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| Guidelines: * Accepting **ONLY** version June 2022 of the ROC Application Form
* Please provide your **typed responses** on this *ROC Application Form* and submit along with applicable documents to research@gmh.edu. The Office of Research Administration (ORA) will not review Forms submitted with written responses.
* See page 6 for additional guidelines and instructions.
* Current ORA forms are available on the [ORA Webpage](http://www.gradyhealth.org/static/office-of-research-administration)
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|  |
| **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 is required. |
|  | [ ]  **Renewal:** | **A study that has been previously approved by the ROC, including Exempt and Common Rule (CR) approved studies.** 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; IRB Continuing Review Submission Form; updates to any other IRB approved documents that have been renewed; and a current Financial Clearance approval.[ ]  **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 has been amended.** 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. Submit to researchfinance@gmh.edu to obtain the required Financial Clearance approval or acknowledgement.**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 ORA and copy researchfinance@gmh.edu to assure all financial responsibilities are complete. If the study involved Grady Investigational Drug Services, notify Grady Pharmacy to prevent additional monthly charges. |
|  | [ ]  **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 with each ROC submission*** *(see Section G).* [ ]  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.)* |
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| **B.**  | **Study Information**: |
|  | IRB #:***(Required)*** |       | IRB Expiration Date:***(Required)*** |       |
|  |  | *Indicate “Exempt” or “Common Rule” if applicable.* |
|  | Institutional/Central IRB:  | [ ]  Emory [ ]  Morehouse [ ]  Other: |       |
|  |  |  |
|  | Study Title: |       |
|  |  |
| **C.** | **Principal Investigator(s)**: *(Person noted as “Principal Investigator” on the IRB Approval Letter)* |
|  | PI Name: |       |  |
|  | Email: |       | Phone #: |       |
|  | 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 contact in addition to PI)* |
|  | 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 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:****The Financial Clearance approval document is a required component of every ROC application.** This is applicable for ALL ROC submissions (i.e. New, Renewal and Modification submissions) and all submission types (i.e. Full Board, Exemption, and Common Rule). If you have not yet submitted your Financial Clearance to researchfinance@gmh.edu, please do so to avoid delays in ROC approval. **To obtain Financial Clearance:** * Submit the [Financial Clearance Application Packet](http://www.gradyhealth.org/static/office-of-grants-administration)to researchfinance@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[*ORA Webpage*](http://www.gradyhealth.org/static/office-of-research-administration)*.** Allow 10-14 business days after the receipt of a complete Financial Clearance Application Packet for processing. 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 ORA Finance** at researchfinance@gmh.edu.Current versions of ORA Finance Forms and Tip Sheets are located on the [ORA Webpage](http://www.gradyhealth.org/static/office-of-research-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.** | **Grady Badge Request:**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.
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| **J.** | **Grady EPIC Access Request:** If EPIC access is needed for this study, please do the following:* Complete the *EPIC and/or Remote Access 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.****Important:*** Initiate review requests early to avoid delays in study start-up. |
|  | **[ ]  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 Packet. |
|  | **[ ]  Use of Investigational Products & Medical 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 instructions. \*Proof of Value Analysis approval is a required component of the Financial Clearance Application Packet.  |
|  | **[ ]  Use of Medical Equipment** **All research studies that propose the use of Medical Equipment must contact Grady’s Clinical Engineering/BioMedical Department (Clinical Engineering) for inspection and tagging prior to use.** Refer to Section II of the *Financial Clearance Form* for instructions. \*Proof of requested Clinical Engineering services is a required component of the Financial Clearance Application Packet. |
|  | **[ ]  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. |

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|  | **GHS Departmental & Other Committee Reviews Continued*****Important:*** Initiate review requests early to avoid delays in study start-up.**[ ]  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. |
|  | **[ ]  Heart and Vascular Center****All research studies involving Heart and Vascular patients must be presented to and approved by the Heart and Vascular Center prior to submission for ROC review.** For submission and review requirements contact GHVCresearch@gmh.edu. \*The Heart and Vascular Center Approval letter is a required component of a complete ROC Application. |
|  | **[ ]  Language Interpretive Services****All research studies involving participants that require Language Interpretive Services (LIS) must obtain approval for services prior to submission for ROC review.** For submission and review requirements contact Kippie Lipham at kclipham@gmh.edu. \*Approval documentation for Interpretive Services is a required component of a complete ROC Application. |
|  | **[ ]  Radiology/Imaging Services** **All research studies involving special radiology services must be presented to and approved prior to submission for ROC review.** For submission and review requirements contact Davian Strozier at dstrozier@gmh.edu.\*Approval documentation for Radiology/Imaging services is required to obtain Financial Clearance. |
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|  | The use of Grady Departmental resources may require additional approvals from the Grady Executive and/or Administrative Leadership. Please contact ORA Finance at researchfinance@gmh.edu for assistance with obtaining the required approval. |
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| **N.** | **Signatures**: *\*****Required****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 required approvals, communication, and operations (e.g., Protocol Education, Budgeting, Study Start-up and Conduct) with Executive Leadership, Medical, Nursing, Grady Administrative staff, and Support/Ancillary Services. |
|  |  |  |       |  |       |
|  | **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:* **ROC submission and approval** is required prior to starting research in the Grady Health System.
* **The ROC Application Form** 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 is required to be completed with each submission (i.e., New, Renewal or Modification). A ROC Application is not considered complete until fully authorized.
* **IRB Approval** is required **prior** tosubmitting for ROC approval. If relying on another Institution, IRB documents are required from that Institution.
* **The Submission Deadline** is on the **Monday** week prior to the ROC meeting. The ROC meeting occurs on the **second Tuesday** of every month unless the Tuesday is an observed holiday**.** ROC Submissions may be emailed to research@gmh.edu or delivered to the address listed on Page 1 of this application.
* **ROC approved studies,** including Common Rule and Exempt approved studies, **are required to be renewed** prior to the ROC expiration date to continue study procedures. Financial Clearance is required to obtain ROC renewal.
* **Notification of Approval** will be forwarded electronically within 1**0-14 business days** after the ROC meeting to the persons listed as contacts.
* **A Study Payor Code** may be assigned based onthe type ofFinancial Clearance approval granted. 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.
* **A Grady Based Investigator**, at minimal, is defined as the Grady Credentialed Physician overseeing the study who spends 50% 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).
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| **The Designated Grady Chiefs of Service Permitted to Sign the ROC Application Form** Revised June 2022 |
| **Department** | **Chief of Service** | **Contact Number** |
| Anesthesiology | Raphael Y. Gershon, MD | (404) 616-9655 |
| Cardiology | Allen Dollar, MD | (404) 616-4452 |
| Cardiology - MSM | Anekwe Onwuanyi, MD | (404) 616-8804  |
| Dental Medicine | David A. Reznik, DDS | (404) 616-9770 |
| Dermatology | Laura Aspey, MD | (404) 778-5225 |
| Emergency Medicine - ER | Daniel Wu, MD | (404) 616-6419 |
| Extended Care | Yuan Xiang-Meng, MD | ymeng@msm.edu |
| Community Health | Kelley Carroll, MD | (404)-655-8909 |
| Family & Com. Medicine- MSM | Keila Simmons, MD | kesimmons@msm.edu |
| Gynecology/Obstetrics - Emory | Michael K. Lindsay, MD | (404) 616-5411 |
| Gynecology/Obstetrics - MSM | Franklyn H. Geary, MD | (404) 616-1691 |
| Hematology & Medical Oncology | Leon Bernal-Mizrachi, MD | (404) 778-1347 |
| Hospice & Palliative | Paul L. DeSandre, DO | (404) 616-4201 |
| Laboratory Medicine | Karen P. Mann, MD | (404) 616-5483 |
| Medicine - Emory | Jeffrey L. Lennox, MD | (404) 251-8784 |
| Medicine - MSM | Richard Snyder, MD | rsnyder@msm.edu |
| 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 | Michelle Wallace (VP of Operations) | (404) 616-6183 |
| Ophthalmology | Yousuf Khalifa, MD | yousuf.khalifa@emoryhealthcare.org |
| Oral Maxillofacial Surgery | Steven Roser, MD | (404) 778-4555 |
| Orthopedics | Mara L. Schenker, MD | (404) 778-1550 |
| Otolaryngology | Charles E. Moore, MD | (404) 616-4681 |
| Pathology | George G. Birdsong, MD | (404) 616-4126 |
| Pediatrics - Emory | Wendalyn Little, MD | wendalyn.little@emory.edu |
| Pediatrics - MSM | Chevon Brooks, MD | (404) 756-1330 |
| Pharmacy | Rondell Jaggers, PharmD | (404) 616- 3141 |
| Plastic Surgery | Robert Fang, MD | (404) 251-8774 |
| Psychiatry - Emory | Grayson S. Norquist, MD | grayson.norquist@emory.edu |
| Psychiatry - MSM | John Gaston, MD | jgaston@msm.edu |
| 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 |  Keith Delman, MD | (404) 778-3303 |
| Surgery - MSM | Patricia Ayoung-Chee, MD | payoungchee@msm.edu |
| Trauma / Acute Care Surgery | S. Rob Todd, MD | (404) 616- 4212 |
| Urology | Aaron Lay, MD | aaron.han.qiao.lay@emory.edu |
| Vascular Surgery | Ravi Rajani, MD | (404) 251-8916 |
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| **Instructions*** Please type all requested information and submit along with applicable documents to research@gmh.edu. Handwritten responses will not be accepted.
* 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)
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|  |  |
| **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:**  |       |  |
|  |

**INSTRUCTIONS:** Please type all requested information. Handwritten responses will not be accepted.

*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 the 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 ROC approved research, please forward the completed form to the Office of Research Administration, via email at* *research@gmh.edu**.*

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| **INSTRUCTIONS:** Please type all requested information. Handwritten responses will not be accepted. 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.       |       |       |
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| 10.       |       |       |

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| **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: |       |
|  |
|  |