

State of Connecticut Office of Health Care Access CON Determination Form Form 2020

All persons who are requesting a determination from OHCA as to whether a CON is required for their proposed project must complete this Form 2020. The completed form should be submitted to the Director of the Office of Health Care Access, 410 Capitol Avenue, MS#13HCA, P.O. Box 340308, Hartford, Connecticut 06134-0308.

SECTION I. PETITIONER INFORMATION

If this proposal has more than two Petitioners, please attach a separate sheet, supplying the same information for each Petitioner in the format presented in the following table.

	Petitioner	Petitioner
Full Legal Name	Kenneth Marek	
Doing Business As	Molecular NeuroImaging, LLC	
Name of Parent Corporation	None	
Petitioner's Mailing Address, if Post Office (PO) Box, include a street mailing address for Certified Mail	60 Temple Street, Suite 8A, New Haven, CT 06510	
What is the Petitioner's Status: P for profit and NP for Nonprofit	P	
Contact Person at Facility , including Title/Position: This Individual at the facility will be the Petitioner's Designee to receive all correspondence in this matter.	Kim Fabrizio Senior Director of Regulatory Affairs	

Contact Person's Mailing Address, if PO Box, include a street mailing address for Certified Mail	MNI 60 Temple Street, Suite 8A New Haven, CT 06510	
Contact Person's Telephone Number	203-401-4313	
Contact Person's Fax Number	203-401-4304	
Contact Person's e-mail Address	kfabrizio@mnim aging.com	

SECTION II. GENERAL PROPOSAL INFORMATION

a. Proposal/Project Title: Purchasing a PET CT Scan Camera

b. Estimated Total Project Cost: \$ 600,000

c. Location of proposal, identifying Street Address, Town and Zip Code:

60 Temple Street, Suite 8A, New Haven, CT 06510

d. List each town this project is intended to serve:

Project would add a research use only PET camera, serving the advancement in medical science to benefit all residents of CT.

e. Estimated starting date for the project:

November 1, 2014 (pending CON Approval).

SECTION IV. PROPOSAL DESCRIPTION

Please provide a description of the proposed project, highlighting each of its important aspects, on at least one, but not more than two separate 8.5" X 11" sheets of paper. At a minimum each of the following elements need to be addressed, if applicable:

1. If applicable, identify the types of services currently provided and provide a copy of each Department of Public Health license held by the Petitioner.

Molecular NeuroImaging, LLC (MNI) is a neuroimaging services company specializing in the efficient application of scintigraphic biomarkers in drug development and research for neurodegenerative and neuropsychiatric disorders. The use of PET Imaging is a pivotal component of the human research conducted at MNI focused on developing new therapies for unmet medical needs such as Alzheimer's disease, Parkinson disease and Huntington disease.. PET imaging is a key component of therapeutic studies and MNI has increasing opportunity to meet these research needs to accelerate vital ongoing research for these largely untreatable conditions. MNI is exclusively a research company. MNI does not participate in any health care reimbursement programs and is not a Point of Service for any medical needs. The DPH issued Physician Licensure held by the Petitioner is attached.

MNI is based in New Haven, CT with over 30,000 sq ft. of space and the imaging division has extensive experience and expertise in conducting PET imaging research.

Our research staff has leadership roles in numerous research PET imaging trials and in several research consortiums and international research organizations focused on neuroscience research and nuclear medicine research aimed at advancing knowledge about the causes and developing more effective treatments for neurodegenerative disorders. MNI was founded in 2000 by Drs. Marek and Seibyl to create a unique research company that combines knowledge in neurology/neuropsychiatry with state-of-art imaging using custom radiopharmaceuticals for investigational purposes and researching of neurodegenerative and neuropsychiatric disorders. This fusion of internationally-recognized expertise in the neuroscience and imaging arenas into a unified research-dedicated organization allowed MNI to efficiently develop and execute imaging studies to support early drug development and investigational trials for assessing disease progression that emphasize quantitative imaging outcome measures. Drs. Marek and Seibyl had previously established their collaboration while on faculty at Yale University and founded MNI with twenty staff members with long-term experience in imaging trials. During the past thirteen years MNI has greatly expanded in size and is a privately-held, limited liability company incorporated in the state of Connecticut. MNI has developed a number of strategic alliances and corporate partnerships and research contracts with pharmaceutical companies.

2. Identify the types of services that are being proposed and what DPH licensure categories will be sought, if applicable.

MNI would like to propose the purchase of an additional imaging camera to allow to meet the increased demands for investigational PET imaging studies to evaluate new therapies for neurodegenerative disorders. MNI seeks to continue to be a leader in PET research and therefore must update the imaging camera technology to the current state of the art.

3. Identify the current population served and the target population to be served.

The current and target population to be served are human research subjects participating in studies to advance research to help to develop new therapies for neurodegenerative disorders. Subjects may be healthy volunteers or may carry a diagnosis of a

neurodegenerative disease (ie Alzheimer's, Parkinson's Disease, etc.). MNI is strictly a research company. Under no circumstances would MNI or its physicians provide, charge or participate in any health care reimbursement programs or clinical care to the population being served. MNI nor its physicians are point of service providers.

SECTION V. AFFIDAVIT

(Each Petitioner must submit a completed Affidavit.)

Petitioner: Kenneth Marek, M.D.

Project Title: Purchasing a PET CT Scan Camera

I, Kenneth Marek, M.D., General Partner
(Name) (Position – CEO or CFO)

of Molecular NeuroImaging, LLC being duly sworn, depose and state that the
(Organization Name)

information provided in this CON Determination form is true and accurate to the best of my
knowledge.

[Signature] Date Aug 11, 2014
Signature Date

Subscribed and sworn to before me on 11 August 2014

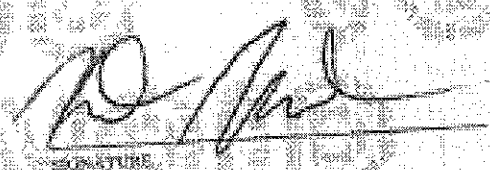
Rebecca Evans Ewin Rebecca Evans Ewin
~~Notary Public~~ Commissioner of Superior Court


~~My commission expires:~~ 11 Aug 2014

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
PURSUANT TO THE PROVISIONS OF THE GENERAL STATUTES OF CONNECTICUT
THE INDIVIDUAL NAMED BELOW IS LICENSED
BY THIS DEPARTMENT AS A
PHYSICIAN / SURGEON

KENNETH L. MAREK, MD

LICENSE NO.
030034
CURRENT THROUGH
09/30/14
VALIDATION NO.
03-645533


SIGNATURE


DATE

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

August 26, 2014

VIA FACSIMILE ONLY

Kim Fabrizio
Senior Director of Regulatory Affairs
Molecular NeuroImaging, LLC
60 Temple Street
Suite 8A
New Haven, CT 06510

RE: Certificate of Need Determination Report Number 14-31933-DTR
Acquisition of a Positron Emission Tomography-Computed Tomography Scanner

Dear Ms. Fabrizio:

On August 12, 2014, the Office of Health Care Access ("OHCA") received your Certificate of Need ("CON") Determination Form on behalf of Molecular NeuroImaging, LLC ("Petitioner" or "MNI") with respect to the acquisition of a Positron Emission Tomography-Computed Tomography Scanner ("PET-CT").

MNI is a neuroimaging services company specializing in the application of scintigraphic biomarkers in drug development and research for neurodegenerative and neuropsychiatric disorders. MNI is exclusively a research company which conducts research on humans but does not act as a Point of Service for any medical needs. MNI seeks to purchase a PET-CT to conduct human research.

Connecticut General Statutes §19a-638(a)(9) requires CON authorization for the "acquisition of ... positron emission tomography-computed tomography scanners, by any person...except as provided for in subdivision (22) of subsection (b) of this section". Connecticut General Statutes §19a-638(b)(22) provides an exception to the CON requirement for the "acquisition of any equipment by any person that is to be used exclusively for scientific research that is not conducted on humans." Since MNI conducts scientific research on humans, it does not fall under the exception outlined in Connecticut General Statutes §19a-638(b)(22). Additionally, MNI is considered a "person" as that term is defined by Connecticut General Statutes §19a-630(13). Therefore, OHCA hereby determines that a **CON is required** for the Petitioner's proposal.

Sincerely,

Kimberly R. Martone
Director of Operations

C: Rose McLellan, License and Applications Supervisor, DPH, DHSR.

An Equal Opportunity Provider

(If you require aid/accommodation to participate fully and fairly, contact us either by phone, fax or email)
410 Capitol Ave., MS#13HCA, P.O.Box 340308, Hartford, CT 06134-0308
Telephone: (860) 418-7001 Fax: (860) 418-7053 Email: OHCA@ct.gov

* * * COMMUNICATION RESULT REPORT (AUG. 26. 2014 2:38PM) * * *

FAX HEADER:

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REASON FOR ERROR
 E-1) HANG UP OR LINE FAIL
 E-3) NO ANSWER

E-2) BUSY
 E-4) NO FACSIMILE CONNECTION



**STATE OF CONNECTICUT
 DEPARTMENT OF PUBLIC HEALTH
 OFFICE OF HEALTH CARE ACCESS**

FAX SHEET

TO: KIM FABRIZIO

FAX: 203 401-4304

AGENCY: MNI

FROM: OHCA

DATE: 8/26/14 **Time:** _____

NUMBER OF PAGES: 2
(including transmittal sheet)

Comments:
 Determination is attached.

PLEASE PHONE Barbara K. Olejrz IF THERE ARE ANY TRANSMISSION PROBLEMS.

Phone: (860) 418-7001 Fax: (860) 418-7053
 410 Capitol Ave., MS#13HCA
 P.O.Box 340308
 Hartford, CT 06134