



The Commonwealth of Massachusetts
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March 1, 2021

Andrew Levine
Summit Health Law Partners
One Beacon Street, Suite 1320
Boston, MA 02108-3106

Re: Brigham and Women's Hospital, Inc. – Application for a Substantial Change in Service Pursuant to Order of the Commissioner of Public Health Regarding Determination of Need Approvals Related to COVID-19

Dear Mr. Levine:

The Department received the notification above on February 16, 2021 to convert the research-only neonatal intensive care unit (“NICU”) magnetic resonance imaging (“MRI”) modality at Brigham and Women’s Hospital (BWH) to clinical use.

Presently, BWH has an Aspect Imaging Embrace Neonatal MRI scanner installed and available for investigational applications in its NICU, located on the 6th floor of the Connors Center for Women’s Health (“CCWH”) at 75 Francis Street in Boston (“NICU MRI”). This NICU MRI is operated pursuant to an approved research exemption from the DoN program. Since receiving DoN approval to operate the NICU MRI for research purposes and going live in September 2018, the Applicant and BWH have been committed to researching the applications of the NICU MRI technology for neonatal patients and using the NICU MRI unit to elevate and expand the Hospital’s Neonatology Department’s focus on neurocritical care.

The Applicant notes the importance of diagnostic imaging generally in the care of neonates particularly for preterm babies at a higher risk of feeding, vision, and hearing problems, as well as cognitive, behavioral, and social difficulties whose problems are generally the result of premature neonatal brain injuries.¹ In this context, diagnostic imaging is required to identify the presence and extent of any brain injuries and guide treatment and care management² and MRI is the preferred imaging method for

¹ Stephen A. Back, *White Matter Injury in the Preterm Infant: Pathology and Mechanisms*, 134 ACTA NEUROPATHOLOGICA 331-349 (2017), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5973818/>

² Stephen A. Back & Steven P. Miller, *Brain Injury in Premature Neonates: A Primary Cerebral Dysmaturation Disorder?*, 75 Annals of Neurology 469-486 (2014), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5989572/>.

assessing brain injury and development for neonates.

While the Hospital operates other MRI units that are licensed by the Department for clinical use, none of these clinical-use MRI units are located within the NICU. Accordingly, infants in the NICU that require MRI must be transported outside of the NICU for imaging to one of three locations across the hospital campus. Transporting infants to an MRI poses a public health risk for such infants in the context of the COVID-19 emergency as the process of transporting the infant out of the NICU through the Hospital increases the potential for COVID-19 exposure. Overall, clinical access to this technology within the NICU will reduce COVID-19 exposure risk associated with transport to traditional MRI, allow the sickest patients to undergo imaging for targeted neurological care.

In consideration of the above-outlined information as part of its infection prevention protocols to manage and prevent the spread of COVID-19, the Applicant seeks approval for the Proposed Project and convert the current research-only NICU MRI at BWH to clinical use to assist in keeping infants safe from potential COVID-19 exposure by not moving them out of the NICU for MRI services.

The projected cost associated with the Proposed Project is \$1,220,052, which includes the cost of the MRI unit when originally purchased and related construction costs.

After review, DPH has determined the need for the Proposed Project relates to the State of Emergency and therefore the DoN approval requirement is temporarily waived pursuant to the COVID-19 order. As a result, you may begin to use the NICU MRI for clinical use for the remainder of the COVID-19 State of Emergency. Upon termination of the COVID-19 State of Emergency, the Applicant must cease using the NICU MRI for clinical purposes. If the Applicant would like to continue to use the NICU MRI for clinical use, it must submit a request for review to the DoN at which time the Department will make a determination if the Applicant must apply for a full Notice of Determination of Need, including all applicable Factors.

Sincerely,



Lara Szent-Gyorgyi
Director, Determination of Need

cc: Sherman Lohnes, Division of Health Care Facility Licensure and Certification, DPH
Rebecca Rodman, Senior Deputy General Counsel, DPH
Elizabeth Kelley, Director Bureau of Health Care Safety and Quality, DPH
Margret Cooke, Deputy Commissioner, DPH
Crystal Bloom, Esq.

