



North Carolina Department of Health and Human Services  
Division of Health Service Regulation

Pat McCrory  
Governor

Richard O. Brajer  
Secretary DHHS

Mark Payne, Director  
Health Service Regulation

September 15, 2016

Elizabeth Kirkman  
CHS Management Company  
2709 Water Ridge Parkway, Suite 200  
Charlotte, North Carolina 28217

**Exempt from Review – Proposed Research Activity**

**Record #:** 2061  
**Facility Name:** Carolinas Medical Center  
**Type of Facility:** Hospital  
**FID #:** 943070  
**Business Name:** The Charlotte-Mecklenburg Hospital Authority  
**Business #:** 1772  
**Project Description:** Acquire a mobile CT unit to be used by Levine Cancer Institute for research activities  
**County:** Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letter of September 7, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-179. Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Gloria C. Hale  
Project Analyst

Martha J. Frisone  
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR  
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR



**Healthcare Planning and Certificate of Need Section**

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

An Equal Opportunity/ Affirmative Action Employer





Carolinus HealthCare System



September 7, 2015

Ms. Martha Frisone, Assistant Chief  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
809 Ruggles Drive  
Raleigh, NC 27603

**RE: Request for Research Activities Exemption**

Dear Ms. Frisone:

Please accept this letter and the completed Notice of Proposed Research Activity form attached as The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center's request for a research activities exemption for a new institutional health service.

The project involves the acquisition of a mobile CT unit to be used by Levine Cancer Institute, a facility of Carolinas Medical Center, for research efforts as defined under NCGS 131E-179. It is estimated the mobile CT unit will cost \$1.1 million.

Sincerely,

Elizabeth Kirkman  
Assistant Vice President  
CHS Management Company

Attachments

## Notice of Proposed Research Activity

N.C.G.S. §131E-179 allows a health service facility to offer a new institutional health service to be used solely for research without a certificate of need, if the Department grants an exemption. To request an exemption to offer a new institutional health service to be used solely for research, please respond to the following:

### 1. Facility Information:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center

(Name)

943070

(FID #)

### 2. Facility Address:

1000 Blythe Boulevard

(Street)

Charlotte

(City)

Mecklenburg

(County)

### 3. Project Description:

Levine Cancer Institute (LCI) has been awarded a \$1.6 million grant from the Bristol Meyers Squibb Foundation for its **Lung B.A.S.E.S.** (Bringing Awareness, Screening & Education to improve Survivorship) **4 Life** program.

**Lung B.A.S.E.S. 4 Life** entails deploying a specialized mobile CT unit into vulnerable communities where access to care is limited in order to provide free low-dose CT lung cancer screenings, smoking cessation education and navigation services to assist with follow-up, monitoring, and transition to active intervention for those identified with a positive screen. LCI anticipates conducting research in the following areas:

- The impact of early detection
- The impact of navigation and program coordination
- The effectiveness of outreach approaches for vulnerable, unserved communities
- The effectiveness of existing criteria used to determine eligibility for patient screening
- The effectiveness of low-dose CT screening versus other diagnostic tools

The project includes the purchase of a mobile CT unit for \$1.1 million. The vehicle, a 35-foot coach, is a self-powered unit which does not require a pad. The scanner is clinically effective and can serve any location such as health

departments, community clinics, churches, etc. Additional grant funds will be used for fuel costs, medical supplies, and physician fees.

**4. Document that the proposed project will not:**

- a. Affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research;**

No patients or payors will be billed for any services performed on this equipment.

- b. Substantially change the bed capacity of the facility; or**

The proposed project will be not impact the bed capacity of any facility.

- c. Substantially change the medical or other patient care services of the facility.**

The proposed project will not change the medical or other patient care services of any facility.