CAPE FEAR VALLEY HEALTH

Criteria for Quality Improvement/Quality Assurance Projects

Purpose: To assist investigators in determining if their proposed scholarly activities or project meets the criteria for QI/QA and does not meet the definition of research. QI/QA project conducted at non-CFVH owned sites should be submitted to the GME Research Program for tracking purposes and determination but must follow the non-CFVH covered entity's policies and HIPAA procedures.

A Quality Improvement and Quality Assessment (QI/QA) project/activities are **not** considered to meet the definition of **research** if **all** of the following criteria are met:

- ☐ When the intervention involves patients, all patients who get the intervention are expected to benefit; and
- ☐ The purpose of measurement related to the QI/QA project is to determine the effect of process change, measure performance, or for submission to an authorized national or state registry and/or database that has the intent to improve the delivery of clinical care; and
- ☐ The purpose of the QI/QA project is to improve institutional processes or delivery of care consistent with established quality standards; and
- ☐ When the initiative involves patients, all patients involved in the initiative will receive standard of care at a minimum; and
- ☐ The project involves systemic data collection to monitor and compare performance to defined standards; and
- ☐ The project will be described as "quality improvement" or "quality assurance" in public presentations, academic curriculum vitae, publications, and/or other representations to any third-party audience, with a planned statement similar to: "This project was undertaken as a Quality Improvement Initiative at Cape Fear Valley Health (CFVH), and as such was not formally supervised by the Institutional Review Board per their policies."; and
- ☐ There is an agreement (letter of support) with the leadership of the clinical practice unit in which the project will take place (the unit in the hospital, clinic, division, or care group) that this is a QI/QA project that will be undertaken to improve institutional processes or delivery of care; and
- ☐ The project will be conducted by clinicians and staff where the project will take place, and involves staff and/or patients of CFVH or of component of CFVH; *(if conducted at a non-CFVH entity, investigators must follow the external sites' policies)* and

All following additional conditions must be met:

- ☐ The intent of the project is NOT to test a novel hypothesis, answer a research question or replicate another researcher's original study; and
- ☐ The project does NOT seek to test interventions, treatments or practices that are not currently considered standard of care in any existing practice (neither consensus-based, nor evidence-based); and
- ☐ The project does NOT involve withholding any aspect of standard of care; and
- ☐ The intent of the project is NOT to design or develop a new standard of care or benchmark; and
- ☐ No physician or staff member will be blinded to any aspect of the patient's care; and
- ☐ No persons (including patients and investigators) will be exposed to risks beyond those involved in clinical care that are greater than minimal risk; and
- ☐ The project does NOT involve a research design (e.g., randomization) that over-rides clinical decision-making; and
- ☐ The project does NOT involve using a medication or medical device or procedure outside

of usual medical practice; and

- ☐ The project does NOT involve funding from a research grant or other research agreement; and
- ☐ The project will NOT be described as research in representations such as publications, presentations, or academic dossier; and
- ☐ Chart/Record reviews are NOT the only activities of the entire QI project. QA projects may involve chart/record reviews only.

Projects that do not meet all of the above criteria should be submitted to the IRB for review.

All PHI must be transmitted, stored, analyzed, or otherwise exist only on HIPAA-compliant electronic systems that meet CFVH's security standards for protection of PHI.