

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 12, 2023

Anna Mickleberry apost@wakehealth.edu

Exempt from Review

Record #: 4170

Date of Request: March 21, 2023

Facility Name: Wake Forest Baptist Medical Center

FID #: 943495

Business Name: North Carolina Baptist Hospital

Business #: 1819

Project Description: Acquisition of a new High Intensity Focused Ultrasound

County: Forsyth

Dear Ms. Mickleberry,

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced proposal is exempt from certificate of need review in accordance with G.S. 131E-184(f)(3). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Terris S. Riley, J.D.

Project Analyst

Micheala Mitchell

Chief

cc: Construction Section, DHSR (Not Hospice Home Care/ Home Health/ESRD)

Acute and Home Care Licensure and Certification 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

Project Focused Ultrasound Installation at MR 3

Project ID 2022.073 Budget Leve Wake Forest Baptist Region AHWFBMC Campus Building MRI Purpose service for neuro pa Project SF 1,030 SF Land AC 0.00 AC DHSR/DHEC DHSR - Hospital CON Yes Author T. R. Bowers Reviewed Eric Walters Origin Date 9/26/2022 1/13/2023

\$2,108,000 \$25,000

Atrium Health

B-Level budgets are based on early schematic level information with site and tenants identified. Budgets include a general contractor's pre-construction estimate.

UPFRONT FUNDS REQUESTED

 % Professional Fees + (100% Pre-Con)
 40.00%

 Amount Requested
 \$ 9,000

ESCALATION (included in project costs below)

2022 2023 2024 2025+	\$0 \$5,188 \$0 \$0	Escalation included in project costs below
TOTAL Escalation	\$5.188	

BUDGET SUMMARY

PROJECT DESCRIPTION

This project is the installation of the Insightec Exablate Incisionless Neurosurgery System to be accommodated on existing MR 3, a Siemens Aero 1.5 T MRI in the MRI Building. The project requires ramping down the magnet for the installation. Purchase of the Siemens HIFU package is required for the magnet to operate with the new system. The project also requires the addition of a deionized water system and the removal of existing storage cabinets in the Magnet Room for the Exablate front end unit. In the adjacent equipment room to the MRI, the project requires new 480 VAC, 3-phase, 50 amp power, a UPS, space for the Exablate electronic cabinet and system cooling unit, and a vertical ladder to carry the equipment cables and chilled water to the penetration panel. The project also requires modifications to the penetration panel for the MRI shielding.

CAPEX Totals

Target Value

Code Category	Amount	\$/AC	Comments
100 LAND ACQUISITION COST	\$ -	\$ 0/AC	
100 SITE DEVELOPMENT COST	\$ -	\$ 0/AC	
CAPEX SITE WORK & LAND COST	\$ _	\$ 0/AC	

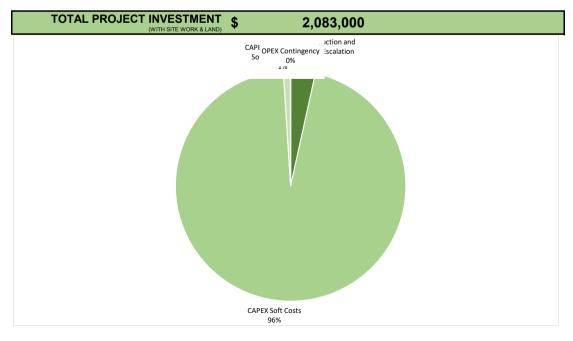
Code Category	Amount	\$/SF	Comments
200 CONSTRUCTION	\$ 72,000	\$ 70/SF	
300 MEDICAL EQUIPMENT	\$ 1,965,000	\$ 1,908/SF	
350 INTERIORS	\$ -	\$ 0/SF	
400 INFORMATION & ANALYTICS SERVICES	\$ 1,000	\$ 1/SF	
450 SECURITY	\$ -	\$ 0/SF	
500 INTERNAL RESOURCES	\$ -	\$ 0/SF	
600 PROFESSIONAL FEES	\$ 22,000	\$ 21/SF	
700 ADMINISTRATIVE	\$ 2,000	\$ 2/SF	
CAPEX BUILDING COST	\$ 2,062,000	\$ 2,002/SF	

Code Category	Amount	\$/SF	Comments
800 CONTINGENCY, SOFT COST & OTHER ESCALATION	\$ 21,000	\$ 20/SF	
CAPEX CONTINGENCY, SOFT COST & OTHER ESCALATION	\$ 21,000	\$ 20/SF	

OPEX Totals

Code Category	 Amount	\$/SF	Comments
300 MEDICAL EQUIPMENT	\$ -	\$ -	
350 INTERIORS	\$ -	\$ -	
400 INFORMATION & ANALYTICS SERVICES	\$ -	\$ -	
700 ADMINISTRATIVE	\$ -	\$ -	
800 CONTINGENCY	\$ -	\$ -	
OPEX SUB-TOTAL	\$ -	\$ 0/SF	

TOTAL PROJECT INVESTMENT \$ 2,083,000 \$ 2,022/SF



March 16, 2023

Ms. Micheala Mitchell, Chief Mr. Greg Yakaboski, Project Analyst Healthcare Planning and Certificate of Need Section Division of Health Service Regulation 809 Ruggles Drive Raleigh, NC 27603

Re: Request for Confirmation of No Review for North Carolina Baptist Hospital (FID # 943495; Lic # H0011), Acquire a Focused Ultrasound

Dear Ms. Mitchell and Mr. Yakaboski,

We are writing to notify the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Department") of North Carolina Baptist Hospital's ("NCBH") plan to acquire a new High Intensity Focused Ultrasound ("HIFU") to be placed at NCBH's main campus, located at Medical Center Boulevard, Winston-Salem, NC 27157, and to request a "no review" determination for the acquisition of this equipment.

Our understanding is that the HIFU is not subject to certificate of need review unless the cost of acquiring the equipment exceeds the \$2,108,000 threshold for "Major Medical Equipment" set forth in N.C. Gen. Stat. § 131E-176(140). The total capital expenditure for this project, inclusive of the cost of the equipment, construction, installation, other activities, and contingency will be \$2,083,000 which is below the statutory threshold for certificate of need review. Therefore, we respectfully request the Department's confirmation that this transaction is not subject to certificate of need review.

If you have any questions or require any additional information, please do not hesitate to contact Nicole Moore at nsmoore@wakehealth.edu or (336) 716-968. Thank you for your attention to this matter.

Sincerely,

anna Post Mickleberry

Anna Mickleberry AVP, Strategy, Regulatory Planning, and Business Development Telephone Number 336-608-7460 Email address apost@wakehealth.edu From: <u>Nicole Moore</u>

To: <u>Stancil, Tiffany C; Waller, Martha K</u>

Subject: [External] NCBH request for no review - HIFU Date: Tuesday, March 21, 2023 2:35:44 PM

All all was a 2003 0334 NORTH HITCH No. Do in July 578

Attachments: 2023 0321 NCBH HIFU No Review Letter FINAL.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to Report Spam.

Good Afternoon Tiffany and Martha,

Please find the attached request for confirmation of no review for North Carolina Baptist Hospital (FID # 943495; Lic # H0011) to acquire a focused ultrasound. Please reach out to me if there are additional questions. Thank you!

Warm regards, Nicole

Nicole Moore, MBA

Director, Regional Strategy and Planning

Growth, Strategy & Business Development – Atrium Health Wake Forest Baptist

Medical Center Boulevard | Winston-Salem | NC | 27157

Office: 336-716-6968 | Cell: 469-831-6587

Atrium Health

Wake Forest Baptist Health is now Atrium Health Wake Forest Baptist

CONFIDENTIAL – This document contains competitive healthcare information pursuant to N.C. Gen. Stat. 131E-97.3 and is not public record. The information contained in this message is privileged and confidential information intended for the sole use of the addressee. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this message in error, please notify the person listed above immediately by e-mail, and delete the original message and attachments.