Mass Eye and Ear Center for Clinical Research Operations

Welcome to the Center for Clinical Research Operations (CCRO), your comprehensive resource for clinical research. We aim to streamline your clinical research projects' design, launch, and management through close-out. We're committed to the highest regulatory and ethical compliance standards, prioritizing high-quality patient care in every study.

Service Overview

Management & Administration
Our experienced team handles daily operations, project management, and personnel administration, effectively balancing workload across our unit. As a key liaison for the principal investigator (PI), we're here to support you from project inception to completion. We'll help you design your study, review its feasibility, and guide it through to execution.

Budgeting & Agreement Facilitation
Our unit offers extensive assistance with financial planning and management. We specialize in crafting internal and federal budgets, estimating time and effort for industry trials, tracking budget deficits, and ensuring accuracy in milestone tracking and invoice review. Additionally, we oversee the submission of agreements and maintain ongoing communication with CTO and RM.

Training & Standardization
We collaborate with the grant team to establish and revise administrative processes, SOPs, guidelines, and departmental policies. Our unit offers extensive training programs encompassing both departmental and study-specific needs, ensuring that everyone from Study Coordinators to PIs, and Clinic to Pharmacy staff are well prepared and informed.

Regulatory & Ethical Compliance
Our unit is dedicated to maintaining the highest compliance standards with regulatory and ethical policies. We manage IRB and IBC administration, coordinate DSMB, handle FDA submissions for IND/IDE studies, and provide FDA audit consultation and support. We also prioritize keeping investigators updated with any changes in regulatory and institutional policies.

Study Management & Oversight
We are committed to ensuring seamless oversight and operations for studies, including multi-site studies. Our responsibilities range from regulatory management, monitoring study performance and compliance to updating CT.gov records, managing multicenter study data, and clinical coordination among sites. Our unit also organizes study visits, administers an inventory of investigational devices, and maintains regulatory documents.

Patient Interaction
We serve as a dependable point of contact for study subjects, providing clear communication and support throughout their participation in the study. Our team facilitates recruitment, patient consent, and study visits, manages subject billing compliance, enters data into CRF/EDC, and processes study specimens.

Our Research Process

We manage all phases of clinical research, from startup through to closeout.

Startup	Run Phase	Close Out
We help with study design, budget development, feasibility review, protocol/ICF development, and initial submissions/reviews to IRB, FDA, and CT. Gov, among other preparatory tasks.	Our unit manages regular meetings with the PI and the study team, coordinates study visits, ensures data quality, tracks time, handles continuous reviews and reporting to IRB, NIH, and DoD, coordinates patient communications, and oversees subject recruitment.	We oversee the conclusion of studies, including site closeout visits, IRB and IBC closeout, final CT. Gov results reporting, study fund closeout, and archiving of materials after 2 years.

Leverage our expansive capabilities and dedication to excellence. The Center for Clinical Research Operations is your partner in propelling clinical research. Let's advance research together!

Contact us!
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CENTER FOR CLINICAL RESEARCH OPERATIONS
MASS EYE AND EAR - SCOPE OF WORK

Tasks	Team Lead	Project Mgt	Study Coord.	Research Monitor
Study Start-Up				
Feasibility Review	•			
Sponsor Feasibility Review	•			
Study Timeline and Communication Plan	•			
Site Qualification Visit *		•		
Assign PM/SC roles and responsibilities	•			
Site Agreements & Budgets				
Develop CCRO and Procedural Budget for Internal/Federal Budgets	•			
Communicating with Research Administration and Research Management on budget and agreements for Internal/Federal Trials	•			
Develop CCRO and Procedural Budget for Industry Trials	•			
Agreement and Budget submissions/communications with CTO for Industry Trials	•			
Budget amendments	•			
Communication & Meetings				
Managing communications with granting organization	•	•		
Scheduling & Maintaining Regular Meetings with all Stakeholders		•		
Managing communications with regulatory agencies		•		
Stakeholders Meeting				
Identity stakeholders		•		
Preparing reports for stakeholders' meetings		•		
Attend stakeholders' meetings		•		
Run stakeholders' meetings & follow up on issues as appropriate		•		
Regulatory				
Protocol and ICF Development		•		
Source Document Development and Preparation		•		
Study Document Development & Revisions		•		
Develop a Manual of Procedures		•		
Recruitment materials		•		
IRB submissions: Initial, Annual Review, Amendments, Close Out		•		
Single IRB (Multi-Site): Coordination and submissions		•		
IRB Response to Review (site IRB comments/questions)		•		
Continuing Review (assist sites with IRB queries/comments)		•		
Review site-specific IRB amendment (assist sites)		•		
FDA initial submission, Annual reports, amendments, and final reporting		•		
Sponsor and FDA audit preparation and support				
IP/Device SOP Preparation and Accountability		•		
Biosafety Submission/Review and Response to Reviews		•		
CT. Gov Initial Set-Up, Yearly Updates, and Results Reporting		•		
Mass Controlled Substance Registration (for drug studies)		•		
Federal funding required monthly/annual reporting, i.e. NIH, DoD, PCORI, etc.		•		

Developing DSMB Charter		•		
Scheduling DSMB meetings (twice a year)		•		
Preparing reports for DSMB meetings		•		
Attend DSMB meetings		•		
Document DSMB meetings & follow up on issues as appropriate		•		
Finalize DSMB reports & letters & share them with regulatory agencies & sites		•		
Regulatory Maintenance				
Collection of all regulatory documentation		•		
Development of Regulatory Binders		•	•	
Development of Subject Binders		•	•	
Maintenance of Regulatory Binders		•		
Investigator Meeting				
Scheduling monthly investigator meetings		•		
Preparing reports for investigator meetings		•		
Attend investigator meetings *		•		
Document investigator meetings & follow up on issues as appropriate		•		
Multi-Site Studies				
Site Training of Investigators, Research Staff & Other Study Personnel		•		
Site Investigator Training		•		
Collection of Staff Training, Certification, and all Regulatory Documentation		•		
Site Monitoring		•		
Managing Communication with Sites		•		
External Monitor				
FDA Regulated Study Monitoring				•
NIH Studies				•
Multi-Site Study Monitoring (Federally funded studies)				•
Electronic Data Capture System, Sharing and Clinical Trials Management Systems				
Create Data Management Plan		•		
Development of EDC Forms for study		•		
Review & Approval of EDC forms for study		•	•	
Revision of EDC		•		
RedCap Build and Management		•		
Veeva Vault Setup and Management		•	•	
Ancillary Service Coordination and Certifications				
BCVA Tech Certification *			•	
Maze Visual Function Test Certification *			•	
Imaging Certification *			•	
Lab Collection and Preparation *			•	
Lab Shipping *			•	
Research Pharmacy Coordination *			•	
IP/Device Delivery to OR *			•	
Recruitment				
Subject Recruitment (Pre-screening, follow-up with potential patients)			•	
MGB RPDR Data Search			•	
MGB Patient Gateway			•	
MGB Rally			•	

Study Visits			•	
Coordinate and facilitate study visits *			•	
Perform Evaluations, e.g., Height, Weight, BP *			•	
Administer Patient Questionnaires **			•	
Facilitate Consenting **		•	•	
Consenting for minimal risk studies (Risk determined by IRB) **		•	•	
Safety Monitoring				
Review of Serious Adverse Events, Unanticipated Problems, and Other Events *		•		
Data Collection		•		
Collection of study data **		•		
Uploading of Study Data into EDC			•	
Ensuring Data Completion and Accuracy		•		
Data Query & Resolution			•	
Yearly Data Review		•		
Research Billing				
Study Billing Grid Execution	•			
Research Association in Epic			•	
Complete Study Patient Billing			•	
Enter Study Visits in Oncore			•	
Invoicing				
Develop Invoicing Templates for Study Sites	•			
Review & Approve Site Invoices		•		
Work with FA and IGA team to Facilitate Payment of Approved Invoices		•		
Reconciliation of Invoices	•			
Study Closeout				
Study Archiving (after 2 years) *			•	

Onsite Duties *

Remote and Onsite **