LKSOM Clinical Research Administration
and
Clinical Research Operations and Regulatory Affairs

TEMPLE UNIVERSITY

Lewis Katz School of Medicine

Clinical Research Team

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LKSOM Clinical Research Administration

Our Role:

- Provide Pre-award and Post Award support to investigators, clinical research staff and department administrators for clinical research in LKSOM
- Create processes and forms to streamline workflow
- Onboard new staff on CRA's pre-award/post award processes
- Liaison with internal and external offices

Types of Clinical Research Studies

- Retrospective
- Prospective
- Interventional
- Observational
- Drug (phase I-III, phase IV)
- Device
- Treatment (behavioral, medical)
- Industry-initiated
- Investigator-initiated

Pre-Award

- Negotiate Confidential Disclosure Agreement (CDA), Non Disclosure Agreements (NDA)
- Create an eRA (TU Research Administration Submission System) for each study, prepare the eSPAF (sponsored for routing approval and follow through until FOAPAL is obtained
- Prepare and approve the Study Initiation Form
- Notify and work with COI, TU IRB, and the Pharmacy on all new and revised studies to ensure all the necessary budgets and approvals are in place so enrollment can begin when the contract is fully executed
- Negotiate Contracts - Work Orders, Sub Contracts, Master Agreements, Letter of Indemnification (LOI), proposals
- Coordinate the completion of a Data Use Agreement or Material Transfer Agreements
- Coordinate the completion of Medicare Coverage Analysis
- Negotiate Budgets
- Develop budgets and complete other documentation required by the sponsors for submission in accordance with sponsor and institutional guidelines
- Prepare, obtain approval, and distribute a Subject Registration and Billing Form
- Obtain University signature on CDA/NDA’s, Contracts, Master Agreements, Work Orders, etc.

Post Award

- Prepare and submit invoices to sponsors/CRO's for study related reimbursements
- Work with Research Accounting on the Progress reports requiring budgets and submission of expenditure reports for studies
- Process invoices for payment in TU Marketplace
- Negotiate amendments (language and or budgets)
- Process Notification of Awards, Continuations, Revisions (budget justifications), No Cost Extension
- Verify FOAPALS on incoming checks and Automated Clearing House (ACH's) for clinical research studies, record the revenue and process revenue jet
- Review and approve all transactions including salary and effort via banner, concur, TU Marketplace, etc.
- Review monthly expenditures and revenue to ensure the expenses are appropriate and revenue is received
- Provide monthly reports to Administrators and PI's
- Complete financial closeouts on each study
- Revise Subject Registration and Billing Form when necessary
- Meet with PI/Coordinator/Administrator as needed
- Maintain the OnCore Database: enter new industry clinical research studies, update contract dates, IRB status, study status and complete quarterly accrual follow-ups with the study coordinator

Clinical Research Operations and Regulatory Affairs (CRORA)

Our Role is to:

- Provide operational and regulatory support to investigators and clinical research staff in LKSOM
- Create processes to facilitate workflow and promote regulatory compliance
- Central location for questions, concerns, problems

U.S. Regulatory Agencies

Federal Agency	What they do
DHHS Office for Human Research Protections (OHRP)	Regulates IRBs, promotes human subject protection, oversees federally-funded research
Food and Drug Administration (FDA)	Regulates research testing products under FDA's authority (ex: drugs/devices)
National Institutes of Health (NIH)	Primary U.S. medical research agency – federal grant funding
Office for Civil Rights (OCR)	Enforces HIPAA privacy rule
Centers for Medicare & Medicaid (CMS)	Created Medicare Clinical trial coverage policy – routine costs in clinical trials
Office of Research Integrity (ORI)	Investigates research misconduct
Dept. of Justice- Office of the Inspector General (DOJ/ OIG)	Investigates & prosecutes fraud, abuse & research misconduct,

CRORA

- Liaison with TU/TUHS departments to resolve problems, facilitate research workflow and maximize regulatory compliance
  - IRB
  - HIPAA Privacy Officer
  - Clinical Research Administration contracts/budget team
  - Conflict of Interest office
  - IDS Pharmacist
  - TUHS Legal Counsel
  - Data Use Agreement contracts team
  - Data Governance Committee
  - EPIC access for research (DCS - Dr. Susan Fisher)

- Liaison with external organizations: WIRB, sponsors, CROs, FDA, TriNetX, CT.gov…

CRORA
Clinical Research Staffing Support

- Work with clinical departments to fill vacancies
- Create requisition; work with HR to post job
- Recruitment only applicants vs. specific job posting
- Interview applicants and check references
- Onboard new hires
- GCP training (Barnett International)
- Ongoing support and guidance

CRORA Services
Regulatory Support

- Regulatory consults with investigators (ex: IND/IDEs)
- On-site assessments to prepare for monitoring visit or FDA audit; Attend visit or audit if needed
- Create/Oversee CAPAs
- Develop guidance documents, forms, processes
- Attend departmental research meetings
- Regulatory support during staff vacancies

CRORA Services

- Document review for industry trials (ICF/CTA)
  - Payment for subject injury
  - Subject stipend

- Clinicaltrials.gov site administrator
  - Create user name for new users
  - Instructions on how to get started
  - Information and assistance with:
    1. Registration - ACT and voluntary
    2. Posting study results

- TriNetX Coordinator

Clinical Research Processes

- Using Interpreters for Clinical Research
- Billing for Adverse Events and Subject Injury
- Dry Ice
- Subject Registration and Billing Form
- Medicare Coverage Analysis
- Onboarding New Clinical Research staff
- ICF-CTA Document Review - Subj. injury & stipend
- Pathology

Stay Compliant

DO'S

- Complete required trainings before starting your research
- Obtain approval from IRB before starting research
- Execute a CDA before seeking funding from outside agency
- Comply with HIPAA to protect patient data

DON'T

- Do Not sign any paperwork on behalf of the institution
- Do Not share data without written approvals and/or DUA
- Do Not access PHI for research without IRB approval and HIPAA authorization or waiver
- Do Not access or view patient data in public spaces

CRA and CRORA Services

For questions, concerns, suggestions, roadblocks…

We’re here to help!

Call CRA and CRORA

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