

GME Research FAQ

1. I have an idea for a project. What is the first step?

The first step is to perform a literature search and collect background information, followed by discussing the project/idea with a faculty advisor.

2. Which library sources are available for GME?

[HCA library](#) and [UCF Library](#) sources are available for GME.

3. How do I have access to the HCA library?

The HCA library can be accessed via the link below when working on an HCA network.

<https://hcahealthcare.ovid.com/>

4. How do I access the UCF library resources?

Open the library's homepage at <http://med.ucf.edu/library>; click on "off-campus login"; click on the yellow button that says "COM Login"; Enter your NID and NID password, then click the "login" button. Once logged in you will automatically be returned to the Health Sciences Library's homepage. From here, you have access to all resources, as well as those from the Main Campus Library. If you have any trouble signing in, contact medlibrary@ucf.edu or call 407-266-1400.

5. What are the steps I need to follow for a scholarly activity?

All projects require program and then division research office approval first. Please see the [flowchart](#) for GME projects.

6. What is the function of the North Florida Division Office of Research?

HCA NF Division has established an [Office of Research](#) for the GME residents and faculty in the UCF College of Medicine/ HCA Consortium. This office guides the residents with their projects. Please see [Office of Research GME mission document](#) for the list of areas the Office of Research can provide.

7. How do I contact the Office of Research?

- Office of Research NF Division: NFRM.Research@HCAHealthcare.com
- Director of Research GME NF Division (Dr. Hale Toklu): hale.toklu@hcahealthcare.com

8. Do I need Division approval for all GME projects?

Once you submit your proposal to [NF Division Research Office](#), you will be guided with the required forms and trainings based on the content and type of project.

9. Are there any forms to sign?

Based on the content and type of project and dataset you will use, you are required to obtain permissions for data use and forms for accessing PHI.

10. Which forms do I use for submitting my proposal? Where do I find these forms?

Forms are available on [Medhub](#). In addition, you may obtain the forms from the Office of Research or program coordinators.

11. Do I need to have any training?

Completion of trainings relevant to their research is a requirement for all researchers. HIPAA is addressed as part of the [Healthstream](#) and [CITI program training](#).

12. How do I have access to the trainings?

There are 2 resources available for trainings. You will be guided by the Office of Research based on the content on your project.

- [Healthstream trainings](#) (via HCA network)
 - Introduction to Clinical Research at HCA
 - Evaluation and Interpretation of Evidence
 - Introduction to Research in the HCA GME Program
 - Research Ethics and Protection of Human Subjects - Part 1
 - Research Ethics and Protection of Human Subjects - Part 2
 - Distinguishing Quality Improvement from Research
 - Clinical Excellence: Impact on the HCA Clinical Agenda
 - Scholarly Presentation and Publication
 - Exploratory Data Analysis
 - Clinical Research
 - Protocol Development
 - Designing IRB Exempt Studies
 - Introduction to Clinical Research

- [CITI program training](#) (via UCF)
 - Group 1. Biomedical Research Investigators and Key Personnel
 - Group 2. Social / Behavioral Research Investigators and Key Personnel
 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
 - Biomedical Responsible Conduct of Research
 - Conflict of Interest

13. Can I transfer my CITI trainings received from another institution?

Once you complete the trainings, the trainings remain active for 3 years. You may have all your trainings under one account. You may do it yourself by clicking `affiliate with another institution`. However, if you cannot add it on your own, you may contact CITI for help. Your previous institutional email address, and/ or login ID may be required.

Contact CITI

- Call [888-529-5929](tel:888-529-5929) (U.S. toll free) or [+1-305-907-3100](tel:+1-305-907-3100) (Outside U.S.) and choose Option 1
- Send email to support@citiprogram.org

14. I would like to write a retrospective patient case report utilizing several cases. Given that case reports are not considered human subjects research- if no PHI is involved- (and do not need to be submitted to the IRB); would I need to submit a protocol for a case series incorporating several files?

Case reports do not need IRB or DataClear submission. However, they require [patient authorization/ consent](#), if protected health information (PHI) is involved (please see the list of 18 HIPAA identifiers). On the other hand, majority of journals require uploading patient authorization forms upon submission.

However, case series need review or clearance by the IRB and division also.

15. What is IRB? Do need to submit to IRB?

Please watch [UCF IRB 101 workshop](#).

16. How do I gain access to the UCF IRB system to submit a protocol?

Login to iRIS at <https://iris.research.ucf.edu/>. You must go to the ID management application (link at the bottom of the iRIS page) to reset/create your username and password. After following the steps, you will be able to access the system.

17. Are there protocol and consent templates that the university expects researchers to utilize?

Templates for studies are available at

<http://www.research.ucf.edu/Compliance/IRB/Investigators/forms.html>.

The facilities you will carry out your research have their own forms also.

18. Now that I've completed the CITI training and have developed the required documents, how do I submit my application to the IRB?

UCF's IRB utilizes the Integrated Research Information System (iRIS). To submit materials, login to the system at <https://iris.research.ucf.edu>. Instructions for setting your username and password are available on the entry page.

An IRB application can be submitted in iRIS prior to completing the CITI training, but final IRB approval cannot be granted until all key study personnel have successfully completed the required training.

19. I'm a GME faculty. I am interested in submitting my research to UCF IRB, what is the process?

At this time, UCF IRB only reviews the projects of UCF/ HCA GME consortium residents and UCF full-time faculty and core faculty. If you are an affiliated UCF faculty, you may be the advisor, but your resident must be the PI for submission on the IRB application. VA projects must be submitted to the VA IRB.

20. May I perform my study at HCA facilities if I have IRB letter?

UCF COM, UCF IRB, HCA and hospitals are separate governing bodies. Under FDA (and HHS) regulations IRB is required to assure ethical and responsive research conduct, protection of human subjects.

However, you still need to have facility, division and corporate approval to document and assure that your work is being conducted in compliance with company policies.

21. When do I submit to DATACLEAR?

After division approval, research proposals are submitted to the corporate through [DATACLEAR](#) using the DATACLEAR proposal form. HCA corporate approval is required regardless of whether or not HCA data is being requested. If not using HCA data, the "no data needed" selection is chosen for Question 6 on the DATACLEAR form.

22. I would like to do a Quality Improvement project. What are the steps?

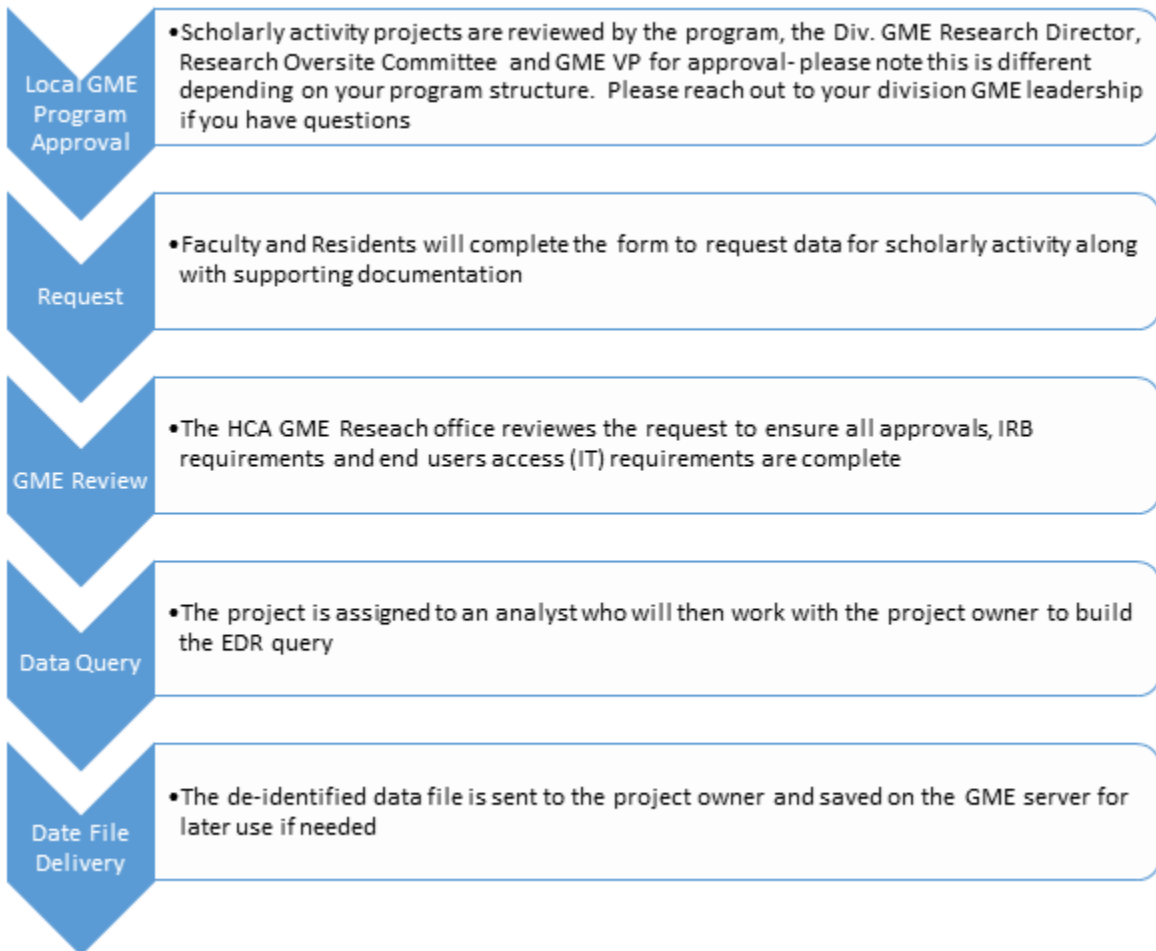
Please refer to [QI FAQ](#).

23. I would like to request data from HCA to analyze for research. What is the process?

Residents and GME faculty may request HCA data with their ¾ ID. All projects must be submitted to [NF Division Research Office](#) first. Please see [flowchart](#) for GME projects.

After division approval, requests are submitted to the corporate through [DATACLEAR](#) with proposal form. Please refer to Data Dictionary for data point/ parameters.

The GME research analysts will then utilize your project outline or protocol to query the Enterprise Data Warehouse (EDW). A flowchart of the project submission process is described below.



Once the researchers are given access to their folder, they can work perform data analysis on the virtual desktop infrastructure (VDI).

24. Where can I store my research data?

NF Division has a data repository folder on the HCA network that is accessed using the VDI. Keeping data stored on the VDI allows the storage of data to be HIPAA compliant.

25. What is PubCLEAR? Do I need approval for publishing my work?

[PubCLEAR](#) is a tool for getting clearance for External Data Release (EDR). This policy pertains to the publication, presentation or any other format for the making public of clinical research results and/or clinical recommendations by HCA employees, facilities, hosted students, medical residents and other “HCA Workforce Members” on behalf of an HCA related entity.

All GME publications (meeting abstracts, oral presentations, journal articles, etc.) require [EDR/ PubCLEAR](#) approval prior to submission.

In order to facilitate the process, please refer to PubCLEAR tips file in Medhub.