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Ethical, legal, and policy challenges in field-based neuroimaging research using emerging portable MRI technologies: guidance for investigators and for oversight

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ABSTRACT

Researchers are rapidly developing and deploying highly portable MRI technology to conduct field-based research. The new technology will widen access to include new investigators in remote and unconventional settings and will facilitate greater inclusion of rural, economically disadvantaged, and historically underrepresented populations. To address the ethical, legal, and societal issues raised by highly accessible and portable MRI, an interdisciplinary Working Group (WG) engaged in a multi-year structured process of analysis and consensus building, informed by empirical research on the perspectives of experts and the general public. This article presents the WG's consensus recommendations. These recommendations address technology quality control, design and oversight of research, including safety of research participants and others in the scanning environment, engagement of diverse participants, therapeutic misconception, use of artificial intelligence algorithms to acquire and analyze MRI data, data privacy and security, return of results and managing incidental findings, and research participant data access and control.

KEYWORDS: portable MRI, neuroimaging, neuroethics, research ethics, vulnerable populations, rural and remote communities

I. INTRODUCTION

Over the past decade, MRI physics and engineering have advanced to make highly portable and accessible MRI scanning a reality.¹ We use the term 'portable MRI' to refer to highly portable and accessible brain MRI technologies, which vary in field strength, spatial resolution, temporal resolution, intended use, cost, and ease of use

1 W. Taylor Kimberly et al., *Brain Imaging with Portable Low-Field MRI*, NATURE REV. BIOENG. (2023), <https://doi.org/10.1038/s44222-023-00086-w>; Mathieu Sarraclanie et al., *Low-Cost High-Performance MRI*, 5 SCI. REPS. 15177 (2015); Lawrence L. Wald et al., *Low-cost and Portable MRI*, 52 J. MAGN. RESON. IMAGING 686 (2019); Francis X. Shen et al., *Emerging Ethical Issues Raised by Highly Portable MRI Research in Remote and Resource-Limited International Settings*, 238 NEUROIMAGE 118210 (2021); Francis X. Shen et al., *Ethical Issues Posed by Field Research Using Highly Portable and Cloud-Enabled Neuroimaging*, 105 NEURON 771 (2020). Portable MRI could be used to image different body parts, but we focus in this article on portable brain MRI.

(Table 1). This emerging technology is now being deployed in places previously beyond the reach of MRI, including in a moving ambulance, at the bedside, and even at a research participant's home (Table 2). As portable MRI technologies proliferate they will facilitate broad use in field-based research with rural, economically disadvantaged, and historically underrepresented populations.² Utilizing artificial intelligence (AI) and cloud platforms, these new MRI technologies will be less expensive and offer more user-friendly interfaces that will invite use by MRI machine operators without extensive training, while maintaining sufficient image quality for neuroscience research and even some clinical applications. Portable MRI will deliver improvements along five key dimensions of MRI accessibility recognized in the literature and aligned with the World Health Organization's (WHO) medical devices strategy and policy: geographical, temporal, financial, cultural, and digital.³ The development of even more 'autonomous MRI' systems that can scan in remote sites at the press of a button and without skilled technicians may address shortages of trained staff.⁴

These developments may greatly enlarge and diversify the makeup of the MRI research community. MRI researchers have historically been trained in fields such as neuroscience, radiology, and neurology. Portable MRI will be smaller, less expensive, and thus widely accessible to biomedical and social science researchers, as well as patient and participant communities. Fields such as neurolaw,⁵ neuroeconomics,⁶ educational neuroscience,⁷ neuropolitics,⁸ neuromarketing,⁹ neurophilosophy,¹⁰ and neurosociology¹¹ may increasingly integrate scanning into their research.¹²

We use the term 'MRI researcher' to refer to all individuals on the research team who play a role in the design, conduct, interpretation, sharing, and storage of data acquired from portable MRI. As we use the term, an MRI researcher need not be an expert in MRI. For example, an economist using MRI in a decision-making study would be an MRI researcher. We use the term 'MRI innovators' to refer to those individuals (eg physicists, engineers) and companies that study, improve, and develop MRI technologies. We use the term 'MRI operator' to refer to those individuals who are

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- 2 Sean C.L. Deoni et al., *Development of a Mobile Low-Field MRI Scanner*, 12 SCI. REPS. 5690 (2022); Sairam Geethanath & John T. Vaughan Jr, *Accessible Magnetic Resonance Imaging: A Review*, 49 J. MAGN. RESON. IMAGING 65 (2019).
 - 3 Geethanath & Vaughan Jr, *supra* note 2, at 67 (noting that these 'five access dimensions also map to the WHO's medical devices strategy and policy with geographical and temporal accesses accommodating the definition of availability and accessibility—financial and cultural accesses mapping to affordability and appropriateness').
 - 4 See Table 1 for definition of AMRI. Keerthi Sravan Ravi & Sairam Geethanath, *Autonomous Magnetic Resonance Imaging*, 73 MAGN. RESON. IMAGING 177 (2020).
 - 5 OWEN D. JONES, JEFFREY D. SCHALL & FRANCIS X. SHEN, *LAW AND NEUROSCIENCE* (2nd ed. 2020).
 - 6 George Loewenstein et al., *Neuroeconomics*, 59 ANN. REV. PSYCHOL. 647 (2008).
 - 7 JOHN G. GEAKE, *THE BRAIN AT SCHOOL: EDUCATIONAL NEUROSCIENCE IN THE CLASSROOM* (2009).
 - 8 Darren Schreiber, *Neuropolitics: Twenty Years Later*, 36 POL. LIFE SCI. 114 (2017).
 - 9 Nick Lee et al., *What is 'Neuromarketing'? A Discussion and Agenda for Future Research*, 63 INT. J. PSYCHOPHYSIOL. 199 (2007).
 - 10 PATRICIA S. CHURCHLAND, *BRAIN-WISE: STUDIES IN NEUROPHILOSOPHY* (2002).
 - 11 Will Kalkhoff et al., *Developments in Neurosociology*, 10 SOC. COMPASS 242 (2016).
 - 12 This is part of a broader trend of increasing use of neurotechnology in society. See Francis X. Shen, *NeuroX: The Emergence of Neuroscience X Society Fields* (2024) (on file with author).

Table 1. Definition of terms

| Term | Definition as used in this article |
|---|---|
| Accessible MRI | We adopt Geethanath and Vaughn's definition of 'MRI accessibility' as including five dimensions: geographical, temporal, financial, cultural, and digital. ¹³ |
| Autonomous MRI | We follow Ravi and Geethanath in defining 'autonomous MRI' (AMRI) as an MRI machine that can be operated: (i) by any MR-safety-aware worker, even one without technical training on MRI, who can administer the scan, and/or (ii) by any safety-aware research participant/patient who wants an MRI. ¹⁴ |
| Brain data | We use the term 'brain data' to refer to both the raw data generated by the MRI pulse sequences and the processed data that are cleaned and analyzed. |
| Brain image | We use the phrase 'brain image' to refer to the image constructed based on MRI brain data. |
| Brain scan/Scanning | We use the terms 'brain scan' and 'scanning' to refer to the process of obtaining MRI data. |
| Brain scanner | We use the term 'scanner' to refer to the physical MRI device used to acquire the brain data. |
| Citizen science | Here we follow the CitizenScience.gov definition: 'In citizen science, the public participates voluntarily in the scientific process, addressing real-world problems in ways that may include formulating research questions, conducting scientific experiments, collecting and analyzing data, interpreting results, making new discoveries, developing technologies and applications, and solving complex problems'. ¹⁵ |
| Funder | We use the term 'funder' broadly to include federal, state, and international bodies that supply material support for research, as well as private sponsors of research. |
| Mid-field MRI/ Low-field MRI/ Ultra-low field MRI | Consistent with the definitions recommended in the International Society for Magnetic Resonance in Medicine (ISMRM) 2022 Workshop on Low Field MRI, we define 'mid-field' as 0.1-1 T, 'low-field' (LF) as 0.01 < 0.1 T, and 'ultra-low field' (ULF) as <0.01 T. ¹⁶ |

(continued)

Table 1. Continued

| Term | Definition as used in this article |
|--------------------------------------|---|
| MRI Operator | We use the term ‘MRI operator’ to refer to those individuals who are physically next to the portable MRI machine and controlling it, as well as assisting the research participant and completing the necessary tasks to acquire the images. Operators include technicians, but because of portable MRI’s ease of use, operators also include anyone who can run the machine. |
| MRI Researcher/ MRI Research Team | We use the term ‘MRI researcher’ to refer to all individuals on the research team who play a role in the design, conduct, interpretation, sharing, and storage of data acquired from portable MRI. As we use the term, an MRI researcher may not be an expert in MRI. For example, an economist using MRI for the first time in a decision-making study would be an MRI researcher, but not an expert in MRI. |
| MRI Innovator | We use the term ‘MRI innovator’ to refer to those individuals (eg physicists, engineers) who study, improve, develop, and innovate MRI technologies. |
| MRI research | We use the term ‘MRI research’ to refer to research based on inferences from and interpretation of brain data and images. |
| Portable MRI | We use the term ‘portable MRI’ to refer to the suite of highly portable and accessible MRI technologies. These technologies vary in field strength, spatial resolution, temporal resolution, intended use, cost, and ease of use. |
| Report/Laboratory report | We use the term ‘report’ (or ‘laboratory report’) to refer to the physical or electronic document that communicates clinical interpretation and analysis of a brain scan image, eg the document that communicates a report of the radiologist’s expert analysis and clinical conclusions after examining a brain scan image. |

13 Geethanath & Vaughan Jr, *supra* note 2.

14 Ravi & Geethanath, *supra* note 4.

15 [Citizenscience.gov, About CitizenScience.gov, https://www.citizenscience.gov/about/#](https://www.citizenscience.gov/about/#) (accessed Apr. 4, 2023).

16 Adrienne E. Campbell-Washburn et al., *Low-Field MRI: A Report on the 2022 ISMRM Workshop*, 90 MAGN. RESON. MED. 1682 (2023).

Table 2. Current applications of portable MRI

Highly portable MRI is already being utilized in the following research, clinical, and teaching contexts. Deploying these technologies often relies on data transfer to, and storage, in cloud-based servers, as well as the use of AI and machine learning (ML) in data acquisition, analysis, and image construction. The list of applications is sure to expand as multiple MRI technologies are in development to increase portability, reduce cost, and reach more people.¹⁷

Academic Research and Clinical Research Uses:

- **Research on neurodevelopment in low-resource settings:** Researchers have deployed LF MRI systems in low-resource countries to measure brain volume in children (6-weeks to 16-years old), and to investigate how environmental factors affect brain development.¹⁸
- **Studies of brain injury in infants:** The Bill & Melinda Gates Foundation is funding deployment of LF MRI scanners in low-resource countries to ‘identify and potentially mitigate labor- and delivery-related brain damage resulting in HIE (hypoxic ischemic encephalopathy) in infants’.¹⁹
- **Neuroimaging research at participants’ homes:** Researchers studying brain development in children have installed an LF MRI system inside a van and acquired brain imaging data outside the homes of research participants.²⁰
- **Imaging of critically ill patients at the bedside:** Clinical researchers have used a portable LF scanner to acquire brain images of patients who cannot be moved (eg on bypass/life support, or in Covid-19 isolation or incubators), finding that the brain scan images are suitable for clinician assessment of intracranial pathology such as brain injury and stroke.²¹
- **Characterization of changes in brain structure in neurodegenerative diseases such as multiple sclerosis (MS):** Researchers are investigating the use of LF scanners to detect white matter lesions in MS patients,²² as well as look at white matter hyperintensities in the general emergency room (ER) population.²³
- **Feasibility studies of brain imaging patients in intensive care receiving life support:** Clinical researchers have studied the safety and feasibility of using a portable, LF MRI scanner at point-of-care to acquire brain MRI from patients on life support.²⁴
- **Improved accessibility of brain imaging in stroke diagnosis and treatment:** Multiple teams are investigating the use of portable LF and ULF MRI to improve diagnosis of stroke (hemorrhagic or ischemic) and monitor treatment effectiveness.²⁵
- **Utilization in an ambulance:** Clinical researchers in neuroradiology and in teleneurology at the University of South Carolina partnered with the local Emergency Medical Services (EMS) team to demonstrate proof of concept by completing the first-ever acquisition of brain images in a moving ambulance.²⁶

(continued)

Table 2. Continued**Clinical Outreach and Educational Uses:**

- **Improved clinician access to MRI in Sub-Saharan Africa:** A hospital in Malawi is using an LF, portable MRI system to inform routine clinical care through identification of evidence of developmental delay and infections.²⁷
- **Teaching tool:** Low-cost, open-source tabletop MRI scanners have been utilized to teach over 800 students (undergraduate, graduate, and medical school) about neuroimaging, MR physics, and engineering.²⁸

physically next to the portable MRI machine operating it, assisting the research participant, and completing the necessary tasks to acquire the images. Operators include technicians, but because of portable MRI's ease of use, operators also include anyone who can operate the machine.

Expansion of who can conduct MRI research can yield great benefits in knowledge and participant access. But broad democratization of the technology is likely to

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- 17 See Marina Manso Jimeno et al. *Superconducting Magnet Designs and MRI Accessibility: A Review*, 36 NMR BIOMED. e4921 (2023); Teresa Guallart-Naval et al., *Portable Magnetic Resonance Imaging of Patients Indoors, Outdoors and at Home*, 12 SCI. REPS. 13147 (2022); Patrick C. McDonald et al., *The MR Cap: A Single-Sided MRI System Designed for Potential Point-of-Care Limited Field-of-View Brain Imaging*, 82 MAGN. RESON. MED. 1946 (2019).
 - 18 Sean C.L. Deoni et al., *Accessible Pediatric Neuroimaging Using a Low Field Strength MRI Scanner*, 238 NEUROIMAGE 118273 (2021).
 - 19 Keri Stephens, *Hyperfine Initiates Program Using Portable MRI To Identify Infant Brain Injury*, AXIS IMAGING NEWS (Nov. 16, 2020), <https://www.proquest.com/openview/33b45a7b583819c055e0df47af4392c2/1?pq-origsite=gscholar&cbl=2037571> (accessed Mar. 19, 2024).
 - 20 Deoni et al., *supra* note 2.
 - 21 Kevin N. Sheth et al., *Assessment of Brain Injury Using Portable, Low-field Magnetic Resonance Imaging at the Bedside of Critically Ill Patients*, 78 JAMA NEUROLOGY 41 (2020); Kevin N. Sheth et al., *Bedside Detection of Intracranial Midline Shift Using Portable Magnetic Resonance Imaging*, 12 SCI. REP. 67 (2022).
 - 22 Thomas C. Arnold, et al., *Sensitivity of Portable Low-Field Magnetic Resonance Imaging for Multiple Sclerosis Lesions*, 25 NEUROIMAGE: CLIN. 103101 (2022).
 - 23 Adam de Havenon et al., *Identification of White Matter Hyperintensities in Routine Emergency Department Visits Using Portable Bedside Magnetic Resonance Imaging*, 12 J. AM. HEART ASSOC. e029242 (2023).
 - 24 Sung-Min Cho et al., *Assessing the Safety and Feasibility of Bedside Portable Low-Field Brain Magnetic Resonance Imaging in Patients on ECMO (SAFE-MRI ECMO Study): Study Protocol and First Case Series Experience*, 26 CRIT. CARE 1 (2022).
 - 25 Seema S. Bhat et al., *Low-Field MRI of Stroke: Challenges and Opportunities*, 54 J. MAGN. RESON. IMAGING 372 (2021); Yilong Liu et al., *A Low-Cost and Shielding-Free Ultra-Low-Field Brain MRI Scanner*, 12 NAT. COMMUN. 1 (2021).
 - 26 Summer Huechtler, *MUSC and Georgetown EMS Test First Mobile MRI Scanner in Moving Ambulance*, WSCS Live 5 News (Jan. 7, 2022), <https://www.live5news.com/2022/01/07/musc-georgetown-ems-test-first-mobile-mri-scanner-moving-ambulance/> (accessed Mar. 19, 2024); Josef Blaszkiewicz, *Blue Sky Award Winners Will Be First to Use Ambulance-Mounted Portable Scanners to Monitor Stroke Patients En Route to the Hospital*, MUSC (May 16, 2022), <https://web.musc.edu/about/news-center/2022/05/16/mri-equipment-ambulance> (accessed Mar. 19, 2024).
 - 27 Karen Chetcuti et al., *Implementation of a Low-Field Portable MRI Scanner in a Resource-Constrained Environment: Our Experience in Malawi*, 43 AM. J. NEURORADIOL. 670 (2022).
 - 28 Clarissa Z. Cooley et al., *Design and Implementation of a Low-Cost, Tabletop MRI Scanner for Education and Research Prototyping*, 310 J. MAGN. RESON. 106625 (2020).



Figure 1. Illustration of how a portable MRI system might be deployed for field-based research in a school gymnasium. Image credit: Alexis Kocken.

generate an influx of researchers as well as citizen scientists using MRI and producing MRI research beyond the reach of the regulations requiring IRB oversight. Thus, the conventional academic neuroscience research safeguards will not consistently apply, creating a major challenge — how to govern MRI research carried out by those without neuroscience and/or bioethics training and outside of traditional neuroimaging research institutions. New strategies will be needed to ensure effective oversight of human subjects research, safety for those being scanned and bystanders, and training for investigators new to portable MRI research.

These issues are already pressing. MRI scanning is now reported in low-resource settings, ambulances, intensive care units (ICUs), and vans making home visits (Table 2). Additional locations in the future may include nursing homes, community centers, school gymnasiums, private clinics, and college psychology departments.

Widespread proliferation of MRI will allow for new research designs, while also raising significant ethical, legal, and societal issues (ELSI).²⁹ These ELSI issues emerge from the distinctive advantages of portable MRI. Portable MRI increases the physical proximity of researcher, participant, bystanders, and surrounding community. While fixed MRI machines are accessed through locked doors in dedicated health care settings or imaging centers, some portable MRI devices may be separated from the community by only a movable rope or partition (see Fig. 1).

Terms such as ‘brain scan’ and ‘MRI’ are used both colloquially by the general public and scientifically. Because the meanings in the two spheres may differ, and because it is important to be precise with our definitions, in Table 1, we provide definitions of key terms as they are used in this article.

Addressing the ELSI challenges raised by portable MRI is the focus of our project funded by the National Institutes of Health (NIH) Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative (*Highly Portable and Cloud-Enabled Neuroimaging Research: Confronting Ethics Challenges in Field Research with New Populations*, NIH RF1MH123698). This article presents consensus guidance from the project’s Working Group (WG) on key ethical and legal issues arising from the widening research use of portable and accessible MRI. Our analysis is primarily focused on the US context. Comparative and international research is needed but beyond the scope of this initial guidance document.³⁰

29 Shen et al. (2020), *supra* note 1; Shen et al. (2021), *supra* note 1.

30 For more on international research with portable MRI, see Shen et al. (2021), *supra* note 1.

Although portable neuroimaging will also have clinical impact, we focus here on research for several reasons. First, at this point early in the development of portable MRI, these devices are primarily being used for investigation before widespread clinical use. Second, as described above, this suite of technologies could revolutionize the conduct of MRI research and thus requires a dedicated analysis. Third, the potential for research use by non-clinical and non-traditional researchers raises unique ethical and legal challenges that are less likely to arise in a clinical environment where access to the technology is more circumscribed.

In Part II, we detail the emergence of portable and accessible MRI. In Part III, we discuss the methods used to develop this ELSI analysis and formulate recommendations. In Part IV, we identify key gaps in current ethical and legal guidance applicable to portable MRI. In Parts V and VI, we present 15 core ELSI issues, recommended solutions, and strategic approaches to implementation. We argue that wider and more decentralized MRI research will require the involvement of more actors and stakeholders using new strategies to ensure that the technology is appropriately utilized. Traditional MRI safeguards will be important, but not sufficient, and to develop new safeguards will require increased investments from funders sponsoring portable MRI research in the field.

II. KEY FEATURES OF PORTABLE AND ACCESSIBLE NEUROIMAGING

Since its invention in the 1970s, MRI has revolutionized brain research and clinical practice, but access to MRI remains limited.³¹ MRI does not directly measure brain function, but rather transmits radiofrequency (RF) pulses into the body and measures the response of the body's water molecules to the RF pulses. The response shows the location of different types of tissue, which, in turn, allows for the creation of brain images.

Most MRI scanners require a massive infrastructure investment in (i) a large, heavy magnet (often weighting >10,000 lbs.), (ii) cryogenics including liquid helium for cooling the magnet, (iii) a dedicated room having magnetic and RF and shielding, (iv) chilled processed water for thermal management, (v) sound proofing, and (vi) large energy-consuming RF amplifiers and gradient power supplies.³² Traditional MRI scanners operate at very high magnetic field and are required by the American College of Radiology (ACR) safety guidelines to be secured in a safety zone with heavily restricted access.³³ To date, 'mobile MRI' has referred to a traditional MRI machine on a flat-bed truck or trailer.³⁴ While the truck can be driven to different locations, imaging still occurs under most of the same constraints as conventional MRI.

31 Marina Manso Jimeno et al., *Superconducting Magnet Designs and MRI Accessibility: A Review*, 36 NMR BIOMED. e4921 (2023), <https://doi.org/10.1002/nbm.4921>.

32 *MR Project Implementation Guide*, GE Healthcare (2012), https://www3.gehealthcare.com/~/media/downloads/us/support/site-planning/site-readiness/gehc-mr_project_implementation_guide_pdf.pdf (accessed Mar. 19, 2024).

33 *ACR Manual on MR Safety*, American College of Radiology Committee on MR Safety (2020), <https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf> (accessed Mar. 19, 2024).

34 Keith Loria, *Still Rolling: Changing Roles in Mobile Imaging*, RADIOLOGY TODAY, July 1, 2018, at 10, <https://www.radiologytoday.net/archive/rt0715p24.shtml> (accessed Mar. 19, 2024); Greg Miller, *Investigating the Psychopathic Mind*, 321 SCIENCE 1284 (2008).

The highly portable and accessible MRI we analyze in this article is fundamentally different (Fig. 2). The technical details of portable, accessible, and AMRI systems have been described elsewhere.³⁵ In brief, portable MRI technology typically utilizes compact magnets, which have reduced power and cooling needs, thus allowing researchers to move beyond traditional siting constraints. Portable MRI is not a single technology. Different strategies are currently being explored to produce a suite of new machines. Some machines, called ‘low-field’ or ‘ultra-low field’ MRI, use a lower strength magnet to acquire imaging data, and then utilize advanced data analysis techniques to extract signals from noisy data.³⁶ Consistent with the definitions recommended in the International Society for Magnetic Resonance in Medicine (ISMRM) 2022 Workshop on Low Field MRI, we define ‘mid-field’ as 0.1-1 T, ‘low-field’ (LF) as 0.01 < 0.1 T, and ‘ultra-low field’ (ULF) as < 0.01 T.³⁷ As noted in this 2022 Workshop, mid-field systems (0.1-1 T) ‘have been providing accurate diagnosis worldwide for decades, including body-part specific systems and open bore geometries’.³⁸ Images produced by new low field (0.01 to < 0.1 T) and ULF (< 0.01 T) systems, however, ‘should not be expected to resemble those of standard clinical systems, especially since different clinical questions are addressed with these systems’, and ‘these low field systems are purpose-built to support clinical decision making in scenarios where high-field MRI is impractical, unobtainable, or ill suited’.³⁹ Multiple LF/ULF devices are in development, with one granted FDA 510(k) clearance and already being used in hospitals, a research van, and ambulance settings (see Fig. 2 for images of selected LF/ULF devices in development).

A second approach retains the high signal-to-noise ratio of ‘mid-’ to ‘high field’ (> 1 T) devices, but reduces the size of the magnet. Using a smaller magnet produces a magnetic field that is very non-uniform so that new RF pulse and image reconstruction strategies are harnessed.⁴⁰ With advances in engineering, physics, and AI, clinical-grade magnetic resonance images (with high spatial and contrast resolution, potentially equivalent to that generated by standard MRI scanners operating at 1.5 T) will soon be produced by machines that are much smaller; sit in a room without RF-shielding;

35 See, eg Wald et al., *supra* note 1; Mercy H. Mazurek et al., *Portable, Bedside, Low-Field Magnetic Resonance Imaging for Evaluation of Intracerebral Hemorrhage*, 12 NAT. COMMUN. 5119 (2021); Matthew M. Yuen et al., *Portable, Low-Field Magnetic Resonance Imaging Enables Highly Accessible and Dynamic Bedside Evaluation of Ischemic Stroke*, 8(16) SCI. ADV. eabm3952 (2022), DOI: <https://doi.org/10.1126/sciadv.abm3952>; José P. Marques et al., *Low-field MRI: An MR Physics Perspective*, 49 J. MAGN. RESON. IMAGING 1528 (2019); Thomas C. Arnold et al., *Low-field MRI: Clinical Promise and Challenges*, 57 J. MAGN. RESON. IMAGING 25 (2022).

36 ROBERT KRAUS JR ET AL., *ULTRA-LOW FIELD NUCLEAR MAGNETIC RESONANCE: A NEW MRI REGIME* (2014); Sarracanie et al., *supra* note 1; Michelle Espy et al., *Applications of Ultra-low Field Magnetic Resonance for Imaging and Materials Studies*, 19 IEEE TRANS. APPL. SUPERCOND. 835 (2010); Neha Koonjoo et al., *Boosting the Signal-to-Noise of Low-Field MRI with Deep Learning Image Reconstruction*, 11 SCI. REP. 8248 (2021); Juan Eugenio Iglesias et al., *Quantitative Brain Morphometry of Portable Low-Field-Strength MRI Using Super-Resolution Machine Learning*, 306 RADIOLOGY e220522 (2023).

37 Campbell-Washburn et al., *supra* note 16.

38 *Id.*

39 *Id.*

40 Naoharu Kobayashi et al., *Magnetic Resonance Imaging Under Highly Inhomogeneous B0 Fields Using Missing-Pulse Steady-State Free Precession (MP-SSFP)*, ISMRM 25th Annual Meeting Electronic Poster Session (Apr. 26, 2017), https://www.ismrm.org/17/program_files/EP15.htm (accessed Mar. 19, 2024); Sebastian Theilenberg et al., *Multi-Coil Array for Combined Imaging and B0 Shimming in a Portable Head-Only Scanner*, 27 PROC. INT. SOC. MAGN. RESON. MED. 1480 (2019).

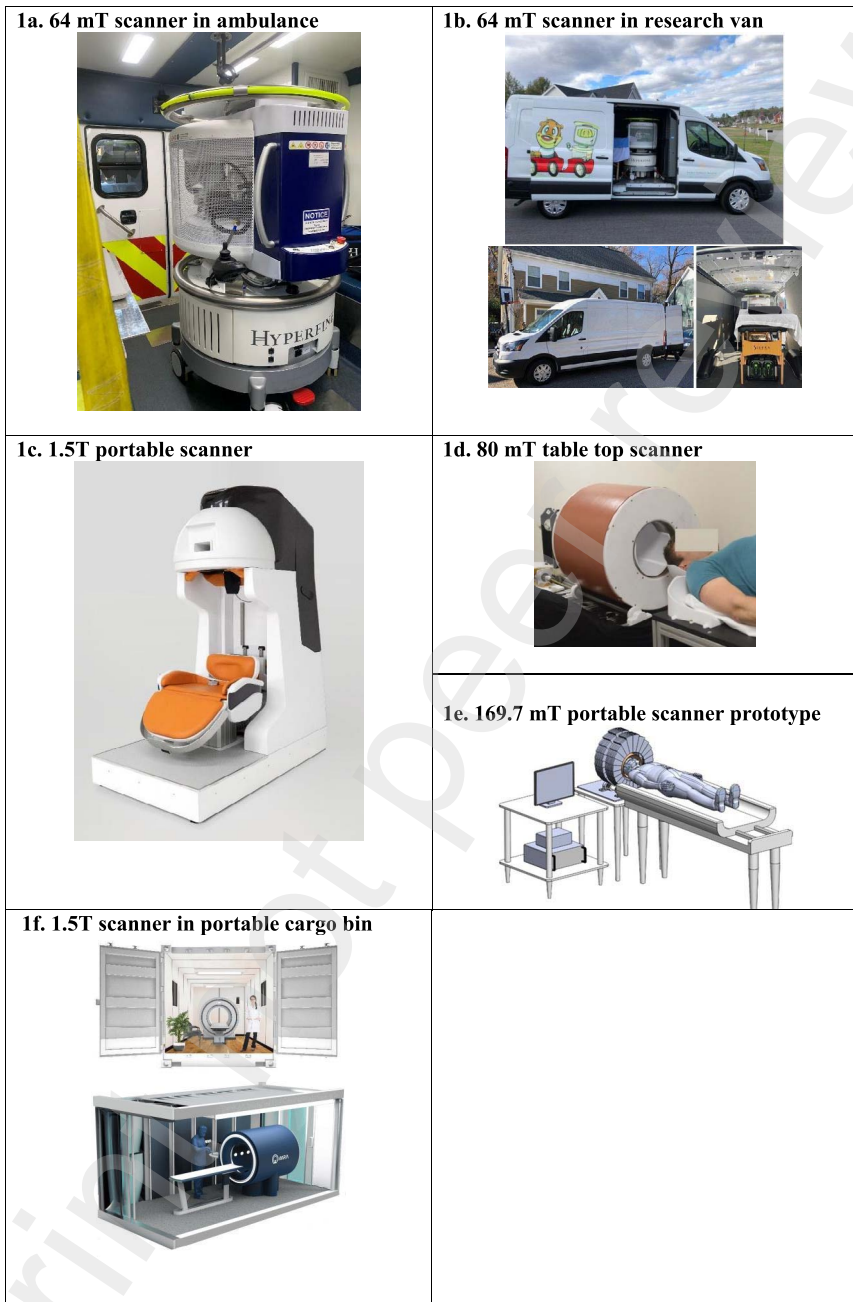


Figure 2. Images of portable, accessible, and autonomous brain MRI scanners in use and in development. (1a) 64 mT scanner in ambulance. (1b) 64 mT scanner in research van. (1c) 1.5 T portable scanner. (1d) 80 mT table top scanner. (1e) 169.7 mT portable scanner prototype. (1f) 1.5 T scanner in portable cargo bin.

run on batteries, power generator, or a standard 120v outlet; and do not require an elaborate helium cooling system. These high-field portable MRI machines, while larger than lower-field devices, could facilitate *functional* MRI (fMRI) research as well. It is not expected that LF/ULF devices can be used for fMRI.

A third strategy is AMRI, which involves a scanner, cloud-based servers to transmit and store the data, and a user interface (which may not be in the same location as the scanner) to control the system.⁴¹ The AMRI strategy, currently in a proof-of-concept stage, would allow end users with little to no MRI operating experience to acquire MRI data. This addresses one of the biggest barriers to making MRI more accessible: the lack of highly trained personnel required to operate MRI systems and to interpret diagnostics data acquired from them. By automating MRI data acquisition and diagnostics processes, the expertise required to attend and operate an AMRI

Figure 2. (Continued) These examples of portable, accessible, and AMRI technologies are illustrative, not exhaustive, of the new MRI technologies being developed. Reproduction of these images here is not meant to be an endorsement of any particular technology, but instead illustrates the range of devices being created. (1a) A research team is exploring the efficacy of using portable MRI in an ambulance.⁴² (1b) A research team has installed a portable MRI scanner in a cargo van that can arrive at a participant's home and be ready for scanning in 5 min.⁴³ (1c) An international research team has developed portable 1.5 Tesla MRI system technology with support from NIH BRAIN.⁴⁴ (1d) A research team has developed a 'prototype portable brain MRI scanner based on the Halbach permanent magnet described in Cooley et al. (2018) and configured for rotational encoding as in Cooley et al. (2015).⁴⁵ The magnet weighs ~125 kg and achieves an 80 mT B0 field'.⁴⁶ (1e) A research team has developed a portable, LF MRI head imager, with a permanent magnet array that generates strong magnetic fields inside the bore, but negligible magnetic fields outside the bore. This device uses an inward-outward ring array that supplies field in the axial direction.⁴⁷ (1f) A research team has developed an accessible MRI system, including portable imaging suite, currently being developed to meet the WHO criteria for 'accessibility'. Accessibility criteria will be met with a high temperature superconducting magnet and accompanying system incorporated into a standard shipping container.⁴⁸

41 Ravi & Geethanath, *supra* note 4.

42 Huechtker, *supra* note 26; Blaszkiewicz, *supra* note 26. Image used with permission from Donna D. Roberts.

43 Deoni et al., *supra* note 2. Image used with permission from Sean C.L. Deoni.

44 Imaging Human Brain Function with Minimal Mobility Restrictions, NIH #1U01EB025153-01. Mailin Lemke & Ben Parkinson, Photograph of Portable 1.5 Tesla MRI system technology (used with permission from Mailin Lemke and Ben Parkinson).

45 Clarissa Z. Cooley et al., *Design of Sparse Halbach Magnet Arrays for Portable MRI Using a Genetic Algorithm*, 54 IEEE TRANS. MAGN. 5100112 (2018); Clarissa Z. Cooley et al., *Two-Dimensional Imaging in a Lightweight Portable MRI Scanner Without Gradient Coils*, 73 MAGN. RESON. MED. 872–83 (2015).

46 Wald et al., *supra* note 1 (image used with permission from Lawrence L. Wald).

47 Zhi Hua Ren et al., *An Irregular-Shaped Inward-Outward Ring-Pair Magnet Array with a Monotonic Field Gradient for 2D Head Imaging in Low-Field Portable MRI*, 7 IEEE ACCESS 48715, 48715–24 (2019); Zhi Hua Ren et al., *Design and Optimization of a Ring-Pair Permanent Magnet Array for Head Imaging in a Low-Field Portable MRI System*, 55 IEEE TRANS. MAGN. 1 (2019). Image of MRI head imager used with permission from Huang Shaoying.

48 J. Thomas Vaughan, Image of MR Access, Inc. System. Image used with permission from J. Thomas Vaughan.

could be reduced to a single research staff member in the field to provide a human interface for the research participant. In an AMRI system, scan protocols would be downloaded from the cloud, image data acquisition would be uploaded to the cloud, and diagnostic analytics would be performed in the cloud making use of ML and AI tools. In addition to automating MRI, highly portable MRI will reduce the system cost, weight, dimensions, and dependence on modern infrastructure by use of new magnet technologies, 5G cell phone controllers, satellite links, cloud platforms, and AI diagnostics algorithms.

One AMRI approach uses a high-temperature superconducting magnet and accompanying system incorporated into a standard shipping container. The magnet is smaller and lighter compared with conventional magnets. The shipping container serves as the RF and magnetic shield, and is designed for shipping to most locations. Once delivered on site, the scanner and requisite pulse sequences can be controlled remotely by researchers or clinicians far from the site of the scanner, and data analysis can be performed in the cloud.

These technological advances make portable MRI different from conventional MRI in four ways. First, the user-friendly interface of many portable MRI machines will greatly enlarge the number of people who can operate the scanner and thus expand the range of disciplines in which MRI is used for research. Rather than being restricted to a small set of trained technicians and experienced researchers, MRI will be available to new researchers after a short training session. For instance, an economist could add MRI to a decision-making study, a college psychology department could allow students to use MRI in an introductory class, or a political research firm studying voters could add MRI to its market research capabilities.

Second, portable MRI will allow researchers to scan in many new locations. New MRI technologies can be deployed in remote locations—stationed next to a battlefield, wheeled into the ER and ICU, brought to community centers, and placed in vans that can make home visits. More universal access to MRI will facilitate research in field settings with more diverse participants.

Third, the proliferation of MRI means more inclusive scanning. Neuroimaging research has historically focused on participants who can access a well-resourced hospital, university, or stationary imaging center. Additional but limited research has involved conventional MRI in a semi-truck trailer or equivalent. Few studies have been able to reach remote populations. The challenges of bringing MRI to remote populations in locations without a major hospital or imaging center and without trained MRI technicians have been substantial. Many of these barriers will be reduced with the advent of smaller, less expensive, and more portable MRI that can be operated without extensive training and interpreted by researchers at a different location, including researchers without a large research budget. Widespread access to MRI paves the way for population neuroscience research with greatly increased numbers and diversity of participants.

Fourth, the images produced by portable MRI scanning may often be of lower resolution than traditional fixed 1.5 T MRI systems. As noted above, LF/ULF is not meant to be a wholesale replacement for fixed MRI, but LF/ULF images may be sufficient for some purposes. Researchers will need to decide which scanning quality is required for specific applications. Moreover, portable MRI technology will often rely

on AI and ML algorithms to improve acquisition and processing of lower resolution images, while preserving the ability to capture often subtle images indicative of disease.

III. METHODOLOGY

The full benefit of emerging portable MRI technology cannot be realized until associated ethical and legal issues are addressed. Using the methods described in this section, our interdisciplinary WG has identified the core ELSI challenges and recommended solutions.

The analysis and recommendations in this paper were developed by an interdisciplinary WG and three Principal Investigators (PIs). Over the course of the project, the WG included 15 members comprised of members with expertise in neuroscience, neuroimaging, radiology, research ethics, community engagement, law, neurology, and AI. The WG met in full or in part 10 times over 3 years, completing a structured process of analysis and consensus building.

In our first WG meeting, we deployed a modified Delphi process. Based on an initial literature review, the PIs developed an online Qualtrics survey presenting key issues for WG evaluation. The survey included closed-response Likert scale questions as well as open-ended response questions. WG members completed two waves of the same survey. Wave 1 (pre-meeting) garnered 14 responses (out of 15 WG members and 3 PIs who were invited to complete the survey). Wave 2 (post-meeting), conducted after the WG meeting, garnered responses from 12 of 18 potential respondents. The Delphi data were used to generate WG discussion; identify areas of agreement, disagreement, and uncertainty; and move toward WG consensus. The Delphi process clarified the initial roster of ELSI issues, which were discussed at subsequent WG meetings.

Building on this Delphi method to identify the initial issues to consider, the WG developed the consensus analysis and recommendations in this article. The group sought to anticipate the societal implications of emerging portable MRI technology and generate recommendations to create an oversight and governance strategy to achieve societal benefit while mitigating potential harms. Methodologically, we were able to learn from scholarly, governmental, and professional society efforts underway across the globe to improve the anticipatory analysis of emerging technologies.⁴⁹

A central challenge for proactive ethics work is projecting the trajectory of technological development and identifying the attendant ethical issues.⁵⁰ A variety of approaches have been used, including: responsible research and innovation (RRI),⁵¹ anticipatory governance,⁵² a framework from the Committee on Emerging Science, Technology, and Innovation (CESTI) at the National Academies of Science, Engineering, and Medicine (NASEM),⁵³ ethical technology assessment

49 James H. Moor, *Why We Need Better Ethics for Emerging Technologies*, 7 ETHICS INFORM. TECH. 111 (2005).

50 Philip Brey, *Ethics of Emerging Technology*, in THE ETHICS OF TECHNOLOGY: METHODS AND APPROACHES 175 (Sven O. Hansson ed., 2017).

51 Richard Owens et al., *Responsible Research and Innovation: From Science in Society to Science for Society, with Society*, in EMERGING TECHNOLOGIES: ETHICS, LAW AND GOVERNANCE 117 (Gary E. Marchant & Wendell Wallach eds., 2020).

52 David H. Guston, *Understanding 'Anticipatory Governance'*, 44 SOC. STUD. SCI. 218 (2014).

53 Debra J.H. Mathews et al., *Governance of Emerging Technologies in Health and Medicine—Creating a New Framework*, 386 NEW ENGL. J. MED. 2239 (2022); Debra J.H. Mathews et al., *Imagining Governance for Emerging Technologies*, 38 ISSUES SCI. TECH. 40 (2022).

(eTA),⁵⁴ the techno-ethical scenarios approach,⁵⁵ ethical dilemma scenarios,⁵⁶ and anticipatory technology ethics (ATE).⁵⁷ Specific to the development of neurotechnology, we reviewed guidance from NIH BRAIN⁵⁸ and the Global Neuroethics Summit.⁵⁹ We also examined how RRI was integrated into the Human Brain Project (HBP) supported by the European Union.⁶⁰ In the HBP, an RRI analysis deployed the AREA (anticipation, reflection, engagement, and action) framework.⁶¹

IV. GAPS IN CURRENT GUIDANCE AND FRAMEWORKS FOR RECOMMENDATIONS

Existing guidance offers little on research use of highly portable MRI.⁶² However, frameworks for governance of fixed MRI and other emerging biomedical technologies informed our recommendations. We briefly review those frameworks here, identifying the gaps that emerge when that guidance is applied to research with portable MRI.

IV. A. Gaps in Ethical Guidance and Governance for Portable Neuroimaging

MRI research is governed by a mix of federal, state, professional society, and local institutional policy.⁶³ The US Food and Drug Administration (FDA) publishes guidance on MRI machine safety and efficacy, and has noted the coming trend of more LF MRI machines,⁶⁴ and the ACR sets standards and facilitates accreditation so the

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- 54 Elin Palm & Sven O. Hansson, *The Case for Ethical Technology Assessment (eTA)*, 73 *TECH. FORECAST SOC.* 543 (2006).
- 55 Tsjalling Swierstra et al., *Exploring Techno-Moral Change: The Case of the Obesity Pill*, in *EVALUATING NEW TECHNOLOGIES: METHODOLOGICAL PROBLEMS FOR THE ETHICAL ASSESSMENT OF TECHNOLOGY DEVELOPMENTS* 119 (P. Sollie & M. Duwell eds., 2009).
- 56 David Wright et al., *Ethical Dilemma Scenarios and Emerging Technologies*, 87 *TECH. FORECAST SOC. CHANGE* 325 (2014).
- 57 Philip A.E. Brey, *Anticipatory Ethics for Emerging Technologies*, 6 *NANOETHICS* 1 (2012).
- 58 Diana W. Bianchi et al., *Neuroethics for the National Institutes of Health BRAIN Initiative*, 38 *J. NEUROSCI.* 10583 (2018); Henry T. Greely et al., *Neuroethics Guiding Principles for the NIH BRAIN Initiative*, 38 *J. NEUROSCI.* 10586 (2018); Henry T. Greely et al., *Neuroethics in the Age of Brain Projects*, 92 *NEURON* 638 (2016); Khara M. Ramos et al., *The NIH BRAIN Initiative: Integrating Neuroethics and Neuroscience*, 101 *NEURON* 394 (2019); Khara M. Ramos et al., *Neuroethics and the NIH BRAIN Initiative*, 5 *J. RESPONSIBLE INNOV.* 122 (2018).
- 59 Jordan Amadio et al., *Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives*, 100 *NEURON* 19 (2018); Jacob T. Robinson et al., *Building a Culture of Responsible Neurotech: Neuroethics as Socio-Technical Challenge*, 22 *NEURON* 2057 (2022).
- 60 Bernd C. Stahl & David Wright, *Ethics and Privacy in AI And Big Data: Implementing Responsible Research and Innovation*, 16 *IEEE SEC. PRIV.* 26 (2018); Arleen Salles et al., *Neuroethics and Philosophy in Responsible Research and Innovation: The Case of the Human Brain Project*, 12 *NEUROETHICS* 201 (2019); Bernd C. Stahl et al., *From Responsible Research and Innovation to Responsibility by Design*, 8 *J. RESP. INNOV.* 175 (2021).
- 61 Bernd C. Stahl et al., *The Responsible Research and Innovation (RRI) Maturity Model: Linking Theory and Practice*, 9 *SUSTAINABILITY* 1036, 1036 (2017) (noting that 'Stilgoe et al. proposed a framework for RRI that focuses on the four integrated dimensions of anticipation, reflexivity, inclusion, and responsiveness. This was adapted and adopted by the UK Engineering and Physical Sciences Research Council to form the AREA (anticipation, reflection, engagement and action) framework'.).
- 62 Shen et al. (2020), *supra* note 1; Shen et al. (2021), *supra* note 1.
- 63 Jennifer J. Kulynych, *The Regulation of MR Neuroimaging Research: Disentangling the Gordian Knot*, 33 *AM. J. L. MED.* 295 (2007).
- 64 U.S. FOOD & DRUG ADMIN., *CRITERIA FOR SIGNIFICANT RISK INVESTIGATIONS OF MAGNETIC RESONANCE DIAGNOSTIC DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF* (2014); Daniel Michael Krainak et al., *US Regulatory Considerations for Low Field Magnetic Resonance*

facility can bill Medicare for MRI scans.⁶⁵ ACR Accreditation is a multifaceted process, including evaluation of the qualifications of personnel, equipment performance, the documentation of quality assurance (QA), quality control (QC) testing through the use of a standardized phantom test object, and the assessment of the quality of clinical image.⁶⁶ No current guidance endorsed by a professional organization such as the Radiological Society of North America (RSNA), American Academy of Neurology (AAN), International Society for Magnetic Resonance in Medicine (ISMRM), and Organization for Human Brain Mapping (OHBM) specifically addresses the ethics of research utilizing portable MRI.

Many of the current debates over traditional fixed MRI are applicable to portable MRI as well. For example, the MRI community is already engaged in debates about data sharing⁶⁷ and associated ELSI issues such as data ownership, privacy, and the adequacy of de-identification.⁶⁸ Data sharing will certainly be important for portable MRI, but whether the data to be shared are generated by a portable or fixed MRI scanner does not fundamentally alter the ethical calculus. Our recommendations do address distinct privacy concerns owing to the placement of the scanner in remote locations outside of health care institutions, but issues such as de-identification and ownership of MRI data are part of a larger conversation that is not specific to portable MRI.⁶⁹

Our analysis recognizes that where existing research regulations and guidance exist, including federal regulations on the protection of human subjects (the Common Rule and DHHS Subparts B-D, as well as the FDA regulations on the protection of human subjects) apply,⁷⁰ certain safeguards are already in place. Additional safeguards stem from the Health Insurance Portability and Accountability Act (HIPAA) regulations (eg

Imaging Systems, 36 *MAGMA* 347, 347 (2023) (offering ‘insight into some of the regulatory considerations involved when the U.S. Food and Drug Administration (FDA) evaluates low field MRI systems for market authorization’).

65 Jeffrey Weinreb et al., *ACR MRI Accreditation: Yesterday, Today, and Tomorrow*, 2 *J. AM. COLL. RADIOL.* 494 (2005).

66 *Id.*

67 Anita S. Jwa & Russell A. Poldrack, *The Spectrum of Data Sharing Policies in Neuroimaging Data Repositories*, 43 *HUM. BRAIN MAPP.* 2707 (2022).

68 Tonya White et al., *Data Sharing and Privacy Issues in Neuroimaging Research: Opportunities, Obstacles, Challenges, and Monsters Under the Bed*, 43 *HUM. BRAIN MAPP.* 278 (2022); Corey Horien et al., *A Hitchhiker’s Guide to Working with Large, Open-Source Neuroimaging Datasets*, 5 *NAT. HUM. BEHAV.* 185 (2021); Angela R. Laird, *Large, Open Datasets for Human Connectomics Research: Considerations for Reproducible and Responsible Data*, 244 *NEUROIMAGE* 118579 (2018); Damian O. Eke et al., *International Data Governance for Neuroscience*, 110 *NEURON* 600, 600–12 (2021); Elizabeth E.L. Buimer et al., *De-identification Procedures for Magnetic Resonance Images and the Impact on Structural Brain Measures at Different Ages*, 42 *HUM. BRAIN MAPP.* 3643 (2021); Mikkel C. Vinding & Robert Oostenveld, *Sharing Individualised Template MRI Data for MEG Source Reconstruction: A Solution for Open Data While Keeping Subject Confidentiality*, 254 *NEUROIMAGE* 119165 (2022).

69 Christopher G. Schwarz et al., *Changing the Face of Neuroimaging Research: Comparing a New MRI De-Facing Technique with Popular Alternatives*, 231 *NEUROIMAGE* 117845 (2021).

70 See generally U.S. Dep’t of Health & Human Services (DHHS), *Revised Common Rule*, 45 C.F.R. pt. 46, <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html> (accessed Mar. 19, 2024); U.S. Food & Drug Administration (FDA), *FDA Policy for the Protection of Human Subjects*, 21 C.F.R. pts. 50, 56, <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fda-policy-protection-human-subjects> (accessed Mar. 19, 2024).

the Privacy Rule⁷¹ and Security Rule⁷²), when the entity conducting the research is a HIPAA-covered entity subject to those regulations. When applicable, related state statutes on research with human subjects and data privacy, as well as data sharing mandates from funders, also may apply. But portable MRI raises concerns about regulatory gaps. For instance, researchers new to MRI may not be governed by, have access to, or have experience with established IRBs, neuroimaging safety committees,⁷³ and oversight procedures; research may be conducted at institutions or rely on private funding sources that are not subject to DHHS regulations; research may be conducted with a device that has already received FDA clearance; and new research actors and their institutions may not be HIPAA-covered entities, for example, if they are not affiliated with a HIPAA-covered academic medical center.

IV. B. Frameworks for Ethics and Regulation of Citizen Science

Additional gaps in research oversight will arise because portable MRI has the potential to empower citizen scientists and individuals engaged in do-it-yourself (DIY) research in the ongoing ‘democratization of science’.⁷⁴ Here we follow the [CitizenScience.gov](https://citizenscience.gov) definition: ‘In citizen science, the public participates voluntarily in the scientific process, addressing real-world problems in ways that may include formulating research questions, conducting scientific experiments, collecting and analyzing data, interpreting results, making new discoveries, developing technologies and applications, and solving complex problems’.⁷⁵ The rise of citizen science has prompted the proposal of new frameworks for applying research ethics,⁷⁶ as ‘newly-emerging, technology-enabled, unregulated citizen science health research poses a substantial challenge for traditional research ethics’.⁷⁷ Because portable MRI could put the power of high resolution brain imaging into the hands of lay researchers, these emerging frameworks for research ethics in citizen science and participant-led research designs are relevant.

A recognized challenge in designing and implementing ethical guidance for citizen science is that ‘regulations about citizen science that do exist usually apply only to grant funding and institutions . . . whereas many citizen science projects take place without

71 45 C.F.R. pt. 160 and pt. 164, subpts. A and E.

72 45 C.F.R. pt. 160 and pt. 164, subpts. A and C.

73 MRI safety plans and MRI safety committees are generally recommended for all sites utilizing MRI. See, eg Susan T. Sotardi et al., *Establishing a Magnetic Resonance Safety Program*, 51 *PEDIATR. RADIOLOG.* 709 (2021).

74 Jonathan Silvertown, *A New Dawn for Citizen Science*, 24 *TRENDS ECOL. EVOL.* 467 (2009); Rick Bonney et al., *Next Steps for Citizen Science*, 343 *SCIENCE* 1436 (2014); Linda Silka, *Silos in the Democratization of Science*, 2(1) *J. DELIBERATIVE MECHANISMS SCI.* 1 (2013), DOI: [10.4471/demesci.2013.06](https://doi.org/10.4471/demesci.2013.06); Sandeep Ravindran, *How DIY Technologies Are Democratizing Science*, 587 *NATURE* 509 (2020); Jonathan Silvertown, *A New Dawn for Citizen Science*, 24 *TRENDS ECOL. EVOL.* 467 (2009); Rick Bonney et al., *Next Steps for Citizen Science*; 343 *SCIENCE* 1436 (2014).

75 About [CitizenScience.gov](https://www.citizenscience.gov/about/), <https://www.citizenscience.gov/about/> (accessed Mar. 12, 2024). We recognize, however, that there are many alternative definitions of citizen science. For discussion, see Mordechai Muki Haklay et al., *What Is Citizen Science? The Challenges of Definition*, in *THE SCIENCE OF CITIZEN SCIENCE* 13 (Katrin Vohland et al. eds., 2021).

76 David B. Resnik et al., *A Framework for Addressing Ethical Issues in Citizen Science*, 54 *ENVIRON. SCI. POLICY* 475 (2015); Lisa M. Rasmussen & Caren Cooper, *Citizen Science Ethics*, 4(1) *CITIZEN SCI.: THEORY PRACT.* 5 (2019).

77 Mark A. Rothstein et al., *Citizen Science on Your Smartphone: An ELSI Research Agenda: Currents in Contemporary Bioethics*, 4 *J. L. MED. ETHICS* 897 (2015).

grant funding and away from academic institutions'.⁷⁸ This challenge will be crucial to oversight of citizen science research with portable MRI, as traditional sources of ethical oversight—for instance, university and hospital IRBs—may not be readily available.⁷⁹ Though independent IRBs are available, some research using portable MRI will not be required to use an IRB under current rules.⁸⁰ If such research is not federally conducted or funded, is not conducted by an institution rendering a broad Federalwide Assurance (FWA) for the Protection of Human Subjects, and does not fall within the scope of FDA medical device regulations (21 C.F.R. pt. 812), IRB review may not be required.⁸¹ For example, a study is not subject to IDE regulations if the objectives of the investigation are not 'studying the safety and/or effectiveness of the device'.⁸²

Citizen science may involve non-expert individuals (eg those without formal training in neuroscience, biomedical engineering, radiology, neurology, or related areas) using portable MRI for their own research projects.⁸³ The WG discussed how to empower these researchers while also addressing concerns that without sufficient oversight and regulation, proliferation of brain scanning could lead to participant and societal harms.

IV. C. Frameworks for Advancing Justice, Equity, Diversity, and Inclusion in Neuroimaging Research

Portable MRI research directly implicates concerns about justice, equity, diversity, and inclusion (JEDI). First, portable MRI has the potential to address long-standing limitations in the representativeness and diversity of participants in neuroimaging research.⁸⁴ High quality science will be inclusive by design. Research on the neurobiology of Alzheimer's disease (AD) shows the perils of inadequate inclusion. That research has

78 Rasmussen & Cooper, *supra* note 76.

79 Effy Vayena & John Tasioulas, *The Ethics of Participant-Led Biomedical Research*, 31 NAT. BIOTECHNOL. 786 (2013).

80 In addition, we note that studies subject to IDE regulations at 21 C.F.R. pt. 812 will require an IRB that meets the FDA's requirements for such boards at 21 C.F.R. pt. 56 to make the NSR determination.

81 OFFICE OF HUMAN RESEARCH PROTECTIONS, *supra* note 81 (noting that the Federalwide Assurance of Protection for Human Subjects (FWA) is required of institutions 'whenever the Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule, unless the research is otherwise exempt from the requirements of the Common Rule or a U.S. federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance'. The FWA requires that 'All of the Institution's human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution'.)

82 NIH Clinical Center, Regulatory Toolbox, IDE Exemption Criteria and Study Risk Determination, <https://www.cc.nih.gov/orcs/ide2.html> (accessed Feb. 23, 2024).

83 Effy Vayena & John Tasioulas, *We the Scientists': A Human Right to Citizen Science*, 28 PHILOS. TECH. 479 (2015).

84 Vonetta M. Dotson & Audrey Duarte, *The Importance of Diversity in Cognitive Neuroscience*, 1464 ANNALS N.Y. ACAD. SCI. 181 (2019); Anuradha Ramamoorthy et al., *Racial/Ethnic Differences in Drug Disposition and Response: Review of Recently Approved Drugs*, 97 CLIN. PHARMACOL. THER. 263 (2015); Jazlyn Nketia et al., *Towards a More Inclusive and Equitable Developmental Cognitive Neuroscience*, 52 DEV. COGN. NEUROSCI.101014 (2021).

led to proposed biomarkers,⁸⁵ but their utility and generalizability has been hampered by nonrepresentative and nondiverse study populations.⁸⁶

Second, the bioethics principle of justice requires that ‘the selection of research subjects needs to be scrutinized’ so that the benefits of research can be fairly distributed.⁸⁷ The Universal Declaration of Human Rights (UDHR) holds that everyone has a right ‘to share in scientific advancement and its benefits’.⁸⁸ For over two decades, there has been momentum for participant-centered and participant-led research in which participants are actively engaged in research as co-creators of knowledge.⁸⁹ In international research in low-resource settings, for instance, the Global Code of Conduct and guidelines from WHO instruct researchers to ensure that local communities are partners and that the research generates local social value.⁹⁰ Researchers often aim to produce general social value, defined as ‘important generalizable knowledge from the research’, but requiring local social value recognizes that ‘populations that host research also ought to benefit from the results of the research’.⁹¹

Given these ethics frameworks, a foundational question is who will benefit the most from the deployment of portable MRI and who is most at risk. The development of any new technology raises questions about distributive justice,⁹² leading in the past decade to scholarship on inclusive innovation and design.⁹³ For portable MRI, these concerns about the distributional consequences of innovation are further complicated

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- 85 Shannon M. Burns et al., *Making Social Neuroscience Less WEIRD: Using FNIRS to Measure Neural Signatures of Persuasive Influence in a Middle East Participant Sample*, 116(3) J. PERS. SOC. PSYCH. e1 (2019).
- 86 Andrea Gilmore-Bykovskiy et al., *Traversing the Aging Research and Health Equity Divide: Toward Intersectional Frameworks of Research Justice and Participation*, 62 GERONTOLOGIST 711 (2022); National Institute on Aging, National Institutes of Health, *Together We Make the Difference* (Oct. 2018), <https://www.nia.nih.gov/sites/default/files/2018-10/alzheimers-disease-recruitment-strategy-final.pdf> (accessed Mar. 19, 2024).
- 87 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW Publication No. (OS) 78-0012, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* Commission (1978); Andrea Gilmore-Bykovskiy et al., *The Urgency of Justice in Research: Beyond COVID-19*, 27 TRENDS MOL. MED. 97, 97–100 (2021).
- 88 *Universal Declaration of Human Rights*, GA Res 217A (III), UNGAOR, 3rd Sess., Supp. No. 13, UN Doc. A/810 (1948) 71.
- 89 LAWRENCE W. GREEN, *EXPLORING CHALLENGES, PROGRESS, AND NEW MODELS FOR ENGAGING THE PUBLIC IN THE CLINICAL RESEARCH ENTERPRISE* (2003).
- 90 DORIS SHROEDER ET AL., *EQUITABLE RESEARCH PARTNERSHIPS: A GLOBAL CODE OF CONDUCT TO COUNTER ETHICS DUMPING* (2019); COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES, *INTERNATIONAL ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS* (2016), <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (accessed Mar. 19, 2024).
- 91 Nicola Barsdorf & Joseph Millum, *The Social Value of Health Research and the Worst Off*, 31 BIOETHICS 105 (2017).
- 92 Susan E. Cozzens, *Distributive Justice in Science and Technology Policy*, 34 SCI. PUBLIC POLICY 85 (2007); Theo Papaioannou, *Technological Innovation, Global Justice and Politics of Development*, 11 PROGRESS DEV. STUD. 321 (2011); SUSAN E. COZZENS & DHANARAJ THAKUR, *INNOVATION AND INEQUALITY: EMERGING TECHNOLOGIES IN AN UNEQUAL WORLD* (2014).
- 93 Theo Papaioannou, *How Inclusive Can Innovation and Development Be in the Twenty-First Century*, 4 INNOVATION & DEV. 187 (2014); Peter Lee, *Toward a Distributive Agenda for US Patent Law*, 55 HOUS. L. REV. 321 (2017); THEO PAPAIOANNOU, *INCLUSIVE INNOVATION FOR DEVELOPMENT: MEETING THE DEMANDS OF JUSTICE THROUGH PUBLIC ACTION* (2018).

by the history of institutionalized scientific racism and other forms of discrimination within the fields of neuroscience⁹⁴ and radiology.⁹⁵

Of particular importance for portable MRI is the concern that as it becomes easier to scan more diverse participants, there will be more MRI researchers with limited prior neuroimaging research experience, leading to problematic hypotheses, framing, and analysis such as publishing on spurious race-based differences in brain structure and function. As psychologist Jennifer Eberhart has observed, 19th-century efforts to find brain differences by race ‘were inextricably bound to the development of neuroscience as a field and consequently produced dramatic changes in how 19th-century Americans came to reason about race’.⁹⁶ Portable MRI could usher in 21st-century efforts to leverage evidence of brain differences for ideological purposes. For example, as portable MRI research generates large datasets with the ability to compare socially constructed sub-groups or analyze uncritically along socially constructed identities such as race and gender, these data may be misconstrued to support problematic historical practices of defining people through a bio-essentialist lens.

As the 2023 NASEM report on the use of population descriptors in genetics and genomics recommends, researchers ‘should not use race as a proxy for human genetic [and neurologic] variation’ and ‘researchers should avoid typological thinking’.⁹⁷ Given the potential public fascination with brain differences, researchers may need to think carefully about how this research might inadvertently contribute to biases about how individuals and/or groups are perceived or affirm harmful generalizations and stereotypes. Ethical guardrails are needed to prevent novel and resurgent forms of brain-based discriminatory bias.

Third, a JEDI perspective raises awareness about the need to promote inclusive research design in neuroscience. An illustrative example concerns protocol requirements in electroencephalography and fNIRS research related to hair type, in which ‘participants with darker skin pigmentation and coarser hair (for instance, a large subset of the Black and Hispanic/Latino populations) are often excluded from EEG and fNIRS studies’, leading to racially-biased and -exclusive research.⁹⁸ There are also known artifacts related to hair products and dye, which can impact the ability to equitably image various groups not currently well-represented in neuroimaging research.⁹⁹ Industry developers as well as researchers share a responsibility to

94 Termara C. Parker & Jocelyn A. Ricard, *Structural Racism in Neuroimaging: Perspectives and Solution*, 9 LANCET PSYCHIATRY 22 (2022); Ruth S. Shim et al., *Race and Ethnicity of Editorial Board Members and Editors as an Indicator of Structural Racism in Psychiatry and Neuroscience Journals*, 78 JAMA PSYCHIATRY 1161 (2021).

95 Itai Bavli & David S. Jones, *Race Correction and the X-ray Machine—The Controversy Over Increased Radiation Doses for Black Americans in 1968*, 387 NEW ENG. J. MED. 947 (2022).

96 Jennifer L. Eberhardt, *Imaging Race*, 60 AM. PSYCH. 181 (2005).

97 NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, USING POPULATION DESCRIPTORS IN GENETICS AND GENOMICS RESEARCH: A NEW FRAMEWORK FOR AN EVOLVING FIELD (2023).

98 Linzie Taylor & Karen S. Rommelfanger, *Mitigating White Western Individualistic Bias and Creating More Inclusive Neuroscience*, 23 NAT. REV. NEUROSCI. 389 (2022); Jocelyn A. Ricard, *Confronting Racially Exclusionary Practices in the Acquisition and Analyses of Neuroimaging Data*, 26 NAT. NEUROSCI. 4 (2023); Tricia Choy et al., *Systemic Racism in EEG Research: Considerations and Potential Solutions*, 3 AFFECT. SCI. 14 (2022); Katie E. Webb et al., *Addressing Racial and Phenotypic Bias in Human Neuroscience Methods*, 25 NAT. NEUROSCI. 410 (2022).

99 Robert C. McKinstry & Delma Y. Jarrett, *Magnetic Susceptibility Artifacts on MRI: A Hairy Situation*, 182 AM. J. ROENTGENOL. 532 (2004); Brian A. Hargreaves et al., *Metal-Induced Artifacts in MRI*, 197 AM. J.

solicit input from potential research participants, patients, and caregivers or family, especially those from historically marginalized communities, on technology development, including at early stages. Funders and researchers utilizing highly portable MRI technology should prioritize engagement with, and inclusion of, underrepresented and under-resourced communities in co-creation of community-engaged MRI research strategies, especially approaches to data sovereignty. We use the term ‘funder’ broadly to include federal, state, and international bodies that supply material support for research, as well as private sponsors of research. Portable MRI research should be deployed to facilitate engagement with and enrollment of more diverse participants in neuroimaging research by allowing research teams to scan in environments that include a more diverse population.¹⁰⁰

V. RECOMMENDED SOLUTIONS FOR CORE ELSI ISSUES

Using the methodologies described in Part III and guided by the frameworks discussed in Part IV, we developed 15 recommendations for addressing core ethical, legal, and social challenges associated with field-based research with portable MRI in the context of research conducted in the USA as a starting point for discussion and debate (Table 3). In Part VI, we specify actors and approaches to enact these solutions. The terms ‘MRI researcher’ and ‘research team’ are used as defined in Table 1. Our solutions are generally aimed at the research team broadly, without further differentiating which members of the team should have responsibility for particular aspects of the proposed solution.

ESTABLISHING COMPETENCE IN PORTABLE MRI OPERATION AND RESEARCH DESIGN

- **Recommendation #1:** Each member of the portable MRI research team should have demonstrated competence to carry out their research role. For instance, scanner operators should have demonstrated competence to safely operate the portable MRI machine.
 - **Recommendation #2:** Before carrying out the research, researchers conducting portable MRI research should become familiar with the ELSI issues identified in this article, and investigators designing research should engage with the local communities in which research will occur.
-

Recommendation #1: Placing MRI research capabilities into the hands of new users paves the way for innovative research questions and designs. For instance, providing social scientists with greater access to neuroimaging might drive inventive scholarship in neuroeconomics, neurolaw, neurocriminology, neuropolitics, neurosociology,

ROENTGENOL. 547 (2011); Sneha Chenji et al., *Hair Product Artifact in Magnetic Resonance Imaging*, 35 MAGN. RESON. IMAGING 1 (2016).

¹⁰⁰ Adam de Havenon et al., *Identification of White Matter Hyperintensities in Routine Emergency Department Visits Using Portable Bedside Magnetic Resonance Imaging*, 12 J. AM. HEART ASSOC. e029242 (2023) (finding that the emerging department ‘environment is an excellent example of a point of care where there is higher socioeconomic diversity and is a safety net for many patients who may not otherwise have access to medical care or neuroimaging’).

Table 3. Summary of recommendations to address ethical and legal issues arising in research with portable MRI using the USA as the context

| | Ethical & legal challenges, organized by stage of research | Recommended solution |
|--|--|--|
| Establishing competence in portable MRI operation and research design | | |
| #1 | Challenge: Researchers and scanner operators without prior training in neuroimaging may utilize portable MRI without sufficient operational and safety training. | Recommendation: Each member of the portable MRI research team should have demonstrated competence to carry out their research role. For instance, scanner operators should have demonstrated competence to safely operate the portable MRI machine. |
| #2 | Challenge: Portable MRI may be used by researchers unfamiliar with ethical and legal issues raised by field research conducted in remote and underserved settings. | Recommendation: Before carrying out the research, researchers conducting portable MRI research should become familiar with the ELSI issues identified in this article, and investigators designing research should partner with the local communities in which research will occur. |
| Ensuring oversight for portable MRI research | | |
| #3 | Challenge: The rapid development of portable MRI may result in research that is overseen by an IRB not yet familiar with the issues raised by portable MRI research. | Recommendation: To provide additional support for IRBs that are asked to oversee portable MRI research, expert stakeholders such as MRI innovators and professional associations should develop new training resources for IRB personnel such as virtual courses on portable MRI and guidance for multidisciplinary protocol review. |
| #4 | Challenge: The accessibility of portable MRI research will invite more research that is outside IRB purview, including citizen science and industry research. | Recommendation: Where IRB review is not already required, researchers should establish a gatekeeping mechanism such as seeking private IRB review and/or equivalent community-based review so that the research is conducted with oversight guided by the Common Rule and FDA regulations. Use of portable MRI devices in research should be restricted to those entities and individuals who can adhere to relevant FDA and professional society (e.g., ACR) guidance on MRI safety and operation standards. |
| Engaging and recruiting a diverse and representative sample of participants for portable MRI research | | |
| #5 | Challenge: Researchers using portable MRI research in remote and under-resourced settings may engage in extractive, helicopter research practices. | Recommendation: Research teams should be composed of individuals from diverse backgrounds, and should meaningfully engage community members prior to, during, and after the research project. |
| #6 | Challenge: Participants may mistakenly view portable MRI research as providing clinical care, especially if they have had little prior exposure to neuroimaging research and clinical care. | Recommendation: During the community engagement and the consent process, researchers should explain the risk of therapeutic misconception in MRI research. Details should be provided on what research results and incidental findings will be offered to participants and how research findings differ from those produced in clinical care. |
| Protecting research participants in the scanning environment | | |
| #7 | Challenge: Portable MRI scanning may be conducted in an unsafe manner due to improper setup and operation in a community setting outside the hospital. | Recommendation: Safety guidelines and education should be created by the ACR, ISMRM, and other professional bodies, for use of highly portable MRI in field settings. These guidelines should cover safe setup, use, storage, and transport of the equipment and standards for participant privacy and data security. |
| #8 | Challenge: The portable MRI scanning site may not provide sufficient privacy to the person being scanned. | Recommendation: Scanning protocols should be developed by professional associations to maximize participant privacy in different scanning environments, including use of portable drapes, privacy screens, or dedicated rooms to shield the person being imaged and mechanisms to prevent others from viewing acquired data/images. Participant consent/assent should be obtained for the presence of visitors or observers in the scanning environment. |

(continued)

Table 3. Continued

| | Ethical & legal challenges, organized by stage of research | Recommended solution |
|--|--|---|
| Using artificial intelligence (AI) algorithms in portable MRI research | | |
| #9 | Challenge: Portable MRI may rely on AI algorithms whose training dataset did not include members of the population that is now being scanned. | Recommendation: Through community engagement and in the consent process, researchers should describe the use of AI in the portable MRI research. Researchers should discuss with participants potential concerns associated with this use of AI, including the potential biases of AI models being used to generate images and to interpret the meaning of those images. |
| Interpreting and communicating to participants the meaning of portable MRI scans | | |
| #10 | Challenge: Researchers using portable MRI may not know how to interpret the data and scans. | Recommendation: Portable MRI research teams should ensure that those reading the scans have the expertise and training to accurately interpret them, including understanding the role of AI algorithms. Research teams should effectively communicate to participants the nature of the research results and incidental findings generated, as well as the training of those reviewing the images/data and interpretative methods used. |
| Promoting quality control for portable MRI technology | | |
| #11 | Challenge: Scanner quality control may not be properly maintained. | Recommendation: Companies manufacturing and marketing highly portable MRI have a responsibility to ensure ongoing Quality Control (QC) to detect and correct artifacts and algorithmic processing errors. Research teams using the technology should communicate to their research participants and partner researchers their policies regarding QC. |
| Ensuring data privacy, confidentiality, security & participant control of their brain data | | |
| #12 | Challenge: The privacy, confidentiality, and security of participants' brain data may be compromised in the data pipeline that starts with data acquisition in field settings and includes transfer to the cloud, processing, interpretation, de-identification, storage, and data sharing. | Recommendation: Participants should have agency over their data throughout the entire pipeline from data acquisition to data sharing. Every person and entity that will have access to the participant's brain data should commit to responsible data management, transparency, and accountability. During the informed consent process, participants should be given a clear understanding of the rights they have to control their data and any limitations on those rights. |
| #13 | Challenge: Researchers new to MRI research may not have adequate resources to meet the demands of secure MRI data management, storage, and sharing. | Recommendation: A plan for responsible management of acquired MRI data should be developed by the research team before data collection begins. Adequate resources should be in place to ensure safe and secure data acquisition, de-identification, storage, and sharing, and compliance with applicable policies such as NIH data sharing policy. |
| Managing incidental findings (IFs) and research results of clinical concern | | |
| #14 | Challenge: IFs may be identified in participants who are geographically remote from health care facilities and may face barriers to accessing clinical work-up and care. | Recommendation: Researchers should plan pathways to timely care in the event of incidental findings or concerning research results, regardless of the participant's geographic location, insurance status, and ability to pay for care. Research sponsors should support creation of a responsible plan and pathway, including with funding whenever possible. |
| Facilitating participant access to their MRI data | | |
| #15 | Challenge: Participants may not have access to their brain data, despite HIPAA requirements and ethics recommendations. | Recommendation: Researchers should alert participants that they are entitled to request their data and scans. Once a participant makes this request, the researcher should provide the data and scans, in keeping with applicable law and ethics. |

neuroanthropology, and more. But the allure of MRI¹⁰¹ may lead inexperienced MRI researchers to pursue neuroimaging research before they are properly trained, both in how to operate the machinery and in how to interpret the data acquired.

101 Nicholas Scurich & Adam Shnideman, *The Selective Allure of Neuroscientific Explanations*, 9 PLOS ONE e107529 (2014); Deena S. Weisberg et al., *The Seductive Allure of Neuroscience Explanations*, 20 J. COGN. NEUROSCI. 470 (2008); Martha J. Farah & Cayce J. Hook, *The Seductive Allure of 'Seductive Allure'*, 1 PERSPECT. PSYCH. SCI. 88 (2013).

A fundamental requirement for all portable MRI researchers is that they protect participant safety. As described below, new safety guidance is needed to address the issues raised by portable MRI. But the promulgation of new guidance is not sufficient if inexperienced MRI researchers are unaware of it or fail to comply. In addition, safe operation of portable MRI means ensuring safety despite challenging field conditions. For example, there could be a power blackout or a loss of Internet connection at the local scanning location, and the research team should anticipate any safety concerns that could result.

Our first recommendation places the onus on researchers who want to use MRI to become informed about the technology they are using and how to conduct MRI research responsibly and safely. We recommend that all members of the MRI research team should have demonstrated competence for the research role they are playing. That is, those members of the research team who are designing the research must demonstrate competence in neuroimaging research design and sampling; those performing the scans must demonstrate their competence to scan safely; those analyzing data with AI tools must demonstrate competence to identify errors, artifacts, and biases; those de-identifying MRI data for storage and sharing must demonstrate their competence to do so; and so forth.

We envision multiple mechanisms by which individuals on the research team could demonstrate their competence to those providing research oversight, including funders and the IRB. These mechanisms include showing significant relevant experience such as publishing peer-reviewed MRI research studies or completion of relevant training and education. Another route could be to obtain certification and licensure specific to portable MRI, if those options were developed.¹⁰² Although it would not eliminate the possibility, requiring demonstrated competence would help to mitigate concerns that inexperienced MRI researchers might misunderstand what MRI measures, conflate correlation with causation in making inferences with MRI, utilize flawed research designs, or erroneously promote assumptions about biological essentialism.¹⁰³

We recognize that given the rapid emergence of portable MRI technologies, there are currently no dedicated education and training programs specific to these technologies—and especially to their use in field settings. A corollary of our recommendation is thus that training programs specific to portable MRI should be developed. This would be an excellent opportunity for those with portable MRI experience to co-create training materials with experts in community engagement.

At a minimum, all MRI researchers should understand historical examples of misuse of brain science to support spurious claims of racial and cultural superiority,¹⁰⁴ and

102 We note that licensure and certification practices historically have propagated systemic disparities and any effort to institute licensure/certification also needs to address this history and actively reduce disparities. See, eg Evan Senreich & Travis Dale, *Racial and Age Disparities in Licensing Rates Among a Sample of Urban MSW Graduates*, 66 Soc. WORK 19 (2021).

103 At present these inferences are almost entirely qualitative. That is, a human visually examines the image and based on that human's expert judgement arrives at a conclusion about what the brain scan image means. Carlo Pierpaoli, *Quantitative Brain MRI*, 21 TOP MAGN. RESON. IMAGING 63, 63 (2010) (noting that 'clinical neuroradiology still rel[ies] almost completely on qualitative techniques'). Because the human eye can miss hard-to-visually-detect sub-clinical changes in brain tissue, efforts are underway to advance 'quantitative MRI'. Kathryn E. Keenan et al., *Recommendations Towards Standards for Quantitative MRI (qMRI) and Outstanding Needs*, 49 J. MAGN. RESON. IMAGING e26 (2019).

104 OLIVER ROLLINS, *CONVICTION: THE MAKING AND UNMAKING OF THE VIOLENT BRAIN* (2021).

the inherent limitations of MRI research, especially as it relates to causal inferences about the relationship between brain and behavior. For instance, there are multiple documented instances of ‘neurohype’ in which MRI researchers (even those with neuroscience training) have exaggerated or mischaracterized their results, failing to see fundamental flaws in their research designs.¹⁰⁵ Notable examples have included fMRI studies purporting to show that users were in love with their iPhones¹⁰⁶ and that fMRI could reveal how voters’ brains would perceive Hillary Clinton.¹⁰⁷ These claims were heavily criticized by the neuroimaging community, and described as ‘really closer to astrology than . . . to real science’.¹⁰⁸ But both studies were featured in *New York Times* opinion pieces, and were widely circulated. As researcher access to MRI rises, the potential for flawed research designs will increase too, especially if those designing the studies do not have requisite training.

Researchers conducting clinical research trials with portable MRI machines to assess safety and effectiveness will need to consider whether they need IRB determination of ‘nonsignificant risk’ (NSR) or have to apply for an Investigational Device Exemption (‘IDE’) from the FDA before they can scan human participants. While ‘the clinical study of a new indication for an already marketed device falls under the IDE regulations’, clinical studies using a device that has 510(k) clearance and are within the indications for use do not require an IDE.¹⁰⁹

For portable MRI studies that are determined to be a clinical study of a new indication under FDA rules and regulation, those studies would not qualify as an investigation exempted from this process because exemption under 21 C.F.R. § 812.2(c) requires that the device: ‘(i) Is noninvasive, (ii) Does not require an invasive sampling procedure that presents significant risk (SR), (iii) Does not by design or intention introduce energy into a subject, and (iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure’.¹¹⁰ Portable MRI systems likely would not satisfy criterion (iii) because pMRI devices send energy into the body. These systems may, however, meet the

105 Scott O. Lilienfeld et al., *Neurohype: A Field Guide to Exaggerated Brain-Based Claims*, in THE ROUTLEDGE HANDBOOK OF NEUROETHICS 241 (L. Syd M. Johnson & Karen S. Rommelfanger eds., 2017).

106 Martin Lindstrom, Opinion, *You Love Your iPhone. Literally*, NEW YORK TIMES (Sept. 30, 2011).

107 Marco Iacoboni et al., *This is Your Brain on Politics*, NEW YORK TIMES (Nov. 11, 2007).

108 Greg Miller, *Growing Pains for fMRI*, 320 SCIENCE 5882 (2008) (quoting neuroscientist Russell Poldrack).

109 U.S. Food & Drug Administration, FAQs about Investigational Device Exemption, <https://www.fda.gov/medical-devices/investigational-device-exemption-ide/faqs-about-investigational-device-exemption> (accessed Mar. 13, 2024). For example, the low-field MRI device Hyperfine Swoop® Portable MRI Imaging System® received FDA 510(k) clearance with the following indications for use: ‘The Swoop Portable MR Imaging System is a portable, ultra-low field magnetic resonance imaging device for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis’. Letter, from Daniel M. Krainak, PhD, Assistant Director, DHT8C: Division of Radiological Imaging and Radiation Therapy Devices, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, U.S. Food & Drug Administration, to Christine Kupchick, Staff Regulatory Affairs Specialist, Hyperfine, Inc., K232760, Swoop® Portable MR Imaging System® (Oct. 6, 2023) (available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K232760>), at p. 4.

110 We note that even research that is exempt from IDE regulations may require IRB review and approval if the results of the research will be submitted to FDA in support of a research or marketing permit. In addition, state law may require IRB review and approval independent of federal research regulations.

requirements consistent with an *abbreviated* IDE. An abbreviated IDE does not require the investigator to submit an IDE application to the FDA.¹¹¹

The FDA distinguishes between “significant risk” (SR) and “nonsignificant risk” (NSR) device studies. SR devices are those that present ‘a potential for serious risk to the health, safety, or welfare of a subject’, and NSR devices are those that do not meet this definition.¹¹² Sponsors ‘are responsible for making the initial risk determination’ and presenting that determination to the IRB for review, but the FDA ‘is the final arbiter as to whether a device study is SR or NSR and makes the determination when an IDE is submitted to FDA or if asked by the sponsor, clinical investigator, or IRB’.¹¹³ At present, the FDA has determined that MRI systems up to 8T are NSR devices.¹¹⁴ ‘Magnetic Resonance Imaging (MRI) Devices within FDA specified parameters’ is included in the example list of NSR devices in FDA guidance for IRBs determining SR and NSR.¹¹⁵

Portable MRI machines operate at much lower field strengths than 8 T, and thus an IDE may not be required in most cases. Looking ahead, however, some portable MRI technologies could be deemed SR because risk could be considered to include risk of causing harm by returning MRI research results without proper validation. By way of analogy, in research involving genome sequencing, the National Human Genome Research Institute (NHGRI) notes that an IDE may sometimes be required if there is SR and that ‘[w]ith regard to molecular diagnostic devices, the key question when assessing risk is to consider the consequences of either a false positive or false negative result’.¹¹⁶

FDA also plays an important role in restricting use of portable MRI to its FDA-cleared intended use. FDA’s position with respect to ‘keepsake’ ultrasound provides a useful illustration of FDA’s role. In the early 2000s companies such as ‘Womb with a View’ emerged to sell ‘keepsake videos’ that purported to ‘use the latest ultrasound technology to produce high-resolution three-dimensional and four-dimensional (moving)

111 Qualifying for an abbreviated IDE involves meeting the requirements described in 21 C.F.R. § 812.2(b). These include getting ‘IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device.’ 21 C.F.R. § 812.2(b)(1)(ii).

112 21 C.F.R. § 812.3.

113 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION (FDA), INFORMATION SHEET GUIDANCE FOR IRBs, CLINICAL INVESTIGATORS, AND SPONSORS: SIGNIFICANT RISK AND NONSIGNIFICANT RISK MEDICAL DEVICE STUDIES 3–4 (Jan. 2006), <https://www.fda.gov/media/75459/download> (accessed Mar. 19, 2024) (noting that for devices where the ‘FDA has already made the SR or NSR determination for the study, the agency’s determination is final’).

114 Michael N. Hoff et al., *Safety Considerations of 7-T MRI in Clinical Practice*, 292 RADIOLOGY 509, 510 (2019) (noting that ‘The U.S. Food and Drug Administration (FDA) categorized MRI up to 8 T as a nonsignificant risk device for nonneonatal patients in 2003, and in 2009 the International Commission on Non-Ionizing Radiation Protection found that no serious health effects had resulted from acute exposures at this field strength. In 2015, the International Electrotechnical Commission increased the static magnetic field limit for the first-level controlled operating mode (ie, requiring medical supervision) from 4 T to 8 T (3). In 2017, one vendor was given a CE, or “Conformité Européene,” mark for its 7-T clinical system (Fig. 1). The CE mark indicates that the 7-T MRI system conforms with health, safety, and environmental protection standards for products sold within the European economic area. Later that year, the U.S. FDA provided the first 510(k) clearance for a clinical 7-T MRI system’. (citations omitted)).

115 FDA, *supra* note 113.

116 NHGRI, POINTS TO CONSIDER IN ASSESSING WHEN AN INVESTIGATIONAL DEVICE EXEMPTION MIGHT BE NEEDED 5 (July 27, 2017), https://www.genome.gov/Pages/PolicyEthics/IDE/FDA_IDE_Points_to_Consider.pdf (accessed Mar. 19, 2024).

images showing the surface anatomy of babies developing in the womb'.¹¹⁷ The FDA was critical of keepsake ultrasounds on the grounds that they were commercializing a medical device for a use that had not been FDA cleared, and providing these 'results' back to consumers.¹¹⁸ By way of analogy, FDA might be similarly concerned about unapproved commercial use of portable MRI, eg establishment of a brain health club without sufficient review and clearance.

Recommendation #2: Portable MRI will for the first time allow for widespread field-based research using MRI. Thus, portable MRI researchers need to be attuned to the unique ethical and legal issues associated with field-based research. Even if the research team has technical competence to complete the MRI research, the team should not proceed to scanning until they have carefully considered ethical considerations.

In addition to improved training for the research community, education is needed for research participants and their communities. Such campaigns would help potential participants in MRI research understand the scientific basis of the research and know their rights. Educational programs and materials could be developed by a consortium of MRI developers, ethicists, lawyers, patient advocacy groups, and manufacturers for distribution with any portable MRI device and for use by researchers and interested communities.

When engaging in community-based field research with MRI, researchers should make local communities partners in the research enterprise. This can be accomplished by collaborating with individuals who are trusted within the community and empowering local liaisons to build local capacity and groundwork for the work. This should start in the research design phase. Research teams lacking reflective diversity (ie not reflecting the diversity of the populations participating in the research study) should work with community consultants throughout the lifecycle of the research protocol. Researchers should sustain engagement with those participants and communities and work to produce a localized return of value for those participants and communities.¹¹⁹ As several of us have discussed in previous work, an emphasis on producing local social value, in addition to general scientific knowledge, is consistent with ethical guidance for research in resource-limited settings.¹²⁰ Portable MRI research 'may contribute to local social value by: focusing on research questions and health conditions of high priority to the community, using portable MRI as a teaching tool for local scientists, establishing partnerships with major hospital systems to improve training of clinicians, and capacity building such as contributing to a center for excellence or allowing local clinicians to utilize the portable MRI machine when it is not being used for the research study'.¹²¹

The research team could also develop initiatives to provide aggregate results and progress summaries through publicly accessible reports, newsletters, community

117 Carol Rados, *FDA Cautions Against Ultrasound 'Keepsake' Images*, FDA CONSUMER MAG., Jan.-Feb. 2004, at 12, <https://snude.fr/wp-content/uploads/2017/12/FDAKeepsake.pdf> (accessed Mar. 19, 2024).

118 Robert A. Phillips, et al., *Safety and U.S. Regulatory Considerations in the Nonclinical Use of Medical Ultrasound Devices*, 36 ULTRASOUND MED. BIOL. 1224 (2010).

119 Consuelo H. Wilkins et al., *Understanding What Information is Valued by Research Participants, and Why*, 38 HEALTH AFFS. 399 (2019).

120 Shen et al. (2021), *supra* note 1 ('Prominent guidance for research in remote and resource-limited international contexts emphasizes that the research study should produce both general scientific value and local social value, as noted above (GCC 2018, Article 1; WMA 2001, Article 20; WHO and CIOMS 2016)').

121 *Id.*

events, and/or on social media platforms. An awareness, engagement, and education campaign can help participants become familiar with the issues. In addition, many studies show that research participants highly value return of individual-specific research results and IFs.¹²² This is addressed further below in Recommendation #14.

ENSURING OVERSIGHT FOR PORTABLE MRI RESEARCH

- **Recommendation #3:** To provide additional support for IRBs that are asked to oversee portable MRI research, expert stakeholders such as MRI innovators and professional associations should develop new training resources for IRB personnel such as virtual courses on portable MRI and guidance for multidisciplinary protocol review.
 - **Recommendation #4:** Where IRB review is not already required, researchers should establish a gatekeeping mechanism such as seeking private IRB review and/or equivalent community-based review so that the research is conducted with oversight guided by the Common Rule and FDA regulations. Use of portable MRI devices in research should be restricted to those entities and individuals who can adhere to relevant FDA and professional society (eg ACR) guidance on MRI safety and operation standards.
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Recommendation #3: While primary responsibility for conducting ethical research with portable MRI falls to the researchers themselves, research oversight is also essential. IRBs at the small number of institutions where portable MRI innovations are being engineered and initially deployed may be familiar with these technologies, but many IRBs may not yet be familiar with the technology and how it differs from traditional fixed MRI. IRBs and portable MRI experts should work together to improve IRB understanding of portable MRI and the ethical challenges. This could take the form of new training resources such as easily accessible on-demand virtual courses on portable MRI. It could also be achieved through the research review process by incorporating experts such as biomedical and MRI safety engineers. A campus-wide MRI Safety Committee could be utilized as well. An additional solution may be the establishment of cross-institutional partnerships to share knowledge.

IRB review of portable MRI research should prioritize participants' safety, autonomy, and privacy, recognizing that the most vulnerable person in this ecosystem of MRI research is the participant whose brain data are being collected. IRBs should insist that there is effective de-identification of brain data to protect the privacy of participants, and that the informed consent process alerts participants to the limitations of these methods. This approach should not discourage new researchers from proposing portable MRI research protocols. But it should help ensure that these new MRI research protocols are designed to respect and protect participants.

Recommendation #4: Enhancing the knowledge base of IRBs will improve oversight for portable MRI research that occurs within IRB purview, but an even more vexing challenge is how to ensure adequate oversight for research that does not require IRB review. IRB review is not federally required for industry research¹²³ unless that

¹²² Adrian Thorogood et al., *APPLaUD: Access for Patients and Participants to Individual Level Uninterpreted Genomic Data*, 12 *HUM. GENOMICS* 7 (2018).

¹²³ Some states, such as Maryland, require additional safeguards. See Stacey A. Tovino, *Mobile Research Applications and State Research Laws*, 48 *J. L. MED. ETHICS* 82 (2020); Leslie E. Wolf et al., *Protecting*

research takes place at a site that applies the Common Rule to privately funded research, if the research is federally funded, if the study results will be submitted to FDA in support of a research or marketing permit, or if the research involves using medical devices such that the FDA's medical device regulations apply.¹²⁴ Nor is an IRB required for non-industry research under federal human subjects regulations if the research is not federally conducted or funded (unless the research institution has issued a broad FWA extending the scope of review at that institution) or FDA rules triggering need for an IRB apply.¹²⁵

Portable MRI may be utilized in many circumstances where IRB review is not federally required by the Common Rule or FDA regulations, such as research conducted as part of a high school science fair competition, research in a psychology department at a private junior college that does not receive federal funding, and research by a political marketing firm. In addition, with the development of open-source MRI,¹²⁶ citizen science utilizing MRI is likely to expand. Open-source MRI refers to a scanner that can be built with open-source hardware and software parts.¹²⁷ In January 2023, 'the first open-source MRI scanner, the OSI² ONE, [was] . . . built'.¹²⁸ Citizen-initiated and citizen-led research projects, conducted without collaborators in universities, create challenging research oversight questions.¹²⁹ FDA may consider those who build open-source scanners to be 'manufacturers' subject to FDA regulations.

In light of the harms that could be experienced by participants if portable MRI research is not carried out safely, we recommend that use of portable MRI devices in research should be restricted to those entities and individuals who can adhere to relevant FDA guidance on MRI safety and operation standards. At present, 'MRI systems continue to be regulated under 21 CFR 892.1000 (product code LNH) as Class II devices requiring 510(k) notification'.¹³⁰ This premarket notification pathway has been utilized by manufacturers of systems with 'nominal static magnetic field strengths from 0.064 T through 7 T'.¹³¹

In addition, where IRB review is not already required, researchers should establish an oversight mechanism such as private IRB review and/or equivalent community-based review so that the research is conducted with oversight guided by the Common

Participants in Genomic Research: Understanding the 'Web of Protections' Afforded by Federal and State Law, 48 J. L. MED. ETHICS 126 (2020).

124 See U.S. Food & Drug Administration (FDA), FDA Policy for the Protection of Human Subjects, <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fda-policy-protection-human-subjects> (accessed Mar. 13, 2024)

125 U.S. Department of Health & Human Services, *supra* note 81.

126 Open Source Imaging, <https://www.opensourceimaging.org/> (accessed July 17, 2023); Andrew Webb & Johnes Obungoloch, *Five Steps to Make MRI Scanners More Affordable to the World*, 615 NATURE 391, 391–93 (2023).

127 Lukas Winter et al., Open Source Imaging Initiative (2020), <https://www.opensourceimaging.org/> (accessed Mar. 19, 2024).

128 Open Source Imaging, *First Open-Source MRI Scanner Presented: The OSI² ONE*, <https://www.opensourceimaging.org/2023/01/09/first-open-source-mri-scanner-presented-the-osii-one/> (accessed Mar. 19, 2024).

129 David Resnik, *Institutional Review Board Oversight of Citizen Science Research Involving Human Subjects*, 19 AM. J. BIOETHICS 21 (2019).

130 Krainak et al., *supra* note 64, at 347.

131 *Id.* at 347.

Rule and (where applicable) the FDA regulations. It is possible that a community board could also develop to the point where it was functioning as a full IRB. We recognize that implementation and enforcement of this recommendation are challenging. A voluntary code of conduct (such as the one that some biohacker communities have embraced for gene-editing research that occurs outside formal ethics review mechanisms) might be an initial next step.¹³²

It should be emphasized that while some portable MRI devices may be very user-friendly and operate at very low magnetic fields, other portable MRI devices may operate at high-field and would thus introduce significantly more safety concerns. Our recommendations consider the full suite of portable MRI being developed. This recommendation envisions oversight both when researchers are choosing how to conduct their research project, and upstream when researchers initially seek access to buy, lease, or borrow the portable MRI equipment. In short, this equipment should not be in the hands of research teams that cannot comply with relevant safety standards set by the FDA and professional associations.

Additional safeguards could be developed through relevant professional organizations. For instance, imagine that a criminal defense law firm decides to use portable MRI to study whether obtaining brain scans of their clients improves criminal sentencing outcomes. This research, outside of a university setting, would not be governed by an IRB. But the state bar association, through application of their Rules of Professional Conduct and through Continuing Legal Education (CLE) training, could provide targeted oversight and training.¹³³

By ensuring the use of safeguards that apply the ethical standards that would be applied by an IRB, we see a future of ‘responsible democratization’ of portable MRI research. We recognize that our recommended approach may limit the ability of some researchers and citizen scientists to initiate portable MRI research. Interview research with citizen-scientist stakeholders has shown that citizen scientists may object to ethical oversight mechanisms that are mandatory and hierarchical, preferring instead mechanisms of ethical oversight that are voluntary and community-driven.¹³⁴ Recognizing the benefits of citizen-led research, we allow for both private IRB review and ‘equivalent community-based review’. Thus, a voluntary, citizen-led ethical oversight mechanism could apply the spirit of standards in the Common Rule and FDA regulations on human subjects research (although other FDA regulations where they apply, particularly the

132 Maxwell J. Mehlman, Ronald A. Conlon & Alex Pearlman, *Governing Nonconventional Genetic Experimentation*, 10 J. LAW BIOSCI. lsad003 (2023). In addition, for those researchers (eg at a private company) who want to gain an FDA clearance or approval, they might need to submit data from clinical studies to FDA, and if they do that, FDA will require that an IRB reviewed the research that generated the submitted data.

133 By way of analogy, state bar associations have provided guidance in the wake of new technologies such as the Internet and social media. See, eg Elizabeth W. King, *The Ethics of Mining for Metadata Outside of Formal Discovery*, 113 PENN ST. L. REV. 801 (2009); Cassandra R. Hewlings, *Future of Louisiana’s Ethics and Professionalism Rules: As Technology Changes, Will Ethics Stay the Same?*, 64 LA. B.J. 42, 42 (2016) (noting that ‘as each new technology integrates into the practice of law, the questions of how and [to] what extent the ethics rules address the use of technology always arise’ and that ‘the ABA is constantly grappling with the reconciliation of new technologies with ethical obligations’).

134 Meredith Trejo et al., ‘A Cohort of Pirate Ships’: Biomedical Citizen Scientists’ Attitudes Toward Ethical Oversight, 6 CITIZEN SCI. 15 (2021).

IDE rules, may require an IRB). Lessons can be learned from similar efforts in the context of voluntary conduct codes in citizen science research on gene editing.¹³⁵

There may be incentives for some researchers to voluntarily obtain IRB review. For example, researchers could face negative consequences, including legal liability and reputational harm, if research participants are injured while scanning and the research team has not taken reasonable precautions such as IRB review.

ENGAGING AND RECRUITING DIVERSE AND REPRESENTATIVE PARTICIPANTS FOR PORTABLE MRI RESEARCH

- **Recommendation #5:** Research teams should be composed of individuals from diverse backgrounds, and should meaningfully engage community members prior to, during, and after the research project.
 - **Recommendation #6:** During the community engagement and the consent process, researchers should explain the risk of therapeutic misconception in MRI research. Details should be provided on what research results and IFs will be offered to participants and how research findings differ from those produced in clinical care.
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Portable MRI research has the potential to improve the representativeness and diversity of research studies by expanding MRI research to both geographically remote and historically marginalized communities.¹³⁶ Portable MRI may introduce many of these populations to MRI research for the first time. As discussed above in Part II, MRI research to date has relied primarily on convenience samples lacking in geographic, racial, cultural, and socioeconomic diversity. Portable MRI offers an opportunity to address these shortcomings and improve knowledge of the brain. But it also raises a concern about extractive, helicopter research practices. ‘Helicopter’ or ‘parachute’ research refers to situations in which a research team arrives at a community, conducts the study there, and then leaves, without conferring local value.¹³⁷

Recommendation #5: To address these concerns, we recommend that research teams be composed of individuals from diverse backgrounds that fully represent the participant community, and that those teams should meaningfully engage with community members prior to, during, and after concluding the research project. Researchers should include in their research protocols specific diversity and inclusion goals that reflect where the study is being performed and the populations relevant to the research being conducted. The research protocol should also specify plans to address and mitigate lack of diversity and representativeness throughout the research project. Research

¹³⁵ Mehlman et al., *supra* note 132.

¹³⁶ Cooley et al., *supra* note 28; Geethanath & Vaughan Jr, *supra* note 2 (noting that these two categories of marginalized and geographically remote are distinct, in that both poor and wealthy individuals live in both urban and rural communities).

¹³⁷ EQUITABLE RESEARCH PARTNERSHIPS: A GLOBAL CODE OF CONDUCT TO COUNTER ETHICS DUMPING (Doris Schroeder et al. eds., 2019); Council for International Organizations of Medical Sciences (CIOMS), INTERNATIONAL ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS (2016, 4th ed.); Danny Haelewaters et al., *Ten Simple Rules for Global North Researchers to Stop Perpetuating Helicopter Research in the Global South*, 17 PLOS COMPUT. BIOL. e1009277 (2021); Moses Bockarie et al., *Parasitic and Parachute Research in Global Health*, 6 LANCET GLOB. HEALTH e964 (2018).

funders, IRBs, and community research review boards¹³⁸ should hold researchers accountable for meeting inclusion goals by insisting on quantifiable measurements of inclusion.

Consultation with community members should be a core component of protocol design and implementation. This community engagement can lead to the production of local social and economic value such as new knowledge that is meaningful locally.¹³⁹ Moreover, efforts should be instituted to hire community members as research staff or consultants.

Community-engaged research (CEnR) and other forms of community-based participatory research (CBPR) have grown in prominence.¹⁴⁰ Such approaches can improve the depth and policy impact of biomedical research.¹⁴¹ Yet neuroscience has not widely embraced CEnR approaches.¹⁴² Although some large-scale studies such as HCP-D¹⁴³, Adolescent Brain Cognitive Development (ABCD)¹⁴⁴, and All of Us¹⁴⁵ are utilizing community-engagement methods, most human neuroimaging research is not. This contributes to the continued utilization of non-representative convenience samples in neuroimaging research.¹⁴⁶ Human neuroimaging research needs broader samples to better reflect the racial, ethnic, geographic, and socioeconomic diversity of the population.¹⁴⁷ To achieve that goal, enhanced community engagement is required.

Portable MRI research should adopt a more community-engaged approach. CBPR and 'integrated knowledge translation'—IKT, defined as 'the engagement of knowledge users (e.g., policy makers, clinicians, patients) as active participants in the research

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- 138 Phoebe Friesen et al., *Extending Ethical Strides: From Tribal IRBs to the Bronx Community Research Review Board*, 17(11) AM. J. BIOETHICS W5 (2017).
- 139 Shen et al. (2020), *supra* note 1.
- 140 Syed M. Ahmed & Ann-Gel S. Palermo, *Community Engagement in Research: Frameworks for Education and Peer Review*, 100 AM. J. PUB. HEALTH 1380 (2010).
- 141 Megan B. Irby et al., *Community-Engaged Research: Common Themes and Needs Identified by Investigators and Research Teams at an Emerging Academic Learning Health System*, 18 INT. J. ENVIRON. RES. PUB. HEALTH 3893, 3893 (2021) ('[g]rowing evidence suggests that including community members and representatives from community organizations in the design, implementation, and evaluation of research can lead to deeper, more informed, and nuanced understandings of health-related phenomena and identify actions . . . that are more relevant, culturally congruent, and likely to be effective, sustained, and scalable . . . to improve community and population health').
- 142 Shayna La Scala et al., *Equity, Diversity, and Inclusion in Developmental Neuroscience: Practical Lessons from Community-Based Participatory Research*, 16 FRONT. HUM. NEUROSCI. 1007249; Patricia Rodriguez Espinosa & Steven P. Verney, *The Underutilization of Community-based Participatory Research in Psychology: A Systematic Review*, 67 AM. J. COMMUN. PSYCHOL. 312 (2021).
- 143 Jazlyn Nketia et al., *Towards a More Inclusive and Equitable Developmental Cognitive Neuroscience*, 52 DEV. COGN. NEUROSCI.101014 (2021).
- 144 Hugh Garavan et al., *Recruiting the ABCD Sample: Design Considerations and Procedures*, 32 DEV. COGN. NEUROSCI. 16 (2018).
- 145 Brandy M. Mapes et al., *Diversity and Inclusion for the All of Us Research Program: A Scoping Review*, 15 PLOS ONE e0234962 (2020).
- 146 Vonetta M. Dotson & Audrey Duarte, *The Importance of Diversity in Cognitive Neuroscience*, 1464 ANN. N.Y. ACAD. SCI. 181 (2019); Francis X. Shen, *Is There an Ethical Duty to Report the Socioeconomic Status of Research Participants in Human Neuroscience Research?*, Poster presented at Annual Meeting of the Society for Neuroscience (Chicago, IL) (2019).
- 147 Dotson & Duarte, *supra* note 146; Desiree A. Byrd & Monica G. Rivera-Mindt, *Neuropsychology's Race Problem Does Not Begin or End with Demographically Adjusted Norms*, 18 NAT. REV. NEUROL. 125 (2022).

process¹⁴⁸—will be important for formulating research strategies.¹⁴⁹ Community engagement should help shape the protocol. For example, research teams often do not provide aggregate results to the communities they are studying, even though this information is often desired.¹⁵⁰ In addition, research teams may fail to consider return of individual-specific results and IFs, even though these may be highly valued (this issue is addressed at greater length below in discussion of Recommendation #14). A community-centered approach would integrate the community into the entire research lifecycle, from inception of the project goals, through data acquisition, sharing aggregate and individual results, and publication.

Guiding principles for research in resource-poor settings using other technologies have been promulgated by WHO,¹⁵¹ the US Agency for International Development,¹⁵² and the United Nations.¹⁵³ In addition, the European Commission's TRUST Project produced the SAN Code of Research Ethics and the Global Code of Conduct for Research in Resource-Poor Settings (GCC).¹⁵⁴ As applied to research with portable MRI, these codes would require researcher engagement with the community before, during, and after the scanning.

Recommendation #6: In addition to concerns about helicopter research, participants may mistakenly view MRI research as clinical care. The therapeutic misconception is a widely recognized problem in research.¹⁵⁵ Research in remote settings with populations unfamiliar with MRI or facing barriers to clinical access may misconstrue neuroimaging research for clinical care. The therapeutic misconception has been specifically noted as a concern in pediatric neuroimaging research¹⁵⁶ and deep brain stimulation.¹⁵⁷ Multiple strategies have been proposed to address the issue.¹⁵⁸

148 Mehlman et al., *supra* note 132.

149 Luz M. Garcini et al., *Increasing Diversity in Developmental Cognitive Neuroscience: A Roadmap for Increasing Representation in Pediatric Neuroimaging Research*, 58 DEV. COGN. NEUROSCI. 101167 (2022); Anna R. Gagliardi et al., *Integrated Knowledge Translation (IKT) in Health Care: A Scoping Review*, 11 IMPLEMENT. SCI. 38 (2015).

150 Carmen E. Aldinger et al., *Returning Aggregate Results of Clinical Trials: Empirical Data of Patient Preferences*, 2 J. CLIN. TRANSL. SCI. 356 (2018).

151 WORLD HEALTH ORGANIZATION (WHO), STANDARDS AND OPERATIONAL GUIDANCE FOR ETHICS REVIEW OF HEALTH-RELATED RESEARCH WITH HUMAN PARTICIPANTS (2011), <https://www.who.int/publications-detail-redirect/9789241502948> (accessed Mar. 19, 2024).

152 U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT, ARTIFICIAL INTELLIGENCE IN GLOBAL HEALTH: DEFINING A COLLECTIVE PATH FORWARD (2019), <https://www.usaid.gov/cii/ai-in-global-health> (accessed Mar. 19, 2024).

153 UN SECRETARY-GENERAL'S INDEPENDENT EXPERT ADVISORY GROUP, A WORLD THAT COUNTS: MOBILIZING THE DATA REVOLUTION FOR SUSTAINABLE DEVELOPMENT (2014), <https://www.undatarevolution.org/wp-content/uploads/2014/11/A-World-That-Counts.pdf> (accessed Mar. 19, 2024).

154 DORIS SHROEDER ET AL., EQUITABLE RESEARCH PARTNERSHIPS: A GLOBAL CODE OF CONDUCT TO COUNTER ETHICS DUMPING (2019); Doris Shroeder et al., *The San Code of Research Ethics*, in EQUITABLE RESEARCH PARTNERSHIPS 73 (Doris Shroeder et al. eds., 2019); see also TRUST PROJECT, <http://trust-project.eu/> (accessed July 17, 2023).

155 Paul S. Appelbaum et al., *The Therapeutic Misconception: Informed Consent in Psychiatric Research*, 5 INT. J. LAW. PSYCHIATRY 319 (1982).

156 Michael Hadskis et al., *The Therapeutic Misconception: A Threat to Valid Parental Consent for Pediatric Neuroimaging Research*, 15 ACCOUNT. RES. 133 (2008).

157 Carl E. Fisher et al., *The Ethics of Research on Deep Brain Stimulation for Depression: Decisional Capacity and Therapeutic Misconception*, 1265 ANN. N. Y. ACAD. SCI. 69 (2012).

158 Paul S. Appelbaum et al., *Twenty-five Years of Therapeutic Misconception*, 38(2) HASTINGS CENTER REP. 5 (2008); Gavin Campbell et al., *Therapeutic Misconception about Research Procedures: Does a Simple*

Researchers using portable MRI should directly confront the issue by explaining the difference between research and clinical neuroimaging and clearly identifying their use of portable MRI as research. Researchers should also monitor and measure the number of participants who appear to harbor this misconception; this would allow the research team to identify and then intervene with those participants who need further explanation.¹⁵⁹ Evidence on what causes the therapeutic misconception suggests that while the cognitive frame of researchers is science, the cognitive frame of participants is often their personal needs.¹⁶⁰

Solutions to the therapeutic misconception should be tailored to the research project. Measurement of the issue will allow the research team to understand the nature and extent of the challenge in their sample. The core of the solution is likely to be improved communication, leading to improved understanding by the participant.¹⁶¹ This also has implications for the deployment of the research team. Although the machine could be operated by someone with little experience in research, such a machine operator might not be able to address the therapeutic misconception. Researchers and funders should ensure that the research team has sufficient capacity to effectively communicate on site, or by virtual methods, with prospective participants.

Solutions to the therapeutic misconception should address the potential for research to uncover individual research results or IFs of possible clinical concern. This is addressed more fully in Recommendation #14 below.

PROTECTING RESEARCH PARTICIPANTS IN THE SCANNING ENVIRONMENT

- **Recommendation #7:** Safety guidelines and education should be created by the ACR, ISMRM, and other professional bodies, for use of highly portable MRI in field settings. These guidelines should cover safe setup, use, storage, and transport of the equipment and standards for participant privacy and data security.
 - **Recommendation #8:** Scanning protocols should be developed to maximize participant privacy in different scanning environments, including use of portable drapes, privacy screens, or dedicated rooms to shield the person being imaged and mechanisms to prevent others from viewing acquired data/images. Participant consent/assent should be obtained for the presence of visitors or observers in the scanning environment.
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Safety of the scanning environment is of paramount importance. Addressing the safety challenge is urgent because although portable MRI (such as the Hyperfine

Information Chart Improve Understanding?, 42 ETHICS & HUM. RSCH. 18 (2022); Jennifer B. McCormick, *How Should a Research Ethicist Combat False Beliefs and Therapeutic Misconception Risk in Biomedical Research?*, 20 AM. J. ETHICS 1100 (2018).

159 Paul S. Appelbaum et al., *Therapeutic Misconception in Research Subjects: Development and Validation of a Measure*, 9 CLINICAL TRIALS 748 (2012); Gail E. Henderson et al., *Clinical Trials and Medical Care: Defining the Therapeutic Misconception*, 4 PLoS MED. e324 (2007).

160 Charles W. Lidz et al., *Why Is Therapeutic Misconception So Prevalent?*, 24 CAMBRIDGE Q. HEALTHCARE ETHICS 231 (2015).

161 Charles W. Lidz & Paul S. Appelbaum, *The Therapeutic Misconception: Problems and Solutions*, 40 MED. CARE 55 (2002).

Swoop® device) is already being wheeled through corridors to scan research participants, currently there are no portable MRI safety manuals from standard-setting bodies such as the ACR and ISMRM and no guidance for IRBs regarding what type of safety training should be required of study personnel. As portable MRI extends even further beyond the biomedical context—for instance, into neuromarketing research, studies in educational neuroscience where a researcher studies grade school students to see how their brain data are correlated with test score performance, or legal scanning of incarcerated individuals—safety concerns will be even greater.

Recommendation #7: To address these concerns, we recommend that ACR, ISMRM, and other professional bodies coordinate to promulgate safety guidelines for different portable MRI scanners and scanning locations. These guidelines should cover safe setup, use, storage, and transport of the equipment and standards for participant and data privacy and security.

There are extensive safety protocols and safety enforcement in place for fixed MRI scanning, and we recommend adopting a similar approach in the portable MRI context: detailed guidelines should be promulgated, then local safety officers should ensure that everyone who is going to use the portable MRI machine has completed the safety training course. This is especially important in research because, in comparison to the clinical context where scanning will presumably offer benefit to the patient, in many research contexts there are no direct benefits to the participant. Thus, to achieve an acceptable risk–benefit ratio, risks should be minimized in research. For portable MRI research, we recommend that the institution, through its safety officer or equivalent, provide safety training and ensure compliance with safety guidelines. In instances where there is no institution (eg in citizen science research) or when the institution (eg a community college whose faculty have not previously conducted MRI research) does not have an existing MRI safety officer, we recommend establishing a research partnership with a more experienced institution to ensure appropriate safety oversight.

Recommendation #8: Unlike traditional fixed MRI, which occurs behind locked doors in compliance with ACR safety standards, the portable MRI setup will be more flexible. To minimize the possibility that the scanner operational environment fails to protect participant privacy, we recommend that scanning protocols should be developed to maximize participant privacy in different scanning environments, including use of portable drapes, privacy screens, or dedicated rooms to shield the person being imaged and mechanisms to prevent others from viewing acquired data/images.

For research participants with decision-making capacity, consent should be obtained for the presence of visitors or observers in the scanning environment. For research participants not capable of giving consent, the permission of the parent, legal guardian, or legally authorized representative (LAR) plus, where possible, assent of the participant should be required.

In addition to physical privacy that ensures the brain data are acquired without onlookers not approved by the participant, researchers should also ensure data privacy. While the technical details of data privacy protocols are beyond the scope of this article, those protocols should permit the safe and secure acquisition, transfer, and de-identification of imaging data in various public spaces. MRI innovators play a role by building approaches that can facilitate protection of privacy throughout the data lifecycle. Additionally, IRBs can play an important role here. In research projects,

such as federally funded research, where IRB oversight is already required, the IRB should ensure that all members of the study team who will be working in the scanner environment or handling the MRI data complete the safety and privacy training. IRBs often require that research team members have training specific to research protocols, so adding a portable MRI safety training requirement would be a natural extension of current practice. In situations where researchers are not subject to IRB review, a safeguards system is needed to provide similar safety oversight.

Our recommendation also addresses another unique feature of portable and accessible MRI: the possibility that people other than the person being scanned will be in the scanning environment. In a fixed MRI scanning environment, ACR safety guidelines state that no bystanders can be in the scanning environment. The safety zone for MRI scanning is established at the '5 Gauss line'.¹⁶² For the Hyperfine head-only portable scanner, this is marked with a 'collapsible ring guard that extends from the top of the scanner into a circle with a diameter of 158 cm'.¹⁶³ This means that others can be next to the scanner, even holding a participant's hand, and can potentially see the mobile device on which the brain images are appearing. Moreover, portable devices may not require that bystanders surrender their mobile phones and consumer electronics. The research team should develop a policy (eg prohibiting use of photography and video without participant consent), and then enforce the policy with all bystanders. But even if they are instructed not to do so, bystanders may snap photos, capture video of the scanning, or even wirelessly upload data being transferred from the scanners to the cloud.

Some participants may wish to have a friend or relative nearby; others may not. Some participants may see proximity as a threat to physical and informational privacy. These concerns are further heightened if the scanning is happening in a publicly accessible environment such as a school cafeteria or in the driveway of the participant's home, where it is more difficult to restrict smartphone usage. The research team should share with prospective participants the potential risks posed by having individuals nearby during scanning or granting those individuals potential access to sensitive data. Ultimately, the researchers should honor the research participant's preferences.

The process of seeking an individual's consent to participate in the research (or seeking surrogate permission and participant assent) should occur in a space that allows for the potential participant to decline participation without having others know. To illustrate, imagine that a research team is doing a population health study and scanning adults in a community center. If the consent process is occurring in the same space and at the same time as the scanning, others in the waiting area will be able to see who walks into the scanning space. Researchers should instead create a private space for the consent process or provide an option for private conversations prior to the scanning day.

Privacy may be particularly important for certain types of neuroimaging research. For instance, a participant might not want others to know that they are participating in a

¹⁶² ACR Manual on MR Safety, American College of Radiology Committee on MR Safety (2020), <https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf> (accessed Mar. 19, 2024).

¹⁶³ Anjali M. Prabhat et al., *Methodology for Low-Field, Portable Magnetic Resonance Neuroimaging at the Bedside*, 12 FRONT. NEUROL. 760321 (2021).

research project related to early identification of AD.¹⁶⁴ Parents may not want others to know they have enrolled their child in a neuroimaging study looking at early biomarkers for autism.

USING AI ALGORITHMS IN PORTABLE MRI RESEARCH

● **Recommendation #9:** Through community engagement and in the consent process, researchers should describe the use of AI in the portable MRI research. Researchers should discuss with participants potential concerns associated with this use of AI, including the potential biases of AI models being used to generate images and to interpret the meaning of those images.

Many MRI scanners, including portable MRI, will increasingly rely on AI systems for image reconstruction, segmentation, and assisted diagnosis.¹⁶⁵ While not unique to portable MRI, AI approaches are central to portable MRI advances. For instance, a company that develops portable MRI technology has received FDA 510(k) clearance for its AI-fueled image reconstruction technology using deep learning.¹⁶⁶ The utilization of AI in portable MRI makes the emerging literature germane on how to ensure ethical and trustworthy AI (ETAI) in biomedical research¹⁶⁷ and specifically in neuroimaging.¹⁶⁸ The use of AI in radiology goes back decades.¹⁶⁹ AI models were already being explored for use in breast lesion detection in 1985.¹⁷⁰ Today, AI is widespread in radiology, with new questions being raised about the possibility of replacing human radiologists (who are limited in number and expensive to employ) with AI ‘radiologist in a box’ approaches.¹⁷¹ Professional societies, the FDA, and research institutions will need to develop guidance about when a human needs to remain in the loop in research using

- ¹⁶⁴ Emily A. Largent et al., ‘That Would Be Dreadful’: The Ethical, Legal, and Social Challenges of Sharing Your Alzheimer’s Disease Biomarker and Genetic Testing Results with Others, 8 J. LAW. BIOSCI. Isab004 (2021); Shana D. Stites et al., *Advances in Alzheimer’s Imaging Are Changing the Experience of Alzheimer’s Disease*, 10 ALZHEIMERS DEMENT. 285 (2018); Joshua Preston, et al., *The Legal Implications of Detecting Alzheimer’s Disease Earlier*, 18 AMA J. ETHICS 1207 (2016).
- ¹⁶⁵ Isha R. Chavva et al., *Deep Learning Applications for Acute Stroke Management*, 92 ANN. NEUROL. 574, (2022); Sona Laguna et al., *Super-Resolution of Portable Low-Field MRI in Real Scenarios: Integration with Denoising and Domain Adaptation* (Apr. 2022), <https://openreview.net/pdf?id=pinw0Gcot4T>; Koonjoo et al., *supra* note 36; Bo Zhu et al., *Image Reconstruction by Domain-Transform Manifold Learning*, 555 NATURE 487 (2018).
- ¹⁶⁶ Krainak Letter, *supra* note 109.
- ¹⁶⁷ Sandeep Reddy et al., *A Governance Model for the Application of AI in Health Care*, 27 J. AM. MED. INFORM. ASSOC. 491 (202); Kathleen Murphy et al., *Artificial Intelligence for Good Health: A Scoping Review of the Ethics Literature*, 22 BMC MED. ETHICS 1 (2022).
- ¹⁶⁸ Nathalie Lassau et al., *Five Simultaneous Artificial Intelligence Data Challenges on Ultrasound, CT, and MRI*, 100 DIAGN. INTERV. IMAGING 199 (2019); David B. Larson et al., *Ethics of Using and Sharing Clinical Imaging Data for Artificial Intelligence: A Proposed Framework*, 295 RADIOLOGY 675 (2020).
- ¹⁶⁹ John M. Boome et al., *Neural Networks in Radiologic Diagnosis. I. Introduction and Illustration*, 25 INVEST. RADIOL. 1012 (1990).
- ¹⁷⁰ Laurens V. Ackerman & Matthew W. Burke, *Artificial Intelligence and Image Processing*, 33 HENRY FORD HOSP. MED. J. 142 (1985).
- ¹⁷¹ Curtis P. Langlotz, *Will Artificial Intelligence Replace Radiologists?*, 1 RADIOLOGY: A.I. e190058 (2019); Michael Recht & R. Nick Bryan, *Artificial Intelligence: Threat or Boon to Radiologists?*, 14 J. AM. COLL. RADIOLOGY 1476 (2017); Maciej A. Mazurowski, *Artificial Intelligence May Cause a Significant Disruption to the Radiology Workforce*, 16 J. AM. COLL. RADIOLOGY. 1077 (2019).

biomedical imaging. AI developers and researchers in multiple fields will be working to develop policies for ongoing surveillance and QC of algorithms.¹⁷²

For image quality in research using lower-field scanners, AI is important because it can facilitate the capture and creation of images with an increased signal-to-noise ratio that may be on par with higher-field scanners. Developing AI-assisted image interpretation is a natural extension of AI already used in clinical radiology. For both portable and fixed MRI, it is important to communicate with research participants about how AI is being used.

Recommendation #9: In community engagement and in the consent process, researchers should be transparent regarding the use of AI in portable MRI and nature of the dataset used to train the AI. Researchers should discuss with participants both the advantages of using AI and the potential biases of the AI models being used to generate images and to interpret the meaning of those images.

Such transparency is crucial to informed consent.¹⁷³ Participants and community members should be aware of how AI is being used by the imaging device and the research team. Achieving this transparency might require accessible language with supporting media (such as illustrations or videos) about how AI contributes to the research workflow—for example, in optimizing head position, constructing and interpreting images, and screening for IFs.

Researchers proposing to use portable MRI must consider both the benefits and risks of relying on AI tools. A key benefit of training and testing AI in inclusive research using portable MRI is that participants from underrepresented communities can improve the quality and generalizability of future AI models by diversifying training and validation data. However, they themselves may not enjoy the benefits of those future improvements, and potential risks of the research include the possibility of bias in currently available AI tools — for example, those used to identify IFs from the research. While research is underway to determine when LF MRI may be able to identify certain types of IFs, participants need to be aware that bias in current tools can lead to errors. There is a risk of false positives that may prompt unnecessary follow-up testing, fear and worry in the participant, and false negatives that may lead to overlooked IFs and delayed care.

In order to explain AI use in research to participants, the researchers must understand it themselves. Ethicists writing on the use of AI in medicine have argued that in addition to the traditional bioethical principles of beneficence, non-maleficence, autonomy, and justice, we need to add a fifth: explainability.¹⁷⁴ Explainability would

172 MARANKE WIERINGA, WHAT TO ACCOUNT FOR WHEN ACCOUNTING FOR ALGORITHMS: A SYSTEMATIC LITERATURE REVIEW ON ALGORITHMIC ACCOUNTABILITY (ACM Conference on Fairness, Accountability, and Transparency, 2020), <https://dl.acm.org/doi/10.1145/3351095.3372833>; Efiy Vayena et al., *Machine Learning in Medicine: Addressing Ethical Challenges*, 15 PLoS MED. e1002689 (2018); MARTIN EBERS & MARTA CANTERO GAMITO, ALGORITHMIC GOVERNANCE AND GOVERNANCE OF ALGORITHMS: LEGAL AND ETHICAL CHALLENGES (2021).

173 Frank Ursin et al., *Explicability of Artificial Intelligence in Radiology: Is a Fifth Bioethical Principle Conceptually Necessary?*, 36 BIOETHICS 143 (2022).

174 Julia Amann et al., *Explainability for Artificial Intelligence in Healthcare: A Multidisciplinary Perspective*, 20 BMC MED. INFORM. DECI. MAK. 1 (2020); Ashley Deeks, *The Judicial Demand for Explainable Artificial Intelligence*, 119 COLUM. L. REV. 1829 (2019).

require that researchers be able to explain to participants how AI is operating.¹⁷⁵ Sometimes it may not be clear, even to the research team, how AI-generated images or inferences, and in those instances the research team should be transparent about this with participants.

The research team will need to identify the role of AI tools in their data analysis pipeline and be aware of the potential for bias, and, in particular, the potential for disparate impacts along lines of gender, race, and ethnicity that may affect both the research results and detection of IFs. The research team should consult with vendors as needed to clarify, recognizing that vendors may be unwilling to be transparent about their algorithms and training data sets, and that even the vendors of AI tools and algorithms may not fully understand their potential for bias and how to mitigate the effects. Researchers should also develop plans for careful validation to ensure that AI-augmented and AI-generated images are reliable and accurate for their research purposes and that potential model weaknesses are understood. The use of algorithmic bias assessment tools may be of use.¹⁷⁶

INTERPRETING AND COMMUNICATING TO PARTICIPANTS THE MEANING OF PORTABLE MRI SCANS

• **Recommendation #10:** Portable MRI research teams should ensure that those reading the scans have the expertise and training to accurately interpret them, including understanding the role of AI algorithms. Research teams should effectively communicate to participants the nature of the research results and incidental findings generated, as well as the training of those reviewing the images/data and interpretative methods used.

As discussed earlier, portable MRI is not a single device, but a range of technologies varying in field strength, spatial resolution, temporal resolution, intended use, cost, and ease of use. Demand will likely grow for machines built by smaller companies in addition to those clinical magnets made by the ‘the big three’ companies—General Electric, Siemens, and Philips. The proliferation of novel devices, with some scanning at lower field strength than the conventional 1.5T, will soon result in more scans and increased variation in image quality. Indeed, open-source MRI that can be built by researchers themselves is on the horizon.¹⁷⁷

A proliferation of scanning machines and analytical techniques may produce widely varying imaging and interpretations across research teams. How to interpret structural and fMRI scans has been the subject of debate since the inception of MRI, with multiple research teams arriving at different conclusions when they analyze the same dataset.¹⁷⁸ The same underlying MRI data can lead to different interpretations because research

¹⁷⁵ Frank Ursin et al., *Explicability of Artificial Intelligence in Radiology: Is a Fifth Bioethical Principle Conceptually Necessary?*, 36 *BIOETHICS* 143 (2022).

¹⁷⁶ Nicol Turner Lee, Paul Resnick & Genie Barton, *Algorithmic Bias Detection and Mitigation: Best Practices and Policies to Reduce Consumer Harms* (Brookings Institute 2019).

¹⁷⁷ Open Source Imaging, *supra* note 128.

¹⁷⁸ Raphael Silberzahn et al., *Many Analysts, One Data Set: Making Transparent How Variations in Analytic Choices Affect Results*, 1 *ADV. METHODS PRACT. PSYCHOL. SCI.* 337 (2018); Rotem Botvinik-Nezer et al., *Variability in the Analysis of a Single Neuroimaging Dataset by Many Teams*, 582 *NATURE* 84 (2020).

teams may use different analytical strategies to analyze the data and construct images, and may draw different conclusions about what the same pattern of brain activity means.

Recommendation #10: In this changing MRI research ecosystem, portable MRI research teams should ensure that those reading the brain scan images have the expertise and training to accurately interpret them. Research teams should make sure they have the capacity to effectively communicate to participants the aggregate research results and any individual-specific research results and IFs of potential clinical concern. This means that, at a minimum, the research team should include someone who is knowledgeable and/or has training in how images are generated on a particular scanning device, has training and experience in interpreting group-averaged differences, and understands the limits of drawing inferences from MRI.

Communication of MRI results should be presented in a way that participants can understand, so that they receive value.¹⁷⁹ Those lacking expertise in communicating MRI results should collaborate with experts to carry out their research. While this will prevent some research from moving forward without an MRI expert on the team, this recommendation is also an opportunity for collaboration between established MRI experts and new MRI researchers.

What and how to communicate to participants depends greatly on the type of MRI research being conducted. For instance, some fMRI findings, such as those from studies of how brains process information with respect to legal decision-making, may have no established or potential clinical significance. Other MRI studies, for example, clinical research examining the relationship between brain structure and cognitive decline, may produce individual-specific research results that have clinical significance. Still other MRI results, for instance those from MRI-based lie detection studies, may have no clinical significance but tremendous social and legal significance. Because there is a broad spectrum of potential MRI research designs, it is unlikely that there will ever be a single, universally accepted approach to communicating MRI and fMRI research results to participants. But there are existing approaches that research teams should be aware of when developing their own communication strategy. For example, for those studies reporting fMRI results, a wide body of research has established clear limits and cautions about how to interpret fMRI findings.¹⁸⁰ For clinical research studies, emerging best practices on structured reporting in radiology may be instructive.¹⁸¹ There is also a relevant literature examining empirically how patients understand MRI results provided to them and what patients desire in reports.¹⁸²

¹⁷⁹ Wilkins et al., *supra* note 119.

¹⁸⁰ See, eg Russell A. Poldrack et al., *Guidelines for Reporting an fMRI Study*, 40 *NEUROIMAGE* 409 (2008); Owen D. Jones et al., *Brain Imaging for Legal Thinkers: A Guide for the Perplexed*, 2009 *STAN. TECH. L. REV.* 5 (2009); Russell A. Poldrack et al., *Scanning the Horizon: Towards Transparent and Reproducible Neuroimaging Research*, 18 *NAT. REV. NEURO.* 115 (2017).

¹⁸¹ See eg Mark D. Mangano et al., *Radiologists' Role in the Communication of Imaging Examination Results to Patients: Perceptions and Preferences of Patients*, 203 *AM. J. ROENTGENOL.* 1034 (2014); Dhakshinamoorthy Ganeshan et al., *Structured Reporting in Radiology*, 25 *ACAD. RADIOL.* 66 (2018); Jonathan Lee et al., *Structured Reporting in Multiple Sclerosis Reduces Interpretation Time*, 28 *ACAD. RADIOL.* 1733 (2021).

¹⁸² See, eg Bonyong Lee et al., *Radiology Reports: What YOU Think You're Saying and What THEY Think You're Saying*, 46 *CURR. PROBS. DIAGN. RADIOL.* 186 (2017); Andrea G. Rockall et al., *Patient Communication in Radiology: Moving Up the Agenda*, 155 *EUR. J. RADIOL.* 110464 (2022).

PROMOTING QUALITY CONTROL FOR PORTABLE MRI TECHNOLOGY

• **Recommendation #11:** Companies manufacturing and marketing highly portable MRI have a responsibility to ensure ongoing QC to detect and correct artifacts and algorithmic processing errors. Research teams using the technology should communicate to their research participants and partner researchers their policies regarding QC.

Recommendation #11: Ongoing QC is central to the safe and effective use of MRI.¹⁸³ We recommend that companies manufacturing and marketing highly portable and accessible MRI have a responsibility to ensure QC to detect and correct artifacts and algorithmic processing errors, as well as to provide operational guidelines. Research teams using the technology should communicate to their research participants and collaborators their QC policies and practices.

Implementation of QC strategies in MRI research will depend in part on whether the research study is utilizing clinical scans. At present, all MRI providers who bill Medicare for services are required to complete ACR accreditation.¹⁸⁴ As noted above, ACR accreditation is a multifaceted process, examining personnel, MRI machines, and documentation of QC.¹⁸⁵ The process focuses on accreditation for particular clinical purposes, such as imaging for stroke or traumatic brain injury. Specific machines are typically accredited for specific indications and for a particular ‘practice site’. A practice site is defined as each different geographical location where imaging is performed, and ACR policy is that the ‘accreditation process for mobile units differs depending upon the scenario’.¹⁸⁶

This robust ACR accreditation process does not apply, however, to experimental MRI research that is wholly outside of a clinical context. For example, fMRI studies of basic cognitive processes or neuroeconomic fMRI studies may be conducted on an MRI scanner that will not be used for billing for Medicare services. In these contexts, there is not an accreditation requirement or a single universal approach to QC. The onus falls on individual research labs to develop approaches for QC of the portable MRI technology for research tailored to their unique contexts. In developing these approaches, researchers can and should consult fieldwide efforts to promote standardization and establish best practices. For example, the Biomedical Informatics Research Network (BIRN) has ‘developed a federated and distributed infrastructure

183 In some fields, the terms ‘quality assurance’ and ‘quality control’ denote different processes. Here we use the phrase ‘quality control’ as an umbrella term to capture all quality control and quality assurance activities.

184 Centers for Medicare & Medicaid Services, *Accreditation of Advanced Diagnostic Imaging Suppliers*, <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/aaccreditation-of-advanced-diagnostic-imaging-suppliers> (accessed July 17, 2023) (‘Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275) amended section 1834(e) of the Social Security Act (the Act). This amendment requires suppliers of the technical component of advanced diagnostic imaging (ADI) services to be accredited by a designated accrediting organization in order to receive Medicare reimbursement’).

185 Jeffrey Weinreb et al., *ACR MRI Accreditation: Yesterday, Today, and Tomorrow*, 2 J. AM. COLL. RADIOL. 494 (2005).

186 *Mobile Unit Multi-Site Policy*, AMERICAN COLLEGE OF RADIOLOGY, <https://acrsupport.acr.org/support/solutions/articles/11000051009-mobile-unit-multi-site-policy-revised-5-25-2022-> (accessed May 25, 2022).

for the storage, retrieval, analysis, and documentation of biomedical imaging data'.¹⁸⁷ In addition, experts published a special issue in 2023 on 'Demonstrating Quality Control (QC) Procedures in fMRI'¹⁸⁸ and QC in MRI research has been a frequent topic of scholarly analysis.¹⁸⁹ Strategies to promote QC in MRI research include the use of the peer-review process, open access, and transparent data sharing for replicability analyses. Research teams can also publish their approach to QC, for example as done by the ABCD Study.¹⁹⁰

There may be an additional lever for promoting QC at the institutional level. For instance, a college could require that its researchers use only portable MRI technology that has been accredited. This would create an incentive for facilities to gain accreditation. Funders of research could also impose a similar requirement, again creating pressure on the site to gain accreditation for their technology.

ENSURING DATA PRIVACY, CONFIDENTIALITY, SECURITY, AND PARTICIPANT CONTROL OF THEIR BRAIN DATA

● **Recommendation #12:** Participants should have agency over their data throughout the entire pipeline from data acquisition to data sharing. Every person and entity that will have access to the participant's brain data should commit to responsible data management, transparency, and accountability. During the informed consent process, participants should be given a clear understanding of the rights they have to control their data and any limitations on those rights.

● **Recommendation #13:** A plan for responsible management of acquired MRI data should be developed before data collection begins. Adequate resources should be in place to ensure safe and secure data acquisition, de-identification, storage, sharing, and compliance with applicable policies such as NIH data sharing policy.

Neuroethics scholarship emphasizes the importance of ensuring the privacy of brain data and images.¹⁹¹ Our WG similarly viewed privacy as a core ethical commitment. But a commitment to protecting the privacy of participant health data must be balanced against the public's interest in uses of those data.¹⁹² This is an issue relevant to many areas of science, as indicated by the NASEM effort to advise on protecting privacy and

187 David B. Keator et al., *A National Human Neuroimaging Collaboratory Enabled by the Biomedical Informatics Research Network (BIRN)*, 12 IEEE TRANS. INFORM. TECH. BIOMED. 162 (2008).

188 Paul A. Taylor et al., *Editorial: Demonstrating Quality Control (QC) Procedures in fMRI*, 17 FRONT. NEUROSCI. (2023), <https://www.frontiersin.org/articles/10.3389/fnins.2023.1205928/full> (accessed Mar. 19, 2024).

189 See, eg Weizhao Lu et al., *Quality Assurance of Human Functional Magnetic Resonance Imaging: A Literature Review*, 9 QUANT. IMAGING MED. SURG. 1147 (2019); Yassine Benhajali et al., *A Standardized Protocol for Efficient and Reliable Quality Control of Brain Registration in Functional MRI Studies*, 14 FRONT. NEUROINFORM. 7 (2020).

190 Donald J. Hagler Jr et al., *Image Processing and Analysis Methods for the Adolescent Brain Cognitive Development Study*, 202 NEUROIMAGE 116091 (2019); B.J. Casey et al., *The Adolescent Brain Cognitive Development (ABCD) Study: Imaging Acquisition Across 21 Sites*, 32 DEV. COGN. NEUROSCI. 43 (2018).

191 Jesper Ryber, *Neuroethics and Brain Privacy: Setting the Stage*, 23 RES PUBLICA 153 (2017); Greely et al., *supra* note 58.

192 Barbara J. Evans, *Much Ado About Data Ownership*, 25 HARV. J. L. TECHNOL. 69, 129 (2011) (discussing the need to 'address the conflict between patients' desire to control their data and the public's need to use those data for various worthy purposes').

confidentiality, while avoiding harm, throughout the lifecycle of blended data.¹⁹³ In neuroscience research, a recent review of data sharing policies recognized the tension between an ethical duty to share data and duties to protect participant privacy, while finding ‘a wide spectrum of data sharing practices’.¹⁹⁴ NIH has specific data sharing requirements, and institutes such as the NIMH have added requirements.¹⁹⁵

While data sharing requirements are growing, the neuroimaging research community is actively debating how to strengthen participants’ control over their own data. In the United States, who owns data is largely a matter of state law, and many states leave data ownership ill-defined.¹⁹⁶ The United States and other major jurisdictions such as the European Union have rejected legal data ownership in favor of a ‘civil rights’ privacy model in which multiple parties (eg researchers, institutions, patients, and research participants) have shared interests in data, with each party’s interests subject to the other parties’ rights.¹⁹⁷ For example, a hospital has a right to retain patients’ medical records, as it is required to do by law, but must respect various rights the law grants to patients, such as a right of access to the data and to consent to certain data disclosures.¹⁹⁸

Nevertheless, the conventional structure of sponsored research conducted at universities has the effect of giving the university—not the researchers or the participants—a degree of control that resembles a *de facto* ‘ownership’ of the research data.¹⁹⁹ Even though the law largely avoids assigning ownership of data, the metaphor of data ownership has a strong intuitive popular appeal, and there are ongoing calls to allow research participants ‘data ownership’ in order to ‘maximize data-subject control over their personal information’.²⁰⁰ The advocacy group Hu-manity.co has urged that ‘Everyone has the right to legal ownership of their inherent human data as property’.²⁰¹ The problem with such proposals is that property rights, if transferred, leave no rights with the previous owner, so data ownership cannot provide research participants the ongoing, durable control over their data that personal civil rights can provide.²⁰²

Debate remains over the best mechanisms of control (eg whether legal ownership of data genuinely advances the interests of participants), but there is growing consensus that research participants should be able to exert more control over how their data are used and shared. We agree that strengthening participant control over their brain data and images is important. The research team should ensure mechanisms of two-way communication that facilitate such control. For example, telling a participant

193 *Approaches for Data Governance and Protecting Privacy*, NATIONAL ACADEMIES, <https://www.nationalacademies.org/our-work/approaches-for-data-governance-and-protecting-privacy-a-workshop#sectionWebFriendly> (accessed July 17, 2023).

194 Jwa & Poldrack, *supra* note 67.

195 *Id.*

196 Evans, *supra* note 192.

197 *Id.*

198 Barbara J. Evans, *Rules for Robots, and Why Medical AI Breaks Them*, 10 J. LAW BIOSCI. (2023), <https://doi.org/10.1093/jlb/lsad001>.

199 Estelle A. Fishbein, *Ownership of Research Data*, 66 ACAD. MED. 129 (1991); Marc A. Rodwin, *Patient Data: Property, Privacy & the Public Interest*, 36 AM. J.L. MED. 586 (2010).

200 Ignacio Cofone, *Beyond Data Ownership*, 43 CARDOZO L. REV. 501 (2021).

201 *Human Right #31: Powered by Blockchain—Infographic*, Hu-manity.co, <https://hu-manity.co/human-right-31-powered-by-blockchain-infographic/> (accessed July 17, 2023).

202 James Buchwalter et al., *Definition and Nature of Civil Rights*, 14 CORPUS JURIS SECONDUM §§ 1–3 (2018).

that they can withdraw their data from future studies means little if the participant is never contacted again after the scanning session with information about how their data might be re-used in new ways.

We recognize that calls for data ownership will continue because ownership is a powerful metaphor for the strong desires people have to protect personal data. Ownership of health-related data can also be a means of generating wealth, attention, and prestige for the data holder. There are various proposals for operationalizing protections, for example, through payments of royalties aggregated in community research trusts. The metaphor of ownership has continued relevance in community- and participant-led research and citizen science, and in particular contexts where calls for ownership are a response to historical marginalization. For instance, First Nations in Canada have advocated the principles of ownership, control, access, and possession (OCAP).²⁰³ OCAP is 'a political response to tenacious colonial approaches to research and information management'.²⁰⁴ OCAP asserts that 'First Nations have control over data collection processes, and that they own and control how this information can be used'.²⁰⁵

But in practice, participant control over their own data will be limited to some degree and it remains incumbent on the research community to establish and maintain structures of accountability to facilitate oversight of data misuse, data security, and data confidentiality. An example of how to do this comes from the ABCD Study, the largest long-term study of brain development and adolescent health in the United States. Aware of the need for structural accountability, the ABCD Study created an ABCD JEDI Advisory Council (AC) 'to effect change that ensures and promotes justice, equity, diversity and inclusion (JEDI) at all levels of ABCD', as well as three JEDI workgroups: (i) a workgroup on Equitable & Inclusive Methods 'to ensure that all measures and methods used within the ABCD consortium are fair and just to participants of all races, gender, sexual orientation, ability, socioeconomic status, and cultural background'; (ii) a workgroup on Diversity & Inclusion in ABCD 'to better understand the historical, cultural, and institutional racism disproportionately impacting ABCD researchers, staff, and participants who are persons of color, while working to promote anti-racism in our research, organization(s), and universities affiliated with ABCD'; and (iii) a workgroup on Responsible Use of ABCD Study Data to 'promote principles of ethical conduct of research to prevent further stigmatization, marginalization and injustice toward individuals because of racial, ethnic, or gender minority status'.²⁰⁶ Like ABCD, portable MRI researchers need to ensure that there are structures of accountability in place to protect participants.

Recommendation #12: We recommend that participants should be able to determine how their data are used to the fullest extent possible throughout the entire pipeline from data acquisition to data sharing. Every person and entity that will have access to

203 *The First Nations Principles of OCAP*[®], FIRST NATIONS INFORMATION GOVERNANCE CENTRE, <https://fnigc.ca/ocap-training/>; Graham Mecredy et al., *First Nations Data Governance, Privacy, and the Importance of the OCAP[®] Principles*, 3 INT. J. POPULATION DATA SCI. 320 (2018).

204 Brian Schnarch, *Ownership, Control, Access, and Possession (OCAP) or Self-Determination Applied to Research: A Critical Analysis of Contemporary First Nations Research and Some Options for First Nations Communities*, 1 INT. J. INDIGENOUS HEALTH 80 (2004).

205 *The First Nations Principles of OCAP*[®], *supra* note 203.

206 ABCD Study, JEDI Workgroups <https://abcdstudy.org/jedi-workgroups/> (accessed July 17, 2023).

the participant's brain data should be committed to accountability and transparency to participants. During the informed consent process, prospective participants should be given a clear understanding of the rights they have to control their data, choices regarding use, and any limitations.²⁰⁷ Participant agency over their brain data is especially important if portable MRI data may be utilized for purposes that are counter to what either the participant understood or what they desire.

The brain data acquired on site in field-based MRI research may be transferred via the Internet to parties beyond the research team (eg the firm that developed the machine and the machine's cloud-based data analysis system) for data analysis, and then transferred back to an electronic device being held by the research team member on site to facilitate rapid construction of the brain image in the field. Recognizing that multiple individuals and entities beyond the research team may be handling the brain data, we recommend that the duty of accountability and transparency to portable MRI research participants extends to all who will receive or handle the brain data in identifiable format, along the entire pipeline of data flow, including initial data acquisition on site, transfer of data for immediate processing, return of images to site, sharing of images with others, and cloud-enabled storage.

Researchers should take steps to ensure that every person and entity with access to the participant's brain data along the entire pipeline of data flow secures the privacy, confidentiality, and security of the data.²⁰⁸ Researchers should specify data risks and safeguards in seeking consent from potential participants to contribute their data to the study. Researchers, technology providers, and institutional IT security experts should work with community representatives to develop the framework for secure data acquisition, transfer, storage, and de-identification.

In practice, researchers should have recipients of the shared data sign a Data Use Agreement (DUA) that contractually binds the recipient to avoid re-identification of the data, disallows further sharing of the brain data with others without obtaining a further authorization from the original data-holder, and requires the data recipient to follow security standards at least equivalent to the HIPAA security rule (whether or not they are actually a HIPAA-covered entity). DUAs are already utilized by large-scale neuroimaging research projects such as the ABCD Study.²⁰⁹

207 Participants may not always have their HIPAA data access requests fulfilled. For example, 'At present, HHS does not expect laboratories to reidentify "de-identified" data to fulfill access requests. This is true even though data that has been de-identified under HIPAA's standards may not, in fact, be fully anonymized, and might in theory be linkable to the individual'. Marwan K. Tayeh et al., *The Designated Record Set for Clinical Genetic and Genomic Testing: A Points to Consider Statement of the American College of Medical Genetics and Genomics (ACMG)*, 25 GENETICS MED. 100342 (2023).

208 We recognize that under the Common Rule participant rights to control their data will be different in the context of what Brothers and Clayton describe as 'human non-subjects research'. This is research on 'deidentified information on humans', for example the use of de-identified MRI data in subsequent studies. As Brothers and Clayton point out, 'Because human non-subjects research falls within the category of non-human subjects research, it can generally be conducted without oversight from the IRB and without formal informed consent from those persons whose samples or information are included. However, the only barrier between the deidentified research data and it becoming private information as defined in the Common Rule is an act of reidentification'. Kyle Bertram Brothers & Ellen Wright Clayton, *Human Non-Subjects Research: Privacy and Compliance*, 10 AM. J. BIOETHICS 15 (2010).

209 *Data Sharing*, ADOLESCENT BRAIN COGNITIVE DEVELOPMENT (ABCD) STUDY, <https://abcdstudy.org/scientists/data-sharing/> (accessed July 17, 2023).

Our approach rejects as insufficient a ‘notice and consent’ approach, which has been criticized as failing to adequately protect privacy.²¹⁰ The logic of the notice and consent approach is that if participants are put on notice about data privacy, safety, and sharing practices, those participants can make an informed choice about whether or not to participate. But the approach mistakenly presumes that participants fully understand to what they are consenting.²¹¹ While meaningful informed consent is a prerequisite to research, ‘consent rights alone cannot protect people’s privacy, unless those who handle their data have duties to treat the data with care’.²¹² Consent remains useful as a way to demonstrate respect for persons, but protecting their privacy requires more than just respect; those who handle their data must have clear duties to implement data security standards and to avoid reidentifying data, sharing it further, or reusing it for purposes beyond the one for which it was originally shared.²¹³ Because current state and federal medical privacy laws, such as the HIPAA regulations, will not bind all researchers working with portable MRI technology, we recommend that all data sharing should be subject to DUAs imposing privacy standards as a contractual obligation.

Our recommended approach goes beyond consent at a single timepoint, and emphasizes that consent is more of a dynamic, bidirectional process. A ‘people-centered system’ of privacy protection will ‘acknowledge the agency of individuals over their own data’, while also ‘harness[ing] the potential of partnering with people to assemble high-quality longitudinal data resources’.²¹⁴

In complex big data projects, where brain scans and data are acquired at scale, neither the researcher nor the participant may know with certainty how the brain data will be used, who will use it, or the real risks of re-identification.²¹⁵ In anticipation of this dynamic context, robust data protections are needed. Accountability and transparency to participants will require researchers, technology providers, and institutional IT security experts to develop the framework for secure data acquisition, transfer, storage, and de-identification. Participants should be made aware if their data will be commodified, for instance used to improve proprietary algorithms or sold for subsequent data-mining purposes.

One approach would be to give participants the option to consent on a per-analysis basis and prospectively withdraw or destroy their data. This could be done via direct access, where a research participant could log into a cloud-based neuroimaging profile that allows them to dynamically choose settings providing for opt-in or opt-out sharing

210 Robert H. Sloan & Richard Warner, *Beyond Notice and Choice: Privacy, Norms, and Consent*, 14 J. HIGH TECH. L. 370 (2014); Solon Barocas & Helen Nissenbaum, *On Notice: The Trouble with Notice and Consent*, Proceedings of the Engaging Data Forum: The First International Forum on the Application and Management of Personal Electronic Information (Oct. 2009), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2567409; Helen Nissenbaum, *A Contextual Approach to Privacy Online*, 140 DAEDALUS 32 (2011); Evans, *supra* note 192 (specifically focusing on medical data).

211 Robert H. Sloan & Richard Warner, *Beyond Notice and Choice: Privacy, Norms, and Consent*, 14 J. HIGH TECH. L. 370 (2014).

212 Barbara J. Evans, *The HIPAA Privacy Rule at Age 25: Privacy for Equitable AI*, 50 FLA. ST. U. L. REV. 741 (2023).

213 Evans, *supra* note 192.

214 Barbara J. Evans & Harlan M. Krumholz, *People-Powered Data Collaboratives: Fueling Data Science with the Health-Related Experiences of Individuals*, 26 J. AM. MED. INFORM. ASSOC. 159 (2019).

215 Michael Froomkin, *Big Data: Destroyer of Informed Consent*, 18 YALE J. HEALTH POL’Y L. ETHICS 27 (2019).

of their individual brain data, and to retroactively remove their data from publicly available or utilized datasets. Another option would be to create a repository somewhat akin to a secure platform that functions as a hybrid between a social media profile and an electronic medical record, federated into systems that may be monitored by research institutions, advocacy organizations, or local communities. An established literature on the ethical management of archived data and specimens can inform the development of these policies for portable MRI.²¹⁶ To address such concerns, the consent should include clarifying what will happen to the participant's data if they agree to participate, including archiving and future uses. Participants could also be given an 'opt-in' rather than 'opt-out' for data archiving. Moreover, researchers should be obligated to inform participants of data and privacy breaches.

Some of the privacy solutions that already apply to MRI scans and data will apply to portable MRI as well. For instance, all parties involved in the research process should comply with applicable federal and state laws related to privacy and data storage and data sharing. Applicable federal laws may include HIPAA for covered entities.

Recommendation #13: The technical demands of processing, de-identifying, securely storing, transferring, and managing MRI data are significant. This is why, to date, the entities that have most routinely conducted MRI research are hospitals and larger research institutions. The advent of lower-cost portable MRI will allow new researchers and institutions to pursue MRI research. This recommendation recognizes that it is not enough to simply acquire the machine—the institution and research team must also ensure their capacity to secure and manage the data responsibly. A plan for responsible management of acquired MRI data should be developed before data collection begins, with adequate resources to ensure secure data acquisition, de-identification, and storage, as well as responsible data sharing and compliance with applicable policies such as the NIH data sharing policy. Policies should draw on lessons from relevant guidelines developed by the Institute of Electrical and Electronics Engineers (IEEE), the US FDA, and the National Institute of Standards and Technology (NIST).²¹⁷

Every effort should be made to ensure that all data analyses and processing can be audited, and biostatisticians and Data and Safety Monitoring Board personnel should be trained in forensic principles in case data are corrupted or hacked within the analysis pipeline. In addition, data analysts should work to determine whether analytic strategies are appropriate and valid for the sample and applied appropriately for all participants as well as in conjunction with validated common data elements.

216 Susan M. Wolf et al., *Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets*, 14 GENETICS MED. 361 (2012); Mark A. Rothstein, *Expanding the Ethical Analysis of Biobanks*, 33 J. L. MED. ETHICS 89 (2005).

217 IEEE Data Access and Use Policy, IEEE, <https://www.ieee.org/ieee-data-access-and-use-policy.html#:~:text=Data%20Management%20IEEE%20Data%20will%20be%20stored%20in,securely%20and%20is%20not%20accessible%20to%20unauthorized%20individuals> (accessed July 17, 2023); MRI Information for Industry, U.S. FOOD & DRUG ADMINISTRATION, <https://www.fda.gov/radiation-emitting-products/mri-magnetic-resonance-imaging/mri-information-industry> (accessed July 17, 2023); NIST Technical AI Standards, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, <https://www.nist.gov/artificial-intelligence/technical-ai-standards> (accessed July 17, 2023).

A baseline requirement is to follow applicable institutional and data repository guidelines.²¹⁸ As with privacy concerns, many of the data security solutions will be similar to those being employed for management, storage, and sharing of fixed MRI data. But a particular concern may be the lack of capacity of portable MRI research teams to adequately comply with evolving data security standards. While large hospitals have dedicated professionals to support data management and sharing, similar resources may not be available to inexperienced scanners.

Ensuring appropriate de-identification of brain data raises special concerns. Failure to adequately de-identify neuroimaging data leads to a variety of privacy risks.²¹⁹ However, the neuroimaging community has not yet reached consensus on how and when to optimally de-identify neuroimaging data.²²⁰ At a minimum, portable MRI research should follow emerging best practices for de-identifying data in fixed MRI research, such as skull stripping²²¹ and defacing.²²²

MANAGING INCIDENTAL FINDINGS (IFs) AND RESEARCH RESULTS OF CLINICAL CONCERN

• **Recommendation #14:** Researchers should plan pathways to timely care in the event of incidental findings or concerning research results, regardless of the participant's geographic location, insurance status, and ability to pay for care. Research sponsors should support creation of a responsible plan and pathway, including with funding whenever possible.

An extensive literature addresses management of IFs in MRI research.²²³ However, portable MRI research may be conducted far from a hospital or other clinical facility where IFs requiring clinical attention can be evaluated. Moreover, participants in portable MRI research may face barriers to clinical care in addition to distance, such as lack of a primary care physician, health insurance, or other means to pay for clinical

218 The 2023 NIH Data Management and Sharing Policy also points to institutional and repository policies as the appropriate policies for data security. *Data Management and Sharing Policy*, NIH SCIENTIFIC DATA SHARING, <https://sharing.nih.gov/data-management-and-sharing-policy> (accessed July 17, 2023) ('We have removed the prompt for researchers to address provisions related to the security of scientific data. While we agree with the importance of appropriate data security measures, we believe that technical provisions regarding data security are more appropriately addressed by the institutions and repositories preserving and sharing the scientific data'.).

219 Nakeishma Schimke & John Hale, *NEUROIMAGE Data Sets: Rethinking Privacy Policies*, in PROCEEDINGS OF THE 3RD USENIX CONFERENCE ON HEALTH SECURITY AND PRIVACY (2014), <https://www.usenix.org/system/files/conference/healthsec12/healthsec12-final2.pdf> (accessed Mar. 19, 2024); Minqi Zhou et al., *Security and Privacy in Cloud Computing: A Survey*, in SIXTH INTERNATIONAL CONFERENCE ON SEMANTICS, KNOWLEDGE AND GRIDS (2010), <https://doi.org/10.1109/SKG.2010.19>.

220 Christian Haselgrove et al., *A Simple Tool for Neuroimaging Data Sharing*, 8 FRONT. NEUROINFORM. 1 (2014).

221 Palanisamy Kalavathi & Surya Prasath, *Methods on Skull Stripping of MRI Head Scan Images—A Review*, 29 J. DIGIT. IMAGING 365 (2016).

222 Amanda Bischoff-Grethe et al., *A Technique for the Deidentification of Structural Brain MR Images*, 28 HUM. BRAIN MAPPING 892 (2007).

223 See, eg Judy Illes et al., *Ethical Consideration of Incidental Findings on Adult Brain MRI in Research*, 62 NEUROLOGY 888 (2004); Judy Illes et al., *Ethical and Practical Considerations in Managing Incidental Findings in Functional Magnetic Resonance Imaging*, 50 BRAIN COGNIT. 358 (2002); Judy Illes et al., *Discovery and Disclosure of Incidental Findings in Neuroimaging Research*, 20 J. MAGN. RESON. IMAGING 743 (2004).

workup. In addition, emerging portable MRI technologies may be deployed in research without a firm understanding of their potential to generate IFs, and a clear sense of the likelihood of false positives and false negatives.

Multiple ELSI analyses address managing IFs in MRI, without expressly addressing the added challenges of portable MRI.²²⁴ Operative policies range from having every scan read by a radiologist,²²⁵ to having scans reviewed by an expert only if a researcher flags a brain abnormality,²²⁶ to not having scans read by a radiologist.²²⁷ However, accessing radiologists to screen research scans may be especially challenging in portable MRI research conducted outside of a hospital or large research institution.

Recommendation #14: In all MRI research, fixed or portable, the research team should put into place a protocol for management of IFs and research results of potential clinical concern, including determining thresholds for triggering RoR to research participants and sharing information with a clinician. Researchers should plan pathways to timely care in the event of IFs or concerning research results, regardless of the participant's geographic location and insurance status. Research sponsors should support creation of a responsible plan and pathway, including with funding whenever possible.²²⁸

In planning the research protocol for portable MRI research, the research team should address what IFs and individual-specific research results the particular device and protocol are likely to generate. The ability of a scanner to identify findings of potential clinical significance is related to, but not wholly determined by, the strength of the MRI magnet. Additional factors to consider include contrast and artifacts. The research team will need to understand whether the information the device will generate is of sufficiently high quality to spot IFs and returnable results, and if so, what types. The protocol should also address whether and how soon after scanning the research scans will be reviewed by a radiologist. The protocol should further address what is known about the likelihood of false positives and false negatives.

The consent process should address the possibility of IFs and research results raising potential clinical concern. It should specify the types of IFs and research results that may be identified, clarify how and when findings of concern will be evaluated, state what information will be offered to research participants, and clarify how they can access clinical evaluation and at what cost.

Researchers conducting portable MRI research should ensure timely access to a clinical workup for IFs and problematic research results. Researchers should anticipate

224 Judy Illes et al., *ELSI Priorities for Brain Imaging*, 6(2) AM. J. BIOETHICS 24 (2006); Judy Illes et al., *Incidental Findings in Brain Imaging Research*, 311 SCIENCE 783 (2006); Judy Illes et al., *Ethical Consideration of Incidental Findings on Adult Brain MRI in Research*, 62 NEUROLOGY 888 (2004); John P. Phillips et al., *Stakeholder Opinions and Ethical Perspectives Support Complete Disclosure of Incidental Findings in MRI Research*, 25 ETHICS BEHAV. 332 (2015).

225 Alan C. Milstein, *Research Malpractice and the Issue of Incidental Findings*, 36 J.L. MED. ETHICS 356 (2008).

226 Steven C. Cramer et al., *A System for Addressing Incidental Findings in Neuroimaging Research*, 55 NEUROIMAGE 1020 (2011).

227 Jason M. Royal & Bradley S. Peterson, *The Risks and Benefits of Searching for Incidental Findings in MRI Research Scans*, 36 J.L. MED. ETHICS 305 (2008).

228 We are not suggesting that researchers should bear the cost of subsequent care. Rather, our recommendation is that research funding be adequate for the *pathway* to care. This could involve, for instance, providing for a clinical-grade scan if a non-clinical grade research scan shows a finding of potential concern.

geographical and financial barriers, consider the need to transport participants to suitable medical facilities if there are concerning findings, and incorporate into their protocol a plan that overcomes these barriers.

FACILITATING PARTICIPANT ACCESS TO THEIR MRI DATA

• **Recommendation #15:** Researchers should alert participants that they are entitled to request their data and scans. Once a participant makes this request, the researcher should provide the data and scans, in keeping with applicable law and ethics.

A ‘well-established principle’ of modern privacy law is that individuals should have rights to inspect and receive copies of data that others store about them.²²⁹ This principle is implemented, for example, in the HIPAA Privacy Rule,²³⁰ the US federal Privacy Act,²³¹ various US state privacy laws,²³² and the privacy laws of other jurisdictions such as the European Union.²³³ Access to stored personal data serves various objectives. An individual access right displays respect for individuals’ autonomy and their rights of agency and control over their data. It enhances privacy protections because people cannot assess how much privacy risk stored data poses, unless they can know what is being stored.²³⁴ Access rights enable valid consent, because it is impossible to give an informed consent to data sharing if you do not know what data are going to be shared.²³⁵ Access to one’s stored personal data also enables the exercise of other important civil rights, for example, the First Amendment rights to assemble by forming interest groups or patient advocacy groups with others having test results or traits similar to one’s own, and to lobby for increased research funding to understand those traits better.²³⁶ People also have rights to engage in scientific inquiry themselves and to contribute their data for research by others. The DHHS Office for Civil Rights (OCR) has noted that HIPAA’s access right enables people to ‘directly contribute their

229 See, eg Standards for Privacy of Individually Identifiable Health Information, 65 FED. REG. 82462, 82606 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

230 See, eg 45 C.F.R. § 164.524.

231 Privacy Act of 1974, Pub. L. No. 93–579, 88 Stat. 1896.

232 See, eg California Consumer Privacy Act (CCPA) Fact Sheet, https://www.oag.ca.gov/system/files/attachments/press_releases/CCPA%20Fact%20Sheet%20%2800000002%29.pdf (accessed Mar. 19, 2024); see also MINN. STAT. § 13.04(3) (2018).

233 See, eg European Union General Data Protection Regulation (GDPR), Regulation 2016/679, of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data and Repealing Directive 95/46/EC, art. 15, 2016 O.J. (L 119).

234 Standards for Privacy of Individually Identifiable Health Information, 64 FED. REG. 59,918, at 59,980 (Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160, 164).

235 *Confidentiality of Individually Identifiable Health Information: Recommendations of the Secretary of Health and Human Services, Pursuant to Section 264 of the Health Insurance Portability and Accountability Act of 1996*, U.S. Dep’t Health & Hum. Servs. § II.C.2 (Sept. 11, 1997), <https://aspe.hhs.gov/report/confidentiality-individually-identifiable-health-information> (accessed Mar. 19, 2024).

236 U.S. CONST. amend. I.

information to research'.²³⁷ In addition, there is a growing citizen-science movement, and data access fosters this scientific activity.

Some researchers who use portable MRI may be HIPAA-covered entities themselves, for example, if they are employed by or affiliated with an academic medical center that is itself a HIPAA-covered entity. Data they store in the course of their research will be subject to the HIPAA regulations, including the Privacy Rule's individual access right.²³⁸ OCR has provided extensive guidance on how to comply with this access right.²³⁹ Data generated by HIPAA-covered entities during the course of research are subject to the individual access right, with only narrow exceptions, which DHHS has stated should be used 'rarely, if at all' and should be construed narrowly and in favor of granting people access to their data.²⁴⁰ One exception allows researchers to suspend access to data for the duration of a clinical study, if individual access could 'un-blind' a randomized study.²⁴¹ However, to invoke this exception, the original informed consent for the research needs to disclose that access will be temporarily suspended and commit to restore individual access as soon as the study is completed.²⁴² Another exception allows access to be denied if a licensed health care professional has determined that granting access would pose a danger the life or physical safety of the individual requesting access or to another person.²⁴³ However, in this case, the individual has a right to contest the denial and have it reviewed by another healthcare professional.²⁴⁴

Moreover, DHHS has been very clear that there is a very high threshold for such denials: suicide risk would count, but mere concern that the person might misunderstand or be worried by the information does not qualify.²⁴⁵ It also should be noted that the HIPAA access right is a legal right, administered by OCR, and HIPAA does not call for IRBs to be involved with, act as gatekeepers for, or interfere with people's access to their data. A recent Policy Statement by the American College of Medical Genetics and Genomics (ACMG), which focused on HIPAA access to genomic data, provides a good general summary of the access right and offers practical suggestions on how to reconcile the tension between HIPAA's access right and ethical concerns about the possibility that people might suffer harms if granted access to their own data.²⁴⁶ HIPAA-covered researchers should also be aware that HIPAA does not preempt state laws that grant individuals more access to their data than the HIPAA Privacy Rule does, so researchers should always check state law applicable to the sites where research is conducted. The state laws may provide even greater access than HIPAA provides. Before conducting

237 OFFICE FOR CIVIL RIGHTS (OCR), U.S. DEP'T OF HEALTH & HUMAN SERVS., INDIVIDUALS' RIGHT UNDER HIPAA TO ACCESS THEIR HEALTH INFORMATION 45 C.F.R. § 164.524 (Feb. 25, 2016), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html> (accessed Mar. 19, 2024).

238 *Id.*

239 *Id.*

240 Standards for Privacy of Individually Identifiable Health Information; Proposed Rule, 64 Fed. Reg. 59,918 at 59,918 (Nov. 3, 1999).

241 45 C.F.R. § 164.524(a)(2)(iii).

242 *Id.*

243 45 C.F.R. § 164.524(a)(3)(i).

244 45 C.F.R. § 164.524(a)(4).

245 45 C.F.R. § 164.524.

246 Marwan K. Tayeh et al., *The Designated Record Set for Clinical Genetic and Genomic Testing: A Points to Consider Statement of the American College of Medical Genetics and Genomics (ACMG)*, 25 GENETICS MED. 100342 (2023).

their portable MRI research, the PIs should determine how they will handle requests for brain data and images under HIPAA, and should ensure that mechanisms are in place to be compliant with legal requirements. In addition, researchers should alert participants at the time of informed consent that they have a right to request their data and scans, as participants may otherwise be unaware of this option. Researchers should also disclose how they will comply with their duties to provide data and scans on request.

One significant concern in portable MRI research is that many researchers using this technology may not be HIPAA-covered entities and, therefore, may not have a clear legal obligation to provide participants with access to data about themselves, which are generated during research. However, modern standards for privacy protection and for individual agency/control over data call for individual access rights. Therefore, we recommend that researchers who are not legally required to provide access under the HIPAA Privacy Rule or state laws should nevertheless commit to provide individuals with access that is at least equivalent to that provided under the HIPAA Privacy Rule.

VI. IMPLEMENTATION: RECOMMENDED ACTORS AND APPROACHES

Successful implementation of neuroethics guidance is a recognized challenge.²⁴⁷ To support implementation of the recommendations presented in Part V, here we specify the recommended actors and approaches. As discussed in the Introduction, there is variety in portable MRI research designs already implemented, and future research will bring even more variation in portable MRI technologies, investigators, research questions, geographic locations for scanning, participants, and communities. The salience of each of our recommendations will vary based on these factors. For instance, research conducted by a team of experienced MRI investigators should readily be able to follow Recommendation #1 (to demonstrate competency), but if their research project involves scanning in a high-traffic community center the investigators will need to pay particular attention to Recommendation #7 (safe scanning in community environments) and Recommendation #8 (participant privacy). Moreover, if high-field portable MRI one day allows for fMRI research in the field, Recommendation #10 (on properly interpreting brain scan images) will be of heightened importance. Which recommendations are most important for a given research project will depend on the specific protocols and actors in the project.

There is a shared responsibility to use MRI ethically, and many actors will need to play a role. MRI is a powerful research tool, potentially to be used by many researchers with little or no prior familiarity with MRI. Successful deployment of portable MRI will require capacity-building, training, and empowerment of the broad set of stakeholders who will be impacted by this technology.

Implementation will require new structures at the level of professional bodies, manufacturers, institutions, research teams, participants, their parents or guardians and LARs, and communities. For instance, needed innovations include creating a

247 Matthew R O'Shaughnessy, et al., *Neuroethics Guidance Documents: Principles, Analysis, and Implementation Strategies*, 10 J. L. BIOSCI. (2023), <https://doi.org/10.1093/jlb/lsad025>; Anna Wexler & Laura S. Sullivan, *Translational Neuroethics: A Vision for a More Integrated, Inclusive, and Impactful Field*, 12 AM. J. BIOETHICS NEUROSCI. 1 (2021).

‘participant advocate’ to work with other actors across many of these recommendations.²⁴⁸ Participant advocates have been successfully deployed in cancer research, and that model could be adapted for the neuroimaging context.²⁴⁹ The National Cancer Institute’s Advocate in Research Working Group (ARWG) defined ‘research advocate’ as someone who ‘brings a nonscientific viewpoint to the research process and communicates a collective patient perspective’, and ARWG defined ‘collective patient perspective’ as being ‘created when a person has knowledge of multiple disease experiences and conveys this collective perspective rather than his or her own exclusive experience’.²⁵⁰

The function of a participant advocate is to build research literacy among participants, work to minimize study burden on participants, and at the same time vigorously advocate for the decision-making autonomy of participants. Participant advocates may be employed by research institutions, and should be available to work with research teams at the time of study design and prospective participants at the time of screening and consent, as well as over the course of the study. There are precedents for this approach, for example the University of Utah has an Office of Research Participant Advocacy (RPA), which provides both outreach to communities about clinical research but also educates faculty staff to ensure participant engagement in the research process.²⁵¹

Some broadly applicable policies and tools are needed now. For instance, a consensus statement by a professional society delineating protocols for QA for portable MRI research would be of great value. Similarly, the development of model templates for informed consent, including communicating about privacy, informed consent, AI utilization risks, and potential IFs, should be high priorities for the neuroethics community. Training modules are also needed for the stakeholders listed below, including community members, IRBs, and researchers. We organize these recommended approaches below by stakeholder group, but collaboration across groups will be required. There is not a one-to-one mapping between each of our 15 consensus recommendations and the recommended actions listed below, as one action could advance multiple recommendations and one recommendation could require multiple actions. We note next to each action the relevant recommendations in Table 3.

VI. A. Recommended Actions, by Stakeholder Group

MRI researchers. Successful implementation of these ethical recommendations relies heavily on the research community, which ultimately bears the most responsibility for initiating, conducting, and evaluating MRI research in the field. Before the research is

248 Susan Samson et al., *NCI’s Publication Affiliation Conundrum: Reframing Innovation to Incentivize an Equitable Path for Advocate Representation*, 16 *TRANSL. ONCOL.* 101325 (2022); Denise K. Reinke, *Meaningful Engagement of the Patient in Rare Cancer Research: Sarcoma as an Exemplar*, 45 *CURR. PROBS. CANCER* 100772 (2021).

249 Jane Perlmutter, Nancy Roach & Mary Lou Smith, *Involving Advocates in Cancer Research*, 42 *SEMINARS ONCOL.* 681 (2015).

250 U.S. Department of Health & Human Services (DHHS), *NCI Council of Research Advocates: Advocates in Research Working Group Report*, <https://deainfo.nci.nih.gov/advisory/ncri/ARWG-recom.pdf> (accessed July 17, 2023).

251 Sadie Gabler et al., *Increasing Diversity in Research Through Dedicated Language Access Services*, 106 *CONTEMP. CLIN. TRIALS* 106439 (2021).

initiated, and in consultation with the IRB, the participant community, a participant advocate, and experts as needed, researchers should:

- Demonstrate their competence to carry out their primary research roles. Competence could be demonstrated through a track record of successful research with MRI, completion of relevant trainings and education, or relevant certification and licensure (Rec. 1).
- Develop a formal research protocol in advance, with engagement from the prospective participant community throughout the research lifecycle. When scanning in the field, collaborate with community mobilizers and local liaisons to co-design the research and build local capacity during the research design phase (Recs. 1, 5).
- Ensure that members of the research team who will design and carry out data acquisition and perform data analysis have familiarity with the issues raised by integration of AI into scan acquisition, and interpretation of portable MRI data, and identification of IFs, including associated potential for biases and techniques for mitigation (Recs. 1, 9, 14).
- Throughout the informed consent process and community engagement, be transparent about benefits and risks of using AI in the acquisition, processing, and interpretation of data and images (Recs. 5, 9, 10).
- Create a precise sampling frame to facilitate community conversation and input.²⁵² A sampling frame in this context refers to the subset of the population in the catchment area who meet the study criteria imposed by the research team. For example, if researchers are studying the effects of potentially toxic lake water on brain development of those living nearby, they might define the catchment areas as everyone who lives within one mile of the lake, and then the sampling frame might be everyone within one mile who is 18 years and older and can safely be scanned by MRI (eg no metal implants). A method such as random sampling or stratified sampling could then be used to recruit people from within the sampling frame to join the research study (Recs. 2, 5).
- When creating a plan for engagement, recruitment, and analysis, follow guidelines from the National Academies of Sciences, Engineering, and Medicine (NASEM) on the use of population descriptors in biomedical research²⁵³ (Recs. 2, 5).
- Formulate a plan to mitigate the risk of therapeutic misconception (Rec. 6).
- Establish mechanisms for ongoing communication and information dissemination to the community that are aligned with cultural norms and community expectations. This may require use of translation, interpretation, and accessibility services (Rec. 5).

²⁵² A precise sampling frame will be a necessarily biased subset of the catchment area (based on eligibility criteria of the study), potentially stratified by social identifiers. A well-defined sampling frame will additionally highlight the kind of population to which researchers are hoping to generalize. This will help prevent certain populations from being inappropriately sampled or exploited, and will keep researchers honest about who they're trying to reach. It will also greatly facilitate community engagement and partnership.

²⁵³ The NASEM report was written in the context of genetics and genomics research, but can be adapted for research in the neuroimaging context. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, USING POPULATION DESCRIPTORS IN GENETICS AND GENOMICS RESEARCH: A NEW FRAMEWORK FOR AN EVOLVING FIELD (2023).

- Designate an MRI safety officer or the equivalent for each portable MRI research team. The MRI safety officer will have primary responsibility for ensuring that all scanning is conducted in compliance with applicable safety standards (Rec. 7).
- Set up the scanning environment and develop a consent process to protect the physical and informational privacy of participants (Rec. 8).
- Develop a clear protocol for RoR and IFs before scanning begins, including establishing a pathway to timely radiological consultation and clinical evaluation for IFs and concerning research results. Incorporate a clear description of this process into the consent dialogue and documents (Recs. 6, 14).
- Communicate to participants their legal rights under HIPAA to request data in the designated record set (DRS) and any additional rights under federal and state law. Create a process to provide scans and data at participant request, in keeping with applicable law and ethics (Rec. 15).

As discussed above, some of these recommendations are particularly salient for those MRI researchers without previous training in neuroimaging. For example, many social science research projects aim to explain group differences such as variation in school performance,²⁵⁴ arrest rates,²⁵⁵ and voting patterns.²⁵⁶ If portable MRI lowers the cost of scanning, the possibility of adding MRI scans to social science research will be tempting. Group differences that were previously explained by social and institutional factors may now be interrogated with reference to neurobiological differences. However, using neuroimaging in an effort to ‘explain’ the differences between social groups or to define socially constructed groups is highly problematic and risks reinforcing harmful generalization and stereotypes. A history of scientific racism cautions that biologically based explanations can be scientifically spurious and have significant negative consequences.

MRI researchers outside of IRB oversight. In addition to the responsibilities above, additional steps are needed for MRI research conducted with no legal requirement for IRB review:

- Establish an oversight mechanism such as private IRB review and/or equivalent community-based review so that the research is conducted with oversight guided by the Common Rule and FDA regulations on research with human participants and guidance on MRI safety and operation standards (Rec. 4).

These recommendations apply to research that may not currently require IRB review under federal regulations, such as school projects, educational research,

254 THE BLACK-WHITE TEST SCORE GAP (Christopher Jencks & Meredith Phillips eds., 2011); Roland G. Fryer Jr & Steven D. Levitt, *Understanding the Black-White Test Score Gap in the First Two Years of School*, 86 REV. ECON. STAT. 447 (2004).

255 Paula J. Fite et al., *Explaining Discrepancies in Arrest Rates Between Black and White Male Juveniles*, J. CONSULT. CLIN. PSYCH. 916, 916–27 (2009); Cydney Schleiden et al., *Racial Disparities in Arrests: A Race Specific Model Explaining Arrest Rates Across Black and White Young Adults*, 37 CHILD ADOLESC. SOC. WORK 1 (2020).

256 Benjamin Highton, *White Voters and African American Candidates for Congress*, 26 POL. BEHAV. 1 (2004); Linda F. Williams, *White/Black Perceptions of the Electability of Black Political Candidates*, in BLACK ELECTORAL POLITICS 45 (Lucius J. Barker ed., 2017).

journalistic and documentary investigations, and DIY science research. How to ensure oversight of research beyond the reach of federal regulations deserves more work, and future efforts can engage with an emerging literature on ethics in DIY research.²⁵⁷ We urge researchers to ensure oversight. In addition, manufacturers selling or leasing these machines should consider requiring in the contract that there be ethics review of research use.

Community: Portable MRI research in field settings requires sustained engagement with the communities and populations involved, so that they become partners in the research enterprise. The advent of portable MRI presents the brain science community with an opportunity to engage in research co-design, rather than just soliciting narrow feedback from prospective participants. Such an approach promotes the integrity and impact of the science and requires engagement and partnership skills. Researchers should invite the community to:

- Engage with the MRI research team, professional societies, IRB, and neuroethics/neurolaw/neurorights scholars to co-develop guidelines for research with portable MRI research with underrepresented populations, including addressing the therapeutic misconception, role of AI in generating results, and privacy concerns (Recs. 2, 5, 6, 9, 12, 14).
- Co-develop with the MRI research team a process for participant recruitment, informed consent, scanning logistics, remuneration, and management of IFs that is appropriate to the local community's norms and culture. This may require translation and interpretation services for communities in which English is not the primary language and accessibility consultants to ensure that potential participants with physical or cognitive limitations can enroll (Recs. 2, 5, 6, 9, 12, 14).
- Co-develop the plan for responsible management, storage, and sharing of acquired MRI data and images (Rec. 13).
- Co-develop a plan for communicating research progress and aggregate results, and to identify opportunities for sustained local value including initiatives that incorporate and train community members in imaging and research enterprises (Recs. 5, 15)

Return of value should include concrete plans to provide educational and financial benefits to communities in which the research is being performed. Prior to conducting the research, the community should be engaged in conversations about what the research team can and cannot do, which can help minimize the therapeutic misconception as well. For instance, the research team may clarify that the value is contribution to science, plus having data and brain scans returned on request, and that although this research project is not clinical care, the research team has established a feasible pathway to clinical care for IFs and research results of concern.

²⁵⁷ Christi Guerrini et al., *Finding a Regulatory Balance for Genetic Biohacking*, in CONSUMING GENETIC TECHNOLOGIES: ETHICAL AND LEGAL CONSIDERATIONS (I. Glenn Cohen et al. eds., 2020); Camille Castelyn, *Oversight of Biohacking When the Stakes Are High: Ethics Police or FBI?*, 6 VOICES BIOETHICS 1 (2020); Anna Wexler, *The Practices of Do-It-Yourself Brain Stimulation: Implications for Ethical Considerations and Regulatory Proposals*, 42 J. MED. ETHICS 211 (2016); Nicholas S. Fitz & Peter B. Reiner, *The Challenge of Crafting Policy for Do-It-Yourself Brain Stimulation*, 41 J. MED. ETHICS 410 (2015).

The research team could also offer scanning at local sites such as school gymnasiums, social halls, or community centers and provide compensation to the sites as well as hiring community members as research staff. The key is for researchers to determine the community that they are trying to reach, and then to consult them beforehand about the research goals and mutually beneficial means to accomplish the research.

Professional societies, manufacturers, and neuroethics scholars: Research teams need not develop these strategies on their own. Professional societies, manufacturers, and scholars working at the intersection of neuroimaging, ethics, and law have a responsibility to collaborate on guidance documents and tools.

For instance, as new portable MRI technologies are brought to market, variation in scanner hardware, software, and analysis will become the norm. And if research teams are using different technologies, expert bodies will need to consider the standards that researchers should use to report and describe MRI brain data. Although not directly analogous, lessons might be drawn from the ACMG efforts to develop ‘categories of sequence variations for the purposes of clinical reporting’.²⁵⁸

For MRI, a number of standard-setting bodies are well positioned to develop guidance. For instance, Digital Imaging and Communications in Medicine (DICOM) is the accepted standard ‘to transmit, store, retrieve, print, process, and display medical imaging information’.²⁵⁹ Both traditional MRI and the newer lower-field devices such as Hyperfine Swoop® utilize the DICOM standard. The utility of an imaging modality for a particular research question or disease assessment is typically explored through the traditional methods of hypothesis testing and high-quality peer reviewed publications. In clinical contexts, the AAN promulgates practice guidelines regarding the use of MRI in diagnosis of particular diseases.²⁶⁰ For disease-specific imaging uses, other professional societies will take the lead. For instance, in 2018, the National Institutes of Aging and the Alzheimer’s Association called for a research framework that defines AD based on neurobiology (including MRI).²⁶¹ In epilepsy, the International League Against Epilepsy (ILAE) has published guidance on the use of neuroimaging for epilepsy patients.²⁶² Professionals beyond medicine and the natural sciences will also need to consider standards for MRI research. For example, there are no existing guidelines for conducting legal research with portable MRI.

As LF MRI and other types of portable MRI emerge, the peer-reviewed literature and guidelines from professional societies will evolve. Studies will examine the analytic

258 These categories are: ‘benign, likely benign, variant of unknown significance (VUS), likely pathogenic, and pathogenic’. C. Sue Richards et al., *ACMG Recommendations for Standards for Interpretation and Reporting of Sequence Variations: Revisions 2007*, 10 *GENETICS MED.* 294 (2008).

259 Mario Mustra et al., *Overview of the DICOM standard*, in 50th International Symposium ELMAR 39, 39–44 (2008), https://www.vcl.fer.hr/papers_pdf/Overview%20of%20the%20DICOM%20Standard.pdf (accessed Mar. 19, 2024).

260 See, eg *The Role of Diffusion and Perfusion MRI for the Diagnosis of Acute Ischemic Stroke and The Utility of MRI in Suspected MS*, Therapeutics and Technology Assessment Subcommittee (2010), <https://doi.org/10.1212/WNL.0b013e3181e7c9dd>.

261 Jack Clifford et al., *NIA-AA Research Framework: Toward a Biological Definition of Alzheimer’s Disease*, 14 *ALZHEIMERS DEMENT.* 535 (2018).

262 *DIGITAL IMAGING AND COMMUNICATIONS IN MEDICINE*, <https://www.dicomstandard.org/> (accessed July 17, 2023); Commission on Neuroimaging of the International League Against Epilepsy, *Recommendations for Neuroimaging of Patients with Epilepsy*, 38 *EPILEPSIA* 1255 (1997).

and clinical validity of LF MRI technology with respect to brain disorders. Needs include the following:

- Adapt guidelines on safety and research protocols for fixed MRI to address research with portable MRI research in geographically remote sites (Rec. 7, 8).
- Develop guidelines for conducting field-based MRI research with underrepresented and marginalized populations (Recs. 2, 5).
- Adapt existing standards for management, storage, and sharing of fixed MRI data to apply to portable MRI data (Recs. 12, 13)
- Provide guidance to researchers and research oversight personnel on how to evaluate research protocols for use of portable MRI in social science and citizen science research (Recs. 1, 3, 4).
- Co-develop with community leaders (where portable MRI research is being conducted) new training modules specific to portable MRI safety, setup, use, storage, and equipment transport (Recs. 1, 7, 8).
- Establish QC processes for portable MRI in research (Rec. 11).

IRBs: Key to the successful implementation of these recommended solutions is review of research protocols and ongoing oversight. Often this will be done by an IRB. Indeed, IRB oversight may be required by some federal and state rules. In addition to the oversight that an IRB exercises over all studies, in the context of portable MRI research, the IRB should:

- Require all members of the research team to demonstrate their competence to carry out their research roles, eg provide evidence of previous successful MRI research, or completion of relevant education and training (Rec. 1, 3).
- Require researchers to set up a scanning environment that ensures privacy and security and develop a consent process to protect the physical and informational privacy of participants (Rec. 8).
- Require research teams to have the requisite expertise to interpret the scans for research purposes (Rec. 10).
- Require research teams to set diversity participation goals that reflect the prevalence of the disease/condition being studied and composition of the participant community. IRBs can provide access to education and tools such as transcription and translation services for study documents, explainer tools and applications to define and measure participant demographics, and the means to develop participation/prevalence guidelines for the diseases being studied (Recs. 3, 5).
- Require researchers to address management of IFs and research results of potential clinical concern (Rec. 14).
- Require researchers to address community engagement in their protocol²⁶³ (Recs. 3, 4, 5).

²⁶³ This required content could follow the model of Canada's Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans—TCPS 2 (2018). As a condition of funding from the Canadian federal government, researchers must adhere to the TCPS policy on how the 'value of respect for human dignity and the core principles of Respect for Persons, Concern for Welfare, and Justice . . . apply to research involving Indigenous peoples' and 'ethical review of a proposed project shall be attentive to the specific context of the project and the community involved'. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada,

For studies that are monitored by an IRB, the IRB's initial and continuing reviews provide mechanisms for ensuring that researchers implement these recommended solutions. For studies that are not covered by regulations requiring IRB oversight, these recommendations urge that researchers nonetheless arrange for oversight through a private IRB and/or community-based review that provides comparable oversight.

Funders & sponsors: Research funders and sponsors have significant opportunities to shape the trajectory of portable MRI research. Indeed, because our recommendations require financial investment and development of new capacity for multidirectional learning both in the research team and the community, dialogue between the research community and funders should be a top priority. To facilitate the development and adoption of our recommended solutions, when soliciting and evaluating proposals funders should:

- Require researchers to demonstrate their competence to carry out their primary research roles (Rec. 1).
- Require safety training for all study personnel who will utilize portable MRI in research (Recs. 1, 7).
- Require the research team to have the requisite expertise to interpret the scans for research purposes (Recs. 1, 10)
- Require that the research team develop a plan to prioritize resources to facilitate pathways to timely evaluation and care for IFs and research results of potential clinical concern, including for geographically remote and non-insured participants (Rec. 14).
- Provide specific funding support to enable translation and interpretation services to increase access to research participation for non-English speakers, and those with physical and cognitive differences (Recs. 1, 5).

Additional stakeholders: Journal Editors: Ensure that peer reviewers for portable MRI research include individuals familiar with community-based research. In review of submitted manuscripts, evaluate attention to ethics, participant safety, and diversity and inclusion in research.

- **MRI Accreditation Organizations:** Establish a QC accreditation process for portable MRI that includes associated AI components (Rec. 11).
- **FDA:** Promulgate safety guidelines specific to portable MRI and serve as a model for similar regulatory agencies in other countries (Rec. 7).
- **FTC:** Monitor claims being made by firms marketing portable MRI technologies and serve as a model for similar regulatory agencies in other countries (Rec. 10).

VI. B. Engaging the Public

The proliferation of brain imaging technologies will necessitate new strategies to build literacy and dialogue in the diverse publics who will be involved in research and will consume reports of research findings. Community engagement is a cornerstone of our

recommendations. This calls for development of resources and efforts for bidirectional learning, so that communities learn about portable MRI research and researchers learn about community priorities, concerns, and values.

Engaging the broader public will be particularly important if neuroimaging research is weaponized as disinformation, for instance to renew spurious claims of racial or class superiority on the basis of MRI images. Improving public communication has been identified as a priority in neuroscience.²⁶⁴ But few entities currently provide support, and deeper public engagement is needed.²⁶⁵ Professional societies can also help address these concerns through their public engagement efforts and codes of conduct.

VII. CONCLUSION

This article focuses on the ELSI issues requiring most immediate attention. However, more work is needed on the role of government regulation, in particular the FDA's role in ensuring safe and effective MRI scanning in novel sites. We focus primarily on the research context, but issues that will arise if portable MRI is used in direct-to-consumer contexts such as brain spas or brain health clubs may require further guidelines. Finally, this article focuses primarily on the US context, and consideration of international research is warranted.

Our analysis has anticipated likely use cases and associated ELSI issues, but we recognize that the future of portable MRI will include unforeseen developments. The recommendations we propose in this initial guidance document will need to be refined in response to these unanticipated events.

Widely accessible and highly portable MRI has the potential to improve the inclusiveness of neuroimaging research and advance knowledge of the human brain. But this power may be misused. To promote the value of portable MRI, while preventing misuse, this article identifies 15 core ethical and legal challenges and recommended solutions. We identify the key actors and implementation approaches. Working together, these stakeholder groups can usher in a new era of CEnR using portable MRI technologies.

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²⁶⁴ Judy Illes et al., *Neurotalk: Improving the Communication of Neuroscience Research*, 11 NAT. REV. NEUROSCI. 61 (2010).

²⁶⁵ Jayatri Das et al., *Neuroscience Is Ready for Neuroethics Engagement*, 21 FRONT. COMMUN. 1 (2022).

COMPETING INTERESTS

M.S.R. is a founder and equity holder of Hyperfine, Vizma Life Sciences, Intact Data Services, and Q4ML. **M.S.R.** serves on the scientific advisory boards of ABQMR, Synex Medical, Nanalysis, and O2M Technologies. **J.T.V.** is a co-founder of MR Access, Inc. **E.T.** is a co-founder of Adialante.

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HUMAN SUBJECTS REVIEW

The University of Minnesota Institutional Review Board reviewed this study and determined that it meets the criteria for exemption from IRB review (UMN IRB #STUDY00015482, STUDY00015699, STUDY00010304).