Please read ***IRB Guidance: Quality Improvement Projects*** found on the IRB website before completing this form.

**Quality Improvement/Quality Assurance Review/Project Program Evaluation**: The activity is limited to quality improvement, quality assurance, and program evaluation activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting. These types of projects do not meet the federal definition of research because the results are not “generalizable.” If you feel that your project is “generalizable” and answers a research question, contact the GME Research Program Administrator prior to submitting any applications for IRB review.

Note: A QI project is designed for the purpose of improving the quality of a service, program, or process. The purpose of a QA project is to assure known quality and the purpose of Program Evaluation (PE) is to assess a program is doing what it is intended to do. These project types should present NO CHANGE in RISK to participants. These projects are mechanisms to assure a service, program, or process functions optimally. Such projects are usually for internal auditing purposes only.

A project may have **both** a QI/QA/PE focus as well as a ***research*** focus. If after consultation with the Research Program Administrator and/or the Research Director, your project is determined to include research activities, the appropriate IRB application form will need to be submitted for IRB review.

**Instructions:**

* QI/QA/PE projects may be conducted by residents or students in conjunction with a faculty/staff advisor.
* Projects thought to be a QI/QA/PE are to be submitted to the GME Research Program Administrator via email at sleming@capefearvalley.com.
* Since the focus of these projects does not fit the definition of research under 45 CFR 46.102(l), IRB review and determination is not required. If you require an IRB letter of determination the Research Program Administrator will forward to the IRB for official determination. If you do not require an IRB letter of determination the Administrator will notify you of by email if further clarifications are required or the submission is acceptable. For such projects, privacy, and confidentiality regulations (HIPAA) and Institutional policies must still be followed.
* Attach verification of human subjects training certification for all project team members. **See IRB Guidance: Human Subjects Research Training** to determine what training is required.
* Read, sign, and attach the ***GME Investigator Agreement***.
* Letters of support (LOS) from the clinical site or area, acknowledging awareness of and support for the project activities must be attached. The support letter should include the signature of the clinical administrator or clinical leader of the respective site or area.
* Please ensure you have discussed your potential QI/QA/PE project with your Faculty/Staff Advisor, Program Director, and the GME Research Director ***prior*** to submitting this form.

**Fill-in Form begins on next page**

|  |
| --- |
| **Submission Date:** Click or tap to enter a date. |
| Section 1: Project and investigator Information |

|  |
| --- |
| Project Title: *Title* |
| Principal Investigator (PI)(Faculty Advisor or Attending Responsible, if applicable): | Enter Name |
| Rank/Title: | Rank/Title. | Institution/Department: | Institution/Department |
| Role/responsibilities in this project: | Click or tap here to enter text. |
| Preferred Phone Number: | XX-XXX-XXXX | Institutional Email | Click or tap here to enter text. |
| Medical Student/Resident: (if applicable) | Enter Name | Program Year | enter text. |
| University/Residency Program Affiliation: | Click or tap here to enter text. |
| Phone Number: | XX-XXX-XXXX | Email: | Click or tap here to enter text. |
| Clinical Site, if applicable: | Click or tap here to enter text. | Letter of Support attached: | [ ]  Yes |
|  |
| 1. **Purpose:**

*Concisely describe the issue addressed by this project. Provide support that the focus of this project is to implement existing knowledge in a clinical or program practice or access an existing clinical or program practice and not to contribute to generalizable knowledge.* |
| Click or tap here to enter text. |
| 1. **Evidence-Based Literature Review and Synthesis:**

*Critically summarize the evidence that supports the project. The evidence should be convincing to clearly support practice change, improvement, assessment, or evaluation. Demonstrate how the translation of evidence will be/was implemented in clinical or program practice. Emphasize that this project will not produce generalizable knowledge (research) but is to implement or provide evidence into clinical or program practice (QI/QA/PE). Include a list of citations.* |
| Click or tap here to enter text. |
| 1. **Project Aims:**

*List specific aims or goals to be accomplished. Provide details on how your aims or goals support the purpose of the project.* |
| Click or tap here to enter text. |
| 1. **Project Methods:**

*Include the following information in this section:** *Project design, organizational setting, and sample population*
* *Evidence-based innovation that will change the practice or was previously changed, if applicable.*
* *Evidence-based Implementation Strategy (provide details of how the evidence will influence practice change and the specific strategies or steps for implementation; include discussion of key clinical staff engaged in the project; describe the evidence implementation’s potential for sustainability), if applicable*
* *Assessment measures including fidelity and patient outcomes as appropriate.*
 |
| Click or tap here to enter text. |
| 1. **Timeline:**

*Describe the timeline for completion of the project. Include when data collection is to be initiated, when the project implementation phase occurs, and when post implementation data will be collected.* |
| Click or tap here to enter text. |
| 1. **Evaluation Plan:**

*Describe how the project will be evaluated and what statistical measure will be used.* |
| Click or tap here to enter text. |
| 1. **Data Collection Plan:**

*Provide a concise description of how data will be collected. Include how patient data will be identified, who is involved with data collection, and what data will be obtained. Describe where this information is found and how it will be extracted. (NOTE: If data collection plan includes survey of employees/medical staff include confirmation of administrative approval of survey plan).* |
| Click or tap here to enter text. |
| 1. **Privacy, Data Storage and Confidentiality:**

***All*** *the following information must be included in this section:**• Discuss how the patient’s privacy will be protected.**• Describe what media type will be used to store the data (paper or electronic file or both).**• Describe* ***what Protected Health Information (PHI)****, if any, will be stored.**• Specify whether PHI will be destroyed once all data collection is completed. Specify how data will be collected without identifiers or if collected with identifiers will data be de-identified after collection and how will identifiers be stripped.**• Data must be saved on a CFVH secured server or in a secured CFVH clinic. Data must not be on private computers, laptops, and other portable devices.* *• Specify the location where the data will be secured, who will have access to this information and measures to assure confidentiality is maintained.**If the data is collected and stored outside CFVHS, discuss the above information, referencing how it will be maintained at the clinical site. For example, if you are storing paper or electronic data where will you be storing it, at your clinical site or at CFVH? If there is PHI involved, how will it be secured (i.e., locked cabinet in a locked room, HIPAA protected server, CFVH secured server). Once you have completed use of PHI, describe if and when and how will it be destroyed. Discuss how a final data set will be maintained in a secure folder. An electronic pathway needs to be provided.*  |
| Click or tap here to enter text. |

REMINDER: This QI/QA/PE form is to be emailed to the GME Research Program Administrator at sleming@capefearvalley.com.