

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

August 23, 2023

***Effective October 1, 2023***

# MEMORANDUM

To: Principal Investigators and Study Teams

From: Colleen S. Kraft, MD, MSc  
Program Director, Georgia CTSA Clinical Research Centers (GCRCs)

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

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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, Emory Johns Creek, Emory St. Joseph's and Grady Memorial Hospital, we offer a range of services from Outpatient clinical care to Bionutrition & Exercise Physiology, 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*** - \$1984

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*** - \$628

Phlebotomy 101 is an introductory training to venipuncture. The two-day course and clinical, are 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.

#### ***Phlebotomy Renewal*** - \$87

Phlebotomy training renewal places a strong focus on the hands-on application of phlebotomy techniques, with an emphasis on practical demonstrations. The phlebotomy renewal is a mandatory annual credentialing requirement for those performing phlebotomy skills at Emory Healthcare facilities, and it is exclusively available to staff and faculty who have successfully completed an initial phlebotomy training.

### **Clinical Outpatient Rate** (per subject/per visit) - inclusive but not limited to:

#### ***Nursing Level 1*** - \$101

Nursing procedures including minimal intensity, vital signs, specimen collection (1 timepoint), six-minute walk test, medication pick-up, data entry or collection, basic teaching.

#### ***Nursing Level 2*** - \$189

Nursing procedures including minor intensity, 12-Lead ECG (up to 3 timepoints), IV placement, medication administration (PO, injection, topical), specimen collection (multiple timepoints <3 hours between collection), teaching with returned demonstration.

#### ***Nursing Level 3*** - \$276

Nursing procedures including moderate intensity, ECG (> 3 timepoints) IV infusion, coordination with other ancillary services, specimen collection (multiple time points > 3 hours between collection), advanced teaching.

#### ***Nursing Level 4*** - \$389

Nursing procedures including moderate intensity, IV infusion, glucose tolerance test, complex sampling, prolonged monitoring schedule, lumbar puncture, or other invasive procedures.

#### ***Nursing Level 5*** - \$590

Nursing procedures including high intensity, multiple infusions, biopsy (fat, muscle) extended visit with complex nursing intervention/monitoring, procedures requiring multiple nurses.

#### ***Nursing Level 6*** - \$727

Nursing procedures including advanced intensity, medication titration, protocols that require 1:1 nursing care.

#### ***Nursing Level 7*** - \$1076

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

#### ***Nursing Clinical Check Off – 1<sup>st</sup> time*** - \$59

The Nursing Clinical Initial Check-off 101 is designed for staff and faculty seeking training in both theoretical and practical aspects of obtaining vital signs, height, weight, as well as hip and waist circumference measurements. These

checkoffs are required for staff and faculty performing these duties as part of their research functions at Emory Healthcare facilities and should be renewed annually.

***Nursing Clinical Check Off – renewal - \$26***

The Nursing Clinical Renewal focuses on return demonstration of the clinical skills acquired during the Nursing Clinical Check-off 101. This annual skill renewal is required for those wishing to maintain their ability to perform these skills at Emory Healthcare facilities.

## **Hourly Rates**

**Monitored Assisted Fee - \$89/hourly**

The Monitored Assisted Fee is intended to cover nursing services for research studies that fall outside the standard nursing levels. This includes, but is not limited to, studies requiring nursing travel as well as nursing support for studies extending beyond 3:30 pm. Please refer to the outlined visit levels above for more details.

**Coordinator Services**

***GCRC Coordinator Pool Services- \$90/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 - \$58/hourly***

The coordinator service provides regulatory support. 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.

**Bionutrition Services**

***Bionutrition & Exercise Physiology - \$109/hourly***

The GCRC Bionutrition Unit facilitates state-of-the-art nutritional science research that provides consultation on nutrition-related study design and methods, body composition measurements utilizing bioimpedance analysis (BIA), dual x-ray absorptiometry (DEXA), and anthropometric measurements, energy expenditure assessment using indirect calorimetry, exercise testing, education of study participants, recipe and menu development for controlled feeding studies and dietary intake collection and analysis (24-hour recall, 3-day diet records, food frequency questionnaires).

***Meal Preparation - \$65/hourly***

Meal preparation service is provided for inpatient, outpatient, and meal challenge studies using experimental research diets. This service includes implementation of the research diet, organizing and purchasing food and study-specific supplies, food preparation, portioning, assembling, storage and coordination of study participant diet pick-up.

**Laboratory Services**

***Laboratory Labor Rate - \$60/hourly***

The GCRC Core Laboratory offers an array of services to fit your protocol needs at three sites: EUH, EUHM, and Grady. Sample processing and short and long-term sample storage (4°C, -20°C, -80°C). Biorepository samples for testing therapeutics and diagnostics plus platforms that allow CLIA waived chemistry panels for research purposes. Biosample

barcoding, banking and tracking using sophisticated Laboratory Information Management Software (Open Specimen) and Laboratory expertise for your protocol planning, set-up, and initiation.

**Sample Processing Charges:**

**Whole Blood Processing** – \$14/unit (1) Unit = 1 – 5 aliquots

**Serum Processing** - \$19/unit (1) Unit = 1 – 5 aliquots

**Plasma Processing** - \$19/unit (1) Unit = 1 – 5 aliquots

**Buffy Coat Processing** - \$15/unit (1) Unit = 1 – 2 aliquots Urine Processing - \$12/each

**Pregnancy Test** - \$14/each

**Drug Test** - \$12/each

**Dip Stick** - \$15/each

**Saliva Processing** - \$15/unit (1) Unit = 1 -2 aliquots

**Stool Processing** - \$15/unit (1) Unit = 1 -2 aliquots

**PBMC Processing** - \$42/unit (1) Unit = 1 – 2 aliquots

**Lab Sample Storage Service** - \$35/monthly or \$420/annually (long term >= 1 month)

**Laboratory Usage & Equipment Fee** - \$21/per visit

**Medical Lab Orders—Lab ONLY Studies** - \$10/per lab order

**GCRC Biorepository:**

The Georgia CTSA Clinical Research Center at Emory has a Biorepository that includes an array of infectious disease samples.

Our goal is to provide de-identified samples to investigators validating or developing diagnostics and therapeutics in an effort to improve the understanding of the effects, response, and mechanism of a variety of infectious disease samples including SARS-COV-2 and its variants.

**Biorepository Service** - \$55/per sample

**Biorepository Data Retrieval** - \$90/per hour

**Piccolo Xpress:**

A portable diagnostic analyzer to offer a full complement of CLIA-waived blood chemistry tests with results same day. Our site will only be able to test fresh blood samples in a lithium heparin tube, no later than 1 hour after blood draw, for estimated values. This system will not be used for POCT. **EUH** will be able to run the CMP Panel, Lipid Panel and Electrolyte Panel. **Grady** will be able to run the CMP Panel and Renal Function Panel.

**Piccolo Xpress-CMP Panel** - \$11/per sample

**Piccolo Xpress-Lipid Panel** - \$11/per sample

**Piccolo Xpress-Electrolyte Panel** - \$11/per sample

**Piccolo Xpress-Renal Function Panel** - \$11/per sample

*\*See External Fee Schedule for External Rates*

**NOTE:**

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*\* All nursing outpatient fees are charged per visit*

*\*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 2022) 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 are inclusive of Emory University 56.5% F&A costs.*

Administrative	Internal Rate	Laboratory Services	Internal Rate
Study Start-up Fee (one-time cost)	\$ 1,984.00	Biorepository	\$55/sample
		Biorepository Data Retrieval	\$90/hour
Phlebotomy Services	Internal Rate	Laboratory Labor Rate	\$60/hour
Phlebotomy Training Course	\$ 628.00	Laboratory Usage & Equipment Fee	\$21/visit
Phlebotomy Renewal	\$ 87.00	Laboratory Sample Storage Fee ( <i>long term ≥ 1 month</i> )	\$35/month
Outpatient Clinical Services	Internal Rate		
Level 1	\$ 101.00	Whole Blood (1) unit = 1 - 5 aliquots	\$ 14.00
Level 2	\$ 189.00	Serum (1) unit = 1 - 5 aliquots	\$ 19.00
Level 3	\$ 276.00	Plasma (1) unit = 1 - 5 aliquots	\$ 19.00
Level 4	\$ 389.00	Buffy Coat (1) unit = 1 - 2 aliquots	\$ 15.00
Level 5	\$ 590.00	Urine Processing	\$ 15.00
Level 6	\$ 727.00	Pregnancy Test	\$ 14.00
Level 7	\$ 1,076.00	Drug Test	\$ 14.00
Nursing Clinical Check-Off ( <i>1st time</i> )	\$ 59.00	Dip Stick	\$ 15.00
Nursing Clinical Check-Off (renewal)	\$ 26.00	Saliva (1) unit = 1 - 2 aliquots	\$ 15.00
Monitored Assistance* and Space Only Requests	Internal Rate	Stool (1) unit = 1 - 2 aliquots	\$ 15.00
Monitored Assisted Fee	\$89/hour	PBMC Processing (1) unit = 1 - 2 aliquots	\$ 42.00
Space only request	No charge		
Coordinator Services	Internal Rate	Lab Slides (1-2 units)	\$ 16.00
GCRC Coordinator Pool	\$90/hour		
Regulatory Services	\$58/hour	Piccolo Xpress - CMP Panel (per sample)	\$ 11.00
		Piccolo Xpress - Lipid Panel (per sample)	\$ 11.00
Bionutrition Services	Internal Rate	Piccolo Xpress - Electrolyte (per sample)	\$ 11.00
Bionutrition & Exercise Physiology	\$109/hour	Piccolo Xpress - Renal (pers sample)	\$ 11.00
Meal Preparation	\$65/hour		
		Medical Lab Orders - Lab ONLY (per lab order)	\$ 10.00

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Administrative	Academic External Rate	Non-Academic External User Rate	Laboratory Services	Academic External Rate	Non-Academic External User Rate
Study Start-up Fee (one-time cost)	\$3,095	\$6,190	Biorepository	\$86/sample	\$150/sample
			Biorepository Data Retrieval	\$140/hour	\$280/hour
<b>Phlebotomy Services</b>	<b>Academic External Rate</b>	<b>Non-Academic External User Rate</b>	Laboratory Labor Rate	\$94/hour	\$188/hour
Phlebotomy Training Course	\$980	\$1,960	Laboratory Usage & Equipment Fee	\$33/per visit	\$66/per visit
Phlebotomy Renewal	\$132	\$264	Laboratory Sample Storage Fee (long term ≥ 1 month)	\$55/month	\$111/month
<b>Outpatient Clinical Services</b>	<b>Academic External Rate</b>	<b>Non-Academic External User Rate</b>			
Level 1	\$158	\$316	Whole Blood (1) unit = 1 - 5 aliquots	\$21	\$41
Level 2	\$295	\$591	Serum (1) unit = 1 - 5 aliquots	\$30	\$60
Level 3	\$411	\$862	Plasma (1) unit = 1 - 5 aliquots	\$29	\$58
Level 4	\$607	\$1,213	Buffy Coat (1) unit = 1 - 2 aliquots	\$24	\$48
Level 5	\$871	\$1,747	Urine Processing	\$23	\$46
Level 6	\$1,134	\$2,268	Pregnancy Test	\$23	\$45
Level 7	\$1,679	\$3,358	Drug Test	\$22	\$44
Nursing Clinical Check-Off (1st time)	\$92	\$184	Dip Stick	\$24	\$48
Nursing Clinical Check-Off (renewal)	\$40	\$80	Saliva (1) unit = 1 - 2 aliquots	\$23	\$46
<b>Monitored Assistance*</b>	<b>Academic External Rate</b>	<b>Non-Academic External User Rate</b>	Stool (1) unit = 1 - 2 aliquots	\$24	\$48
Monitored Assisted Fee	\$139/hour	\$277/hour	PBMC Processing (1) unit = 1 - 2 aliquots	\$66	\$132
<b>Coordinator Services</b>	<b>Academic External Rate</b>	<b>Non-Academic External User Rate</b>	Lab Slides (1-2 units)	\$26	\$51
GCRC Coordinator Pool	\$140/hour	280/hour			
Regulatory Services	\$90/hour	180/hour	Piccolo Xpress - CMP Panel (per sample)	\$18	\$35
			Piccolo Xpress - Lipid Panel (per sample)	\$18	\$35
<b>Bionutrition Services</b>	<b>Academic External Rate</b>	<b>Non-Academic External User Rate</b>	Piccolo Xpress - Electrolyte (per sample)	\$18	\$35
Bionutrition & Exercise Physiology	171/hour	341/hour	Piccolo Xpress - Renal (pers sample)	\$18	\$35
Meal Preparation	101/hour	203/hour			
			Medical Lab Orders - Lab ONLY (per lab order)	\$16	\$32

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