



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

May 2, 2022

Marjorie McVay
Marjorie.mcvay@unchealth.unc.edu

Exempt from Review – Proposed Research Activity

Record #: 3887
Date of Request: April 22, 2022
Business Name: University of North Carolina School of Medicine
Business #: 3542
Project Description: Acquire a high intensity focused ultrasound for research purposes that will be attached to an existing MRI currently housed in the Biomedical Research Imaging Center
County: Orange

Dear Ms. McVay:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that the project described above 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.

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,

Kim Meymandi
Project Analyst

Micheala Mitchell
Chief

Cc: Elizabeth Runyon, Executive Director of Regulatory Affairs and Special Counsel, UNC Health

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
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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

April 22, 2022

VIA ELECTRONIC MAIL

Ms. Micheala Mitchell, Chief
Ms. Kim Meymandi, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
Micheala.Mitchell@dhhs.nc.gov
Kim.Meymandi@dhhs.nc.gov

**Re: Determination of Exemption for Research Activities / High Intensity Focused
Ultrasound / UNC School of Medicine Biomedical Research Imaging Center /
Orange County**

Dear Ms. Mitchell and Ms. Meymandi:

The University of North Carolina School of Medicine (“UNCSOM”) provides this prior written notice of a project exempt from Certificate of Need (“CON”) review. UNCSOM intends to acquire a High Intensity Focused Ultrasound (“HIFU”) for research purposes and, upon its acquisition, attach the equipment to an existing MRI currently housed in the Biomedical Research Imaging Center (“BRIC”). UNCSOM requests written confirmation that this project, including the use of the existing MRI scanner and the acquisition and use of the new HIFU equipment as described in detail below, is exempt from CON review.¹ The MRI and HIFU are collectively referred to hereinafter as the “Equipment.”

By way of background, HIFU equipment is primarily utilized in the treatment and study of nerve disorder patients. Dr. Vibhor Krishna is a board-certified neurosurgeon with expertise in functional neurosurgery and neuromodulation, who recently joined the Department of Neurosurgery at the UNCSOM as an associate professor. Dr. Krishna has received \$3.4M of NIH grant funding to study patients with Parkinson’s disease and essential tremor, and Dr. Krishna’s research using this grant funding will focus on the ability to diagnose and treat such diseases using the Equipment.

The proposed HIFU equipment will be acquired by the UNCSOM and will be housed in the BRIC, which is located on the UNCSOM campus and adjacent to UNC Hospitals (“UNCH”). As discussed above, the HIFU equipment would leverage an existing MRI machine, currently located in the BRIC, for imaging and tracking output throughout each procedure performed.

The CON exemption for acquisition of the proposed HIFU equipment and use of the existing MRI scanner is pursuant to N.C. Gen. Stat. §131E-179 (“Research Exemption”). Pursuant to subsection (a) of the Research Exemption, “a health service facility may offer new institutional health services to be used solely for research, or incur the obligation of a capital expenditure solely for research, without

¹ Despite a diligent search and inquiry, UNCSOM has been unable to ascertain whether prior written notice has already been provided to the Agency regarding the MRI scanner located at the BRIC, which is used solely for research and meets the requirements of the Research Exemption in N.C. Gen. Stat. §131E-179(a). To the extent such notice has not already been provided to the Agency for the MRI, please accept this correspondence as such notice.

a certificate of need, if the Department grants an exemption.” The Department shall grant the exemption if it receives notice of such intent and finds that the proposed activity will not:

- (1) Affect the charges of the health service facility for the provision of the medical or other patient care services other than services which are included in the research;
- (2) Substantially change the bed capacity of the facility; or
- (3) Substantially change the medical or other patient care services of the facility.

In response to the Research Exemption criteria above, the acquisition and use of the Equipment by UNCSOM will be solely for research (so long as CON approval has not yet been secured) and will not: 1) affect the charges for the provision of the medical or other patient care services other than services which are included in the research; 2) impact bed capacity; or 3) change the medical or other patient care services provided to patients.

After confirmation of this Research Exemption and acquisition of the HIFU, UNCSOM would plan to use the Equipment for research. However, UNCH also plans to submit a certificate of need (“CON”) application later this year, seeking approval to use the Equipment for limited clinical purposes as well, as described in further detail in Dr. Krishna’s NIH grant application. Focused ultrasound ablation using HIFU is FDA-approved and insurance reimbursed for the following conditions: 1) Medication refractory, disabling Essential tremor; and 2) Medication refractory, disabling Tremor dominant Parkinson’s disease. It also became FDA approved for fluctuations or bothersome dyskinesias in patients with advanced Parkinson’s disease, and the insurance reimbursement is pending. The assessment of these patients is multidisciplinary and involves neurology and neurosurgery. Thus, UNCSOM and UNCH recognize that the Equipment must be used solely for research pursuant to the Research Exemption, unless and until CON approval is secured for clinical use, which may then be billed and reimbursed.

UNCSOM will not charge patients or their insurance carriers for costs related to the proposed research using the Equipment, unless and until the subsequent CON approval is secured. Until further CON approval is secured, the cost of the research performed on eligible patients will be paid from either extramural grants or internal institutional resources.² Only patients enrolled in approved research protocols will be studied using the Equipment. The acquisition and use of the Equipment does not involve the addition or deletion of any licensed beds at the UNCSOM or UNCH. Finally, the use of the Equipment will not alter or change any of the medical or other patient care services provided by the School of Medicine or UNCH.

Furthermore, UNCSOM understands that pursuant to N.C. Gen. Stat. §131E-179(b), it shall not offer any new institutional health services in a manner which affects the charges of the facility for the provision of medical or other patient care services (other than the services which are included in the research) and shall not charge patients for the use of the service for which an exemption has been granted, without first obtaining certificate of need approval from the Department.

In consideration of the above, UNCSOM understands that acquisition of the HIFU for research is exempt from CON review, and requests written confirmation that the proposed acquisition and use of the HIFU equipment, and ancillary use of the existing MRI for research purposes (as described in more detail above) are exempt from CON review pursuant to N.C. Gen. Stat. §131E-179.

² As referenced above, Dr. Krishna has received RO1 grant funding for research involving use of the HIFU.

Please do not hesitate to contact me if you require any additional information.

Sincerely,

A handwritten signature in black ink that reads "Wesley Burks". The signature is written in a cursive, slightly slanted style.

A. Wesley Burks, MD
Stuart Bondurant Distinguished Professor
Dean and Vice Chancellor for Medical Affairs
CEO, UNC Health

A handwritten signature in black ink that reads "Weili Lin". The signature is written in a cursive, slanted style.

Weili Lin, Ph.D.
Director, Biomedical Research Imaging Center
Dixie Lee Boney Soo Distinguished Professor of Neurological Medicine
Professor and Vice Chair of Research, Radiology
Professor, Biomedical Engineering, Neurology and School of Pharmacy
University of North Carolina at Chapel Hill

cc: Elizabeth Runyon, Executive Director of Regulatory Affairs and Special Counsel, UNC Health