Roles and Responsibilities Matrix

Pre-Award Roles and Responsibilities

Industry Sponsored Clinical Trials

Responsible Person/Office*	Scientific and Programmatic	Financial and Administrative	Human Subjects	Other Regulatory Compliance	Conflict of Interest
Principal Investigators	• Review sponsor protocol to assess feasibility • Identify staffing needs	• Review Confidential Disclosure Agreement • Review and approve per-patient budget and coverage analysis, if applicable	• Submit sponsor protocol to the Institutional Review Board (IRB) • Communicate any needed protocol changes to sponsor	• Prepare and submit protocol for other regulatory items including Biosafety, etc. • Assure protocol is consistent with contract	• Submit Conflict of Interest (COI) disclosures
Division/Department	• n/a	• Assist with developing study budget and gaining leadership approval *	• Facilitate protocol submission to the IRB	• Facilitate protocol submissions as applicable •	• n/a
Clinical Trials Office	• Assist with pilot projects targeted towards grant applications	• Coordinate external Medicare coverage analysis and budget development for trial billing	• n/a	• n/a	• n/a
Office of Sponsored Programs	• Review and negotiate Confidentiality Agreement with sponsor so PI may receive protocol	• Serve as authorized signer for Confidential Disclosure Agreements and Clinical Trial Agreement • Provide expert guidance on industry contract terms and conditions • Advise on budget development • Negotiate budget and contract terms with sponsor	• Review Informed Consent and ensure it is consistent with Clinical Trial Agreement • Confirm IRB approval before executing contract	• Confirm appropriate compliance approvals before executing contract	• Confirm appropriate COI approval • Notify PI if recent sponsor payments may need to be addressed in COI

** Budget development and invoice processes under review as part of CTMS implementation*

Roles and Responsibilities Matrix

Post-Award Roles and Responsibilities

Industry Sponsored Clinical Trials

Responsible Person/Office*	Scientific and Programmatic	Financial and Administrative	Human Subjects	Other Regulatory Compliance	Conflict of Interest
Principal Investigators	• Conduct trial as outlined in protocol • Oversee scientific integrity of study • Supervise study staff	• Oversee expense management of study consistent with enrollment and institutional policies • Oversee and certify effort of study team • Confirm trial end date for internal closeout	• Confirm training requirements met for study personnel • Submit renewal of protocol including any modifications • Submit FDA IND/IDE applications	• Update protocol(s) for approval as needed • Assure all study personnel listed on protocol are familiar with protocol requirements • Confirm regulatory training requirements met for study personnel	• Update COI disclosures as needed • Comply with COI management letter • Confirm that study personnel submit disclosures as required
Division/ Department	• Supervise project staff shared with PIs in division/department • Retain study data/materials as required • Participate in site inspections and monitoring visits	• Facilitate hiring new study staff • Initiate and maintain payroll allocations for staff and PI • Coordinate reimbursement of study participants • Identify cost centers for any unallowable costs or deficits • Associate and link patients, encounters, and orders in Epic • Submit forms for patient visits • Perform research billing review in Epic • Review and submit invoices for payment from 3rd party professional billing services * • Prepare and track Per Patient Reimbursement sponsor invoices *	• Assist PI with capturing patient study data, completing case report forms, and PI certification • Update protocol under the direction of the PI as applicable • Participate in site visits/audits • Track continuing review requirements and assist PI with modifications • Assist in consenting/reconsenting; obtaining and documenting consent	• Update protocol under the direction of the PI • Provide training for study staff as required	• Maintain COI compliance for any staff responsible for procurement decisions
Clinical Trials Office	• Provide Clinical Research Coordinators as needed (based on availability)	• Create and maintain Epic record for patient charges • Direct study teams to available reports for study management • Provide direction for Drug Accountability Records (DAR) as needed • Assist study teams in understanding Epic Research functionality	• Assist with FDA IND/IDE applications • Assist with compliance related audit finding resolution	• Assist with compliance-related audit finding resolution	• n/a
Sponsored Research Finance Office	• n/a	• Setup funds for PI spending • Review and approve expenses • Advise PI with prior approval requests; provide data as needed • Provide data to PI for cost transfers and re-budgeting requests as needed • Advise PI on budget management and monitoring of award expenditures; provide projection reports • Reconcile gift card logs to replenishment requests • Invoice sponsor for start-up costs • Deposit sponsor payments • Provide financial information for sponsor-required progress reports • Distribute residual funds to PI at contract close	• n/a	• n/a	• n/a

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