Highlight
As the only Academic Medical Center (AMC) in Orange County, we strive to create a reliable and efficient approach to clinical trials management. Our renewed focus is to accelerate the business of clinical trials and expand access to breakthrough therapies as quickly and safely as possible. As an integrated research innovation strategic enterprise, CCR is our dedicated space to do just that.

Notable Accomplishments
✓ Patient satisfaction
✓ Expert investigator
✓ Seamless administration
✓ Trial facts and figures

Latest Insights
LinkedIn Post
Twitter Post
Facebook Post

2,000 Patients | 200 Principal Investigators | 150 Clinical Trial Professionals
Our Focus

UCI - CCR is a growth platform. Focusing on growing our clinical trials portfolio through operational excellence and efficiency is critical in differentiating our organization as a top academic medical center and destination for patient experience and premium health care in our local and regional communities.

Equally important is nurturing our culture of high performance teaming. Continuing to invest in our people by providing the support, tools and resources they need to grow individually and with UCI-CCR will help us to accomplish this.

*Clinical trials portfolio numbers will need to be updated regularly
Clinical trials business management made easy

At your service at the tap of a button

- **On Demand**
  Average response time is less than 24 hr.

- **Seamless startup**
  No institutional start up hassles

- **Priced just right**
  Research rates are up to 40% lower

UCI Health

UCI School of Medicine
Everything we do for patient accruals

Targeted strategies
We know our prospective and existing patients

Quality standards
Our processes were designed with efficiency, standardization and accruals in mind

Rating system
Patients leave anonymous feedback, which we monitor to ensure world class experiences
Fast, simple set up

1. Enroll with a few clicks
2. Budget within a week
3. Negotiate within 30 days
Single information source

No more phone tag or chasing down start up information

- Assigned account manager
- Direct access
- Centrally managed
Direct Partners in Conducting Clinical Research

- Industry Partners
- Center for Clinical Research (CCR) and ASCC
- Sponsored Projects Administration (SPA)
- Human Research Protections (HRP)
- Research Revenue Integrity (RRI)
- Applied Innovation (AI)
- UCI Health
Our priority access solution
Go even faster.

Our Purpose

Why
- World class sponsor and patient experience
- Increased recruitment
- Elevated brand recognition and competitive advantage in industry
- Faster study activation times

Where we were
- Decentralized infrastructure
- Inefficient and non-standard processes
- Does not meet the current and future needs of our sponsors
- Not scalable for growth
- Slower activation and accrual timelines

Where we are now
- Centralized infrastructure
- Efficient, effective and standardized processes
- Meets the current and future needs of our sponsors
- Scalable for growth
- Faster activation and accrual timelines

Our Evolution

Our team

UCI - CCR Priority
Metric driven teaming focused on acceleration and accountability

Differentiators
- Simple, easy setup
- No start up hassles
- Same day, on demand access
- Priority services
- One time membership fee + discounted research rates

UCI Health

UCI School of Medicine
We focus on high value acceleration to deliver a world class experience for our priority sponsors.

<60 days to study activation

Priority Activation

0 Days
Start

CDA processing

2 Days
CDA

3 Days
Feasibility

Feasibility

10 Days
Budget

Budget negotiation

15 Days
Review

Institutional Review

30 Days
CTA

CTA Execution

Activation

Patient accrual

Data mgmt.

<60

Ongoing Support

Protocol Mgmt.

UCI Health

UCI School of Medicine
New Initiatives and Phase 1 Unit

UCI researchers

Preclinical Therapeutics Core

CCR

CCR Phase I Unit

CCR Phase II/III Unit

CCR IND/IDE unit

CCR Late Stage

Other Industry partners

cGMP Facility (12 months)

Clinical Trial Quantitative Imaging Core

Clinical Trial Laboratory and Biomarker Core

Regulatory and Protocol Writing Core
What We Do – Phase 2 and 3 Studies

UCI -CCR has expertise in key clinical trials functional capabilities in finance, operations and administration.

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**Financial management capabilities**
- Budget / Calendar
- Coverage analysis
- Budget development
- Budget negotiation (sponsor and institution)
- Budget approval
- Calendar development
- Account Management
- Study invoicing
- A/P management
- A/R management
- Cash management
- Financial monitoring
- Study reconciliation
- Account close-out

**Operations capabilities**
- Study/ data Management
- Study activation and close
- Site visit coordination
- CRF development
- CRF completion/ eDC
- Source document development
- Monitor visit coordination
- Lab kit inventory management
- Data management and regulatory liaison
- Patient financial counseling
- Protocol reallocation
- Clinical Coordination
- Patient recruitment
- Eligibility determination
- Patient visit coordination
- SAE and deviation reporting
- Specimen collection coordination
- Data management and regulatory liaison
- Data queries
- Data safety monitoring
- Patient financial counseling
- Bioinformatics
- Design study
- CRF design
- Patient screening / enrollment
- Quality data registries
- Statistical planning/development
- CRF design
- Lab kit inventory management
- Data management and regulatory liaison
- Clinical research IT infrastructure
- Core technology and services
- Research pharmacy
- Drug/ Device management
- Pathology / laboratory services
- Clinical research IT infrastructure
- Regulatory
- IRB submission
- Process and SOPs
- Research Mentorship
- Site management
- Audit preparation
- Deviation reporting
- FDA processing (IND and IDE submissions)

**Administrative capabilities**
- Opportunity Management
- Business development
- CDA/Master Agreement development
- Opportunity capture
- Protocol/ grant preparation
- Pipeline management
- Feasibility assessment
- CTA negotiation (sponsor and institution)
- CTA execution

**Legend:**
- Financial Mgmt.
- Operations
- Admin.
- Ancillary Services

**Notes:**
*Financial management capabilities will be developed with strong consideration to segregation of duties and internal controls
*Business development includes a sponsor-relations person(s), who will be responsible for identifying new sponsors and getting the sponsors acclimated to the UCI culture
Our services

Study management and execution
☐ Manage Projects and Trials
☐ Explore Funding Opportunities
☐ Find Co-investigators and Collaborators
☐ Grant Preparation & Submission
☐ Coverage Analysis
☐ Identify Potential Patient Populations
☐ Patient Recruitment/Communications
☐ Clinical Research Coordinator Services
☐ Clinical Research Nursing Services
☐ Regulatory Preparation and Submission
☐ Budget preparation/negotiation
☐ Pre-IND and Pre-IDE Support
☐ Statistician Services
☐ Electronic Case Report Form (e-CRF) Development
☐ Study Marketing
☐ Kuali Coeus Preparation & Submission
☐ Training and Education Coordination:
  IRB, GCP, HIPAA, OHRPP, Lab Safety, Biohazards, GMP, CITI, Professional Development, EMR, OnCore (CTMS)

Sponsored Projects Administration, Office of Research
☐ Confidentiality and Non-Disclosure Agreements
☐ Clinical Trial Agreements
☐ ASCC Clinical Trial Agreement

Human Research Protections, Office of Research
☐ IRB Review
☐ IRB Renewal
☐ IRB Modifications
☐ IRB Reliance (UC Braid, ASCC IRB Reliance, UC)
☐ Institute for Clinical and Translational Science (ICTS)
☐ Clinical Research Services (Nursing)
☐ The Center for BioMedical Informatics (CBMI)
☐ Biostatistics, Epidemiology and Research Design (BERD)
☐ Accrual and Retention Consult Service (ARCS)
☐ The Team Science Unit
☐ Clinical Research Ethics Consult Service
☐ The Community Engagement Unit (CEU)
☐ The Informatics Unit
☐ The ICTS Pilot Program
☐ Biospecimen and Biorepository Core
☐ UCI Committee Review Applicability
☐ Conflict of Interest Oversight Committee (COIOC)
☐ Dual Use Research of Concern (DURC)
☐ Epidemiology and Infection Prevention (EIP) Committee
☐ hSCRO: Human Embryonic Stem Cell Research Oversight Committee
☐ IBC: Institutional Biosafety Committee
☐ LSC: Laser Safety Committee
☐ OR/Procedural Services Committee
☐ Protocol Review Monitoring Committee (cancer)
☐ Radiation Safety Committee Review
☐ Radioactive Drug Research Committee
☐ IRB Scientific Review
☐ Institutional Animal Care and Use Committee

Laboratory and Pathology Services
☐ Anatomic Pathology: Surgical Pathology, Histology, Cytology, Autopsy Services
☐ Blood Bank: Transfusion Medicine, Donor Center
☐ HLA/Tissue Typing, Apheresis
☐ Clinical Chemistry: Immunohistochemistry, Toxicology
☐ Diagnostic Molecular Pathology
☐ Hematopathology: Coagulation, Immunology, Hematology
☐ Medical Microbiology
☐ Neuropathology
☐ Cholesterol and Lipid Testing

Institute for Clinical and Translational Science (ICTS)
☐ Clinical Research Services (Nursing)
☐ The Center for BioMedical Informatics (CBMI)
☐ Biostatistics, Epidemiology and Research Design (BERD)
☐ Accrual and Retention Consult Service (ARCS)
☐ Document Management and Storage
☐ The Team Science Unit
☐ Clinical Research Ethics Consult Service
☐ The Community Engagement Unit (CEU)
☐ The Informatics Unit
☐ The ICTS Pilot Program
☐ Biospecimen and Biorepository Core

UCI Health Information Technology Research Toolkit
☐ Web-Based Access to R, SAS, JMP, SPSS, and Secure Data Hosting Service
☐ REDCap (Research Electronic Data Capture)
☐ OnCore Clinical Trial Management System (CTMS)
☐ The Cohort Discovery Tool (CDT)
☐ The University of California Research eXchange

Investigational Pharmacy
☐ Investigational Product Storage
☐ Investigational Product Dispensing
☐ Chain of Custody, Documentation & Transportation

Investigational Product Storage
☐ Investigational Product Dispensing
☐ Chain of Custody, Documentation & Transportation

UCI School of Medicine
UCI Health
Our services (continued)

Core Labs and Resources
- Patient Advocacy Committee
- Olympus FV3000 Laser-Scanning Confocal Spectral
- Inverted Microscope, Nikon Ti & Zeiss Axio 40
- Dissecting Microscope – Nikon SMZ21500
- Microscope with Screen – AMG EVOS
- Plate Reader – Biotek Synergy HT
- Imager – BioRad VersaDoc MP 5000
- Transfector – Lonza Nucleofector II
- Real Time PCR – Roche LightCycler 480II
- Cell Irradiator – Foxtron 43855D RX-650
- Magnetic Cell Sorter – Miltenyi Biotec autoMACS Pro
- Animal Imager – Caliper Lumina IVIS II
- Animal Video System – Noldus Ethovision XT
- ChemiDoc XRS System
- Zeiss PALM MicroBeam Laser Capture Microdissection
- Zeiss Cell Observer SD Spinning Disk Confocal
- ViiA 7 Real-Time PCR System
- Olympus VivaView FL
- BD Facs Aria II Cell Sorter
- BD LSR Flow Cytometer

Invention Transfer Group (ITG)
- Confidentiality and Non-Disclosure Agreements
- Material Transfer Agreements
- Award and Industry Collaboration Agreements

Stem Cell Processing Laboratory
- Stem Cell Preparation, Processing and Implementation
- Wash, Thaw and Final Product Preparation
- Release Criteria Testing

Quintiles/ Stem Cell Center
- Regulatory Services
- Preclinical/ Nonclinical Research
- Manufacturing and CMC Support
- Clinical Study Conduct
- Commercial Services
- CIRM Grant Application Services
- Asset Development Strategy
- Priority Access to GMP Facilities

Chao Family Comprehensive Cancer Center
- The Stern Center for Clinical Trials and Research
- Disease-Oriented Team (DOT) Access
- Pilot Project Program
- Research Program Access
- Biobehavioral Shared Resource
- Biostatistics Shared Resource
- Experimental Tissue Shared Resource
- Genomics High-Throughput Facility
- In-Vivo Functional Onco-Imaging
- Optical Biology Core
- Transgenic Mouse Facility
Where we work

Ambulatory/ Clinic Locations
- ANESTHESIA PREOP
- BURN CLINIC
- BURN PSYCH
- CARDIAC REHAB
- CARDIOVASCULAR
- BREAST CENTER
- CANCER CENTER - MEDICINE
- CANCER CENTER- SURGERY
- CDCC
- INTERNAL MEDICINE
- NEUROSURGERY
- OCCUPATIONAL HEALTH
- OPHTHALMOLOGY
- ORTHOPAEDICS
- PAV I MED-SPECIALTY
- PLAZA MULTI SPECIALTY
- PLAZA PRIMARY CARE
- REFRACTIVE SURGERY
- SENIOR CENTER
- SURGERY ENT
- SURGICAL SPECIALTY
- UROLOGY
- CLINIC PLASTIC SURGERY
- INFUSION CENTER – CANCER CENTER
- NEWPORT INFUSION CENTER
- PAV III GYN ONC
- GAVIN HERBERT EYE INSTITUTE (GHEI)
- GOTTSCHLAK MEDICAL PLAZA
- UCI SURGERY LASER CLINIC (BECKMAN)

Ancillary and Emergency Service locations
- BLOOD BANK
- CANCER CENTER LAB
- CT SCANNER
- LAB PHLEBOTOMIST
- LAB-CHEMISTRY
- LAB-CYTOLOGY
- LAB-HEMATOLOGY/COAGULATION
- LAB-MICROBIOLOGY
- LAB-MOLECULAR PATHOLOGY
- LAB-OUTSIDE LABS
- LAB-SURGICAL PATHOLOGY
- MAGNETIC RESONANCE IMAGING (MRI)
- NEWPORT LAB
- NUCLEAR MEDICINE
- PAVILION IMAGING
- PET SCAN
- POCT LAB
- RADIATION ONCOLOGY
- RADIOLOGY CANCER CENTER
- RADIOLOGY DIAGNOSTIC
- RADIOLOGY PLAZA
- RADIOLOGY SPECIAL
- RADIOLOGY ULTRASOUND
- NEWPORT PHARMACY
- PHARMACY – INPATIENT and OUTPATIENT
- EMERGENCY DEPARTMENT
- TRAUMA EMERGENCY ROOM
- FAMILY HEALTH CENTER – ANAHEIM and SANTA ANA

Inpatient Units
- IMPLANTS CARDIAC CATH LAB
- IMPLANTS GI LAB
- IMPLANTS OPERATING ROOM
- IMPLANTS RADIOLOGY
- ARU
- EDHU
- ICU BURN
- ICU CORONARY
- ICU MEDICAL
- ICU NEONATAL
- ICU NEURO-SCIENCE
- ICU PEDIATRICS
- ICU SURGICAL
- MED SURG 3 SOUTH
- MEDICAL / SURGICAL (DH48)
- MEDICAL STEPDOWN (DH78)
- MEDICAL/SURGICAL/ONC (DH58)
- MHN
- NEURO SCIENCE
- NEWBORN NURSERY
- OB SPECIALS
- OBSTETRICS POST PARTUM
- ONCOLOGY
- ORTHO
- PROGRESSIVE CARE UNIT
- PSYCH ADULT SERVICES
- PSYCH GERIATRICS MEDICAL
- PSYCH YOUTH SERVICES
- PSYCH-GERIATRICS
Marketing and communications strategy

- Our new positioning will re-energize our brand as a premier AMC that is regarded as a world-class clinical trial center of excellence.

- We have partnered with Barkley REI in developing our website.

- Moving forward, in all internal and external communications we will refer to our clinical research enterprise as **UCI - CCR**.

## UCI - CCR new pilot solution

### Resources
- Website
- RISE video
- UCI-CCR internal resources
- UCI-CCR central email hub
- eNews newsletter
- Launch party

### Channels
- Online
- Video
- Social
- Print
- Events
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