

**Brody School of Medicine at East Carolina University
ECU Physicians**

Title: Expanding or Creating New Clinical Programs/Services	
Section No. 2	Section Name: Clinical
Approval Date: 07/24/09, 11/17/11	Approval: Paul R. G. Cunningham, MD

I. Purpose Statement

The purpose of this policy is to set forth the process by which the Dean, ECU Physicians Board of Directors, Medical Director, Credentialing Committee, ECU Physicians Executive Director, Office of Compliance, Office of Risk Management, and Nursing Services will receive and consider proposals to expand existing clinical programs, services, procedures or to offer new clinical services, procedures or modalities.

II. Policy Statement

ECU Physicians supports the expansion of clinical programs, services and procedures that are intended to improve the health status of patients it serves or to enhance the educational experiences of learners.

ECU Physicians has the duty to ensure that those programs, services and procedures support the overall mission of Brody School of Medicine and ECU Physicians' strategic plan; conform to regulations, standards, and national practice standards within the clinical specialty; and do not create an unacceptable risk for its patient population or the institution.

III. Scope

This policy will apply to, at least, the following:

1. Any new invasive clinical procedure not currently provided by that Department in the outpatient setting.
2. Any new clinical program, service, and/or procedure planned by one Department that is currently provided by another discipline or department.
3. Any new program, service or procedure for which ECU Physicians providers do not already have PCMH or other hospital privileges.

IV. Definitions

Examples of new clinical programs, services, procedures could include a new bariatric surgery technique; new equipment or new approach to traditional surgery, such as the initial introduction of robotic for cardiac and gynecology surgeries (at that time); endoscopic procedures by physicians other than gastroenterology or general surgery;

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interventional pain management; and practices for which ECU Physicians providers do not already have PCMH or other hospital privileges.

V. Procedure

- A. The Department contemplating a new clinical program, services and/or procedures will do the following.
1. Consult with the ECU Physicians Medical Director and provide, at least, the following detailed information.
 - a) Requested date to implement the proposed clinical program, services and/or procedures;
 - b) Patient population to be served, both the diagnosis(es) involved and the anticipated number of patients during the first year of service, plus any anticipated growth in the volume of patients; and
 - c) Known risks, adverse effects, and complications of the proposed clinical program, services and/or procedures.
 - d) Adequate number and skill of personnel to administer the clinical program and provide the services and/or assist with the services and/or procedures.
 2. Provide documentation of the prior training by all providers in the Department who request to provide the new proposed clinical program, services and/or procedures. This documentation must consist of all of the following, when relevant:
 - a) Training during an ACGME accredited graduate medical education program; or
 - b) Training during a formal non-accredited graduate medical education program; or
 - c) Training during an ACCME accredited continuing medical education program; or

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- d) Training in any other setting, in which case the training objectives, curriculum, and outcome measures, in addition to the credentials of the faculty involved, will be included; plus
 - e) Objective evidence of current competency in the proposed new clinical program, services, and/or procedures, to include number of procedures performed, patient outcomes and other relevant data; plus
 - f) Suggested outcome monitors to be used after implementing the proposed clinical program, services and/or procedures to assure quality care is provided to patients with minimal risk.
3. If the proposed clinical program, services and/or procedures is within the normal scope of practice for the specialty of the Department, then documentation from the appropriate specialty certification board should be provided.
- B. The Medical Director will:
- 1. Confer with other departments or services within ECU Physicians to also evaluate the proposal for new clinical programs, services and/or procedures. This may include, but not necessarily be limited to, Nursing Services, Risk Management, Compliance, University Attorney, Clinical Financial Services, and Pharmacy Services.
 - 2. Present, or facilitate a presentation of, the proposed clinical program, service and/or procedures to the ECU Physicians Credentialing Committee for review and consideration as to whether the Committee should submit a recommendation to approve the program to the ECU Physicians Board of Directors. (Proposals may also need to be reviewed by the ECU Physicians Finance Committee if a significant fiscal impact is anticipated.)
- C. The ECU Physicians Board of Directors will make a recommendation to the Dean of the Brody School of Medicine whether to implement the proposed clinical program, services and/or procedures.
- 1. The ECU Physicians Credentialing Committee or Board of Directors may require the department to provide follow-up reports after implementation of the new program.

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- D. The Dean of the Brody School of Medicine will notify the Department of the final decision to approve, disapprove or modify the recommendation of the ECU Physicians Board of Directors.

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