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Office of the Director of Georgia CTSA Clinical Research Centers (GCRCs)

May 17, 2022

Effective March 15, 2022

MEMORANDUM

To: Principal Investigators and Study Teams

From: Colleen S. Kraft, MD, MSc

Director, Georgia CTSA Clinical Research Centers (GCRCs)

Re: Georgia CTSA Clinical Research Centers (GCRCs) Revised Fee Schedule Description

The Georgia CTSA Clinical Research Centers (GCRCs) is a service center focused on providing resources to support Principal Investigators within the Emory research community. With multiple sites located at Emory University Hospital, Emory University Hospital Midtown, and Grady Memorial Hospital, we offer a range of services from Outpatient clinical care to Bionutrition & Exercise Physiology. We also offer Study Coordinator Support and Laboratory Processing.

This memorandum is intended to outline our pay-as-you-go services through the Emory School of Medicine (SOM) approved fee schedule rate.

Georgia CTSA Clinical Research Centers (GCRCs) Services

One-time Cost:

Study Start-up Fee - \$1,842

Research studies utilizing the Georgia CTSA Clinical Research Centers services are assessed a one-time Study Start-up Fee. This cost is inclusive, but not limited to, the administrative team's effort in review of study documentations such as the protocol and lab manual, and development of project specific budget. This fee also covers the Clinical Trial Management (CR Assist) setup process, Coordinator tracking mechanism, SAC application, review and approval process and Roundtable.

Phlebotomy Training Course - \$603

Phlebotomy 101 is an introductory training to venipuncture. The two-day course and clinical, is led by the GCRC nurses who provide hands-on training in teaching venipuncture to research coordinators. This course is offered to Emory University (SOM), Morehouse School of Medicine (MSM), and University of Georgia (UGA) faculty and staff.

<u>Clinical Outpatient Rate</u> (per subject/per visit) - inclusive but not limited to:

Nursing Level 1 - \$95

Nursing procedures including minimal set-up, vital signs, specimen collection, medication pick-up. *See Fee Schedule for External Rates

Nursing Level 2 - \$154

Nursing procedures including routine set-up, 12-Lead EKG (1) or more timepoints, IV placement, medication administration (PO, injection, topical), specimen collection (1 or multiple timepoints), vaccinations. *See Fee Schedule for External Rates

Nursing Level 3 - \$244

Nursing procedures including routine set-up, IV infusion, specimen collection (1 or multiple timepoints), coordination with other ancillary services.

Nursing Level 4 - \$356

Nursing procedures including advanced set-up, IV infusion, glucose tolerance test, complex sampling and monitoring schedule, lumbar puncture, or other invasive procedures.

Nursing Level 5 - \$520

Nursing procedures including advanced set-up, multiple infusions, biopsy (fat, muscle) extended visit with complex nursing intervention/monitoring, procedures requiring multiple nurses.

Nursing Level 6 - \$701

Nursing procedures including advanced set-up, medication titration, protocols that require 1:1 nursing care.

Nursing Level 7 - \$1,059

Nursing procedures that require conscious sedation or other Emory Healthcare competency-based requirements, complex protocols that require 2:1 nursing care.

Hourly Rates

Monitored Assisted Fee - \$50/hourly

Nursing services for study projects that do not fall under the Nursing visit level. Please see visit levels outlined above.

Coordinator Services

GCRC Coordinator Pool Services-\$87/hourly

The GCRC Coordinator pool offers a wide range of research coordination and management services for Investigators. The pool includes highly experienced, credentialed staff who provide a consistent level of service throughout the life of the study. This is ideal for Investigators seeking assistance with management of multi-site trials or day-to-day oversight of research programs.

GCRC Coordinator Regulatory Services -\$55/hourly

The coordinator service provides regulatory support at a rate of \$55/hr. This is inclusive of standard regulatory tasks, in addition to: study start-up at Emory- OCR and ancillary submissions, initial Emory IRB submission, local and central IRB submissions such as amendments/modifications, continuing reviews, reportable events. *See Fee Schedule for External Rates

Bionutrition Service

Bionutrition & Exercise Physiology -\$107/hourly

The GCRC Bionutrition Unit facilitates state-of-the-art nutritional science research that provides consultation on nutrition-related study design and methods in addition to body composition tracking, Bioimpedance analysis (BIA), anthropometric measurements, energy expenditure and exercise testing, nutrition assessment and education of study participants. The Bionutrition unit also provides recipe & menu development for controlled feeding studies and data collection and dietary intake analysis (24-hour recall, 3-day diet records, food frequency questionnaires).

Meal Preparation -\$53/hourly

Meal preparation service is provided by using experimental research diets prepared for both inpatient and outpatient studies including meal challenges. Organizing shopping lists and placing food and study-specific supply orders in conjunction with preparing, portioning, and storing food as directed by study coordinating food pick-up time and location with participants.

*See Fee Schedule for External Rates

Core Laboratory Services

Lab Labor Rate - \$55/hourly

The GCRC Core Laboratory offers Sample Processing to fit your protocol needs. Short and long-term sample storage (4°C, -20°C, -80°C). Sample barcoding and tracking using sophisticated Laboratory Information Management Software (LIMS) and Laboratory expertise for your protocol planning, set-up, and initiation. *See Fee Schedule for External Rates

Sample Processing Charges:

Whole Blood Processing - \$11/unit (1) Unit = 1 – 5 aliquots

Serum Processing - \$18/unit (1) Unit = 1 – 5 aliquots

Plasma Processing - \$18/unit (1) Unit = 1 – 5 aliquots

Buffy Coat Processing - \$13/unit (1) Unit = 1 – 2 aliquots Urine Processing - \$12/each

Pregnancy Test - \$12/each Drug Test - \$12/each Dip Stick - \$12/each

Saliva Processing - \$12/unit (1) Unit = 1 -2 aliquots

Stool Processing - \$13/unit (1) Unit = 1 -2 aliquots

PBMC Processing with CPT Tube (gene expression) - 40/unit (1) Unit = 1 - 2 aliquots

PBMC Processing with CPT Tube (for immediate pickup) - \$35/unit (1) Unit = 1 -2 aliquots

Lab Sample Storage Service - \$33/monthly or \$396/annually (long term >= 1 month)

Biorepository Service - \$50/per sample

The Georgia CTSA Clinical Research Center at Emory has established a COVID-19 Biorepository that includes residual nasopharyngeal (NP) swab samples from over 1,700 patients known to be COVID-19 positive or negative.

*See Fee Schedule for External Rates

^{*} The Laboratory processing cost structure has changed from an hourly rate to fixed cost.

^{*} To align with Industry billing standards, all payments for services will be automatically processed after the 7th-business day of invoice submission.

^{*} A 30-day invoicing and billing dispute policy has been implemented to ensure all accounts are recorded appropriately.

^{*} For price adjustment comparison, please reference the older version (dated 2019) of the GCRC fee schedule.

^{*} All fees are per unit/sample unless noted. N/A = no external service provided

^{*} External rates are to be used for contracts external to Emory University and the Georgia CTSA partner institutions and are inclusive of Emory University 56.5% F&A costs.

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Georgia Clinical Translational Science Alliance Clinical Research Centers (GCRCs)
Fee Schedule - Emory University Hospital, Emory University Midtown and Grady Memorial Hospital locations

Effective FY2022 September 1, 2021

Revision approved March 15, 2022

Administrative	Internal Rate	External Rate*	CoreLaboratory	Internal Rate	External Rate*
Study Start-up Fee (one-time cost)	\$ 1,842	\$ 3,597	Biorepository	\$50/sample	\$98/sample
Training	Internal Rate	External Rate*	Laboratory Labor Rate	\$55/hour	\$114/hour
Phlebotomy Training Course	\$ 603	N/A			
			Laboratory Sample Storage Fee (long term ≥ 1 month)	\$33/month	\$76/month
Outpatient ClinicalServices	Internal Rate	External Rate*			
Level 1	\$ 95	\$ 185	Whole Blood (1) unit = 1 - 5 aliquots	\$ 11	\$ 25
Level 2	\$ 154	\$ 324	Serum (1) unit = 1 - 5 aliquots	\$ 18	\$ 83
Level3	\$ 244	N/A	Plasma (1) unit = 1 - 5 aliquots	\$ 18	\$ 74
Level4	\$ 356	N/A	Buffy Coat (1) unit = 1 - 2 aliquots	\$ 13	\$ 31
Level 5	\$ 520	N/A			
Level 6	\$ 701	N/A	Urine Processing	\$ 12	\$ 32
Level7	\$ 1,059	N/A	Pregnancy Test	\$ 12	N/A
			Drug Test	\$ 12	N/A
Monitored & Unassisted Service	Internal Rate	External Rate*	DipStick	\$ 12	N/A
Monitored Assisted Fee	\$ 50	N/A			
			Saliva (1) unit = 1 - 2 aliquots	\$ 12	\$ 30
			Stool (1) unit = 1 - 2 aliquots	\$ 13	\$ 57
Coordinator Services	Internal Rate	External Rate*			
GCRC Coordinator Pool	\$87/hour	\$151/hour	PBMC Processing with CPT (immediate pickup)	\$ 35	\$ 139
Regulatory Services	\$55/hour	\$105/hour	(1) unit = 1 - 2 aliquots		
Bionutrition Services	Internal Rate	External Rate*	PBMC Processing with CPTTube(gene expression)	\$ 40	\$ 111
Bionutritlon & Exercise Physiology	\$107/hour	\$218/hour	(1) unit = 1-2 aliquots		111
Meal Preparation	\$53/hour	\$91/hour			

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