Northwestern University NUCATS Clinical and Translational Sciences Institute

Center for Clinical Research (CCR): Regulatory & Finance Teams
Summary of Rates & Included Services-FY25

ALL RATES ARE PER STUDY

The below rates are applicable from **September 1, 2024-August 31, 2025**

All CCR rates are reviewed annually and may be revised on an as-needed basis.

Regulatory Services Fee	Included Tasks	Rate
Investigator-Initiated; Non-Industry Sponsored		
Initial Regulatory Prep Rate	Preparation of study documents for initial IRB (Institutional Review Board) submission & approval FDA document preparation (1572, FDFs, CVs, etc.) Regulatory Binder Creation, including e-Reg. Interface with Study Team and IRB First year of annual regulatory maintenance	$6,000
Annual Regulatory Maintenance Rate	Protocol Amendments Modifications to study documents including consent forms, IBs (Investigator Brochures), recruitment materials. FDA Document Maintenance (1572, FDFs, CVs, etc.) Personnel Modifications Continuing Review/Study Close Out. Regulatory Binder Maintenance, including e-Reg. clinicaltrials.gov support. Interface with Study Team and FDA/IRB	$3,600
FDA Annual Reporting **Inclusive of protocol amendment(s) submitted annually (minor changes not requiring a separate submission and external consultation).* *Reference*.	Assisting the PI (Principal Investigator) with FDA annual report submission Review cover letter and application document for submission Prepare regulatory documents for signature Prepare submission for E-submission or mailing if required (make copies of submission, pack in envelope/box, fill out shipping label) Triage and facilitate correspondence with FDA and study team	$3,500
Industry Sponsored		
Initial Regulatory Prep Rate	Preparation of study documents for initial IRB submission & approval FDA document preparation (1572, FDFs, CVs, etc.) Regulatory Binder Creation, including e-Reg or Complion™ management. (Please note there is a separate FSM-issued fee for Complion™) Interface with Study Team, Sponsor, CRO (Clinical Research Organization), and IRB of record First year of annual regulatory maintenance	$9,000

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Consent Drafting Only	Drafting consent only. This fee is charged if an investigator and/or sponsor withdraws study start-up activity on the project due to unforeseen events.	$2,500
eIRB+ drafting with PI or Sponsor request to discontinue	Drafting the eIRB+ submission, inclusive of consent development. This fee is charged if an investigator and/or sponsor withdraws study start-up activity on the project due to unforeseen events.	$7,000
Annual Regulatory Maintenance Rate	Protocol Amendments Modifications to study documents including consent forms, IBs, recruitment materials. Personnel Modifications Continuing Review/Study Close Out Regulatory Binder Maintenance, including e-Reg or Complion™ management. Interface with Study Monitors, CRO, Sponsor, and IRB FDA Document Maintenance (1572, FDFs, CVs, etc.)	$4,200
Finance Service Fee	**Included Tasks**	**Rate**
Industry Sponsored		
Initial Budget Rate	Development and negotiation of budget Building budget in Study Tracker First year of annual maintenance	$8,000
Annual Finance Maintenance Rate	Invoicing sponsors Tracking patient visits for accounts receivable Reconciling payments received Revision budget in Study Tracker (as needed) Updates on account status and accounts receivable for study Processing subject stipend and Northwestern Medicine (NM) invoices for payment Negotiation of budget amendments (if needed)	$2,500
Study Budget Development- Non-Industry Sponsored (Pre-Award Only)	Developing a formalized study budget on a per-patient basis, including a cost analysis with accrual goals and prospective effort	$1,200

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Study Tracker Budget Build-Only. Investigator-Initiated, or Industry Sponsored	Building out a final negotiated budget into study tracker. Study team not engaged otherwise with CCR (Center for Clinical Research) Finance on the project	$500