



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**  
Division of Health Service Regulation

ROY COOPER • Governor  
MANDY COHEN, MD, MPH • Secretary  
MARK PAYNE • Director

June 6, 2018

Jason D. Kaplan  
Wake Forest School of Medicine  
Medical Center Boulevard  
Winston-Salem, NC 27157

**Exempt from Review – Proposed Research Activity**

**Record #:** 2602  
**Business Name:** Wake Forest School of Medicine  
**Business #:** 1980  
**Project Description:** Acquire a CT scanner for research only to be located on the Wake Forest School of Medicine Clarkson Campus of NCBH  
**County:** Forsyth

Dear Mr. Kaplan:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of May 31, 2018, 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.

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

Sincerely,

Celia C. Inman  
Project Analyst

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

cc: mbarone@wakehealth.edu  
lpitman@wakehealth.edu  
Construction Section, DHSR  
Radiation Protection Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR  
Amy Craddock, Assistant Chief, Healthcare Planning, 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: 2704 Mail Service Center, Raleigh, NC 27699-2704  
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

May 31, 2018

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



**Re: Request for Confirmation of Exemption for Wake Forest School of Medicine Purchase of Research CT Scanner**

Dear Ms. Frisone and Ms. Inman,

Pursuant to N.C.G.S. § 131E-179, Research Activities, I am writing to request confirmation that the project described below for Wake Forest School of Medicine (WFSM) is exempt from review.

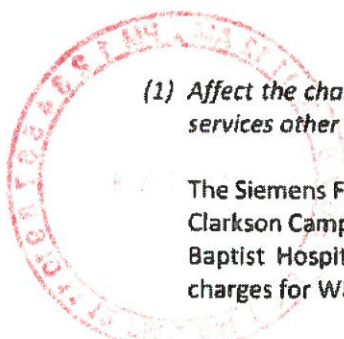
WFSM intends to purchase a Siemens Flash CT scanner for large animal research only use. The estimated cost of the Siemens Flash CT is \$1,433,000.

The Siemens Flash CT will be used solely to support Comparative Medicine programs for large animal models requiring CT imaging for characterization of physical phenotypes, including the presence of tumors, the distribution of fat, and characteristics of bone, muscle, fat, and internal organs. The Siemens Flash CT Scanner will be located at the WFSM Clarkson Campus.

Currently, large animals from the Clarkson Campus must be transported to the Richard H. Dean Biomedical Research Building in downtown Winston-Salem or the WFSM Main Campus on Medical Center Boulevard for CT scanning. These locations are approximately nine miles from the Clarkson Campus. Transport of large animals between the Clarkson Campus and these facilities presents a potential hazard to precious experimental animals due to the possibility of accidents, disruptions to social groups, and stressors to the animals. In addition, transportation of animals presents special handling issues for the assessments of mothers and infants, adds expense to research studies, and is a potential public health hazard if an accident occurred in transit.

N.C.G.S. § 131E-179, Research Activities, exempts new institutional health services from CON review if that service will be used solely for research purposes. WFSM believes this project is exempt from review, as described below. Pursuant to N.C.G.S. § 131E-179,

- (a) Notwithstanding any other provisions of this Article, 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 a certificate of need, if the Department grants an exemption. The Department shall grant an exemption if the health service facility files a notice of intent with the Department in accordance with rules promulgated by the Department and if the Department finds that the offering or obligation will not:*



- (1) *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;*

The Siemens Flash CT Scanner will be utilized solely for nonhuman primate research at the WFSM Clarkson Campus / Primate Center. There will be no change to hospital charges at North Carolina Baptist Hospital (NCBH), the primary academic teaching hospital for WFSM, or professional charges for WFSM faculty physician services as a result of the acquisition of this of CT scanner.

- (2) *Substantially change the bed capacity of the facility; or*

This service will have no impact on bed capacity. The CT scanner will be located off of the NCBH and WFSM main campus at the Clarkson Campus / Primate Center.

- (3) *Substantially change the medical or other patient care services of the facility.*

This service will not impact medical or other patient care services. The CT scanner will be located off of the NCBH and WFSM main campus at the Clarkson Campus / Primate Center.

- (b) *After a health service facility has received an exemption pursuant to subsection (a) of this section, it shall not offer the new institutional health services, or use a facility acquired through the capital expenditure, 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 a certificate of need from the Department; provided, however, that any facility or service acquired or developed under the exemption provided by this section shall not be subject to the foregoing restrictions on its use if the facility or service could otherwise be offered or developed without a certificate of need.*

- (c) *Any of the activities described in subsection (a) of this section shall be deemed to be solely for research even if they include patient care provided on an occasional and irregular basis and not as a part of the research program. (1983, c. 775, s. 1; 1987, c. 511, s. 1; 1991, c. 692, s. 4.)*

WFSM respectfully requests that the CON Section confirm that, based on the facts stated above, the described project is exempt from CON pursuant to N.C.G.S. § 131E-179.

Please let me know if you have any questions or if additional information is needed.

Sincerely,

Jason D. Kaplan  
Associate Vice President  
Wake Forest School of Medicine

## 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 or Business Information:**

Wake Forest School of Medicine	N/A
(Name)	(FID #)

**2. Facility Address:**

Medical Center Blvd	Winston-Salem, NC	Forsyth
(Street)	(City)	(County)

**3. Project Description:**

Purchase of a Siemens Flash CT scanner to be used solely for large animal research at the Wake Forest School of Medicine Clarkson Campus. The estimated cost is \$1,433,000.

**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;**

The Siemens Flash CT Scanner will be utilized solely for large animal research at the WFSM Clarkson Campus. There will be no change to hospital charges at North Carolina Baptist Hospital (NCBH), the primary academic teaching hospital for WFSM, or professional charges for WFSM faculty physician services as a result of the acquisition of this of CT scanner.

- b. Substantially change the bed capacity of the facility; or**

This service will have no impact on bed capacity. The CT scanner will be located off of the NCBH and WFSM main campus at the Clarkson Campus.

- c. Substantially change the medical or other patient care services of the facility.**

This service will not impact medical or other patient care services. The CT scanner will be located off of the NCBH and WFSM main campus at the Clarkson Campus.