



NC DEPARTMENT OF  
HEALTH AND  
HUMAN SERVICES

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

November 8, 2019

Catharine W. Cummer, Regulatory Counsel, Strategic Planning  
Duke University Health System  
3100 Tower Blvd, Suite 1300  
Durham NC 27707

**Exempt from Review – Proposed Research Activity**

**Record #:** 3124  
**Facility Name:** Duke University Hospital  
**Type of Facility:** Hospital  
**FID #:** 943138  
**Business Name:** Duke University Health System, Inc.  
**Business #:** 640  
**Project Description:** Transfer existing PET/CT equipment to the Duke School of Medicine for the school's use as research equipment  
**County:** Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letter of October 17, 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 Acute and Home Care Licensure and Certification and Radiation Protection 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,

Michael J. McKillip  
Project Analyst

Martha J. Frisone  
Chief

cc: 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  
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



# Duke University Health System

Catharine W. Cummer  
Regulatory Counsel, Strategic Planning



October 17, 2019

Via Electronic Mail

Ms. Martha Frisone  
Mr. Michael McKillip  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: Exempt PET-CT Replacement Project at Duke University Hospital ~~943148~~

943138

Dear Ms. Frisone:

The purpose of this letter is to request the CON Section's written confirmation that Duke University Hospital's acquisition of replacement PET-CT scanner satisfies the requirements under N.C.G.S. 131E-184(f) for replacement equipment that exceeds the two million dollar (\$2,000,000) threshold on a hospital's main campus.

In addition, we request approval to transfer the existing equipment to the Duke School of Medicine to be used as a research-only machine pursuant to N.C.G.S. 131E-179.

As set forth below, we believe that Duke University Hospital's project meets these requirements and is exempt from certificate of need review.

## Replacement of PET-CT Scanner

The replacement of the PET-CT scanner meets the requirements of NCGS 131D-184(f) for replacement equipment on the main campus of a licensed facility.

### (1) Main Campus

The purpose of this project is to replace a PET scanner existing located in the Duke Cancer Center, which is part of the main building of Duke University Hospital. The "main campus" of the facility is defined in N.C.G.S. 131E-176(14n) to include both "[t]he site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds

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adjacent to that main building” and “[o]ther areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.”

In this case, Duke University Hospital is a licensed health service facility, and the main hospital building from which Duke University Hospital provides its clinical services and exercises financial and administrative control is the physically contiguous structure that includes Duke South, Duke North, the Duke Children’s Hospital, the Duke Medicine Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the Hudson Building. A plan showing the site of this replacement within of Duke North is enclosed. The hospital’s license and campus map have been previously provided to the CON Section.

(2) Previous Certificate of Need

The existing equipment was acquired and put into service in 2008 pursuant to CON Project No. J-7794-07.

(3) Replacement equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment provide PET scanning procedures. The total project cost exceeds \$2,000,000 reflecting major medical equipment, related equipment, and renovation/installation expenses. Copies of the equipment quotations are available upon request. Duke will not acquire any other major medical equipment or develop any other new institutional health services other than those described in Section 131E-176(16)(b).

Research exemption

Rather than physically taking the existing equipment out of the state, Duke proposes the transfer of the equipment to the Duke School of Medicine for the school’s use as research equipment. The equipment will accordingly be taken out of service as clinical equipment, consistent with the exemption set forth in N.C.G.S. 131E-179 for research activities. The equipment will not be used for clinical purposes billable to patients or payors.

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Thank you for your attention to this request. If you have questions about this information, please let me know.

Very truly yours,

A handwritten signature in cursive script that reads "Catharine W. Cummer". The signature is written in black ink and is positioned below the typed name.

Catharine W. Cummer

Enclosures

### EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	PET/CT	PET/CT
Manufacturer	GE	GE
Model number	Discovery 690	Discovery MI 5-ring
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	CC 1N23	CC 1N23
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2008	NA
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	\$3,140,800
Total cost of the equipment	\$3,202,823	\$3,037,000
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Duke University Hospital Cancer Center	Duke University Hospital Cancer Center
Document that the existing equipment is currently in use	In use	NA
Will the replacement equipment result in any increase in the average charge per procedure?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	PET/CT procedures	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	PET/CT procedures

## Notice of Proposed Research Activity

N.C. Gen. Stat. §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:

Duke University Hospital	943138
(Name)	(FID #)

2. Facility Address:

2301 Erwin Road	Durham	Durham
(Street)	(City)	(County)

3. Project Description:

In connection with a planned replacement of an existing GE Healthcare 690 PET/CT scanner, Duke University Hospital plans to transfer the existing asset to the Duke University School of Medicine for research use rather than to trade the equipment in or otherwise remove it from the state.

Duke would note that the School of Medicine is not a "health service facility" but submits this notice to confirm that the transfer to the School is exempt from certificate of need review.

4. Document that the proposed project will not:

- 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;
- Substantially change the bed capacity of the facility; or
- Substantially change the medical or other patient care services of the facility.

As the existing asset will no longer be used for clinical services, this transfer will not affect the charges of Duke University Hospital for the provision of medical or other patient care services other than services which are included in the research, change the bed capacity of the facility, or substantially change the medical or other patient care services of the facility.