



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

February 23, 2018

Catharine W. Cummer
3100 Tower Blvd, Suite 1300
Durham, NC 27707

Exempt from Review – Proposed Research Activity

Record #: 2527
Facility Name: Duke University Hospital
Type of Facility: Hospital
FID #: 943138
Business Name: Duke University Health System
Business #: 640
Project Description: Use of replaced bypass equipment removed from Duke Regional Hospital for research and training purposes at Duke University Hospital in the School of Medicine
County: Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letters of January 9, 2018 and February 21, 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 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.

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

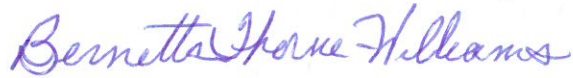
LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



Sincerely,



Bernetta Thorne-Williams
Project Analyst



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

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Shareta Blackwell, Program Assistant, Healthcare Planning, DHSR

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:

Duke Regional Hospital recently replaced one of its existing bypass machines. Rather than disposing of the old machine out of state, Duke University Health System seeks permission to retain the replaced equipment for use as a research/training tool at Duke University Hospital. Specifically, the pump will be made available to a Duke School of Medicine animal lab for research and training purposes, and also used for simulation training to assist with DUHS staff education.

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.

This equipment will not be used for any reimbursable clinical procedures, and will not affect the charges for any patient care services. It will have no effect on the bed capacity of the facility. It will be used for research and training only.

Williams, Bernetta

From: Catharine Cummer <catharine.cummer@duke.edu>
Sent: Wednesday, February 21, 2018 12:40 PM
To: Williams, Bernetta
Subject: RE: [External] Acquisition of bypass equipment for research/training purposes
Attachments: Bypass research request.docx

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to [Report Spam](#).

Here you go! Thanks for your consideration of this request.

Catharine

Catharine Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd, Suite 1300
Durham NC 27707
(919) 668-0857 (office)
(919) 423-6928 (cell)

From: Williams, Bernetta [mailto:bernetta.williams@dhhs.nc.gov]
Sent: Wednesday, January 31, 2018 2:29 PM
To: Catharine Cummer
Subject: RE: [External] Acquisition of bypass equipment for research/training purposes

Good afternoon Catharine,

I've attached the form that needs to be completed concerning this request. Once I receive this form, we can move forward with the exemption request. Please feel free to contact me should you have any questions.

Regards,

Bernetta Thorne-Williams

Project Analyst
Division Health Service Regulation, Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services

919 855 3873 office
bernetta.williams@dhhs.nc.gov

809 Ruggles Drive
2704 Mail Service Center
Raleigh, NC 27699-2704

From: Catharine Cummer [mailto:catharine.cummer@duke.edu]
Sent: Tuesday, January 09, 2018 11:02 AM
To: Williams, Bernetta
Cc: Shannon Baker
Subject: [External] Acquisition of bypass equipment for research/training purposes

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to report.spam@nc.gov.

Bernetta,

Happy new year! I wanted to request confirmation that the Duke University Health System could use bypass equipment that it would otherwise dispose of pursuant to a recent replacement for research and training purposes. As set forth in the attached correspondence, Duke was recently approved to replace existing bypass equipment at Duke Regional Hospital. The new equipment has arrived, and the question arose whether we could retain the old equipment to use for research and training at the Duke University Medical Center rather than disposing of it. The equipment would not be used for regular clinical purposes, but rather only in connection with research and related education and staff training purposes.

After speaking to Martha about this question, it is my understanding that this use would be exempt from CON review pursuant to Section 131E-179, which is included at the end of this message. We would appreciate your confirmation that we can use this old equipment pursuant to this exemption. Please let me know if you have any questions. Thanks very much!

Catharine

§ 131E-179. Research activities.

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

(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.

Catharine Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd, Suite 1300
Durham NC 27707
(919) 668-0857 (office)
(919) 423-6928 (cell)

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

Williams, Bernetta

From: Catharine Cumber <catharine.cumber@duke.edu>
Sent: Tuesday, January 09, 2018 11:02 AM
To: Williams, Bernetta
Cc: Shannon Baker
Subject: [External] Acquisition of bypass equipment for research/training purposes
Attachments: 0718_durham_drh.pdf

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to report.spam@nc.gov.

Bernetta,

Happy new year! I wanted to request confirmation that the Duke University Health System could use bypass equipment that it would otherwise dispose of pursuant to a recent replacement for research and training purposes. As set forth in the attached correspondence, Duke was recently approved to replace existing bypass equipment at Duke Regional Hospital. The new equipment has arrived, and the question arose whether we could retain the old equipment to use for research and training at the Duke University Medical Center rather than disposing of it. The equipment would not be used for regular clinical purposes, but rather only in connection with research and related education and staff training purposes.

After speaking to Martha about this question, it is my understanding that this use would be exempt from CON review pursuant to Section 131E-179, which is included at the end of this message. We would appreciate your confirmation that we can use this old equipment pursuant to this exemption. Please let me know if you have any questions. Thanks very much!

Catharine

§ 131E-179. Research activities.

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

(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.

Catharine Cumber
Regulatory Counsel, Strategic Planning
Duke University Health System

3100 Tower Blvd, Suite 1300
Durham NC 27707
(919) 668-0857 (office)
(919) 423-6928 (cell)



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. Cummer
3100 Tower Boulevard, Suite 1300
Durham, NC 27707

Exempt from Review – Replacement Equipment

Record #: 2312
Facility Name: Duke Regional Hospital
FID #: 923142
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace bypass 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 June 23, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the S5 Heart Lung Perfusion System to replace the S3 Heart Lung System. 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# 2312
FID#923142

 **Duke University Health System**

Catharine W. Cummer
Regulatory Counsel, Strategic Planning

June 23, 2017

Via Electronic Mail

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



Re: Equipment Replacement Project at Duke Regional Hospital – Bypass Equipment

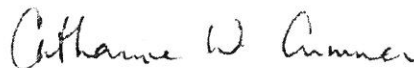
Dear Ms. Frisone:

I am writing to provide you with prior written notice of the planned acquisition of replacement bypass equipment at Duke Regional Hospital. A completed equipment comparison form and capital cost form are enclosed. The total project cost is less than \$2 million. The vendor's quote is available for your review upon request. The existing equipment is currently in use at Duke Regional Hospital, but upon acquisition of the replacement equipment the existing equipment will be removed from service in the state unless its use elsewhere is first approved by the state.

It is our understanding that with this prior notice, this acquisition is exempt from certificate of need review as the acquisition of replacement equipment pursuant to N.C.G.S. Section 131E-184, and we accordingly intend to proceed immediately with this project. If you have any questions, please let me know as soon as possible.

Thank you for your attention to this matter. Should you have any questions, please let me know.

Very truly yours,



Catharine W. Cummer

Enclosures

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	S3 Heart Lung System	S5 Heart Lung Perfusion System
Manufacturer of Equipment	Stockert	LivaNova/SorinGroup
Tesla Rating for MRIs	N/A	N/A
Model Number	S3 console 43-40-000	tbd
Serial Number	43S3098	tbd
Provider's Method of Identifying Equipment	Clinical Engineering #	Clinical Engineering #
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	N/A Cart	N/A
Mobile Tractor Serial Number/VIN #	N/A Cart	N/A
Date of Acquisition of Each Component	12/1/1992	tbd
Does Provider Hold Title to Equipment or Have a Capital Lease?	Yes, hold title	Will hold title to new equipment
Specify if Equipment Was/Is New or Used When Acquired	New	Will purchase new
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	N/A	\$200,623.00
Total Cost of Equipment	\$94,365.00	\$200,623.00
Fair Market Value of Equipment	0 (equipment not supported, end of life)	\$200,623.00
Net Purchase Price of Equipment	\$94,365.00	\$199,553.00
Locations Where Operated	Duke Regional Hospital	Duke Regional Hospital
Number Days In Use/To be Used in N.C. Per Year	365	365
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	Back up to the current machine for cardiopulmonary bypass	NA
Type of Procedures New Equipment is Capable of Performing	NA	Cardiopulmonary Bypass

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: SS Heart Lung Perfusion System
Provider/Company: Liva Nova/Sorin Group

A. Site Costs

- (1) Full purchase price of land
 Acres _____ Price per Acre \$ _____ \$ _____
- (2) Closing costs \$ _____
- (3) Site Inspection and Survey \$ _____
- (4) Legal fees and subsoil investigation \$ _____
- (5) Site Preparation Costs
 - Soil Borings..... \$ _____
 - Clearing-Earthwork... \$ _____
 - Fine Grade For Slab... \$ _____
 - Roads-Paving..... \$ _____
 - Concrete Sidewalks.... \$ _____
 - Water and Sewer..... \$ _____
 - Footing Excavation.... \$ _____
 - Footing Backfill..... \$ _____
 - Termite Treatment.... \$ _____
 - Other (Specify)..... \$ _____
- Sub-Total Site Preparation Costs \$ _____
- (6) Other (Specify) \$ _____
- (7) Sub-Total Site Costs \$ _____

B. Construction Contract

- (8) Cost of Materials
 - General Requirements \$ _____
 - Concrete/Masonry \$ _____
 - Woods/Doors & Windows/Finishes \$ _____
 - Thermal & Moisture Protection \$ _____
 - Equipment/Specialty Items \$ _____
 - Mechanical/Electrical \$ _____
 - Other (Specify) \$ _____
- Sub-Total Cost of Materials..... \$ _____
- (9) Cost of Labor..... \$ _____
- (10) Other (Specify)..... \$ _____
- (11) Sub-Total Construction Contract \$ _____

C. Miscellaneous Project Costs

- (12) Building Purchase..... \$ _____
- (13) Fixed Equipment Purchase/Lease \$ _____
- (14) Movable Equipment Purchase/Lease \$ 200,623.00
- (15) Furniture \$ _____
- (16) Landscaping \$ _____
- (17) Consultant Fees
 - Architect and Engineering Fees \$ _____
 - Legal Fees..... \$ _____
 - Market Analysis..... \$ _____
 - Other (Specify)..... \$ _____
 - Other (Specify)..... \$ _____
- Sub-Total Consultant Fees..... \$ _____
- (18) Financing Costs (e.g. Bond, Loan, etc.) \$ _____
- (19) Interest During Construction. \$ _____
- (20) Other (Specify) \$ _____
- (21) Sub-Total Miscellaneous.. \$ _____
- (22) Total Capital Cost of Project (Sum A-C above) \$ 200,623.00

I certify that, to the best of my knowledge, the costs of the proposed project named above are complete and correct.

 (Signature of Licensed Architect or Engineer) Date Certified: _____

I assure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

Kate Galbraith
 _____ Date Signed: 6/22/17
 (Signature and Title of Officer Authorized to Represent Provider/Company)