



Clinical Trials Enterprise (CTE)

ICTS Luncheon
Tuesday, May 7, 2019



How it all started

In 2018, UCI School of Medicine brought top talent together in its Orange County university and medical center campuses to develop an enhanced experience in clinical trials. We have a rich history of great successes and breakthrough discoveries with our clinical trials, but we had a hard time competing for studies that provide life-changing opportunities for our patients due to slow activation times and preferred site lists. So, we set out to create a world-class infrastructure that strengthens and accelerates our clinical trials portfolio and provides an unmatched experience for our people, investigators, partners and patients.

We're dedicated to creating a seamless clinical trials infrastructure that makes working in research and serving our patients a world-class experience.

Our purpose

Build a cutting edge clinical trials infrastructure to better serve our patients, community, investigators and partners. Our goals are to:

Innovate.

Capitalize on opportunities by developing fresh ideas and innovative approaches to improving our daily work.

Accelerate.

Work as a team of teams, driving process simplification and standardization to surpass our study activation and enrollment targets.

Grow & inspire.

Set the industry bar for world-class experiences for each other, our patients and partners; and elevate our brand as high performers.

Our vision for the future

Clinical Trial Enterprise is a premier, local and national clinical research organization providing life saving clinical trials by strengthening and accelerating the pathway of discovery from bench to bedside.

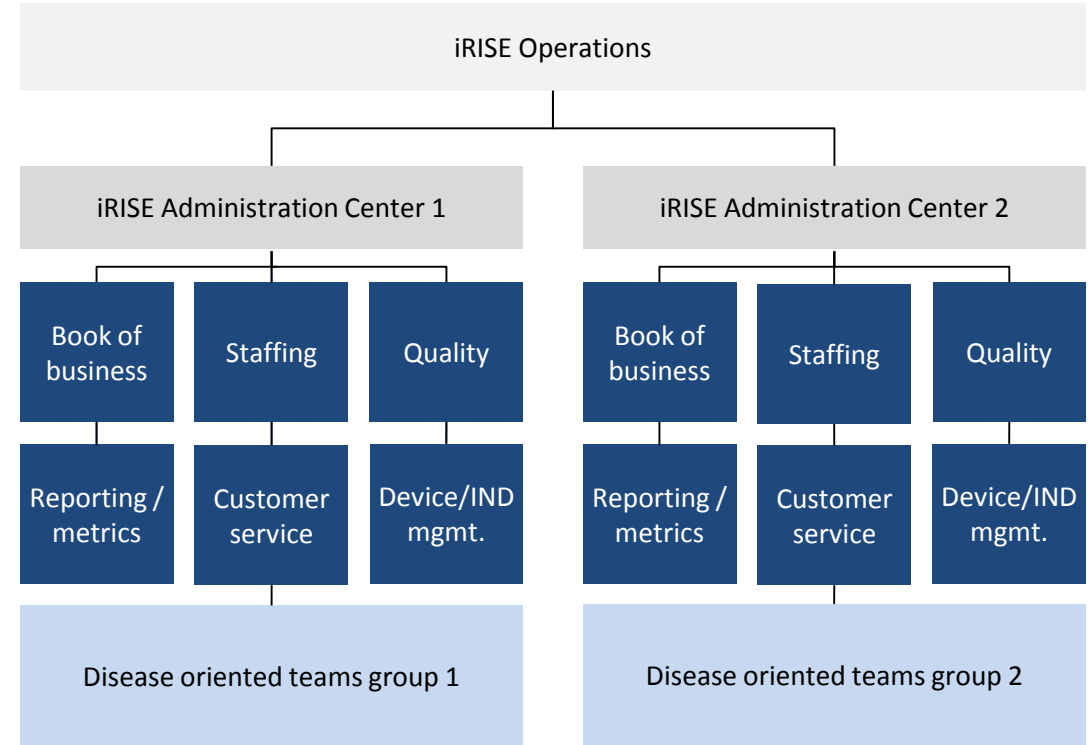
Today's mission

To improve the health and wellness of people in Orange County and the world by supporting academic discovery and healing.

CTE administration centers

Our mission-critical goal is to provide exceptional care and experiences for our patients and seamless service to our PIs while providing consistent experiences and training opportunities for our CRCs to learn new clinical areas as well as study types.

CRCs are organized into disease-oriented teams, called “Administration Centers.” Our operating model optimizes how CRCs will grow and support our patients, PIs and the institution, as CRCs are part of the foundation of successful clinical research.



What we do

The Clinical Trial Enterprise has expertise in key clinical trials functional capabilities in finance, operations and administration.

Financial management capabilities*		Operations capabilities				Administrative capabilities			
Budget / Calendar	Account Management	Study/ data Management	Clinical Coordination	Biostatistics/ Bioinformatics	Core technology and services	Regulatory	Training and education	Opportunity Management	Contracting
Coverage analysis	Research patient billing/ reconciliation (hospital, professional)	Study activation and close	Patient recruitment	Design study	Research pharmacy	IRB submission	Process and SOPs	Business development^	CDA/Master Agreement development
Budget development		Site visit coordination	Eligibility determination	CRF design	Drug/ Device management	Committee review	Research Mentorship	Recruitment strategy	CDA/Master Agreement management
Budget negotiation (sponsor and institution)	Study invoicing	Multi site coordination	Patient screening / enrollment	Data integrity/ quality	Biospecimen management	Amendment management	Research navigators	Opportunity capture	Protocol/ grant preparation
	A/P management	CRF development	Patient visit coordination	Quality data registries	Pathology / laboratory services	Site management		Pipeline management	Contracting request creation
Budget approval	A/R management	CRF completion/ eDC	SAE and deviation reporting	Statistical planning/ development	Radiology services	Audit preparation	Feasibility assessment	CTA negotiation (sponsor and institution)	
Calendar development	Cash management	Source document development	Specimen collection coordination	Statistical analysis	Clinical research IT infrastructure	Deviation reporting			
	Financial monitoring	Monitor visit coordination	Lab kit inventory management	Statistical monitoring		FDA processing (IND and IDE submissions)		CTA execution	
	Study reconciliation	SAEs monitoring and reporting	Data management and regulatory liaison						
	Account close-out	Data queries	Patient financial counseling						
		Data safety monitoring							
		Protocol reallocation							

Legend:

Financial Mgmt.	Operations	Admin.	Ancillary Services
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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

Research 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
- Quali 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)

Investigational Pharmacy

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

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

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

Research services

Core Labs and Resources

- Patient Advocacy Committee
- Olympus FV3000 Laser-Scanning Confocal Spectral
- Inverted Microscope, Nikon Ti & Zeiss Axio 40
- Dissecting Microscope – Nikon SMZ1500
- Microscope with Screen – AMG EVOS
- Plate Reader – Biotek Synergy HT
- Imager – BioRad VersaDoc MP 5000
- Transfecto – Lonza Nucleofector II
- Real Time PCR – Roche LightCycler 480II
- Cell Irradiator – Foxitron 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

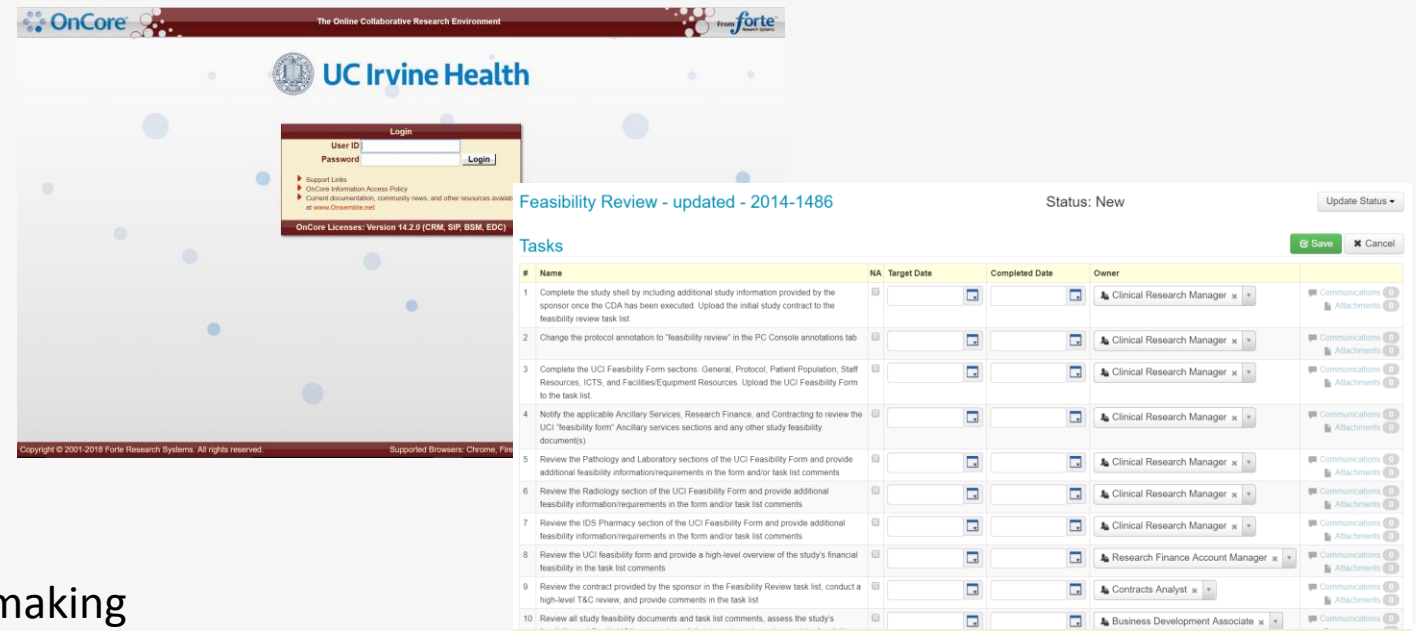
Quintiles/ Stem Cell Center

- 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

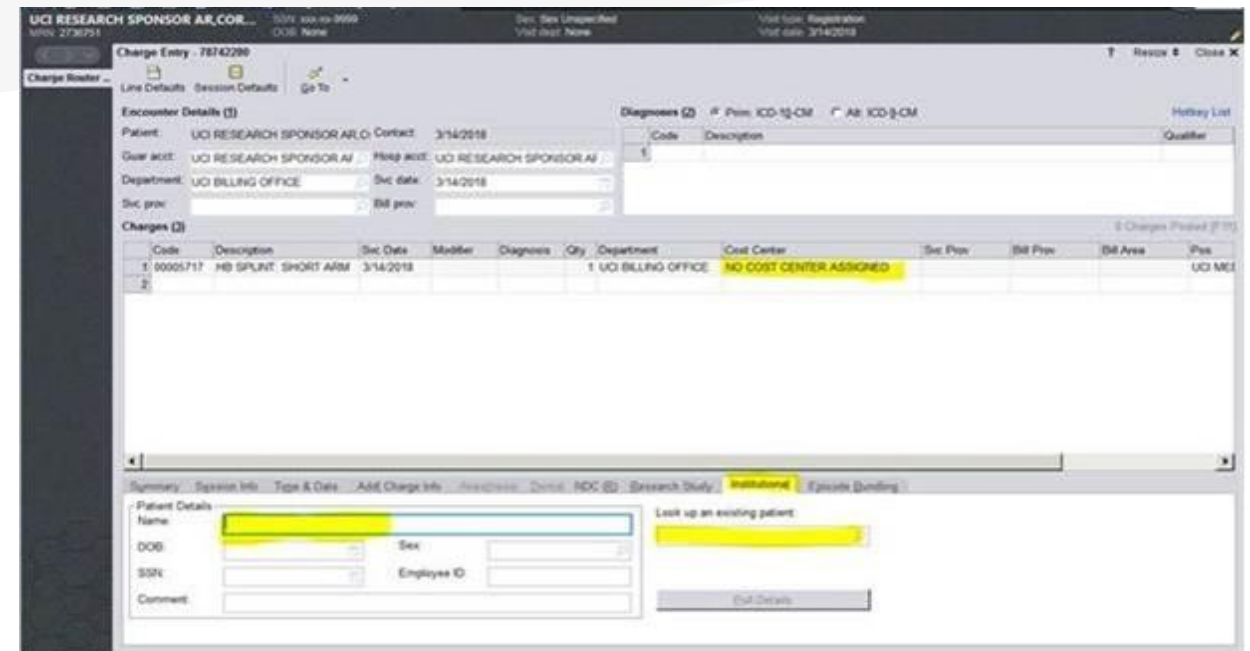
- The Stern Center for Clinical Trials and Research
- Disease-Oriented Team (DOT) Access
- Pilot Project Program
- Research Program Access
- Biobehavioral Shared Resource
- Biostatistics Shared Resource
- Experimental Tissue Shared Resource
- Genomics High-Throughput Facility
- In-Vivo Functional Onco-Imaging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

Study information at your fingertips in OnCore



- 1 Standardized task list to drive teaming
- 2 Feasibility infused into work flow
- 3 Powerful management data to drive decision-making

Real time bill review in Epic



- 1 Live research patient flag interface
- 2 Configured patient billing interface
- 3 Real time patient billing work queues



RISE → iRISE → CTE → ?

UCI School of Medicine

UCI Health