

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

May 15, 2014

IN THE MATTER OF:

An Application for a Certificate of Need filed
Pursuant to Section 19a-638, C.G.S. by:

Notice of Final Decision
Office of Health Care Access
Docket Number: 14-31889-CON

University of Connecticut

**Acquisition of a Magnetic Resonance
Imaging Scanner at the University of
Connecticut at Storrs**

To:

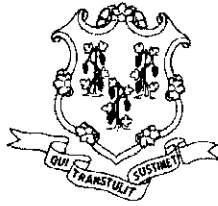
Lesley N. Salafia, Esq.
University of Connecticut
Office of the General Counsel
343 Mansfield Road, Unit 1177
Storrs, CT 06269-1177

Dear Attorney Salafia:

This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Section 19a-638, C.G.S. On May 15, 2014, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

Kimberly R. Martone
Director of Operations

Enclosure
KRM:amv



**Department of Public Health
Office of Health Care Access
Certificate of Need Application**

Final Decision

Applicant: University of Connecticut
343 Mansfield Road, Unit 1177, Storrs, CT

Docket Number: 14-31889-CON

Project Title: Acquisition of a 3.0 Tesla MRI Scanner

Project Description: The University of Connecticut at Storrs ("University" or "Applicant") seeks authorization to acquire a new 3.0 Tesla ("3T") Magnetic Resonance Imaging ("MRI") scanner for research purposes. The total capital expenditure associated with this proposal is \$8,000,000.

Procedural History: The Applicant published notice of its intent to file the Certificate of Need ("CON") application in the *Chronicle* on November 25, 26 and 27, 2013. On January 10, 2014, the Office of Health Care Access ("OHCA") received the CON application from the Applicant for the above-referenced project and deemed the application complete on March 21, 2014. OHCA received no responses from the public concerning the Applicant's proposal and no hearing requests were received from the public pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a. In rendering her decision, Deputy Commissioner Davis considered the entire record in this matter.

To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc., v. S & H Computer Systems, Inc.*, 605 F.Supp. 816 (Md. Tenn. 1985).

Findings of Fact and Conclusions of Law

1. The Applicant is a public research University with its main campus located in Storrs, Connecticut. <http://www.uconn.edu>
2. The Applicant proposes to acquire and install a 3T MRI scanner at its Storrs campus. The MRI will be used for functional magnetic resonance imaging (“fMRI”)¹ research and will be located at the University’s Phillips Communication Sciences Building, 850 Bolton Road, Storrs, Connecticut (“UConn MRI Center”). Ex. A., p. 5
3. The proposed MRI will be used by the Departments of Psychology, Physiology and Neurobiology, Linguistics, Kinesiology, Speech-Language-and-Hearing-Sciences and Economics. Researchers will utilize the scanner to study brain correlates of typical and atypical language processing, developmental disabilities (e.g., autism spectrum disorders or dyslexia), decision making and the processing of emotional or social stimuli. Ex. A., p. 5
4. The research performed using fMRI technology will provide key insights into various areas of cognitive neuroscience, behavioral genetics and educational neuroscience. It will help physicians understand developmental disorders such as autism, especially the unique brain adaptations associated with the disorder. Ex. A., p. 17
5. Due to its lack of fMRI technology, the University is severely limited in conducting research in the areas of brain correlates of typical and atypical language processing, developmental disabilities such as autism and dyslexia and the processing of decision making. Ex. A., p. 8
6. As there is no research MRI scanner available within the University’s service area of Mansfield, Tolland or Windham, University researchers currently must travel to other research institutions in Connecticut or other states in order to use these institutions’ fMRI scanners. Several researchers from the University’s Department of Psychology and Cognitive Science program lease session times at other research MRI scanners in Connecticut or Rhode Island. Ex. A., pp. 5, 8-9
7. The University proposes to acquire a 3T MRI because of its desired Signal-to-Noise ratio which makes it the standard research tool in cognitive neuroscience and other brain research areas. Ex. A., p. 6
8. In accordance with State of Connecticut procurement practices, the University has released a competitive RFP for this acquisition, and will be seeking proposals from Siemens, Philips and GE. Thus, the acquired model could be one of the following: a 3T Siemens Prisma, a 3T Philips Ingenia or a 3T GE Discovery. Ex. A., p. 8

¹ fMRI uses a combination of a magnet and radio frequencies to study oxygen flow to areas of the brain. Resulting images help researchers map which parts of the brain are used for speech, hearing, vision and motor skills. Ex. A, p. 5

9. Having the UConn MRI Center at the Storrs campus will help recruit new research faculty and attract and secure federal research funds granted to academic research sites that have fMRI technology. Ex. A., p. 9
10. The UConn MRI Center at the Storrs campus was selected as the location for the UConn MRI Center due to its ideal site parameters for an MRI scanner and the most centralized location, space availability and the greatest level of safety. Ex. A., p. 10
11. The proposed MRI will be used exclusively for research purposes and will not be used for the delivery of health care services. Ex. A., pp. 5-6
12. Volunteer research participants will be recruited from surrounding towns, University students, staff or faculty members. These research participants will not be provided any health care services. Ex. A., pp. 6, 10
13. All volunteer research subjects recruited for research studies at the UConn MRI Center will grant Informed Consent in accordance with the University's Institutional Review Board ("IRB") applicable policies. Ex. A., p. 10
14. The Applicant projects the following volume statistics for the first four years of 3T MRI operation:

Table 1: Projected Utilization for Research 3T MRI

FY 2015*	FY 2016**	FY 2017***	FY 2018****
182 hours*****	600 hours	1,000 hours	1,250 hours

Note: Applicant's Fiscal Year is from July 1st – June 30th

*The Applicant projects that FY 2015, as a partial period (6 mos), is expected to have 182 hours of use time at 7 hours per week for 26 weeks as the UConn MRI Center develops its operations and user base.

**For FY 2016, it is expected that the UConn MRI Center will be fully operational and usage will ramp up to 12 hours per week for 50 weeks.

***In FY 2017, it is expected that 20 hours per week of use time will be established, for which there will be a net gain for the UConn MRI Center due to billable hours and Office of Sponsored Program rates on grants for plant and administrative costs.

****In FY 2018, the operational goal is 25 hours per week for 50 weeks per year.

*****Unit of service is calculated in terms of use hours, as internal and external grant charges will be accrued on an hourly basis. The Applicant estimates that the MRI will be used 50 weeks per year with 2 weeks of service time. Ex. A., p. 12

15. This proposal will have no impact on existing clinical MRI service area providers in Mansfield, Tolland or Windham, since the proposed MRI will be used for research purposes only and will not be offering clinical services. The existing MRI scanners in the area are used for clinical purposes and are not suitable for University research because their magnet strengths are lower than 3T. Ex. A., p. 9, 11

16. The UConn MRI Center will operate as a non-profit research entity that will rely upon research grants from federal agencies and private foundations, as well as on internal operational support from the University, for its operating costs. The initial capital expenditures for this proposal were allocated by the University's Board of Trustees as part of internal appropriations for scientific research initiatives. Ex. A., p. 6
17. The funding for this acquisition is secured through UConn 2000 State bond funds, as follows:

Table 2: Funding Source

Description	Amount
UConn 2000 Phase III-FY14DM	\$4,700,000
UConn 2000 Equipment	\$3,225,000
University Plant Funds	\$75,000

Ex. A., pp. 6, 19, 243

18. The proposal's total capital expenditure is itemized as follows:

Table 3: Total Capital Expenditure

Description	Amount
Imaging Equipment Purchase	\$3,225,000
Construction/Renovation*	\$4,225,000
Project Contingency	\$550,000
Total Project Cost	\$8,000,000

* Construction/Renovation costs includes construction (\$3,500,000), design services (\$350,000), telecommunications (\$35,000), construction administration (\$90,000), project management and architectural engineering expenses (\$150,000), relocation of existing space uses (\$10,000), environmental costs (\$60,000), insurance and legal costs (\$10,000), and miscellaneous expenses (\$20,000).

Ex. A., pp. 18, 243

19. The University anticipates an operational loss for direct UConn MRI Center operations in FY 2015 and 2016 but an overall gain in institutional wealth and prestige through this project. The University is financially prepared to assume short-term financial losses in direct operations of the UConn MRI Center.

Table 4: Projected Incremental Revenues and Expenditures

Description	FY 2015	FY 2016	FY 2017	FY 2018
Revenue from Operations*	\$172,536	\$568,800	\$948,000	\$1,185,000
Total Operating Expenses**	\$518,797	\$816,066	\$867,855	\$897,682
Gain/(Loss) from Operations	(\$346,261)	(\$247,266)	\$80,145	\$287,318

*It is assumed that there will be a billable rate of \$600/hour per use time on grants.

**Operating expenses include salaries/fringe benefits and depreciation.

Note: Incremental losses for each of the FY 2015 and FY 2016 are due to a number of factors. FY 2015 is a partial year of operation. Also, MRI research has not been conducted on the Storrs campus before; as such, there is a level of ramp-up expected and a level of conservatism with use hour projections. In addition, this is not a full accounting of the benefits/revenues derived or other costs that could be attributable to these other revenue generating activities.

Ex. A., p. 353

20. The proposed MRI will allow University researchers to have greater access to necessary fMRI equipment, greater flexibility in scheduling their research and better control over their research. Ex. A., p. 9
21. The research performed using the fMRI technology will provide key insights into various areas of cognitive neuroscience and thus enable continuous development and improvement of health care practices and technology. Ex. A., p. 19
22. This proposal will indirectly benefit the State's health care system by improving the quality of available research in cognitive neuroscience, behavioral genetics, and educational neuroscience, and provide enhanced techniques and technology. Ex. A., p. 19
23. This proposal will have no impact on access to services for Medicaid recipients or indigent persons because the proposed MRI will be used for research purposes only and will not be offering or providing clinical services. Ex. A., p. 20
24. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))
25. This CON application is consistent with the overall goals of the State Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))
26. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

27. The Applicant has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
28. The Applicant has satisfactorily demonstrated that its proposal is for research only and will not be used to provide any clinical services. Therefore, it has no impact on the accessibility and cost effectiveness of health care delivery in the region. The proposal has the potential to improve the quality of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5))
29. The Applicant has shown that there will be no change in access to the provision of health care services to the relevant populations and payer mix since the proposed equipment is for research purposes only. (Conn. Gen. Stat. § 19a-639(a)(6))
30. The Applicant has satisfactorily identified the population to be served and has satisfactorily demonstrated that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7))
31. The utilization of existing health care facilities and health care services in the Applicant's service area is not applicable for this application since it is for research purposes only. (Conn. Gen. Stat. § 19a-639(a)(8))
32. The Applicant has satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))
33. The Applicant has satisfactorily demonstrated that the proposal will not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10))

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in General Statutes § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727 (2013).

The University of Connecticut, a public research university with its main campus located in Storrs, Connecticut, proposes to acquire and install a 3T MRI scanner at its Storrs campus. *FF1-2* The MRI will be used for functional magnetic resonance imaging (“fMRI”) research and will be utilized by the Departments of Psychology, Physiology and Neurobiology, Linguistics, Kinesiology, Speech-Language-and-Hearing-Sciences and Economics. Researchers will utilize the scanner to provide key insights into various areas of cognitive neuroscience, behavioral genetics and educational neuroscience. *FF3-4*

Due to its lack of fMRI technology, the University is severely limited in conducting research in the areas of brain correlates of typical and atypical language processing, developmental disabilities such as autism and dyslexia and the processing of decision making. *FF5* Currently, there is no research MRI scanner available within the University’s service area of Mansfield, Tolland or Windham. *FF6* Other top-tier public research-intensive universities have one or more 3T MRI scanners dedicated specifically to research. *Ex. A, p. 9* As a result, the University’s researchers must travel to other in-state research institutions or out-of-state to use other universities’ fMRI scanners. *FF6*

The proposed MRI will be used exclusively for research purposes and will not be used for the delivery of health care services. *FF11* Volunteer research participants will be recruited from surrounding towns, University students, staff and faculty members. *FF12* All volunteer research participants will grant Informed Consent in accordance with the University’s Institutional Review Board applicable policies. *FF13*

The UConn MRI Center will operate as a non-profit research entity that will rely on research grants from federal agencies and private foundations, as well as on internal support from the University, for its operating costs. The initial capital expenditures for this proposal were allocated by the University’s Board of Trustees as part of internal appropriations for scientific research initiatives. *FF19* This proposal is financially feasible as the funding for this acquisition is secured through UConn 2000 State bond funds and will be operating at a net gain after the first two years of operation. *FF17-19*

Because the proposed MRI will be used for research purposes only, the proposal will not have an impact on existing clinical MRI service providers in the area, access to care, cost effectiveness or financial strength of the state’s health care system. *FF16* Likewise, it will not have any impact on the services provided to the Medicaid population. It will, however, indirectly benefit the strength of the state’s health care system by improving the quality of available research for cognitive neuroscience, behavioral genetics and educational neuroscience. *FF20-23* The research conducted will help physicians better understand developmental disorders such as autism, especially the

unique brain adaptations associated with the disorder. *FF 4* In addition, the University's research efforts will enhance the knowledge about such disorders and have the potential to improve future treatment and quality of life outcomes for individuals suffering from these neurological and behavioral disorders. *FF22* This research-oriented MRI has the potential to advance the quality and effectiveness of health care delivery services in Connecticut as well as improve the state's position in the field of biomedical research. Therefore, OHCA concludes the Applicant has demonstrated clear public need for the proposal.

Order

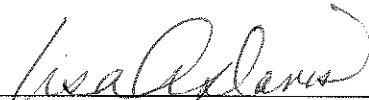
Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of University of Connecticut for the acquisition of one Human Subject Research 3T MRI scanner is hereby **approved**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Department of Public Health
Office of Health Care Access

Date

5/15/14



Lisa A. Davis, MBA, BS, RN
Deputy Commissioner