



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 28, 2024

Kelli Collins
kcollins@greensboroimaging.com

Exempt from Review – Proposed Research Activity

Record #: 4452
Date of Request: May 15, 2024
Facility Name: Diagnostic Radiology & Imaging
Type of Facility: Diagnostic Center
FID #: 031122
Business Name: Diagnostic Radiology & Imaging, LLC
Business #: 609
Project Description: Retain a fixed MRI scanner that was to be replaced pursuant to Project ID #G-12082-21 and use solely for patient research
County: Guilford

Dear Ms. Collins:

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,

Handwritten signature of Yolanda W. Jackson

Yolanda W. Jackson
Project Analyst

Handwritten signature of Micheala Mitchell

Micheala Mitchell
Chief

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



May 14, 2024

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

RE: Proposed Research Activity – DRI W. Wendover Ave. Diagnostic Center / Guilford County

Dear Ms. Mitchell:

Diagnostic Radiology & Imaging (DRI) has been offering diagnostic imaging services with an existing MRI scanner that is scheduled for replacement. Pursuant to N.C.G.S. § 131E-179, Research Activities, DRI is writing to request confirmation that the proposed research activity described below at the DRI W. Wendover Avenue diagnostic center is exempt from certificate of need review.

In June 2021, DRI submitted a CON application (CON Project ID# G-12082-21) to replace one of its existing fixed MRI scanners located in Greensboro, and locate the replacement fixed MRI scanner to a new Guilford County location in Summerfield, establishing a new diagnostic center (DRI Lake Brandt). DHSR approved the CON application in September 2021, and issued the CON on October 19, 2021. See Attachment 1. DRI has submitted regular Progress Reports to the Agency summarizing development of the project, most recently in February 2024. See Attachment 2. In conformity to the conditions of CON approval, DRI will maintain its current SMFP inventory of three fixed MRI scanners in Guilford County, and was planning to schedule the replaced fixed MRI scanner to be removed from North Carolina.

DRI desires to continue to use the fixed MRI scanner - scheduled for replacement - solely for patient research purposes. DRI has two on-going research studies that have been affected by DRI magnet changes:

- CHIMES, a Phase IV research study, assesses disease activity during treatment with ocrelizumab in minority patients with relapsing multiple sclerosis. This study is of significant importance in understanding the impact of the treatment on this specific patient group. For the MS study, patients undergo annual MRIs of the brain with and without contrast using the study protocol.
- AACI is a phase III dementia research study that assesses the safety, tolerability, and efficacy of donanemab in patients with early symptomatic Alzheimer's Disease. For the Alzheimer's study, patients get a Brain MRI without contrast every six months.

Both research studies may require additional MRI exams if the patient were to have an exacerbation. These MRI studies are crucial for tracking disease progression and treatment efficacy. It is essential that DRI complete these pending MRI studies to ensure the accuracy and comprehensiveness of the research study data. Below is the list of MRI research studies still needed. This lists the scheduled exam date, or an approximate time period if the MRI exam is required, but not yet scheduled.

There are six TOTAL PENDING MRIs left for CHIMES (Multiple Sclerosis)

Subject Initials/ID	Visit Number	MRI Scheduled/Approximate Date
SKR 3006	V192	MRI 05/29/2024
ALE 3013	V192	MRI 06/27/2024
TNJ 3034	V192	MRI around 12/2024
SLS 3047	V192	MRI around 04/2025
AG 3098	V144	MRI 07/26/2024
AG 3098	V192	MRI around 08/2025

One more MRI is PENDING FOR AACI (Alzheimer's Disease)

TWC 15603	V41	6 months from now, around 11/2024.
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Applicable Regulations

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. DRI 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;

(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.

Compliance

DRI has completed the DHSR Proposed Notice of Research Activity (see Attachment 3). DRI hereby certifies that:

1. The project has no cost because the fixed MRI scanner proposed to be used solely for research purposes is already operational and utilized at the DRI W. Wendover Avenue diagnostic center.
2. This fixed MRI scanner will be used solely for research purposes at the DRI W. Wendover Avenue diagnostic center, and will not be used to perform any diagnostic imaging scans of non-research patients.
3. The project does not affect the charges of the DRI W. Wendover Avenue diagnostic center for the provision of patient care services; there will be no change to the DRI charges for diagnostic MR imaging services on non-research patients.
4. DRI W. Wendover Avenue is a diagnostic center and not a hospital, and thus does not operate acute care beds.
5. The project will not substantially change the medical or other patient care services of the DRI W. Wendover Avenue diagnostic center. DRI is currently performing

imaging research studies, as summarized above, and proposes to continue the research studies on the older MRI scanner.

DRI respectfully requests that the Division of Health Service Regulation confirm that, based on the facts stated, the described project to continue to utilize – solely for medical research purposes - a fixed MRI scanner scheduled to be replaced at DRI W. Wendover Avenue diagnostic center, is exempt from certificate of need pursuant to N.C.G.S, § 131E-179.

Please contact me at 336.207.2712 regarding any questions concerning this request.

Sincerely,

Kelli Collins

Kelli Collins
Chief Operating Officer

Attachments:

1. Certificate of Need, Project ID# G-12082-21
2. Most recently submitted Progress Report
3. Notice of Proposed Research Activity

Attachment 1

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Certificate of Need

for

Project ID #: G-12082-21

FID #: 200818

ISSUED TO: Diagnostic Radiology & Imaging, LLC

Pursuant to G.S. 131E-177(6), the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the certificate holder) to develop the project described below. The certificate holder shall develop the project in a manner consistent with the representations in the application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein, as documented by the periodic progress reports required by G.S. 131E-189(a). The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by G.S. 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in G.S. 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to G.S. 131E-189 for any of the reasons provided in that section.

SCOPE: Develop a new diagnostic center by relocating and replacing 1 existing fixed MRI scanner / Guilford County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: DRI Summerfield
6191 Lake Brandt Road
Summerfield, NC 27455

CAPITAL EXPENDITURE: \$1,520,605

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: February 1, 2022

This certificate is effective as of October 19, 2021



Micheala Mitchell, Chief

CONDITIONS:

1. **Diagnostic Radiology and Imaging, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall develop a new diagnostic center by replacing no more than one existing fixed MRI scanner located at W. Wendover Avenue Imaging Center and relocating and operating the new fixed MRI scanner at DRI Summerfield.**
3. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on February 1, 2022. The second progress report shall be due on June 1, 2022 and so forth.**
4. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
5. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. **Payor mix for the services authorized in this certificate of need.**
 - b. **Utilization of the services authorized in this certificate of need.**
 - c. **Revenues and operating costs for the services authorized in this certificate of need.**
 - d. **Average gross revenue per unit of service.**
 - e. **Average net revenue per unit of service.**
 - f. **Average operating cost per unit of service.**
6. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

A letter acknowledging of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on September 30, 2021.

(G-12082-21 Con't)

Timetable

Milestone		Date <i>mm/dd/yyyy</i>
1	Financing Obtained	01/15/2022
2	Drawings Completed	03/01/2022
3	Land Acquired	02/01/2022
4	Construction / Renovation Contract(s) Executed	03/15/2022
5	25% of Construction / Renovation Completed (25% of the cost is in place)	04/07/2022
6	50% of Construction / Renovation Completed	05/01/2022
7	75% of Construction / Renovation Completed	05/22/2022
8	Construction / Renovation Completed	06/15/2022
9	Equipment Ordered	02/05/2022
10	Equipment Installed	06/18/2022
11	Equipment Operational	06/25/2022
12	Building / Space Occupied	06/15/2022
14	Services Offered	07/01/2022
16	Facility or Service Accredited	07/01/2023
17	First Annual Report Due*	04/01/2024

Attachment 2

**Certificate of Need
Progress Report Form**

County: Guilford Date of Progress Report: 31 Jan. 2024
Facility: Diagnostic Radiology & Imaging, LLC Facility ID #: 200818
Project ID #: G-12082-21 Effective Date of Certificate: 19 October 2021
Project Description: Develop a new diagnostic center by relocating and replacing one existing fixed MRI scanner.

A. Status of the Project

1. Describe in **detail** the **steps taken** to complete the project since the CON was issued or since the last progress report was submitted. **Inadequate responses to this question will result in the certificate holder being asked to redo the progress report.**

Construction is underway and on schedule. No changes from October 2023 Progress Report.

2. Identify all changes to this project approved after the issuance of the certificate, including:
 - a. Cost Overruns and/or Changes of Scope (Include the Project ID #s);
 - b. Material Compliance determinations; and
 - c. Declaratory Rulings

Not applicable. DRI does not anticipate seeking any cost overrun/change of scope authorization, nor any material compliance determinations for this CON project.

3. If the project is not going to be developed exactly as approved (including the previously approved changes identified in #2 above), describe all differences between the project as approved and the project as currently proposed. Such changes include, but are not limited to, changes in the:
 - a. Site;
 - b. Design of the facility;
 - c. Number or type of beds to be developed;
 - d. Medical equipment to be acquired;
 - e. Proposed charges; and
 - f. Capital cost of the project.

Not applicable. DRI anticipates developing the project as described in the approved CON application.

4. Pursuant to N.C. Gen. Stat. § 131E-181(d), the Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) cannot determine that a project is complete until “*the health service or the health service facility for which the certificate of need was issued is licensed and certified and is in material compliance with the representations made in the certificate of need application.*” To document that new or replacement facilities, new or additional beds or dialysis stations, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate sections within the Agency and the Centers for Medicare and Medicaid Services (CMS).

Not applicable. The project does not involve a facility license or new certification.

B. Timetable

1. Complete **the following table**. The first column **must** include the timetable dates found on the certificate of need. If the Agency has previously authorized an extension of the timetable in writing, you may substitute the dates from that letter in the first column.
2. **Are you requesting a timetable extension?** Yes No If the answer is **yes**, enter your proposed completion dates in the third column of the table below. **Proposed completion dates are contingent upon Agency approval.**
3. Explain **the reason(s) for the delay in development:**

The project is not experiencing a delay at this time.

Project Milestones	Projected Completion Date from Certificate	Actual Completion Date	Proposed Completion Date*
	mm/dd/yyyy	mm/dd/yyyy	mm/dd/yyyy
Financing Obtained	01/15/2022	03/01/2022	
Drawings Completed	03/01/2022	10/25/2022	
Land Acquired	NA	NA	
Construction / Renovation Contract(s) Executed	03/15/2022	03/21/2023	
25% of Construction / Renovation Completed (25% of the cost is in place)	04/07/2022	11/07/2023	
50% of Construction / Renovation Completed	05/01/2022	12/29/2023	
75% of Construction / Renovation Completed	05/22/2022	02/10/2024	
Construction / Renovation Completed	06/15/2022		03/29/2024
Equipment Ordered	02/05/2022	10/15/2023	
Equipment Installed	06/18/2022		04/01/2024
Equipment Operational	06/25/2022		04/08/2024
Building / Space Occupied	06/15/2022		04/01/2024
Licensure Obtained	N/A		N/A
Services Offered (Required)	07/01/2022		04/09/2024
Medicare and / or Medicaid Certification Obtained	N/A		N/A
Facility or Service Accredited	07/01/2022		04/09/2024
Final Annual Report Due	04/01/2024		07/01/2025

*Proposed completion dates are contingent upon Agency approval.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in N.C. Gen. Stat. § 131E-176(14o); 2) the specific equipment listed in G.S. 131-176(16); or 3) equipment that creates a diagnostic center as defined in N.C. Gen. Stat. § 131E-176(7a), provide the following information for each piece or unit of equipment:

- 1) Manufacturer
- 2) Model
- 3) Date Acquired

DRI ordered the fixed MRI scanner, which will be a 1.5T manufactured by Siemens. DRI ordered the equipment in Fall 2023, but it is not yet installed.

D. Capital Expenditure

1. What is the total approved capital cost of the project indicated on the certificate of need?
\$1,520,605
2. Complete the table below and provide supporting documentation, which may include:
 - a. Copies of executed purchase orders for major medical equipment (as defined in N.C. Gen. Stat. 131E-176(14o)), MRIs, PET scanners, Cath equipment, linacs or simulators, etc. If you previously provided them, you do not need to provide another copy.
 - b. If applicable, copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Purchase Price of Land	\$0	\$0
Closing Costs	\$0	\$0
Site Preparation	\$0	\$0
Construction/Renovation Contract(s)	\$262,403	\$280,823
Landscaping	\$0	\$0
Architect / Engineering Fees	\$5,289	\$47,599
Medical Equipment	\$0	\$0
Non-Medical Equipment	\$0	\$0
Furniture	\$0	\$0
Consultant Fees (CON-related)	\$0	\$49,883
Financing Costs	\$9,750	\$9,750
Interest during Construction	\$1,942	\$1,942
Other (consulting services)	\$16,046	\$42,788
Total Capital Cost	\$295,430	\$432,786

3. What is the projected remaining capital expenditure required to complete the project? \$1,087,819

4. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference.

Not applicable. DRI does not expect that the project cost will exceed 115% of the approved CON capital expenditure.

- E. Certification** – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief. In addition, I acknowledge that incomplete progress report forms **will not** be accepted and **must** be resubmitted upon notification from the Agency Project Analyst.

Signature: *Kelli Collins*

Name and Title Kelli Collins, Chief Operating Officer

Telephone Number 336.207.2712

Email address kcollins@greensboroimaging.com

Attachment 3

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

Diagnostic Radiology & Imaging W. Wendover Avenue

2. Facility Street Address

315 W. Wendover Avenue

3. Describe the project

DRI proposes to continue to utilize its retiring fixed MRI scanner solely for patient research at W. Wendover Avenue imaging center. This project has no cost, because DRI already owns and operates the fixed MRI scanner (which has reached the end of its useful life, and is being replaced by a new fixed MRI scanner which will be located at DRI Lake Brandt diagnostic center (CON Project ID# G-12082-21)).

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;

The MRI scanner will be used solely for medical research at W.Wendover Avenue diagnostic center. This project does not affect the charges of the health service facility for the provision of patient care services; there will be no change to the DRI charges for diagnostic MR imaging services.

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

Not applicable. DRI is not a hospital but rather a diagnostic center, and does not operate acute care beds.

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

This project will not impact medical or patient care services at Diagnostic Radiology & Imaging. DRI will continue to provide diagnostic MR imaging services on its other existing fixed MRI scanner at the W. Wendover Avenue diagnostic center. This fixed MRI scanner will be used, going forward, solely for research purposes.

Name (print or type)	Kelli Collins
Title	Chief Operating Officer
Date	6 May 2024
Signature	<i>Kelli Collins</i>

From: [Kelli Collins](#)
To: [Jackson, Yolanda W](#); [Stancil, Tiffany C](#)
Subject: [External] Research-only MRIs Request
Date: Wednesday, May 15, 2024 10:08:43 AM
Attachments: [image001.png](#)
[Exemption letter - Proposed Research Activity MRI scanner.pdf](#)

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Good morning –

Please find attached a request from DRI regarding the use if an MRI for studies. Please contact me with any questions and thank you for your review.

Be well,

Kelli

Kelli Collins
Chief Operating Officer
Greensboro Imaging
1150 Revolution Mill Drive, Suite 9 Greensboro, NC 27405
P: 336.433.5010 Fax: 336.217.1608 C: 336.207.2712
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Lily Mood
Executive Assistant
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