High-Level Process for Type #3 and Type #4	Central (IND/IDE Program)	Central (Regulatory Compliance)	Monitoring & EDC Build (e.g., CReST)	Site Team/PI	
Central Intake					**RACI Definitions:**
Project triage	R/A				**R = Responsible** (entity or team who is directly responsible for successful completion)
Pre-Clinical / Translational					**A = Accountable** (entity or team with final authority over successful completion)
Project specific Intake	C			R/A	**C = Consulted** (entity or team with unique insights that will be consulted)
PreClinical Project Plan and Activities	I			R/A	**I = Informed** (entity or team that isn't direclty involved, but who should be kept up to speed)
Regulatory Strategic Plan and Activities	R/C	I		R/A	****= dependent on study/submission**
Pre-IND Preparatory Work	C			R/A	
pIND Meeting	R/A			R	
Clinical Trial Prep Work					
Protocol Review and Scientific Approval		R/A			
Feasibility Review	R/A	R/A		R/C	recruitment feasibility, competing studies, operational limitations, scientific review
Administrative Budget Review and Feasibility	R/A			R/C	team staffing, monitoring, EDC, D/SMB, stats, FDA submission, external IRB, recruitment
Training Verification	R/A				CITI GCP, HIPS, IND/IDE specific trainings, AE assessment and reporting
Protocol Development	I			R/A	
IND Preparation and Development	C			R/A	
IND Submission and Responses	R/A			R	
Securing Institutional Approvals	C			R/A	HSRP, IRB, IBC, IPRC
Site Development Plan & Training	I/C			R/A	assessment of site capacity and closing any gaps, plan for education
ClinicalTrials.gov Registration and Maintenance	I	R/A		R	assistance through CRAO
Contracting and Financial					
MTAs, CDAs		R/A**		R	follows institutional processes
Study-Specific Contracts		R/A**		R	follows institutional processes
Budget Development, Financial Management and Oversight	C			R/A	
Invoicing Management and Payment				R/A	
In-Flight Trial Activities					
Operations					
Protocol Specific Training				R/A	
Changes to Protocol and/or IND/IDE Application	R/A			R/C	
Version Tracking - FDA Submissions	R/A			R	
Version Tracking - Protocol Changes	R			R/A	study team provides tracked protocol and summary of changes document to IND/IDE Office; IND/IDE Office cross checks FDA materials prior to submission
Site Initiation Meeting	R		R	R/A	OVCR contributes: sponsor responsibilities, AE responsibilities, TMF overview, EDC overview
Enroll Patient	I		C	R/A	
Approval of Planned Deviations Prior to Implementation	C	I		R/A	
Data Collection, Entry and Query Resolution			I	R/A	
Data Management in Advarra eDC	R	R	R	R/A	user access and PV CRF review (central). Building/reviewing CRFs, calendars, etc.
Sample Collection				R/A	
IRB Reporting and Amendments - Preparation and Submission	C/I			R/A	
Sample Oversight (Transport, Processing, Shipping)				R/A	
Safety Oversight					
Pharmacovigilance	R/A			R	
AE Data Collection	C/I		I	R/A	
AE Assessment	C/I		I	R/A	
Notification of Reportable Events	C/I	C/I	I	R/A	
Safety Data Query Generation	C/I		R/A**	R/A**	if deemed low risk and external monitoring n/a, PI is responsible and accountable
Individual and Aggregate Report Development	C		I	R/A	
Case Processing / SAE Determination / Submission Prep	C		I	R/A	
Safety Signals	C/I			R/A	PI notifies IND/IDE Office based on data safety plan
Review of Safety Data / Data Compilation	R/A**	I		R/A	based on data safety plan and contingent on data in Advarra EDC. Central PV will pull data for PI
Medical Monitoring		I		R/A**	
Clinical Monitoring					
Development of Monitoring Plan	I	I	R/A	C	
Responding to Findings and Appropriate Regulatory Follow-Up	I	I	I	R/A	
(Non-)Adherence to CAPAs	C	R	C/I	R/A	
Identification and Follow Up - Safety Concerns	C	C/I	R	R/A	
Identification and Follow Up - Clinical Concerns	C	C/I	R	R/A	
Identification and Follow Up - Clinical Noncompliance	C	C/I	R	R/A	
Safety Oversight Committees					
DSM Formation and Management	C/I**	I	R**	R/A	
DSM Data Compilation and Responses	I	I	C	R/A	
Regulatory Oversight					
Preparation of ongoing FDA Communications (Amendments, Urgent Issues, Annual Reports, SAEs)	R/A			R	
FDA Communications (Amendments, Urgent Issues, Annual Reports, SAEs)	R/A			C	
Trial Master File					
Filing Structure / eReg Template	R/A		I	I	
Filing FDA Communications, Submissions and Approvals	R/A				
All Other Documents			I	R/A	last person to have final version responsible for filing
Site Level Subject Documentation					
Filing			C/I	R/A	
Review	I	R	R/A	R	
Auditing and Inspections - Site and Sponsor					
Communications with FDA/Entity	R/A	I		C	
Staff Preparations	C	C	C	R/A	
Document Preparations	C	C	C	R/A	two-tier process for preparation
Document Review	C	C	C	R/A	two-tier process for preparation
Escort	C**			R/A	
Responses to Findings	I**			R/A	
Monitoring for Adherence to Audit Resolution	Accountable entity dependent on findings. Regulatory/human subjects findings: IRB. All else: Regulatory Compliance.				