

**Clinical Research Center
Start-Up Fees**

	Fee Description:	Amount:	Covers:
<i>a la carte pricing</i>	CRC Administrative Start-Up Fee (Bundled Service - discounted)	\$ 4,230.00	CRC administrative start-up fee includes: IRB Application/Consent Preparation, Coverage Analysis and Budget Negotiations.
	IRB Application/Consent Preparation	\$ 2,500.00	
	Budget Negotiation	\$ 1,200.00	
	Coverage Analysis	\$ 1,000.00	

Protocol Amendment Fees

<i>a la carte pricing</i>	Protocol Amendment Fee (Bundled Service - discounted)	\$ 1,350.00	Amendments including regulatory submission, coverage analysis and/or budgetary changes.
	Protocol Amendment Fee - Regulatory Submission	\$ 1,000.00	
	Protocol Amendment Fee - Budget	\$ 500.00	

Annual Maintenance Fees

Annual Regulatory Maintenance Fee--After 1st Year	\$ 2,000.00	Continuing regulatory and administrative maintenance. Covers IRB continuing reviews, modifications, personnel changes, safety reports, filing, binder upkeep, IT maintenance (eReg, CTMS), paperwork, regulatory documentation (1572, CVs, Financial Disclosures) and monitor visits
Annual Study Coordinator Maintenance Fee – Annually after 1 st Year – Non-interventional or data only coordination *Coordinator effort on milestone visits will still apply*	\$ 1,000.00	<input type="checkbox"/> Binder Fee and Source Documents (Time required printing documents from electronic portal for regulatory binder. This includes money needed to pay for supplies: paper, printer, ink, binder.) <input type="checkbox"/> Conference Calls <input type="checkbox"/> Pre-Screening Subject Fee <input type="checkbox"/> Re-consent Fee <input type="checkbox"/> Weekly/Monthly Enrollment Logs <input type="checkbox"/> Sponsor Specialized Training
Annual Study Coordinator Maintenance Fee – Annually after 1 st Year – Single arm studies with minimal complexity *Coordinator effort on milestone visits will still apply*	\$ 2,500.00	<input type="checkbox"/> Binder Fee and Source Documents (Time required printing documents from electronic portal for regulatory binder. This includes money needed to pay for supplies: paper, printer, ink, binder.) <input type="checkbox"/> Conference Calls <input type="checkbox"/> Pre-Screening Subject Fee <input type="checkbox"/> Re-consent Fee <input type="checkbox"/> Weekly/Monthly Enrollment Logs <input type="checkbox"/> Sponsor Specialized Training
Annual Study Coordinator Maintenance Fee – Annually after 1 st Year – Complex studies to include multiple arms, varying hours and/or adaptive/platform/umbrella trials *Coordinator effort on milestone visits will still apply*	\$ 5,000.00	<input type="checkbox"/> Binder Fee and Source Documents (Time required printing documents from electronic portal for regulatory binder. This includes money needed to pay for supplies: paper, printer, ink, binder.) <input type="checkbox"/> Conference Calls <input type="checkbox"/> Pre-Screening Subject Fee <input type="checkbox"/> Re-consent Fee <input type="checkbox"/> Weekly/Monthly Enrollment Logs <input type="checkbox"/> Sponsor Specialized Training

Study Closeout

Study Closeout (Clinical and Administrative)	\$ 750.00	Covers all closeout activities when the CRC provides both clinical (coordination) and regulatory support.
Study Closeout (Clinical or Administrative)	\$ 500.00	Covers all closeout activities when the CRC provides either clinical (coordination) or regulatory support.

CRC CHARGEMASTER

Procedure Code	Procedure Name	Charge		Flat Rate Charge/ Per Budget Negotiation	Comments for Budget Negotiations
	CRU Space Fee (GCHS & UT)	\$ 65.00	per hour	Flat Rate Charge - Actual Time	A space fee is not charged for CRC coordinated studies; could be applied for studies with multiple PK draws
	CRU Space Fee (when non CRC-staff administer study drug)	\$ 100.00	per hour	Flat Rate Charge - Actual Time	A space fee is not charged for CRC coordinated studies; could be applied for studies with multiple PK draws
	CRU Space Fee (Negative Pressure Room: non-Federal)	\$ 100.00	per hour	Flat Rate Charge - Actual Time	A space fee is not charged for CRC coordinated studies; could be applied for studies with multiple PK draws
	CRU Space Fee (GCHS: federal)	\$ 33.53	per visit	Flat Rate Charge	This is a per visit fee
	CRU Coordination/Data Coordination	\$85-\$125	per hour	Per Budget Negotiation	\$85/hr for IIT, consortium, coop, etc. & \$100-\$125 for industry NIH - based on actual salary plus benefits - must see LuAnn for rates
	EKG (Technical Fee)	\$ 100.00	each	Flat Rate Charge	Professional Fee (Read) with NM Billables Items
	EKG (Technical Fee) Triplicate	\$ 140.00	each	Flat Rate Charge	Professional Fee (Read) with NM Billables Items. \$20 per each additional EKG
	Central Scan Uploads	\$85-\$125	per hour	Per Budget Negotiation	one hour allotted per scan 1 scan= CT of chest/abd/Pelvis if done at same time
	Infusion	\$ 125.00	per hour	Flat Rate Charge - Actual Time	Time is determined from the time patient checks in until they check out of the CRU
	Oral Glucose Tolerance Test (OGTT)	\$ 250.00	each (up to 3hrs)	Flat Rate Charge	Includes: supplies, glucose drink, venous access, monitoring patient; up to 3 hours of draws. Discuss with LuAnn for studies requiring additional time. Need to add costs of glucose tests at NM lab.
Collection/Processing/Shipping for CRC Coordinated Studies					
	Collection/Processing/Shipping	\$ 85.00	per hour	Per Budget Negotiation	Each collection/processing/shipping should be billed at 1 hour of time. When PK samples are perform if all PK samples can be completed within the hour, 1 hour is acceptable for the budget. Add 30 minutes for each PK draw if they are spaced out.
	Dry Ice	Actual Cost		Actual Cost	Billed directly to grant account; account for \$15 in budget under NM Billable items
Collection/Processing/Shipping for Non-CRC Coordinated Studies					
58000078	Collection w/out supplies (venipuncture)	\$ 15.00	per draw	Flat Rate Charge	Venipuncture
58000081	Collection w/ supplies (venipuncture)	\$ 15.00	per draw	Flat Rate Charge	Venipuncture
	IV Start	\$ 60.00	per start	Flat Rate Charge	IV
	IV Draw (from existing IV)	\$ 20.00	per draw	Flat Rate Charge	IV
30036592	Port Draws	\$ 75.00	per draw	Flat Rate Charge	Includes supplies
	Subcutaneous Injection	\$ 35.00	per injection	Flat Rate Charge	
58000077	Processing w/out supplies (Blood)	\$ 15.00	per draw/timepoint	Flat Rate Charge	
58000080	Processing w/ supplies (Blood)	\$ 15.00	per draw/timepoint	Flat Rate Charge	
58000083	Urine/Stool/Swabs Processing (Non-Blood)	\$ 10.00	each sample/per timepoint	Flat Rate Charge	each processed sample (i.e. blood, stool, etc.) drops a fee
	Shipping	\$ 10.00	per shipment	Flat Rate Charge	
	Sample Storage	\$ 10.00	per box per month	Flat Rate Charge	
	Dry Ice	Actual Cost		Actual Cost	Billed directly to grant account; account for \$15 in budget under NM Billable items
These prices are subject to increases with prior notice.					

Clinical Research Center Fee Structure

Unfunded/Unbilled	<ul style="list-style-type: none"> - "Unfunded" means the study has no funding sources for study related activities and costs, "Unbilled" means that the study has fee waivers in place and is not billed for CRC related activities and costs -Fee waiver request submitted prior to regulatory work being performed -Reviewed at end of year 2 - At end of year 2 with a fee waived study; if no accrual the department takes over regulatory and/or budget or pays annual maintenance fee at 75% discounted rate to CRC
Fee Waiver	<ul style="list-style-type: none"> -Reviewed at two years and every year thereafter; may also be reviewed with amendments -If no accruals occur in the first two years a discounted maintenance fee will be implemented or the study will be transitioned back to the department for regulatory oversight. -Can receive a full fee waiver or a reduced fee waiver (reduced fee is discounted 75%) -Amount of studies receiving full fee waiver may be restricted to an annual amount or study volume -Fee waivers to be reviewed by CRC Administrator
Fee Reduction	<ul style="list-style-type: none"> -Reduced fees will be discounted at 75% of the full CRC rate -Reviewed at two years and every year thereafter; may also be reviewed with amendments -Fee reductions to be reviewed by CRC Administrator
Annual Fee Structure Review	<ul style="list-style-type: none"> -CRC Fee structure will be reviewed annually prior to UNMC/NM budget submissions for the next FY -Changes to the CRC fee structure will be communicated prior to implementation -Changes to the CRC fee structure should be implemented at the beginning of the next FY -Changes to the CRC fee structure will only be applied to new studies (not retroactive)
<p>Please note that the fees listed are for services performed by the Clinical Research Center and may be separate from budget negotiations that may occur with a study sponsor.</p>	

CRC Study Invoicing Support

CRC Hourly Rate – (\$50.00 per hour)

Hourly rate will apply to all tasks associated with study financials and will be billed on a monthly basis to the division.

Rate will be waived for studies that are CRC coordinated.

Examples of study financial tasks are:

- Invoice creation
- Payment reconciliation
- Subject stipend and/or travel reimbursement processing
- CTMS budget entry
- Multi-site IIT payments to sub-sites

Tracking & Reporting – (Study related activities)

Study effort will be tracked at the individual study level utilizing the “Effort Tracking” module in CTMS. The financial contact will log the total hours worked on a specific date for each study. Reporting will be performed on a monthly basis and the effort hours per study will be converted to a fee per study using the current CRC hourly rate. The fees will then be captured in the monthly invoice that is generated by the CRC staff and submitted to the department for review and approval.

Study financial reporting will be provided to department leadership on a quarterly basis.