



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

June 30, 2017

Catharine W. Cumber
3100 Tower Boulevard, Suite 1300
Durham, NC 27707

Exempt from Review – Replacement Equipment

Record #: 2313
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace and relocate two cardiac MRI scanners
County: Durham

Dear Ms. Cumber:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 23, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Magnetom Aera 1.5T and the Magnetom Skyra 3T to replace the Avanto 1.5T and the Verio 3T, respectively. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, 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 the 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 office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Bernetta Thorne-Williams
Project Analyst

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

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

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

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



Record# 2313
FID# 943138

Duke University Health System

Catharine W. Cumber
Regulatory Counsel, Strategic Planning

June 23, 2017

Via Electronic Mail

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



Re: Exempt Replacement Project at Duke University Hospital

Dear Ms. Frisone:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of two dedicated cardiac MRI scanners at Duke University Hospital satisfies the requirements under N.C.G.S. 131E-184(f) for "replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:

- (1) The equipment being replaced is located on the main campus.
- (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
- (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

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

(1) Main Campus

The purpose of this project is to replace existing MRI equipment, one of which is located in Duke South and one of which is located in Duke North, with new equipment which

will be installed in the Duke Medicine Pavilion , all of which locations are 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 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. The hospital’s license, a campus map and a floor plan showing these replacements within the Duke Medicine Pavilion (“DMP” on the campus map) for these replacements are enclosed.

(2) Previous Certificate of Need

The Certificate of Need for the existing equipment is enclosed.

(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 MRI procedures. The total project cost exceeds \$2,000,000 reflecting equipment and 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).

Material Compliance with Project J-8030-07

We would further note that the Duke Medicine Pavilion portion of the Duke University Hospital building was constructed pursuant to Project J-8030-07, which project is not yet complete. We also seek your confirmation that installing replacement cardiac MRI scanners in the DMP is in material compliance with the CON for Project J-8030-07, which originally included plans to accommodate MRI and other imaging services.

Ms. Martha Frisone
June 23, 2017
Page 3

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".

Catharine W. Cummer

Enclosures

State of North Carolina

Department of Health and Human Services Division of Health Service Regulation

*Effective January 01, 2017, this license is issued to
Duke University Health System, Inc.*

*to operate a hospital known as
Duke University Hospital
located in Durham, North Carolina, Durham County.*

*This license is issued subject to the statutes of the
State of North Carolina, is not transferable and shall remain
in effect until amended by the issuing agency.*

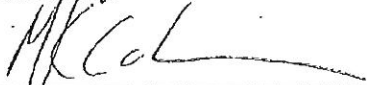
Facility ID: 943138
License Number: H0015

Bed Capacity: 957

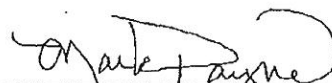
General Acute 938, Psych 19,

Dedicated Inpatient Surgical Operating Rooms: 6
Dedicated Ambulatory Surgical Operating Rooms: 9
Shared Surgical Operating Rooms: 50
Dedicated Endoscopy Rooms: 10

Authorized by:

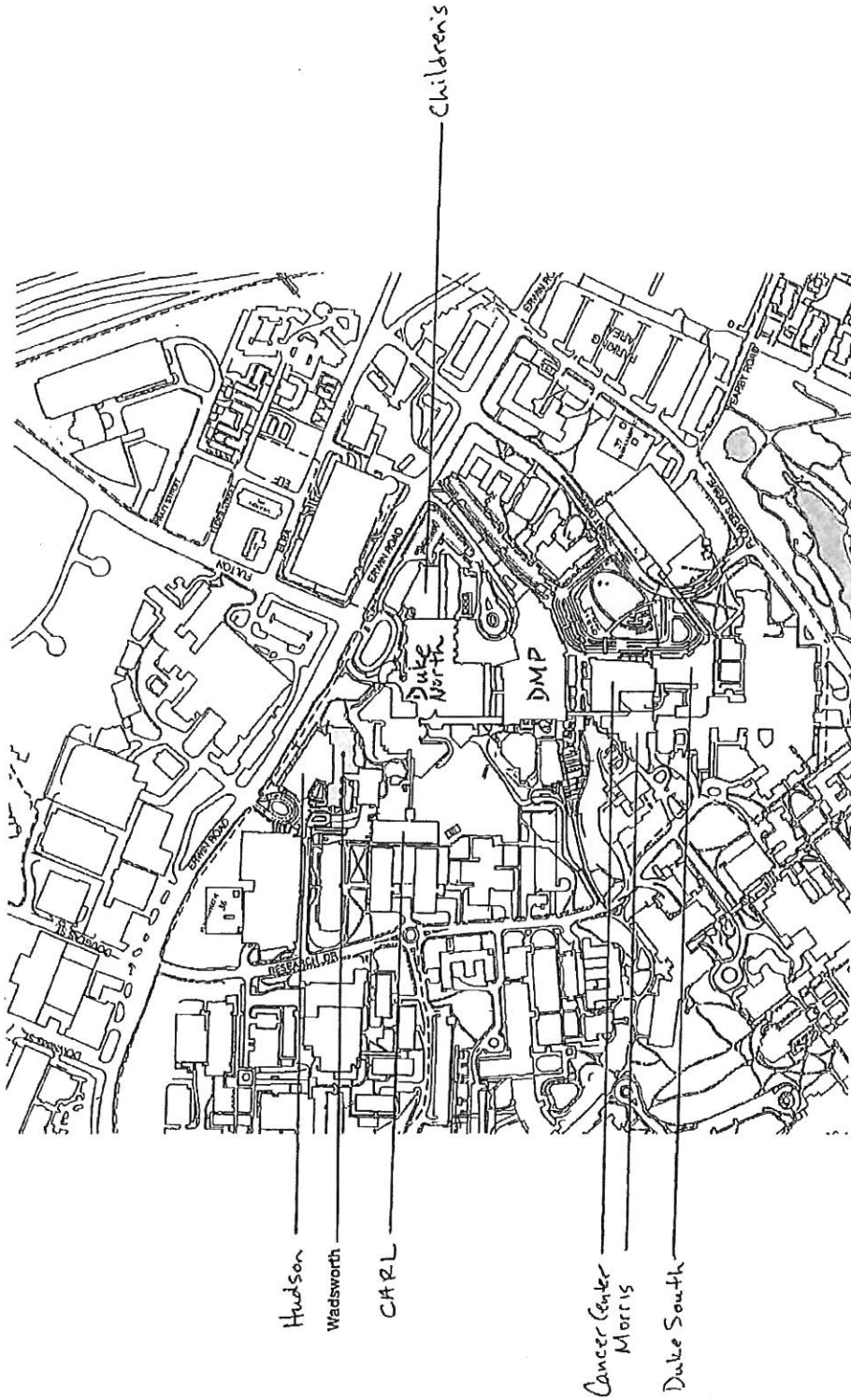


Secretary, N.C. Department of Health and
Human Services



Director, Division of Health Service Regulation

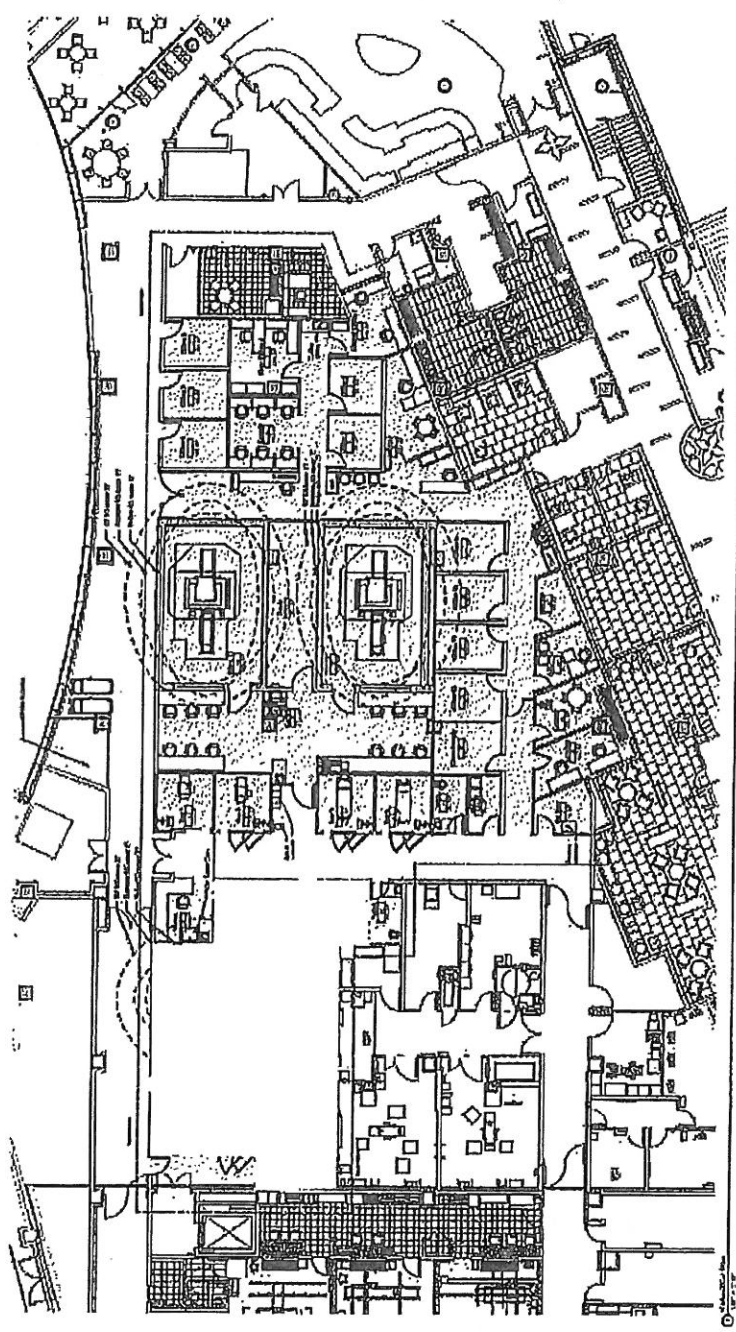
EX B



Campus Plan

1:5000

SHELL SPACE SHOWING EXEMPT
RENOVATION FOR EXISTING CMRI EQUIPMENT



STATE OF NORTH CAROLINA

file
CAROLINE MRI
COW

Department of Health and Human Services
Division of Facility Services

CERTIFICATE OF NEED for Project Identification Number J-6511-01 FID #943374

ISSUED TO: Duke University Health Systems, Inc.
3000 Erwin Road
Durham, NC 27710

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the obligations contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Duke University Health Systems, Inc. shall, pursuant to Policy AC-3 in the 2001 SMPT, convert a research only MRI scanner to clinical research use and acquire a second MRI scanner for clinical research use by the Cardiovascular and Magnetic Resonance Center, Durham County.

CONDITIONS: See Reverse Side

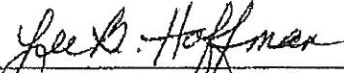
PHYSICAL LOCATION: Duke University Hospital
3000 Erwin Road
Durham, NC 27710

MAXIMUM CAPITAL EXPENDITURE: \$6,459,500

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: June 30, 2002

This certificate is effective as of the 30th day of April, 2002.



Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS

1. Duke University Health System Inc., shall materially comply with all representations made in the certificate of need application except as modified by the supplemental information received April 15, 2002, April 18, 2002, and April 19, 2002. In those instances in which representations conflict, Duke University Health System, Inc. shall materially comply with the last-made representation.
2. The two MRI scanners shall be used exclusively by the Cardiovascular Magnetic Resonance Center and shall not be configured or used to perform any procedures except cardiovascular MRI procedures.
3. Duke University Health System, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in section VIII of the application or that would otherwise require a certificate of need.
4. Duke University Health System, Inc. shall provide, at the request of the Certificate of Need Section, documentation of the number of cardiovascular MRI procedures performed in accordance with data format and reporting requirements that will be formulated by the Agency.

TIMETABLE

Phase I (conversion of research only scanner to clinical research use)

Operation of equipment	July 1, 2002
Occupancy/offering of service(s)	July 1, 2002

Phase II (addition of second clinical research scanner)

Contract Award	May 6, 2002
Ordering equipment	May 6, 2002
25% completion of construction	June 19, 2002
50% completion of construction	August 2, 2002
75% completion of construction	September 18, 2002
Completion of construction	November 1, 2002
Arrival of equipment	November 4, 2002
Operation of equipment	April 1, 2003
Occupancy/offering of service(s)	April 1, 2003

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Avanto 1.5T cardiac MRI Verio 3T cardiac MRI	Magnetom Aera 1.5T Magnetom Skyra 3T
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	Avanto -- 1.5T Verio -- 3T	1.5T 3T
Model Number	Avanto Siemens FL# 400-199705 Verio Siemens FL# 400-484507	Magnetom Aera 1.5T Magnetom Skyra 3T
Serial Number	Avanto 26244 Verio 40416	Not yet available
Provider's Method of Identifying Equipment	Avanto- Duke North cardiac MRI Verio -- Duke South cardiac MRI	NA
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #		
Date of Acquisition of Each Component	1/26/2004 (completion date for Project J-6511-01)	
Does Provider Hold Title to Equipment or Have a Capital Lease?	Avanto -- Title Verio -- Lease	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$5,879,704 (capital cost of J-6511-01 for conversion of existing research cardiac MRI to clinical use and acquisition of second clinical scanner)	\$13,168,682 (2 scanners, renovation, project contingency)
Total Cost of Equipment		Aera -- \$1,418,250 Skyra -- \$1,648,250
Fair Market Value of Equipment		Aera -- \$1,418,250

Net Purchase Price of Equipment			Skyra -- \$1,648,250 Aera -- \$1,418,250 Skyra -- \$1,648,250
Locations Where Operated		Avanto -- Duke North 7 th floor; Verio -- Duke South Clinic SB	
Number Days In Use/To be Used in N.C. Per Year		260	260
Percent of Change in Patient Charges (by Procedure)		NA	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)		NA	0
Type of Procedures Currently Performed on Existing Equipment		Cardiac MRI; Cardiac MR Stress; Chest MRA; Abdominal MRA, Pelvic MRA; lower extremity MRA;	
Type of Procedures New Equipment is Capable of Performing			Cardiac MRI; Cardiac MR Stress; Chest MRA; Abdominal MRA, Pelvic MRA; lower extremity MRA