UCLA David Geffen School of Medicine
Study Activation Team

List of Services

Study Activation Team (SAT)	
SAT Service	**Description**
IRB preparation & submission	
New Study IRB Submission	Initial IRB application submission and correspondence through approval.
IRB Amendment Submission	IRB Amd application submission and correspondence through approval.
IRB Continuing Review Submission	IRB CR application submission and correspondence through approval.
IRB Post Approval Report Submission	IRB PAR application submission and correspondence through approval.
Financial Management	
CDA Execution Support	Submission of minimum documents to contract/award office for CDA execution.
Contract/Award Support	Submission of minimum documents to contracting office, submission of final documents, and correspondence through contract execution.
Budget Development	Develop comprehensive clinical trial budget including per patient costs, mandatory start up and invoiceables.
Budget Negotiation	Negotiate comprehensive clinical trial budget with funding source.
Coverage Analysis certification	Liaise with centralized offices (IRB, FCA, CRBP, CRIS) through Final Budget Signoff to satisfy UCL Policy 915 - Coverage Analysis
Research Quality Support	Facilitate Research Quality review and inquiry resolution.
OnCore sign-offs (ALL)	Perform all OnCore sign offs including: Study Team Signoff, Open for Accrual Sign off, Final Budget Signoff.
OnCore sign-offs (REG ONLY)	Perform subset of OnCore Sign offs including: Study Team Signoff and Open for Accrual Signoff. Department fund manager performs other sign offs.
Reconciliation of study documents against final budget	FOR DEPARTMENTS MANAGING BUDGET DEVELOPMENT/NEGOTIATION: SAT involvement in final RQ/FCA approvals. SAT review of final budget against protocol
Ancillary Services and Other Committee Submissions	
Scientific Review Approval	CTSI-ORA or JCCC-ORA Scientific Review application preparation, submission, and correspondence through approval
Medical Radiation Safety Committee Approval	MRSC application preparation, submission, and correspondence through approval
Nuclear Medicine Approval	Nuclear medicine application preparation, submission, and correspondence through approval
Institutional Biosafety Committee Approval	IBC application preparation, submission, and correspondence through approval
Conflict of Interest Review Committee Approval	CIRC application preparation, submission, and correspondence through approval Forms 700U/Addendum or 740/Addendum, eDGE
ESCRO Approval	ESCRO application preparation, submission, and correspondence through approval
Clinical & Translational Research Center Nursing Services Approval	CTRC application preparation, submission, and correspondence through approval
Nutritional Services Approval	CTSI Nutrition services application preparation, submission and correspondence thorugh approval.
Sleep Center Approval	Sleep Center services application preparation, submission and correspondence thorugh approval.
Informatics Program Approval	Informatics Program setup for data abstraction from EHR.
DSMB Approval	DSMB application preparation, submission, and correspondence through approval

BIOSTAT Support Setup	Liaise with BIOSTATs in support of Statistical Analysis Plan development, Database development, and/or CRF development
Value Analysis Committee Approval	VAC application preparation, submission, and correspondence through approval
Investigational Pharmacy Approval	Investigational Drug Services (Pharmacy) application preparation, submission, and correspondence through approval
CPRS Approval (Lab, blood-urine)	Center for Pathology Research Services (CPRS) application preparation, submission, and correspondence through approval
CPRS Approval (Pathology, tissue)	Center for Pathology Research Services (CPRS) application preparation, submission, and correspondence through approval
Radiology Research Services Approval	Radiology application preparation, submission, and correspondence through approval
Pulmonary Function Testing	Setup to use DOM-Pulmonary PFT lab
Ophthamology Approval	Opthamology application preparation, submission, and correspondence through approval
Cardiology Notification	Cardiology department requires that protocol be sent via email prior to ordering services on a study to support compliant on-study data collection.
CareConnect Content Build	Management of clinical order build by CareConnect Research Team and correspondence through approval. CC content is a best practice to ensure consistent visit management and order entry
Nursing Practice Research Council	Nursing Practice Research Council (NPRC) application preparation, submission and correspondence through approval. Required when using Health System nursing staff in the performance of protocol-required procedures (for standard of care and research procedures).
Clinical Engineering Approval	Clinical Engineering application preparation, submission, and correspondence through approval
Stem Cell Lab Application	Assistance with department-required feasibility process, if appilcable
Operating Room Admin Setup	Administrative setup to perform study procedures in operating room
Inpatient Unit Admin Study Setup	Submit protocol to unit director and facilitate unit setup process
Study Design	
Protocol Development	The development of protocol document which satisfies regulatory and institutional standards.
Consent Form Development	Develop consent form from protocol
E-CRF Development (Red-Cap)	Develop CRFs to capture relevant data points
E-CRF Validation	Review of CRFs developed by CTSI Biostats for protocol conformity.
Essential document collection (Regulatory Binder)	Collection of regulatory documents, gaining signature (where applicable) of regulatory documents, correspondence with sponsor, and completion of regulatory binder. Creation of regulatory documents as needed.
Blinding Plan Development	Develop operationaly feasible blinding plan to support blinded study design
Monitoring Visits, Monitoring, and Audit Services	
Study Feasibility Questionnaire	Assistance completing Sponsor Feasibility or Qualifcation questionnaires.
Department-required feasibility	Assistance with department-required feasibility process, if appilcable
Site Qualification Visit (SQV)	Scheduling of SQV visit between sponsor, study personnel and UCLA facilities.
Site Initiation Visit (SIV)	Scheduling of visit between sponsor, study personnel and UCLA facilities.
Audit Preparation	Assistance with reviewing study records for audit readinesss. Development of Corrective and Preventive Action Plan
(CAPA) development and implementation support	Assistance with development of Corrective and Preventive Action Plan and implementation of CAPA.
Study Registration and Reporting	

FDA Reporting for Investigator Initiated Studies	Annual Report preparation, submission and correspondence with FDA[#]
FDA and Regulatory Submissions	
IND/IDE Submission Support	Application preparation, submission and correspondence with FDA[#]
Prep e-submission of IDE	Requires that full submission and documents are finalized

List of Services

Clinical Research Coordinator (CRC) Services

All CRC Services include engaged oversight and support by OCR-CSE CRC Supervisor, and Unit Director, including regular quality assurances reviews, laptop for remote access to research systems and applications, storage space for study requirements, fulfillment of annual evaluation requirements and sustained study-specific operational support.

CRC Service	Delegated Tasks
Recruitment	•Prescreening procedures •Identify potential participants from chart review
Study Management (SM)	•Administrative Support •Register participants in OnCore (ResearchConnect) •Facilitate CareConnect workflows (ResearchConnect) •Sponsor/Sponsor-Investigator communication •Patient Management (including, communication and payment reimbursements/stipends, if applicable) •Scheduling and Visit Management •Consenting •Randomization •Study Drug Management •Biospecimen Management •Perform Regular Quality Assurance Reviews •Manage communication with Participants, Sponsor, Institutional Collaborators, Servicing Departments, etc
Regulatory (Reg)	•Maintain patient research records including source and source worksheets •Data capture in source documents •Process protocol amendments and ICF revisions including submission to applicable institutional entities •Maintain required study approvals and authorizations •Manage updates to ancillary requisition forms •IRB submissions (Amendments, Post-Approval Reports, Continuing Reviews)
Data Management (DM)	•Data entry in CRF/eCRF, including query resolution •Schedule and manage monitoring visits
Financial Management Support (FM)	•Weekly charge review of HB and PB transaction reports •Facilitate inquiries from fund management related to sponsor invoice generatio •Reconcile payments received from Funding Source

Notes: Studies that require blinded and unblinded clinical research coordinator staff will need multiple coordinators assigned.

OCRCoordinator@mednet.ucla.edu ● http://www.researchgo.ucla.edu/coordination-services-education