|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Research Financial Clearance Form | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **About Financial Clearance:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Financial Clearance is required for all studies conducted within the Grady Health System. This requirement is independent of study funding or intended patient contact. Financial review enables the Office of Research Administration (ORA) to evaluate a study’s proposed conduct as it involves the use of Grady’s resources and services; and, as applicable, equipment and investigational/ medical products or devices.  **FINANCIAL CONSULTATION**:  To obtain Grady clinical fee information or information for the use of Grady resources, email [researchfinance@gmh.edu](mailto:researchfinance@gmh.edu). The study’s requirements for clinical services at Grady must be pre-determined by the PI to facilitate the consultation.  **Submission Information by Category:**   * **Initial and Renewal Submission.** Financial clearance approval is required to commence or continue the conduct of a study. A response to the IRB expiration date question is required for processing. * **Modification Submission.** Financial clearanceapproval is required for a proposed modification when the modification 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. This is a formal submission for review/approval.   ***Note:*** ORA Finance allows for an “informal” submission for changes to data collection forms and advertisements; and for the addition of personnel not related to financial processes. In this circumstance, copy [researchfinance@gmh.edu](mailto:researchfinance@gmh.edu) on the ROC submission email and include text about to substantiate the information submission. Written acknowledgement will be provided if the informal submission is accepted, or a formal submission will be requested.   * **Study Completion.** For study completion, only provide a copy of the IRB Notification of Close-Out document. Timely notification of approaching study completion is requested to allow for verification that all financial responsibilities have been met.   **Financial Clearance Review & Approval:**   * **To initiate Financial Clearance review submit a complete Financial Clearance Application Packet** (Packet)**.** A complete Packet includes the *FCF*, study protocol and applicable support documents (see below). * **Institutional Review Board (IRB) approval is required to obtain Financial Clearance.** * **The review process** **takes** **10-14 business days after a complete Financial Clearance Application Packet recieved**. Submissions for Financial Clearance and to 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 to the ROC ([research@gmh.edu](mailto:research@gmh.edu)). Please pay special attention to study specific comments provided in the ORA Comments Section. Comments 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.   *Financial forms are available on the* [*ORA Webpage*](mailto:ORA%20Webpage)***~*** *Contact ORA Finance at* [*researchfinance@gmh.edu*](mailto:researchfinance@gmh.edu) *with questions* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **SUPPORT DOCUMENT LIST** | **INITIAL REVIEW** | **CONTINUING REVIEW** | **MODIFICATION** | **STUDY**  **CLOSURE** | | **Study Protocol**  *A current version of the protocol must remain in the ORA FINANCE 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* | **Required** | **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 “ORA Finance Product-Device Tip Sheet” for instructions.* | If Applicable | If New or Amended | If New or Amended | **N/A** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Instructions:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Provide typed responses only. Questions indicated as “required” must have a response.** 2. **Submit a complete Financial Clearance Application Packet to** [**researchfinance@gmh.edu**](mailto:researchfinance@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 10-14 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.** These sections should remain complete for **ALL** subsequent submissions. | | | | | | | | | | | | | | | | | | | | | | |
| **Modification Submission:** | | | | | | | | | | | | | | | | | | | | **Complete Section IV. Only update the Sections of the Form that are applicable to the modification.** Review Sections I-III for accuracy and completeness. | | | | | | | | | | | | | | | | | | | | | | |
| **Annual Renewal:** | | | | | | | | | | | | | | | | | | | | **Complete Section V & Provide the Current IRB Expiration Date.**  Review Sections I-III for accuracy and completeness. ONLY update Sections I – III or Attachment A if a modification is being submitted with the renewal. | | | | | | | | | | | | | | | | | | | | | | |
| **Study Completion:** | | | | | | | | | | | | | | | | | | | | **Submission for Financial Clearance is not required.**  Provide a copy of the IRB Notification of Close-Out document to [research@gmh.edu](mailto:research@gmh.edu) and cc: researchfinance@gmh.edu. | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SECTION I - Study Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **General Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
| **IRB Number(s):** | | | | | | | | | | | | | | | ***\*Required*** | | | | | | | | | | | | ***Note:*** If review has been ceded, the IRB number for the IRB of note is required. | | | | | | | | | | | | | | | |
| **Current IRB Expiration Date:** | | | | | | | | | | | | | | | | | | | | | ***\*Required*** | | | | | | | | | | | | | | | | | | | | | |
|  | | | Indicate *“Exemption”* or *“Common Rule”* if the IRB approval document indicates either review type with no IRB Expiration date.The IRB approval letter is required to support the response to this question. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Full Study Title:** | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Study Acronym:** | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Funding Source:** | | | | | | | | | | | | | | | | Not Funded | | | | | | | | Federal | | | | | | | | Industry | | | | | | | Foundation / Non-Profit | | | |
|  | | | | | | | | | | | | | | | | Other: | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Sponsor Information:** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Contact Information *\*Required*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Principal Investigator Institution:** | | | | | | | | | | | | | | | | | | | | | | 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:** | | | | | | | | | | | | | | | | | | | | | | 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 | | | | | | | | | | | | | |
| 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***  See Definition below  ***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:**  See Note below  **Note:** A study is considered complete when the study conduct and data analysis has ended; and, IRB Closeout will be requested (i.e. a 4 year study that begins in 01/2022 has an anticipated completion date of 01/2026). | | | | | | | | | | |
| **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***  Georgia CTSA Clinical Research Centers (GCRC - Grady Satellite only) | | | | | | | | | | | | | | | | | | | | | | | | | | | | Infectious Disease / Ponce de Leon Center (IDP)  Neighborhood Clinic, specify:  CHOA – Hugh Spalding  Other Grady Location, specify: | | | | | | | | | | | | | | |
| **Will the majority (50% or more) of the research/study activity be performed at a Grady location?**  Yes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| No | | | | | | | | | | | | | ***If No,*** indicate the type(s) of study activity that **will** occur at Grady: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Recruitment Only | | | | | | | | | | | | | | | | | | | | | Enrollment | | | | | | | | | | | Screening | | | | | | |
|  | | | | Other, specify: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Specimen collection/retrieval (i.e., blood, tissue, other) by PI/ Research Staff  ***Note:***  Specimen collection/retrieval requires Departmental approval (see Section IIIA) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |  | | | | | | | | | |  | | |
| **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 *ORA Finance (*[*researchfinance@gmh.edu*](mailto:researchfinance@gmh.edu)*) to initiate the process*  No  Unknown | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Comments (SI):** Provide additional comments or clarification for Section I | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **SECTION II - Equipment, Products, Devices & Supplies** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ***IMPORTANT:*** *Approval from the Grady Department Leader (i.e.* Administrative or Executive Director*) and/or Departmental Committee is required for the use of equipment, medical products, a device, and supplies in research. A Contract or Agreement may be required.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **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 4. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Non-Grady Medical Equipment** *(i.e., equipment not currently approved for use at Grady)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | Refer to the *Non-Grady Medical Equipment Form* for Grady inspection/tagging instructions.  Item Name:  The Item will be stored at Grady:  No  Yes ***If Yes,*** specify the location:  The Item will be obtained as follows:  Purchased  Sponsor Provided/Free  On Consignment  Other, specify: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. **Grady Approved Medical Equipment** *(i.e., equipment currently approved for use at Grady)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | Item Name:  Indicate the Grady Clinical Department that is fiscally responsible for the Item:  Name and Title of the Grady Department Leader *(defined above):*  *Note:* Written acknowledgement/approval is required for Financial Clearance. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. **Non-Grady** **Medical Product or Device** *(FDA Approved or Investigational)*  Refer to the *Research Product /Device Tip Sheet* for submission instructions. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | Item Name:  The Item will be stored at Grady:  No  Yes ***If Yes,*** specify the location:  The Item will be obtained as follows:  Purchased  Sponsor Provided/Free  On Consignment  Other, specify: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. **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 research product/device manual with the FCF to facilitate verification that the research and Grady Items are identical. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. **Handheld or Personal Use Device** *(e.g., smart phone, 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: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6. **Disposables and other Supplies** *(other than supplies obtained through Clinical Pharmacy)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | Item Name(s):  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: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Comments (SII):** Provide additional comments or clarification for Section II | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | |
| **SECTION III - Ancillary Services, Resource Use & Billable Procedures** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Section IIIA Grady Ancillary Services / Resource Use** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Does this study require Grady services or the use of resources that are not directly billable to the patient?**  ***Note:*** *This section refers to activity that* ***exceeds*** *routine care, services and resource use. A written agreement/acknowledgement from Grady Leadership is required and* *fees may be applicable.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | **No.** **Skip to Section IIIB** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | **Yes. *If Yes,*** Indicate the required services and/or resources below | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. | | | | | | | | | **Grady Nursing / Patient Care Services.**  All research studies proposing the use of Grady Nursing services must be submitted to the Nursing Research Committee (NRC). Refer to the ROC Application-Section M for additional information.  *Note:* Support services provided by Grady Nurses are not synonymous with services provided at Grady GCRC/GCTSA/ ACTSI. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. | | | | | | | | | **Does this study propose novel or non-standard procedures/services in any of the following Grady Departments?**  No  Yes ***If Yes, check the service area(s) and provide a brief overview*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | Laboratory  Radiology  Pathology  Infusion Center  Cardiology  Other: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | Specify service(s): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | Grady Department Leader Name: | | | | | | | | | | | | | | | | | | | | | | | | | | | Agreement Date: | | | | | | | |
|  | | | | | | | | | *Note: Novel or non-standard services* ***exceed*** *the routine (CPT driven) services captured on Attachment A.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. | | | | | | | | | **Use of Grady Space, Participation of Clinical Staff, or other resource use** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | GradyClinicalDepartment where the study activity is proposed: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Grady Department Leader Name: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Specify the space request (e.g. room 2b2): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Specify Grady staff participation requirements (e.g., study-specific training): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Other, specify: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | | | | | | | | | **Data Extraction.**  If Grady data is required for this study, complete the *Research Data Request Form.* See the ROC Combined Forms.  *Note: Any study requiring a DICOM imaging node to reside outside the Grady network will require payment of $2,500.00 to Grady Information Technology before the work can be initiated.  DICOM nodes that reside on the Grady network, can be provided for no additional cost.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. | | | | | | | | | **Medical Records or Imaging CD Request.**  Medical records and CD requests are processed by the Grady Health InformationManagement (HIM) Department***\*\****. Refer to the ROC Application Form for additional information. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Note:*** *Data extraction (Q4) and HIM (Q5) services require formal requests to the appropriate departments and are not synonymous with the extraction of patient data from Epic by the PI and/or Research team.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6. | | | | | | | | | **Other**, specify (e.g., patient billing data, Radiology or other Departmental IT services): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Comments (SIIIA):** Provide additional comments or clarification regarding ancillary services or resource use | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Section IIIB Billable Procedures & Services** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | |
| ***DEFINITIONS:***  **A Billable Procedure/Service** is performed at the patient level. It includes, but is not limited to clinical and pharmacy services.  **A Grady Research Billable Procedure/Service** is paid by the study’s Sponsor, or determined to be billable to the participants’ Insurance (i.e., for Routine/Standard of Care services).  **Grady related sites** are a part of the Grady campus (i.e. GCRC-Grady (GCTSA/ACTSI), CHOA-HS and Neighborhood Clinics). Emory, MSM, or any affiliate academic buildings on Grady’s campus are EXCLUDED from this definition.  **Current Procedural Terminology (CPT) codes** are a part of an American Medical Association (AMA) system developed for standardizing the terminology and coding used to describe medical procedures, services and supplies. The CPT® codes and the related AMA Descriptor is required on the FCF. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | |
| 1. **Does this study include billable procedures or services?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | **No** | | | | | | | **STOP.** You have completed this Form unless this submission includes an Modification or Annual Renewal (Sections IV & V). | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | **Yes** | | | | | | | ***If Yes,*** provide responses to the questions below. | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Will this study be invoiced for procedures/services by any of the following Grady related sites?** (not ORA)   No  Yes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | *If Yes,* indicate the Service Category and Location where the procedures/services will be performed:  Service Category:  Clinical  Pharmacy  Location:  Grady GCRC  CHOA-HS  Neighborhood Clinic(s), specify: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Does this study include Grady Pharmacy/Investigational Drug Services (IDS)?**  No  Yes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | *If Yes,* check all applicable responses below. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | Grady Pharmacy/IDS services are required. **Request a *Pharmacy Estimate* from Grady IDS and submit it with this Form.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | This study involves an Investigational New Drug (IND). IND Number: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | This study requires other pharmacy services (i.e., purchase or distribution of supplies). Specify: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | This study includes procedures/services that will be paid by 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).* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | *IMPORTANT:* Provide your institution’s Determination Document (e.g. PRA, Clinical Procedure List)  *Note:* *If procedures/services identified as* *being billable to Insurance are determined not to be “routine clinical services” the cost of the services are billable to the Sponsor.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | This study includes procedures/services that occur in the following setting *(check all applicable)*:  Hospital during In-patient stay  Out-patient (e.g. hospital, IDP)  CHOA-HS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | This study includes procedures/services that will generate Professional Fees (e.g., Radiology, Cardiology, Pathology services etc).  *IMPORTANT:* Professional Fees are not captured on this document or invoiced by Research-Finance. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Comments (SIIIB):** Provide additional comments or clarification regarding the billable procedures or services for this study | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | | |
| **SECTION IV - Modification** | | | | |
|  | | | | |
| **Modification Information** | | | | |
| **Indicate the Section(s) of the FCF that will include amended information:**  **NA/Other**  **Section I**  **Section II**  **Section III**  **Section IV**  **Attachment A**  ***Note:*** *The IRB approval document and other applicable support documents are REQUIRED for processing.* | | | | |
| **Provide a summary of the modification and a statement about its applicability to the study’s conduct at Grady.** | | | | |
|  | | | | |
|  | | | | |
| **SECTION V - Annual Renewal** | | | | |
|  | | | | |
| **Annual Renewal Information** | | | | |
|  | | | | |
| **A Renewal submission must include:**   1. A current IRB Expiration date response (page 1); 2. Renewal Support Documentation; and   3) Responses to the questions below.   1. **What is the current cumulative enrollment at Grady** (*CHOA-HS*)**?**       \****Required with every renewal***   *‘Enrollment’ refers to the number of participants; charts that have been reviewed; specimen and/or samples that have been collected.* | | | | |
| 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 (final)**  (e.g., Participant visits are complete; no additional data is being collected, and the research protocol is closed to enrollment) | | | |
| 1. **This study includes Grady IDS/Pharmacy services:**  Yes  No   **This study includes Clinical procedures/services:**  Yes  No  ***If Yes***to one or both services check all applicable responses below. | | | | |
|  | | **I Certify that there are NO changes to the previously approved Pharmacy and/or Clinical procedures/ services.**  ***STOP.*** *You have completed this Form.* | | |
|  | | **This submission includes an modification to the previously approved Pharmacy and/or Clinical procedures/ services.**  *To amend IDS/Pharmacy services contact your provider to obtain an updated Pharmacy Estimate.*  *To amend clinical procedures/services refer to instructions on Attachment A.* | | |
|  | | **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’ 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. | | |
|  |  | | | |
| **Comments (SV):** Provide additional comments or clarification for Sections IV or V | | | | |
|  | | | | |
|  | **Please Review The Data Provided On This Form For Accuracy.** | | | |

|  |
| --- |
|  |
| **Financial Clearance Disclaimer** |
| This Financial Clearance is being granted based on the information provided to the Office of Research Administration by the Study’s Principal Investigator (PI) or the 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/Pharmacy Services, and other ancillary service fees.  Any patient care or operational procedures not covered or disclosed under the study protocol submitted to and approved by the Office of Research Administration shall be governed by the applicable Grady policy and/or procedure. |
|  |
| **OFFICE OF RESEARCH ADMINISTRATION USE ONLY** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Grady Payor Code:** |  | | |  |
| **Financial Clearance Approver:** | | |  | |
| **Approval Date/Type of Review:** | | |  | |
| **Approval Comments:** | |  | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ATTACHMENT A**  **Clinical Billable Procedures / Services** | | | | | | |
| **Instructions:** Indicate the applicable Submission Category and follow the directions carefully | | | | | | |
|  | **New Submission**  **The PI/designee is responsible for providing data for the first 4 columns below.**   1. Provide the CPT Code(s) for each procedure/service. Each item must be on a separate line. 2. Provide the accepted descriptor for each procedure/service.   Instructions: If you or your Institution received consultation 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.   1. Check “Insur” (i.e., Insurance) if the procedure/service is billable to a Third Party Payor (i.e. Insurance/Medicare/ Medicaid). Customarily “Insur” procedures/services are labeled “routine” in the protocol.   *IMPORTANT:* It is the responsibility of the PI/designee to provide Institutional or Departmental verification that a procedure/service is routine 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.   1. Provide the Quantity per person for their participation in the entire study. Delineate between Insurance and Sponsor quantities.   Instructions: If the study includes a procedure/service that will occur as billable to the patient’s Insurance and to the Sponsor, indicate the quantity for Insurance then the quantity for the Sponsor (e.g. # **/** #).  ***For example,*** the study requires lab A to be drawn 6 times/per person for diagnosis *X*. The first four (4) labs are routine and covered by Insurance and the remaining 2 labs are billable to the Sponsor. This would be indicated as 4/2 in the Quantity column with “Insur” checked.  **The EAP and Price Per Unit data is provided by GHS.** Do not populate these columns unless this information was provided during consultation. | | | | | |
|  | **Modification Submission**  **ONLY provide information for procedures/services that are being added or removed.**   1. To add a new procedure/service, provide the CPT® code and Descriptor; Insurance allocation (as applicable), and the quantity/person. 2. To amend the quantity for a procedure/service, indicate the new quantity. 3. To delete a procedure/service indicate “0” for the quantity. | | | | | |
|  | | | | | | |
| **CPT Code** | | **Procedure/Service Descriptor** | **Insur** | **Quantity**  ***(Per Subject)*** | **EAP Code**  **(ORA Use Only)** | **Price per Unit**  **(ORA Use Only)** |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
| **CPT Code** | | **Procedure/Service Descriptor** | **Insur** | **Quantity**  ***(Per Subject)*** | **EAP Code**  **(ORA Use Only)** | **Price per Unit**  **(ORA Use Only)** |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
| . | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |
|  | |  |  |  |  |  |