

February 16, 2021

Via E-Mail

Lara Szent-Gyorgyi, MPA
Director, Determination of Need Program
Department of Public Health
250 Washington Street
Boston, MA 02108

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 Ms. Szent-Gyorgyi:

Pursuant to the Order of the Commissioner of Public Health Regarding Determination of Need (“DoN”) Approvals Related to COVID-19 (“COVID-19 DoN Order”), issued on March 24, 2020, and the related Memorandum from Lara Szent-Gyorgyi, Director of the Determination of Need Program, dated November 24, 2020, Brigham and Women's Hospital, Inc. (“Applicant”), located at 800 Boylston Street, Suite 1150, Boston, MA 02199, respectfully requests that the Department of Public Health (“Department”) review and approve a Substantial Change in Service by Brigham and Women's Hospital (“BWH” or “Hospital”), located at 75 Francis Street, Boston, MA 02115. The proposed project is for the conversion of the Hospital's research-only neonatal intensive care unit (“NICU”) magnetic resonance imaging (“MRI”) modality to clinical use. The Department's approval will allow the Hospital to safely provide care to its patients during the outbreak of COVID-19 (“Proposed Project”). We offer the following comments.

I. Importance of BWH's NICU MRI, Particularly in the Context of COVID-19

BWH presently 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.

To this point, we note the importance of diagnostic imaging generally in the care of neonates. While mortality rates related to preterm birth have drastically decreased in the United States over the last 30 years, such improved survival has been accompanied by higher rates of longer-term health issues, as preterm babies are at a higher risk of feeding, vision, and hearing problems, as

well as cognitive, behavioral, and social difficulties than babies born near or at term.¹ These problems are generally the result of premature neonatal brain injuries.² In this context, diagnostic imaging is required to identify the presence and extent of any brain injuries and guide treatment and care management.³

MRI has long been recognized as the preferred imaging technology for high-risk infants, including very preterm, low birth weight, and critically ill infants.⁴ Other imaging modalities lack the sensitivity needed to determine the extent of injuries when compared to MRI diagnostic capabilities.⁵ For this reason, MRI is the preferred imaging method for assessing brain injury and development for neonates.⁶

Despite MRI being the superior imaging technology for neonate imaging, the use of a conventional MRI unit nonetheless presents risks and complications for NICU infants. Notably, 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, either to the Lee Bell Center located on the 2nd Floor of the CCWH at 75 Francis Street; the Hospital's Lower-Level Radiology Department located at 45 Francis Street, L1; or the Hale Building for Transformative Medicine ("BTM") located at 60 Fenwood Road.

The table below shows the number of NICU infants in need of clinical MRI scans that were transported outside of the Hospital's NICU for scans on these conventional MRI units in Fiscal Year ("FY") 19, FY20, and FY21 year-to-date:

¹ *Death rate from neonatal preterm birth complication, 1990 to 2017*, OUR WORLD IN DATA, <https://ourworldindata.org/grapher/deaths-from-preterm-birth-complications?tab=chart&country=~USA> (last visited Jan. 26, 2021); 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/>; *Preterm Birth*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm> (last updated Oct. 30, 2020); Lianne J. Woodward et al., *Neonatal MRI to Predict Neurodevelopmental Outcomes in Preterm Infants*, 355 NEJM 685-694 (2006), available at <https://www.nejm.org/doi/full/10.1056/nejmoa053792>.

² Back, *supra* note 1.

³ 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/>.

⁴ Linda S. de Vries et al., *Imaging the premature brain: ultrasound or MRI?*, 55 NEURORADIOLOGY 13-22 (2013), available at <https://doi.org/10.1007/s00234-013-1233-y>.

⁵ Hannah C. Glass et al., *MRI and Ultrasound Injury in Preterm Infants with Seizures*, 24 J. CHILD NEUROLOGY 1105-1111 (2009), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3014150/>; Terrie E. Inder et al., *White Matter Injury in the Premature Infant: A Comparison between Serial Cranial Sonographic and MR Findings at Term*, 24 AM. J. NEURORADIOLOGY 805-809 (2003), available at <http://www.ajnr.org/content/24/5/805.long>.

⁶ Christopher D. Smyser et al., *Magnetic resonance imaging of the brain at term equivalent age in extremely premature neonates: to scan or not to scan?*, 48 J. PAEDIATRICS & CHILD HEALTH 794-800 (2012), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3595093/>; Woodward et al., *supra* note 1.



	FY19	FY20	FY21 YTD
Lee Bell Center MRI	160	129	9
Radiology L1 MRI	40	43	13
BTM MRI	20	14	20
Total	220	186	42

This 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’s hallways and between units, floors and buildings increases the potential for COVID-19 exposure. Amplifying this risk is the fact that most NICU monitoring equipment is not designed to be portable and may not function properly when being transported.⁷ 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.

While research into the applications and uses of this MRI technology for critically ill neonatal patients is still at an early stage in the United States (as the Aspect Imaging Embrace Neonatal MRI System was the first MRI machine built for use in the NICU to be granted FDA clearance in 2017)⁸, by way of its research exemption, the Hospital now has extensive experience and comparison of the NICU MRI system confirming its diagnostic capability as an MRI system for 90% of all MRIs that need to be done for neonates. Moreover, in addition to being built to size for infants, the NICU MRI system has unique advantages over typical MRI technology for a NICU environment, with a self-shielding permanent magnet that allows greater access to sensitive patients and the opportunity to locate it in a location that would typically be size prohibitive.⁹

II. Request for Approval

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. While this would typically require a full Notice of DoN as a Substantial Change in Service, the Applicant seeks approval pursuant to the COVID-19 DoN Order and the Department’s related guidance. By submitting this request, the Applicant hereby attests that the Proposed Project is intended for use in the management and treatment of the COVID-19 virus. Specifically, the Proposed Project is

⁷ Hubert Messner & Alex Staffler, *Transport of the high-risk neonate*, 41 ITALIAN J. PEDIATRICS A22 (2015), available at <https://doi.org/10.1186/1824-7288-41-S1-A22>.

⁸ *FDA clears first neonatal magnetic resonance imaging device*, U.S. FOOD & DRUG ADMIN. (Jul. 20, 2017), <https://www.fda.gov/news-events/press-announcements/fda-clears-first-neonatal-magnetic-resonance-imaging-device>.

⁹ *Embracing neonatal MRI*, PRACTICAL PATIENT CARE (Feb. 16, 2018), <http://www.practical-patient-care.com/features/featureembracing-neonatal-mri-6818220/>.

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intended to assist in keeping infants safe from potential COVID-19 exposure by not moving them out of the NICU for MRI services. Please see Attachment A for an affidavit signed by the Applicant's President and CEO.

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

We thank you for our attention to this matter. Please contact me or Crystal Bloom, Esq. if you have any questions or require any additional information.

Respectfully,



Andrew S. Levine

Enclosure

cc: Rebecca Rodman, Esq., DPH
B. Jones, BWH
J. McGillivray, BWH
T. Sykes, BWH
C. Philbin, MGB

Attachment A

Pursuant to the Order of the Commissioner of Public Health Regarding Determination of Need Approvals Related to COVID-19, dated March 24, 2020, and the Memorandum from Lara Szent-Gyorgyi, Director of the Determination of Need Program, dated November 24, 2020, providing updated guidance on requesting Determination of Need ("DoN") approval for projects related to COVID-19 during the State of Emergency, I, Elizabeth Nabel, M.D., the undersigned President of Brigham and Women's Hospital, Inc., hereby submit this DoN application under the pains and penalties of perjury.

Elizabeth G Nabel

Elizabeth Nabel, M.D., President