Conducting Research with Highly Portable MRI in Community Settings: A Practical Guide to Navigating Ethical Issues and ELSI Checklist

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Keywords: Portable MRI, Neuroimaging, Research Ethics, ELSI, Community Engagement, Checklist

Abstract: Highly portable and accessible MRI technology will allow researchers to conduct field-based MRI research in community settings. Previous guidance for researchers working with fixed MRI does not address the novel ethical, legal, and societal issues (ELSI) of portable MRI (pMRI). Our interdisciplinary Working Group (WG) previously identified 15 core ELSI challenges associated with pMRI research and recommended solutions. In this article, we distill those detailed recommendations into a Portable MRI Research ELSI Checklist that offers practical operational guidance for researchers contemplating using this technology.

Introduction

The growth of neuroscience research has been fueled by advances in neuroimaging.[1] Magnetic resonance imaging (MRI) research, however, remains expensive and is generally limited to academic institutions and hospitals because this research has traditionally required participants to travel to a fixed scanner.[2] The advent of new, highly portable MRI (pMRI) technologies ushers in a new era of MRI research that can now be conducted outside of medical centers and in community settings.[3] Such expanded access to MRI may help facilitate more diverse and representative MRI research participation, and empower participant communities as co-creators of MRI research designs.[4]

This technological breakthrough also introduces ethical, legal, and societal issues (ELSI).[5] Some of these ELSI issues are familiar, and have been addressed in prior ELSI analyses of fixed MRI neuroimaging as well as guidance from MRI research sites on informed consent,[6] incidental findings (IFs),[7] adverse events,[8] privacy,[9] data management and sharing,[10] and screening participants for safety in the scanning environment.[11] While this existing guidance for traditional

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The Journal of Law, Medicine & Ethics, 52 (2024): 769-785.
DOI: 10.1017/jme.2024.162

fixed MRI researchers and related literature such as that on designing functional MRI research[12] are a useful starting point, they are insufficient guidance for ethical pMRI research.

In a companion article, we identified four features of pMRI research that are new: (**1**) **users:** new types of researchers, including those who have not previously used MRI, may be able to utilize pMRI; (**2**) **locations:** pMRI can be deployed in many new locations outside the hospital; (**3**) **participant populations:** with more user-friendly pMRI deployed in new locations, pMRI research will reach communities and participants who have not previously participated in MRI research studies; and (**4**) **variable image quality:** the introduction of new pMRI technologies, varying in field strength and deployed in new settings, will introduce increased variation in image resolution and contrast.[13]

Transformative innovations in MRI have historically required a corresponding innovation in neuroethics frameworks as well. For example, the National Institute of Mental Health (NIMH) Council Workgroup on MRI Research Practices convened in 2005 because the evolution of MRI from "a tool used primarily for medical diagnosis" to a tool for "clinical and basic cognitive and affective neuroscience research" had resulted in a "lack…of any comprehensive guidance to assist investigators in reviewing the issues posed by MRI research concerning the safety and protection of human participants."[14] American College of Radiology (ACR) guidance at the time focused primarily on medical settings, rather than MRI research in non-medical settings.[15]

Twenty years ago, though, the NIMH Workgroup did not anticipate the pMRI technologies now emerging.[16] For example, most guidance for MRI researchers is silent on how researchers should engage communities prior to scanning at a community site and does not provide guidance on how researchers should manage the geographic distance between the site of data acquisition and the researchers' home institutions.[17]

Over the past four years a Working Group (WG) hosted by the University of Minnesota Consortium on Law and Values in Health, Environment & the Life Sciences has developed guidance to fill this gap. As noted above, we identified 15 core pMRI research ELSI issues along with recommended solutions.[18] These consensus recommendations were developed through an iterative working group process supported 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).

Our prior publication is devoted to deriving and explicating those 15 recommendations. However, operationalizing that guidance requires practical tools that investigators contemplating pMRI research can use, including new researchers outside of research institutions with a history of MRI research. To address this need we have created a new tool — an ethics checklist for pMRI investigators.[19]

Checklists have been utilized in many sectors to improve decision-making in complex tasks that involve multiple steps and can help minimize errors.[20] Checklists have also been utilized in bioethics.[21] By operationalizing the 15 recommendations into a sequential set of checklist steps, we aim to make our ethics guidance readily accessible to pMRI researchers who are not familiar with the complex ELSI issues they are likely to face. We are not, however, suggesting that complex ethical issues can be reduced to simple steps, nor that the checklist can be read once and then set aside. For example, we include as a step in our check-

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list "Regularly seek community feedback throughout project including scanning." In this and other steps, the checklist suggests a dynamic process in which research strategy and ethical issues are regularly revisited in conversation with community partners.

Checklists are familiar in MRI research. However, existing checklists and screening tools for MRI researchers typically focus on safety concerns such as ensuring that MRI participants have no contraindications for scanning (e.g., a pacemaker or metal in their body).[22] While ensuring safety is of paramount importance, the lack of attention to ELSI issues in existing checklists leaves pMRI investigators unprepared to identify and navigate the range of ethical and legal issues likely to arise in their work. The Portable MRI Research ELSI Checklist provides clear, actionable steps across all stages of the research lifecycle.

Using the 15 recommendations previously published as the starting point, we aim here to provide MRI investigators with the steps needed to operationalize those recommendations as they design and implement pMRI research in new community field settings, including those that are rural or remote. While pMRI research is also occurring within the hospital, for instance at the bedside and in ICUs,[23] we focus in this article on the setup and use of pMRI in community settings. We adopt a commonly used definition of community: "[a] group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings."[24]

The co-authors of this article are the 3 project Principal Investigators and an expert Working Group. "Over the course of the project, the WG included 15 members with expertise in neuroscience, neuroimaging, radiology, research ethics, community engagement, law, neurology, and artificial intelligence."[25] We met across 4 years, completed a structured process of analysis and consensus building, and used a modified Delphi process in Year 1.[26] In December 2023, we hosted a public conference, and feedback from conference attendees, including community researchers, was utilized to further refine this article and the accompanying symposium articles.[27]

I. Context: A Brief Introduction to Highly Portable and Accessible MRI

Innovations in engineering and physics are improving the accessibility and portability of MRI.[28] To date, MRI that is considered to be mobile has required installation of an MRI machine on a flatbed truck or inside a large trailer.[29] Although the trailer can be driven to different locations, and in this sense is mobile, new technologies have made greater strides to facilitate accessibility by reducing scanner size and weight, lowering cost, providing open source MRI build instructions, relaxing requirements for extensive cooling systems, and running off a battery, standard power outlets, and even a low-cost gasoline powered generator.[30] These design features allow pMRI machines to be used to scan in locations that MRI research has not reached before.

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Three technological developments are especially relevant to pMRI ethical analysis. First, new pMRI machines are being developed for research outside the hospital and can be temporarily set up in a variety of non-hospital community settings. These pMRI machines vary in terms of field strength, spatial resolution, image contrast, temporal resolution, cost, portability, and ability to provide clinical-grade scans.[31] Second, accessibility may be expanded by delivery of autonomous MRI systems that can scan in remote sites even without skilled technicians in those locations.[32] Autonomous MRI (aMRI) is "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."[33] Third, communities and researchers may be able to build their own MRI machines. Multiple groups are pursuing build-your-own MRI projects.[34]

Portable MRI scanners vary in accessibility and portability,[35] but a key distinction is between high-field (HF), mid-field (MF), low-field (LF), and ultra-low-field (ULF) MRI. Consistent with the defini-

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tions recommended in the International Society for Magnetic Resonance in Medicine (ISMRM) 2022 Workshop on Low Field MRI, we define HF as above 1T, MF as 0.1–1T, LF as 0.01<-0.1T, and ULF as < 0.01T.[36] Lower-field strength machines generally are more portable than higher-field scanners but produce lower resolution images than higher-field systems. At present, LF pMRI is limited to structural imaging, not functional MRI.

II. The Dawn of Community-Based Research with Portable MRI

Scientific advances enabling pMRI are rapidly progressing. An online supplementary Figure illustrates the timeline of key pMRI scientific discoveries and accompanying milestones in funding, ethical guidance, and professional meetings (https://perma.cc/NYW7-LVF5). Members of the WG who have been at the forefront of pMRI development identify 2007 as a critical genesis moment. In 2007, the Defense Advanced Research Projects Agency (DARPA) issued a request for proposals (RFP) "for the development of a transportable Magnetic Resonance Imaging (MRI) system capable of field deployment to in-theater Combat Support Hospitals for diagnosis and assessment of traumatic brain injuries to front-line soldiers, sailors, and airmen."[37] While DARPA ultimately did not fund projects based on this RFP, multiple inventors and institutions submitted proposals that would develop into significant technological advances.

Starting in 2010, physicist Matthew Rosen received funding from the U.S. Department of Defense Congressionally Directed Medical Research Programs (CDMRP) to develop ULF-MRI.[38] Research supported by CDMRP contributed to technological development that led to the founding of LF-MRI company Hyperfine in 2014. In 2014, biomedical engineer J. Thomas Vaughan, physicist Michael Garwood, and a team at the University of Minnesota received funding from the NIH for a project on "Imaging Brain Function in Real World Environments & Populations with Portable MRI."[39] Additional NIH funding in subsequent years to support pMRI led to the creation of a novel pMRI scanner capable of scanning at 1.5T.[40] Further important innovations have been made in noise cancellation and the use of artificial intelligence (AI) to improve image resolution.[41]

These advances in science and engineering are starting to translate into real-world clinical and research applications. Since 2020 pMRI has been used for the first time to scan participants in a small van that travels to participants' homes (2020),[42] in an ambulance (2022),[43] and in community hospitals in low-resource settings (2022).[44] The Ultra-Low field Neuroimaging In The Young project began in 2020 to use LF-MRI to conduct scans of children in many low- and middle-income countries.[45] A research team in Canada has piloted the use of LF-MRI in a remote hospital serving primarily Indigenous populations.[46] Another research team has created a "Scan-a-Van" designed to "(1) travel on local and dirt roads without a commercial license to allow access to rural communities; (2) use portable or fixed power; and (3) maintain the ability to easily load and unload the scanner for imaging in or outside the vehicle (e.g., in a family garage, in a school, or in an assisted living center)."[47]

The user-friendly nature of new pMRI scanners will also enable researchers who do not have previous MRI experience to initiate neuroimaging research. New MRI users might include psychology professors at a college that does not have a robust research infrastructure, social science researchers who wish to explore the neural correlates of socially relevant decision-making, or community researchers investigating brain changes relating to toxic exposures or trauma. By empowering new researchers and research in new populations, pMRI has the capacity to democratize brain research. Still, ethical and legal concerns associated with adequate training, oversight of this new brain research, and safety for those being scanned and bystanders, are significant.[48]

To illustrate what research will look like in community settings, **Box 1** provides 3 vignettes describing current and future hypothetical research involving pMRI. The first use case considers a pMRI research team that describes their approach as aiming for "Residential MRI: Development of a mobile *anywhere-everywhere MRI lab*."[49] The second use case describes open-source MRI, to allow teams in remote and low-resource settings to build their own machines with open-source materials.[50] The third use case is hypothetical. It imagines how pMRI could be utilized by social science researchers in tandem with community members to study the relationship between brain structure and financial decision-making in older adults.

III. Portable MRI Research ELSI Checklist

To facilitate practical implementation of previously published recommendations (see **Appendix**), the Portable MRI Research ELSI Checklist addresses four basic stages in the life cycle of pMRI research conducted in the community (**Figure 1**):

- Stage I: Creating Research Protocol
- Stage II: Preparing for Scanning
- Stage III: Conducting Scanning
- Stage IV: After Scanning

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Box 1

Current pMRI use cases in progress and a future hypothetical use case.

***Currently in Progress:* The "Anywhere-Everywhere MRI Lab"**[51]

An MRI physicist and "a pediatric neuroscientist by passion," Dr. Sean Deoni is working with colleagues to engineer a new approach to MRI research that will "allow 'anywhere and everywhere' scanning and achieve three functional aims: 1. Travel on local and dirt roads without a commercial license; 2. Use portable or fixed power; and 3. Maintain the ability to easily load and unload the scanner, for imaging in or outside the vehicle." To pilot this idea, Deoni and colleagues at Rhode Island Hospital have built a Scan-a-Van containing a 64mT LF-MRI scanner. Customizing a Ford transit van, the team installed a scanner, lifting system, and accessories such as a power generator, battery packs, and a WiFi router. To date, Scan-a-Van has acquired brain images outside research participant homes for research on child brain development, and future goals are to scan "in rural locations, at daycares, schools, assisted living centers, [and] … in-patient facilities …."[52] Two members of our Working Group (Jackson and Shen) have collaborated with Scan-a-Van researchers to conduct pilot scanning as part of a demonstration project at a community health center in Roxbury, Massachusetts.

***Currently in Progress:* Build It Yourself Open-Source MRI** [53]

MRI machines have historically been manufactured by a small number of large companies. But over the past several years a movement toward open-source MRI has emerged with a goal of building "MR scanners mostly if not fully consisting of open source components."[54] A version of this approach has been implemented by a research team led by radiologist Andrew Webb at Leiden University Medical Center (LUMC). In 2022 this LUMC team "worked with local students and professionals at the Mbarara University of Science and Technology (MUST) [in Uganda] to construct, on site, the first custom-built point-of-care MRI system in Africa."[55] Parts were shipped from the Netherlands to Uganda and built on site. The advent of open-source MRI could allow communities across the world to build their own MRI scanners, both for clinical and research use.

***Hypothetical Case:* Community-Engaged Research on MRI and Financial Decision-Making in Older Adults**

In the future both LF- and HF-portable MRI could be used to facilitate community-engaged partnerships to explore many cognitive neuroscience questions. For example, older adults are at risk of financial fraud in part due to changes in cognition associated with age-related changes in brain structure and function.[56] Portable MRI could be used to better understand the relationship between brain structure (and brain function with HF-MRI), MRI correlates of mild cognitive impairment (MCI), and performance on a financial decision-making task. The scanning could be integrated into a behavioral research study and could take place in the community room at a senior living center. The research could be jointly designed by a group of residents at a senior living community and psychology professors at a local college or university.

At each stage, we cluster together the checklist items within five sub-sections: Community, Personnel, Safety & Oversight, Data & Incidental Findings, and Informed Consent. Each stage includes the Community sub-section, as we place strong emphasis on community engagement throughout the research lifecycle. The additional sub-sections appear within the stage(s) where they are most timely.

Conducting pMRI research in the community will be more complicated for investigators than conducting traditional MRI research with a fixed machine inside a hospital or research facility. The reasons for this added complexity are:

- **Lack of established protocols:** Research with traditional fixed MRI is conducted using well-established operational, safety, and ethical governance protocols. Because research with pMRI in the community is new, there is not yet consensus on best practices. Indeed, many pMRI studies in the community in the next few years will be the first of their kind.
- **Greater variation in scanning environment:** Research with traditional fixed MRI machines occurs in a relatively homogenous set of environments. The ACR guidelines on MRI safety require the machines be placed in certain areas of buildings, and the requirements to keep the machines running necessarily constrain where they can be located. By contrast, pMRI will be used in a wide variety of locations.
- **Increased physical distance between site of data acquisition and medical expertise:** The physical distance between the scanning site and the location of the researchers, medical expertise, and medical facilities will increase with many pMRI protocols. As a result, managing

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Figure 1

Portable MRI Research ELSI Checklist

I. CREATING RESEARCH PROTOCOL

A. COMMUNITY

- ☐ Researchers should clarify: Why are we pursuing this research, what community do we hope to work with, and what value do we hope to create for science and for the participant community?
- ☐ Initiate engagement with local community to build trust, assess community needs, and local capacity
- ☐ Co-create research questions
- ☐ Identify ethical issues, including establishing plans for safety, incidental findings, data management, storage & sharing
- ☐ Formalize community partnership agreements

B. PERSONNEL

- ☐ Establish diverse research team
- ☐ Ensure expertise to interpret scans

C. SAFETY & OVERSIGHT

- ☐ Ensure all research team members have safety training and demonstrated competence to fulfill roles
- ☐ Obtain IRB (or equivalent) approval, form Safety Committee, establish Community Advisory Board, and ensure regulatory compliance

D. DATA & INCIDENTAL FINDINGS

- ☐ Establish plan for data management across full pipeline, including data acquisition, de-identification, cloud storage, AI analysis, and data sharing
- ☐ Ensure adequate resources for implementing data management plan
- ☐ Establish a pathway for participants with incidental findings to access clinical evaluation and care

II. PREPARING FOR SCANNING

A. COMMUNITY

- ☐ Engage and recruit participants through sustained engagement even after the scanning concludes
- ☐ Set up scanner with community input on logistics

B. SAFETY & OVERSIGHT

- ☐ Check for updated safety guidelines from professional bodies
- ☐ Comply with ongoing quality control protocols

C. INFORMED CONSENT

- ☐ Utilize community engagement, background education, and consent process to address potential participant misunderstanding about clinical benefits deriving from research
- ☐ Obtain informed consent, including discussion of how AI will be used in this research

III. CONDUCTING SCANNING

A. COMMUNITY

- ☐ Regularly seek community feedback throughout project including scanning

B. SAFETY & OVERSIGHT

- ☐ Comply with safety requirements and QC when acquiring and interpreting brain data
- ☐ Maximize participant privacy in scanning environment, with consent for presence of observers

IV. AFTER SCANNING

A. COMMUNITY

- ☐ Share aggregate research findings with community

B. DATA & INCIDENTAL FINDINGS

- ☐ Ensure competent data analysis, interpretation, and write-up in research publications
- ☐ Inform participants of rights to request data
- ☐ Securely store brain data, and communicate with participants about the data
- ☐ Give participants access to and agency over their brain data
- ☐ Share data with researchers and commit to responsible data management, transparency, and accountability
- ☐ Ensure that all scans are read by qualified experts, with IFs and concerning findings offered to participants
- ☐ Ensure that participants with IFs and concerning findings have access to timely clinical evaluation and care

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> IFs and establishing a pathway to follow-up evaluation may prove more difficult.[57] In addition, because MRI researchers may scan at the community site and then return to their research home far away from the site of data acquisition there is a heightened concern about 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."[58]

Recognizing that pMRI research will require that investigators meet the ELSI challenges, we now consider what steps are needed before, during, and after scanning. The Checklist (**Figure 1**) is designed primarily for research that is being conducted in the community, where pMRI can realize its greatest potential for revolutionizing MRI research by increasing the representativeness of populations studied and deepening community engagement.

Research in the community brings with it additional obligations not typically required of standard MRI research protocols, for example the duty of researchers to partner with the local community in the research enterprise.[59] We offer below general guidance, but recognize that a core tenet of community-engaged research is that "the experience of community differs from one setting to another."[60] This general guidance will need to be adapted in partnership with the relevant community to fit the particular research context.

Stage I. Creating Research Protocol

The steps under the "Creating Research Protocol" heading are intended to strengthen connections between the research team and the community in which the pMRI research will occur. In this early stage of the project, the research team should engage the community, build a team with appropriate personnel, put into place a safety and oversight plan, and prepare to securely handle the pMRI data and potential IFs.

A. Community

A key feature of pMRI is the flexibility it allows researchers in choosing where to scan. Thus, it is critical for investigators to carefully reflect on where they propose to scan, why they want to scan there, what type of pMRI scanner to use, and what value they hope to create both for the research community and for the participant community. As a first step that researchers should clarify for themselves and for research oversight bodies such as the institutional review board (IRB) and community oversight board: Why are we pursuing this research, what community do we hope to work with, and what value do we hope to create for science and for the participant community? In some instances, for example in the second vignette where a community itself initiates the MRI research, this question will be answered jointly by an integrated community research team. This is also the stage at which the research team will need to determine what type of pMRI scanner they will utilize.[61]

The research team must determine why pMRI is scientifically justified for the research, and why acquiring brain data from participants in a particular field site is valuable. For example, a scan-anywhere van can theoretically be driven to any neighborhood. Deciding on which neighborhoods to approach and why is a crucial first step. Similarly, a study of financial decision-making and brain structure compels researchers to decide where to conduct their study and in what population, for example collaborating with a senior living home in a higher-income neighborhood or in a lower-income neighborhood.

Initiating engagement with the local community, co-creating research questions, and developing sufficient local capacity to support the proposed pMRI research are crucial steps. The third vignette, for example, envisions researchers working closely with leadership and community members at the senior living center to create the research protocol. This early stage is also the time to identify and begin to address ELSI issues. These include issues such as establishing plans for scanning safety; managing IFs; and data management, storage, and sharing. A community partnership agreement can be used to formalize the plans developed in this first stage. Such an agreement establishes the mutual expectations of the community, the researchers, and their institution.[62]

While neuroimaging researchers may be relatively new to community-engaged research practices, extensive resources for initiating and sustaining community-engaged research have been developed in other fields (see **Appendix**).[63] Strategies include identifying and partnering with community members who are trusted in the community, building local capacity to partner in the research enterprise, and working with community leaders to identify community needs and how the proposed MRI research can add local value. For example, developing plans for return of both aggregate and individual-specific results, as well as establishing pathways to clinical evaluation and care for IFs and concerning research results may be valued by the community. Community-engaged research is not a single practice, but rather encompasses a spectrum of community engagement strategies.[64] The

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extent of community involvement can vary, ranging from simply informing the community about research opportunities and outcomes, to fully collaborating with the community on all aspects of the research project and enabling community-led research.[65]

B. Personnel

With a community partnership agreement in place and community trust established, the project should next identify the personnel needed to carry out the research protocol. The researchers should establish a team reflecting the diversity of the community in which the research is taking place. Research teams are likely to find that including diverse backgrounds on their research teams, especially members who can work effectively with the local community, will advance successful community collaboration. Community members can also be hired as research staff or consultants.

It is important that the research team has the expertise to interpret scans. Some projects, such as the scan-anywhere van, are connected to a health system and so may have less difficulty engaging radiologists to read pMRI research scans. But in the open-source MRI example, where MRI is being introduced in a remote setting for the first time, it may be more challenging to find such expertise. Similarly, for a social science team new to MRI research and without ties to a biomedical research facility, it may not be clear how to recruit and pay for experts to interpret the MRI scans. These issues should be resolved early in creating the research protocol.

C. Safety & Oversight

Ensuring proper oversight and safe scanning is essential for pMRI research, as it is for fixed MRI research. Our WG emphasized that all research team members should have safety training and demonstrate competence to fulfill their roles. Preparation for pMRI research will look different depending on the previous experience of the research team. For example, some research teams may have decades of experience with fixed MRI research, but have no experience working in the community. In our vignette involving research in a senior living center, for example, the social scientists on the team might need to collaborate with experienced MRI investigators in order to ensure safe and effective scanning. By contrast, some research teams may have extensive experience conducting community-engaged research, but little prior exposure to MRI. Whatever the prior experience of the research team, our project's consensus recommendation is that "all members of the MRI research team should have demonstrated competence for the research role they are playing."[66]

Competence can be demonstrated in a variety of ways, including through published research, relevant training, or certification/licensure. Our companion article argues that professional societies should promulgate new safety guidelines and training programs, and research teams should monitor and implement those guidelines. In the meantime, those engaging in pMRI research should take advantage of existing training mechanisms and adapt them as needed for field-based research. The research team should also be aware of the limitations of the pMRI machine they are using and how MRI findings can be misused.

Oversight of pMRI research and compliance with applicable laws and regulations (e.g., Food and Drug Administration [FDA] regulation and Common Rule requirements) must be ensured.[67] MRI is not always safe.[68] Whether portable or fixed, MRI can cause negative health outcomes such as anxiety, skin burns, headaches, and interference with implanted health devices such as pacemakers.[69] In addition, research uses of pMRI will involve new prototype methods (pulse sequences), RF coils, monitoring devices, and other hardware. Pulsed coils can interfere with sensors and other devices and can cause burns to the participant. To minimize these potential harms, the research protocol should be reviewed and approved by an MRI Safety Committee, and this may involve working through a detailed safety checklist. If an MRI Safety Committee is not yet in place, establishing one is important. At the University of Minnesota, for example, an MRI Safety Committee works with the University IRB to prescreen all MR research studies. The Safety Committee (comprised of clinicians and physicists who understand MRI technology and safety) can provide the IRB with expert review of the safety of the different procedures and prototype devices used in MRI research, many of which may not yet have gone through safety testing or received FDA approval.

Additional oversight is needed. Establishing a Community Advisory Board (CAB) or similar mechanism involving community liaisons offers important advantages. IRB review is also a key element of oversight to ensure ethical conduct and protection of human participants. As discussed elsewhere in this symposium, a subset of pMRI research may not technically require IRB review; in those cases, we suggest alternative mechanisms for ensuring independent review of research protocols.[70]

D. Data & Incidental Findings

Establishing a data management plan when creating a research protocol is also essential to ensure ethical conduct of research and compliance with require-

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ments imposed by research sponsors.[71] The plan should protect participants' brain data across the full pipeline of data acquisition, de-identification, cloud storage, AI analysis, and data sharing. The research team also needs to establish a plan for managing IFs and a pathway to timely clinical evaluation and care, including the challenge of responding to pMRI IFs when the research is conducted in remote settings.[72] For example, if the scan-anywhere van is acquiring data hundreds of miles from a hospital, referring a participant for timely clinical evaluation of an IF may be challenging.

Stage II. Preparing for Scanning

A. Community

Scanning in a community setting will require steps that may differ from traditional MRI research. Conducting pMRI research in communities that have not previously been engaged in MRI research can improve representativeness in MRI data, but it could also lead to extractive helicopter research that fails to confer local benefit.[73] For example, a research team using a scan-anywhere van could scan participants and then drive away without returning to the community or recontacting participants to respond to community needs and offer aggregate and individual-specific results. To minimize extractive practices, the research team should look for opportunities to build sustained engagement with the community. This should include, for instance, setting up the scanner with community input on logistics. In our senior living home vignette, for example, placement of the scanner will require consultation with administrators and community members at the home. A focus group could be used to determine what scanner set-ups will provide sufficient privacy for residents. In addition, plans could be made for returning to the senior living center to share aggregate results of the study, once available.

Because pMRI can be set up in so many different locations, determining where and how to conduct field-based pMRI scanning will require the research team to consider ease of access, participant privacy, and safety. Researchers should consider the use of portable drapes or privacy screens, ensure that the scanner has reliable energy sources and Internet access, and identify where participants will wait while others are being scanned. Internet access is especially important if the pMRI scanner relies on network connections to link the user-friendly tablet interface with the scanner and then to convey the data collected to the researchers directly or to a cloud-based platform.[74]

B. Safety & Oversight

Once there is an established research protocol, IRB approval, Safety Committee approval, regulatory compliance, and safety training, the research team can begin preparation for scanning. Safety remains a central concern, and researchers need to check for updated safety guidelines from professional bodies such as the ACR and comply with quality control protocols from the device manufacturer. For investigators who are new to MRI, this step may prove challenging. Consider, for example, our vignette of an open-source scanner built in a community that has not previously had access to MRI. Quality control will require that the team construct and test the machine properly, while ensuring that they have sufficient local expertise and institutional oversight to conform to applicable safety guidelines.

C. Informed Consent

The final step before conducting scanning is to obtain informed consent from participants. For pMRI research, it is important for investigators to address the therapeutic misconception. As suggested by our survey data from both the general public and subject-matter experts, research participants in pMRI studies may mistake research for clinical care.[75] To address this, investigators should clearly communicate the distinction between brain research and clinical care and address any misconceptions about the clinical benefits of the pMRI research. As we discuss at greater length in the WG consensus article, "the core of the solution is … improved communication, leading to improved understanding by the participant."[76] This conversation should be part of the informed consent process.

In addition, pMRI research may raise concerns about the use of AI in acquiring and processing brain data. During the informed consent process, investigators should clarify for participants how AI will be used in the research and address potential concerns, such as bias when the AI was not trained on a dataset representative of the population under study. Whether and how to explain the use of AI in the informed consent process remains an active area of scholarly debate.[77] In the context of community-based MRI scanning, transparency about AI use in pMRI is essential to community trust. This requires that the investigators themselves fully understand how AI will function in their research process and ensure that any AI-generated or modified images are accurate and reliable.

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Stage III. Conducting Scanning

A. Community

The research team should engage and work with the community throughout the project's life cycle, including during data acquisition. For example, if a research team is scanning in a senior living center over the course of a month, they might hold weekly listening sessions with those who have been scanned and those thinking about participating. Community feedback could also improve scanning protocols in real time, for example by calling for adjustments in privacy shades, or improvements in how the technology is described during the consent process.

This is also a stage at which community mobilizers and local liaisons can facilitate communication between the research team and participants. These community leaders may, for instance, see a need for modifying the scanning procedures to align with cultural norms and community expectations. As participants join the study, the research team should also ensure that plans for translation, interpretation, and accessibility services are adequate.

B. Safety & Oversight

Investigators should comply with all applicable safety requirements and quality control (QC) procedures when acquiring brain data. Safety and QC are especially important for pMRI research because, unlike the secure room in which traditional MRI research is carried out, the scanning environment for pMRI research will not be temperature controlled and could include people moving and objects near the scanner. Safety concerns could arise in each of our three vignettes. The research team using a scan-anywhere van needs to ensure that they are parked in a secure area, and that onlookers are not invading the privacy of participants being scanned. Researchers using a build-your-own MRI machine need to ensure that their DIY machine is functioning properly. The research team in the senior living home needs to ensure that residents (who may have mobility challenges) can safely move in and out of the scanner.

In addition to scanner placement, pMRI research raises the possibility that non-participants could be near the scanner during data acquisition. In traditional MRI research, this is not an issue because the safety profile of HF-MRI machines requires that observers be excluded from the scanning room. But LF-MRI allows others to be close by. Out of respect for participant privacy and autonomy, researchers should obtain participant consent for the presence of observers, such as family members or other participants standing in line. Additional measures should be taken to maximize participant privacy in the scanning environment. For instance, the research team might set up their registration and waiting room area in a different space than where pMRI scanning takes place. The research team also needs to develop a policy with respect to participants and onlookers taking photographs or videos and needs to anticipate violations of that policy. For example, if scanning in a school gymnasium, a passer-by may take photos on their phone. The research team should take precautions to prevent this.

Stage IV. After Scanning

A. Community

The ELSI Checklist ends where it began: by centering the community in pMRI research. At the end of the research study, researchers can bring value to local communities by sharing key research findings with community members. Researchers can use email newsletters, host community meetings, and partner with community leaders to disseminate the results. As the research team shares data with the participant community, they should adhere to the data management, storage, and sharing plan, with a commitment to responsible data management, transparency, and accountability. Ending a research study with contributions to the community demonstrates respect, fulfills ethical responsibilities, and sets a foundation for future renewed engagement in that community.

B. Data & Incidental Findings

After collection of brain data in pMRI research, researchers have multiple responsibilities. These include protecting the privacy and security of brain data and communicating to participants about IFs and concerning research results. The first step is to securely store the brain data. This should be done in accordance with the data management plan developed in the research protocol and approved by the IRB or IRB equivalent.

Once data are acquired from participants, researchers must ensure that every individual and entity with access to the data, including secondary researchers, commits to the research team's protocol for responsible data handling and providing participants with control over their data. For example, a framework should be in place for secure data acquisition, transfer, storage, and de-identification. This framework should cover the entire data pipeline, "from 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."[78] The researchers may consider using a Data Use Agreement to prevent unauthorized data sharing and re-identification of the

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data. As discussed earlier in the context of informed consent, we recommend that participants have as much agency as possible over their brain data. For example, if the brain data will be used commercially, participants should be made aware of this and might be provided an opportunity to opt-out and to "consent on a per-analysis basis and prospectively withdraw or destroy their data."[79]

Data analyses and processing may require additional expertise, for instance adding biostatisticians to the research team and ensuring oversight by a Data and Safety Monitoring Board. When sharing and storing data, applicable institutional and data repository guidelines should be followed, and appropriate de-identification methods used.

Once data are analyzed, it is incumbent upon researchers to communicate with participants about their data and results. We recognize that protocols for radiological reads of MRI research scans with fixed MRI currently "range from having every scan read by a radiologist, to having scans reviewed by an expert only if a researcher flags a brain abnormality, to not having scans read by a radiologist."[80] For pMRI research 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 return of results to research participants and sharing information with a clinician," and "researchers and funders should plan and fund pathways to timely care in the event of IFs or concerning research results, regardless of the participant's geographic location and insurance status."[81]

The process for managing IFs and research results of concern needs to be established and written into the study protocol before the research begins. For example, if researchers are using a mobile van to scan, the research team could be hundreds of miles away from the participant's location when an IF is discovered. Researchers will need to ensure prompt access to expert assessment and then timely referral for clinical evaluation as needed. For some studies, a pathway to care may be straightforward. But this will not always be the case. These challenges should be identified and addressed before the protocol is approved. This symposium provides additional guidance on addressing the IFs challenge.[82]

Researchers have an ethical duty to be good data stewards. This includes empowering participants by informing them of their rights to request data, as well as giving participants access to, and agency over, their brain data. Our WG's companion article discusses the data access requirements imposed by the HIPAA Privacy Rule. Even if researchers are not HIPAA-covered entities legally required to provide access under this Rule, researchers should use it as a baseline for setting their data access policy. The companion article also discusses ways that participants' agency over their brain data might be facilitated.[83]

Conclusion

This article provides a Portable MRI Research ELSI Checklist for researchers who wish to pursue research with pMRI outside an academic or hospital setting. The Checklist identifies tasks that researchers need to complete when creating the research protocol, preparing for scanning, conducting the study, and after acquiring brain data with pMRI in the field. Over time pMRI may be used in additional contexts not addressed here, for instance in citizen-science initiatives utilizing pMRI without academics or clinicians, and in corporate development of direct-to-consumer pMRI services. Such uses deserve further discussion.

Community leaders, IRBs, professional societies, funders and sponsors, government agencies such as NIH and FDA, journal editors, and neuroethics scholars are additional actors who must play a role to ensure successful deployment of pMRI in the field. Other target articles in this symposium issue discuss many of these ELSI considerations.

The Checklist is novel in its coverage of ELSI issues for pMRI researchers, and it thus provides a critical starting point for all researchers wishing to conduct pMRI research outside of traditional settings. The Checklist can also be utilized by IRBs as they work with research teams to ensure ethical pMRI research. Importantly, the Checklist offers a tool that community leaders can use as they consider whether to conduct or partner on pMRI research in their community. Communities can then utilize the Checklist throughout the life of a research project to hold researchers accountable for the ethical conduct of pMRI research.

Acknowledgments

Preparation of this article was supported by the National Institute of Mental Health of the National Institutes of Health under award number RF1MH123698. The content is solely the responsibility of the authors and does not necessarily represent the views of the funder. M.S.R. acknowledges the generous support of the Kiyomi and Ed Baird MGH Research Scholar award. For administrative and logistics support, we thank Dori Henderson, Ph.D., Debra Mock, and staff at the University of Minnesota's Consortium on Law and Values in Health, Environment & the Life Sciences.

Disclosures

M.S.R. is a founder and equity holder of Hyperfine, Vizma Life Sciences, Intact Data Services, and Q4ML. M.S.R. is an equity holder of DeepSpin GmbH. M.S.R. also serves on the scientific advisory boards of ABQMR, Synex Medical, Nanalysis, and O2M Technologies. E.T. is a co-founder of Adialante. J.T.V. is a co-founder of MR Access, Inc. All other authors have no relevant disclosures.

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and recording injuries occurring from MRI scanning. "Diagnostic Imaging Compliance Checklist," Joint Commission, https://www.jointcommission.org/-/media/tjc/documents/accred-and-cert/ahc/imaging-checklist.pdf (last visited Mar. 11, 2024).

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Appendix

Table 1 (Continued on page 784)

Summary of recommendations to address ethical and legal issues arising in U.S. research with portable MRI (pMRI).

	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.

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Table 1 (Continued from page 783)

Summary of recommendations to address ethical and legal issues arising in U.S. research with portable MRI (pMRI).

	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.

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Table 2

Toolkits for initiating community-engaged research.

There are many resources and toolkits to facilitate community-engaged research. The list below provides a starter set for researcher who wish to conduct research in a community setting using portable MRI.	
In It Together: Community-Based Research Guidelines for Communities and Higher Education [i]	"These guidelines, developed by a community-campus collective, offer advice for both community-based and campus-based people who want to do collaborative research."
Community-Engaged Research: A Quick-Start Guide for Researchers [ii]	This quick-start guide aims to "help academic researchers develop effective and mutually-satisfying collaborations with community-based organizations, clinicians or other community stakeholders."
Community Engagement Studio Toolkit 2.0 [iii]	Introduces the community engagement studio model, which is a "way for researchers to get community or patient input on the development, implementation or dissemination of a research project."
Toolkit for Developing Community Partnerships [iv]	"This guide is intended to be a resource for researchers, health care providers and the community who are interested in conducting community-engaged research."
Community Partnered Research "How To" Series [v]	These "'How To' documents are designed to help inform and guide community partners on a range of clinical research topics."
Tools and Resources for Project-Based Community Advisory Boards Community Voice and Power Sharing Guidebook (2021) [vi]	"This toolkit offers practical guidance, questions, and approaches for incorporating a community advisory board (CAB) into a project or initiative to strengthen community empowerment, buy-in, and participation."

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