

Clinical Research Center Fee Structure

The Clinical Research Center (CRC) offers a wide variety of Clinical Research Services throughout the life cycle of a clinical trial. The services can be utilized in an a la carte or bundled manner to meet the needs of each unique study. The following sections provide an overview of the fees associate with the services provided by the CRC.

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Definitions

Funded Studies

Refers to clinical research adequately funded by either a grant or contract to cover all costs associated with the performance of the clinical research.

Underfunded Studies

Refers to clinical research that receives funding by grant or contract but is insufficient to cover all costs associated with the performance of the clinical research. Institutional support may be required in the form of fee reductions, clinical research development fund, etc.

Unfunded Studies

Refers to clinical research that has no funding source for study related activities and costs. Institutional support will be required in the form of fee waivers, clinical research development fund, etc.

Fee Waiver

Fee waivers are 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; requests must be submitted prior to regulatory work being performed.

Fee Reduction

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

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 will only be applied to new studies (not retroactive)

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.

CRC Administrative Billing to Department

Fee Description	Amount	Covers
Start-Up Fees		
IRB Application/Consent Preparation	\$2,500.00	This fee is the administrative cost for the time and effort required for our staff to review study protocol, develop IRB application, create consent forms, and submit study to the IRB.
Budget Negotiation	\$1,500.00	This fee covers the associated effort for development and negotiation of the study budget.
Coverage Analysis	\$1,250.00	1-2 treatment arms = \$1,250. \$500 for each additional treatment arm. <i>See page 5 for tiered service information</i>
Protocol Amendment Fees		
Protocol Amendment Fee – Regulatory Submission	\$1,000.00	Preparation of documents, editing of informed consents, IRB applications, and addressing all raised IRB concerns.
Protocol Amendment Fee –Coverage Analysis	\$750.00	This fee covers the associated effort for modification of the study coverage analysis when a protocol amendment occurs.
Protocol Amendment Fee - Budget	\$500.00	This fee covers the associated effort for modification and negotiation of the study budget when a protocol amendment occurs.
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	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.) Conference Calls, Pre-Screening Subject Fee, Re-consent Fee, Weekly/Monthly Enrollment Logs, 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	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.) Conference Calls, Pre-Screening Subject Fee, Re-consent Fee, Weekly/Monthly Enrollment Logs, Sponsor Specialized Training.

Fee Description	Amount	Covers
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	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. Conference Calls, Pre-Screening Subject Fee, Re-consent Fee, Weekly/Monthly Enrollment Logs, 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.

Coverage Analysis & Budget Negotiations Tiers

The Clinical Research Center has the following tiered service offering for clinical research Coverage Analysis and Budget Negotiation.

Silver

- Current level of Clinical Trials Analyst (CTA) support delivered by the Clinical Research Center. New submissions are queued for coverage analysis and budget negotiation in the order they are received.

Gold

- \$4,000 per study; an individual study request submitted to study intake for prioritization of CTA support of new trials requiring coverage analysis and/or budget negotiation and is inclusive of any future amendment coverage analysis and budget renegotiation. The request can only be made at the individual investigator level (not a division); the fee must be paid up front and cannot be negotiated into a study budget.

Platinum

- An individual investigator (not a Department/Division) can support up to 0.5 FTE per annum for immediate CTA support of new trials requiring coverage analysis and/or budget negotiation and is inclusive of any future amendment coverage analysis and budget renegotiation. The salary support must be done at the individual investigator level (not a division) and will require a Memorandum of Understanding (MOU) be executed between both parties.

Gold and Platinum service levels are offered at the individual investigator level, not at the department/division level. All fees for the Gold and Platinum levels are paid at the investigator level and cannot be negotiated into a study budget.

CRC Clinical Billing to Department

- Supplies for services are included in the pricing if carried as normal stock in the Clinical Research Unit; specialty supplies will be ordered & charged to the research study account.
- These prices are subject to increases with prior notice.

Hospital Code	Procedure Name	Industry Rate	Federal / Cooperative Group Rate	Comments
Facility Usage Fee				
	CRU Space Fee (UT - University Tower)	\$67.50 per hour	\$67.50 per hour	
	CRU Space Fee (GCHS - Global Center for Health Security)	\$67.50 per hour	\$33.53 per visit	
	CRU Space Fee (GCHS) Negative Pressure Room	\$100.00 per hour	\$33.53 per visit	
Procedures & Services				
300956366	Infusion (performed by CRC staff)	\$150.00 per hour	\$75.00 per hour	Infusion rate is billed based upon check-in & check-out and is inclusive of all supplies and vitals during infusion.
300956366	Infusion (performed by non-CRC staff)	\$100.00 per hour	\$50.00 per hour	Infusion rate is billed based upon check-in & check-out and is inclusive of all supplies and vitals during infusion.
	Oral Glucose Tolerance Test (OGTT)	\$250.00 each		Inclusive of supplies, venous access, monitoring patient; up to 3 hours of draws.
30096372	IM/SQ Injection	\$112.50 each	\$56.25 each	
41293079	EKG (in CRC space)	\$115.00 each	\$57.50 each	Triplicate EKGs will be invoiced at 3x the listed rate.
41293056	EKG (outside of CRC space)	\$132.50 each	\$66.25 each	Triplicate EKGs will be invoiced at 3x the listed rate.
41693015	6 Minute Walk Test	\$198.80 each	\$99.40 each	Inclusive of any vitals and surveys performed during the test.
41618024	Spirometry	\$167.20 each	\$83.60 each	Inclusive of any vitals and surveys performed during the test.

Hospital Code	Procedure Name	Industry Rate	Federal / Cooperative Group Rate	Comments
	Vital Signs	\$20.00 each		Inclusive of height, weight, blood pressure, heart rate, temperature, respiration rate, O2 saturation.
30036592	Collection Blood, Established Central or Peripheral Venous Catheter	\$133.50 per draw/timepoint	\$66.75 per draw/timepoint	If putting in PIV the charge will be the same.
30036591	Collection Blood, Implanted VAD (Port Draws)	\$117.50 per draw/timepoint	\$58.75 per draw/timepoint	Includes port access
30036416	Collection Blood, Finger Prick or Heel Stick	\$11.50 each	\$5.75 each	
366G2023	Collection Fee-COVID 19 (Nasal Swab)	\$25.00 each	\$12.50 each	
45136416 55010000	Collection Blood, Venipuncture	\$15.00 per draw/timepoint	\$7.50 per draw/timepoint	
45136423	Research Specimen Processing (Blood & Urine)	\$30.50 per sample/timepoint**	\$15.25 per sample/timepoint**	**Complex specimen processing may increase the charge rate. This will be determined at intake and communicated for budget purposes.
55481025	Pregnancy Test (urine)	\$14.00 each	\$7.00 each	
	Sample Storage	\$10.00 per box per month		
	Shipping	\$15.00 per shipment		Shipping fee is for effort of staff in packaging samples for shipment.
	Dry Ice	N/A	N/A	Billed directly to study account; account for \$15 in budget under NM Billable items
	Nursing Services (not associated with NM codes or listed)	\$125.00 per hour		For clinical related services only, not intended for coordination. (i.e. - oral drug administration, monitoring post drug administration, photographing injection sites, etc...)

CRC Study Invoicing Support

CRC Hourly Rate

\$30.00 PER HOUR

Hourly rate will apply to all tasks associated with study financials and will be billed monthly 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 monthly 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 quarterly.

Contact crcclinic@unmc.edu with additional questions.