



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

August 7, 2024

Terrill Johnson Harris
tjharris@Foxrothschild.com

Exempt from Review – Proposed Research Activity

Record #: 4509
Date of Request: July 31, 2024
Facility Name: Cone Health
Type of Facility: Hospital
FID #: 943494
Business Name: The Moses H. Cone Memorial Hospital Operating Corporation
Business #: 1815
Project Description: Acquire a linear accelerator solely for research purposes at the Cone Health Cancer Center at Wesley Long Hospital
County: Guilford

Dear Ms. Harris:

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,

Yolanda Jackson
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR
Construction 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
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Terrill Johnson Harris
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July 31, 2024

Micheala Mitchell, Chief
Micheala.mitchell@dhhs.nc.gov
Yolanda Jackson, Project Analyst
yolanda.jackson@dhhs.nc.gov
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

Via e-mail only

Re: Prior Written Notice for Research Exemption
The Moses H. Cone Memorial Hospital Operating Corporation d/b/a Cone Health
FID # 943494

Dear Ms. Mitchell and Ms. Jackson:

Our firm represents The Moses H. Cone Memorial Hospital Operating Corporation d/b/a Cone Health. This letter provides prior written notice pursuant to N.C. General Statute §131E-179 of Cone Health's intention to acquire a linear accelerator solely for research purposes at the Cone Health Cancer Center at Wesley Long Hospital.

Attached you will find a completed copy of the Agency's research exemption form. It certifies that the proposed linear accelerator will not affect Cone Health's charges for the provision of medical or other patient care services, will not change the bed capacity of Wesley Long Hospital where it will be located, and will not change the medical or other patient care services of Cone Health.

As noted in the research exemption form, Cone Health would be one of two locations in the United States for validation of the Leo Cancer Care "Grace" upright linear accelerator system. The primary objective of this research project is to evaluate the clinical efficacy and safety of the Grace upright linear accelerator in preparation for FDA approval. Specific goals include

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assessing treatment accuracy, monitoring patient outcomes and experience, and validating technological performance.

The Grace upright linear accelerator system represents a significant advancement in radiation therapy, with the potential to transform the way cancer is treated based on the advantages it offers over current technology. Current linear accelerator technology treats patients in the supine position, lying flat on their back or in a similar prone position, much like lying down on a table. This setup presents several challenges. Transferring patients from wheelchairs or those with limited mobility onto a hard treatment table can be difficult and uncomfortable. Maintaining this position can be very challenging for some patients due to back or neck pain. For patients nearing the end of life, the discomfort associated with lying flat can be so significant that they may choose to discontinue treatment altogether.

Treating patients in an upright position offers several potential advantages over conventional horizontal treatment methods. By utilizing an upright posture, the system aims to provide superior treatment to organs situated between the lungs and the prostate. The upright position can potentially lead to:

1. **Enhanced Patient Comfort and Compliance:** Many patients may find the upright position more comfortable, reducing anxiety and discomfort associated with lying down for extended periods. Improved comfort can lead to a better overall treatment experience.
2. **Improved Organ Positioning and Stabilization:** Upright positioning may result in better organ alignment and stability, reducing the likelihood of organ motion during treatment as well as keeping organs in their normal position relative to gravity. This can be particularly beneficial for targeting tumors in the thoracic and abdominal regions. Additionally, organs subject to deformation during respiration, such as the lungs, experience additional extension without the weight of the abdominal cavity contents pushing against the lungs in the typical supine position. This allows potentially superior visibility of lung features, including small developing tumors.
3. **Optimized Dosimetric Outcomes:** Preliminary research suggests that upright treatment can enhance dose distribution and sparing of surrounding healthy tissues. This can result in more effective tumor targeting while minimizing the risk of radiation-induced side effects.



Micheala Mitchell, Chief
Yolanda Jackson, Project Analyst
July 31, 2024
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Cone Health's proposed acquisition of the Grace upright linear accelerator is exempt from CON review pursuant to N.C. General Statute §131E-179 because the linear accelerator will be used solely for research purposes and will not be used in a manner that affects Cone Health's charges for the provision of medical or other patient care services. In addition, Cone Health will not charge patients for the use of the upright linear accelerator without first obtaining a certificate of need from the Agency, unless the upright linear accelerator can be offered or developed without a certificate of need at the relevant time.

By conducting rigorous research using this experimental system, Cone Health aims to gather critical data that will support the system's future commercial availability and FDA approval, ultimately contributing to improved cancer care and patient outcomes.

We look forward to receiving your letter confirming that Cone Health's acquisition of the Grace linear accelerator system is exempt from certificate of need review pursuant to N.C. Gen. Stat. § 131E-179. If you have any questions, please let me know.

Sincerely,

A handwritten signature in black ink that reads "Terrill Johnson Harris". The signature is written in a cursive, flowing style.

Terrill Johnson Harris

Enclosure

c: Melissa Shearer, Executive Director, Strategy and Planning

Notice of Proposed Research Activity

G.S. 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 complete the following:

1. Facility Name:

**The Moses H. Cone Memorial Hospital Operating Corporation d/b/a Cone Health
FID # 943494**

2. Facility Street Address:

Wesley Long Hospital, 2400 West Friendly Avenue, Greensboro, NC 27403


3. Describe the project:

Cone Health seeks to acquire a linear accelerator from Leo Cancer Care solely for research purposes for the Cone Health Cancer Center at Wesley Long Hospital. Leo Cancer Care's "Grace" linear accelerator is an innovative radiation therapy system designed to treat patients in an upright position, a method currently not available commercially. This system is pre-FDA approval, and the planned acquisition is intended for research purposes to evaluate its efficacy and safety. It includes an integrated upright CT scanner and upright patient positioning system, which are groundbreaking features in the field of radiation oncology. Grace is not available anywhere in the world, and there are currently plans to add the technology at only two validation locations in the United States, one being at Cone Health in Greensboro, North Carolina. Additional information is available in the attached cover letter.

4. Certify 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;
- b. Substantially change the bed capacity of the facility; or
- c. Substantially change the medical or other patient care services of the facility.

Cone Health certifies that its charges for the provision of medical or other patient care services will not be affected by this project, that the project will not change the bed capacity of Wesley Long Hospital where it will be located, and that the project will not change the medical or other patient care services of Wesley Long Hospital or Cone Health.

Name (print or type):	CHRISTOPHER M. CORNUE
Title:	EVP + CHIEF STRATEGY OFFICER
Date:	30 July 2024
Signature:	

From: [Mitchell, Micheala L](#)
To: [Stancil, Tiffany C](#)
Cc: [Jackson, Yolanda W](#); [Waller, Martha K](#)
Subject: FW: [External] Cone Health Research Exemption Notice
Date: Wednesday, July 31, 2024 4:22:56 PM
Attachments: [2024.07.31Cone Health upright linear accelerator exemption notice letter-C.pdf](#)

Tiffany,

Would you mind logging this and assigning to Yolanda? (I copied Martha as I see you're out tomorrow and Friday)

Thanks,

Micheala Mitchell, JD
[NC Department of Health and Human Services](#)
[Division of Health Service Regulation](#)
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

From: Harris, Terri <TJHarris@foxrothschild.com>
Sent: Wednesday, July 31, 2024 4:20 PM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>; Jackson, Yolanda W <yolanda.jackson@dhhs.nc.gov>
Cc: Melissa Shearer (melissa.shearer@conehealth.com) <melissa.shearer@conehealth.com>
Subject: [External] Cone Health Research Exemption Notice

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Good afternoon – I hope you are both well and having a good summer. Please find attached a Research Exemption Notice letter and signed Notice of Proposed Research Activity. Please let us know if you have any questions. We look forward to your response.

Kind regards.

Terri Harris (she/her)
Partner
230 N. Elm Street
Suite 1200

Greensboro, NC 27401

[\(336\) 378-5383](tel:(336)378-5383)

[\(336\) 202-9587](tel:(336)202-9587)

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