Obtaining Data and Navigating Oversight for QI and Research Projects

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Emory@Grady Division of General Medicine and Geriatrics, Division Lunch
7/16/20
Session Outline

1. Overview of QI and Research Oversight Process
2. Grady Research & Quality Data Request Process
   Chadrick Anderson, MHA, Manager, Research Administration, Grady Health System
   Prerna Kahlon, BDS, MPAH, CPHQ, Vice President, Quality and Process Improvement, Grady Health System
   Donna Williams, Developer, Business & Clinical Intelligence Development, Grady Health System
   Bill Batchelder, Manager, Business & Clinical Intelligence Development, Grady Health System
3. QI and Research in Action: Examples from Grady Liver Clinic
4. Navigating the IRB Process
   Shara Karlebach, WHNP-BC, CIP Assistant Director, Emory IRB
5. Grady Research Oversight Committee
   Chadrick Anderson, MHA, Manager, Research Administration, Grady Health System
6. Q and A
Clinical Question
Research, Quality (or both)
Go to Gradynet and fill out questionnaire
https://gradynet.gmh.edu/DocumentsAndResources/Pages/QIResearchDataRequests.aspx

Research +/- Quality (Grant funded) → IRB (CITI certification for all involved) → GROC review/approval

Quality → Submit QI request form

Clarity from PI specialist

Approved, investigator contacted

Approved

Broad Overview
Research & Quality Data Request Process

Overview
Grady Health System
Offices of Clinical Research Administration & Quality
and Process Improvement
Research & Quality Data Request Structure

• Rationale
  • To distinguish and facilitate Research and Quality Improvement projects as a part of the organizational Mission and Vision
  • To limit barriers when requesting Research and/or Quality data

• Structure Re-Design
  • Multidisciplinary group met to define and design new structure and process
  • Marketing and Educational Plan developed
QI & Research Data Requests

Grady’s Research Administration and Quality & Process Improvement Teams have partnered to implemented a new process to distinguish quality improvement projects from quality improvement research or human subjects research, and to effectively process QI and research data requests. Before submitting a research or QI data request, please complete the QI v Research Reference Questionnaire first. Proceed with the appropriate data request based on the response on the questionnaire.

Process & Reference
- QI & Research Data Request Process
- QI v Research Reference Questionnaire

Data Request Forms
- EPIC Data Request Form
- Quality PI Data Request Form

Frequently Asked Questions

1. Is IRB Review is Required to Publish?
   The mere intent to publish the findings of a QI project does not obligate IRB review. As long as the publication does not refer to the activity as research and makes it clear the publication is the result of a quality improvement or educational/competency assessment as defined above, there is no need for any action on behalf of the IRB. If a journal requires an IRB, then an IRB review may be requested. If the IRB is approved, then Grady Health System must be referenced in the publication as per the Grady Health System Affiliation Agreement.

2. Do QI Projects Involve Statistical Analysis?
   While most QI projects do not rely on statistical analysis, some QI projects “may yield publishable data if conducted over a sufficient period of time for results to be statistically valid.”

3. Do QI Projects Receive External Funding?
   QI projects can receive external funding. External funding does not necessitate IRB review.

4. How long will it take the respond to a data request to be completed after submission of the data request form?
   We will respond to you within a week of submission of your data request form with any clarifying questions and information on the timeline for completion based on the complexity of your data request. However, if there is no response from you after this touch point, the request will expire after a week, and a new data request form will need to be completed and resubmitted.

5. Can QI data requests be modified after submission is complete?
   Generally, we encourage you to spend time clearly defining your data request when completing the form and also taking the opportunity to...
Research and QI Data Request Overview

• Stakeholder completes the QI v Research Reference Questionnaire
• Based on results stakeholder completes applicable data request form
Research Data Request Overview

• If Research, Study team ensures that IRB and Grady ROC approval has been obtained
• Research Data Request Form is completed and submitted to the Office of Research Administration (ORA) at research@gmh.edu
• ORA performs administrative review and submits request to Grady’s Business and Clinical Intelligence team (BCI)
• BCI team contacts Study team in order to review the requested data points and creates the BCI Specifications document
• Study team agrees to terms of the BCI Specifications document
• Data Use Agreement is created through Grady’s Legal/Compliance Office
• Study team agrees to Data Use Agreement
• Sample data set is developed per specifications and delivered through a secured manner for requester to review/validate data
• BCI makes changes to query that extracts data if required after requester’s validation. This is an iterative process until sign off of data by requester
Quality Data Request Overview

• If Quality, then the Quality PI Data Request Form is completed and submitted to the quality and process improvement team via gpi@gmh.edu

• Completed Quality PI Data Request Form is reviewed by Quality Analyst

• Quality Analyst has Phone call or Meeting with Stakeholder for any clarifications

• Data Request is reviewed by VP Quality & Process Improvement for approval

• Once approved stakeholder is notified and request is completed

• If request is determined to be Research or Operational, then it forwarded to the Research or BI team
# Quality Improvement Vs Research Reference Questionnaire

**Last Updated: July 30, 2019**

**Purpose:**
To distinguish quality improvement projects from quality improvement research or human subjects research in order to determine whether your project will require IRB review.

**Directions:**
Please choose the appropriate response to each of the questions below.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the purpose of this project?</td>
<td>☐ A. To develop or contribute to generalizable knowledge (e.g. to design new evidence-based clinical practice guidelines)</td>
</tr>
<tr>
<td></td>
<td>☐ B. To improve clinical care to better conform to established/accepted standards (e.g. to increase compliance with evidence-based or consensus-based practice)</td>
</tr>
<tr>
<td>2. How is the project designed?</td>
<td>☐ A. It has a rigid protocol that will remain unchanged throughout the research</td>
</tr>
<tr>
<td></td>
<td>☐ B. It has an adaptive, iterative design (e.g. PDSA and rapid cycle testing)</td>
</tr>
<tr>
<td>3. What potential risks exist in this project?</td>
<td>☐ A. The activity poses risks greater than those presented by routine clinical care</td>
</tr>
<tr>
<td></td>
<td>☐ B. Does not increase risk to patients, with exception of possible patients' privacy or confidentiality of data</td>
</tr>
</tbody>
</table>
**Purpose:**
To distinguish quality improvement projects from quality improvement research or human subjects research in order to determine whether your project will require IRB review.

**Directions:**
Please choose the appropriate response to each of the questions below.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Will the project require randomization?</td>
<td>□ A. Yes, subjects or groups of subjects may be randomized to different interventions or treatments</td>
</tr>
<tr>
<td></td>
<td>□ B. No, subjects or groups of subjects will not be randomized to different interventions or treatments</td>
</tr>
<tr>
<td>5. When will the results be implemented into patient care?</td>
<td>□ A. Results will be disseminated to the academic community prior to adoption into routine care (e.g. chart review results prior to intervention)</td>
</tr>
<tr>
<td></td>
<td>□ B. Results will be rapidly adopted into local care delivery (i.e. results will be used immediately to create or modify interventions to improve routine care)</td>
</tr>
<tr>
<td>6. Where will the project be conducted?</td>
<td>□ A. Grady Memorial Hospital and satellite locations as well as external institutions</td>
</tr>
<tr>
<td></td>
<td>□ B. Grady Memorial Hospital and satellite locations only</td>
</tr>
</tbody>
</table>

If you checked ‘A’ in response to any of the questions above, you will need to submit a protocol to the IRB for review and submit a Research Data Request Form.
What is SlicerDicer?

Overview

- Self-service reporting tool
- On-demand drill down reports
  - Removes the need to request reports from reporting team
  - Refine your own reports on-the-fly
  - Share your reports with your colleagues
- Within Hyperspace
- Intuitive data manipulation and visualization
- With advanced security – can export to Excel or RWB to further explore data
- Long term goal: Facilitate a culture of self-service reporting

Contact our SlicerDicer Support Team to sign up for Training and access to the tool:
SlicerDicerSupport@gmh.edu
Questions?
Thank You
QI and Research in Action: Examples from the Grady Liver Clinic

• First Liver Clinic Study
• Description of model and population; comparing treated and untreated patients
• Data source: 870 paper charts reviewed

Original Communication

Improving Access to Hepatitis C Care for Urban, Underserved Patients Using a Primary Care–Based Hepatitis C Clinic

Lesley Miller, MD; Shelly-Ann Fluker, MD; Melissa Osborn, MD; Xiaoxia Liu, MS; Akilah Strawder, PharmD, CDE
QI and Research in Action: Examples from the Grady Liver Clinic

- HCV screening and linkage to care
  - Implemented HCV screening program 2012-2013
  - Reported implementation and care cascade
  - Outcomes of QI project, non-research
  - Data source: internal project records from chart review

High-Yield Birth-Cohort Hepatitis C Virus Screening and Linkage to Care Among Underserved African Americans, Atlanta, Georgia, 2012–2013
QI and Research in Action: Examples from the Grady Liver Clinic

- Grady HCV Registry
  - Worked with Epic team and CDC collaborators to construct registry of all HCV-positive pts, 2004-2016
  - Data source: EHR (clarity reports, drug usage reports)
  - Original registry non-human subjects research; use of the EHR to evaluate a public health intervention
  - Secondary analyses considered research
Navigating the IRB Process

General medicine 7-16-2020
Shara Karlebach, WHNP-BC, CIP Assistant Director, Emory IRB
Objectives

IRB SCOPE OF REVIEW
REQUIRED TRAINING
COMPONENTS OF SUBMISSION
PROCESS OF REVIEW
WHERE TO FIND RESOURCES
The Process...

It doesn’t have to be scary
Is IRB Review Needed?
IRB Review Required?

• Is it Research?
  • The "Common Rule," generally used by the Emory IRB to evaluate all human subjects research, defines "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
  • The FDA regulations use the term "clinical investigation" to define which FDA regulations apply to studies.
IRB Review Required?

• Does it involve a “human subject”?
  - The Common Rule defines a human subject as a living individual about whom an investigator conducting research obtains
    (1) information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens;
    (2) uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens
  - The FDA regulations define a human subject as an individual who is or becomes a participant in research, either as a recipient of the Test Article or as a control
Access the Non-Human Subject Research Determination Form

As described in the preceding page, the IRB is responsible for reviewing all human subjects research activities. If you are relatively sure that your upcoming project meets the definition of "human subjects research," you may go ahead and submit the study in the eIRB system. If, however, you are unsure whether your project needs IRB review, you should use our Non-Human Subjects Research Determination Electronic Form by clicking the button below. This form will indicate if the study needs IRB submission or not. If not, the study team is expected to keep a copy of the form responses as an attestation of the researchers’ intent for the project. For more information, refer to this memo. The responses from the form and this memo can be provided to others as needed.

This form is solely for use by Emory faculty, staff, and students. You may first need to log in to your Office365 account (email.emory.edu) in your internet browser before clicking the below link in order to view the form.
Required Trainings
The training requirement applies to all Emory personnel conducting "human subjects research" activities at Emory. This includes anyone working with identifiable data or biological specimens for research purposes.

You will need to take either biomedical or sociobehavioral. It depends on your study activities.

Here is where you can find guidance on which course is most appropriate and how to navigate the system.
For all investigators and many research staff who are conducting FDA-regulated or NIH funded clinical trials at Emory, the institution requires completion of additional training every three years.

Investigators must take an online GCP-ICH course that contains three additional Emory-specific modules, also through the CITI online system.

[Link to guidance]
The Submission Process
The Documents Required

- Protocol, Lay Summary
- ICF/HIPAA doc, Assent Forms
- Recruitment materials
- Other documents as applicable
Assigning PI Proxy/Primary Contact

• Highly recommended, since the PI Proxy can create and submit Modifications and Continuing Reviews, and respond to changes requested by the IRB.

• There can be multiple PI Proxies, but only one Primary Contact.

• **Note:** These assignments must be done by the PI in the main study workspace (cannot be done from within a Modification or Continuing Review)

• [Assign a PI Proxy and Primary Contact](#) video
Once you submit...

- Is it “research” with “human subjects”?
- If it is, is it exempt?
- If it is nonexempt, is it eligible for expedited review?
- Which regulations does it invoke?
  - HIPAA Privacy Rule
  - FDA, VA, OHRP regulations
  - Special rules for vulnerable populations
IRB Review Process

Meeting: review, discussion, vote

- Defer
- Pending Approval
- Approve
- Table
- Disapprove

If Expedited, one IRB member will review and approve. If FB, convened board would make a determination.

After meeting (review), IRB staff convey pending issues, or send approval documents.

Please: do NOT start HSR activities before getting your final approval in hand!
Also, check with OSP and OCR.
Exception: physicians should treat patients.
Resources
Protocols

Study Submission Guidance

Technical instructions for using the eIRB system are found here: eIRB Training

Below are templates, tools, and guidance documents for your IRB submission. Click any header to expand the section.

Initial Submission Decision Charts »

Lay Summary Requirements »

Protocol Templates - Required »

- Grant applications are not acceptable in lieu of protocols
- Sponsor-developed multisite protocols are acceptable, but when Emory is IRB of record, we also need the "Supplement to Sponsor Protocol" below.
- Emory Investigator-initiated protocols: You must use the relevant template below.
Consent Toolkit

For the IRB's current guidance for informed consent documentation and process, including the use of family members and research staff as interpreters, please go to this page.

NOTE: As of 12/14/2018, the ICF and ICF/HIPAA templates comply with the Revised Common Rule. Even if your study is FDA or DOJ regulated, make sure you use our updated templates.

Screening Consent Template »

To determine if you need to consent your subjects to be screened (in person, on the phone, or online), please see the section below for more information on consent for screening (also available in our FAQs page), and you may use this template. It can be used in person, or as a verbal (phone) script, or may be formatted to be presented online. If HIPAA does not apply to your study, please remove the HIPAA-related content.

• SaaS Verbal Screening Consent/HIPAA (ver. 06-10-20)

Modular Language for Consent Forms »

This language is to be inserted as applicable into the biomedical templates below; see templates for indication of where to place the modular language. It includes language on things like Certificates of Confidentiality, genetic research, incidental findings, etc.

• Modular Language for Consent Forms (ver. 12-14-2018)

Certificate of Confidentiality Addendum for NIH-funded Research »

To be presented to prospectively-enrolled subjects on NIH-funded studies for which informed consent is not waived. This is required as of October 1, 2017, the effective date of the NIH policy providing automatic CoCs to all NIH-funded human subjects research ongoing on/after December 13, 2016.

Certificate of Confidentiality Addendum (ver. 10-4-17)

Spanish Version (ver. 10-4-17)

Clinical Consent/HIPAA Templates »

Note: "SaaS" indicates a template with a header designed to be used in the updated eIRB system. Pre-existing studies should remove the current header on approved consent documents before submitting continuing reviews or modifications to make their forms compatible.

• SaaS Biomedical Consent/HIPAA Template (ver. 06-16-20)

• SaaS Emory Biomedical Consent Template - HIPAA does not apply (ver. 06-16-20)
  • If Using Site-specific consent forms below instead for studies for which HIPAA does not apply, refer to this form as a model.

Consents
Factors impacting review:

- The quality of the submission
  - Use our ICF/HIPAA templates
  - See our guidance information for new studies, and...
  - Our Protocol templates for investigator-designed studies
  - Instructional video for eIRB submission
- Whether grant/contract negotiations and any ancillary reviews are still outstanding
  - Submit to other departments in parallel whenever possible
- How quickly the study team replies to requests for clarification or changes
- Spikes in submissions to the IRB
- Our Targets
NIH policy and single IRB

- If your study is sponsored by the NIH and you are participating in a multicenter trial, you may be required to use one IRB as the IRB of record for all sites.
- Start your conversation early with our office to guide you with this process—a single IRB plan must be submitted with the grant application.
- For more information, go to our website at http://irb.emory.edu/forms/external-irbs/index.html.
QUESTIONS?

General inquiries: IRB@emory.edu
"Does my study need IRB review?" inquiries: use our determination tool
Study-specific inquiries: You may contact your study analyst directly.
For Education/Outreach questions, Complaints from study participants, Compliance, and Adverse Event issues, please contact the Education and Quality Assurance Team.
If you cannot reach anyone and have an urgent matter, you may call the central line at 404-712-0720.
Research Oversight Committee (ROC)

Mission:
The Office of Research Administration partners with Grady’s Research Oversight Committee and Research personnel to protect the rights, welfare, and well-being of human subjects involved in research within Grady Health System.

Responsibilities:
• Adhering to and abiding by all regulatory requirements including those from the Office of Human Research Protections (OHRP), the Institutional Review Boards of the affiliated institutions (IRBs) and The Joint Commission.
• Maintenance for various systems required for providing management reports.

Services:
• Review all research protocols and required documents in order to support Grady’s Research Oversight Committee in determining risks and benefits to patients.
• Serve as liaisons for but not limited to Grady's Research Oversight Committee, Compliance, Information Security, Information Technology, Legal and On-Boarding/Training departments.

Meeting Date & Submission Deadline:
• 2nd Tuesday of each month.
• Submission is required the Monday (week prior) to the ROC meeting.
Research Oversight Committee (ROC) Review Process

Obtain IRB Approval - The IRB letter must be from an institutional IRB recognized by Grady’s OHRP-filed FWA.

Submission to ROC for Review & Approval:
• Signed ROC Application to research@gmh.edu by the Monday prior to the ROC meeting.
• ROC Application includes but is not limited to:
  • All documents submitted to the IRB
  • Financial Clearance approval (obtained from OGA)
  • Department / Committee approvals as necessary (Pharmacy, HIM, IS, VAC, GCRC, Nursing, Clinical Engineering etc)
Research Oversight Committee (ROC) Review Process

**ROC Review:**
- Conducted every second Tuesday of the month

**ROC Approval:**
- Approval Letters will be sent electronically to the study contact stated on the ROC Application unless otherwise informed
- Study may commence once ROC Approval Letter has been received.

**ROC Approval:**
- Approval Letters will be sent electronically to the study contact stated on the ROC Application unless otherwise informed
Research Oversight Committee (ROC)  
Review Process

**Modifications & Audits**
- **Modifications:** Submission of study amendments / modifications to ROC is required (includes Financial Clearance as appropriate). Any changes to a research study require IRB approval.
- **Audits:** Notification provided to GHS OGA, ORA and appropriate department of Audit

**Renewals & Close-Out**
- **Renewal:** Submission annually to obtain ROC approval for study continuation. All Continuing Reviews must be IRB approved. Renewals should all required documents and be submitted prior to expiration date.
- **Close Out:** Provide IRB approval for study closure to ROC
ROC Administrative Offices

Research Administration (Medical Affairs)
The Office of Research Administration (ORA) provides oversight and support for the initiation and execution of research within Grady Health System in accordance with government regulations, The Joint Commission standards and Grady policies. ORA provides administrative support for the ROC process.

Grants Administration (Finance)
The Office of Grants Administration (OGA) partners with program directors, administrators, research personnel and staff for the purpose of obtaining and administering extramural funds in compliance with government regulations, sponsor requirements and Grady policies. OGA provides Financial Clearance and oversight for Research conducted at Grady.
Contact Information

**Grants Administration**  
(Finance)

David G. Noble  
T: 404.616.1828  
E: dnoble@gmh.edu

Yvette Benjamin  
T: 404.616.4731  
E: ybenjamin@gmh.edu

Office Location:  
50 Hurt Plaza, Suite 301,  
Atlanta, GA 30303

Central Email: grants@gmh.edu  
Web: [http://www.gradyhealth.org/static/office-of-grants-administration](http://www.gradyhealth.org/static/office-of-grants-administration)

**Research Administration**  
(Medical Affairs)

Chadrick M. Anderson  
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E: canderson@gmh.edu

Shirley Marshall  
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E: smarshal@gmh.edu

Office Location:  
80 Jesse Hill Jr. Drive, SE, 3H005  
Atlanta, GA 30303

Central Email: research@gmh.edu  
Web: [http://www.gradyhealth.org/static/office-of-research-administration](http://www.gradyhealth.org/static/office-of-research-administration)
Questions!