

# GME Research Step-by-Step

## This page is for research involving MAHEC residents/fellows (a.k.a GME Research)

Follow these steps when you have a resident or a fellow as member of your MAHEC research team. This process is required before you begin any research.

1. Online training in protection of human subjects via [CITI Program](#).

2. Create an account with IRBNet and download a protocol template.

**PLEASE NOTE: LINKS ONLY WORK WHEN CONNECTED TO THE MAHEC NETWORK EITHER ON-SITE OR CONNECTED VIA VPN (Global Protect)! THIS ENSURES THE PRIVACY OF THE LINKED DOCUMENTS.**

### How to use IRB net

- Much GME research will be retrospective chart review. Use the *Study Protocol- Medical Records Research* form
- Surveys or other benign interactions should use the *Study Protocol- Minimal Risk Research* form
- If your GME research involves an *intervention* or *interaction* with subjects, you will want to use IRB Manger resources, specifically, "IRB Manager Initial Submission" This document details submission of your research protocol. Includes all questions that will be asked.

3. Once your protocol is completed, it needs IRB review.

If you are using Mission Data and have a GME researcher, you will submit to CARRIE for IRB screening for exemption.

If you are using MAHEC Data only and have a GME researcher, you will submit to the Mission IRB through IRBNet.

- Regardless of route (CARRIE or Mission IRB) you will need to attach your research protocol, surveys, data collection sheets, etc. to the submission.
- Please send all research protocols using Mission Data to the HCA NC Division Director of Research - Tokesha Warner.
- Questions about the Mission IRB request for Exemption may be directed to Elizabeth Hamilton.

## 4. After IRB exemption or approval, data collection may begin.

If you are using Mission Data and have a GME researcher, you will submit to DataClear to request data.

- Once approved, an HCA GME data analyst will set up an Initial Statement of Work (SOW) conference call with the Principal Investigator and team to discuss.
- HCA GME does not conduct data analysis at this time. Please contact MAHEC Research for assistance with data analysis and statistical support.

If you are using MAHEC Data only, proceed to data collection, keeping HIPAA protections in mind.

- Keep data sets on secure MAHEC servers and encrypt/protect with a password.
- Create a de-identified data set for analysis with a crosswalk to patient identifiers kept separately.

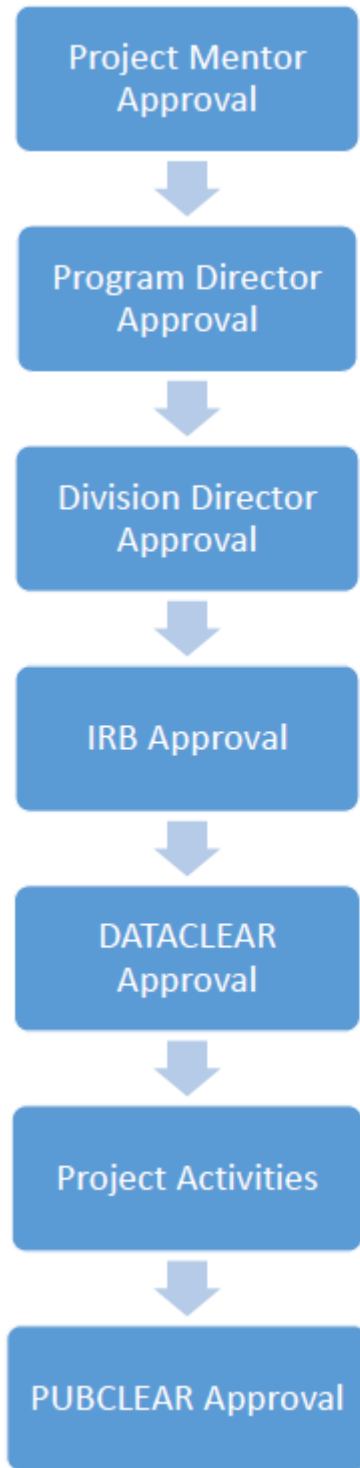
## 5. All research done with Mission Data requires clearance before dissemination of results.

If you are using Mission Data and have a GME researcher, you will submit to PubClear for review.

- When your research has been analyzed, you will likely want to present and/or publish your results. Any and all dissemination requires clearance prior to presentation via PubClear.
  - This requirement applies to *abstracts, posters, presentations, manuscripts, and all other dissemination* of research results outside of MAHEC and/or Mission hospital.

If you are using Mission data but does not include GME researchers or is Dental research, you will submit to External Data Release for review. (page under construction)

## Mission GME Research process



- Ensure that your project mentor has reviewed and approved your proposal.
- Program Director approval requirements differ by program. Please check with Program Director.
- All proposals must be approved by Division Director.
- Use IRB Manager. Most protocols will be exempt.
- All projects except for review papers and case reports need DATACLEAR approval. If unclear, check with Division Director.
- Everything should receive Division Director and PUBCLEAR approval before submission to conference or journal.