Coordination Services & Education

- Overview
- Study Activation Team
- Clinical Research Coordinator Team
- Education and Training

Overview

About Us

Coordination Services & Education (CSE) is a resource within the Office of Clinical Research (OCR) that assists UCLA faculty, staff and clinical research teams with the regulatory, financial and compliance-related components of clinical research during study activation, conduct and closeout of a clinical trial. CSE includes three dedicated teams focused on advancing contributions in study activation, study conduct and study team training and education.

- Study Activation Team
- Clinical Research Coordinator Team
- Education and Training

Contact us to meet with one of our team members to discuss your project needs. Together we'll develop a Statement of Work that outlines the services and associated costs that CSE can provide.

Last updated: 26 Aug 2022

Study Activation Team (SAT)

The Study Activation Team (SAT) provides regulatory, budgetary and workflow expertise that translates into efficient study activation timelines. Open your study sooner! SAT services include:

Regulatory Services

- IRB Submission
- Application completion and submission of institutional committee and ancillary service approvals, including:

Institutional Committees or Approvals:

- Scientific Review
- Coverage Analysis

- Institutional Biosafety Committee (IBC)
- ESCRO
- DSMB
- MRSC
- CIRC
- Value Analysis Committee (VAC)

Ancillary Services:

- Centralized Pathology Research Services (CPRS)
- Radiology Research Services
- Investigational Pharmacy Services
- Clinical & Translational Research Services (CTRC)
- Jules Stein Opthalmology Services
- Clinical Engineering
- Regulatory Binder development

Budget and Contract Management

- Contract Office (CTC-SR, TDG, or OCGA) document submission
- Budget Development
- Budget Negotiation

ResearchConnect, OnCore, CareConnect Activation

- OnCore sign-offs for activation
- careConnect activation
- careConnect content build review

Study Document Development

- e-CRF Development
- Consent Form Development
- Source Document Template Development

FDA Submissions (IND/IDE)

- Preparation/Submission of complete FDA submissions for IND or IDE applications. Consultation provided in conjunction with Office of Clinical Research FDA Affairs.

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Clinical Research Coordinator Team

The Clinical Research Coordinator Team (CRCT) carries through the compliant set-up of the clinical trial and oversees

patient and study visit management, scheduling, and assists with general conduct of a clinical trial with PI oversight.

Clinical Research Coordinator Services

- Trained and credentialed clinical research coordinators that assist with patient recruitment, patient and study visit management, scheduling, orders development, facilitating monitoring visits, communication with campus and sponsor contacts and ensuring protocol and regulatory compliance during the conduct and closeout of a project.

Data Management Services

- CRF and eCRF data transcription from medical record and source documents
- Query resolution
- Source Document Verification – a review of the source document templates against the protocol and CRF to assist with protocol-compliant data collection during study visits

Budget and Contract Management

- Contract Office (CTC-SR, TDG, or OCGA) document submission for amendments
- OnCore patient management to facilitate sponsor invoicing
- Manage budget amendments

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Education and Training

The Education Team promotes established best practices for investigators, clinical research coordinators, regulatory coordinators, data managers, research assistants and other research roles.

Training

- Clinical Research Coordinator On-boarding
- Clinical Investigator On-boarding
- Clinical Research Coordinator certification

Education

- Clinical Research Coordinator Council
- Clinical Research Coordinator Forum
- Clinical Research Best Practices

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