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Currents in Contemporary Ethics

The Confidentiality and Privacy Implications of Functional Magnetic Resonance Imaging

Stacey A. Tovino

Advances in science and technology frequently raise new ethical, legal, and social issues, and developments in neuroscience and neuroimaging technology are no exception. Within the field of neuroethics, leading scientists, ethicists, and humanists are exploring the implications of efforts to image, study, treat, and enhance the human brain.¹

This article focuses on one aspect of neuroethics: the confidentiality and privacy implications of advances in functional magnetic resonance imaging ("fMRI"). Following a brief orientation to fMRI and an overview of some of its current and proposed uses, this article highlights key confidentiality and privacy issues raised by fMRI in the contexts of health care, research, employment, insurance, criminal justice, litigation, and cognitive privacy.

Functional Magnetic Resonance Imaging

Magnetic resonance imaging ("MRI") uses radiofrequency waves and a strong magnetic field to provide detailed images of internal organs and tissues. Functional MRI is based on the same technology as MRI. However, instead of imaging static, soft-tissue structures, fMRI measures localized changes in the brain that occur when an individual performs a mental task, such as viewing an image, responding to a question, or listening to a voice. By subtracting a control image from an experimental image, physicians and scientists can create maps showing the regions of the brain to which a surplus of oxygenated blood flows when an individual performs a task.²

Functional MRI has several clinical applications. Preoperatively, physicians and scientists use fMRI

to study patients while they complete a battery of mental tasks and to identify the regions of the brain that are associated with tactile, motor, language, and visual functions.³ Scientists believe these cortical maps can help neurosurgeons assess surgical risk, plan surgical routes, and direct intraoperative electrophysiological procedures,⁴ although others caution against the leap from functional imaging to functional neurosurgery.⁵

Scientists also use fMRI to examine the physiological correlates of well-known social psychological phenomena. For example, several groups of scientists have used fMRI to explore the neural substrates involved when research subjects view faces of white and black individuals.⁶ In one study, the authors concluded that representations of social groups that differ in race evoke differential amygdala activity related to unconscious social evaluation.⁷ Although the authors stated that their results cannot be taken as a means of testing for racism in individuals, others speculate that refinement of fMRI technology could unveil racial preferences and prejudices.⁸

The neural correlates of deception also have been studied using fMRI.⁹ In one popular study, scientists asked subjects to hold a 5 of Clubs playing card in their pocket and to deny that they held the card while their brains were being imaged.¹⁰ The scientists concluded that cognitive differences between deception and truth have neural correlates detectable by fMRI and that refinements in study design could establish an activation pattern predictive of deception on an individual level.¹¹ Although some scientists and ethicists caution against premature use of fMRI to detect deception in non-research settings,¹²

About this Column

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other individuals speculate that fMRI might enable government and criminal justice officials to determine whether criminal suspects and terrorists are lying or telling the truth.¹³

Scientists also have used fMRI to study the neural correlates of altruism and social cooperation.¹⁴ In one study involving two separate experiments, scientists scanned the brains of thirty-six women as they played the Prisoner's Dilemma, a game in which two players independently choose whether to cooperate with each other or betray each other for immediate gain.¹⁵ The scientists concluded that mutual cooperation was associated with consistent activation in regions of the brain linked to reward processing.¹⁶ Others speculate that employers might want to use fMRI to recruit applicants for employment who experience more or less pleasure from cooperation, depending on the requirements of the job.¹⁷

Functional MRI has been used to study a range of other conditions and characteristics including, but certainly not limited to, Alzheimer's disease,¹⁸ major depression,¹⁹ schizophrenia,²⁰ bipolar disorder,²¹ dyslexia and hyperlexia,²² minimal consciousness,²³ pedophilia,²⁴ cocaine addiction,²⁵ compulsive gambling,²⁶ satiety and obesity,²⁷ extraversion,²⁸ self-consciousness,²⁹ maternal and romantic love,³⁰ and sexual arousal,³¹ as well as individuals' preferences regarding soft drinks,³² automobiles,³³ campaign advertisements,³⁴ and the content of movie trailers.³⁵

Confidentiality Implications

An oft-stated principle is that physicians and scientists have an ethical and legal duty to maintain the confidentiality of medical and study records in their possession. Applying existing confidentiality obligations to neuroimages and related data sets, reports, and interpretations (collectively, "neuroimaging information") raises several questions. First, do existing confidentiality protections apply to the growing number of scientists who create, use, and disclose neuroimaging information? Second, do existing protections apply

to neuroimaging information that is interpreted to reveal social qualities and characteristics, but not particular physical or mental conditions? Third, when is neuroimaging information individually identifiable? Finally, how can scientists disclose neuroimaging information to neuroimaging databanks in accordance with publication requirements and peer suggestion without violating confidentiality requirements?

The Department of Health and Human Services' standards for the privacy of individually identifiable health information (the "Privacy Rule")³⁶ will apply to some, but not all, of the individuals and institutions that create, maintain, or desire to obtain neuroimaging information. Very

employers, life insurance companies, litigants, and marketing companies.

Understanding how the Privacy Rule applies to the growing number of scientists who use fMRI technology can be confusing. The Privacy Rule generally does *not* apply to: (1) scientists who do not provide health care as part of their research; and (2) scientists who do provide health care but who do not electronically bill for such health care or do not otherwise transmit health information in electronic form in connection with a standard transaction.⁴⁰ However, the Privacy Rule *does* apply to the scientists described in the preceding sentence if they are employees or work-force members of a university that: (1) is a single legal entity; (2) has a

Do existing confidentiality protections apply to the growing number of scientists who create, use, and disclose neuroimaging information?

generally, the Privacy Rule regulates covered entities' use and disclosure of protected health information.³⁷ Covered entities include health care providers who transmit health information in electronic form in connection with certain standard transactions, as well as health plans and health care clearinghouses.³⁸

Many health care providers (including hospitals, imaging centers, radiologists, and neurosurgeons) transmit health information in electronic form in connection with claims sent to health insurers for reimbursement and other standard transactions. These health care providers, as well as the health insurance companies to which the providers' claims are sent, constitute covered entities and must maintain the confidentiality of their protected health information in accordance with the Privacy Rule or risk civil and criminal penalties.³⁹ However, the Privacy Rule generally does not apply to many other individuals and institutions reported to have an interest in neuroimaging information, including federal and state governments, criminal justice officials, em-

health care component, such as a clinic or hospital; and (3) has not designated the scientists as part of the non-health care component in accordance with the Privacy Rule's provisions relating to hybrid entities.⁴¹ Thus, the Privacy Rule will apply to some, but not all, scientists.

The Privacy Rule regulates covered entities' use and disclosure of protected health information.⁴² A second issue is whether neuroimages that are used to study (or are interpreted to reveal) social characteristics that do not rise to the level of physical or mental conditions are protected by the Privacy Rule. In relevant part, the Privacy Rule defines *health information* as information that relates to the past, present, or future physical or mental health or condition of an individual, or the provision of health care to an individual.⁴³ A neuroimage that shows the precise location of a brain tumor or an arteriovenous malformation certainly relates to the present physical condition of an individual and would constitute health information under the Privacy Rule.

But, what about a neuroimage that

is taken for the purpose of studying one-time deception that does not constitute pathological lying ("I do not have the 5 of Clubs card")? What about a neuroimage that shows amygdala activity interpreted as unconscious social evaluation? What about a neuroimage that is interpreted to reveal an individual's preference for a particular soft drink, automobile, campaign advertisement, or movie trailer? A very technical argument exists that these latter pieces of neuroimaging information do not constitute health information under the Privacy Rule because they do not relate to the physical or mental health or condition of an individual or the provision of health care to an individual.

A third issue is whether neuroimaging information is individually identifiable. The Privacy Rule only protects health information if it is individually identifiable, meaning that the information identifies the individual who is its subject or there is a reasonable basis to believe that the information could be used to identify the individual.⁴⁴ Neuroimaging information that contains a patient's name, telephone number, social security number, medical record number, account number, or other similar identifier generally is considered individually identifiable.⁴⁵

When is neuroimaging information sufficiently de-identified such that a covered entity can use and disclose the information without regulation by the Privacy Rule? The Privacy Rule contains a de-identification safe harbor that requires removal of eighteen different types of identifiers before data is considered de-identified.⁴⁶ Satisfying the de-identification safe harbor in the context of neuroimaging is slightly more difficult than in the traditional medical record context because of reports that individuals' facial features can be reconstructed from high resolution fMRIs.⁴⁷ Because the Privacy Rule's safe harbor requires removal of full-face photographs and comparable images, covered entities also must remove from neuroimaging information any data or voxels from

which an individual's face can be recognized or reconstructed.

As a condition of publication, the *Journal of Cognitive Neuroscience* requires its authors to submit their complete fMRI study data to the fMRI Data Center, a neuroimaging databank located in Hanover, New Hampshire.⁴⁸ At least two other journals strongly encourage submis-

sure that, "[w]hen appropriate, there are adequate provisions to...protect the confidentiality of [subjects'] data."⁵² The Office for Human Research Protections has stated that the "adequate provisions" language in the Common Rule requires investigators to replace names and other identifiers with codes and to store paper and electronic research

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sion of complete study data to neuroimaging databanks to support the findings, outcomes, and claims in the journals' published articles, and some scientists encourage the disclosure of neuroimaging information to neuroimaging databanks to speed the understanding of cognitive processes and the neural substrates that underlie them.⁴⁹ Thus, a fourth issue is how covered entities can disclose neuroimaging information to neuroimaging databanks without violating the Privacy Rule. The Privacy Rule allows covered entities to disclose de-identified information to databanks without the prior written authorization of the individuals who are the subjects of the information.⁵⁰ Accordingly, if a covered entity removes from the data it sends to a databank all eighteen identifiers listed in the Privacy Rule's de-identification safe harbor, including any data from which a subject's face can be recognized or reconstructed, the Privacy Rule would allow the disclosure to the databank.⁵¹

Several other laws establish confidentiality protections that may apply to individuals who create, maintain, or desire to obtain neuroimaging information. For example, federal protection of human subjects regulations (the "Common Rule") requires institutional review boards approving federally-funded research to en-

records securely.⁵³ Unlike the Privacy Rule, the Common Rule protects all federally-funded, human subject study data,⁵⁴ not just health information in the possession of covered entities. Similar to the Privacy Rule, the Common Rule contains a de-identification standard that would require the removal of data from which the identity of the subject can or may be readily ascertained, including data or voxels from which an individual's face can be recognized or reconstructed.⁵⁵

In addition to federal confidentiality protections, many states have medical practice acts, hospital licensing laws, imaging center licensing laws, and other similar laws and regulations that require certain individuals and institutions to maintain the confidentiality of health information in their possession. These laws typically define health information as information that relates to the diagnosis, treatment, or prognosis of patients.⁵⁶ However, many of these laws do not: (1) extend their protections to scientists who do not provide health care to patients; (2) state whether their protections extend to social information in addition to health information; or (3) specify whether, or the conditions under which, a provider may disclose neuroimaging information to a neuroimaging databank.

In summary, advances in neuroimaging raise a number of confidentiality issues. Which existing confidentiality laws protect social information created and maintained by non-provider scientists? Does the Common Rule adequately protect the confidentiality of neuroimaging information in the possession of scientists? Should Congress or state legislatures enact new laws providing heightened confidentiality protections for neuroimaging information? If so, how would such laws define the neuroimaging information to be protected?⁵⁷ How would we reconcile such heightened protections with other laws that allow the disclosure of confidential information without authorization for certain public policy purposes?⁵⁸ Would heightened confidentiality protections for neuroimaging information suggest that all neuroimaging information is sensitive or stigmatizing, even though it may not be?⁵⁹ Finally, what lessons can we learn from federal and state efforts to establish heightened confidentiality protections for genetic information?⁶⁰

Privacy Implications

Patients voluntarily disclose some information to health care providers to obtain health care, and human subjects consent to scientists' obtaining some personal information during research studies. But, what if a provider or scientist discovers a condition that the patient or subject would have preferred to keep private? Recent studies analyze the extent to which scientists have discovered arteriovenous malformations, brain tumors, developmental abnormalities, and other conditions in healthy controls who participate in neuroimaging research.⁶¹ The question becomes, can fMRI violate an individual's interest in keeping certain information private? Physicians and scientists might be able to minimize an individual's perception that her privacy has been violated by identifying, as part of the informed consent process, the type of information potentially discoverable by fMRI, and by negotiating a notification and treatment referral process

to be followed in the event of an unanticipated finding.⁶²

Although the cost to employers of conducting their own fMRI tests likely would be prohibitive, employers might be interested in obtaining the results of past fMRI tests to assist in decision making relating to the selection and retention of employees.⁶³ Thus, the issue in the employment context is whether applicants for employment and employees have the ability to keep their neuroimaging information private or whether they can be forced to reveal such information pursuant to a compelled authorization. A handful of laws regulate employers' use of employment tests, medical examinations, and related inquiries. Two examples include Title I of the Americans with Disabilities Act (the "ADA")⁶⁴ and the Employee Polygraph Protection Act.⁶⁵

Among other activities, Title I of the ADA regulates certain employers' use of qualification standards, employment tests and other selection criteria that screen out or tend to screen out individuals with disabilities on the basis of such disabilities (the "screening provisions").⁶⁶ Equal Employment Opportunity Commission ("EEOC") regulations interpreting Title I define *disability* to include physical and mental impairments (including neurological disorders, mental illnesses, and specific learning disabilities) that substantially limit one or more major life activities of an individual.⁶⁷ EEOC regulations also clarify, however, that pedophilia, compulsive gambling, homosexuality, and certain other characteristics do not constitute disabilities protected by the ADA.⁶⁸ The result is that the ADA's screening provisions would regulate a covered employer's use of fMRI in an attempt to screen out individuals who have depression, schizophrenia, or bipolar disorder if such conditions substantially limit a major life activity of the individuals tested. On the other hand, the screening provisions would not regulate attempts to screen out individuals based on fMRI "findings" of pedophilia, compulsive gambling, and homosexuality.

Title I of the ADA also regulates the conduct and timing of medical examinations and inquiries.⁶⁹ The EEOC has issued enforcement guidance that defines a *medical examination* as a procedure or test that seeks information about an individual's health or physical or mental impairments.⁷⁰ Although a number of factors are relevant in determining whether a procedure or test is a medical examination, the EEOC clarifies that the term includes tests that provide evidence leading to the identification of conditions listed in the American Psychiatric Association's most recent Diagnostic and Statistical Manual of Mental Disorders, including anxiety, depression, and certain compulsive disorders that have been studied by fMRI.⁷¹ The EEOC also clarifies, however, that psychological tests designed and used only to measure honesty, tastes, and habits are not medical examinations.⁷² A determination of how the ADA's medical examination and inquiry provisions apply to particular fMRI tests will require application of the factors and interpretations set forth by the EEOC in its enforcement guidance.

With some exceptions, the federal Employee Polygraph Protection Act ("EPPA") prohibits employers from requiring employees to submit to lie-detector tests,⁷³ defined to include polygraphs, deceptographs, voice stress analyzers, psychological stress evaluators, and "any other similar device...that is used, or the results of which are used, for the purpose of rendering a diagnostic opinion regarding the honesty or dishonesty of an individual."⁷⁴ Thus, the EPPA could be interpreted to prohibit employers from requiring neuroimaging examinations that could form the basis of an opinion regarding an individual's dishonesty.

Functional MRI has privacy implications beyond the health care, research, and employment contexts. In the insurance context, the concern is that health, life, and auto insurers will use individuals' neuroimaging information in an attempt to predict future illness, a propensity to violence, or other conditions or charac-

teristics relevant to underwriting decisions.⁷⁵ Is special legislation or regulation needed to prevent the gathering or use of neuroimaging information by insurance companies?⁷⁶ If so, how can recent legislative efforts to restrict the use of genetic information by health and life insurers guide efforts to protect the privacy of neuroimaging information?⁷⁷

In the criminal justice and civil litigation contexts, the issue is whether fMRI has the potential to violate the privacy rights of individuals suspected of being terrorists, individuals suspected of engaging in other criminal activity, and participants in civil litigation.⁷⁸ For example, does an fMRI of a criminal suspect's brain constitute a search under the Fourth Amendment?⁷⁹ Could an fMRI of a criminal defendant's brain violate her Fifth Amendment privilege against compulsory self-incrimination?⁸⁰ Can counsel use fMRI during *voir dire* to exclude jurors whose neuroimages are interpreted to reveal racial prejudices?⁸¹ Finally, and regardless of the context, do all individuals have the right to cognitive privacy, or the privacy of their own thoughts?⁸² Can state action that punishes an individual or holds an individual responsible for thoughts, but not actions, violate the individual's cognitive privacy?⁸³

Although neuroimaging research has improved our understanding of the neural bases of personality, behavior, and consciousness, it raises additional questions relating to the concept of the self, emotional and moral judgment, prediction of future illness, unanticipated findings, truth telling, social and legal responsibility and, central to this article, confidentiality and privacy. Existing confidentiality and privacy protections tend to be tied to the concepts of physical and mental health, not individuals' thoughts, preferences, and social conduct. Identification of potential gaps in coverage can inform policy discussions about the need to protect social qualities and characteristics and to promote mental autonomy as attempts to transfer fMRI

technology beyond the research context are made.

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51. If one or more of the eighteen identifiers remain in the information, the Privacy Rule would require the covered entity to: (1) obtain a prior written authorization containing certain required elements and statements from each subject whose identifiers are disclosed to the databank; or (2) satisfy a research-related exception to the Privacy Rule's authorization requirement. One potentially applicable exception permits an institutional review board or privacy board to waive the authorization required by the Privacy Rule if certain criteria are satisfied. See *id.* § 164.508(c)(1) and (2); *id.* § 164.512(i).
52. *Id.* § 46.111(a)(7).
53. See generally J. Kulynych, "Legal and Ethical Issues in Neuroimaging Research: Human Subjects Protection, Medical Privacy, and the Public Communication of Research Results," *Brain and Cognition* 50, no. 3 (2002): 345-57, at 349-50.
54. See 45 C.F.R. § 46.102(f) (2005) (protecting data that results from "intervention or interaction with [an] individual" or "identifiable private information").
55. *Id.* § 46.102(f).
56. See, e.g., CAL. CIV. CODE §§ 56.05-.37, 56.05(g) (West 2005) (California Confidentiality of Medical Information Act provisions protecting "medical information," defined as "individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment"); TEX. HEALTH & SAFETY CODE ANN. §§ 241.151-.153, 241.151(2) (Vernon 2005) (Texas Hospital Licensing Law provision establishing confidentiality protections for "health care information," defined as information that relates to the "history, diagnosis, treatment, or prognosis of a patient").
57. See H. T. Greely, "Prediction, Litigation, Privacy, and Property: Some Possible Legal and Social Implications of Advances in Neuroscience," in B. Garland, ed., *Neuroscience and the Law: Brain, Mind, and the Scales of Justice* (New York: Dana Press, 2004): 144-45 (identifying five arguments against applying special confidentiality protections to neuroimaging information).
58. *Id.*
59. *Id.* at 144.
60. See, e.g., Illes and Racine, *supra* note 2, at 10-12; B. S. Wilfond and V. Ravitsky, "On the Proliferation of Bioethics Sub-Disciplines: Do We Really Need 'Genethics' and 'Neuroethics'?" *American Journal of Bioethics* 5, no. 2 (2005): 20-21; L. Reid and F. Baylis, "Brains, Genes, and the Making of the Self," *American Journal of Bioethics* 5, no. 2 (2005): 21-23, at 22-23; H. Doucet, "Imagining a Neuroethics Which Would Go Further Than Genethics," *American Journal of Bioethics* 5, no. 2 (2005): 29-31.
61. See Proceedings, *Detection and Disclo-*

- sure of Incidental Findings in Neuroimaging Research, Bethesda, MD, January 6-7, 2005, at <http://accessible.ninds.nih.gov/news_and_events/proceedings/ifexecsummary_pr.htm> (last visited September 15, 2005); J. Illes, et al., "Discovery and Disclosure of Incidental Findings in Neuroimaging Research," *Journal of Magnetic Resonance Imaging* 20, no. 5 (2004): 743-47; J. Illes, et al., "Ethical Consideration of Incidental Findings on Adult Brain MRI in Research," *Neurology* 62, no. 6 (2004): 888-90; J. Illes, et al., "Ethical and Practical Considerations in Managing Incidental Findings in Functional Magnetic Resonance Imaging," *Brain and Cognition* 50, no. 3 (2002): 358-65; G. L. Katzman, A. P. Dagher, and N. J. Patronas, "Incidental Findings on Brain Magnetic Resonance Imaging from 1000 Asymptomatic Volunteers," *JAMA* 281, no. 1 (1999): 36-39.
62. See Illes, et al., "Ethical Considerations," *supra* note 61, at 889; Illes, et al., "Ethical and Practical Considerations," *supra* note 61, at 362-64.
63. See, e.g., Moreno, *supra* note 17, at 152; K. R. Foster, P. R. Wolpe, and A. L. Caplan, "Bioethics & the Brain," *IEEE Spectrum* 40, no. 6 (2003): 34-39, at 34.
64. 42 U.S.C. §§ 12111-12117 (2005).
65. 29 U.S.C. §§ 2001-2009 (2005).
66. 42 U.S.C. § 12112(b)(6) (2005); 29 C.F.R. § 1630.10 (2005).
67. *Id.* § 1630.2(g).
68. *Id.* § 1630.3(d)(1) (pedophilia not disability); *id.* § 1630.3(d)(2) (compulsive gambling not disability); *id.* § 1630.3(e) (homosexuality not impairment so not disability).
69. 42 U.S.C. § 12112(d) (2005); 29 C.F.R. § 1630.13-.14 (2005).
70. Equal Employment Opportunity Commission Notice No. 915.002, Enforcement Guidance: Preemployment Disability-Related Questions and Medical Examinations (October 10, 1995).
71. *Id.*
72. *Id.*
73. 29 U.S.C. § 2002(1) (2005).
74. *Id.* § 2001(3).
75. H. Phillips, "Private Thoughts, Public Property," *New Scientist* 183, no. 2458 (2004): 38-41.
76. Greely, *supra* note 57, at 124-25.
77. See generally M. A. Rothstein, ed., *Genetics and Life Insurance: Medical Underwriting and Social Policy* (Cambridge: MIT Press: 2004).
78. Greely, *supra* note 57, at 120-23, 127-37, 141-42, and 145-48.
79. R. G. Boire, "Searching the Brain: The Fourth Amendment Implications of Brain-Based Deception Detection Devices," *American Journal of Bioethics* 5, no. 2 (2005): 62-63.
80. Greely, *supra* note 57, at 146.
81. *Id.* at 136.
82. See generally R. G. Boire, "On Cognitive Liberty," *Journal of Cognitive Liberties* 1, no. 1 (1999/2000): 7-13.
83. See, e.g., *Palko v. Connecticut*, 302 U.S. 319, 326-27 (1937) ("[F]reedom [of thought]...is the matrix, the indispensable condition, of nearly every other form of freedom"); *Jones v. Opelika*, 316 U.S. 584, 618 (1942) ("[F]reedom to think is absolute of its own nature; the most tyrannical government is powerless to control the inward workings of the mind"); *Aboud v. Detroit Board of Education*, 431 U.S. 209, 234-35 (1977) ("[A]t the heart of the First Amendment is the notion that an individual should be free to believe as he will..."); *Ashcroft v. Free Speech Coalition*, 535 U.S. 234, 253 (2002) ("The right to think is the beginning of freedom..."). See generally Brief of Amici Curiae Center for Cognitive Liberty & Ethics, at 3-7, *Sell v. United States*, 539 U.S. 166 (2003) (No. 02-5664) (arguing that the First Amendment guarantees freedom of thought).