



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

March 22, 2019

Elizabeth Kirkman
2709 Water Ridge Parkway, Suite 200
Charlotte, NC 28217

Exempt from Review – Proposed Research Activity

Record #: 2905
Facility Name: Carolinas Medical Center
Type of Facility: Hospital
FID #: 943070
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Acquire a mobile CT unit to be used by the 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 March 15, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §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, Radiation Protection, 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,

Julie M. Faenza
Julie M. Faenza
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief, Healthcare Planning and Certificate of Need Section

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr • TEL: 919-855-3873



Atrium Health



March 15, 2019

Ms. Martha Frisone, 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 \$982,000.

Sincerely,

Elizabeth Kirkman
Assistant Vice President
Strategic Services Group
Atrium Health

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 \$982,000 grant from the Leon Levine Foundation for the expansion of 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 \$982,000. 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.

LCI currently operates one mobile CT scanner which was first launched in 2016. This project proposes to expand the Lung B.A.S.E.S. 4 Life program by purchasing a second mobile CT scanner. This new unit would be used to expand screenings statewide to newly identified high-risk populations where access to care is limited.

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.