|  |
| --- |
| Guidelines: * Please provide your **typed responses** on this *ROC Application Form* and submit along with applicable documents to research@gmh.edu. Written responses will not be reviewed.
* See page 6 for additional guidelines and instructions.
* ***Accepting only version November 2018 of the ROC Application Form***
 |
|  |
| **A.** | **Submission Categories**: *(Please check all that apply)*  |
|  | [ ]  **New Protocol:**  | **A study not previously reviewed by the ROC.** Please include all documents listed in the *Documents Section*, as applicable. Financial Clearance approval. |
|  | [ ]  **Renewal:** | **A study that has been previously approved by the ROC.** Please include the completed ROC Application Form, IRB Renewal Approval letter; the current IRB approved Informed Consent with date stamp; HIPAA Authorization; amended Lay Summary; Continuing Review Submission Form; and updates to any other IRB approved documents that have been renewed. Financial Clearance re-approval is required for ROC renewal.[ ]  **Please check here if the approved research is in the “Data Analysis” phase.**There is no study-related patient care or visits occurring; the research protocol is closed to enrollment; all patient visits are complete, including patient follow-up visits, and the IRB and ROC expiration dates will occur during this time.  |
|  | [ ]  **Modification:**  | **A study that has been previously approved by the ROC and contains amendments.** Please include the completed ROC Application Form, IRB “Request for Modification” form; IRB Approval letter for Modification; amended Lay Summary; any other documents that have been modified, approved and date stamped by the IRB. Provide an updated Financial Clearance form if applicable.**Check all that apply:** [ ]  Informed Consent [ ]  Protocol [ ]  Personnel [ ]  Other       |
|  | [ ]  **Study Closure:**  | **A study that has received officially closure notification by the governing IRB.** Provide the IRB Closure Letter to the Office of Research Administration (ORA). Notify the Office of Grant Administration (OGA) by copying grants@gmh.edu on the ROC submission email to assure all financial responsibilities are complete. If the study requires Pharmaceutical Services, the Grady Pharmacy should be notified so that no further fees can be incurred. |
|  | [ ]  **Reportable Event:** | **Events that are reported to the Sponsor and institutional IRB.** Reportable events are unanticipated problems involving risk to participants or others, non-compliance, safety reports.Please provide the IRB report. |
|  | **Documents**: **Check all documents that are included with the complete ROC Application submission**[ ]  ROC Application Form *(signed by the PI and appropriate Grady Chief of Service)***[ ]**  Financial Clearance *\*****Required*** *(see Section G).* **The status of the attached Financial Clearance Form is:**  [ ]  IRB Approval Letter *(Initial, Continuing Review or Modification)* [ ]  IRB Submission Form *(Initial, Continuing Review or Modification)*[ ]  IRB Approved Informed Consent Form *(Date stamp required)*[ ]  IRB Approved HIPAA Authorization [ ]  Research Protocol [ ]  Lay Summary[ ]  ORA Personnel Confirmation Form (*see Section I))*[ ]  EPIC Access Request Form (*see Section J))*[ ]  Research Data Request Form (*see Section K)*[ ]  Data Collection Forms *(e.g. Surveys, Questionnaires, Telephone Scripts)*[ ]  Advertisements *(e.g. Flyers, Brochures, etc.)* |
|  |  |
| **B.**  | **Study Information**: |
|  | IRB #:***(Required)*** |       | IRB Expiration Date:***(Required)*** |       |
|  | Institutional / Central IRB:  | [ ]  Emory [ ]  Morehouse [ ]  Other: |       |
|  |  |  |
|  | Study Title: |       |
|  |  |
| **C.** | **Principal Investigator(s)**: *(Person noted as “Principal Investigator” on the IRB Approval Letter)* |
|  | PI Name: |       |  |
|  | PI Institution: | [ ]  Grady [ ]  Emory [ ]  Morehouse [ ]  Other: |       |
|  | Department & Division: |       |  |
|  | Grady Based Investigator *(see page 6 for definition)*: |       |
|  | Grady Based Investigator Phone #: |       |  |
|  | Grady Based Investigator Email: |       |
|  |  |
| **D.** | **Contact Person**: *(Person to be notified for any questions, concerns, and of approval status)* |
|  | Name: |       | Phone #: |       |
|  | Email: |       | Pager #: |       | Cell#: |       |
|  |  |
| **E.** | **Locations of Patient Interaction / Enrollment**: *(i.e. Medical Clinic I, OBGYN, IDP, Pharmacy, etc.)* |
|  |       |
| **F.** | **Funding**: |
|  | **Is this study is funded?** [ ]  Yes [ ]  No [ ]  Funding is Pending |  |  |
|  |  ***If Yes or Pending,*** Provide Sponsor information: |       |
|  | ***Note:* ALL studies conducted within the Grady Health System MUST obtain Financial Clearance approval notwithstanding funding or intended patient contact** *(see Section G).* |
|  |  |
| **G.** | **Financial Clearance:****Financial Clearance approval documentation is a required component of the ROC application.** This is applicable for ALL ROC submissions (i.e. New, Renewal and applicable Modification submissions). **Please indicate the status of your Financial Clearance review in Section A of this Form**. If you have not yet submitted your Financial Clearance to grants@gmh.edu, please do so. ROC approval will not be granted without Financial Clearance.**To obtain Financial Clearance:** * Submit the [Financial Clearance Application Packet](http://www.gradyhealth.org/static/office-of-grants-administration)to grants@gmh.edu.

The Financial Clearance Application Packet includes the *Financial Clearance Form* (FCF),support documents and applicable approvals from Committees indicated in Section M of this Form. The current version of the *FCF* is required and can be obtained on the[OGA Webpage](http://www.gradyhealth.org/static/office-of-grants-administration)*.** Allow 7-10 business days for processing after OGA has received your “complete” Financial Clearance Application Packet. The Submitter will be contacted if clarification is required.

**The Financial Clearance approval** is distributed electronically to the PI and Contacts listed on the *FCF* and to ORA for inclusion in the ROC Application Packet. **For assistance obtaining Financial Clearance** **contact OGA** at grants@gmh.edu.Current versions of OGA Forms and Tip Sheets are located on the [OGA Webpage](http://www.gradyhealth.org/static/office-of-grants-administration). |
| **H.** | **Consent Form Requirements**:1. **GHS Disclaimer**: This statement must be included on the Informed Consent Form and should read as follows:  “We will give you emergency care if you are injured by this research. However, **Grady Health System** (*you may also include any other institutions that are participating in the study*) has not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. \_\_\_\_\_\_\_ (Phone \_\_\_\_)”.2. **Patient Rights:** This statement must be included on the Informed Consent Form and should read as follows: “If you are patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.” |
| **I.** | **ORA Personnel Confirmation:**If a Grady badge is required for study personnel, please do the following:* Complete the *ORA Personnel Confirmation Form*attached
* Submit the Form to research@gmh.edu along with IRB approval documentation of research personnel being added to the study.
 |
| **J.** | **EPIC Access:** If EPIC access is needed for this study please do the following:* Complete the *EPIC Request Form* attached
* Submit the Form to research@gmh.edu along with evidence of CITI training and IRB approval documentation of research personnel being added to the study.
 |
| **K.** | **Research Data Request:** If Grady data is required for this study, please do the following:* Complete the *Research Data Request Form*attached
* Submit the Form to research@gmh.edu.
 |
| **L.** | **Data Collection**: Will a data collection form be used in this study? Yes [ ]  No [ ]  ***If Yes,*** will this form remain permanently in the patient’s GMH medical record? Yes [ ]  No [ ] ***\*If you indicated “Yes” to this question,*** the Grady Forms Committee must approve the form. For more information, please contact the Director of Health Information Management at HIMResearch@gmh.edu. |
| **M.** | **GHS Departmental & Other Committee Reviews**  |
|  | **Instructions:** Check ALL categories that are applicable to the proposed study.*Please follow the directions provided to obtain the required approval and provide approval documentation with the ROC or Financial Clearance Application as noted.* |
|  | **[ ]  Use of an Investigational Drug** **All research studies involving an investigational drug and/or requires any form of participation by Pharmacy personnel must obtain approval for Investigational Drug Services (IDS).** To obtain IDS approval submit a request for services to the Executive Director of Pharmacy or his/her designee (*see Contact Information on page 7*). The agreed upon services and fees are documented in a *Pharmacy Estimate.*\*The *Pharmacy Estimate* is a required component of the Financial Clearance Application.***Note:*** Initiate the review request early to avoid delays in study start-up.  |
|  | **[ ]  Use of Investigational Products & Devices** **All research studies that propose the use of an investigational medical product or clinical device must obtain approval from the Grady Value Analysis committee prior to its use.** Value analysis approval may also be required when a research study proposes novel usage of a Grady approved medical product or device. Refer to Section II of the *Financial Clearance Form* for submission instructions. \*Proof of Value Analysis approval is a required component of the Financial Clearance Application. ***Note:*** Initiate the review request early to avoid delays in study start-up.  |
|  | **[ ]  Use of Medical Equipment** **All research studies that propose the use of Medical Equipment must contact Grady’s Clinical Engineering /BioMed Department (Clinical Engineering) for inspection and tagging prior to use.** Refer to Section II of the *Financial Clearance Form* for submission instructions. \*Proof of requested Clinical Engineering services is a required component of the Financial Clearance Application.***Note:*** Initiate the service request early to avoid delays in study start-up. |
|  | **GHS Departmental & Other Committee Reviews Continued****[ ]  Grady Nursing Services** **All research studies involving Grady Nursing services and/or any form of participation by Nursing staff must be submitted to and approved by the Nursing Research Committee.** For information contact nursing\_research@gmh.edu. \*The Nursing Research Committee Approval document is a required component of a complete ROC Application. |
|  | **[ ]  Oncology Studies****All research studies involving Oncology patients must be presented to and approved by the Clinical Research Committee in the Cancer Center prior to submission for ROC review.** For submission and review requirements contact GCRC-research@gmh.edu. \*The Oncology Clinical Research Committee Approval letter is a required component of a complete ROC Application. |
|  | If your study proposes novel procedures or the use of Grady Departmental resources, additional approvals may be required from the Grady Executive or Administrative Director. Please contact OGA for assistance with obtaining the required approval. |
|  |  |
|  |
| **N.** | **Signatures**: *\*****Required*****The Signatures Below Are Required Before Submitting to the ROC.** *See Page 7 for a listing of Grady Chief of Services, Executive Directors and other Signatory Authorities.*  |
|  |
|  |  |  |       |  |       |
|  | **Signature of Principal Investigator** |  | **Printed Name** |  | **Date** |
|  | By signing the Research Oversight Committee Application, as the Principal Investigator, I accept full responsibility for all relevant and necessary aspects of communication and study logistics (e.g., protocol education, budgeting, study start-up and conduct) with Medical, Nursing and Grady Administrative staff. |
|  |  |  |  |  |  |
|  |  |  |       |  |       |
|  | **Signature of Grady Chief of Service** |  | **Printed Name** |  | **Date** |
|  |  |  |  |  |  |
|  | By signing the Research Oversight Committee Application, as the Grady Chief of Service, I am confirming that the Principal Investigator and associated personnel will adhere to the responsibilities described above and that I approve this research to be performed in my service area. |
|  |
| General Guidelines & Instructions:* **Research at GHS**: A research study must be submitted to the ROC and receive ROC approval prior to starting any research procedures in the Grady Health System.
* **ROC Application Form**: The ROC Application includes a signed *ROC Application Form* *(pages 1-5)* and only one (1) copy of the required support documents *(see page 2*). A ROC Application must be completed with each (New, Renewal or Modification) submission.
* **IRB Approval**: The research study must have IRB approval **prior** tosubmitting for ROC approval.
* **Submission Deadline**: All submissions are due **Monday** week prior to the ROC meeting, which takes place on the **second Tuesday** of every month**.** Email or deliver submission documents to the ROC at the address listed on Page 1 of this application.
* **ROC Renewals:** Submissions are required annually prior to the ROC expiration date in order to continue study procedures. Financial Clearance is required to obtain ROC renewal.
* **Notification of Approval**: You will be notified by email regarding the status of your study within **7-10 business days** after the ROC meeting.
* **Study Payor Code**:Based onthe type ofFinancial Clearance approval granted, the research study may be assigned a Payor Code. This code will be located on the ROC Approval letter. A research study may be identified in Grady’s Electronic Health Record (EPIC) using the Payor Code.
* **Definition of Grady Based Investigator:** The Grady Based Investigator is defined as the Grady Credentialed Physician overseeing the study who spends 50% or more of their clinical time at Grady. The exception would be for a Pharmacy or Nursing project that does not include a Physician.
* **Current ORA forms are available on the** [ORA Webpage](http://www.gradyhealth.org/static/office-of-research-administration).
 |

|  |
| --- |
| **The Designated Grady Chiefs of Service Permitted to Sign the ROC Application Form** Revised 10/2018 |
| **Department** | **Chief of Service** | **Contact Number** |
| Anesthesiology | Raphael Y. Gershon, MD | (404) 616-9655 |
| Cardiology | Allen Dollar, MD | (404) 616-4452 |
| Dental Services | David A. Reznik, DDS | (404) 616-9770 |
| Dermatology | Laura Aspey, MD | (404) 778-5225 |
| Emergency Medicine - ER | Hany Y. Atallah, MD | (404) 616-6419 |
| Extended Care | Isioma C. Okwumabua, MD | (404) 616-2321 |
| Community Health | Kelley Carroll, MD | (404)-655-8909 |
| Family Medicine | Denise M. Bell-Carter, MD | (404) 756-1248 |
| Gynecology/Obstetrics - Emory | Michael K. Lindsay, MD | (404) 616-5411 |
| Gynecology/Obstetrics - MSM | Franklyn H. Geary, MD | (404) 616-1691 |
| Hematology Oncology | Sidney F. Stein, MD | (404) 778-1493 |
| Hospice & Palliative | Paul L. DeSandre, DO | (404) 616-4201 |
| Lab Medicine | Karen P. Mann, MD | (404) 616-5483 |
| Medicine - Emory | Jeffrey L. Lennox, MD | (404) 251-8784 |
| Medicine - MSM | Nicholas Bakinde, MD | (404) 616-8201 |
| Neonatology | George W. Bugg, Jr., MD | (404) 778-1463 |
| Neurology | Michael R. Frankel, MD | (404) 616-8743/4013 |
| Neurosurgery | Gustavo Pradilla, MD | (404) 778-1398 |
| Nursing | Jacqueline Herd, PhD, RN | (404) 616-3782 |
| Ophthalmology | Yousuf M. Khalifa, MD | (404) 616-4675 |
| Oral Maxillofacial Surgery | Gary Bouloux, DMD, MD | (404) 778-5883 |
| Orthopedics | William M. Reisman, MD | (404) 778-1556 |
| Otolaryngology | Charles E. Moore, MD | (404) 616-4681 |
| Pathology | George G. Birdsong, MD | (404) 616-4126 |
| Pediatrics - Emory | Robert J. Geller, MD | (404) 616-4403 |
| Pediatrics - MSM | Chevon Brooks, MD | (404) 756-1330 |
| Pharmacy | Rondell Jaggers, PharmD | (404) 616- 3141 |
| Plastic Surgery | Robert Fang, MD | (404) 251-8774 |
| Psychiatry | Grayson S. Norquist, MD | (404) 616-4755 |
| Radiation Oncology | Joseph Shelton, MD | (404) 616-6349 |
| Radiology | Laura Findeiss, MD | (404) 712-4583 |
| Rehab Medicine | Mark Hendricks, MD | (404) 616-7229 |
| Surgery - Emory | Sheryl G.A. Gabram, MD | (404) 251-8914 |
| Surgery - MSM | Omar Danner, MD | (404) 616-1415 |
| Trauma - MSM | Ed W. Childs, MD | (404) 616-4733 |
| Urology | Jeff Carney, MD | (404) 616-2258 |
| Vascular Surgery | Ravi Rajani, MD | (404) 251-8916 |
|  |

|  |
| --- |
| **Instructions*** When requesting a Grady badge as research personnel on IRB and ROC approved study, please type all requested information and submit along with applicable documents to: research@gmh.edu. Please allow at least 24 hours for a response.
* Contact the Office of Research Administration with any questions at research@gmh.edu.
* Current forms are available on the [ORA Webpage](http://www.gradyhealth.org/static/office-of-research-administration)
 |
|  |  |
| **Name**: |       |  |
| **Email**:  |       |  |
| **Phone #**: |       |  |
| **Title/Role**: |       |  |
| **IRB#**: |       |  |
| **Principal Investigator/Designee Name:** |       |  |
| **Principal Investigator/Designee Email**: |       |  |
| **Principal Investigator/Designee Phone#**: |       |  |
|  |
| **Acknowledgment** |
| **As the PI or Designee, my signature below attests to the fact that I have read, understand and agree to all the above information**. |
| **Principal Investigator/Designee Signature**: |  |  |
|  |
|  |
| **Office of Research Administration Use Only** |
| **ORA Approval:** |       |  |
| **Date Approved:** |       |  |
| **Comments:**  |       |  |
|  |

*Please reference the IS-01-101 Computer Systems Acceptable Use Policy & IS-01-102 Remote Access Policy for further guidelines regarding network access*

**USER INFORMATION:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** |       | **Job Title/Department** |       |
| **Email Address – personal emails not acceptable** |       | **Institution/Vendor Name** |       |
| **Telephone #** |       | **Last four digits of SSN – if non-Grady employee**  |       |
| *Access end dates are as follows: Grady Employee – termination of employed; Non-Grady employees hired thru Grady’s temporary service – termination date; Student/Intern – End of rotation but no longer than 6 months; Researcher – access expires at annual renewal of study. exceptions must be approved by compliance department* |

**The User requesting access is a** *(Please select all that apply) and* **the User will need the following access to perform his/her job** *(select appropriately)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Category** |  | **Access Request** |  | **\*Grady Employees User Purpose** |
| \*Grady Employee | [ ]  | EPIC Only | [ ]  | Salaried | [ ]  Yes [ ]  No |
| \*Non-Grady Employee | [ ]  | Remote-Access (EPIC) | [ ]  | If not salaried, the employee need access for:       | [ ]  Current[ ]  Another PositionOn call [ ] Yes [ ]  No |
| \*Student/Intern | [ ]  | VPN (Non-EPIC) | [ ]  | List other Positions/Depts. |  |
| \*Vendor/Temp Worker  | [ ]  | 3M ChartView/ChartScan | [ ]  |       |
| \*Nurse (RN, LPN, NP) | [ ]  |       | [ ]  |       |
| \*\*Researcher | [ ]  |       | [ ]  |       |
| Other, please describe | [ ]  |       |
|  |
| ***USER PURPOSE: ACCESS WILL NOT BE GRANTED UNLESS THIS PORTION IS COMPLETED. PLEASE INDICATE NA, WHERE APPLICABLE*** |
| **\*\*\*NON-RESEARCH USER PURPOSE** |
|       |
| **\*\*RESEARCH USER PURPOSE** |  |
| **Title of Study** |       |
| **IRB Number and Expiration Date** |       |
| **Description of Duties** *(i.e. how PHI will be used)*  |       |
| **Access will be internal or external to Grady** please specifically indicate location. |       |
| **List any and all external sources who you will share PHI with** *(i.e. CDC, Georgia Health, other institutions)* |       |
| **If access is for recruitment please explain process:**  |       |
| **PI Signature** | **Date:**       |
| **Internal Use Only – Director/Manager or Above Must Approve:** |
| ***As the Grady Authorizing Approver, you acknowledge that the user listed above is requesting access to perform his/her job and you certify that all required forms and onboarding requirements have been completed. By signing this form, you acknowledge that you have read and understand the IS-01-101 Computer Systems Acceptable Use Policy & IS-01-102 Remote Access Policy.*** |
| **Authorizing Director/Manager Signature/Title:** |  |
| **Information Security Signature/Title:** |  |
| **Research Signature/Title:** |  |
| **Compliance Signature** *(when applicable):* |  |

*INSTRUCTIONS: Please forward completed form to the Office of Information Security via email at* *infosec@gmh.edu* *or fax at 404-489-3102. If the request is for IRB research purposes, please forward the completed form to the Office of Research Administration (Grady Memorial Hospital – 3H005), via email at* *research@gmh.edu* *with a copy of CITI training. After approval from Grady’s Office of Compliance, Office of Information Security, and/or Research Administration, EPIC training requirements and Log-In credentials will be provided from the Office of Information Security.*

|  |
| --- |
| **INSTRUCTIONS: Upon completion, please forward this document to research@gmh.edu** |
|  |
| **PRINCIPAL INVESTIGATOR INFORMATION:** |
| **Name:** |       |
| **Phone:** |       |
| **Department:** |       | **Email:** |       |
|  |
| **DATA REPORT DETAILS:** |
| **This report request will be used to complete Resident’s research requirements:**  | **[ ]  Yes** | **[ ]  No** |
| **The research related to this request is Human Subject based per the IRB:** | **[ ]  Yes** | **[ ]  No** |
| **This is a funded research study:** | **[ ]  Yes** | **[ ]  No** |
| **Purpose for which access to data is being requested (describe in detail):** |
|       |
|  |
| **Frequency of Report:** *(e.g. once quarterly)* |       |
|  |
| **DATA ELEMENTS BEING REQUESTED:** |
| **Identified Dataset:**  |
| Data Elements | ICD9/10 Code | Description |
| 1.       |       |       |
| 2.       |       |       |
| 3.       |       |       |
| 4.       |       |       |
| 5.       |       |       |
| 6.       |       |       |
| 7.       |       |       |
| 8.       |       |       |
| 9.       |       |       |
| 10.       |       |       |
|  |  |  |
| **De-Identified Dataset:** |
| Data Elements | ICD9/10 Code | Description |
| 1.       |       |       |
| 2.       |       |       |
| 3.       |       |       |
| 4.       |       |       |
| 5.       |       |       |
| 6.       |       |       |
| 7.       |       |       |
| 8.       |       |       |
| 9.       |       |       |
| 10.       |       |       |
|  |
| **IRB INFORMATION & ATTESTATION** |
| **IRB Number:** |       | **Expiration Date:** |       |
|  |  |  |
| **Data Requestors must certify the following:*** The data for which use or access is sought is the minimum necessary for the stated research purposes.
* Access and use of the data will be limited to the research purposes described above.
* I will comply with all Grady Health System policies concerning individuals’ privacy, information security and HIPAA.
* If the data is disclosed outside of the Grady Health System, I have a process/procedure in place for tracking and documenting any such disclosures.
* I have a duty to immediately report to the appropriate Grady Health System personnel any breach or suspected breach of the data for which use or access is sought.
* When preparing publications or presentations of work substantially aided by the Grady Health System, I will acknowledge the participation of Grady Health System.
 |
| **Signature:**  |  | **Date:** |       |
|  |
|  |
|  | **FOR GRADY HEALTH SYSTEM INTERNAL USE ONLY:** |  |
|  |
| **Research Administration Review:** |
| Name: |       | Title: |       |
| Signature: |  | Date: |       |
|  |
| **Grant Administration Review:**  |
| Name: |       | Title: |       |
| Signature: |  | Date: |       |
|  |
| **Legal Review:** |
| Name: |       | Title: |       |
| Signature: |  | Date: |       |
|  |
|  |