EMORY | **Emory Clinical Research Office**

MEMORANDUM

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To: Whom It May Concern

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RE: Emory University Standard Research Fees for Industry-Sponsored and/or Funded Studies

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Emory University staff are authorized to act on behalf of Emory University (EU) and Emory Healthcare (EHC) to complete the Coverage Analysis (CA) and develop and negotiate budgets for research studies to cover costs. The following provides documentation and justification of the standard research fees generally required to conduct an industry study at Emory University; however, it is not to be construed as being all-inclusive.

Facility and Administrative Cost

The EU Facilities and Administrative (F&A) cost results from shared services such as libraries, facilities management, utility costs, general, departmental, unit/school, and sponsored projects' administrative expenses, interest costs and depreciation for buildings and equipment. The F&A for industry-funded clinical trials involving human subjects is **35 percent,** assessed on all research study items and services, study team effort, and all administrative fees including patient stipends and travel expenses.

Study Start-up

A Study Start-up Fee is assessed to cover the study team's effort to open the study and includes:

- Pre-study document preparation, completion of critical study documents and sponsor correspondence
- Protocol review by principal investigator and research personnel
- Protocol analysis, staff training, pre-screening and recruitment activities, supplies, completion of study-specific financial and clinical documents, source document preparation, study team/sponsor communications, and other items and services not including investigational drug services (IDS) or Institutional Review Board (IRB) and other committee submissions
- Site initiation visit (SIV) planning and execution

Study start-up fees cover these study activities and supplies and could vary depending on the complexity and nature of the study.

Coverage Analysis (CA)

The EU policy dictates that we oversee and/or develop a CA for all clinical trials and certain other research studies involving human subjects with EHC or Grady Health System (GHS) billable items and services. The CA is an objective determination of what can and cannot be billed to third party payers using the National

Coverage Determinations (NCDs) and the Local Coverage Determinations (LCDs) adopted by the Centers for Medicare and Medicaid Services (CMS), as well as other clinical care guidelines. The CA is used by the EHC Clinical Trials Billing Department (CTBD) as a guide to ensure items are correctly billed to insurance or the study/grant account. Industry-funded clinical trials and research studies are assessed a CA fee for this analysis. A CA Amendment Fee is assessed for each study amendment with changes to EHC or GHS billable items and services requiring a change to the CA. The CA fee is assessed if work commences on the CA, regardless of whether the study is withdrawn before contract execution.

Budget Development

A charge for effort is assessed to develop the budget for all clinical trials and research proposals. Where applicable, the budget is based on the CA by Emory to ensure the budget is compliant with federal and clinical care guidelines, and includes all protocol-mandated procedures, site costs including personnel efforts, other relevant fees, and the cost of budget development and negotiation time.

OnCore

OnCore is a clinical trials management system (CTMS) used at Emory. Oncore manages the planning, performing, reporting, billing compliance, and invoicing functions at the study and subject level. It also enables the study team to set up and manage all protocols and subjects in one place and automates the flow of information between Emory-based IT systems, including eIRB, Complion, Vestigo, and EPIC. Start-up and amendment fee(s) will be assessed to cover the effort to ensure all OnCore elements are set up in a compliant fashion.

Institutional Review Board (IRB)

EU has standard administrative fees for study submissions to the Emory IRB which include the Initial IRB Review Fee, the IRB Renewal Fee, the IRB Amendment Fee, as well as an Administrative Fee for all non-Emory IRB initial review submissions. Studies that are reviewed by a non-Emory IRB require a local EU IRB submission to verify that institutional requirements are met, including study team training requirements, ancillary committee reviews, etc.

Emory prefers sponsors to pay non-Emory/external IRB fees directly. Since fees can change after contracts have been executed, Emory budgets will include language that state the sponsor agrees to pay the prevailing rates at the time the service is provided, and not the rate in effect at the time the contract is executed.

Emory also has standard fees for study-team based effort for preparation of the IRB application and regulatory documents. The Initial IRB Submission Prep Fee, the IRB Renewal Prep Fee, and the IRB Amendment Prep Fee are relevant separate study-team based effort fees.

Investigational Drug Services (IDS)

An individualized budget for each research study is prepared by the Emory IDS Pharmacy. The IDS is an integral part of the research process at EU for the management and dispensing of research drugs. It is a requirement for investigators who conduct drug studies to use the IDS Pharmacy, and the policy applies to all investigational drugs or drugs provided free of charge for clinical studies, regardless of whether the drugs are Food & Drug Administration (FDA)-approved. The IDS Study Initiation Fee is assessed for protocol review and budget development, the site initiation visit, procurement, inventory and storage of the study drug, development of drug information sheets, computerization, study sponsor consultation and staff education. The monthly IDS Maintenance Fee includes inventory maintenance and re-ordering, record keeping, drug distribution, monitor visits, patient randomization, and special packaging/labeling. The IDS Study Close-Out Fee includes monitor close-out, reconciliation, drug destruction, and return of drug supplies. There are also compounding and dispensing fees for each infusion, IV bolus and infusion fees, dispensing and patient return fees for each prescription, repurposed drug fees, and courier fees, if needed, to transport the study drug to the facility where administration of the study drug to the subject will occur. If there are any changes or additions to the duties of the IDS Pharmacist due to protocol requirements, additional fees may apply. These IDS fees are determined by the Emory IDS Pharmacy and are subject to change.

Radiology Processing and Authorized Users

Radiology works very closely with the principal investigators, the clinical departments, as well as other research administrative departments to ensure safe and efficient conduct of the scans/imaging and overall

adherence to the study protocol. The Radiology Processing Fee covers the review of the research protocols to verify that the requested imaging devices, sequences, and personnel (radiology technologists and radiologists) are available to conduct the study protocol, as well as the frequent involvement of the medical physicists to acquire phantom images and other pre-study data required to certify the devices for a particular study for the sponsor. Studies that involve Nuclear Medicine scans often require an Authorized User for research driven and non-standard radiotracer use, and being a designated Authorized User is a significant responsibility. The Authorized User Fee will be assessed when Radiology is serving as the Authorized User on a trial. Studies may also require physicist time for tasks such as pre-study imaging device survey completion and study protocol (e.g., MRI sequence) set up. A Physicist Fee will be assessed when such tasks are required.

Precision Imaging Metrics System (PIMS) is a database at Winship that tracks tumor response based on protocol-directed response criteria. If PIMS is used to assess changes in tumor burden for response to therapy and endpoints categorized by defined criteria (e.g., RECIST), a fee is assessed for analysis. If additional research-based assessments beyond **standard research imaging and timing analyses** are to be done by Radiology faculty, **an additional** fee is assessed for each protocol response criteria and time point. This fee is assessed at each time point to cover staff effort to measure the cancer patient response during treatment by assessment of target lesions, non-target lesions, new lesions, and lymph nodes. The cost for measurements is **assessed for each individual scan**. Multiple tumors/lesions may be measured per each scan. Cases that require more than one type of measurement (e.g., RECIST and iRECIST or RECIST and mRECIST done separately for each time point) will be charged for **additional scans** per time point for each additional type of measurement being done.

ClinicalTrials.gov Service Center

For investigator-initiated, Emory-sponsored studies, a one-time fee will apply for initial registration of the study in Emory's ClinicalTrials.gov Protocol Registration & Results System (PRS) organizational account. The management of updates, amendments, addressing ClinicalTrials.gov reviewer comments, and results reporting, if applicable, will also result in additional fees to ensure compliance with all federal regulations, NIH policies, and other relevant requirements.

Reconsenting

A Reconsenting Fee will be assessed each time the patient needs to be re-consented for protocol amendments.

Georgia Clinical and Translational Science Alliance (Georgia CTSA) Clinical Research Centers (GCRCs)

The GCRC 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, the GCRC offers a range of services from outpatient clinical care to bio-nutrition & exercise physiology. The GCRC also offers Nursing Support, Study Coordinator Support and Laboratory Processing, and all fees are for the *pay-as-you-go* services. All industry studies utilizing the GCRC will have a one-time Study Start-up Fee assessed that includes, but is not limited to, the administrative team's effort in review of study documentation such as the protocol and lab manual, development of project specific budget, the Clinical Trial Management (CR Assist) setup process, coordinator tracking mechanism, Scientific Advisory Committee (SAC) application, review and approval process and Roundtable.

Treatment Order Set(s) Development

Treatment Order Set(s) Development is a collaborative approach by Pharmacists and Infusion Nurses, as well as the study PI and Clinical Research Coordinator (CRC), to document orders to ensure adherence to protocol requirements. These orders include not only the drugs and dosages for the various cycles and study arms, but also include any required labs or procedures before, during, and after drug administration. The Treatment Order Set(s) Development fee is assessed to cover the staff time to develop these orders. This fee is separate from the IDS fee and focuses on delivery of care on trial rather than agent-specific management as outlined above.

Winship Cancer Institute Phase I Unit and Dedicated Infusion Center Research Areas

It is the standard practice of the Winship Cancer Institute and dedicated research areas that clinical trial subjects requiring frequent blood draws, vital signs, and/or Electrocardiograms (ECGs) solely for research purposes, be assessed an hourly fee for the time in those areas. This fee is not applicable during and up to 30

minutes following a documented intravenous (IV) infusion when nurse oversight and facility fees are captured by the infusion billing Current Procedural Terminology (CPT) code.

Software for Regulatory Support
Emory uses a cloud-based eRegulatory platform that improves efficiency, compliance and transparency for research sites and sponsors. An initial fee will be assessed per trial, as well as an annual fee to cover the cost of effort needed to maintain the system, archive, and manage users and modules done by Emory staff.

DSMB Monitoring Plan for PI-initiated Studies (for non-Winship protocols, as applicable)
A formal monitoring plan is required for PI-initiated, high complexity studies, which are greater than minimal risk and are categorized as any of the following: Phase I – III interventional studies, all studies under an Investigational New Drug [IND] or Investigational Device Exemption [IDE] with the FDA, or studies that may not be under an IND or IDE, but a participant is exposed to risk for an extended period or for which the risk might change with time. These studies are expected to have a monitoring plan in the protocol that specifies who will serve as the study monitor and the frequency and percentage of the files to be reviewed. The monitoring fee will be assessed per hour for each study monitor as needed per study.

Study Team Effort
The EU School of Medicine requires a minimum percentage of effort to be covered by sponsor funds for research oversight responsibilities of the PI for the sole purpose of conducting the research per the contractual agreement between EU and the Sponsor; this allocation of effort is separate from the PI's time conducting clinical procedures. Physician effort for ancillary services, (e.g., Radiology, Ophthalmology, etc.), may also be assessed for services and/or documentation required of the study protocol not covered by CPT codes. Coordinator, data management and regulatory effort is also assessed for the study and varies depending on the number and complexity of study services, and documentation of such based on the protocol.

EHC Clinical Items and Services
EU clinical research personnel are required to utilize the standardized research fee schedule for pricing any items, services, or procedures done at EHC for the development of clinical research budgets to ensure study budgets cover costs. The research fee schedule is proprietary and includes **discounted** fees for items and services conducted at EHC. EHC charges will be assessed in accordance with the EHC research fee schedule, which is updated twice each year. Fees for drugs and supplies may change based on variation in supplier charges and may not be listed in the research fee schedule. The fees for these clinical items and services are not negotiable. **Clinical items and services accommodate price increases for the years the study is open.**

Record Retention/Storage
An annual fee will be assessed for each year the study is open in IRB and/or the number of years the study needs to remain open per the sponsor and Emory requirements. This fee covers the cost of storing essential study documents in accordance with all institutional, study, and federal requirements.

Study Closeout Fee
The Study Closeout fee will be assessed at study closeout to cover the cost of closing out the study including, but not limited to, closing the IRB record, reconciling Case Report Forms (CRFs) and source documents, ensuring the study investigator binders are up to date, reconciling all study-related charges and payments, and scheduling a closeout meeting with the sponsor.

Emory Affiliate Sites
Studies conducted at Children's Healthcare of Atlanta (CHOA), Grady Health System, and other Emory-affiliated sites have clinical items/services, administrative fees and indirect cost rates that are included in the Emory budget in addition to the Emory fees. Some of those fees are, but not limited to, institutional administrative fees and IDS charges for drug studies conducted at those sites.

Prescreening/Subject Recruitment
There is an abundance of study team work to prescreen and recruit subjects prior to consent. This fee is assessed to cover study team effort to review physician schedules and medical records to determine if subjects can be eligible for consent. This fee also includes effort to provide sponsor screening log updates and communication.

Withdrawn Study Reimbursement

Emory will expect to be reimbursed for compensation for study team effort and administrative fees which have occurred during the Pre-Award process should the study not move forward **before** contract execution. These fees may include but are not limited to the cost of the study start-up fee, IRB fees, OCR CA Fee, Budget Development fee, Radiology Fee, Treatment Order Set(s) Development Fee, regulatory support software, and other external fees (e.g., IRB) paid by Emory.

Safety Reports

An **Investigational New Drug** (**IND) Safety Report fee will be assessed for each IND safety report** reviewed by the PI and reported to the sponsor.

Each **Serious Adverse Event (SAE), Unanticipated Adverse Device Event (UADE)** or **Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO)** will incur a fee for the documentation required per the study reporting requirements for the initial and follow-up documentation conducted by the study team. The fee includes the time for each SAE, UADE or UPIRSO and includes staff time for both the initial review and follow-up.

Monitoring Fees

An hourly monitoring fee will be assessed **per** study monitor to cover the study staff's time for both **in-person and/or remote monitoring visits,** which includes, but is not limited to, the preparation and scheduling by the study team, review of data, copying and de-identifying study records, sending study records to the sponsor, and data queries for the monitoring visit.

There will be an additional charge for each **study monitor personnel change** to compensate for the study team for acquainting a new monitor to the site, systems, procedures, etc., and to compensate for re-work on subjects/visits that are already cleaned and for re-resolution of resolved queries.

Should an **FDA or sponsor audit** occur, an hourly fee will be assessed for **each** study monitor to cover the study staff's time for the preparation and scheduling by the study team, and review of data to prepare for the audit.

Screen Failures

If **screen failures** occur, sponsors are charged for the screening visit total, or a proration of procedures performed for that study visit up to the negotiated screening visit total.

Translation and Interpretation Services

Translation of the informed consent and interpretation of the protocol required services may be needed for those patients where a language other than English is needed to fully understand the research study consent and services. An hourly fee is applied for the **Translation and Interpretation Services**, if needed.

APPENDIX – Fee Schedule, With Facilities and Administrative Rate Applied

Emory University Facilities and Administrative Fee Rate	**35%**
Study Start-Up	$12,150
Coverage Analysis	$6,750
Coverage Analysis – Amendment	$2,700
Budget Development	$8,100
OnCore Initial Setup	$5,400
OnCore Amendment	$2,025
Institutional Review Board (IRB) Submission	$6,075
IRB Renewal	$3,375
IRB Amendment	$1,350
Investigational Drug Service (IDS) Activation	$3,500
IDS Maintenance	$200 per month
IDS Closeout	$750
Radiology Processing and Authorized Users	$1,500
Precision Imaging Metrics	$540 per assessment of response criteria
Emory ClinicalTrials.gov Service Center Fee (PI-initiated only)	$5,400
Reconsenting	$270 per research participant
GCRC	Emory GCRC Rates
Treatment Order Set Development	$2,025
Winship Phase I Unit/Infusion Center Research Bay	$135 per hour
eRegulatory Software	$4,050 at initiation, $1,755 annually
DSMB Monitoring	$135 per hour per monitor
Record Retention/Storage	$675 annually
Study Closeout Fee	$4,050
Withdrawn Study	$16,200
IND Safety Report	$50 each
SAE, UADE, or UPIRSO	$475 each
Monitors	$150 per hour per monitor
Study Monitor Personnel Change Fee	$1,000 per change
FDA or Sponsor Audit	$135 per hour per monitor
Interpretation & Translation Service	$405 per hour