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| Research Financial Clearance Form |
| **About Financial Clearance:** |
| Financial Clearance is required for all studies conducted within the Grady Health System. The requirement for Financial Clearance is independent of study funding or intended patient contact. This process enables the Office of Grant Administration (OGA) to evaluate a study’s proposed conduct as it involves the use of Grady’s resources and services. Financial Clearance review also encompasses the use of equipment and investigational products or devices. **OGA FINANCIAL CONSULTATION**: If Grady fee information for billable items/procedures/services or for the use of Grady resources is required, contact OGA prior to completing this form. The study’s clinical requirements at Grady must be pre-determined by the PI.**Submission Information by Category:*** **Initial and Renewal Submission.** Financial clearance approval is required to commence or continue the conduct of a study. The provision of a current IRB expiration date is required for processing an Initial and Continuing Review.
* **Amendment Submission.** Financial clearanceapproval is required for a proposed amendment when the proposed amendment changes information provided on the previously approved *Financial Clearance Form* *(FCF)* or any component of the study’s conduct that is pertinent to the financial clearance process.

***Note:*** Submission for Financial Clearance is not required for changes to data collection forms and advertisements; and for the addition of personnel not related to financial processes. In these instances, you must copy OGA (grants@gmh.edu) on the ROC submission email and include the text *“This amendment is not applicable to Financial Clearance.”* OGA will provide written confirmation or request a formal submission if applicable.* **Study Completion Submission.** Submission for Financial Clearance is not required at the time of study completion. To notify OGA of study completion, submit a copy of the IRB Notification of Close-Out document. OGA also requests timely notification of approaching study completion to allow for verification that all financial responsibilities have been met.

**Financial Clearance Review & Approval:*** **For Review, submit a complete Financial Clearance Application Packet** (Packet)**.** A complete Packet includes the *FCF*, study protocol and applicable support documents (see below).OGA provides a preliminary review for research that requires a fee assessment, includes billable items/services.
* **Institutional Review Board (IRB) approval is required to obtain Financial Clearance.**
* **The review process** **takes** **7-10 business days after OGA receives a complete Financial Clearance Application Packet**. Submissions to OGA and the ROC can occur concurrently by including both offices in the email.
* **Financial Clearance Approval** is disseminated by email to persons in the Contact Section of this form and ORA (research@gmh.edu). With approval, OGA provides study specific comments that include, but are not limited to, operationalization guidance; billable activity reporting requirements; and potential fees for services.
* **The Financial Clearance Approval Document is a required component of the Research Oversight Committee (ROC) Application.** ROC approval will not be granted without Financial Clearance.

*OGA forms are available on the* [*OGA Webpage*](http://www.gradyhealth.org/static/office-of-grants-administration)***~*** *Contact OGA at* *grants@gmh.edu* *with questions* |
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| **SUPPORT DOCUMENT LIST** | **INITIAL REVIEW** | **CONTINUING REVIEW** | **AMENDMENT** | **STUDY****CLOSURE** |
| **Study Protocol***A current version of the protocol must remain in the OGA file* | **Required** | **Required** | **Required**if Amended | **N/A** |
| **IRB Approval Document**  | **Required** | **Required** | **Required** | **Required** |
| **IRB Submission Document(s)***See the ORA ROC Application for details* | If Requested | **Required** | **Required** | **N/A** |
| **Informed Consent Form**  *Required if participants will consent* | **Required** if Applicable | If New or Amended | If Applicable | **N/A** |
| **List of Clinical Procedures/Services** *(i.e., itemized budget or PRA) Required if there are Grady billable or SOC items, services or procedures* | **Required** if Applicable | If New or Amended | If Applicable | **N/A** |
| **Grady Pharmacy Estimate for IDS** *Required if there are investigational drug services (IDS) at Grady* | **Required** if Applicable | If New or Amended | If Applicable | **N/A** |
| **Research Equipment Questionnaire** *Required if non-Grady equipment will be used on Grady's campus* | **Required** if Applicable | If New or Amended | If Applicable | **N/A** |
| **Clinical Trial Agreement / Subcontract** *Required if GHS is being subcontracted* | If Applicable | If New or Amended | If Applicable | **N/A** |
| **Investigational Product, Device & Supply Approval***This approval is obtained from the Grady Value Analysis (VA) Committee. Refer to the “OGA Product-Device Tip Sheet” for instructions.* | If Applicable | If New or Amended | If New or Amended | **N/A** |

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| Research Financial Clearance Form |
| **Instructions:** |
| 1. **Provide Typed responses only. Questions indicated as “required” must have a response.**
2. **Submit a complete Financial Clearance Application Packet to** **grants@gmh.edu****.** A complete Packet includes:
* The Financial Clearance Form in MSWord format
* The Study Protocol
* Support documents. See the *Support Documents List* for guidance*.*
1. **Allow 7-10 business days for** **processing**

***Note:*** *Submissions that are not in accordance with the Instructions will be returned without review*  |
|  |
| **Check the Applicable Submission Categories & Complete the Appropriate Sections of this Form: *\*Required*** |
| **[ ]  Initial Submission:**  | **Complete Sections I – III.** Section I-III completion is required for **ALL** subsequent submission types. |
| **[ ]  Amendment Submission:** | **Complete Section IV. Review Sections I-III for accuracy and completeness.** Only update Sections of this Form that are applicable to the amendment. |
| **[ ]  Annual Renewal:** | **Complete Section V & Provide the Current IRB Expiration Date. Review Sections I-III for accuracy and completeness.** Do not update data in Sections I – IV or Attachment A if an amendment is not being submitted. |
| **[ ]  Study Completion:** | **Submission for Financial Clearance is not required.** Provide a copy of the IRB Notification of Close-Out document. |
|  |
| **SECTION I - Study Information** |
|  |
| **General Information** |  |
|  **IRB Number:** |       ***\*Required*** | **Current IRB Expiration Date:**  |       ***\*Required*** |
|  **[ ]  N/A if an *IRB Exemption* was granted. Please provide the IRB Determination Letter** |
|  **Full Study Title:** |       |
|  **Study Acronym:** |       |
|  **Funding Source:** | [ ]  Not Funded  | [ ]  Federal | [ ]  Industry | [ ]  Foundation / Non-Profit  |
|  | [ ]  Other:       |
|  **Sponsor Name:** |       |
|  |
| **Contact Information**  |
| **Requesting Organization:** | [ ]  Grady [ ]  CHOA [ ]  Emory [ ]  GSU [ ]  Morehouse [ ]  Other:       |
| **Principal Investigator** |  |  |  |
| Name: |       | E-mail: |        | Phone: |       |
| **Research Coordinator** |  |  |  |
| Name: |       | E-mail: |       | Phone: |       |
| **Other** *(Specify Title):*      |
| Name: |       | E-mail: |       | Phone: |       |
| **Grady Based Investigator:** ***\*Only required for Non-Grady Affiliated PIs*** | Name:      | E-mail: |       |
| **Affiliate Institution’s Study Acct. Mgr:*****Only required for research with Grady Billables*** | Name:      | E-mail: |       |
| **Financial clearance approval, invoices, and other official communication will only be distributed to individuals listed above.**  |
|  |
| **Study Type** |
| ***Instructions:*** *Choose the most applicable research category below. The choice should correspond with the study type indicated in the Protocol, IRB submission, and ROC Application Form.****Note:*** *Some categories are inclusive of several types of research activities.* *For example, a clinical research study involves data collection, a survey, and tissue collection you would* ***only*** *check “Clinical Research.” A study will look at medical records with no patient interaction,* ***only*** *check Data and provide inclusion dates.* |
| [ ]  Clinical Trial – NCT#       ***\*Required***[ ]  Clinical Research – NCT#       *(If Applicable)*[ ]  Qualitative/Quantitative/Observational Research | [ ]  Data Only Study *(i.e., medical record review or data retrieval)*Data collection inclusion dates: from       to       ***\*Required***[ ]  Tissue / Sample Collection *(No participant interaction)* |
| [ ]  Survey / Questionnaire [ ]  Registry [ ]  Public Health Surveillance | [ ]  Humanitarian/Emergency Use Device, specify #      [ ]  Other:        |
|  |
| **Study Details: Enrollment & Research Location Information** |
|  **Estimated Enrollment at Grady** *(also CHOA-HS)*:     *\*****Required*** ***Definition****:* **Enrollment refers to** participants; the number of charts, data sets and/or specimen. A study with undetermined enrollment should provide an approximate enrollment in a year. | **Anticipated Study Completion Date:**       (mm/yyyy) *\*****Required*** **Note:** A study is considered complete when the study conduct and data analysis has ended (i.e. a 4 year study that begins in 01/2018 has an anticipated completion date of 01/2022). |
|  **Indicate the Grady Location(s) where participants will be seen:** |
| [ ]  Not Applicable *(There is no direct participant interaction)* [ ]  Main Hospital *(Specify the location below)*  Floor or Unit:       *\*****Required*** Department:       *\*****Required***[ ]  GCTSA / ACTSI (Grady Satellite only)  | [ ]  Infectious Disease / Ponce de Leon Center (IDP)[ ]  Neighborhood Clinic, specify:      [ ]  CHOA – Hugh Spalding[ ]  Other, specify:        |
|  **Will the majority (50% or more) of research/study activity be performed at a Grady location?** [ ]  Yes |
| [ ]  No  | ***If No,*** indicate the types of activity that will occur at Grady:  |
|  | [ ]  Recruitment Only |  |
|  | [ ]  Recruitment, Enrollment and/or Screening |  |
|  | [ ]  Specimen collection/retrieval (i.e., blood, tissue, other) by PI/ Research Staff |
|  | [ ]  Other, specify:       |
|  |  |  |  |
| **Subcontracts & Agreements**  |  |
| **Will a subcontract or other contractual agreement between the Sponsor and/or the PI’s Institution and Grady be required for the conduct of this study?**   [ ]  Yes ***If Yes,*** please contact *OGA (**grants@gmh.edu**) to initiate the process* [ ]  No [ ]  Unknown  |
|  |
| **Comments:** Provide additional comments or clarification for Section I |
|       |
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| **SECTION II - Equipment, Products, Devices & Supplies** |
|  |
| ***IMPORTANT:*** *Grady Departmental and/or Committee approval is required for the use of equipment, medical products, a device, and supplies in research. If a Contract or Agreement is required, please notify OGA.* |
| **Does the study protocol specify the use of medical equipment, a product, device, and/or supplies (an ‘Item’)?** |
| [ ]  No | ***If No,*** **Skip to** **Section III**  |
| [ ]  Yes | ***If Yes,*** Indicate the Item(s) below, respond to statements, and follow the directions to obtain approval. ***Note:*** The list of Items continues on page 3.  |
| [ ]  **Non- Grady Medical Equipment** |
|  | Item Name:      The Item will be stored at Grady: [ ]  No [ ]  Yes ***If Yes,*** specify Clinical Department:      The Item will be obtained as follows: [ ]  Purchased [ ]  Sponsor Provided/Free [ ]  On Consignment  [ ]  Other, specify:       Refer to the *OGA Research Equipment Form* for Grady inspection/tagging instructions. |
| [ ]  **Grady Approved Medical Equipment** *(i.e., equipment currently approved for use at Grady)* |
|  | Item Name:      Indicate the Grady Clinical Department that is responsible for the Item:       |
| [ ]  **Non- Grady** **Medical Product or Device** *(FDA Approved or Investigational)* |
|  | Item Name:      The Item will be obtained as follows: [ ]  Purchased [ ]  Sponsor Provided/Free [ ]  On Consignment  [ ]  Other, specify:       Refer to the *OGA Research Product /Device Tip Sheet* for submission and approval instructions. |
|  |
| [ ]  **Grady** **Medical Product or Device** *(i.e., an Item currently approved for use at Grady)* |
|  | Item Name:      Grady Catalog Number:      *\*****Required*** *Obtain the catalog number from the Grady Clinical Department where the Item is used.*Submit the product/device Manual with this Form to facilitate verification that the research and Grady Item are identical. |
| [ ]  **Handheld or Personal Use Device** *(e.g., iPad, pedometer, glucometer)* |
|  | Item Name:      The Item will be stored at Grady: [ ]  No [ ]  Yes ***If Yes,*** specify Clinical Department:      The Item will be obtained as follows: [ ]  Purchased [ ]  Sponsor Provided/Free [ ]  On Consignment  [ ]  Other, specify:        |
| [ ]  **Disposables and other Supplies** *(other than supplies obtained through Clinical Pharmacy)* |
|  | Item Name:      The Item will be stored at Grady: [ ]  No [ ]  Yes ***If Yes,*** specify Clinical Department:       |
|  |
| **Comments:** Provide additional comments or clarification for Section II |
|       |
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| **SECTION III - Ancillary Services, Resource Use & Billable Procedures** |
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| **Grady Ancillary Services / Resource Use**  |
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| **Does this study require Grady services or the use of resources that are not directly billable to the patient?*****Note:* *(\*\*)*** *indicates that fees may apply for the service or resource use.* |
| [ ]  | **No.** Skip to Billable Procedures/Services  |
| [ ]  | **Yes. *If Yes,*** Indicate the services and/or resources below  |
| [ ]  | **Grady Nursing / Patient Care Services.** All research studies involving Grady Nursing services must be submitted to the Nursing Research Committee. Refer to the ROC Application Form for additional information.*Note: Support services provided by Grady Nurses are not synonymous with services provided at GCTSA/ACTSI.* |
| [ ]  | **Use of Departmental Space or Clinical Staff.** |
|  | GradyClinicalDepartment:       *\*****Required*** |
|  | **Grady** Department Administrator Name:       *\*****Required Note:*** This person is not the Chief of Service |
|  | Specify the space request***\*\**** (e.g. room 2b2):        |
|  | Specify Grady Staff participation requirements (e.g., study-specific training, etc.):        |
| [ ]  | **Data Extraction and Reporting.** Data extraction and Reporting services are provided by the Grady Business & Clinical Intelligence (BCI) Department***\*\****. Refer to the ROC Application Form for additional information. |
| [ ]  | **Medical Records or Imaging CD Request.** Medical records and CD requests are processed by Grady Health InformationManagement (HIM) Department***\*\****. Refer to the ROC Application Form for additional information.*Note:**BCI and HIM services are not synonymous with the extraction of patient data from Epic by the PI/Research team.*  |
| [ ]  | **Other**, specify (e.g., patient billing data):      |
|  |
| **Comments:** Provide additional comments or clarification regarding ancillary services or resource use |
|       |

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| **Billable Procedures & Services** |
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| ***DEFINITIONS:*****A Billable Procedure/Service** is performed at the patient level. It includes but is not limited to clinical and pharmacy services. These procedures/services are billed to the Sponsor or Insurance as agreed upon.**A Grady Billable Procedure/Service** is invoiced by OGA to the Sponsor or billed to the participants’ Insurance by GHS (i.e., for Routine/Standard of Care services). **A Grady Non-Billable Procedure/Service** is provided, processed and invoiced by a Grady related site (e.g., CHOA-HS or Grady GCTSA). Emory or MSM billable activity is EXCLUDED from this. **Current Procedural Terminology (CPT)** is a system developed for standardizing the terminology and coding used to describe medical procedures, services and supplies. *CPT is a registered trademark of the American Medical Association (AMA).***Charge Description Master (CDM)** (i.e. service item or procedure master) is a “master” table file that contains the basic elements for identifying, coding and pricing any item that may be provided to patients, including procedures, services and supplies. |
|  |  |
| 1. **Does this study include billable procedures or services?**
 |
| [ ]   | **No** | **STOP.** You have completed this Form unless this submission includes an Amendment or Annual Renewal (Sections IV & V).  |
| [ ]  | **Yes** | ***If Yes,*** provide a response to the questions below.  |
|  |
| 1. **Does this study include Grady non-billable procedures or services at a Grady related site?** [ ]  No [ ]  Yes
 |
|  | *If Yes,* indicate the service Category and Grady related site location where it will be performed:Category: [ ]  Clinical [ ]  Pharmacy Location: [ ]  Grady GCTSA/ACTSI [ ]  CHOA-HS [ ]  Neighborhood Clinic, specify:       |
| 1. **Does this study include Grady Pharmacy or Investigational Drug Services (IDS)?** [ ]  No [ ]  Yes
 |
|  | *If Yes,* check all applicable responses below. |
| [ ]  | This study requires GradyInvestigational Drug Services. **Please request a *Pharmacy Estimate* from Grady IDS and submit it with this Form.** |
| [ ]  | This study involves an Investigational New Drug (IND). Provide the IND Number:        |
| [ ]  | This study requires other pharmacy services (i.e., purchase or distribution of supplies). Specify:       |
| 1. **Does this study require Grady’s Laboratory to provide study specific (novel) services?** [ ]  No [ ]  Yes
 |
|  | *If Yes,* check all applicable responses below. An agreement for specialty services and its associated fees are provided after consultation. *Note: These services are different from services captured in Attachment A.* |
| [ ]  | Phlebotomy, collection only. No Grady processing or storage required.  |
| [ ]  | Specimen collection/retrieval (i.e., blood, tissue, other). specify:      |
| [ ]  | Special specimen processing and/or storage. specify:       |
| *Note: Services provided by Grady’s Laboratory and personnel are not synonymous with services requested from GCTSA/ACTSI. Specialty services* ***exceed*** *the routine services captured on Attachment A.*  |
| 1. **Does this study include clinical procedures or services that are identified with a CPT code?**
 |
| [ ]   | **No** | *If No,* You have completed this Form |
| [ ]  | **Yes** | ***If Yes, check all applicable responses below AND* complete *Attachment A*** *– Billable Procedures/ Services* |
| [ ]  | This study includes procedures/services that will be billed to the Sponsor. |
| [ ]  | This study includes procedures/services that have been verified by the PI’s Institution as being billable to a Third Party Payer *(i.e., Medicare/Medicaid or a Health Insurance Provider).* |
|   | *Note:* *If procedures/services identified as* *being billable to Insurance are not “routine clinical services” at Grady the cost of the services are billable to the Sponsor.* |
| [ ]  | This study includes procedures/services that occur in the following hospital setting *(check all applicable)*:[ ]  during In-patient stay [ ]  Out-patient |
| [ ]  | This study includes procedures/services that will generate Professional Fees (e.g., Reading an MRI, EEG). *Note:* ProFees are billed by Emory Medical Care Fdn (EMCF). |
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| **Comments:** Provide additional comments or clarification regarding the billable procedures or services for this study |
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| **SECTION IV - Amendment** |
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| **Amendment Information**  |
| **Indicate the sections of this Form that include amended information:**  [ ]  **NA** [ ]  **Section I** [ ]  **Section II** [ ]  **Section III** [ ]  **Attachment A – Billable Procedures/Services** ***Note:*** *Provide the IRB approval document and other applicable support documents for processing.* |
| **Provide a summary of the amendment and a statement about its applicability to the study’s conduct at Grady.** [Amendment Text - Example 1](#AM1" \o "Amendment 1 updates the study protocol (information only) and recruitment flyers .  The amendment does not change the conduct of the study at Grady. ) [Amendment Text - Example 2](#AM2" \o "AM 2 changes the data collection inclusion dates.  The date has been changed in Section I. ) [Amendment](#AM3) Text - Example 3 |
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| **SECTION V - Annual Renewal** |
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| **Annual Renewal Information** |
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| **The current IRB Expiration date is** [**required**](#IRBx) **on page 1.****What is the current enrollment at Grady?**       \****Required with every renewal****‘Enrollment’ refers to the number of participants; charts that have been reviewed; specimen and/or samples that have been collected.* *Note:* *Enrollment information is also required for research that occurs at CHOA-HS.* |
|  |
| 1. **Indicate the current study status:** *(Check* ***All*** *applicable descriptors)*
 |
| [ ]   | **Ongoing** *(i.e., enrollment, data collection continues)*  | [ ]  **Closed to Enrollment**  |
| [ ]  | **Continuing for Participant Follow-up only**  |  |
| [ ]  | **Data Analysis Phase** (i.e., Participant visits are complete; no additional data is being collected, and the research protocol is closed to enrollment) |
| [ ]  | **Complete.** Submission for Financial Clearance is not required. Provide a copy of the IRB Notification of Close-Out document. |
| 1. **Does this study include IDS/Pharmacy or Clinical procedures/services?** [ ]  Yes [ ]  No

*If Yes,* Check all applicable responses below. |
| [ ]  | **I Certify that there are NO changes to the previously approved IDS/Pharmacy and/or Clinical procedures/services.** ***STOP.*** *You have completed this form.* |
| [ ]  | **I am submitting an Amendment to update previously approved IDS/Pharmacy and/or Clinical procedures/services.***Refer to instructions on Attachment A to amend clinical procedures/services.* |
| [ ]  | **Participants’ Clinical Visits are Complete.** **Note:** The procedures/services for this study will be removed from the FCF and the study’s Epic profile. |
| [ ]  | **Participants’ IDS or Pharmacy Services are Complete** **Note:** You will continue to receive Pharmacy Invoices until you have provided IDS with official notification. Pharmacy services are not complete until a Final Invoice has been issued. |
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| **Comments:** Provide additional comments or clarification for Sections IV or V |
|       |
|  | **Please review the data provided on this form for accuracy.** |

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| **Financial Clearance Disclaimer** |
| This Financial Clearance is being granted based on the information provided to Office of Grant Administration by the Study’s Principal Investigator (PI) or his/her designee. It is the PI’s responsibility to submit a revised Financial Clearance Application Packet in the event that the above information changes, particularly with modifications to contact persons, funding, billable items/procedures/services, and the utilization of Grady resources (staff, supplies, equipment, products/devices, etc.). The Sponsor is responsible for payment of ALL research-related procedures/services charged to patient accounts; Investigational Drug or Pharmacy Service, and other ancillary service fees.  |
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| **OFFICE OF GRANTS ADMINISTRATION USE ONLY** |

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| **Other Costs & Fees** |
| **[ ]** Investigational Drug Services Estimate Dated        | **[ ]** Estimate Attached**[ ]** Previously Provided |
| **[ ]** BCI Data Extraction: Ticket        | Fee for Service:       $      |
| **[ ]**        | $      |
|  |  |
| **Grady Payor Code:** |  |  |
| **OGA Approver:** |       |
| **Approval Date / Type of Review:** |       |
| **OGA Comments:** |       |

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| **ATTACHMENT A****Clinical Billable Procedures / Services** |
| **Instructions:** Indicate the applicable Submission Category and follow the directions carefully |
| [ ]  | **New Submission**  **Provide the following information for each clinical procedure or service:*** Provide the CPT Code and the accepted Descriptor for each procedure/service.

Instructions: If you or your Institution consulted with OGA about this study’s billable items please use the list of procedures/services and CPT codes agreed upon based on Grady’s CDM. Only add items that may have been omitted in consultation. * Check “Insur” (i.e., Insurance) if the procedure/service is billable to Insurance/Medicare/Medicaid. Customarily these procedures/services are considered “Routine” or “Standard of Care” (SOC).

*Note:* It is the responsibility of the PI/designee to provide Institutional or Departmental verification that a procedure/service is SOC at Grady and billable to a third-party. Procedures/services that can not be verified as billable to a third-party will be invoiced for Sponsor payment. Consult with OGA for guidance.* Provide the Quantity per person.

Instructions: If the study includes a procedure/service that will initially occur as a billable to the patient’s Insurance and then to the Sponsor based on allowable quantities, indicate the quantity for Insurance then the quantity for the Sponsor. For example, the study requires lab A to be drawn 6 times/per person for diagnosis *X*. The first four (4) labs are routine for this diagnosis and covered by Insurance and the remaining 2 labs, which are research specific, are billable to the Sponsor. This would be indicated as 4 / 2 in the Quantity column.**The EAP and Price Per Unit data is provided by GHS.** Do not populate these columns even if the data was provided previously. |
| [ ]  | **Amendment Submission****ONLY provide information for procedures/services that are being added or removed.** * To add a new procedure/service, provide the CPT code, Description, Insurance allocation (if applicable) and Quantity/person.
* To increase or decrease the quantity for a procedure/service, indicate the new quantity.
* To delete a procedure/service indicate “0” for the quantity.

**OGA Administrative Amendment Notification:** OGA will provide notification and a revised Financial Clearance for amendments initiated by changes in Grady’s standard clinical practices. Administrative amendments should be communicated to the Affiliate Institution’s Account Manager to ensure payment of charges. |
|  |
| **CPT Code** | **Procedure/Service Descriptor** | **Insur** | **Quantity** ***(Per Subject)*** | **EAP Code****(OGA Use Only)** | **Price per Unit****(OGA Use Only)** |
|       |       | **[ ]**  |       |       |       |
|       |       | **[ ]**  |       |       |       |
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