CAPE FEAR VALLEY HEALTH SYSTEM
Policy – Procedure

Resident/Student Research
APPENDIX A
Quality Improvement Project

SUBMISSION CHECKLIST:

Prior to submitting request please ensure the following are included:

____ **Completed Resident/Student Project Approval Request form (attached)**

____ **Completed Project Description Checklist (attached)**

____ **Project Description including all elements identified in the "Quality Improvement Project Template" (attached)**

____ **Clinical Site letter of support (as referenced in final element of attached "Quality Improvement Project Template")**

____ **Documentation of current research education for each investigator and protocol coordinator (One option for meeting this requirement is completion of Good Clinical Practice web-based training course (all modules) https://gcp.nidatraining.org).**

RESIDENT/STUDENT PROJECT APPROVAL REQUEST

NOTE TO PI: Any publication related to this study will require approval by Hospital Legal Services prior to publication. Please contact Legal Services at extension 5937 for additional information.

Completed form and a summary of the proposed research should be returned via e-mail to Lenelle Davis at ldavis@capefearvalley.com. For questions please contact Lenelle Davis at the noted e-mail address.

Proposal Title: _____

Your Name: _____ Date: _____

Contact Information: E-mail _____/Phone _____

University/Residency Program Affiliation:_____

Name/Contact Information for Faculty Advisor/Attending Responsible for Oversight of Project:

Name: _____ E-Mail _____/Phone _____

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Preliminary Determination:
In compliance with policy titled "Resident/Student Research" I have made the following preliminary determination regarding the type of project being submitted:

___ Quality Improvement Project – Documentation as required in Appendix A is attached.
___ Case Study/Limited Case Series – Documentation as required in Appendix B is attached
___ Exempt Research (indicate specific category below) –Documentation as required in Appendix C is attached
  ___ Retrospective Review (collection and analysis of existing medical record information; ordinarily seek to evaluate relationships between one or more biomedical, treatment, and/or demographic variables and one or more outcome measures in patients.)
  ___ Case Series (greater than three case studies; a case study is a detailed examination of an event)
  ___ Educational Survey – (includes evaluation of teaching sessions, curricula, courses, programs, simulations and surveys)
___ Non-Exempt Research – Documentation as required in Appendix D is attached

_____ _____
RESIDENT/STUDENT SIGNATURE DATE

FACULTY STATEMENT: I confirm that I have reviewed this project proposal and approve for submission to the CFVHS IRB:

_____ _____
Faculty Member Signature Date

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Date Proposal Forwarded to IRB: _____

Resident/Student Research
APPENDIX A
Project Description Checklist

Please utilize the following questions to determine whether your proposed activity is a Quality Improvement Project. If all of the questions below can be answered as a "yes", the proposed activity should be submitted as a Quality Improvement Project.

NOTE: If you believe your project meets the definition of a quality improvement project but the answer to any of these questions is 'no", please consult with a representative of the IRB for clarification prior to proceeding with your submission.

PROJECT DESCRIPTION CHECKLIST	YES	NO
Purpose Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?		
Scope Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge?		
Evidence Is there sufficient existing evidence to support implementing this activity to create practice change?		
Clinician/Staff Is the activity conducted by clinicians and staff who provide care or are responsible for the practice change in the institutions where the activity will take place?		
Methods Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes?		
Sample Population Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place?		
Consent Will the planned activity only require consent that is already obtained in clinical practice, and could the activity be considered part of the usual care?		
Benefits Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?		
Risk Is the risk to patients/participants no greater than what is involved in the care they are already receiving OR can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented within a health care environment?		

If all the above are answered "yes" (or if confirmation that submission is a QI project has been obtained from the IRB), please prepare a summary of your project utilizing the following Quality Improvement Project template. Have your summary reviewed/approved by your faculty advisor, attach it to the Project Approval Request Form and forward to the Medical Staff Office for review by the IRB.

Resident/Student Research

APPENDIX A
Quality Improvement Project Template

Projects that are thought to be quality improvement (QI) projects may be submitted to the CFV IRB for an authoritative determination of their status by using the "Project Approval Request Form". As a result of this review, the submission will be declared to be exempt from further IRB review, or determined to be a research study involving humans that is subject to further IRB review.

The template presented below is designed for projects involving the translation of existing knowledge into clinical practice. Evaluating the effectiveness of knowledge implementation in creating clinical practice change is measured by the QI project outcomes. Since the focus of these projects does not fit the definition of research under 45 CFR 46.102(d), they will be evaluated as not involving research with humans. For such projects, privacy and confidentiality regulations (HIPAA) must still be followed. The IRB will review and provide consultative assistance, but is not responsible for approving how privacy, data storage and confidentiality measures are implemented in the quality improvement project. A clinical site letter is requested to document support and agreement with this project by individuals engaged in direct clinical care at the site where the study activity is to occur.

The project summary for the IRB should be no more than 5 pages. Please use the template on page 4 of this document to complete the proposal. Please utilize the checklist on page 4 of this document to ensure required documentation is submitted.

TEMPLATE

Project Title
and
Clinical Site

Statement of the Problem

Concisely describe the issue addressed by this quality improvement project. Provide support that the focus of this project is to implement existing knowledge in clinical practice and not to generate new knowledge.

Evidence-Based Literature Review and Synthesis

Critically summarize the evidence that supports the quality improvement project. The evidence should be convincing to clearly support practice change. Demonstrate how the translation of evidence will be implemented in clinical practice. Emphasize that this project will not produce new knowledge (research) but is to implement evidence into clinical practice (quality improvement).

Project Aims

Identify the purpose of this project and list specific aims or goals to be accomplished.
The aims should clearly support that the project is to implement evidence into clinical practice (quality improvement) and that it will not produce new knowledge (research).

Project Methods

Include the following information in this section:

- Design, organization setting, sample
- Evidence-based innovation that will change practice
- 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
- Assessment measures including fidelity and patient outcomes as appropriate

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).**

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.

Evaluation Plan

Describe how the quality improvement project will be evaluated and what statistical measures will be used**.**

Protected Health Information

Indicate how you intend to use Protected Health Information of patients whose information is used to measure the change in practice as a result of the evidence-based implementation project.

Privacy, Data Storage & Confidentiality

All of 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 de-identified.
- Specify the location where the paper or electronic file will be stored.
- 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 in reference to 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, encrypted jump drive). Once you have completed use of PHI, describe when and how will it be destroyed. Discuss how a final de-identified data set will be maintained in a secure folder. An electronic pathway needs to be provided.

Letter of support from the clinical setting

A clinical site letter of support acknowledging awareness of and support for the QI activity should be attached. The support letter should include the signature of the clinical administrator or clinical leader of the respective clinical area.

Approved: 7/19/18
Revised: 6/20/19