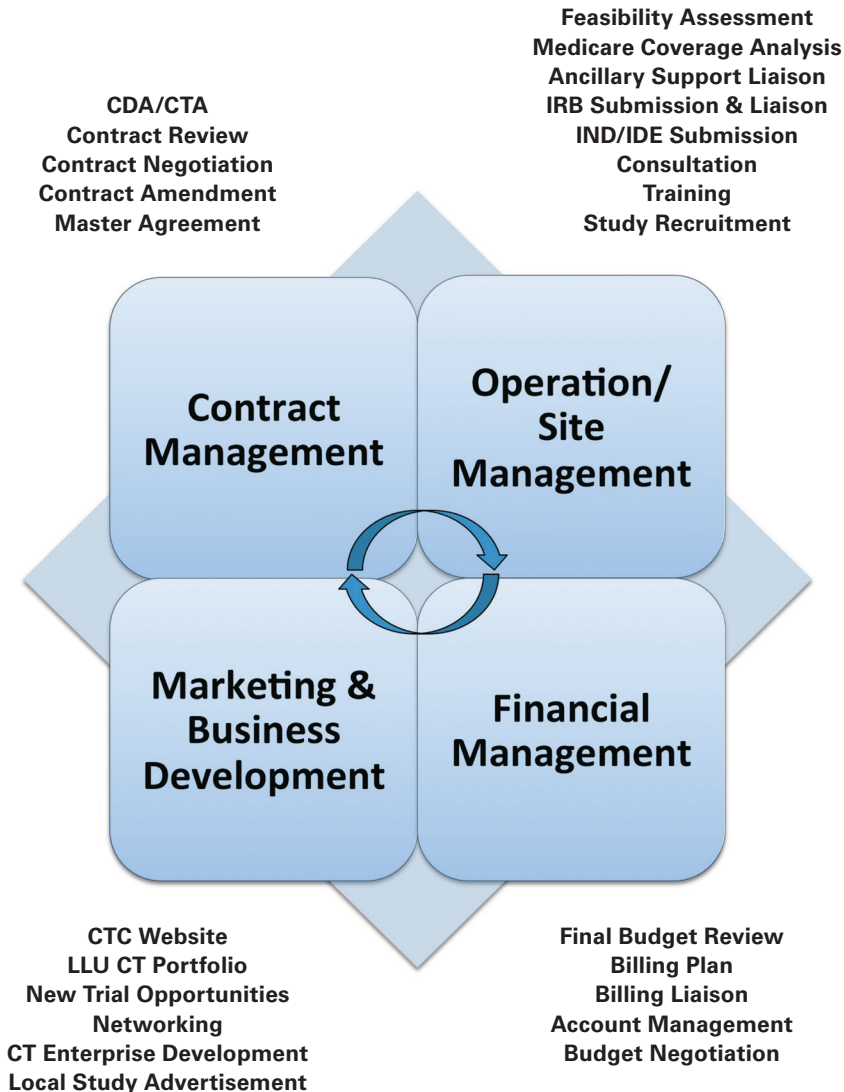
The mission of the Clinical Trial Center (CTC) is to facilitate the timely execution of quality clinical trials with information, resources and expertise in order to foster and promote the clinical trial enterprise within the institution. The CTC provides centralized support for Loma Linda University (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
- ✦ Contract review 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
 - ~ 348 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)
- ♦ 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)
- ♦ Heart & Surgical Hospital
 - ~ 28 inpatient beds, 4 ICU beds, 20 PACU beds
 - ~ Ambulatory infusion center
- ♦ Highland Springs Medical Plaza
 - ~ Joint venture with Redlands Community Hospital and Beaver Medical Group
 - ~ Provides clinical lab, outpatient rehabilitation, radiation medicine and medical oncology and cancer infusion center
- ♦ Ranked #1 hospital in Inland Empire since 2010 by *U.S. News & World Report*





Research Areas

Anesthesiology

Behavioral Medicine

Cancer - Adult & Pediatrics

Cardiology

Critical Care

Dentistry

Dermatology

Emergency Medicine

Gastroenterology

General Surgery

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

Urology

On-Site Information

IDS Pharmacy Loma Linda University Medical Center

Office

Investigational Pharmacist
Investigational Drug Service
Study Drug Management

- ♦ *Labeling*
- ♦ *Randomization Services*

Loma Linda University
Medical Center
Department of Pharmacy
Shryock Hall, Room 228
Loma Linda, CA 92354
909-558-4500 x83773
Fax 909-558-0323
dwallace@llu.edu

Shipping

Attn: IDS Research Pharmacy
11223 Campus Street, Dock B

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

Contracts

- ✦ Contract reviews run concurrently with IRB review
- ✦ 6-8 weeks to obtain fully executed contract

Loma Linda University
Clinical Trial Center
Coleman Pavilion 11113
11175 Campus Street
Loma Linda, CA 92350
909-651-5002
Fax 909-558-0587
www.llu.edu/clinical-trials

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/](http://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

Notes

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A Logistics Center for Transforming Lives Through Clinical Research



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Clinical Trial Center**
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